UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2014
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 (do not check if a smaller reporting company)	[ ]	Smaller reporting company	[X]

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

As of February 13, 2015, 1,473,528 shares of the registrant's common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended December 31, 2014

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

VISTAGEN THERAPEUTICS, INC.

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

	December 31, 2014 (Unaudited)	March 31, 2014 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,200	$ -
Prepaid expenses and other current assets	62,300	40,500
Total current assets	75,500	40,500
Property and equipment, net	137,000	176,300
Security deposits and other assets	46,900	46,900
Total assets	$ 259,400	$ 263,700
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 2,415,300	$ 2,443,900
Accrued expenses	1,192,800	625,600
Advance from officer	-	3,600
Current portion of senior secured convertible promissory notes and accrued interest	2,842,700	-
Current portion of notes payable and accrued interest	1,929,900	1,442,300
Current portion of notes payable to related parties and accrued interest	343,100	290,400
Convertible promissory notes and accrued interest, net of discount of $1,182,100 and $697,400 at December 31, 2014 and March 31, 2014	2,038,800	396,000
Capital lease obligations	1,000	3,900
Total current liabilities	10,763,600	5,205,700
Non-current liabilities:		
Senior secured convertible promissory notes, net of discount of $0 at December 31, 2014 and $2,085,900 at March 31, 2014 and accrued interest	1,490,400	1,929,800
Notes payable, net of discount of $577,000 at December 31, 2014 and $848,100 at March 31, 2014 and accrued interest	2,129,800	1,797,600
Notes payable to related parties, net of discount of $67,500 at December 31, 2014 and $103,200 at March 31, 2014 and accrued interest	1,124,100	1,057,100
Warrant liability	2,445,600	2,973,900
Deferred rent liability	87,700	97,400
Capital lease obligations	1,400	2,100
Total non-current liabilities	7,279,000	7,857,900
Total liabilities	18,042,600	13,063,600
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares, including 500,000 Series A shares, authorized at December 31, 2014 and March 31, 2014; 500,000 Series A shares issued and outstanding at December 31, 2014 and March 31, 2014	500	500
Common stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2014 and March 31, 2014; 1,460,843 and 1,310,093 shares issued at December 31, 2014 and March 31, 2014, respectively	1,400	1,300
Additional paid-in capital	64,484,400	62,001,400
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2014 and March 31, 2014	(3,968,100)	(3,968,100)
Note receivable from sale of common stock	-	(198,100)
Accumulated deficit	(78,301,400)	(70,636,900)
Total stockholders' deficit	(17,783,200)	(12,799,900)
Total liabilities and stockholders' deficit	$ 259,400	$ 263,700

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2014	2013	2014	2013
Revenues:	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	445,400	551,300	1,476,600	1,916,100
General and administrative	671,300	897,000	2,024,600	2,047,500
Total operating expenses	1,116,700	1,448,300	3,501,200	3,963,600
Loss from operations	(1,116,700)	(1,448,300)	(3,501,200)	(3,963,600)
Other expenses, net:				
Interest expense, net	(792,400)	(360,900)	(2,182,900)	(1,000,500)
Change in warrant liability	953,700	1,940,200	528,300	3,823,700
Loss on early extinguishment of debt	-	-	(2,371,400)	-
Other expense	(134,900)	-	(134,900)	-
(Loss) income before income taxes	(1,090,300)	131,000	(7,662,100)	(1,140,400)
Income taxes	-	-	(2,400)	(2,700)
Net (loss) income	$ (1,090,300)	$ 131,000	$ (7,664,500)	$ (1,143,100)
Basic net (loss) income per common share	$ (0.84)	$ 0.12	$ (6.03)	$ (1.06)
Diluted net loss per common share	$ (1.08)	$ (0.44)	$ (6.14)	$ (2.30)
Weighted average shares used in computing:				
Basic net (loss) income per common share	1,302,300	1,110,529	1,270,495	1,077,746
Diluted net loss per common share	1,302,300	1,110,529	1,288,674	1,087,087
Comprehensive (loss) income	$ (1,090,300)	$ 131,000	$ (7,664,500)	$ (1,143,100)

See accompanying notes to Condensed Consolidated Financial Statements.

VISTAGEN THERAPEUTICS, INC.

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

	Nine Months Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (7,664,500)	$ (1,143,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	39,200	40,200
Amortization of discounts on convertible and promissory notes	1,294,700	356,100
Change in warrant liability	(528,300)	(3,823,700)
Stock-based compensation	564,000	893,700
Expense related to modification of warrants	-	174,500
Non-cash rent and relocation expense	(9,700)	56,700
Interest income on note receivable for stock purchase	2,800	(400)
Loss on settlement of note receivable for stock purchase	134,900	-
Fair value of common stock granted for services	134,000	-
Fair value of warrants granted for services and interest	38,700	54,000
Gain on currency fluctuation	(22,000)	(30,100)
Loss on extinguishment of debt	2,371,400	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	74,300	56,100
Security deposits and other assets	-	(17,900)
Accounts payable and accrued expenses, including accrued interest	1,696,100	1,725,000
Net cash used in operating activities	(1,874,400)	(1,658,900)
Cash flows from investing activities:		
Purchases of equipment, net	-	(9,600)
Net cash used in investing activities	-	(9,600)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	2,128,200	597,900
Proceeds from exercise of modified warrants	-	264,200
Proceeds from sale of note and warrant to Platinum	-	250,000
Advance from officer	-	64,000
Repayment of capital lease obligations	(3,700)	(5,700)
Repayment of notes	(236,900)	(119,300)
Net cash provided by financing activities	1,887,600	1,051,100
Net increase (decrease) in cash and cash equivalents	13,200	(617,400)
Cash and cash equivalents at beginning of period	-	638,100
Cash and cash equivalents at end of period	$ 13,200	$ 20,700

See accompanying notes to Condensed Consolidated Financial Statements.

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

Note 1. Description of Business

Overview

VistaGen Therapeutics, Inc., a Nevada corporation, is a clinical-stage biopharmaceutical company focused on developing novel medicine to treat depression and other conditions involving the central nervous system and 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.

AV-101 and Major Depressive Disorder

AV-101 (4-Cl-KYN) is our drug candidate in Phase 2 development as a potential new generation treatment for major depressive disorder (*MDD*), one of the most common mental disorders in the U.S., affecting 6.7% of U.S. adults each year. AV-101 also has potential as a new treatment for other conditions of the central nervous system (*CNS*), including epilepsy and chronic neuropathic pain, and neurodegenerative diseases such as Parkinson's disease and Huntington's disease.

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). Because of their mechanism of action, currently approved antidepressant drugs often take many weeks to relieve depressive symptoms and induce remission of a major depressive episode. During this multiple-week lag period 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 out of three patients may find an antidepressant drug combination that induces remission of depressive symptoms. Unfortunately, this serial trial and error period to find an effective antidepressant medication can take months to more than a year to achieve, with an increasing rate of potentially significant side effect risks with each successive treatment attempt.

In randomized, placebo-controlled, double-blind clinical trials conducted by Dr. Carlos Zarate, Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*), ketamine, an NMDA receptor antagonist which acts as an NMDA channel blocker, produced robust and rapid, within hours, antidepressant effects in MDD patients who had not responded to approved antidepressant drugs. Although the potential for widespread therapeutic use of ketamine may be severely limited by its potential for abuse, its dissociative and psychosis-like side effects, as well as practical challenges associated with its required intravenous administration in a medical center, the discovery of ketamine's rapid onset antidepressant effects revolutionized thinking about the MDD treatment paradigm and mechanism of action of antidepressant medicines. It also increased interest in the development of a new generation of drug candidates with a mechanism of action similar to ketamine's and a more rapid therapeutic benefit compared to currently approved antidepressants.

AV-101 is a unique prodrug candidate that produces, in the brain, 7-chlorokynurenic acid (7-Cl-KYNA), one of the most potent and selective antagonists of the required glycine-binding site of the N-methyl-D-aspartate (*NMDA*) receptor, resulting in the down-regulation of NMDA signaling. Growing evidence suggests that the glutamatergic system is central to the neurobiology and treatment of MDD and other mood disorders.

The fundamentally novel mechanism of action of AV-101 places it among a new generation of glutamatergic antidepressants with breakthrough potential to treat millions of depression sufferers worldwide who are poorly served by SSRIs, SNRIs and other currently available depression therapies. Like ketamine, AV-101 modulates (down-regulates) NMDA receptor channel activity. However, unlike ketamine's antagonistic activity, which results from its blocking the NMDA receptor channel, AV-101's antagonistic activity results from its selective binding to, and blocking, the functionally-required glycine-binding co-agonist site of the NMDA receptor.

The NIH previously awarded VistaGen $8.8 million to advance preclinical and Phase 1 clinical development of AV-101. In two randomized, double-blind, placebo-controlled Phase 1 safety studies, AV-101 was well tolerated and not associated with any severe adverse events. There were no signs of sedation, hallucinations or schizophrenia-like side effects often associated with ketamine and traditional NMDAR channel blockers. AV-101's preclinical efficacy data, novel mechanism of action, rapid and efficient oral-delivery and demonstrated clinical safety, support our belief that it has breakthrough potential to address the urgent need for antidepressant agents with rapid-acting therapeutic benefits, in a manner similar to results seen in MDD studies with ketamine, but without any delivery limitations or safety concerns of ketamine.

NIH Cooperative Research and Development Agreement for NIH-Sponsored AV-101 Phase 2 Study in MDD

On February 10, 2015, we entered into a Cooperative Research and Development Agreement (*CRADA*) with the NIMH to collaborate with Dr. Zarate and his colleagues at the NIMH on an NIH-sponsored Phase 2 clinical study of the efficacy and safety of AV-101 in subjects with MDD. Dr. Zarate will be the Principal Investigator for the NIH-funded AV-101 Phase 2 MDD study under the CRADA. The study is expected to commence during the first half of 2015 and be completed at the end of 2015.

Stem Cell Technology-based Drug Rescue

With mature, adult human heart cells and liver cells produced using our proprietary pluripotent stem cell technology, we have developed two customized human cellular bioassay systems, *CardioSafe* 3D™ and *LiverSafe* 3D™, for predicting heart toxicity and liver toxicity of new drug candidates, long before they are ever tested in animal or human studies. We are leveraging *CardioSafe* 3D and *LiverSafe* 3D for drug rescue focused on producing proprietary new chemical entities (NCE's) which are safer variants of drug rescue candidates previously optimized and tested for efficacy by pharmaceutical companies and others but terminated before FDA approval due to heart or liver toxicity concerns. Our initial drug rescue programs are focused on NCEs for cancer and CNS disorders.

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, 2014 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three and nine months ended December 31, 2014 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2015 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, 2014 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (*SEC*) on June 25, 2014. Effective August 14, 2014, we consummated a 1-for-20 reverse split of our authorized, and issued and outstanding shares of common stock (the *Stock Consolidation*). Each reference to shares of common stock or the price per share of common stock in these financial statements is post-Stock Consolidation, and reflects the 1-for-20 adjustment as a result of the Stock Consolidation. See Note 8, *Capital Stock*, for more information regarding the Stock Consolidation.

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 $78.3 million accumulated from inception through December 31, 2014. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further potential development of AV-101 and launch and execute our drug rescue programs and pursue potential drug discovery, drug development and regenerative medicine opportunities.

Since our inception in May 1998 through December 31, 2014, we have financed our operations and technology acquisitions primarily through the issuance and sale of equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately $28.0 million, as well as from an aggregate of approximately $16.4 million of government research grant awards, strategic collaboration payments and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $13.0 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services. At December 31, 2014, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations, including expected cash expenditures of approximately $7.5 million over the next twelve months.

To meet our cash needs and fund our working capital requirements after December 31, 2014, between January 1, 2015 and February 13, 2015, we entered into securities purchase agreements with certain accredited investors and institutions to sell units of our securities, for aggregate proceeds of $768,500 consisting of: (i) 10% subordinate convertible promissory notes in the aggregate face amount of $768,500 maturing on March 31, 2015; (ii) an aggregate of 128,350 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 128,350 restricted shares of our common stock at an exercise price of $10.00 per share. See Note 10, *Subsequent Events*, for additional information.

In April 2013, we entered into a Securities Purchase Agreement (as amended, *Securities Purchase Agreement*) with Autilion AG, a company organized and existing under the laws of Switzerland (*Autilion*), under which Autilion remains contractually obligated to purchase an aggregate of 3.6 million restricted shares of our common stock at a purchase price of $10.00 per share for aggregate cash proceeds to us of $36.0 million (*Autilion Financing*). Autilion is currently in default on its obligations under the Securities Purchase Agreement. Substantial doubt exists that the Autilion Financing will close, and therefore no assurances can be provided that Autilion will complete any material portion of its obligations under the Securities Purchase Agreement. In the event that Autilion does not complete a material portion of the Autilion Financing under the Securities Purchase Agreement in the near term, we estimate that we will need to obtain approximately $10 million to $15 million from alternative financing sources during the course of the next 12 months to execute our business plan. We believe our participation in potential strategic collaborations, including potential transactions involving development and commercialization of AV-101, may provide us with cash in support of our future cash needs and working capital requirements. To the extent necessary, we may also seek to meet our current and future cash needs, and fund our current and future working capital requirements, through a combination of private placements and/or registered public offerings of our securities, which may include both debt and equity securities, research and development collaborations, license fees, and government grant awards and collaborations. 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 financing from 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.

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.

The table below summarizes stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income for the three and nine months ended December 31, 2014 and 2013:

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2014	2013	2014	2013
Research and development expense:				
Stock option grants	$ 30,000	$ 126,900	$ 156,100	$ 240,300
Warrants granted to officer in March 2014 and 2013	36,200	33,400	108,800	100,300
	66,200	160,300	264,900	340,600
General and administrative expense:				
Stock option grants	18,600	242,200	86,700	352,500
Warrants granted to officers and directors in March 2014 and 2013	70,700	66,900	212,300	200,600
	89,300	309,100	299,000	553,100
Total stock-based compensation expense	$ 155,500	$ 469,400	$ 563,900	$ 893,700

We did not grant any stock options to employees or consultants during the nine months ended December 31, 2014. During the nine months ended December 31, 2013, we granted stock options to purchase an aggregate of 156,000 shares of our common stock at exercise prices from $8.00 per share to $16.40 per share (the quoted market price on the grant dates after giving effect to the Stock Consolidation) to certain employees and consultants. During the quarter ended December 31, 2013, we modified certain outstanding stock options granted from our 2008 Stock Incentive Plan to reduce the exercise price to $8.00 per share or $10.00 per share and modified certain stock options granted from our 1999 Stock Incentive Plan to reduce the exercise price to $10.00 per share. The expense indicated in the table above for the three and nine months ended December 31, 2013 includes an aggregate of $252,000 attributable to these modifications. At December 31, 2014, there were stock options outstanding to purchase 207,638 shares of our common stock at a weighted average exercise price of $10.09 per share.

Warrant Liability

We have issued a substantial number of warrants to purchase unregistered shares of our common stock to Platinum Long Term Growth VII, LLC, our largest investor (*Platinum*), and, subject to Platinum's exercise of its rights to exchange shares of our Series A Preferred Stock that it holds, we are also obligated to issue additional warrants to purchase unregistered shares of common stock to Platinum (collectively, the *Platinum Warrants*). The Platinum Warrants contain an exercise price adjustment feature that will lower the exercise price of the warrants in the event we subsequently issue equity instruments at a price lower than the exercise price of the Platinum Warrants. We account for the Platinum Warrants as non-cash liabilities and estimate their fair value as described in Note 4, *Fair Value Measurements*, Note 7, *Convertible Promissory Notes and Other Notes Payable*, and Note 8, *Capital Stock*. We compute the fair value of the warrant liability at each reporting period and record 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 is 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 is therefore also subject to significant fluctuation and will continue to be so until all of the Platinum Warrants are issued and exercised, amended or expire. Assuming all other fair value inputs remain generally constant, we will record an increase in the warrant liability and non-cash losses when our stock price increases and a decrease in the warrant liability and non-cash gains when our stock price decreases.

Comprehensive Income (Loss)

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

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 adjust the numerator for the change in the fair value of the warrant liability attributable to outstanding warrants, only if dilutive, and increase the denominator to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method. As a result of our net loss for the periods presented, potentially dilutive securities were excluded from the computation, as their effect would be antidilutive. Potentially dilutive securities were assumed to be converted into common shares and outstanding during the periods for purposes of calculating diluted earnings per share as indicated in the table below.

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2014	2013	2014	2013
Numerator:				
Net (loss) income attributable to common stockholders for basic earnings per share	$ (1,090,300)	$ 131,000	$ (7,664,500)	$ (1,143,100)
less: change in fair value of warrant liability attributable to Exchange, Investment and Bridge Warrants issued to Platinum	(314,900)	(620,800)	(251,500)	(1,354,400)
Net loss for diluted earnings per share attributable to common stockholders	$ (1,405,200)	$ (489,800)	$ (7,916,000)	$ (2,497,500)
Denominator:				
Weighted average basic common shares outstanding	1,302,300	1,110,529	1,270,495	1,077,746
Assumed conversion of dilutive securities:				
Warrants to purchase common stock	-	-	18,179	9,340
Potentially dilutive common shares assumed converted	-	-	18,179	9,340
Denominator for diluted earnings per share - adjusted weighted average shares	1,302,300	1,110,529	1,288,674	1,087,087
Basic net (loss) income attributable to common stockholders per common share	$ (0.84)	$ 0.12	$ (6.03)	$ (1.06)
Diluted net loss attributable to common stockholders per common share	$ (1.08)	$ (0.44)	$ (6.14)	$ (2.30)

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

	As of December 31,	
	2014	2013
Series A preferred stock issued and outstanding [1]	750,000	750,000
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	375,000	375,000
Outstanding options under the 2008 and 1999 Stock Incentive Plans	207,768	235,264
Outstanding warrants to purchase common stock	999,840	785,545
10% convertible Exchange Note and Investment Notes issued to Platinum in October 2012, February 2013 and March 2013, including accrued interest through December 31, 2014 and 2013, respectively [2]	404,420	363,582
10% convertible note issued to Platinum on July 26, 2013, including accrued interest through March 31, 2014 through December 31, 2014 and 2013, respectively	28,891	26,117
10% convertible notes issued as a component of Unit Private Placements, including accrued interest through March 31, 2014 accrued interest through December 31, 2014 and 2013, respectively [3]	322,091	59,305
Total	3,088,010	2,594,813

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

[2] Assumes conversion under the terms of the October 11, 2012 Note Exchange and Purchase Agreement with Platinum and the terms of the individual notes

[3] Excludes effect of conversion premium upon conversion into securities which may be issued in a Qualified Financing, as defined in the notes

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. This ASU is based on the principle that revenue is recognized to depict the transfer of 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 ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The effective date will be the first quarter of our fiscal year ending March 31, 2018, using one of two retrospective application methods. We have not determined the potential effects of adopting this ASU on our consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this ASU remove all incremental financial reporting requirements for development stage entities. Among other changes, this ASU no longer requires development stage entities to present inception-to-date information about income statement line items, cash flows, and equity transactions. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014, with early adoption permitted. We have adopted ASU 2014-10 effective with our fiscal year beginning April 1, 2014 and, accordingly, have eliminated inception-to-date information in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss and Condensed Consolidated Statements of Cash Flows.

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, 2014, 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, we have indicated in Note 2, *Basis of Presentation and Going Concern*, management's plans for additional financing that is expected to permit us to continue our operations for at least one year. 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 assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

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

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

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

We 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 related Exchange Warrant and Investment Warrants to Platinum in October 2012, February 2013, March 2013, and the potential issuance of the Series A Exchange Warrant (see Note 9, *Capital Stock*), all pursuant to the Note Exchange and Purchase Agreement of October 2012 between the Company and Platinum (see Note 7, *Convertible Promissory Notes and Other Notes Payable*), and the issuance of the warrant related to the Senior Secured Convertible Promissory Note issued to Platinum in July 2013, we determined that the Platinum Warrants included certain exercise price adjustment features requiring the warrants to be treated as non-cash liabilities, which were recorded at their estimated fair value. We determined the initial fair value 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 include 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. We have recognized the change in the fair value of these warrant liabilities since the end of the prior fiscal year and the prior fiscal quarter as a non-cash component of other expense, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended December 31, 2014 and 2013, respectively.

The fair value hierarchy for the warrant liability 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)**
December 31, 2014:				
Warrant liability	$ 2,445,600	$ -	$ -	$ 2,445,600
March 31, 2014:				
Warrant liability	$ 2,973,900	$ -	$ -	$ 2,973,900

During the nine month period ended December 31, 2014, there was no significant change to the valuation models used for purposes of determining the fair value of the Level 3 warrant liability. The decrease in the market price of our common stock since March 31, 2014 is the primary factor resulting in the decrease in the 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, 2014	$ 2,973,900
Mark to market income included in net loss	(528,300)
Balance at December 31, 2014	$ 2,445,600

We carried no assets or other liabilities at fair value at December 31, 2014 or March 31, 2014.

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at December 31, 2014 and March 31, 2014:

	December 31, 2014	March 31, 2014
Insurance	$ 52,100	$ 21,800
Legal fees	3,400	3,400
Interest receivable on note receivable from sale of common stock	-	2,800
Technology license fees and all other	6,800	12,500
	$ 62,300	$ 40,500

Note 6. Accrued Expenses

Accrued expenses are composed of the following at December 31, 2014 and March 31, 2014:

	December 31, 2014	March 31, 2014
Accrued professional services	$ 206,400	$ 135,700
Accrued compensation	986,400	489,900
	$ 1,192,800	$ 625,600

Note 7. Convertible Promissory Notes and Other Notes Payable

The following table summarizes our secured and unsecured promissory notes and other notes payable at December 31, 2014 and March 31, 2014.

	December 31, 2014			March 31, 2014		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
Senior Secured 10% Convertible Promissory Notes issued to Platinum:						
Exchange Note issued on October 11, 2012	$ 1,272,600	$ 320,000	$ 1,592,600	$ 1,272,600	$ 203,400	$ 1,476,000
Investment Note issued on October 11, 2012	500,000	125,700	625,700	500,000	79,900	579,900
Investment Note issued on October 19, 2012	500,000	124,400	624,400	500,000	78,600	578,600
Investment Note issued on February 22, 2013	250,000	51,500	301,500	250,000	29,400	279,400
Investment Note issued on March 12, 2013	750,000	150,000	900,000	750,000	84,100	834,100
	3,272,600	771,600	4,044,200	3,272,600	475,400	3,748,000
Convertible promissory note issued on July 26, 2013	250,000	38,900	288,900	250,000	17,700	267,700
Total Senior notes	3,522,600	810,500	4,333,100	3,522,600	493,100	4,015,700
Aggregate note discount	-	-	-	(2,085,900)	-	(2,085,900)
Net Senior notes	3,522,600	810,500	4,333,100	1,436,700	493,100	1,929,800
less: current portion	(2,272,600)	(570,100)	(2,842,700)	-	-	-
Senior notes - non-current portion and discount	$ 1,250,000	$ 240,400	$ 1,490,400	$ 1,436,700	$ 493,100	$ 1,929,800
10% Convertible Promissory Notes (Unit Notes)						
2013/2014 Unit Notes, due 7/31/14	$ -	$ -	$ -	$ 1,007,500	$ 35,700	$ 1,043,200
2014 Unit Notes, including amended notes, due 3/31/15	3,048,400	172,500	3,220,900	50,000	200	50,200
	3,048,400	172,500	3,220,900	1,057,500	35,900	1,093,400
Note discounts	(1,182,100)	-	(1,182,100)	(697,400)	-	(697,400)
Net convertible notes (all current)	$ 1,866,300	$ 172,500	$ 2,038,800	$ 360,100	$ 35,900	$ 396,000
Notes Payable to unrelated parties:						
7.5% Notes payable to service providers for accounts payable converted to notes payable:						
Burr, Pilger, Mayer	$ 90,400	$ 11,900	$ 102,300	$ 90,400	$ 6,800	$ 97,200
Desjardins	169,900	23,000	192,900	178,600	14,100	192,700
McCarthy Tetrault	347,600	43,600	391,200	360,900	24,800	385,700
August 2012 Morrison & Foerster Note A	918,200	166,300	1,084,500	918,200	87,900	1,006,100
August 2012 Morrison & Foerster Note B [1]	1,379,400	299,100	1,678,500	1,379,400	195,200	1,574,600
University Health Network [1]	549,500	91,700	641,200	549,500	60,600	610,100
	3,455,000	635,600	4,090,600	3,477,000	389,400	3,866,400
Note discount	(577,000)	-	(577,000)	(848,100)	-	(848,100)
	2,878,000	635,600	3,513,600	2,628,900	389,400	3,018,300
less: current portion	(1,176,700)	(244,800)	(1,421,500)	(1,130,100)	(133,600)	(1,263,700)
non-current portion and discount	$ 1,701,300	$ 390,800	$ 2,092,100	$ 1,498,800	$ 255,800	$ 1,754,600
5.75% and 10.25% Notes payable to insurance premium financing company (current)	$ 30,200	$ -	$ 30,200	$ 4,900	$ -	$ 4,900
10% Notes payable to vendors for accounts payable converted to notes payable	$ 404,100	$ 46,100	$ 450,200	$ 119,400	$ 34,700	$ 154,100
less: current portion	(404,100)	(46,100)	(450,200)	(119,400)	(34,700)	(154,100)
non-current portion	$ -	$ -	$ -	$ -	$ -	$ -
7.0% Note payable (August 2012)	$ 58,800	$ 6,900	$ 65,700	$ 58,800	$ 3,800	$ 62,600
less: current portion	(21,100)	(6,900)	(28,000)	(15,800)	(3,800)	(19,600)

7.0% Notes payable - non-current portion	$ 37,700	$ -	$ 37,700	$ 43,000	$ -	$ 43,000
Total notes payable to unrelated parties	$ 3,948,100	$ 688,600	$ 4,636,700	$ 3,660,100	$ 427,900	$ 4,088,000
less: current portion	(1,632,100)	(297,800)	(1,929,900)	(1,270,200)	(172,100)	(1,442,300)
non-current portion	2,316,000	390,800	2,706,800	2,389,900	255,800	2,645,700
less: discount	(577,000)	-	(577,000)	(848,100)	-	(848,100)
	$ 1,739,000	$ 390,800	$ 2,129,800	$ 1,541,800	$ 255,800	$ 1,797,600

Notes payable to related parties:

October 2012 7.5% Note to Cato Holding Co.	$ 293,600	$ 49,500	$ 343,100	$ 293,600	$ 30,800	$ 324,400
October 2012 7.5% Note to Cato Research Ltd. [(1)]	1,009,000	182,600	1,191,600	1,009,000	117,300	1,126,300
	1,302,600	232,100	1,534,700	1,302,600	148,100	1,450,700
Note discount	(67,500)	-	(67,500)	(103,200)	-	(103,200)
Total notes payable to related parties	1,235,100	232,100	1,467,200	1,199,400	148,100	1,347,500
less: current portion	(293,600)	(49,500)	(343,100)	(259,600)	(30,800)	(290,400)
non-current portion and discount	$ 941,500	$ 182,600	$ 1,124,100	$ 939,800	$ 117,300	$ 1,057,100

(1) Note and interest payable solely in restricted shares of the Company's common stock.

Approximately $2.3 million in principal amount of our outstanding unsecured promissory notes summarized above are currently past due, and are currently payable on demand. Although no assurances can be given, management currently is engaged in on-going and cooperative discussions with the holders of these notes regarding continuing extensions of the maturity date of such promissory notes, or to otherwise restructure them.

Significant changes in our convertible promissory notes and other promissory notes since March 31, 2014 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 late March 2014 and December 31, 2014, we issued to accredited investors 10% convertible notes (the *2014Unit Notes*) in the aggregate face amount of $2,115,000, including an aggregate face amount of $750,000 of such notes issued to Platinum and 2014 Unit Notes in the aggregate principal amount of $50,000 issued prior to March 31, 2014, in connection with our private placement offering of Units. (See Note 10, *Subsequent Events*, for information regarding additional notes issued in connection with the 2014 Unit Private Placement after December 31, 2014, including additional Unit Notes issued to Platinum.) The 2014 Unit Notes mature on March 31, 2015 (*Maturity*) and the outstanding principal of the 2014 Unit Notes and their related accrued interest (the *Outstanding Balance*) is 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 will 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). This automatic conversion feature results in a contingent beneficial conversion feature which will be recognized subject to our consummation of a Qualified Financing. Under certain circumstances, the holders of the 2014 Unit Notes may request payment in cash in lieu of automatic conversion into the securities of 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 contain an embedded conversion feature, most of which had an 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 amortize the aggregate discount attributable to the 2014 Unit Notes using the effective interest method over the respective term of each 2014 Unit Note. Based on their respective discounts and the period between issuance and maturity, the effective interest rates attributable to the 2014 Unit Notes range from 38.7% to 2,594.7%, with a weighted average rate of 510.5%. During November 2014, we repaid the $10,000 face amount of a 2014 Unit Note issued in October 2014.

Amendment of 2013 Unit Notes and Warrants

Effective May 31, 2014, we entered into note and warrant amendment agreements with substantially all holders of our 2013 Unit Notes and 2013 Unit Warrants, each of whom agreed to (i) modify certain terms of their 2013 Unit Note to conform to the corresponding terms of the 2014 Unit Notes, including an extension of the maturity date of their 2013 Unit Note from July 30, 2014 to March 31, 2015, as well as adoption of the automatic conversion and 25% conversion premium features related to consummation of a Qualified Financing, as described above (*Amended 2013 Unit Notes*), and (ii) modify certain terms of their 2013 Unit Warrants, including the exercise price and expiration date, to conform to the corresponding terms of the 2014 Unit Warrants (*Amended 2013 Unit Warrants*). Holders of 2013 Unit Notes having an aggregate initial face amount of $895,000 agreed to such amendments. The maturity date of 2013 Unit Notes payable to holders who did not agree to amend their 2013 Unit Note and 2013 Unit Warrant remained July 30, 2014 and the $20.00 per share exercise price and July 30, 2016 expiration date of the 2013 Unit Warrants held by such holders remains unchanged. Between April 1, 2014 and August 15, 2014, we repaid 2013 Unit Notes having an initial face value of $ 112,500 and since the later date, no un-amended 2013 Unit Notes remain outstanding.

We determined that the modification of the 2013 Unit Notes and the 2013 Unit Warrants should be accounted for as an extinguishment of debt. Considering the cash flows and the non-contingent and contingent beneficial conversion features of the Amended 2013 Notes and other factors, including market interest rates for unsecured debt of similar quality and the probability of their conversion to securities in a Qualified Financing, we determined that the fair values of the Amended 2013 Unit Notes, aggregating $1,394,000, represented a substantial premium over their aggregate $943,400 face values. In accordance with the provisions of ASC 470-20, *Debt with Conversion and Other Options*, we recognized the premium in excess of the face value, $450,600, as a credit to additional paid-in capital, an equity account. Consequently, we recorded the liability for the Amended 2013 Unit Notes at their face values. We recognized the difference between the pre-modification carrying values of the notes and their fair values, an aggregate of $867,500, as a non-cash charge to loss on extinguishment of debt in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss. As described in greater detail in Note 8, *Capital Stock*, we determined the incremental fair value of the Amended 2013 Unit Warrants, which are treated as equity instruments, to be $272,900. We recognized this incremental fair value as an additional component of loss on extinguishment of debt in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss and as a credit to additional paid-in capital. Certain of the 2013 Unit Notes contained a beneficial conversion feature when they were originally issued. We have accounted for the repurchase of the beneficial conversion feature at the time of the modification, an aggregate of $614,200, 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. The net amount of the loss on extinguishment of debt related to the Amended 2013 Unit Notes and Amended 2013 Unit Warrants recognized in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss is $526,200. Since the Amended 2013 Unit Notes have the same features and maturity as the 2014 Unit Notes, the two sets of notes are aggregated in the summary table above.

Note Conversion and Warrant Amendment Agreement with Platinum

On July 18, 2014, we entered into an Amended and Restated Note Conversion Agreement and Warrant Amendment with Platinum (*Amendment*), pursuant to which Platinum agreed to convert into our unregistered equity securities all Senior Secured Convertible Promissory Notes (*Senior Notes*) held by Platinum, including accrued but unpaid interest thereon (*Outstanding Balance*), in the aggregate amount of approximately $4.3 million at December 31, 2014, upon our consummation on or before August 31, 2014 (*Closing Date*), of either (i) a private equity financing resulting in aggregate gross proceeds of at least $36.0 million (*Private Financing*), or (ii) a public offering of our equity securities registered with the SEC resulting in gross proceeds of at least $10.0 million (*Public Offering*) (the Private Financing and Public Offering are referred to in this discussion as a *Platinum Qualified Financing*). In August and September 2014, we amended the Amendment to extend the Closing Date until October 31, 2014. Upon consummation of a Private Financing, the Senior Notes would have converted into that number of unregistered shares of our common stock equal to the Outstanding Balance on the Closing Date, divided by $10.00 per share. Upon consummation of a Public Offering, the Senior Notes would have converted into shares of newly created Series B Convertible Preferred Stock (*Series B Preferred*) at the lower of $10.00 per share or the lowest per-share price in the Public Offering and having an aggregate liquidation preference equal to the Outstanding Balance on the Closing Date (see Note 8, *Capital Stock*, regarding *Creation of Series B Preferred Stock*).

Additionally, pursuant to the terms and conditions of the Amendment, in the event we had consummated a Platinum Qualified Financing on or before the Closing Date, the exercise price of the Platinum Warrants we have issued to Platinum in connection with the Senior Notes, and warrants that we may still issue pursuant to the Note Exchange and Purchase Agreement between us and Platinum, dated October 11, 2012 (*NEPA*), if any, would have been fixed at the lower of $10.00 per share or the purchase price of common stock sold in the Platinum Qualified Financing. Finally, the anti-dilutive provisions contained in the Platinum Warrants, other than typical adjustments for stock splits, combinations and dividends, would have been terminated as of the Closing Date.

At December 31, 2014, and as of the date of this report, we have not requested Platinum to extend the Closing Date of the Amendment or entered into any other agreement with Platinum regarding the conversion of the Senior Notes, fixing the exercise price of the Platinum Warrants or terminating the anti-dilution provisions of the Platinum Warrants.

At the execution of the Amendment, we determined that the Amendment resulted in a modification of the Senior Notes that should be accounted for as an extinguishment of debt. Considering, among other factors, the cash flows and conversion features of the Senior Notes as modified by the Amendment, market interest rates for debt of similar quality and the relative probabilities of conversion of the Senior Notes into either shares of our common stock or Series B Preferred upon consummation of a Qualified Financing, we determined that the fair values of the Senior Notes at July 18, 2014, aggregating $6,475,000, represented a substantial premium over their aggregate $4,138,700 face values plus accrued interest. In accordance with the provisions of ASC 470-20, *Debt with Conversion and Other Options*, we recognized the premium in excess of the face value and accrued interest, $2,336,300, as a non-cash component of loss on extinguishment of debt in the accompanying Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income with a credit to additional paid-in capital, an equity account. Consequently, we recorded the liability for the Senior Notes at their face values plus accrued interest. We recognized the difference between the pre-modification carrying values of the notes and their face values, an aggregate of $1,983,700, as an additional non-cash charge to loss on extinguishment of debt in the accompanying Condensed Consolidated Statement of Operations and Comprehensive (Loss) Income. Certain of the Senior 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 modification, an aggregate of $2,716,600, as a reduction to the loss on extinguishment of debt in the accompanying Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income, with a corresponding reduction to additional paid-in capital. The net amount of the loss on extinguishment of debt related to the amendment of the Senior Notes recognized in the accompanying Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income for the nine months ended December 31, 2014 is $1,603,400.

Extension of McCarthy Tetrault Note Maturity Date

On June 11, 2014, we agreed with McCarthy Tetrault, our legal counsel in Ontario, Canada *(McCarthy*), to extend the maturity date of our promissory note payable to McCarthy from June 14, 2014 to the earlier of (i) September 30, 2014, (ii) consummation of a financing in which we receive gross cash proceeds of at least $15.0 million, or (iii) consummation of a change of control of the Company, as defined in the McCarthy note. McCarthy also agreed to forbear with respect to the requirement that we make monthly payments on the McCarthy note from the date of the agreement until maturity and granted us a waiver with respect to previously missed monthly payments. At December 31, 2014, the McCarthy note remained outstanding.

Interest on Notes Payable to be Repaid upon Exercise of Common Stock Warrants

Between August 2012 and October 2012, we issued to Morrison & Foerster, LLP, our intellectual property counsel (*M&F*), Cato Research Ltd., our contract research organization for development of AV-101 (*CRL*), and University Health Network, our long-term stem cell research collaborator (*UHN*), certain unsecured promissory notes and related warrants. The respective notes are payable solely in restricted shares of our common stock pursuant to M&F's, CRL's, and UHN's surrender from time to time of all or a portion of the principal and interest balance due on their respective notes in connection with their concurrent exercise of their respective warrant exercisable at $20.00 per share. Between April 1, 2014 and December 31, 2014 we adjusted the M&F warrant, the CRL warrant and the UHN warrant to increase the number of restricted shares available for purchase by 5,198 shares, 3,265 shares and 1,554 shares, respectively, based on interest accrued on the underlying notes through December 31, 2014. We have recorded the fair value of the additional warrant shares, an aggregate of $38,700, as a charge to interest expense and a corresponding credit to additional paid-in capital.

Note 8. Capital Stock

Reverse Split (Stock Consolidation)

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

Creation of Series B Preferred Stock

On July 17, 2014, our Board of Directors authorized the creation of a class of Series B Preferred Stock (*Series B Preferred*) to provide for the potential conversion of the Senior Secured Convertible Promissory Notes held by Platinum totaling approximately $4.3 million in principal and accrued interest at December 31, 2014 (*Outstanding Balance*) into Series B Preferred. However, we have not yet filed a certificate of designation with the Nevada Secretary of State to amend our Articles of Incorporation to formally establish the Series B Preferred.

2014 Unit Private Placement

Between late-March and December 31, 2014, we entered into securities purchase agreements with accredited investors, including Platinum, pursuant to which we sold units to such accredited investors in private placement transactions (*2014 Units*), for aggregate cash proceeds of $2,115,000, consisting of (i) 2014 Unit Notes in the aggregate face amount of $2,115,000 due on March 31, 2015 or automatically convertible into securities we may issue upon the consummation of a Qualified Financing, defined as (a) an equity-based public financing registered with the SEC, or (b) a private equity-based financing or series of private equity-based financings, in either case in which we receive at least $10 million in gross cash proceeds prior to March 31, 2015; (ii) an aggregate of 128,250 restricted shares of our common stock (*2014 Unit Stock)*; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 128,250 restricted shares of our common stock at an exercise price of $10.00 per share (*2014 Unit Warrants*). The Outstanding Balance of each 2014 Unit Notes is convertible into shares of our common stock at a conversion price of $10.00 per share at or prior to maturity, at the option of each investor. In addition, however, the Outstanding Balance is automatically convertible into securities substantially similar to those we may issue in a Qualified Financing at an amount determined by multiplying the Outstanding Balance by 1.25, and dividing the resulting number by the price per share of securities offered in the Qualified Financing. Under certain circumstances, the holders of the 2014 Unit Notes may request payment in cash in lieu of automatic conversion into the securities of the Qualified Financing. We sold $50,000 of Units prior to March 31, 2014, which Units are reflected in the figures above.

We allocated the proceeds from the sale of the 2014 Units to the various securities based on their relative fair values on the dates of the sales. As described in Note 7, *Convertible PromissoryNotes 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 at the 2014 Unit sales date.

	Unit Warrants										Aggregate Allocation of Proceeds Based on Relative Fair Value of:		
	Weighted Average Issuance Date Valuation Assumptions												
Warrant Shares Issued	Market Price	Exercise Price	Term (Years)	Risk free Interest Rate	Volatility	Dividend Rate	Per Share Fair Value of Warrant	Aggregate Fair Value of Unit Warrants	Aggregate Proceeds of Unit Sales	Unit Stock	Unit Warrant	Unit Note
128,250	$ 10.59	$ 10.00	2.44	0.67%	74.34%	0.0%	$ 4.90	$ 628,700	$ 2,115,000	$ 658,600	$ 308,300	$ 1,148,100

Amendment of Notes and Warrants issued in 2013/2014 Unit Private Placement

As indicated in Note 7, *Convertible Promissory Notes and Other Notes Payable*, effective May 31, 2014, we entered into note and warrant amendment agreements with substantially all holders of 2013/2014 Unit Notes and 2013/2014 Unit Warrants to (i) modify certain terms of their 2013/2014 Unit Notes, including the maturity date and certain conversion features, to conform to the corresponding terms of the 2014 Unit Notes and (ii) to modify certain terms of the 2013/2014 Unit Warrants, including the exercise price and expiration date, to conform to the corresponding terms of the 2014 Unit Warrants. Holders of 2013/2014 Unit Notes having an aggregate initial face amount of $895,000 and warrants to purchase an aggregate of 93,250 restricted shares of our common stock agreed to the amendments.

We calculated the fair value of the modified 2013/2014 Unit Warrants immediately before and after the modifications and determined that the fair value of the warrants increased by an aggregate of $272,900, which we treated as a component of loss on extinguishment of debt in the accompanying Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income, with a corresponding credit to additional paid-in capital, an equity account. The warrants subject to the exercise price modifications were valued using the Black-Scholes Option Pricing Model and the following assumptions:

Assumption:	**Pre-modification**	**Post-modification**
Market price per share	$ 12.60	$ 12.60
Exercise price per share	$ 20.00	$ 10.00
Risk-free interest rate	0.44%	0.62%
Remaining contractual term in years	2.17	2.59
Volatility	75.6%	76.6%
Dividend rate	0.0%	0.0%
Fair Value per share	**$ 3.73**	**$ 6.65**

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

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

Issuance of Common Stock to Consultant

In May 2014, we entered into a consulting agreement for strategic advisory and business development services pursuant to which we issued 10,000 restricted shares of our common stock as partial compensation for such professional services. We determined the fair value of stock to be $134,000, based on the $13.40 per share quoted market price of our common stock on the date of the agreement. Additionally, under the terms of the agreement, we paid an aggregate of $80,000 between May 2014 and December 31, 2014 as additional compensation for professional services rendered by the strategic consultant. See Note 10, *Subsequent Events*, for information regarding a new contract entered into with this consultant.

Note Receivable from sale of Common Stock

On October 2, 2014 we received a cash payment of $60,000 from the maker of the May 2011 note receivable issued to us as consideration for the purchase of shares of our common stock. We have considered that payment to be in full satisfaction of the outstanding principal balance of the note and related accrued interest, aggregating $194,900, at the date of the payment and recognized a loss of $132,900 on the settlement of the note, which is reflected as a component of Other expenses, net in the accompanying Statement of Operations and Comprehensive (Loss) Income.

Autilion AG Securities Purchase Agreement

On April 8, 2013, we entered into the Securities Purchase Agreement with Autilion, a company organized and existing under the laws of Switzerland. Under the terms of the Securities Purchase Agreement, Autilion remains contractually obligated to consummate the Autilion Financing and purchase an aggregate of 3.6 million restricted shares of our common stock at a purchase price of $10.00 per share for aggregate cash consideration of $36.0 million. Through our fiscal year ended March 31, 2014, Autilion had completed only a nominal initial closing under the Securities Purchase Agreement, in the amount of $25,000, and we had issued 2,500 restricted shares of our common stock. At December 31, 2014 and through the date of this report, Autilion has not completed a material closing of the Autilion Financing and remains in default on its obligations under the Securities Purchase Agreement. Substantial doubt exists that the Autilion Financing will close, and therefore no assurances can be provided that Autilion will complete any material closing under the Securities Purchase Agreement.

Warrants Outstanding

Following the issuances and modifications described above, at December 31, 2014, we had outstanding warrants to purchase shares of our unregistered common stock at a weighted average exercise price of $15.52 per share as follows:

Exercise Price per Share	Expiration Date	Weighted Average Years to Expiration	Shares Subject to Purchase at December 31, 2014
$ 10.00	1/31/2015 to 3/31/2019	2.40	523,368
$ 12.80	3/3/2023	8.17	147,000
$ 17.60	5/31/2015	0.41	772
$ 20.00	7/30/2016 to 9/30/2017	2.68	183,069
$ 25.00	5/31/2015	0.41	300
$ 30.00	1/31/2015 to 3/4/2018	1.69	117,627
$ 40.00	9/15/2017	2.71	21,250
$ 50.00	5/31/2015	0.41	2,126
$ 52.50	1/31/2015	0.08	3,078
$ 60.00	2/13/2016	1.12	1,250
		3.21	999,840

Note 9. Related Party Transactions

Between September and December 2013, our Chief Executive Officer provided short-term cash advances aggregating $64,000 to meet our short-term working capital requirements. In lieu of our cash repayment of the advances, in December 2013, he elected to invest $50,000 in the 2013 Unit Private Placement. Since March 31, 2014, we have repaid the remaining $3,600 balance of the advances and the $50,000 promissory note issued in connection with his investment in the 2013 Unit Private Placement and related accrued interest.

Cato Holding Company, doing business as Cato BioVentures (*CBV*), the parent of Cato Research Ltd. (*CRL*), is one of our largest institutional stockholders at December 31, 2014. In October 2012, we issued a 7.5% promissory note (*CHC Note*) and a warrant (*CHC Warrant*) to CHC in settlement of prior indebtedness. Total interest expense, including amortization of note discount, on the CHC Note was $7,400 and $7,900 in the three month periods ended December 31, 2014 and 2013, respectively, and $22,500 and $24,000 in the nine month periods ended December 31, 2014 and 2013, respectively.

During fiscal year 2007, we entered into a contract research arrangement with CRL, a contract research organization, related to the development of AV-101, our prodrug candidate which has successfully completed Phase 1 clinical development, and subsequent other projects under which we incurred expenses of $7,500 in each of the three month periods ended December 31, 2014 and 2013 and $22,500 and $45,000 in the nine month periods ended December 31, 2014 and 2013, respectively.

In October 2012, we issued to CRL (i) a 7.5% promissory note (*CRL Note*) as payment in full for all contract research and development services and regulatory 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*). The CRL Note is payable solely by CRL's surrender from time to time of all or a portion of the principal and interest balance due on the CRL Note in connection with its concurrent exercise of the CRL Warrant at an exercise price of $20.00 per share. Total interest expense, including amortization of the note discount, on the CRL Note was $36,300 and $32,000 for the three month periods ended December 31, 2014 and 2013, respectively, and $109,900 and $103,500 for the nine month periods ended December 31, 2014 and 2013, respectively.

Note 10. Subsequent Events

2014 Unit Private Placement

From January 1, 2015 to February 13, 2015, we entered into securities purchase agreements with accredited investors pursuant to which we sold units to such accredited investors in private placement transactions consisting of (i) 10% convertible 2014 Unit Notes maturing on March 31, 2015 in the aggregate face amount of $768,500, including an aggregate of $500,000 of such 2014 Unit Notes to Platinum; (ii) an aggregate of 128,350 shares of our restricted common stock, including 62,500 shares to Platinum; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 128,350 restricted shares of our common stock at an exercise price of $10.00 per share, including warrants to purchase 62,500 restricted shares of our common stock issued to Platinum. We received cash proceeds of $768,500 from the sales of the Units.

Warrant Grants and Modifications

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

Common Stock Grant to Consultant

Effective January 12, 2015, we entered into a consulting agreement for strategic advisory and business development services through December 31, 2015 pursuant to which we issued 20,000 restricted shares of our common stock as compensation for such professional services.

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 other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward- looking statements. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward- looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Our business is subject to significant risks including, but not limited to, our ability to obtain additional financing, the results of our research and development efforts, the results of non-clinical and clinical testing, the effect of regulation by the United States Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the effect of our accounting policies, and other risks as detailed in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended March 31, 2014 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

We are a clinical-stage biopharmaceutical company focused on developing innovative medicine to treat depression, other conditions involving the central nervous system, and cancer.

AV-101 and Major Depressive Disorder

AV-101 (4-Cl-KYN) is our drug candidate in Phase 2 development as a potential new generation treatment for major depressive disorder (*MDD*), one of the most common mental disorders in the U.S., affecting 6.7% of U.S adults each year. AV-101 also has potential as a new treatment for other conditions of the central nervous system (*CNS*), including epilepsy and chronic neuropathic pain, and neurodegenerative diseases such as Parkinson's disease and Huntington's disease.

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). Because of their mechanism of action, currently approved antidepressant drugs often take many weeks to relieve depressive symptoms and induce remission of a major depressive episode. During this multiple-week lag period 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 out of three patients may find an antidepressant drug combination that induces remission of depressive symptoms. Unfortunately, this serial trial and error period to find an effective antidepressant medication can take months to more than a year to achieve, with an increasing rate of potentially significant side effect risks with each successive treatment attempt.

In randomized, placebo-controlled, double-blind clinical trials conducted by Dr. Carlos Zarate, Chief, Section on the Neurobiology and Treatment of Mood Disorders and Chief of the Experimental Therapeutics and Pathophysiology Branch at the U.S. National Institute of Mental Health (*NIMH*), part of the U.S. National Institutes of Health (*NIH*), ketamine, an NMDA receptor antagonist which acts as an NMDA channel blocker, produced robust and rapid, within hours, antidepressant effects in MDD patients who had not responded to approved antidepressant drugs. Although the potential for widespread therapeutic use of ketamine may be severely limited by its potential for abuse, its dissociative and psychosis-like side effects, as well as practical challenges associated with its required intravenous administration in a medical center, the discovery of ketamine's rapid onset antidepressant effects revolutionized thinking about the MDD treatment paradigm and mechanism of action of antidepressant medicines. It also increased interest in the development of a new generation of drug candidates with a mechanism of action similar to ketamine's and a more rapid therapeutic benefit compared to currently approved antidepressants.

AV-101 is a unique prodrug candidate that produces, in the brain, 7-chlorokynurenic acid (7-Cl-KYNA), one of the most potent and selective antagonists of the required glycine-binding site of the N-methyl-D-aspartate (*NMDA*) receptor, resulting in the down-regulation of NMDA signaling. Growing evidence suggests that the glutamatergic system is central to the neurobiology and treatment of MDD and other mood disorders.

The fundamentally novel mechanism of action of AV-101 places it among a new generation of glutamatergic antidepressants with breakthrough potential to treat millions of depression sufferers worldwide who are poorly served by SSRIs, SNRIs and other currently available depression therapies. Like ketamine, AV-101 modulates (down-regulates) NMDA receptor channel activity. However, unlike ketamine's antagonistic activity, which results from its blocking the NMDA receptor channel, AV-101's antagonistic activity results from its selective binding to, and blocking, the functionally-required glycine-binding co-agonist site of the NMDA receptor.

The NIH previously awarded VistaGen $8.8 million to advance preclinical and Phase 1 clinical development of AV-101. In two randomized, double-blind, placebo-controlled Phase 1 safety studies, AV-101 was well tolerated and not associated with any severe adverse events. There were no signs of sedation, hallucinations or schizophrenia-like side effects often associated with ketamine and traditional NMDAR channel blockers. AV-101's preclinical efficacy data, novel mechanism of action, rapid and efficient oral-delivery and demonstrated clinical safety, support our belief that it has breakthrough potential to address the urgent need for antidepressant agents with rapid-acting therapeutic benefits, in a manner similar to results seen in MDD studies with ketamine, but without any delivery limitations or safety concerns of ketamine.

NIH Cooperative Research and Development Agreement for NIH-Sponsored AV-101 Phase 2 Study in MDD

On February 10, 2015, we entered into a Cooperative Research and Development Agreement (*CRADA*) with the NIMH to collaborate with Dr. Zarate and his colleagues at the NIMH on an NIH-sponsored Phase 2 clinical study of the efficacy and safety of AV-101 in subjects with MDD. Dr. Zarate will be the Principal Investigator for the NIH-funded AV-101 Phase 2 MDD study under the CRADA. The study is expected to commence during the first half of 2015 and be completed at the end of 2015.

Stem Cell Technology-based Drug Rescue

With mature, adult human heart cells and liver cells produced using our proprietary pluripotent stem cell technology, we have developed two customized human cellular bioassay systems, *CardioSafe* 3D™ and *LiverSafe* 3D™, for predicting heart toxicity and liver toxicity of new drug candidates, long before they are ever tested in animal or human studies. We are leveraging *CardioSafe* 3D and *LiverSafe* 3D for drug rescue focused on producing proprietary new chemical entities (NCE's) which are safer variants of drug rescue candidates previously optimized and tested for efficacy by pharmaceutical companies and others but terminated before FDA approval due to heart or liver toxicity concerns. Our initial drug rescue programs are focused on NCEs for cancer and CNS disorders.

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, 2014, as filed with the SEC on June 25, 2014, 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

Throughout our fiscal year ended March 31, 2014 and during the nine months ended December 31, 2014, our scientific personnel have successfully expanded the drug rescue capabilities of our novel, customized bioassay systems, *CardioSafe* 3D™ and *LiverSafe* 3D™, and advanced our internal review and assessment in *CardioSafe* 3D of multiple prospective *Drug Rescue Candidates*. 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.

Throughout fiscal 2014 and during the first three quarters of fiscal 2015, our executive management has been significantly focused on providing sufficient operating capital to continue to advance our drug development and research objectives while meeting our continuing operational needs. Although, in April 2013, we entered into a Securities Purchase Agreement (as amended, *Securities Purchase Agreement*) with Autilion AG, an institutional investor organized and existing under the laws of Switzerland (*Autilion*), under which Autilion remains contractually obligated to purchase an aggregate of 3.6 million restricted shares of our common stock at a purchase price of $10.00 per share for aggregate cash proceeds to us of $36.0 million (*Autilion Financing*), to date, Autilion has not completed a material closing under the Securities Purchase Agreement and remains in default thereunder. Substantial doubt exists that the Autilion Financing will close, and therefore no assurances can be given that Autilion will consummate any material closing under the Securities Purchase Agreement.

To meet our working capital needs for our current fiscal year as a result of Autilion's continuing default under the Securities Purchase Agreement, between late-March 2014 and December 31, 2014, we entered into private placement subscription agreements with Platinum and certain accredited investors pursuant to which we sold units (*Units*) consisting of: (i) 10% convertible notes maturing on March 31, 2015 in the aggregate principal amount of $2,115,000; (ii) an aggregate of 128,250 restricted shares of our common stock; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 128,250 restricted shares of our common stock at an exercise price of $10.00 per share. We received cash proceeds of $2,115,000 from the sale of the Units. We have sold an additional $768,500 of Units in private placements to accredited investors between January 1, 2015 and February 13, 2015. Further, to minimize our current cash requirements, as described in Note 7, *Convertible Promissory Notes and Other Notes Payable*, in the notes to our Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q, we entered into agreements with accredited investors holding $895,000 face value of convertible promissory notes issued in our 2013 Unit Private Placement to extend the maturity of such notes from July 31, 2014 to March 31, 2015, unless converted earlier pursuant to a qualified financing, as defined in the agreements.

Given our working capital constraints throughout fiscal 2014 and to date during fiscal 2015, we have attempted to minimize to the greatest extent possible our cash commitments and expenditures for external research and development and general and administrative services, particularly during the later portion of our fiscal year ended March 31, 2014 and during the nine months ended December 31, 2014. As a consequence, throughout the nine months ended December 31, 2014, Shawn Singh, our CEO, voluntarily elected to receive no cash compensation. In addition, during the nine months ended December 31, 2014 each of Ralph Snodgrass, PhD, our President and CSO, and Jerrold Dotson, our CFO, voluntarily elected to receive only 36% and 50% of his contractual salary, respectively. In particular, during the three-month period ended December 31, 2014, Messrs. Singh and Dotson and Dr. Snodgrass voluntarily elected to receive 0%, 15% and 0%, respectively, of their contractual salary. Such unpaid compensation has been accrued for accounting purposes, but has not yet been paid at the date of this report.

Comparison of Three Months Ended December 31, 2014 and 2013

The following table summarizes the results of our operations for the three months ended December 31, 2014 and 2013 (amounts in thousands).

	Three Months Ended December 31,	
	2014	**2013**
Revenue	$ -	$ -
Operating expenses:		
Research and development	445	551
General and administrative	671	897
Total operating expenses	1,116	1,448
Loss from operations	(1,116)	(1,448)
Interest expense, net	(792)	(361)
Change in warrant liabilities	953	1,940
Other expense	(135)	-
(Loss) income before income taxes	(1,090)	131
Income taxes	-	-
Net (loss) income	$ (1,090)	$ 131

Revenue

We reported no revenue for the quarters ended December 31, 2014 or 2013. We have successfully completed our Phase 1 development of AV-101, our novel, orally-available, non-sedating prodrug candidate for the treatment of depression, epilepsy, pain Parkinson's disease. Our NIH grant related to preclinical and Phase 1 development of AV-101 expired in its normal course on June 30, 2012. On February 10, 2015, we entered into a Cooperative Research and Development Agreement with the NIMH, part of the NIH, to collaborate on a NIH-sponsored Phase 2 clinical study of AV-101 in Major Depressive Disorder. We presently have no other revenue generating arrangements.

Research and Development Expense

Research and development expense totaled $445,000 for the quarter ended December 31, 2014, a decrease of 19% compared to $551,000 for the quarter ended December 31, 2013. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2014	**2013**
Salaries and benefits	$ 230	$ 223
Stock-based compensation	66	160
UHN research under SRCA	-	-
Consulting services	23	-
Technology licenses and royalties	43	29
Project-related third-party research and supplies:		
AV-101	7	6
All other including CardioSafe and LiverSafe	10	68
	17	74
Rent	55	54
Depreciation	11	11
Total Research and Development Expense	$ 445	$ 551

To conserve cash resources, during both 2013 and 2014, Ralph Snodgrass, Ph.D., our Chief Scientific Officer (*CSO*), accepted a voluntary salary reduction to substantially less than his contractual pay rate. Although it has not been paid, at December 31, 2014 we have accrued the difference between the CSO's contractual pay rate and his recent pay rate for the period from April 1, 2014 through December 31, 2014. Pay rates for other scientific personnel remained constant between years. Partially offsetting the effect of the accrual 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 during the quarter ended December 31, 2014.

Stock based compensation expense for 2014 reflects the ratable amortization of new option grants made to scientific staff and consultants in October 2013 and March 2014 as well as amortization of grants of warrants made to our CSO in March 2014 and March 2013. The stock options are being amortized over their four-year vesting period, and warrants granted to the CSO are being amortized over a three-year vesting period, but are subject to certain vesting acceleration events. In addition to similar ratable amortization of option and warrant grants, stock-based compensation expense for the quarter ended December 31, 2013 includes approximately $82,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to $8.00 per share or $10.00 per share,

Our sponsored research project budget under the collaboration agreement with Dr. Gordon Keller's laboratory at UHN ended on September 30, 2013 and we incurred no expense under the agreement in the quarters ended December 31, 2014 or 2013. We have been conducting discussions with Dr. Keller and UHN regarding the scope of our 2015 sponsored research projects and budget under the agreement, and we anticipate finalizing such project definitions and budgets in the near term.

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

General and Administrative Expense

General and administrative expense was $671,000 for the quarter ended December 31, 2014, a 25% decrease from the $897,000 reported for the quarter ended December 31, 2013. The following table indicates the primary components of general and administrative expenses for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2014	**2013**
Salaries and benefits	$ 254	$ 155
Stock-based compensation	89	309
Consulting Services	28	24
Legal, accounting and other professional fees	158	74
Investor relations	34	30
Insurance	32	33
Travel and entertainment	7	2
Rent and utilities	39	40
Warrant modification expense	-	207
All other expenses	30	23
Total General and Administrative Expense	$ 671	$ 897

To conserve cash resources, during both 2013 and 2014, Shawn Singh, our Chief Executive Officer (*CEO*), accepted a voluntary salary reduction to substantially less than his contractual pay rate. Similarly, Jerrold Dotson, our Chief Financial Officer (*CFO*), has also accepted a voluntary salary reduction to less than his agreed pay rate. Although it has not been paid, at December 31, 2014, we have accrued the difference between the CEO's and CFO's agreed pay rates and their recent pay rates for the period from April 1, 2014 through December 31, 2014, which amount primarily accounts for the increase in expense between the periods reported. Pay rates for other administrative employees remained stable between the periods presented.

Stock compensation expense for 2014 reflects the ratable amortization of the fair value of prior years' option and warrant grants over the requisite service period. Amortization of stock-based compensation expense related to certain option grants made during 2009 and 2010 has ceased during 2014 as the awards became fully-vested. In addition to such ratable amortization, stock-based compensation expense for the quarter ended December 31, 2013 includes approximately $170,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to $8.00 per share or $10.00 per share.

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

The increase in legal, accounting and other professional expenses is primarily the result of the write-off of approximately $102,000 of legal, accounting and other fees incurred in connection with our Registration Statement on Form S-1, that was withdrawn in December 2014.

Outsourced investor relations service expenses are essentially flat between periods.

The increase in travel expenses reflects costs associated with presentations to potential investors in connection with the fall 2014 attempted registered public offering of our securities.

Warrant modification expense in 2013 reflects the impact of October 2013 and December 2013 strategic reductions in the exercise price of certain outstanding warrants, generally from $35.00 per share or $30.00 per share, to $10.00 per share, and in limited cases, the extension of the term of certain outstanding warrants.

Interest and Other Expenses, Net

Interest expense, net totaled $792,000 for the quarter ended December 31, 2014, an increase of 120% compared to the $361,000 reported for the quarter ended December 31, 2013. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Three Months Ended December 31,	
	2014	**2013**
Interest expense on promissory notes	$ 317	$ 229
Amortization of discount on promissory notes	496	154
Other interest expense, including on capital leases and premium financing	1	2
	814	385
Effect of foreign currency fluctuations on notes payable	(22)	(21)
Interest Income	-	(3)
Interest Expense, net	$ 792	$ 361

The increase in interest expense between the periods is primarily attributable to the accrued interest recorded for the issuances between October 2013 and December 2014 of an aggregate of approximately $2.8 million of 10% convertible promissory notes pursuant to the 2013 Unit Private Placement and the 2014 Unit Private Placement. As a result of the significant inception-date discounts recorded in connection with the Unit Notes and the relatively short period between issuance and maturity over which the discount must be amortized, and the increasing amount of amortization expense recorded using the effective interest rate method as the notes approach maturity, discount amortization increased by approximately $342,000 between the periods shown in the preceding table.

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 in October 2012, February 2013 and March 2013. We also issued a similar senior secured promissory note and related warrant to Platinum in 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. During the quarter ended December 31, 2014 we recognized non-cash gains of $953,700 related to the net decrease in the estimated fair value of these non-cash liabilities since September 30, 2014, which resulted primarily from the decrease in the market price of our common stock in relation to the exercise price of the warrants. During the quarter ended December 31, 2013, we recognized non-cash gains of $1,940,200 related to the net decrease in the estimated fair value of the warrant liabilities since September 30, 2013, which again resulted primarily from the decrease in the market price of our common stock in relation to the exercise price of the warrants.

As described in Note 8, *Capital Stock*, to the Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q, in October 2014, we accepted a cash payment of $60,000 as settlement in full for a promissory note issued to us in May 2011 for the purchase of shares of our common stock. At the time of the payment, the principal and accrued interest due to us on the note receivable was $194,900, resulting in a recognized loss of $134,900 related to the settlement.

Comparison of Nine Months Ended December 31, 2014 and 2013

The following table summarizes the results of our operations for the nine months ended December 31, 2014 and 2013 (amounts in thousands).

	Nine Months Ended December 31,	
	2014	**2013**
Revenue	$ -	$ -
Operating expenses:		
Research and development	1,477	1,916
General and administrative	2,024	2,048
Total operating expenses	3,501	3,964
Loss from operations	(3,501)	(3,964)
Interest expense, net	(2,183)	(1,000)
Change in warrant liabilities	528	3,824
Loss on extinguishment of debt	(2,371)	-
Other expense	(135)	-
Loss before income taxes	(7,662)	(1,140)
Income taxes	(2)	(3)
Net loss	$ (7,664)	$ (1,143)

Revenue

We reported no revenue for the nine months ended December 31, 2014 or 2013. We have successfully completed our Phase I development of AV-101, our novel, orally-available, non-sedating prodrug candidate for the treatment of depression, epilepsy, pain Parkinson's disease. Our NIH grant related to AV-101 expired in its normal course on June 30, 2012. On February 10, 2015, we entered into a Cooperative Research and Development Agreement with the NIMH, part of the NIH, to collaborate on a NIH-sponsored Phase 2 clinical study of AV-101 in Major Depressive Disorder. We presently have no other revenue generating arrangements.

Research and Development Expense

Research and development expense totaled $1,477,000 for the nine months ended December 31, 2014, a decrease of 23% compared to $1,916,000 for the nine months ended December 31, 2013. The following table indicates the primary components of research and development for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2014	**2013**
Salaries and benefits	$ 680	$ 679
Stock-based compensation	265	340
UHN research under SRCA	-	160
Consulting services	85	-
Technology licenses and royalties	177	365
Project-related third-party research and supplies:		
AV-101	23	44
All other including CardioSafe and LiverSafe	49	166
	72	210
Rent	165	129
Depreciation	33	33
Total Research and Development Expense	$ 1,477	$ 1,916

To conserve cash resources, during both 2013 and 2014, Ralph Snodgrass, Ph.D., our Chief Scientific Officer (*CSO*), has accepted a voluntary salary reduction to substantially less than his contractual pay rate. Although it has not been paid, at December 31, 2014, we have accrued the difference between the CSO's contractual pay rate and his recent pay rate for the period from April 1, 2014 through December 31, 2014. Pay rates for other scientific personnel remained constant between years. Offsetting the effect of the accrual 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 during the quarter ended December 31, 2014.

Stock based compensation for 2014 generally reflects the ratable amortization attributable to new option grants made to scientific staff and consultants in October 2013 and March 2014 and earlier as well as amortization attributable to grants of warrants made to our CSO in March 2014 and 2013. The stock options are being amortized over their four-year vesting period; the warrants granted to the CSO are being amortized over a three-year vesting period, but are subject to certain vesting acceleration events. In addition to such ratable amortization, stock-based compensation expense for 2013 includes approximately $82,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to $8.00 per share or $10.00 per share. Further, amortization of stock-based compensation expense related to certain option grants made during 2009 and 2010 has ceased during 2014 as the awards became fully-vested.

Our sponsored research project budget under the collaboration agreement with Dr. Gordon Keller's laboratory at UHN ended on September 30, 2013 and we have incurred no expense under the agreement since that date. We have been engaged in discussions with Dr. Keller and UHN regarding the scope of our 2015 sponsored research projects and budget under the agreement, and we anticipate finalizing such project definitions and budgets in the near term.

Consulting services reflects fees paid or accrued for scientific services rendered to us by third-parties, including by members of our scientific 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. Certain of our technology licensors invoiced us for significant legal fees for patent protection and prosecution during 2013.

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.

The 2014 increase in rent expense reflects increased rental costs related to our relocation to expanded facilities in late-July 2013.

General and Administrative Expense

General and administrative expense was $2,024,000 for the nine months ended December 31, 2014, a decrease of 1% compared with $2,048,000 for the nine months ended December 31, 2013. The following table indicates the primary components of general and administrative expenses for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2014	**2013**
Salaries and benefits	$ 530	$ 553
Stock-based compensation	299	553
Consulting Services	84	87
Legal, accounting and other professional fees	658	275
Investor relations	98	90
Insurance	103	97
Travel and entertainment	49	18
Rent and utilities	117	98
Warrant modification expense	-	174
All other expenses	86	103
Total General and Administrative Expense	$ 2,024	$ 2,048

To conserve cash resources, during both 2013 and 2014, Shawn Singh, our Chief Executive Officer (*CEO*), has accepted a voluntary salary reduction to substantially less than his contractual pay rate. Similarly, Jerrold Dotson, our Chief Financial Officer (*CFO*), has also accepted a voluntary salary reduction to less than his agreed pay rate. Although it has not been paid, at December 31, 2014 we have accrued the difference between the CEO's and CFO's agreed pay rates and their recent pay rates for the period from April 1, 2014 through December 31, 2014, an aggregate of $119,000. Offsetting this amount is the impact of the voluntary resignations of two administrative employees in August and November 2013 who have not been replaced. Pay rates for other administrative employees remained stable between the periods presented.

Stock compensation expense in 2014 reflects the ratable amortization of the fair value of option grants made in prior years and warrant grants made in the current and prior years over the requisite service period. Amortization of stock-based compensation expense related to certain option grants made during 2009 and 2010 has ceased as the awards became fully-vested during 2014. In addition to such ratable amortization, stock-based compensation expense for 2013 includes approximately $170,000 as the impact of October 2013 and December 2013 modifications to reduce the exercise price of certain outstanding option grants to $8.00 per share or $10.00 per share.

Consulting services primarily reflects fees paid or accrued for the services of the independent members of our Board of Directors.

The increase in legal, accounting and other professional fees results primarily from the impact of (i) a consulting agreement for strategic advisory and business development services pursuant to which we issued 10,000 restricted shares of our common stock valued at $134,000 at the date of issuance and have paid $80,000 as cash compensation for such professional services through December 31, 2014; (ii) the write-off of approximately $102,000 of legal, accounting and other fees upon the December 2014 cancellation of the prospective public offering of our equity securities and related withdrawal of our Registration Statement on Form S-1; (iii) legal and other costs related to the 1:20 reverse split of our common stock in August 2014 and legal and filing fees for our private placement Unit financing offerings; and (iv) costs related to temporary employee fees for part-time administrative services.

Outsourced investor relations service expenses are essentially flat between periods; we have conducted no special awareness or other initiatives during either 2014 or 2013. Travel expenses related to late summer and fall 2014 roadshow meetings with potential investors in our attempted registered public offering account for the increase compared to 2013.

The 2014 increase in rent and utilities reflects increased costs related to our relocation to expanded facilities in late-July 2013.

Warrant modification expense in 2013 reflects the impact of October 2013 and December 2013 strategic reductions in the exercise price of certain outstanding warrants, generally from $35.00 per share or $30.00 per share, to $10.00 per share, and in limited cases, the extension of the term of certain outstanding warrants, and from which we used the proceeds of the warrant exercises as a source of short-term working capital..

The decrease in other expenses relates to one-time relocation costs incurred in connection with our relocation to expanded facilities in late-July 2013.

Interest and Other Expenses, Net

Interest expense, net totaled $2,183,000 for the nine months ended December 31, 2014, an increase of 118% compared to the $1,000,000 reported for the nine months ended December 31, 2013. The following table summarizes the primary components of interest expense for each of the periods (amounts in thousands):

	Nine Months Ended December 31,	
	2014	**2013**
Interest expense on promissory notes	$ 909	$ 676
Amortization of discount on promissory notes	1,295	356
Other interest expense, including on capital leases and premium financing	6	6
	2,210	1,038
Effect of foreign currency fluctuations on notes payable	(22)	(30)
Interest Income	(5)	(8)
Interest Expense, net	$ 2,183	$ 1,000

The increase in interest expense between the periods is primarily attributable to the accrued interest recorded for the issuances between August 2013 and December 2014 of an aggregate of approximately $3.2 million of 10% convertible promissory notes pursuant to the 2013 Unit Private Placement and the 2014 Unit Private Placement. As a result of the significant inception-date discounts recorded in connection with the Unit Notes, the relatively short period between issuance and maturity over which the discount must be amortized, and the increasing amount of amortization expense recorded using the effective interest rate method as the notes approach maturity, discount amortization increased by $939,000 between the periods shown in the preceding table.

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 in October 2012, February 2013 and March 2013. We also issued a similar senior secured promissory note and related warrant to Platinum in 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. During the nine months ended December 31, 2014 we recognized non-cash gains of $528,300 related to the net decrease in the estimated fair value of these non-cash liabilities since March 31, 2014, which resulted primarily from the decrease in the market price of our common stock in relation to the exercise price of the warrants. During the nine months ended December 31, 2013, we recognized non-cash gains of $3,823,700 related to the net decrease in the estimated fair value of the warrant liabilities since March 31, 2013, which resulted primarily from the decrease in the market price of our common stock in relation to the exercise price of the warrants.

As described more fully in Note 7, *Convertible Promissory Notes and Other Notes Payable*, and Note 8, *Capital Stock*, in the Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q, effective May 31, 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. 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 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, as described more completely in Note 8, *Capital Stock*, in the Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

As described more completely in Note 7, *Convertible Promissory Notes and Other Notes Payable*, to the Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q, in July 2014, we entered into an agreement with Platinum, as further amended in September 2014, pursuant to which Platinum agreed to convert into our unregistered equity securities all Senior Notes and accrued but unpaid interest thereon held by Platinum upon our consummation prior to October 31, 2014 (*Closing Date*) of either (i) a Private Financing or a Public Offering, each as defined in the agreement. Upon consummation of a Private Financing, the Senior Notes would have converted into that number of unregistered shares of our common stock equal to the Outstanding Balance on the Closing Date, divided by $10.00 per share. Upon consummation of a Public Offering, the Senior Notes would have converted into shares of newly created Series B Convertible Preferred Stock with an aggregate liquidation preference equal to the Outstanding Balance on the Closing Date. Prior to the agreement, the Senior Notes were convertible, at Platinum's option, at any time prior to maturity at a conversion price of $10.00 per share. The modification of the conversion feature in the Senior Notes was treated as an extinguishment of the debt for accounting purposes. Accordingly, since the fair value of the amended Senior Notes substantially exceeded the carrying amount of the original notes, we recognized a non-cash loss on the extinguishment of debt in the aggregate amount of $1,603,400 attributable to the amendment.

As described in Note 8, *Capital Stock*, to the Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q, in October 2014, we accepted a cash payment of $60,000 as settlement in full for a promissory note issued to us in May 2011 for the purchase of shares of our common stock. At the time of the payment, the principal and accrued interest due to us on the note receivable was $194,900, resulting in a recognized loss of $134,900 related to the settlement.

Liquidity and Capital Resources

Since our inception in May 1998 through December 31, 2014, we have financed our operations and technology acquisitions primarily through the issuance and sale of equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately $28.0 million. In addition, we have obtained an aggregate of approximately $16.4 million in government research grant awards, strategic collaboration payments and other revenues. Additionally, we have issued equity securities with an approximate value at issuance of $13.0 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services. At December 31, 2014, we did not have sufficient cash and cash equivalents to enable us to fund our planned operations, including expected cash expenditures of approximately $7.5 million through the next twelve months. In April 2013, we entered into a Securities Purchase Agreement (as amended, *Securities Purchase Agreement*) with Autilion AG, a company organized and existing under the laws of Switzerland (*Autilion*), under which Autilion remains contractually obligated to purchase an aggregate of 3.6 million restricted shares of our common stock at a purchase price of $10.00 per share for aggregate cash proceeds to us of $36.0 million (*Autilion Financing* or *Private Financing*). To date, Autilion has completed only a nominal closing under the Securities Purchase Agreement. Autilion is currently in default under the Securities Purchase Agreement. Substantial doubt exists that the Autilion Financing will close, and therefore no assurances can be provided that Autilion will complete an additional closing under the Securities Purchase Agreement. We currently anticipate that will need to obtain approximately $10 million to $15 million in financing over the course of the next twelve months to execute our business plan.

To continue to meet our cash needs and fund our working capital requirements after December 31, 2014 and prior to the completion of a material financing, through February 13, 2015, we entered into securities purchase agreements with accredited investors and institutions pursuant to which we sold to such accredited investors in private placement transactions units, for aggregate cash proceeds of $768,500, consisting of: (i) 10% convertible 2014 Unit Notes maturing on March 31, 2015 in the aggregate face amount of $768,500, including an aggregate of $500,000 of such 2014 Unit Notes to Platinum; (ii) an aggregate of 128,350 shares of our restricted common stock, including 62,500 shares to Platinum; and (iii) warrants exercisable through December 31, 2016 to purchase an aggregate of 128,350 restricted shares of our common stock at an exercise price of $10.00 per share, including warrants to purchase 62,500 restricted shares of our common stock issued to Platinum.

We believe that our participation in potential strategic collaborations, including potential transactions involving AV-101, such as our February 2015 Cooperative Research and Development Agreement with the U.S. Natural Institutes of Health (*NIH*) for an NIH-funded and sponsored Phase 2 study of AV-101 in major depressive disorder, may provide resources to support a portion of our future cash needs and working capital requirements. If and as necessary, we may supplement the proceeds from a material financing through a combination of additional private placements and/or registered public offerings of our securities, which may include both debt and equity securities, stem cell technology-based research and development collaborations, stem cell technology and drug candidate license fees, and government grant awards and collaborations. 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.

In July 2014 and as subsequently amended in September 2014, we entered into an Amended and Restated Note Conversion Agreement and Warrant Amendment (*Amendment*) with Platinum, wherein Platinum agreed to convert into our unregistered equity securities all Senior Secured Convertible Promissory Notes (*Senior Notes*) currently held by Platinum, in the aggregate amount of approximately $4.3 million at December 31, 2014, including accrued but unpaid interest thereon (*Outstanding Balance*), upon our consummation on or before October 31, 2014 (*Closing Date*), of either a private financing or a public offering that would result in gross proceeds to us of at least $10.0 million or more. We have not extended the applicability of this Amendment beyond October 31, 2014. Unless we reach a new agreement with Platinum regarding the conversion contemplated by the Amendment , we may be required to repay in cash the Senior Notes otherwise maturing between October 2015 and July 2016, which would be detrimental to our liquidity and would increase our intermediate-term cash requirements.

The 2013 Amended Unit Notes and the 2014 Unit Notes and related accrued interest, in an aggregate amount of approximately $4.0 million, mature at March 31, 2015. Although these notes may be converted into restricted shares of our common stock at or before maturity, the holders have the right to request repayment in cash at maturity. If we are unable to complete a substantial financing prior to the maturity of the Unit Notes, and should the holders of a significant amount of the Unit Notes elect repayment in cash rather than conversion of their notes into shares of our common stock, then we may lack adequate cash resources to repay the Unit Notes in full on a timely basis.

In the event the Autilion Financing is completed in an amount exceeding $15.0 million, and we issue more than 1.5 million shares of our restricted common stock in connection with such funding, Autilion will control in excess of 50% of our issued and outstanding common stock, resulting in a change in control of the Company. In the event that we consummate either the Autilion Financing or a substantial alternative financing involving the issuance of shares of our common stock, our existing stockholders will experience significant dilution.

Cash and Cash Equivalents

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

	Nine Months Ended December 31,	
	2014	**2013**
Net cash used in operating activities	$ (1,875)	$ (1,659)
Net cash used in investing activities	-	(9)
Net cash provided by financing activities	1,888	1,051
Net increase (decrease) in cash and cash equivalents	13	(617)
Cash and cash equivalents at beginning of period	-	638
Cash and cash equivalents at end of period	$ 13	$ 21

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.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any legal proceedings nor do we know of any legal proceedings which are threatened or contemplated that would have a material adverse impact on our financial position.

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, 2014 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 Our Business and Strategy

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.

Our future success is highly dependent upon our ability to successfully develop AV-101 and produce proprietary new chemical entities (NCEs) using our stem cell technology, human cells derived from stem cells, our proprietary human cell-based bioassay systems and medicinal chemistry, and we cannot provide any assurance that we will successfully develop AV-101 or NCEs, or that, if produced, AV-101 or any drug rescue-related NCEs 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 sales, marketing or distribution experience. We may seek to collaborate with others to develop and commercialize AV-101, drug rescue NCEs and other future 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.

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.

Our CardioSafe* 3D *internal studies have not been subjected external peer review or validation.

Our internal studies conducted to correlate our *CardioSafe* 3D results with reported clinical results of reference compounds, and our ability to use *CardioSafe* 3D to predict the cardiac effects, both toxic and nontoxic, of drug rescue candidates, have not been subjected to external peer review or validation. It is possible, therefore, that the results we have obtained from our internal validation studies may not be replicable by external peer reviewers. We are currently focused on identifying and assessing drug rescue candidates available in the public domain. However, should we ever seek to license or acquire drug rescue candidates from third-parties in the future, and such third-parties are unable to replicate our results or do not have confidence in the capabilities of *CardioSafe* 3D, it may be difficult for us to in-license or acquire from them certain drug rescue candidates which might be of interest to us in the future. In addition, such third-parties may conclude that their current screening models are better than our *CardioSafe* 3D assay system and that granting a license to the drug rescue candidates we seek from them is not warranted.

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 business 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.

Our human pluripotent stem cell technology is new and technically complex, and the time and resources necessary to develop new cell types and customized bioassay systems are difficult to predict in advance. We intend 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 may encounter difficulties in differentiating particular cell types, even when following these proprietary protocols. These difficulties may 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.

If we are unable to keep up with rapid technological changes in our field, we will be unable to operate profitably.

We are engaged in activities in the life sciences field, which is characterized by rapid technological changes, frequent new product introductions, changing needs and preferences, emerging competition, and evolving industry standards. If we fail to anticipate or respond adequately to technological developments, our business, revenue, financial condition and operating results could suffer materially. Although we believe we are the first stem cell technology company focused primarily on drug rescue, there can be no assurance that others are not also working toward or involved in such objectives, and we anticipate that we will face increased competition in the future as competitors develop or access new or improved bioassay systems and explore and enter the drug rescue market with new technologies. Competitors may have significantly greater financial, manufacturing, sales and marketing resources and may be able to respond more quickly and than we can to new opportunities. In light of these advantages, even if our technology is effective in producing proprietary drug rescue NCEs, potential development partners might prefer NCEs available from others or develop their own NCEs in lieu of licensing or purchasing our drug rescue NCEs. We may not be able to compete effectively against these organizations. Our failure to compete effectively could materially and adversely affect our business, financial condition and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing product candidates before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to our development of AV-101 and our design, production, development and commercialization of proprietary drug rescue NCEs. Our competitors may succeed in developing product candidates for the same indications we are pursuing before we do, obtaining regulatory approval for competing products or gaining acceptance of their products within the same markets that we are targeting for AV-101 and any drug rescue NCEs we produce. If, either on our own or in collaboration with a strategic partner, we are not "first to market" with AV-101 or one of our drug rescue NCEs, our competitive position could be compromised because it may be more difficult for us or our partner to obtain marketing approval for AV-101 or our drug rescue NCEs and successfully market it as a second competitor. We expect that AV-101 and any drug rescue NCEs that we commercialize, either internally or in collaboration with others, will compete with products from other companies in the biotechnology and pharmaceutical industries.

Many of our competitors have substantially greater research and development and commercial infrastructures and financial, technical and personnel resources than we have. We will not be able to compete successfully unless we:

- design, develop, produce and commercialize, either on our own or with collaborators, products that are superior to other products in development or in the market;
- attract qualified scientific, medical, sales and marketing and commercial personnel or collaborators;
- obtain patent and/or other proprietary protection for AV-101 and any drug rescue NCEs we produce; and
- obtain, either on our own or in collaboration with strategic partners, required regulatory approvals for AV-101 and any drug rescue NCEs we may produce.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make AV-101 and any of our proprietary drug rescue NCEs obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Other companies, academic institutions, government agencies and other public and private research organizations are conducting research, seeking patent protection and establishing collaborative arrangements for research, development and marketing of assays similar to ours, and proprietary drug rescue NCEs we may produce, as well as AV-101. These companies and institutions also compete with us in recruiting and retaining qualified scientific and management personnel, obtaining collaborators and licensees, as well as in acquiring technologies complementary to our programs.

As a result of the foregoing, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization than we will. Most significantly, competitive products may render any technologies and product candidates we develop obsolete, which would negatively impact our business and ability to sustain operations.

With respect to drug rescue candidates not otherwise available to us in the public domain, the licensing and acquisition of proprietary small molecule compounds, even compounds that have failed in development due to heart or liver safety concerns, is a highly competitive area, and a number of more established companies may also pursue strategies to license, acquire, rescue and develop small molecule compounds that we may consider to be drug rescue candidates. These established companies have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to sell or license drug rescue candidate rights to us should we ever seek them. We have limited experience in negotiating licenses to drug candidates and there can be no assurances that we will be able to acquire or obtain licenses to drug rescue candidates in the future, on commercially reasonable terms, if at all, should we ever decide to pursue any such third-party licenses. If we are unable to acquire or obtain licenses to drug rescue candidates we seek, our business may be adversely affected.

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.

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 and any additional 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 senior management, as well as other employees, consultants and scientific collaborators. As of the date of this report, we have nine full-time employees, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of services of any of these individuals could delay or prevent the successful development of AV-101 and potential expansions and applications of our stem cell technology platform, 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 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, assay development, drug discovery, drug rescue, and drug rescue NCE development 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.

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 or regenerative medicine-related products, either on our own or in collaboration with others, we will face an inherent risk 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 products. For example, we may be sued if AV-101, any drug rescue NCE or regenerative medicine product 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.

To the extent we enter into licensing or collaboration agreements to develop and commercialize our product candidates, including AV-101 and drug rescue NCEs, our dependence on such relationships may adversely affect our business.

We may enter into strategic partnerships in the future, including collaborations with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our product candidates. Our strategy to produce, develop and commercialize our product candidates, including AV-101 and any drug rescue NCEs, may depend on our ability to enter into such agreements with third-party collaborators. We face significant competition in seeking appropriate strategic partners. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in entering into one or more strategic collaboration agreements with third-parties, such collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary internal development and commercialization programs. We may determine that continuing a collaborative arrangement under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could also delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other products that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting preclinical studies, clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

We cannot provide any assurance that our future collaborations will not terminate development before achievement of revenue-generating milestones or market approval, that our future collaborative arrangements will result in successful development and commercialization of AV-101 or any drug rescue NCEs, or that we will derive any revenues from such future arrangements.

Our and our collaborators' relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our or our future collaborator's arrangements with third-party payors and customers may 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 products for which we or they obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare 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 and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, 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 and also includes provisions allowing for private, civil whistleblower or "qui tam" actions;

- the federal Health Insurance Portability and Accountability Act of 1996 (*HIPAA*), as amended by the Health Information Technology for Economic and Clinical Health Act (*HITECH*), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA and HITECH also regulate the use and disclosure of identifiable health information by health care providers, health plans and health care clearinghouses, and impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of identifiable health information as well as requiring notification of regulatory breaches. HIPAA and HITECH violations may prompt civil and criminal enforcement actions as well as enforcement by state attorneys general;

- 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 under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies 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, 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 health care providers or marketing expenditures; and

- analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries.

Efforts to ensure that our and our future collaborators' business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our or their business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our or their operations are 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we or our collaborators expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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.

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.

Our human cells and human cell-based bioassay systems, including *CardioSafe* 3D and *LiverSafe* 3D, are not currently sold, for research 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 cells we derive from human pluripotent stem cells 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.

We intend to rely on third-party contract manufacturers to produce AV-101 and drug rescue NCEs for development purposes and, if AV-101 and/or any drug rescue NCEs is/are approved, to produce commercial supplies of those and any other approved product candidates we may develop. Any failure by a third-party manufacturer to produce for us supplies of our product candidates may delay or impair our ability to initiate or complete clinical trials, commercialize our product candidates, or continue to sell any products we commercialize.

We do not currently own or operate any manufacturing facilities, and we lack sufficient internal staff to produce product candidate supplies ourselves. As a result, we have worked with, and plan to continue to work with, third-party contract manufacturers to produce sufficient quantities of our product candidates, including AV-101 and any drug rescue NCEs we may develop, for future preclinical and clinical testing and commercialization, as the case may be. If we are unable to arrange for such a third-party manufacturing source or sources, or fail to do so on commercially reasonable terms or on a timely basis, we or our potential strategic partner may not be able to successfully produce, develop, and commercialize our product candidates or may be delayed in doing so.

Reliance on third-party manufacturers entails risks to which we or our potential collaborators would not be subject if we or they manufactured product candidates ourselves or themselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us, or misappropriation of proprietary formulas or protocols. We will be, and our potential strategic partners may be, dependent, on the ability of these third-party manufacturers to produce adequate supplies of drug product to support development programs and future commercialization of our product candidates. In addition, the FDA and other regulatory authorities require that all product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our or our collaborators' third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval for trial initiation or marketing of any product candidates we may produce, including AV-101 and drug rescue NCEs we may develop. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We will, and our potential strategic partners may, rely on contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for required studies. There may be a small number of suppliers for certain capital equipment and materials that we or our collaborators use to manufacture our product candidates. Such suppliers may not sell these materials to our manufacturers at the times we or they need them or on commercially reasonable terms. We will not have any control over the process or timing of the acquisition of these materials by our manufacturers. Although we and our collaborators generally will not begin a required study unless we or they believe a sufficient supply of a product candidate exists to complete the study, any significant delay in the supply of a product candidate or the material components thereof for an ongoing study due to the need to replace a third-party manufacturer could considerably delay completion of the studies, product testing and potential regulatory approval. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

In addition, we or our potential strategic partner may need to optimize the manufacturing processes for a particular drug substance and/or drug product so that certain product candidates may be produced in sufficient quantities of adequate quality, and at an acceptable cost, to support required development activities and commercialization. Contract manufacturers may not be able to adequately demonstrate that an optimized product candidate is comparable to a previously manufactured product candidate which could cause significant delays and increased costs to our or our collaborators' development programs. Our manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our drugs, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, assuming that our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing, third party manufactures with whom we work will need to increase their scale of production or we will need to secure alternate suppliers.

Risks Related to Production, Development, and Regulatory Approval of Product Candidates

Even if we are able to continue clinical development of AV-101, or commence development of any drug rescue NCEs, we may encounter considerable delays and/or expend considerable resources without producing a marketable product capable of generating revenue.

We may never generate revenues from sales of AV-101, any drug rescue NCE or any other product because of a variety of risks inherent in our business, including the following:

- future clinical trials may not demonstrate the safety and efficacy of AV-101, any drug rescue NCE, other new drug candidate, biological candidate or regenerative medicine product candidate;
- completion of nonclinical or clinical trials may be delayed, or costs of nonclinical or clinical trials may exceed anticipated amounts;
- we may not be able to obtain regulatory approval of AV-101, any drug rescue NCE, other new drug candidate, biological candidate or regenerative medicine product candidate; or we may experience delays in obtaining any such approval;
- we may not be able to manufacture, or have manufactured for us, AV-101, any drug rescue NCE*s*, other new drug candidates, biological candidates or regenerative medicine product candidates economically, timely and on a commercial scale;
- we and any licensees of ours may not be able to successfully market AV-101, any drug rescue NCE*s*, other new drug candidates, biological candidates or regenerative medicine product candidates;
- physicians may not prescribe our products, or patients or third party payors may not accept our AV-101 or *Drug Rescue Variants*, other drug candidates, biological candidates or regenerative medicine product candidates;
- others may have proprietary rights which prevent us from marketing AV-101, drug rescue NCEs, other new drug candidates, biological candidates or regenerative medicine product candidates; and
- competitors may sell similar, superior or lower-cost products.

In the event we are able to continue clinical development of AV-101, or commence development of any drug rescue NCE, our or our potential collaborator's future clinical trials may be delayed or halted for many reasons, including:

- delays or failure reaching agreement on acceptable terms with prospective contract manufacturing organizations (*CMO*s), contract research organizations (*CRO*s), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of third-party contractors, such as CROs and CMOs, or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- delays or failure in obtaining the necessary approvals from regulators or institutional review boards (IRBs) in order to commence a clinical trial at a prospective trial site;
- inability to manufacture, or obtain from third parties, a supply of drug product sufficient to complete preclinical studies and clinical trials;
- the FDA requiring alterations to study designs, preclinical strategy or manufacturing plans;
- delays in patient enrollment, and variability in the number and types of patients available for clinical trials, or high drop-out rates of patients;
- clinical trial sites deviating from trial protocols or dropping out of a trial and/or the inability to add new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our product candidates during clinical trials;
- safety issues, including serious adverse events associated with our product candidates and patients' exposure to unacceptable health risks;
- receipt by a competitor of marketing approval for a product targeting an indication that one of our product candidates targets, such that we are not "first to market" with our product candidate;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We or our collaborator could also encounter delays if a clinical trial is suspended or terminated by us, our collaborator, the IRBs of the institutions in which a trial is being conducted, by the Data Safety Monitoring Board (*DSMB*) for a trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, if we or our collaborators are able to complete a clinical trial of AV-101 or other product candidate, the results of such trial may not be adequate to support marketing approval. For any such trial, if the FDA disagrees with the choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including overall survival or complete response rate, the FDA may refuse to approve a BLA or NDA. The FDA may require additional clinical trials as a condition for approving our product candidates.

If we or our collaborator experience delays in the completion of, or termination of, any clinical trial of AV-101 or any other product candidate, the commercial prospects of AV-101 or our product candidates, as the case may be, will be harmed, and our ability to commence product sales and generate product revenues from AV-101 or any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow our AV-101 or other product candidate development and approval process. Delays in completing clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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 or 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.

We, as well as any future strategic partner, will need to receive regulatory approval for any new drug candidate, including AV-101, and any drug rescue NCE, biological candidate or regenerative medicine product, before it may be marketed and distributed, and such regulatory approval may never occur.

Our future success depends heavily on AV-101 and our ability to use stem cell technology, human cells derived from stem cells, proprietary human cell-based bioassay systems, especially *CardioSafe* 3D, and medicinal chemistry to produce drug rescue NCEs and, develop, obtain regulatory approval for, and commercialize AV-101 and any such drug rescue NCEs, on our own or in strategic collaborations. We have not previously submitted a new drug application or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate. We cannot be certain that AV-101 or any other product candidate will be successful in clinical trials or receive regulatory approval. Further, AV-101 and other product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for AV-101 or other product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market AV-101 and/or one or more drug rescue NCEs or other product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

Regulatory approval will require, among numerous other things, completing carefully controlled and well-designed clinical trials demonstrating the safety and efficacy of each new product candidate. This process is lengthy, expensive and uncertain. If we encounter delays in the regulatory approval process beyond our control, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

If we, or our potential strategic partners, experience delays in the enrollment of patients in clinical trials involving our product candidates, our receipt of necessary regulatory approvals could be delayed or prevented.

We or our potential strategic partners may not be able to initiate or continue clinical trials for our product candidates if we or they are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we or our collaborators may be investigating. If we or they fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested is safe and effective. Additionally, enrollment delays in clinical trials may result in increased development costs for our product candidates, which would cause the value of our common stock to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials, and, therefore, product candidates, altogether.

Even if we receive regulatory approval for AV-101 or any drug rescue NCE or other product candidates, we and/or our potential strategic partners will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our potential strategic partners receive for AV-101, any drug rescue NCE or other product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate, all of which could adversely affect the product’s commercial potential and our revenues. In addition, if the FDA approves any of our product candidates, the manufacturing processes, testing, packaging, labeling, storage, distribution, field alert or biological product deviation reporting, adverse event reporting, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with cGMP for commercial manufacturing and good clinical practices, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions, fines or the imposition of other civil or criminal penalties.

Risks Related to Our Financial Position and Capital Requirements

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

We have incurred significant net losses in each fiscal year since our inception in 1998, including net losses of $3.0 million and $12.9 million during the fiscal years ending March 31, 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of $78.3 million. We do not know whether or when we will become profitable. 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. Our losses have resulted principally from costs incurred in our research and development programs and from general and administrative expenses. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our drug rescue, stem cell technology research and development, drug development and potential commercialization activities. Additionally, we expect that our general and administrative expenses will increase in the event we achieve our goal of obtaining a listing on a national securities exchange. The net losses we incur may fluctuate from quarter to quarter.

If we do not successfully develop, out-license, sell or obtain regulatory approval for our future product candidates and effectively manufacture, market and sell, or collaborate to accomplish such activities, any product candidates that are approved, we may never generate revenues from product sales, and even if we do generate product sales revenues, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock also could cause you to lose all or a part of your investment.

As of December 31, 2014, we had outstanding indebtedness in the aggregate principal amount of approximately $11.8 million, including approximately $9.5 million that may be converted into, exchanged for, or is payable with, our equity securities. Unless we are able to convert such indebtedness into our equity securities, according to existing agreements or otherwise restructure such indebtedness, we may be unable to pay up to approximately $7.2 million of such indebtedness when due in the next twelve months.

At December 31, 2014, we had outstanding indebtedness in the aggregate principal amount of approximately $11.8 million, including approximately $9.5 million of promissory notes that may be converted into or exchanged for our equity securities, or extinguished upon the exercise of warrants to purchase shares of our common stock associated with certain of such indebtedness. Up to approximately $7.2 million of our outstanding indebtedness is due or will become due from time to time during the next 12 months, to the extent it is not otherwise (i) restructured or (ii) converted into our equity securities, or otherwise in accordance with certain agreements evidencing, or related to, such indebtedness. No assurances can be given that such conversions, exchanges or extinguishment of indebtedness will occur within the next twelve months, or at all. In the event our indebtedness is not restructured or exchanged or converted into our equity securities, we cannot assure you that we will generate sufficient revenue to repay this indebtedness in full when due. Unless we are able to restructure the terms of such indebtedness, we may be required to raise additional capital through debt and/or equity financing to continue our operations. No assurances can be given that any such financing will be available to us on favorable terms, if at all. Our inability to obtain debt or equity financing in a timely manner and in amounts sufficient to fund our operations, if necessary, would have an immediate and substantial adverse impact on our business, financial condition or results of operations.

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, 2014 included in our Annual Report on Form 10-K have been prepared assuming we will continue to operate as a going concern. However, due to our ongoing operating losses and our accumulated deficit, there is 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 generate a profit and/or 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.

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.

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. In particular, we have expended substantial resources advancing AV-101 through preclinical development and Phase 1 safety studies and developing *CardioSafe* 3D and *LiverSafe* 3D, 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. Furthermore, we expect to incur additional costs associated with operating as a public company.

We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, we out-license or sell AV-101, a drug rescue NCE, customized drug discovery and predictive toxicology assays or other product candidates to a third party, 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, 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.

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.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate research and development activities for one or more of our product candidates, or cease or reduce our operating activities and/or sell or license to third parties some or all of our intellectual property, any of which could harm our operating results.

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of the new capital may include liquidation or other preferences that adversely affect existing stockholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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.

If we do not generate sufficient taxable income we may not be able to use a material portion, or any portion, of our existing net operating losses (*NOL*s). Furthermore, our existing NOLs may be subject to limitations under Section 382 of the Internal Revenue Code of 1986, as amended, which in general provides that a corporation that undergoes an "ownership change" is limited in its ability to utilize its pre- change NOLs to offset future taxable income. Our existing NOLs are subject to limitations arising from previous ownership changes, and if we undergo an ownership change, in connection with a future equity-based financing, series of equity-based financings or otherwise, our ability to utilize NOLs could be further limited by Section 382 of the Internal Revenue Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Internal Revenue Code.

Risks Related to Intellectual Property

We utilize certain technologies that are licensed to us, including key aspects of our stem ell technology platform. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position and market share will be harmed, and our business could be adversely affected.

We currently use certain licensed technologies to produce cells that are material to our research and development programs, including our drug rescue programs, and we may enter into additional license agreements in the future. Our rights to use such licensed technologies are subject to the negotiation of, continuation of and compliance with the terms of the applicable licenses, including payment of any royalties and diligence, insurance, indemnification and other obligations. If a licensor believes that we have failed to meet our obligations under a license agreement for non-payment of license fees, non-reimbursement of patent expenses, or otherwise, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected.

Our license rights are further subject to the validity of the owner's intellectual property rights. As such, we are dependent on our licensors to defend the viability of these patents and patent applications. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Legal action could be initiated by or against the owners of the intellectual property that we license. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent these other companies or institutions from continuing to license intellectual property that we may need to operate our business. In some cases, we do not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties.

Certain of our license agreements are subject to termination by the licensor in specific circumstances, including non-payment of license fees, royalties and patent-related expenses. Any such termination of these licenses could prevent us from producing cells for our research and development programs and future commercial activities, including selling or marketing products. Because of the complexity of our human pluripotent stem cell technology and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties or other amounts due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology would be severely adversely affected.

We may engage in discussions regarding possible commercial, licensing and cross-licensing agreements with third parties from time to time. There can be no assurance that these discussions will lead to the execution of commercial license or cross-license agreements or that such agreements will be on terms that are favorable to us. If these discussions are successful, we could be obligated to pay license fees and royalties to such third parties. If these discussions do not lead to the execution of mutually acceptable agreements, we may be limited or prevented from producing and selling our existing products and developing new products. One or more of the parties involved in such discussions could resort to litigation to protect or enforce its patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. In addition, if we enter into cross-licensing agreements, there is no assurance that we will be able to effectively compete against others who are licensed under our patents.

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.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain, and we could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates.

Our commercial success will depend in part on our ability to protect our intellectual property and proprietary technologies. We rely on patents, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, license agreements and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Pending patent applications of ours or our licensors may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or maintain our competitive advantage. Any patents we have obtained or may obtain in the future, or the rights we have licensed, may be subject to re-examination, reissue, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or products that avoid infringement of these patents or technologies. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

The patent positions of companies in the life sciences and biopharmaceutical industries can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. A number of life sciences, biopharmaceutical and other companies, universities and research institutions have filed patent applications or have been issued patents relating to stem cells, use of stem cells and other modified cells to treat disease, disorder or injury, and other technologies potentially relevant to or required by our existing and planned products. We cannot be certain that patents we have filed or may file in the future will be issued or granted, or that issued or granted patents will not later be found to be invalid and/or unenforceable. The standards applied by the United States Patent and Trademark Office (*US PTO*) and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending or future patent applications. As such, we do not know the degree of future protection that we will have on certain of our proprietary products and technology.

Our patents and patent applications may not be sufficient to protect our products, product candidates and technologies from commercial competition. Our inability to obtain adequate patent protection for our product candidates or platform technology could adversely affect our business.

Publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by at least several months and sometimes several years. Therefore, the persons or entities that we or our licensors name as inventors in our patents and patent applications may not have been the first to invent the inventions disclosed in the patent applications or patents, or the first to file patent applications for these inventions. As a result, we may not be able to obtain patents for discoveries that we otherwise would consider patentable and that we consider to be extremely significant to our future success.

Where several parties seek U.S. patent protection for the same technology, the US PTO may declare an interference proceeding in order to ascertain the party to which the patent should be issued. Patent interferences are typically complex, highly contested legal proceedings, subject to appeal. They are usually expensive and prolonged, and can cause significant delay in the issuance of patents. Moreover, parties that receive an adverse decision in interference can lose patent rights. Our pending patent applications, or our issued patents, may be drawn into interference proceedings, which may delay or prevent the issuance of patents or result in the loss of issued patent rights. As more groups become engaged in scientific research related to hESCs, the number of patent filings by such groups and therefore the risk of our patents or applications being drawn into interference proceedings may increase. The interference process can also be used to challenge a patent that has been issued to another party.

Outside of the U.S., certain jurisdictions, such as Europe, Japan, New Zealand and Australia, permit oppositions to be filed against the granting of patents. Because we may seek to develop and commercialize our product candidates internationally, securing both proprietary protection and freedom to operate outside of the U.S. is important to our business. In addition, the European Patent Convention prohibits the granting of European patents for inventions that concern “uses of human embryos for industrial or commercial purposes”. The European Patent Office is presently interpreting this prohibition broadly, and is applying it to reject patent claims that pertain to hESCs. However, this broad interpretation is being challenged through the European Patent Office appeals system. As a result, we do not yet know whether or to what extent we will be able to obtain European patent protection for our proprietary hESC-based technology and systems.

Patent opposition proceedings are not currently available in the U.S. patent system, but legislation is pending to introduce them. However, issued U.S. patents can be re-examined by the US PTO at the request of a third party. Patents owned or licensed by us may therefore be subject to re-examination. As in any legal proceeding, the outcome of patent re-examinations is uncertain, and a decision adverse to our interests could result in the loss of valuable patent rights.

Successful challenges to our patents through interference, opposition or re-examination proceedings could result in a loss of patent rights in the relevant jurisdiction(s). As more groups become engaged in scientific research and product development areas of hESCs, the risk of our patents being challenged through patent interferences, oppositions, re-examinations or other means will likely increase. If we institute such proceedings against the patents of other parties and we are unsuccessful, we may be subject to litigation, or otherwise prevented from commercializing potential products in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business.

Furthermore, if such challenges to our patent rights are not resolved promptly in our favor, our existing business relationships may be jeopardized and we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could materially harm our business.

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

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technologies, the defendant could counterclaim that our patent 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 could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the US PTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the patent validity, we cannot be certain, for example, 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 one or more of our products or certain aspects of our stem cell platform technology. Such a loss of patent protection could have a material adverse impact on our business.

Claims that any of our product candidates, including AV-101 or drug rescue NCEs, or, if commercialized, the sale or use of our products infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our product candidates, the use of our product candidates, or our stem cell platform technology, do not or will not infringe third party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future. Our failure to successfully defend against any claims that our product candidates or platform technology infringe the rights of third parties could also adversely affect our business. Failure to obtain any required licenses could restrict our ability to commercialize our products in certain territories or subject us to patent infringement litigation, which could result in us having to cease commercialization of our products and subject us to money damages in such territories.

It is also possible that we may fail to identify relevant patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

To avoid or settle potential claims with respect to any patent rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or any future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing one or more of our products, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other business.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation, and could result in unfavorable outcomes that could limit our research and development activities and/or our ability to commercialize certain products.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Moreover, if third parties successfully assert intellectual property rights against us, we might be barred from using certain aspects of our platform technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner to continue our research and development programs or to market our product(s). It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize certain products, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our internal research programs, conduct clinical trials, continue to in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how, and proprietary information concerning our business strategy in order to protect our competitive position in the field of stem cell research and product candidate development. In the course of our research and development activities and other business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining the Company. We take steps to protect our proprietary information, and our confidentiality agreements are carefully drafted to protect our proprietary interests. These confidentiality agreements may not effectively prevent disclosure of our technical know-how and proprietary information and may not provide an adequate remedy in the event of unauthorized disclosure of such technical know-how and proprietary information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we would not be able to assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

There can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we may own or have exclusively licensed;
- We or our licensors or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we may own or have exclusively licensed;
- We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- Others may be able to develop technologies around some of our issued patents without infringing such patents;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

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 development stage biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity. Therefore, obtaining and enforcing patents is costly, time-consuming and inherently uncertain. In addition, Congress has passed patent reform legislation which provides new limitations on attaining, maintaining and enforcing intellectual property. Further, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the US PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are not able to obtain and enforce patent protection or other commercial protection for AV-101, the value of AV-101 will be harmed.

Commercial protection of AV-101, our small molecule drug candidate for Major Depressive Disorder, neuropathic pain, epilepsy and other neurological conditions is important to our business. Our success related to AV-101 will depend in part on our or a potential collaborator's ability to obtain and enforce potential patents, maintain our trade secrets and secure New Drug Product Exclusivity provided by the FDA under section 505(c)(3)(E) and 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act.

Additional patents may not be granted, and potential U.S. patents, if issued, might not provide us with commercial benefit or might be infringed upon, invalidated or circumvented by others. The principle U.S. method of use patent and its foreign counterparts for AV-101 have expired. Although we have filed three (3) international applications under the Patent Cooperation Treaty (*PCT Applications*) including, among others, claims regarding unit dose, method-of-use, and novel methods of synthesizing AV-101, we or others with whom we may collaborate for the development and commercialization of AV-101 may choose not to seek, or may be unable to obtain, patent protection in a country that could potentially be an important market for AV-101.

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

Our ability to execute on our business plan will depend on the talents and efforts of highly skilled individuals with specialized training in the field of stem cell research and bioassay development, as well as medicinal chemistry and in vitro drug candidate screening and nonclinical and clinical development. Our future success depends on our ability to identify, hire and retain these highly skilled personnel during our development stage. We may hire additional highly skilled scientific and technical employees, including employees who may have been previously employed at biopharmaceutical companies, including our competitors or potential competitors, and who may have executed invention assignments, nondisclosure agreements and/or non-competition agreements in connection with such previous employment. As to such future employees, we may become subject to claims that we, or these future employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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 OTC Markets (*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, another over-the-counter quotation system, or in the "pink sheets." In those venues, 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. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- financial projections we may provide to the public, any changes to those projections, or our failure to meet those projections;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the biopharmaceutical and life sciences sectors;
- failure to complete significant sales;
- changes in legislation and government regulation;
- public concern regarding the safety, efficacy or other aspects of our products;
- entering into, changing or terminating collaborative relationships;
- any shares of our common stock or other securities eligible for future sale;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

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 report, there has been a limited public market for shares of our common stock on the OTC Markets. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exchange of our Series A Preferred Stock, conversion of convertible promissory notes and exercise of outstanding options and warrants for common stock, in the public market, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

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 approximately 24% of our outstanding capital stock. Accordingly, these stockholders may continue to have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock may depend in part on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In the event we obtain analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. If one or more equity research analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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 and our Board has authorized the issuance of 500,000 shares of Series A Preferred, all of which shares are currently issued and outstanding. 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.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our management is currently required to assess the effectiveness of our controls and we are required to disclose changes made in our internal control over financial reporting on a quarterly basis. As a "smaller reporting company," however, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot continue to favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls whenever required in the future, investors could lose confidence in our financial information and the price of our common stock could decline. Additionally, should we cease to be a "smaller reporting company," we will incur additional expense and management effort to facilitate the required attestation of the effectiveness of our internal control over financial reporting by our independent registered public accounting firm.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Any payment of cash dividends will depend upon our financial condition, contractual restrictions, financing agreement covenants, solvency tests imposed by corporate law, results of operations, anticipated cash requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may incur indebtedness that may severely restrict or prohibit the payment of dividends.

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

Sale of Units in 2014 Unit Private Placement

Between November 26, 2014 and February 13, 2015, we entered into private placement subscription agreements with accredited investors pursuant to which we sold to such investors 2014 Units, as described more completely in Note 8, *Capital Stock*, in the Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q, consisting of (i) 2014 Unit Notes in the aggregate face amount of $943,500; (ii) an aggregate of 159,600 shares of 2014 Unit Stock; and (iii) 2014 Unit Warrants to purchase an aggregate of 159,600 restricted shares of our common stock at an exercise price of $10.00 per share. We received cash proceeds of $943,500 from the sales of these 2014 Units, which we expect to use for general corporate purposes. The 2014 Units were offered and sold in transactions exempt from registration under the Securities Act of 1933, as amended (the *Securities Act*), in reliance on Section 4(2) thereof and/or Rule 506 of Regulation D thereunder.

Issuance of Shares for Consulting Services

Effective January 12, 2015, we entered into a consulting agreement for strategic advisory and business development services through December 31, 2015 pursuant to which we issued 20,000 restricted shares of our common stock as compensation for such professional services. The shares were issued in a transaction exempt from registration under the Securities Act of 1933, as amended (the *Securities Act*), in reliance on Section 4(2) thereof and/or 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

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: February 17, 2015

EXHIBIT 31.1

CERTIFICATION

I, Shawn K. Singh, certify that;

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 13, 2015

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

EXHIBIT 31.2

CERTIFICATION

I, Jerrold D. Dotson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VistaGen Therapeutics, Inc.;

2. Based on my knowledge, this report, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 13, 2015

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

EXHIBIT 32

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

In connection with the Quarterly Report on Form 10-Q of VistaGen Therapeutics, Inc. (the "*Company*") for the quarter ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), Shawn K. Singh, JD, the Company's Principal Executive Officer, and Jerrold D. Dotson, the Company's Principal Financial Officer, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirement of Section 13(a) or Section 15 (d) of the Securities Exchange Act of 1934, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 17, 2015

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

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