VistaGen Therapeutics, Inc.
Form 10-Q
August 14, 2017

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 June 30, 2017
or

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: 001-37761

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

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

343 Allerton Avenue
South San Francisco, 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 No

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

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-Accelerated filer	[ ]	Smaller reporting company	[X]
		Emerging growth company	[ ]

(do not check if a smaller reporting company)

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

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

As of August 11, 2017, 9,380,044 shares of the registrant’s common stock, $0.001 par value, were issued and outstanding.

VistaGen Therapeutics, Inc.
Quarterly Report on Form 10-Q
for the Quarter Ended June 30, 2017

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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)

	June 30, 2017 (Unaudited)	March 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$1,628,200	$2,921,300
Prepaid expenses and other current assets	498,000	456,600
Total current assets	2,126,200	3,377,900
Property and equipment, net	262,900	286,500
Security deposits and other assets	47,800	47,800
Total assets	$2,436,900	$3,712,200
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$632,000	$867,300
Accrued expenses	204,900	443,000
Current portion of notes payable and accrued interest	165,500	54,800
Capital lease obligations	2,400	2,400
Total current liabilities	1,004,800	1,367,500
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	1,825,100	1,577,800
Deferred rent liability	202,500	139,200
Capital lease obligations	11,300	11,900
Total non-current liabilities	2,038,900	1,728,900
Total liabilities	3,043,700	3,096,400

Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2017 and March 31, 2017:		
Series A Preferred, 500,000 shares authorized and outstanding at June 30, 2017 and March 31, 2017	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2017 and March 31, 2017; 1,160,240 shares issued and outstanding at June 30, 2017 and March 31, 2017	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2017 and March 31, 2017; 2,318,012 shares issued and outstanding at June 30, 2017 and March 31, 2017	2,300	2,300
Common stock, $0.001 par value; 30,000,000 shares authorized at June 30, 2017 and March 31, 2017; 9,437,137 and 8,974,386 shares issued at June 30, 2017 and March 31, 2017, respectively	9,400	9,000
Additional paid-in capital	147,611,900	146,569,600
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2017 and March 31, 2017	(3,968,100)	(3,968,100)
Accumulated deficit	(144,264,000)	(141,998,700)
Total stockholders' equity (deficit)	(606,800)	615,800
Total liabilities and stockholders' equity (deficit)	$2,436,900	$3,712,200

See accompanying notes to Condensed Consolidated Financial Statements.

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VISTAGEN THERAPEUTICS, INC.

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

	Three Months Ended June 30,	
	2017	2016
Operating expenses:		
Research and development	$1,096,200	$825,700
General and administrative	1,164,300	1,137,600
Total operating expenses	2,260,500	1,963,300
Loss from operations	(2,260,500)	(1,963,300)
Other expenses, net:		
Interest expense, net	(2,400)	(1,400)
Loss before income taxes	(2,262,900)	(1,964,700)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	(2,265,300)	(1,967,100)
Accrued dividend on Series B Preferred stock	(247,300)	(539,800)
Deemed dividend on Series B Preferred Units	-	(111,100)
Net loss attributable to common stockholders	$(2,512,600)	$(2,618,000)
Basic and diluted net loss attributable to common stockholders per common share	$(0.28)	$(0.51)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	9,034,213	5,097,832

See accompanying notes to Condensed Consolidated Financial Statements.

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VISTAGEN THERAPEUTICS, INC.

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

	Three Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(2,265,300)	$(1,967,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	23,600	13,300
Stock-based compensation	367,000	107,900
Expense related to modification of warrants, including exchange of warrants for common stock	-	40,300
Amortization of deferred rent	63,300	(7,900)
Fair value of common stock granted for services	49,800	-
Fair value of Series B Preferred stock granted for services	-	375,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	101,000	34,600
Accounts payable and accrued expenses, including accrued interest	(473,500)	(267,100)
Net cash used in operating activities	(2,134,100)	(1,671,000)
Cash flows from investing activities:		
Purchases of equipment	-	(2,000)
Net cash used in investing activities	-	(2,000)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants, including Units	873,300	9,537,100
Net proceeds from issuance of Series B Preferred Units	-	278,000
Repayment of capital lease obligations	(600)	(300)
Repayment of notes	(31,700)	(70,400)
Net cash provided by financing activities	841,000	9,744,400
Net increase (decrease) in cash and cash equivalents	(1,293,100)	8,071,400
Cash and cash equivalents at beginning of period	2,921,300	428,500
Cash and cash equivalents at end of period	$1,628,200	$8,499,900
Supplemental disclosure of noncash activities:		
Insurance premiums settled by issuing note payable	$142,400	$117,500
Accrued dividends on Series B Preferred	$247,300	$539,800
Accrued dividends on Series B Preferred settled upon conversion by issuance	$-	$1,683,400

of common stock

See accompanying notes to Condensed Consolidated Financial Statements.

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

Note 1. Description of Business

Overview

VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a Nevada corporation, is a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders.

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

Clinical studies conducted at the U.S. National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), by Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, have focused on the antidepressant effects of low dose ketamine hydrochloride injection (ketamine), an NMDA receptor antagonist, in MDD patients with inadequate responses to multiple standard antidepressants. These NIMH studies, as well as clinical research at Yale University and other academic institutions, have demonstrated robust antidepressant effects in these MDD patients within twenty-four hours of a single sub-anesthetic dose of ketamine administered by intravenous (IV) injection.

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

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

Study). Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, will be the Principal Investigator of our AV-101 MDD Phase 2 Adjunctive Treatment Study. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We currently anticipate completing our AV-101 MDD Phase 2 Adjunctive Treatment Study by the end of 2018 with top line results available in the first quarter of 2019.

VistaGen Therapeutics, Inc., a California corporation dba VistaStem Therapeutics (VistaStem), is our wholly-owned subsidiary focused on applying human pluripotent stem cell (hPSC) technology, internally and with third-party collaborators, to discover, rescue, develop and commercialize (i) proprietary new chemical entities (NCEs), including small molecule NCEs with regenerative potential, for CNS and other diseases and (ii) cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. Our internal drug rescue programs are designed to utilize CardioSafe 3D, our customized cardiac bioassay system, to develop small molecule NCEs for our pipeline. To advance potential regenerative medicine (RM) applications of our cardiac stem cell technology, in December 2016, VistaStem exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established in 2016 by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease (the BlueRock Agreement). In a manner similar to its exclusive sublicense agreement with BlueRock Therapeutics, VistaStem may pursue additional collaborations and potential RM applications of its stem cell technology platform, including using blood, cartilage, and/or liver cells derived from hPSCs, for (i) cell-based therapy, (ii) cell repair therapy, and/or (iii) tissue engineering.

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Subsidiaries

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

Note 2. Basis of Presentation

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, 2017 has been derived from our audited consolidated financial statements at that date but does not include all disclosures required by U.S. GAAP. The operating results for the three months ended June 30, 2107 are not necessarily indicative of the operating results to be expected for our fiscal year ending March 31, 2018, or for any other future interim or other 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 our fiscal year ended March 31, 2017 contained in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) on June 29, 2017.

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared assuming we will continue as a going concern. As a company having not yet developed commercial products or achieved sustainable revenues, we have experienced recurring losses and negative cash flows from operations resulting in a deficit of $144.3 million accumulated from inception (May 1998) through June 30, 2017. We expect losses and negative cash flows from operations to continue for the foreseeable future as we engage in further development of AV-101, initially as an adjunctive treatment for MDD, and subsequently as a new treatment alternative for other CNS-related conditions, as well as exploring and potentially executing drug rescue and development opportunities using CardioSafe 3D, and potential RM programs related to VistaStem's technology platform.

From our inception through June 30, 2017, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities for cash proceeds of approximately $45.5 million, as well as from an aggregate of approximately $17.6 million of government research grant awards, strategic collaboration payments, intellectual property sublicensing and other revenues. We have also issued equity securities with an approximate value at issuance of $30.8 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services. Additionally, pursuant to our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIH, substantial ongoing Phase 2 clinical development activities relating to AV-101 as a potential new generation antidepressant are being sponsored in full, at no cost to us other than supplying clinical trial material, by the NIMH under the direction of Dr. Carlos Zarate Jr. as Principal Investigator.

At June 30, 2017, we had a cash and cash equivalents balance of $1.6 million. This amount was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately $12 million for the twelve months following the issuance of these financial statements, including expenditures required to launch and

satisfy a significant portion of the projected expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study.

Our limited cash position at June 30, 2017 considered with our recurring and anticipated losses and negative cash flows from operations make it probable, in the absence of additional financing, that we will not be able to meet our obligations as they come due within one year from the date of this Report, raising substantial doubt that we can continue as a going concern. However, to alleviate that doubt, we plan, as we have numerous times in the past, to raise additional financing when and as needed, primarily through the sale of our equity securities in one or more private placements to accredited investors or public offerings. Additionally, we have filed a Registration Statement on Form S-3 (Registration No. 333-215671) (the S-3 Registration Statement) that has been declared effective by the Securities and Exchange Commission (the Commission) to cover our potential future sale of our equity securities in one or more public offerings from time to time. As of the date of this Report, we have not yet sold any securities under the S-3 Registration Statement, nor do we have an obligation to do so. Further, at June 30, 2017, we had a limited number of unallocated or unreserved shares of our common stock available for issuance in future offerings or for other purposes. To facilitate potential future issuances and sales of our equity securities for ordinary corporate finance and general corporate purposes, our Board of Directors (Board) has approved an amendment to our Restated and Amended Articles of Incorporation to increase the number of shares of common stock available for issuance thereunder from 30 million shares to 100 million shares, an amount our Board has determined is customary and appropriate for a Nasdaq-listed, clinical-stage biopharmaceutical company. Before taking effect, this amendment must be approved by a majority of our stockholders at our 2017 annual meeting of stockholders in September 2017.

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In addition to the sale of our equity securities, we may also seek to enter research and development collaborations that could generate revenue or provide substantial funding for development of AV-101 and additional product candidates. We may also seek additional government grant awards or agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH AV-101 MDD Phase 2 Monotherapy Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations with the U.S. government or other third-parties that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates and technologies, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

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

Notwithstanding the foregoing, there can be no assurance that our stockholders will authorize the issuance of additional shares of our common stock to facilitate further financing opportunities and for other general corporate purposes, or that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. If we are unable to obtain substantial additional financing on a timely basis when needed later in 2017 and beyond, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern. As noted above, these Condensed Consolidated Financial Statements do not include any adjustments that might result from the negative 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 share-based compensation, and assumptions that have been used historically to value warrants and warrant modifications. With the exception of the $1.25 million of sublicense revenue recorded in the quarter ended December 31, 2016 under the BlueRock Agreement, we do not currently have, nor have we had during the periods covered by this report, any arrangements requiring the recognition of revenue.

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 our scientific personnel and direct project costs. External research and development expenses consist primarily of costs associated with nonclinical and clinical development of AV-101, now in Phase 2 clinical development, initially for MDD, stem cell technology-related research and development costs, and costs related to the filing, maintenance and prosecution of patents and patent applications, technology licenses and protection of other intellectual property. All such costs are charged to expense as incurred.

Stock-Based Compensation

We recognize compensation cost for all stock-based awards to employees or consultants 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 or consultant 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 change in 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 for the three months ended June 30, 2017 and 2016.

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	Three Months Ended June 30,	
	2017	2016
Research and development expense:		
Stock option grants	$191,400	$44,000
	191,400	44,000
General and administrative expense:		
Stock option grants	175,600	63,900
	175,600	63,900
Total stock-based compensation expense	$367,000	$107,900

In April 2017, our Board approved the grant of options to purchase an aggregate of 880,000 shares of our common stock at an exercise price of $1.96 per share to the independent members of our Board, our officers and our employees. In June 2016, our Board approved the grant of options to purchase an aggregate of 655,000 shares of our common stock at an exercise price of $3.49 per share to the independent members of our Board and to our officers, including our then-newly-hired Chief Medical Officer. We valued the options granted in April 2017 and June 2016 using the Black-Scholes Option Pricing Model and the following weighted average assumptions:

Assumption:	April 2017	June 2016
Market price per share at grant date	$1.96	$3.49
Exercise price per share	$1.96	$3.49
Risk-free interest rate	2.02%	1.34%
Contractual or estimated term in years	6.48	6.68
Volatility	83.24%	81.69%
Dividend rate	0.0%	0.0%
Shares	880,000	655,000
Fair Value per share	$1.42	$2.50

Comprehensive Loss

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

Income (Loss) per Common Share

Basic net income (loss) per share of common stock excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue shares of common stock were exercised or converted into shares of common stock.

As a result of our net loss for the periods presented, potentially dilutive securities were excluded from the computation of net loss per share, as their effect would be antidilutive. For the three-month periods ended June 30, 2017 and 2016, the accrual for dividends on our Series B 10% Convertible Preferred Stock (Series B Preferred) and the deemed dividend attributable to our sale and issuance of Series B Preferred Units, each consisting of one share of Series B Preferred and a five-year warrant to purchase one share of our common stock for $7.00, represent deductions from our net loss to arrive at net loss attributable to common stockholders for those periods.

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

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	As of June 30,	
	2017	2016
Series A Preferred stock issued and outstanding (1)	750,000	750,000
Series B Preferred stock issued and outstanding (2)	1,160,240	1,247,740
Series C Preferred stock issued and outstanding (3)	2,318,012	2,318,012
Outstanding options under the Amended and Restated 2016 (formerly 2008) and 1999 Stock Incentive Plans	2,522,593	986,987
Outstanding warrants to purchase common stock	4,796,506	4,606,480
Total	11,547,351	9,909,219

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

Fair Value Measurements

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. We carried no assets or liabilities at fair value at June 30, 2017 or March 31, 2017.

Recent Accounting Pronouncements

Except as described below, there have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended June 30, 2017, as compared to the recent accounting pronouncements described in our Form 10-K for the fiscal year ended March 31, 2017, that are of significance or potential significance to us.

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-2, “Leases.” This ASU requires substantially all leases, including operating leases, to be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability. This ASU is effective for our interim and annual reporting periods beginning April 1, 2019 and early adoption is permitted. We are currently evaluating the impact that the adoption of this ASU will have on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which simplified several aspects of the accounting for share-based payments, including immediate recognition of all

excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. This ASU became effective for our interim and annual reporting periods beginning April 1, 2017, and the adoption of this standard did not have a material impact on our financial statements. As part of the adoption of this standard, we elected to account for the impact of option forfeitures as they occur.

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are composed of the following at June 30, 2017 and March 31, 2017:

	June 30, 2017	March 31, 2017
Insurance	$189,200	$85,800
AV-101 materials and services	274,500	352,800
Public offering expenses	22,100	11,600
All other	12,200	6,400
	$498,000	$456,600

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Note 5. Accrued Expenses

Accrued expenses are composed of the following at June 30, 2017 and March 31, 2017:

	June 30, 2017	March 31, 2017
Accrued professional services	$139,200	$37,000
Accrued AV-101 development and related expenses	59,000	402,400
All other	6,700	3,600
	$204,900	$443,000

Note 6. Notes Payable

The following table summarizes our unsecured promissory notes at June 30, 2017 and March 31, 2017.

	June 30, 2017			March 31, 2017		
	Principal Balance	Accrued Interest	Total	Principal Balance	Accrued Interest	Total
7.95% and 8.25% Notes payable to insurance premium financing company (current)	$165,500	$-	$165,500	$54,800	$-	$54,800

In May 2017, we executed a 7.95% promissory note in the principal amount of $142,400 in connection with insurance policy premiums. The note is payable in monthly installments of $14,800, including principal and interest, through March 2018, and had a remaining outstanding balance of $128,600 at June 30, 2017. In February 2017, we executed a promissory note in the principal amount of $60,700 in connection with other insurance policy premiums. That note is payable in monthly installments of $6,300, including principal and interest, and had an outstanding balance of $36,900 at June 30, 2017.

Note 7. Capital Stock

Common Stock and Warrants Issued in Private Placement

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

Issuance of Common Stock to Professional Services Providers

During the quarter ended June 30, 2017, we issued 25,000 shares of our unregistered common stock having a fair value on the date of issuance of $49,800 as partial compensation to an investor relations service provider.

Warrants Outstanding

Following the warrant issuances in the self-placed private placement described above, at June 30, 2017, we had outstanding warrants to purchase shares of our common stock at a weighted average exercise price of $6.19 per share as follows:

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Exercise Price per Share	Expiration Date	Warrants Outstandingat June 30, 2017
$3.51	12/31/2021	50,000
$3.96	4/30/2021	43,750
$3.98	4/30/2021	25,125
$4.00	4/30/2021	178,625
$4.50	9/26/2019	25,000
$5.30	5/16/2021	2,705,883
$6.00	9/26/2019 to 11/30/2019	97,750
$7.00	12/11/2018 to 3/3/2023	1,346,931
$8.00	3/25/2021	185,000
$10.00	11/15/2017 to 1/11/2020	24,394
$20.00	9/15/2019	110,448
$30.00	11/20/2017	3,600
		4,796,506

With the exception of 2,705,883 shares of common stock underlying the warrants exercisable at $5.30 per share issued in our May 2016 public offering, all of the common shares issuable upon exercise of our outstanding warrants are unregistered.

Note 8. Related Party Transactions

Cato Holding Company (CHC), doing business as Cato BioVentures (CBV), is the parent of Cato Research Ltd. (CRL). CRL is a contract research, development and regulatory services organization (CRO) recently engaged by us for certain material aspects of the development and regulatory affairs associated with Phase 2 development of AV-101 for MDD. CBV is among our largest institutional stockholders at June 30, 2017, holding approximately 6.5% of our outstanding common stock. In October 2012, we issued certain unsecured promissory notes in the aggregate principal amount of approximately $1.3 million to CBV and CRL (the Cato Notes) as payment in full for all contract research and development services and regulatory advice previously rendered to us by CRL for preclinical and Phase 1 development of AV-101. In June 2015, the Cato Notes and additional amounts payable to CRL for CRO services related to AV-101 were extinguished in exchange for our issuance of an aggregate of 328,571 shares of Series B Preferred stock to CBV, which shares of Series B Preferred stock were automatically converted in accordance with their terms into an equal number of registered shares of our common stock as a result of our May 2016 public offering.

Under the terms of our contract research arrangement with CRL related to the development of AV-101, we incurred expenses of $128,200 and $50,400 for the three months ended June 30, 2017 and 2016, respectively. We anticipate periodic expenses for CRO services from CRL related to Phase 2 development of AV-101 will increase in future periods.

See Note 9, Subsequent Events, for disclosure of additional transactions with CRL.

Note 9. Subsequent Events

We have evaluated subsequent events through August 11, 2017 and have identified the following matters requiring disclosure:

Master Services Agreement and Share Issuance to CRL

In July 2017, we entered into a Master Services Agreement (MSA) with CRL, which replaced a similar May 2007 agreement, pursuant to which CRL may assist us in the evaluation, development, commercialization and marketing of our potential product candidates, including AV-101, and provide regulatory and strategic consulting services as requested from time to time. Specific projects or services will be delineated in individual work orders negotiated from time-to-time under the MSA.

In July 2017, we issued to CRL 50,000 shares of our unregistered common stock having a fair value of $85,500 on the date of issuance in recognition of a milestone achievement under the terms of a negotiated AV-101-related work order.

Private Placement of Common Stock and Warrants

In August 2017, in a self-placed private placement transaction, we sold to an accredited investor units consisting of (i) 28,572 shares of our unregistered common stock and (ii) warrants exercisable through April 30, 2021 to purchase 28,572 unregistered shares of our common stock at an exercise price of $4.00 per share. The warrants are not exercisable until six months and one day following the date of issuance. We received cash proceeds of $50,000 from this sale of our securities.

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

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

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

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) disorders. Unless the context otherwise requires, the words "VistaGen Therapeutics, Inc." "VistaGen," "we," "the Company," "us" and "our" refer to VistaGen Therapeutics, Inc., a Nevada corporat All references to future quarters and years in this Item 2 refer to calendar quarters and calendar years, unless reference is made otherwise.

AV-101 is our oral CNS product candidate in Phase 2 clinical development in the United States, initially as a new generation adjunctive treatment for Major Depressive Disorder (MDD) in patients with an inadequate response to standard antidepressants approved by the U.S. Food and Drug Administration (FDA). AV-101's mechanism of action (MOA) involves both NMDA (N-methyl-D-aspartate) and AMPA

(alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptors in the brain responsible for fast excitatory synaptic activity throughout the CNS. AV-101's MOA is fundamentally differentiated from all FDA-approved antidepressants, as well as all atypical antipsychotics such as aripiprazole often used adjunctively to augment them. We believe AV-101 also has potential as a new treatment alternative for several additional CNS indications, including epilepsy, Huntington's disease, levadopa (L-DOPA)-induced dyskinesia associated with Parkinson's disease, and as a potential non-opioid treatment for neuropathic pain.

Clinical studies conducted at the U.S. National Institute of Mental Health (NIMH), part of the U.S. National Institutes of Health (NIH), by Dr. Carlos Zarate, Jr., Chief of the NIMH's Experimental Therapeutics & Pathophysiology Branch and its Section on Neurobiology and Treatment of Mood and Anxiety Disorders, have focused on the antidepressant effects of low dose ketamine hydrochloride injection (ketamine), an ion-channel blocking NMDA receptor antagonist, in MDD patients with inadequate responses to multiple standard antidepressants. These NIMH studies, as well as clinical research at Yale University and other academic institutions, have demonstrated robust antidepressant effects in treatment-resistant MDD patients within twenty-four hours of a single sub-anesthetic dose of ketamine administered by intravenous (IV) injection.

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

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Pursuant to our Cooperative Research and Development Agreement (CRADA) with the NIMH, the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, a small Phase 2 clinical study of AV-101 monotherapy in subjects with treatment-resistant MDD (the NIMH AV-101 MDD Phase 2 Monotherapy Study). We are preparing to launch our 180-patient Phase 2 multi-center, multi-dose, double blind, placebo-controlled efficacy and safety study of AV-101 as a new generation adjunctive treatment of MDD in adult patients with an inadequate response to standard, FDA-approved antidepressants (the AV-101 MDD Phase 2 Adjunctive Treatment Study). Dr. Maurizio Fava, Professor of Psychiatry at Harvard Medical School and Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute, will be the Principal Investigator of our AV-101 MDD Phase 2 Adjunctive Treatment Study. Dr. Fava was the co-Principal Investigator with Dr. A. John Rush of the STAR*D study, the largest clinical trial conducted in depression to date, whose findings were published in journals such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA). We currently anticipate launching our AV-101 MDD Phase 2 Adjunctive Treatment Study in the first quarter of 2018 and completing it by the end of 2018, with top line results available in the first quarter of 2019.

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

AV-101 and Major Depressive Disorder

Background

The World Health Organization (WHO) estimates that 300 million people worldwide are affected by depression. According to the NIH, major depression is one of the most common mental disorders in the U.S. The NIMH reports that, in 2014, approximately 16 million adults in the U.S. had at least one major depressive episode in the past year. According to the U.S. Centers for Disease Control and Prevention (CDC) one in 10 Americans over the age of 12 takes a standard, FDA-approved antidepressant.

Most standard antidepressants target neurotransmitter reuptake inhibition – either serotonin (antidepressants known as SSRIs) or serotonin/norepinephrine (antidepressants known as SNRIs). Even when effective, these standard depression medications take many weeks to achieve adequate antidepressant effects. Nearly two out of every three drug-treated depression patients do not obtain adequate therapeutic benefit from initial treatment with a standard antidepressant. Even after treatment with many different standard antidepressants, nearly one out of every three drug-treated depression patients still do not achieve adequate therapeutic benefits from their antidepressant medication. Such patients with an inadequate response to standard antidepressants often seek to augment their treatment regimen by adding an atypical antipsychotic (drugs such as aripiprazole), despite only modest potential therapeutic benefit and the significant risk of additional side effects.

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

AV-101

AV-101 is our oral CNS drug candidate in Phase 2 development in the United States, initially focused as a new generation antidepressant for the adjunctive treatment of MDD patients with an inadequate response to standard, FDA-approved antidepressants. As published in the October 2015 issue of the peer-reviewed, Journal of Pharmacology and Experimental Therapeutics, in an article titled, The prodrug 4-chlorokynurenine causes ketamine-like antidepressant effects, but not side effects, by NMDA/glycineB-site inhibition, using well-established preclinical models of depression, AV-101 was shown to induce fast-acting, dose-dependent, persistent and statistically significant ketamine-like antidepressant effects following a single treatment, responses equivalent to those seen with a single sub-anesthetic control dose of ketamine, without the negative side effects seen with ketamine. In addition, these studies confirmed that the antidepressant effects of AV-101 were mediated through both inhibition of the GlyB site of NMDA receptors and activation of the AMPA receptor pathway in the brain, a key final common pathway feature of certain new generation antidepressants such as ketamine and AV-101, each with a MOA that is fundamentally different from all standard antidepressants and atypical antipsychotics used adjunctively to augment them.

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We have completed two NIH-funded, randomized, double blind, placebo-controlled AV-101 Phase 1 safety studies. Currently, pursuant to our CRADA with the NIMH and Dr. Carlos Zarate, Jr., the NIMH is funding, and Dr. Zarate, as Principal Investigator, and his team are conducting, a small NIMH AV-101 MDD Phase 2 Monotherapy Study. Although we are not involved in conducting this study, we currently anticipate that the NIMH will complete the NIMH AV-101 MDD Phase 2 Monotherapy Study by the end of 2017, with top line results during the first half of 2018.

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

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

CardioSafe 3D™; NCE Drug Rescue and Regenerative Medicine

VistaStem Therapeutics is our wholly owned subsidiary focused on applying hPSC technology to discover, rescue, develop and commercialize proprietary small molecule NCEs for CNS and other diseases, as well as potential cellular therapies involving stem cell-derived blood, cartilage, heart and liver cells. CardioSafe 3D™ is our customized in vitro cardiac bioassay system capable of predicting potential human heart toxicity of small molecule NCEs in vitro, long before they are ever tested in animal and human studies. Potential commercial applications of our stem cell technology platform involve using CardioSafe 3D internally for NCE drug discovery and drug rescue to expand our proprietary drug candidate pipeline. Drug rescue involves leveraging substantial prior research and development investments by pharmaceutical companies and others related to public domain NCE programs terminated before FDA approval due to heart toxicity risks and RM and cellular therapies. To advance potential RM applications of its cardiac stem cell technology, in December 2016, VistaStem exclusively sublicensed to BlueRock Therapeutics LP, a next generation regenerative medicine company established by Bayer AG and Versant Ventures, rights to certain proprietary technologies relating to the production of cardiac stem cells for the treatment of heart disease. In a manner similar to the BlueRock Agreement, VistaStem may also pursue additional potential RM applications using blood, cartilage, and/or liver cells derived from hPSCs for (A) cell-based therapy (injection of stem cell-derived mature organ-specific cells obtained through directed differentiation), (B) cell repair therapy (induction of regeneration by biologically active molecules administered alone or produced by infused genetically engineered cells), or (C) tissue engineering (transplantation of in vitro grown complex tissues) using hPSC-derived blood, bone, cartilage, and/or liver cells.

Financial Operations Overview and Results of Operations

Our critical accounting policies and estimates and recent accounting pronouncements are disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2017, as filed with the SEC on June 29, 2017, and in Note 3 to the accompanying unaudited Condensed Consolidated Financial Statements included in Part 1, Item 1 of this Report.

Summary

Net Loss

Although in December 2016 we generated $1.25 million of sublicense revenue from the BlueRock Therapeutics Agreement, we have not yet achieved recurring revenue-generating status from any of our product candidates or technologies. Since our inception in May 1998, we have devoted substantially all of our time and efforts to developing our lead CNS product candidate, AV-101, from early nonclinical studies to our ongoing Phase 2 clinical development program in MDD, as well as stem cell technology research and development, bioassay development, small molecule drug development, and creating, protecting and patenting intellectual property related to our product candidates and technologies, with the corollary initiatives of recruiting and retaining personnel and raising working capital. As of June 30, 2017, we had an accumulated deficit of approximately $144.3 million. Our net loss for the three months ended June 30, 2017 and 2016 was approximately $2.3 million and $2.0 million, respectively. We expect losses to continue for the foreseeable future, primarily related to our further clinical development of AV-101 for the adjunctive treatment of MDD, as well as a range of other CNS indications.

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Summary of the Quarter Ended June 30, 2017

During the quarter ended June 30, 2017, we continued to (i) advance nonclinical, including manufacturing, and clinical development of AV-101 as a potential new generation antidepressant and as a potential new therapeutic alternative for several other CNS indications with significant unmet medical need, (ii) expand the regulatory foundation to support broad Phase 2 clinical development of AV-101 in the U.S. and, (iii) on a limited basis, advance both (a) the predictive toxicology capabilities of CardioSafe 3D for drug rescue and development applications, and (b) regenerative medicine opportunities related to our stem cell technology platform.

Pursuant to our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIH, the NIH continues to fund, and Dr. Carlos Zarate Jr. of the NIMH continues to conduct, the NIMH AV-101 MDD Phase 2 Monotherapy Study, a small Phase 2 clinical study of AV-101 as a monotherapy for treatment-resistant MDD at no cost to us other than supplying clinical trial material. Although we do not direct or control the progress of this study, we currently anticipate that the NIMH will complete the NIMH AV-101 MDD Phase 2 Monotherapy Study by the end of 2017, with top line results during the first half of 2018.

We continue to prepare for the launch of our AV-101 MDD Phase 2 Adjunctive Treatment Study with initiatives that include improving the efficiency of our AV-101 manufacturing processes and producing sufficient quantities to enable a robust initiation of the study. We currently anticipate the launch of the AV-101 MDD Phase 2 Adjunctive Treatment Study, with Dr. Maurizio Fava of Harvard Medical School serving as Principal Investigator, in the first quarter of 2018.

Additionally, we are pursuing initiatives to secure a broad spectrum of intellectual property protection for AV-101 covering multiple CNS indications in both the U.S. and abroad. The European Patent Office (EPO) has recently issued a Notice of Intention to Grant our European Patent Application for AV-101. The granted claims, covering multiple dosage forms of AV-101, treatment of depression and reduction of dyskinesia associated with L-DOPA treatment of Parkinson's disease, will be in effect until at least January 2034.

Between late-March 2017 and June 2017, we entered into self-placed private placement transactions involving securities purchase agreements with individual accredited investors, pursuant to which we sold units consisting of an aggregate of (i) 495,001 shares of our unregistered common stock; and (ii) warrants which are not exercisable until six months and one day following issuance and expire on April 30, 2021, to purchase an aggregate of 247,500 shares of our common stock at a weighted average fixed exercise price of $3.99 per share, subject to adjustment only for customary stock dividends, reclassifications, splits and similar transactions. We received cash proceeds of approximately $1 million in this self-placed private placement transaction.

Following the expansion of our Clinical and Regulatory Advisory Board during 2016 with the appointment of pre-eminent opinion leaders in the field of depression, in July 2017, we appointed Mark Wallace, M.D., Distinguished Professor of Clinical Anesthesiology at the University of California, San Diego, to our Clinical and Regulatory Advisory Board to assist us in advancing development of AV-101 as a potential non-opioid treatment alternative for neuropathic pain. Dr. Wallace is an internationally recognized leader in the field of multi-modal pain management, with over 30 years of professional experience, board certifications, licensures, honors/awards, grants, articles and abstracts

As a matter of course, we continue to minimize to the greatest extent possible cash commitments and expenditures for both internal and external research and development and general and administrative services. To further advance the nonclinical and clinical development of AV-101 and our stem cell technology platform, as well as support our operating activities, we continue to carefully manage our routine operating costs, including our internal employee

related expenses, as well as external costs relating to regulatory consulting, contract research and development, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and internal costs.

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016

The following table summarizes the results of our operations for the three months ended June 30, 2017 and 2016 (amounts in thousands).

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	Three Months Ended June 30,	
	2017	2016
Operating expenses:		
Research and development	$1,096	$826
General and administrative	1,165	1,138
Total operating expenses	2,261	1,964
Loss from operations	(2,261)	(1,964)
Interest expense, net	(3)	(1)
Loss before income taxes	(2,264)	(1,965)
Income taxes	(2)	(2)
Net loss	(2,266)	(1,967)
Accrued dividend on Series B Preferred Stock	(247)	(540)
Deemed dividend on Series B Preferred Stock	-	(111)
Net loss attributable to common stockholders	$(2,513)	$(2,618)

Revenue

We reported no revenue for the quarters ended June 30, 2017 or 2016 and we presently have no recurring revenue generating arrangements with respect to AV-101 or other potential product candidates. While we may potentially receive future milestone payments and royalties under the BlueRock Agreement we entered in December 2016, in the event certain performance-based milestones and commercial sales are achieved, there can be no assurance that the BlueRock Agreement will provide additional revenue to us in the near term or at all.

Research and Development Expense

Research and development expense, including both cash and noncash components, totaled $1,096,200 for the quarter ended June 30, 2017, an increase of approximately 33% compared to the $825,700 reported for the quarter ended June 30, 2016. Noncash expenses, including stock compensation, depreciation and a portion of rent expense in both periods totaled approximately $251,000 and $48,000 in the quarters ended June 30, 2017 and 2016, respectively. Current period expense reflects the increasing impact of our continued nonclinical and clinical development of AV-101, particularly our preparations for the launch of the AV-101 MDD Phase 2 Adjunctive Treatment Study, which is currently anticipated in the first quarter of 2018, subject to securing adequate financing. The following table indicates the primary components of research and development expense for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2017	2016
Salaries and benefits	$318	$250
Stock-based compensation	191	44
Consulting and other professional services	10	27
Technology licenses and royalties	60	160
Project-related research and supplies:		
AV-101	324	252
Stem cell and all other	66	28
	390	280
Rent	105	56
Depreciation	19	9
All other	3	-
Total Research and Development Expense	$1,096	$826

The increase in salaries and benefits reflects the impact of the hiring of our Chief Medical Officer (CMO) in June 2016, and salary increases granted to our Chief Scientific Officer (CSO) in June 2016 and to the non-officer members of our scientific staff in June 2017 and June 2016.

Stock based compensation expense increased in the current period primarily as a result of the routine amortization of option grants made to our CSO, CMO and scientific staff in April 2017 and November 2016, plus the new-hire grant made to our CMO in June 2016. These grants are being amortized over a three-year or four-year vesting period based on the terms of the respective grants. Substantially all option grants made prior to September 2015 were fully-vested and fully-expensed prior to the quarter ended June 30, 2017.

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Consulting services reflects fees paid or accrued for scientific, nonclinical and clinical development and regulatory advisory services rendered to us by third-parties, primarily by members of our scientific and CNS clinical and regulatory advisory boards. The reduction in expense in the current period primarily reflects the change in terms of consulting agreements with our stem cell-related scientific advisory board members.

Technology license expense reflects both recurring annual fees as well as legal counsel and other costs related to patent prosecution and protection pursuant to our stem cell technology license agreements or have elected to pursue for commercial purposes. We recognize these costs as they are invoiced to us by the licensors and they do not occur ratably throughout the year or between years. In both periods, but to a greater extent in the quarter ended June 30, 2016, this expense includes legal counsel and other costs we have incurred to advance in the U.S. and numerous foreign countries numerous pending patent applications with respect to AV-101 and our stem cell technology platform.

AV-101 project expense for the quarter ended June 30, 2017 includes continuing costs incurred to develop more efficient and cost-effective proprietary manufacturing methods for AV-101, and to produce clinical trial material for the AV-101 MDD Phase 2 Adjunctive Treatment Study, as well as costs incurred for certain other nonclinical trial analyses to facilitate further clinical development of AV-101 in MDD and potentially for other indications. The increase in stem cell and other project related expenses for the quarter ended June 30, 2017 primarily reflects in-house costs associated with our participation in the FDA’s Comprehensive In Vitro Proarrhythmia Assay (CiPA) project and other in-house stem cell technology-related initiatives.

The increase in rent expense for the quarter ended June 30, 2017 reflects both the impact of the scheduled rent increase effective in August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of our headquarters facilities by five years from July 31, 2017 to July 31, 2022.

General and Administrative Expense

General and administrative expense, including both cash and noncash components, increased slightly to approximately $1,165,000 from $1,138,000, for the quarters ended June 30, 2017 and 2016, respectively. Noncash expense, including, in both periods, stock compensation expense, a portion of investor relations and investment banking expenses, and a portion of rent expense, and, in 2016, warrant modification expense, aggregated approximately $253,000 and $443,000 for the quarters ended June 30, 2017 and 2016, respectively. The modest overall increase in general and administrative expenses was primarily attributable to increased salary and benefits and noncash stock compensation expenses offset by a reduction in professional services fees. The following table indicates the primary components of general and administrative expenses, including noncash stock compensation expense, for each of the periods (amounts in thousands):

	Three Months Ended June 30,	
	2017	2016

Salaries and benefits	$271	$190
Stock-based compensation	176	64
Board fees	39	33
Legal, accounting and other professional fees	307	542
Investor relations	166	108
Insurance	61	40
Travel expenses	40	49
Rent and utilities	73	40
Warrant modification expense	-	40
All other expenses	32	32
Total General and Administrative Expense	$1,165	$1,138

The increase in salaries and benefits reflects the impact of the hiring of our Vice President of Corporate Development (VP-Corporate Development) in September 2016 and salary increases granted in June 2016 to our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), and in June 2017 and June 2016 to a non-officer member of our administrative staff.

Stock based compensation expense increased in the current period primarily as a result of the routine amortization of option grants to independent members of our Board of Directors and our CEO, CFO and administrative staff in April 2017 and November 2016, plus the new-hire grant made to our VP-Corporate Development in September 2016. These grants are being amortized over a three-year or four-year vesting period based on the terms of the respective grants. Substantially all option grants made prior to September 2015 were fully-vested and fully-expensed prior to the quarter ended June 30, 2017.

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

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Legal, accounting and other professional fees for the quarters ended June 30, 2017 and 2016 includes expense related to routine legal fees as well as the accounting expense related to the annual audit of the prior year's financial statements and the review of the financial statements for the first quarter of the current fiscal year. We incurred no non-cash expense in the quarter ended June 30, 2017. Noncash expense for the quarter ended June 30, 2016 included approximately $338,000 recognized pursuant to the June 30, 2015 grant of an aggregate of 90,000 shares of our Series B 10% Convertible Preferred Stock (Series B Preferred) having an aggregate fair value of $1,350,000 as compensation for financial advisory and corporate development service contracts with two independent providers for services to be performed through June 30, 2016.

Investor relations expense includes the fees of our various external service providers for a broad spectrum of investor relations and market awareness and support functions, as well as initiatives that included numerous meetings in multiple U.S. markets and other communication activities focused on expanding market awareness of the Company, including among registered investment professionals and investment advisors, and individual and institutional investors. In the quarter ended June 30, 2017, in addition to cash fees and expenses we incurred, we granted 25,000 unregistered shares of our common stock to an investor relations and awareness service provider as partial compensation for its services and recognized noncash expense of approximately $50,000, representing the fair value of the stock at the time of issuance. We did not recognize any noncash investor relations expense in the quarter ended June 30, 2016.

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

The increase in rent expense for the quarter ended June 30, 2017 reflects the impact of the scheduled rent increase effective in August 2016 as well as the impact of accounting for the November 2016 lease amendment extending the lease of our headquarters facilities by five years from July 31, 2017 to July 31, 2022.

In April and May 2016, we entered into warrant exchange agreements with certain warrant holders pursuant to which the warrant holders exchanged outstanding warrants to purchase an aggregate of 41,649 shares of our common stock for an aggregate of 31,238 shares of our unregistered common stock. As we had with similar prior transactions, we accounted for these transactions as warrant modifications, resulting in our recognition of approximately $40,000 in noncash expense in the quarter ended June 30, 2016. We had no such transactions during the quarter ended June 30, 2017.

Interest and Other Expenses, Net

Interest expense, net totaled $2,400 for the quarter ended June 30, 2017 compared to $1,400 reported for the quarter ended June 30, 2016. Interest expense in both periods relates to interest paid on insurance premium financing and on a capital lease of office equipment.

We have recognized $247,300 and $539,800 for the quarters ended June 30, 2017 and 2016, respectively, representing the 10% cumulative dividend payable on our Series B Preferred as an additional deduction in arriving at net loss attributable to common stockholders in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report. The reduction in the quarterly dividend accrual results from the automatic conversion of an aggregate of 2,403,051 shares of Series B Preferred into an equal number of shares of our common stock upon our completion of our May 2016 public offering of shares of our common stock and warrants, and a subsequent voluntary conversion of 87,500 shares of our Series B Preferred in August 2016. There has been no change in the number of Series B Preferred shares outstanding since August 2016.

During the quarter ended June 30, 2016, we allocated the proceeds from our self-placed private placement sales of Series B Preferred Units to the Series B Preferred stock and the Series B Warrants based on their relative fair values on the dates of the sales. The difference between the relative fair value per share of the Series B Preferred, approximately $4.20 per share, and its Conversion Price (or stated value) of $7.00 per share represented a deemed dividend to the purchasers of the Series B Preferred Units. Accordingly, we recognized a deemed dividend in the aggregate amount of $111,100 in arriving at net loss attributable to common stockholders for the quarter ended June 30, 2016 in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss included in Part I of this Report.

Liquidity and Capital Resources

From our inception in May 1998 through June 30, 2017, we have financed our operations and technology acquisitions primarily through the issuance and sale of our equity and debt securities, including convertible promissory notes and short-term promissory notes, for cash proceeds of approximately $45.5 million, as well as from an aggregate of approximately $17.6 million of government research grant awards, strategic collaboration payments, intellectual property sublicensing and other revenues. We have also issued equity securities with an approximate aggregate value at issuance of $30.8 million in non-cash settlements of certain liabilities, including liabilities for professional services rendered to us or as compensation for such services. Additionally, pursuant to our February 2015 Cooperative Research and Development Agreement (CRADA) with the NIH, substantial ongoing Phase 2 clinical development activities relating to AV-101 as a potential new generation antidepressant are being sponsored in full, at no cost to us other than supplying clinical trial material, by the NIMH under the direction of Dr. Carlos Zarate Jr. as Principal Investigator.

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Between late-March 2017 and June 30, 2017, we sold to accredited investors, in a self-placed private placement, units consisting of an aggregate of 495,001 unregistered shares of our common stock and warrants to purchase an aggregate of 247,500 unregistered shares of our common stock pursuant to which we received proceeds of approximately $1.0 million (the Spring 2017 Private Placement), resulting in our cash and cash equivalents balance of $1.6 million at June 30, 2017. In August 2017, in a self-placed private placement transaction, we sold to an accredited investor units consisting of 28,572 shares of our unregistered common stock and warrants to purchase 28,572 unregistered shares of our common stock at an exercise price of $4.00 per share. We received cash proceeds of $50,000 from this sale of our securities. Our cash balance at June 30, 2017 plus the proceeds from subsequent sales of our securities was not sufficient to enable us to fund our planned operations, including expected cash expenditures of approximately $12 million for the next twelve months, including expenditures required to further prepare for, launch and satisfy a significant portion of the projected expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study.

Although our current financial resources are not yet sufficient to fully fund completion of the AV-101 MDD Phase 2 Adjunctive Treatment Study, we anticipate, as we have numerous times in the past, raising sufficient additional capital as and when necessary and advisable to sustain our operations and achieve our key corporate objectives through at least the next twelve months, including initiating and conducting the AV-101 MDD Phase 2 Adjunctive Treatment Study in an ordinary course manner. We expect to secure additional capital primarily through the sale of our equity securities in one or more private placements to accredited investors or public offerings. We have filed a Registration Statement on Form S-3 (Registration No. 333-215671) (the S-3 Registration Statement) that has been declared effective by the Securities and Exchange Commission (the Commission) to cover our potential future sale of our equity securities in one or more public offerings from time to time. As of the date of this Report, we have not yet sold any securities under the S-3 Registration Statement, nor do we have an obligation to do so. There can, however, be no assurance that future financing will be available in sufficient amounts, in a timely manner, or on terms acceptable to us, if at all. Further, at June 30, 2017, we had a limited number of unallocated or unreserved shares of our common stock available for issuance in future offerings or for other purposes. To facilitate potential future issuances and sales of our equity securities for ordinary corporate finance and general corporate purposes, our Board of Directors (Board) has approved an amendment to our Restated and Amended Articles of Incorporation to increase the number of shares of common stock available for issuance thereunder from 30 million shares to 100 million shares, an amount our Board has determined is customary and appropriate for a Nasdaq-listed, clinical-stage biopharmaceutical company. Before taking effect, this amendment must be approved by a majority of our stockholders at our 2017 annual meeting of stockholders in September 2017.

We may also seek research and development collaborations that could generate revenue, funding for development of AV-101 and additional product candidates, as well as additional government grant awards and agreements similar to our current CRADA with the NIMH, which provides for the NIMH to fully fund the NIMH's ongoing NIMH AV-101 MDD Phase 2 Monotherapy Study. Such strategic collaborations may provide non-dilutive resources to advance our strategic initiatives while reducing a portion of our future cash outlays and working capital requirements. In a manner similar to the BlueRock Agreement, we may also pursue similar arrangements with third-parties covering other of our intellectual property. Although we may seek additional collaborations that could generate revenue and/or non-dilutive funding for development of AV-101 and other product candidates, as well as new government grant awards and/or agreements similar to our CRADA with NIMH, no assurance can be provided that any such collaborations, awards or agreements will occur in the future.

Our future working capital requirements will depend on many factors, including, without limitation, the scope and nature of opportunities related to our success and the success of certain other companies in clinical trials, including our development and commercialization of AV-101 as an adjunctive treatment for MDD and other potential CNS conditions, and various applications of our stem cell technology platform, the availability of, and our ability to obtain,

government grant awards and agreements, and our ability to enter into collaborations on terms acceptable to us. To further advance the clinical development of AV-101 and our stem cell technology platform, as well as support our operating activities, we plan to continue to carefully manage our routine operating costs, including our employee headcount and related expenses, as well as the timing of and projected costs relating to key research and development projects, including our expenses associated with our proposed AV-101 MDD Phase 2 Adjunctive Treatment Study, regulatory consulting, CRO services, investor relations and corporate development, legal, acquisition and protection of intellectual property, public company compliance and other professional services and working capital costs.

Notwithstanding the foregoing, substantial additional financing may not be available to us on a timely basis, on acceptable terms, or at all. If we are unable to obtain substantial additional financing on a timely basis when needed in 2017 and beyond, our business, financial condition, and results of operations may be harmed, the price of our stock may decline, we may be required to reduce, defer, or discontinue certain of our research and development activities and we may not be able to continue as a going concern.

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Cash and Cash Equivalents

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

	Three Months Ended June 30,	
	2017	2016
Net cash used in operating activities	$(2,134)	$(1,671)
Net cash used in investing activities	-	(2)
Net cash provided by financing activities	841	9,744
Net increase (decrease) in cash and cash equivalents	(1,293)	8,071
Cash and cash equivalents at beginning of period	2,921	429
Cash and cash equivalents at end of period	$1,628	$8,500

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

In our Annual Report on Form 10-K for our fiscal year ended March 31, 2017 filed with the Securities and Exchange Commission on June 29, 2017, we identified two material weaknesses in our internal control over financial reporting relating to (i) segregation of duties and (ii) the functionality of our accounting software. Management has determined that current resources would be more appropriately applied elsewhere and when resources permit, they will alleviate such material weaknesses through various steps, which may include the addition of qualified financial personnel and/or the acquisition and implementation of alternative accounting software. Accordingly, 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 Report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

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 (Report) and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended March 31, 2017 before investing in our securities. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and/or operating results. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected.

Risks Related to Product Development, Regulatory Approval and Commercialization

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

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

We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application (NDA) from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We expect the FDA to require us to complete the planned AV-101 MDD Phase 2 Adjunctive Treatment Study and at least two pivotal Phase 3 clinical trials in order to submit an NDA for AV-101 as an adjunctive treatment for MDD patients with an inadequate response to standard, FDA-approved antidepressants. Also, we anticipate that

the FDA will require that we conduct additional toxicity studies, additional non-clinical and certain small clinical studies before submitting an NDA for AV-101. The results of all of these studies are not known until after the studies are concluded.

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

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

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

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

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

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

We intend to seek a Fast Track designation from the FDA for AV-101, initially for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants. Even if the FDA approves Fast Track designation for AV-101 for this indication, it may not actually lead to a faster development or regulatory review or approval process.

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

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

The number of patients suffering from MDD has not been established with precision. If the actual number of patients with MDD is smaller than we anticipate, we or our collaborators may encounter difficulties in enrolling patients in AV-101 clinical trials, including the NIMH AV-101 MDD Phase 2 Monotherapy Study and our planned AV-101 MDD Phase 2 Adjunctive Treatment Study, thereby delaying completion such studies or preventing additional clinical development. Further, if AV-101 is approved for adjunctive treatment of MDD patients with an inadequate response to standard antidepressants, and the market for this indication is smaller than we anticipate, our ability to achieve profitability could be limited.

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

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

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. We have not yet completed a Phase 2 clinical trial for AV-101, and if the NIMH fails to produce positive results in the NIMH AV-101 MDD Phase 2 Monotherapy Study, the development timeline and regulatory approval and commercialization prospects for AV-101 and, correspondingly, our business and

financial prospects, could be materially adversely affected.

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

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

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

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

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

Under our CRADA, the NIMH is conducting and funding the NIMH AV-101 MDD Phase2 Monotherapy Study. We will need to complete the planned AV-101 MDD Phase 2 Adjunctive Treatment Study, at least two additional large Phase 2b/3 clinical trials, additional toxicity and non-clinical studies and certain smaller clinical studies prior to the submission of an NDA for AV-101 as a new generation adjunctive treatment for MDD. Successful completion of our clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of AV-101 for MDD and any other product candidates we may develop. We do not know whether the NIMH AV-101 MDD Phase 2 Monotherapy Study, the AV-101 MDD Phase 2 Adjunctive Treatment Study or any of our future-planned non-clinical and clinical trials will be completed on schedule, if at all, as the commencement and completion of non-clinical and clinical trials can be delayed or prevented for a number of reasons, including, among others:

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

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

negative results from our ongoing non-clinical studies;

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

inadequate quantity or quality of a product candidate or other materials necessary to conduct non-clinical or clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;

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

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

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

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

delays in validating any endpoints utilized in a clinical trial;

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

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

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

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

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

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

unforeseen safety issues, including any that could be identified in our ongoing non-clinical carcinogenicity studies, adverse side effects or lack of effectiveness;

changes in government regulations or administrative actions;

problems with clinical supply materials; and

lack of adequate funding to continue clinical trials.

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

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

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

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

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

fail to comply with contractual obligations;

experience regulatory compliance issues;

undergo changes in priorities or become financially distressed; or

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

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

trials comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMPs regulations and will require a large number of test patients. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we design our clinical trials for our product candidates, we plan to have CROs, and in the case of the NIMH AV-101 MDD Phase 2 Monotherapy Study, the NIMH, conduct the AV-101 Phase 2 and Phase 3 clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the CROs or the NIMH, as the case may be, may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of our clinical trials. If the NIMH or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of AV-101 and other product candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs or the NIMH devote to our program or our clinical products. If we are unable to rely on non-clinical and clinical data collected by our CROs or the NIMH, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

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

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We rely completely on third-parties to manufacture and prepare our clinical supplies of AV-101 and other product candidates, and we intend to rely on third parties to produce non-clinical, clinical and commercial supplies of AV-101 and any future product candidate.

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

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

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

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

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

In March 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare

program, and increased the industry's regulatory burdens and operating costs. We cannot predict the full impact of the ACA on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred.

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

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

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

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

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

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

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

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

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

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

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

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

the clinical indications for which our product candidates are approved;

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

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

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

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

publicity concerning our products or competing products and treatments;

pricing and cost effectiveness;

the effectiveness of our sales and marketing strategies;

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

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