



VistaGen Therapeutics Reports Fiscal 2019 First Quarter Financial Results

August 14, 2018

SOUTH SAN FRANCISCO, Aug. 14, 2018 (GLOBE NEWSWIRE) -- [VistaGen Therapeutics, Inc.](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company focused on developing new generation medicines for depression and other central nervous system (CNS) diseases and disorders with high unmet need, today reported financial results for its fiscal 2019 first quarter ended June 30, 2018.

"At VistaGen, among our most important goals is to deliver positive change for millions of patients, as well as their families, friends, caregivers and colleagues, who suffer from the debilitating impact of depression, including suicidal ideation and suicide. Current treatment options fall far short against the growing unmet need. If we are successful in our development efforts for AV-101, we have a rare, game-changing opportunity to deliver an entirely new treatment paradigm for depression and several other major CNS indications beyond the depression spectrum, such as neuropathic pain and Parkinson's disease levodopa-induced dyskinesia, where current treatment options are often associated with significant side effects and safety concerns," said [Shawn Singh, Chief Executive Officer of VistaGen](#).

"During the quarter, arguably our most productive quarter to date, we continued to make great progress executing against our key objectives for 2018 and 2019, with major milestones including multi-center patient dosing in ELEVATE, our U.S. multi-center study of AV-101 for major depressive disorder, the issuance of multiple patents in the U.S. and Europe that provide commercial protection for AV-101 through at least 2034, and expanding our clinical development relationships in the field related to AV-101. We continue to be pleased with progress in ELEVATE and remain confident about delivering topline results in mid-2019, now less than a year away," continued Mr. Singh.

Financial Results for the Fiscal Quarter Ended June 30, 2018:

Net loss attributable to common stockholders for the fiscal quarter ended June 30, 2018 was approximately \$4.5 million, compared to \$2.5 million for the fiscal quarter ended June 30, 2017, primarily attributable to increased research and development activities relating to the Company's AV-101 programs.

Research and development expense totaled approximately \$2.7 million for the fiscal quarter ended June 30, 2018, compared with approximately \$1.1 million for the fiscal quarter ended June 30, 2017. The increase in research and development expense is primarily related to Phase 2 clinical development of AV-101 in the ELEVATE study, which is focused on major depressive disorder (MDD), and nonclinical activities, including production of AV-101 supplies in anticipation of future studies in MDD and other CNS indications with high unmet need.

General and administrative expense was approximately \$1.5 million in the fiscal quarter ended June 30, 2018, compared to approximately \$1.2 million in the fiscal quarter ended June 30, 2017. The increase was primarily attributable to noncash stock compensation and professional services expense.

At June 30, 2018, the Company had cash and cash equivalents of approximately \$7.2 million, compared to approximately \$10.4 million at March 31, 2018. After June 30, 2018, as a result of self-placed private placement transactions of unregistered securities with accredited investors, the Company has received aggregate cash proceeds of approximately \$3.4 million.

About AV-101

AV-101 is an oral, non-opioid, non-sedating NMDA receptor glycine B (NMDAR GlyB) antagonist with potential to be a new at-home treatment for multiple CNS indications with high unmet need. AV-101 is currently in Phase 2 clinical development in the United States. [ELEVATE](#) is VistaGen's ongoing Phase 2 clinical trial designed to evaluate the efficacy and safety of adjunctive use of oral AV-101 for MDD in patients with an inadequate response to standard antidepressant therapy with either an FDA-approved selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI).

AV-101 belongs to a new generation of investigational medicines in neuropsychiatry known as glutamate receptor modulators having the potential to treat major depressive disorder (MDD) faster than current FDA-approved SSRIs and SNRIs. AV-101's [mechanism of action](#) (MOA) is fundamentally different from that of all current FDA-approved SSRIs and SNRIs for depression, most of which, if effective for a given patient, take many weeks to achieve therapeutic benefits. VistaGen believes AV-101 has potential as an oral at-home first line therapy for MDD and as an adjunctive therapy for MDD. As an adjunctive therapy, AV-101 may have potential both to displace atypical antipsychotics such as aripiprazole in the current MDD drug treatment paradigm and to prevent relapse of MDD following successful treatment with ketamine hydrochloride, an ion-channel blocking NMDA receptor antagonist (ketamine), whether administered by injection or as an intranasal spray formulation. AV-101 may have potential to deliver ketamine-like antidepressant effects on an at-home basis, without the requirement for inconvenient administration in a medical setting, and without causing psychological or other side effects and safety concerns which may be associated with ketamine therapy. The FDA has [granted Fast Track designation](#) to AV-101 for development as a potential adjunctive treatment of MDD.

AV-101 may also have the potential to treat neuropathic pain, epilepsy, Parkinson's disease levodopa-induced dyskinesia, suicidal ideation and other CNS diseases and disorders where NMDA receptor modulation and AMPA pathway activation may achieve therapeutic benefits.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for depression and other CNS diseases and disorders with high unmet need. For more information, please visit www.vistagen.com and connect with VistaGen on [Twitter](#), [LinkedIn](#) and [Facebook](#).

Forward-Looking Statements

This release contains various statements concerning VistaGen's future expectations, plans and prospects, including without limitation, our expectations regarding development of AV-101, the potential of AV-101 for the treatment of MDD and various other CNS diseases and disorders and our intellectual property and commercial protection of AV-101 constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and may cause actual results to differ materially from those contemplated in these forward-looking statements. Among these risks is the possibility that (i) we may encounter unexpected adverse events in patients in our ELEVATE study or other clinical studies that cause us to discontinue further development of AV-101, (ii) we may not be able to successfully demonstrate the safety and efficacy of AV-101 at each stage of clinical development, (iii) success in preclinical studies or in early-stage clinical trials may not be repeated or observed in ongoing or future AV-101 studies, and ongoing or future preclinical and clinical results may not support further development of AV-101 or be sufficient to gain regulatory approval to market AV-101, (iv) decisions or actions of regulatory agencies may negatively affect the progress of the ELEVATE study or the initiation, timing and progress of future AV-101 clinical trials, and our ability to proceed with further clinical studies or to obtain marketing approval, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for AV-101, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including clinical development of AV-101 activities described above; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of AV-101 or other product candidates. Certain other risks are more fully discussed in the section entitled "Risk Factors" in our most recent annual report on Form 10-K, and subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. In addition, any forward-looking statements represent our views only as of the issuance of this release and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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FINANCIAL TABLES FOLLOW

**VISTAGEN THERAPEUTICS
Consolidated Balance Sheets**

(Amounts in dollars, except share amounts)

	June 30, 2018	March 31, 2018
	<hr/>	<hr/>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,231,200	\$ 10,378,300
Prepaid expenses and other current assets	617,300	644,800
Total current assets	<hr/> 7,848,500	<hr/> 11,023,100
Property and equipment, net	359,000	207,400
Security deposits and other assets	47,800	47,800
Total assets	<hr/> <hr/> \$ 8,255,300	<hr/> <hr/> \$ 11,278,300

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 629,500	\$ 1,195,700
Accrued expenses	1,057,900	206,300
Current notes payable	181,100	53,900
Capital lease obligations	2,700	2,600
Total current liabilities	<u>1,871,200</u>	<u>1,458,500</u>
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	2,881,800	2,608,300
Deferred rent liability	272,000	285,600
Capital lease obligations	8,600	9,300
Total non-current liabilities	<u>3,162,400</u>	<u>2,903,200</u>
Total liabilities	<u>5,033,600</u>	<u>4,361,700</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2018 and March 31, 2018:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2018 and March 31, 2018	500	500
Series B Preferred; 4,000,000 shares authorized at June 30, 2018 and March 31, 2018; 1,160,240 shares issued and outstanding at June 30, 2018 and March 31, 2018	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at June 30, 2018 and March 31, 2018; 2,318,012 shares issued and outstanding at June 30, 2018 and March 31, 2018	2,300	2,300
Common stock, \$0.001 par value; 100,000,000 shares authorized at June 30, 2018 and March 31, 2018; 23,213,280 and 23,068,280 shares issued and outstanding at June 30, 2018 and March 31, 2018, respectively	23,200	23,100
Additional paid-in capital	167,920,900	167,401,400
Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2018 and March 31, 2018	(3,968,100)	(3,968,100)
Accumulated deficit	<u>(160,758,300)</u>	<u>(156,543,800)</u>
Total stockholders' equity	<u>3,221,700</u>	<u>6,916,600</u>
Total liabilities and stockholders' equity	<u>\$ 8,255,300</u>	<u>\$ 11,278,300</u>

VISTAGEN THERAPEUTICS
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

Amounts in Dollars, except share amounts

	Three Months Ended June 30,	
	2018	2017
Operating expenses:		
Research and development	\$ 2,743,700	\$ 1,096,200
General and administrative	1,466,300	1,164,300
Total operating expenses	<u>4,210,000</u>	<u>2,260,500</u>
Loss from operations	(4,210,000)	(2,260,500)
Other expenses, net:		
Interest expense, net	(2,100)	(2,400)
Loss before income taxes	(4,212,100)	(2,262,900)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	<u>(4,214,500)</u>	<u>(2,265,300)</u>
Accrued dividend on Series B Preferred stock	(273,500)	(247,300)
Net loss attributable to common stockholders	<u>\$ (4,488,000)</u>	<u>\$ (2,512,600)</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (0.20)</u>	<u>\$ (0.28)</u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	<u>22,987,066</u>	<u>9,034,213</u>



Source: VistaGen Therapeutics, Inc.

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