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VistaGen Therapeutics Reports Fiscal Year 2018 Financial Results and Provides Year-to-Date Highlights

AV-101, VistaGen's Oral NMDA Receptor Modulator, Granted FDA Fast-Track Designation for Major Depressive Disorder

Key AV-101 Patents Issued in U.S., Europe and Asia

ELEVATE, AV-101 U.S. Phase 2 Major Depressive Disorder Study, Patient Dosing Initiated and Study Continues

SOUTH SAN FRANCISCO, Calif., June 26, 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, today reported financial results for its fiscal year ended March 31, 2018 and provided an overview of year-to-date highlights.

"VistaGen is committed to developing new generation medicines for millions of people suffering from life-altering CNS diseases and disorders without adequate treatment options. AV-101, our lead CNS product candidate, is an oral, non-opioid, non-sedating NMDA receptor modulator. Because the NMDA receptor is widely distributed throughout the brain and is essential for neuronal plasticity, AV-101 has the potential to impact a wide range of CNS indications, including transforming the current drug treatment paradigm for depression," commented [Shawn Singh, Chief Executive Officer of VistaGen](#)

Mr. Singh continued, "We are excited about AV-101's potential to deliver fast-acting, ketamine-like antidepressant effects without ketamine's side effects or safety concerns, first as an adjunctive treatment with current FDA-approved SSRIs and SNRIs, as we are evaluating in our ELEVATE, and eventually as both an at-home complement to ketamine therapy and as a stand-alone, first-line oral therapy for depression. We believe AV-101 also has the potential to produce gabapentin- and amantadine-like therapeutic benefits for neuropathic pain and Parkinson's disease levodopa-induced dyskinesia, respectively, in each case without involving opioid receptors or causing sedation, hallucinations or other psychological side effects. Overall, during Fiscal 2018, our focused strategy and execution against our core goals resulted in achievement of multiple major milestones that have set the stage for dynamic outcomes in Fiscal 2019 and beyond. The significant progress we have made presents potentially game-changing treatment options for patients and

opportunities to drive value for our stockholders.”

Operational Highlights During Fiscal 2018 and Year-to-Date:

AV-101 Regulatory Milestones

- [FDA](#) authorization to [initiate ELEVATE](#), our U.S. multi-center, Phase 2 study of AV-101 as an adjunctive treatment for Major Depressive Disorder.
- [FDA Fast Track Designation](#) for development of AV-101 as an adjunctive treatment for Major Depressive Disorder.

AV-101 Global Intellectual Property Milestones

- U.S. Patent and Trademark Office (USPTO) issuance of three key U.S. patents, fundamentally expanding commercial exclusivity of AV-101 in the U.S., the world’s largest pharmaceutical market:
 - [U.S. Patent No. 9,993,453](#), therapeutic uses of AV-101 to treat depression. Patent will not expire until at least 2034.
 - [U.S. Patent No. 9,993,450](#), AV-101 oral dosage formulations for neurological indications - not limited to depression. Patent will not expire until at least 2034.
 - [U.S. Patent No. 9,834,801](#), methods of producing AV-101. Patent will not expire until at least 2034.
- European Patent Office grant of [European Patent for AV-101](#), treatment of depression, Parkinson's disease levodopa-induced dyskinesia (PD LID) and use of multiple dosage forms to treat these CNS disorders. This patent has been validated in Belgium, Denmark, France, Germany, Ireland, Italy, Portugal, Spain, Switzerland and the United Kingdom. It will be in effect until January 2034.
- European Patent Office issuance of [Notice of Intention to grant](#) European Patent counterpart to U.S. Patent [No. 9,834,801](#), methods of producing AV-101.
- Japanese Patent Office issuance of Notice of Allowance for the Japanese counterpart to U.S. Patent [No. 9,834,801](#), methods of producing AV-101.
- Chinese Patent Office issuance of Chinese counterpart to U.S. Patent [No. 9,834,801](#), methods of producing AV-101.

AV-101 Peer-Reviewed Publications

- [Journal of Pain](#), featuring AV-101 on the cover and highlighting AV-101’s gabapentin-like potential for treating multiple hyperpathic pain states, without sedation, supporting a future Phase 2 clinical study of AV-101 as a potential oral, non-opioid, non-sedating at-home treatment alternative for neuropathic pain.
- [Scandinavian Journal of Pain](#), discussing the two first-in-human AV-101 Phase 1 safety studies that demonstrated statistically-significant positive results in four well-established preclinical models of pain.

Stem Cell Technology Intellectual Property Milestones

- USPTO issuance of:
 - [U.S. Patent No. 9,834,754](#) related to proprietary methods for producing hematopoietic precursor stem cells, which are stem cells that give rise to all blood cells and most bone marrow cells in the body, with potential to impact both direct and supportive therapy for autoimmune disorders and cancer, with CAR-T cell applications, and foundational technology which may provide approaches for producing bone marrow stem cells for bone marrow transfusions.
 - [U.S. Patent Application No. 14/782,070](#) related to methods of producing pluripotent stem cell-derived chondrocytes, chondrocyte lineage cells, cartilage-like tissue and cartilage. The patent covers claims to the therapeutic administration of these cells and tissues to treat osteoarthritis, the most common chronic condition of the joints, and joint injuries affecting cartilage.
 - In a manner similar to our sublicense agreement with BlueRock Therapeutics involving cardiac stem cell technology, the foregoing patents may enable strategic collaborations involving our intellectual property relating to blood, cartilage and/or liver cells for cell-based therapy, cell repair therapy, regenerative medicine and/or tissue engineering.
- [Japanese Patent Office issuance of a Notice of Allowance](#) for the Japanese counterpart to U.S. Patent [No. 9,834,754](#), methods for producing blood cells, platelets and bone marrow stem cells.

Anticipated Milestones Over Next 12 Months

- Second Half of 2018:
 - NIMH completion of NIMH-sponsored AV-101 Phase 2 MDD monotherapy study
 - FDA authorization to initiate U.S. Phase 2 study of AV-101 for neuropathic pain
 - FDA Fast Track designation of AV-101 for development as a non-opioid, non-sedating treatment for neuropathic pain
- First Half of 2019:
 - Initiate AV-101 Phase 2 study in neuropathic pain
 - FDA authorization to initiate U.S. Phase 2 study of AV-101 for Parkinson's disease levodopa-induced dyskinesia
 - Topline results of ELEVATE, AV-101 Phase 2 study for adjunctive treatment of Major Depressive Disorder

Financial Results for the Fiscal Year Ended March 31, 2018:

Net loss attributable to common stockholders for the fiscal year ended March 31, 2018 ("Fiscal Year 2018") was approximately \$14.3 million, compared to \$10.3 million for the fiscal year ended March 31, 2017 ("Fiscal Year 2017").

Research and development expense totaled approximately \$7.8 million for Fiscal Year

2018, compared with approximately \$5.2 million for Fiscal Year 2017. The increase in research and development expense in Fiscal Year 2018 reflects expanded nonclinical and clinical development of AV-101, particularly preparations for and initiation of our ELEVATE, our AV-101 Phase 2 study in MDD in the fourth quarter of Fiscal Year 2018.

General and administrative expense in Fiscal Year 2018 was relatively flat at approximately \$6.4 million, including approximately \$2.9 million of noncash expense, compared to approximately \$6.3 million, including \$3.1 million of noncash expense, in Fiscal Year 2017.

At March 31, 2018, the Company had cash and cash equivalents of approximately \$10.4 million, compared to approximately \$2.9 million at March 31, 2017.

About ELEVATE

[ELEVATE](#) is VistaGen's U.S. multi-center Phase 2, randomized, double-blind, placebo-controlled clinical trial designed to examine the efficacy and safety of oral AV-101 as an adjunctive treatment 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). Approximately 180 patients will be randomized to receive either AV-101 or placebo, orally, once daily, in conjunction with their ongoing antidepressant. The primary endpoint of the study is the change from baseline as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). Dr. Maurizio Fava of Massachusetts General Hospital and Harvard Medical School is the Principal Investigator of the ELEVATE study. Top-line results are expected in the first half of 2019.

About Major Depressive Disorder (MDD)

MDD is a serious biologically-based mood disorder, affecting approximately 16 million adults in the United States.² Individuals with MDD exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities, for more than a two-week period, as well as impaired social, occupational, educational or other important functioning which has a negative impact on their quality of life. About one in eight Americans aged 12 and over takes an FDA-approved antidepressant.³ While current FDA-approved antidepressants are widely used, about two-thirds of patients with MDD do not respond to their initial antidepressant treatment.⁴ Inadequate response to current antidepressants is among the key reasons MDD is one of the leading public health concerns in the United States, creating a significant unmet medical need for new agents with fundamentally different mechanisms of action.

¹ Zanos, P., et al. (2015) "[The Prodrug 4-Chlorokynurenine Causes Ketamine-Like Antidepressant Effects, but Not Side Effects, by NMDA/GlycineB-Site Inhibition.](#)" J Pharmacol Exp Ther 355:76-85

² Nat. Inst. of Mental Health website, 2017; Available at <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>.

³ Pratt LA, Brody DJ, Gu Q. Antidepressant use among persons aged 12 and over: United States, 2011-2014. NCHS data brief, no 283 (2017). www.cdc.gov/nchs/products/databriefs/db283.htm

⁴ Rush AJ, et al. Am J. Psychiatry. 2006, 163(11): 1905-1917 (STAR*D Study)

About AV-101

AV-101 is an oral, non-opioid, non-sedating NMDA receptor glycine B (NMDAR GlyB) antagonist that offers the potential to be a new at-home treatment for multiple CNS indications with high unmet medical 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 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 a first line oral monotherapy and as an adjunctive oral therapy. As an adjunctive therapy, AV-101 may have potential both to displace atypical antipsychotics such as aripiprazole in the current MDD drug treatment paradigm for patients with an inadequate response to current antidepressants approved by the FDA and to prevent relapse of MDD following successful treatment with the FDA-approved anesthetic, ketamine hydrochloride, an ion-channel blocking NMDA receptor antagonist (ketamine), whether administered by intravenous (IV) 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 associated with ketamine therapy.

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. The FDA has [granted Fast Track designation](#) to AV-101 for development as a potential adjunctive treatment of MDD.

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

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

Commitments and contingencies

Stockholders' equity:

Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2018 and 2017:

Series A Preferred, 500,000 shares authorized, issued

and outstanding at March 31, 2018 and 2017	500	500
Series B Preferred; 4,000,000 shares authorized at March 31, 2018 and 2017; 1,160,240 shares issued and outstanding at March 31, 2018 and 2017	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at March 31, 2018 and 2017; 2,318,012 shares issued and outstanding at March 31, 2018 and 2017	2,300	2,300
Common stock, \$0.001 par value; 100,000,000 and 30,000,000 shares authorized at March 31, 2018 and March 31, 2017, respectively; 23,068,280 and 8,974,386 shares issued and outstanding at March 31, 2018 and March 31, 2017, respectively	23,100	9,000
Additional paid-in capital	167,401,400	146,569,600
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2018 and 2017	(3,968,100)	(3,968,100)
Accumulated deficit	(156,543,800)	(141,998,700)
Total stockholders' equity	<u>6,916,600</u>	<u>615,800</u>
Total liabilities and stockholders' equity	<u>\$ 11,278,300</u>	<u>\$ 3,712,200</u>

VISTAGEN THERAPEUTICS
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

Amounts in Dollars, except share amounts

	Fiscal Years Ended March 31,	
	2018	2017
Revenues:		
Sublicense revenue	\$ -	\$ 1,250,000
Total revenues	<u>-</u>	<u>1,250,000</u>
Operating expenses:		
Research and development	7,762,500	5,203,700
General and administrative	6,437,100	6,294,800
Total operating expenses	<u>14,199,600</u>	<u>11,498,500</u>
Loss from operations	(14,199,600)	(10,248,500)
Other expenses, net:		
Interest expense, net	(8,900)	(4,600)
Loss on extinguishment of accounts payable	<u>(135,000)</u>	<u>-</u>
Loss before income taxes	(14,343,500)	(10,253,100)
Income taxes	(2,400)	(2,400)
Net loss and comprehensive loss	<u>(14,345,900)</u>	<u>(10,255,500)</u>

Accrued dividend on Series B Preferred stock	(1,030,400)	(1,257,000)
Deemed dividend from trigger of down round provision feature	(199,200)	-
Deemed dividend on Series B Preferred Units	-	(111,100)
	<u> </u>	<u> </u>
Net loss attributable to common stockholders	\$ (15,575,500)	\$ (11,623,600)
	<u> </u>	<u> </u>
Basic and diluted net loss attributable to common stockholders per common share	\$ (1.12)	\$ (1.54)
	<u> </u>	<u> </u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	13,890,041	7,531,642
	<u> </u>	<u> </u>



Source: VistaGen Therapeutics, Inc.