February 12, 2019

VistaGen Therapeutics Reports Fiscal 2019 Third Quarter Financial Results

SOUTH SAN FRANCISCO, Calif., Feb. 12, 2019 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for treating depression and other central nervous system (CNS) diseases and disorders with high unmet need, today reported financial results for its fiscal year 2019 third quarter ended December 31, 2018.

“Building on significant progress last quarter, we entered 2019 with an exciting late-stage pipeline comprised of three new generation CNS drug candidates with rapid-onset potential and an excellent safety and tolerability profile. With two candidates having already achieved proof-of-concept efficacy and safety in Phase 2 clinical studies and a third with potentially transformative Phase 2 clinical readouts this year, we look forward to executing our clinical and regulatory plans to achieve the stream of milestones we believe will ultimately make a difference for patients and their support systems, as well as our stockholders,” said Shawn Singh, Chief Executive Officer of VistaGen.

Operational Highlights: Fiscal Year 2019 Third Quarter to Date:

Acquired Two First-in-Class, Late-Stage CNS Drug Candidates

- Acquired a license for exclusive worldwide rights to develop and commercialize PH94B, potentially a first-in-class, rapid-onset neurosteroid nasal spray administered in microgram doses for social anxiety disorder (SAD), a common social phobia which, according to the U.S. National Institute of Mental Health (NIMH), affects approximately 7% of Americans. Based on positive results from Phase 2 and pilot Phase 3 efficacy and safety studies of PH94B, the Company is preparing for Phase 3 clinical development of PH94B for SAD.

- Acquired a license for exclusive worldwide rights to develop and commercialize PH10, potentially a first-in-class, neurosteroid nasal spray administered in microgram doses for major depressive disorder (MDD). Based on positive results of a small exploratory Phase 2a study in MDD in which rapid-onset antidepressant effects were observed without psychological side effects or systemic exposure, the Company is preparing for planned Phase 2b clinical development of PH10 for MDD.

Further Advancements in the Development of AV-101

- Continued enrollment in ELEVATE, the Company's Phase 2 clinical study of the

efficacy and safety of AV-101 as an oral adjunctive treatment of individuals with MDD who have an inadequate response to current FDA-approved antidepressants (SSRIs or SNRIs).

- Announced data from preclinical studies indicating that AV-101 promotes hippocampal neurogenesis, the process by which new neurons are formed in a region of the brain that involves high-level functions such as emotions, memory, and spatial navigation and exploration.

- Received FDA Fast Track Designation for development of AV-101 as an oral, non-opioid treatment for neuropathic pain. Together with the Fast Track Designation for development of AV-101 for MDD, the Company has now received two Fast Track Designations from the FDA for development of AV-101.

Strengthened Board of Directors and CNS Clinical and Regulatory Advisory Board

- Appointed pharmaceutical industry veteran, Ann Cunningham, to the Board of Directors and Corporate Governance and Nominating Committee.

- Appointed to its CNS Clinical and Regulatory Advisory Board, Dr. Michael Liebowitz, a Columbia University psychiatrist and former director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute. Dr. Liebowitz developed the Liebowitz Social Anxiety Scale, or LSAS, which is widely-used as a primary outcome measure in SAD clinical studies, as well as for evaluation of SAD in clinical practice.

Expanded Intellectual Property Portfolio

- Received a patent related to certain methods of production for AV-101 from the Hong Kong Patents Registry Intellectual Property Department.

- Received Notices of Allowance from the IP Australia and the Japan Patent Office related to methods of treating depression with AV-101.

Financial Results: Fiscal Quarter Ended December 31, 2018:

Net loss attributable to common stockholders for the fiscal quarter ended December 31, 2018 was $7.5 million, compared to $3.5 million for the fiscal quarter ended December 31, 2017. Net loss incurred during the quarter ended December 31, 2018 included noncash expense of $2.0 million for the Company's October 2018 exercise of its option to acquire an exclusive worldwide license to develop and commercialize PH10, as well as increased research and development activities relating to the Company's AV-101 ELEVATE study in MDD and preclinical programs related to the Company's CNS pipeline.

Research and development expense totaled approximately $5.3 million for the quarter ended December 31, 2018, compared with approximately $1.6 million for the quarter ended December 31, 2017. The period over period increase is primarily attributable to expenses of the ELEVATE study, manufacturing additional supplies of AV-101 for future clinical and preclinical studies, and several additional preclinical initiatives involving the Company's CNS

pipeline, coupled with the $2.0 million of noncash expense attributable to the Company's exercise of its option to acquire the exclusive, worldwide license to develop and commercialize PH10.

General and administrative expense was approximately $1.8 million in the fiscal quarter ended December 31, 2018, compared to approximately $1.3 million in the fiscal quarter ended December 31, 2017, reflecting an increase in noncash stock-based compensation and in investor and public relations initiatives.

At December 31, 2018, the Company had cash and cash equivalents of approximately $6.3 million, compared to approximately $7.8 million at September 30, 2018.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders with high unmet need. Each of VistaGen's CNS pipeline candidates, AV-101, PH10 and PH94B, has potential to provide rapid-onset therapeutic benefits without the psychological and other side effects, safety concerns or inconvenient clinical administration associated with many current and potential new generation medications for CNS diseases and disorders, such as MDD and SAD. Each drug candidate in VistaGen's pipeline is either currently in or has completed Phase 2 clinical development. AV-101, an oral NMDA receptor glycine B antagonist, is in Phase 2 development, initially as an adjunctive treatment of MDD. The FDA has granted Fast Track designation for development of AV-101, both as a potential adjunctive treatment of MDD and as a non-opioid treatment for neuropathic pain. PH10 intranasal, a potential first-in-class rapid-onset neuroactive steroid, has completed Phase 2a development and is now being prepared for Phase 2b clinical development for MDD. PH94B intranasal, also a potential first-in-class rapid-onset neuroactive steroid, has completed Phase 2 development and is now being prepared for Phase 3 clinical development as an on-demand PRN treatment of SAD.

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 and commercialization of our drug candidates, including AV-101 for MDD, neuropathic pain and suicidal ideation, PH94B for SAD, and PH10 for MDD, as well as our intellectual property and commercial protection of our drug candidates, all of which 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 during our clinical development of any product candidate that cause us to discontinue further development, (ii) we may not be able to successfully demonstrate the safety and efficacy of our product candidates 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 studies, and ongoing or future preclinical and clinical results may not support further development of, or

be sufficient to gain regulatory approval to market AV-101, PH94B, and/or PH10, (iv) decisions or actions of regulatory agencies may negatively affect the progress of, and our ability to proceed with, further clinical studies or to obtain marketing approval for our drug candidates, (v) we may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for our product candidates, (vi) we may not have access to or be able to secure substantial additional capital to support our operations, including our ongoing clinical development activities; and (vii) we may encounter technical and other unexpected hurdles in the manufacturing and development of any of our 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)

	Unaudited December 31, 2018	March 31, 2018
ASSETS		
Current assets:		

Cash and cash equivalents	$ 6,285,300	$ 10,378,300
Prepaid expenses and other current assets	853,800	644,800
Total current assets	7,139,100	11,023,100
Property and equipment, net	334,900	207,400
Security deposits and other assets	47,800	47,800
Total assets	$ 7,521,800	$ 11,278,300

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 1,086,700	$ 1,195,700
Accrued expenses	827,100	206,300
Current notes payable	49,100	53,900
Capital lease obligations	2,900	2,600
Total current liabilities	1,965,800	1,458,500
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	3,456,300	2,608,300
Deferred rent liability	399,800	285,600
Capital lease obligations	7,100	9,300
Total non-current liabilities	3,863,200	2,903,200
Total liabilities	5,829,000	4,361,700
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2018 and March 31, 2018:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at December 31, 2018 and March 31, 2018	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2018 and March 31, 2018; 1,160,240 shares issued and outstanding at December 31, 2018 and March 31, 2018	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at December 31, 2018 and March 31, 2018; 2,318,012 shares issued and outstanding at December 31, 2018 and March 31, 2018	2,300	2,300
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2018 and March 31, 2018; 31,204,380 and 23,068,280 shares issued and outstanding at December 31, 2018 and March 31, 2018, respectively	31,200	23,100
Additional paid-in capital	181,035,800	167,401,400

Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2018 and March 31, 2018	(3,968,100)	(3,968,100)
Accumulated deficit	(175,410,100)	(156,543,800)
Total stockholders' equity	1,692,800	6,916,600
Total liabilities and stockholders' equity	$ 7,521,800	$ 11,278,300

VISTAGEN THERAPEUTICS
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
Amounts in Dollars, except share amounts

Unaudited

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 5,335,500	$ 1,601,800	$ 13,340,300	$ 5,124,600
General and administrative	1,856,800	1,266,000	5,494,100	4,997,400
Total operating expenses	7,192,300	2,867,800	18,834,400	10,122,000
Loss from operations	(7,192,300)	(2,867,800)	(18,834,400)	(10,122,000)
Other expenses, net:				
Interest expense, net	(1,800)	(2,000)	(6,800)	(7,700)
Loss on extinguishment of accounts payable	(22,700)	(135,000)	(22,700)	(135,000)
Loss before income taxes	(7,216,800)	(3,004,800)	(18,863,900)	(10,264,700)
Income taxes	-	-	(2,400)	(2,400)
Net loss and comprehensive loss	(7,216,800)	(3,004,800)	(18,866,300)	(10,267,100)
Accrued dividend on Series B Preferred stock	(290,900)	(263,000)	(848,000)	(766,600)
Deemed dividend from trigger of down round provision feature	-	(199,200)	-	(199,200)

Net loss attributable to common stockholders	$ (7,507,700)	$ (3,467,000)	$ (19,714,300)	$ (11,232,900)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.24)	$ (0.25)	$ (0.75)	$ (1.03)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	30,696,312	13,895,642	26,418,440	10,947,556

Source: VistaGen Therapeutics, Inc.