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VistaGen Therapeutics Reports Fiscal 2020 Third Quarter Financial Results and Provides CNS Pipeline Overview

SOUTH SAN FRANCISCO, Calif., Feb. 13, 2020 /PRNewswire/ --[VistaGen Therapeutics](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for central nervous system (CNS) diseases and disorders with high unmet medical need, today announced financial results for its fiscal year 2020 third quarter ended December 31, 2019.



VistaGen®
Therapeutics

VistaGen has a multi-asset, clinical-stage CNS pipeline, including three differentiated drug candidates, two of which, PH94B and PH10, have positive human clinical data in individuals with social anxiety disorder (SAD) and major depressive disorder (MDD), respectively, and one of which, PH94B, is in preparation to advance into Phase 3 clinical development for the treatment of SAD by the end of this calendar year. Each of VistaGen's CNS product candidates has an exceptional safety profile, potential for rapid-onset therapeutic benefits, and multiple shots on goal in CNS markets where current treatments are inadequate, resulting in high unmet medical need.

Recent CNS Pipeline Updates:

- The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for development of VistaGen's most advanced drug candidate, PH94B neuroactive nasal spray for on-demand treatment of SAD, the first such designation granted by the FDA for development of a drug candidate for SAD.
- VistaGen's Investigational New Drug (IND) application for AV-101, its oral NMDAR (N-methyl-D-aspartate receptor) antagonist prodrug, as a potential new treatment of dyskinesia in patients with Parkinson's disease receiving levodopa therapy, has been cleared by the FDA, permitting VistaGen to proceed with Phase 2a clinical development of AV-101 in this indication.
- The U.S. Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application 16/003,816 related to therapeutic use of AV-101 for treatment of dyskinesia induced by the administration of levodopa. The patent, once issued, will be in effect until at least 2034.
- VistaGen announced successful results from an AV-101 first-step, Phase 1b clinical study with healthy U.S. military Veterans, which measured NMDAR target engagement of AV-101 for potential treatment of suicidal ideation in Veterans. The findings from the study were presented in a poster, titled "[Evoked and Resting State Gamma Mechanics to Test NMDA Receptor Engagement of Kynurenine Pathway Modulator AV-101 in Healthy Veterans](#)," at the 2019 Annual Meeting of the American College of Neuropsychopharmacology (ACNP) on December 11, 2019.
- VistaGen announced positive preclinical data of AV-101 administered in combination with probenecid demonstrating substantially increased brain concentration effects of AV-101 and its active metabolite, 7-CI-KYNA. When given together with AV-101, probenecid increased brain concentrations of AV-101 7-fold and its active metabolite, 7-CI-KYNA, 35-fold. The resulting increased brain levels and duration of 7-CI-KYNA suggest the potential impact of AV-101 with probenecid could result in far more profound therapeutic benefits for patients with MDD than in prior clinical studies that did not involve probenecid, as well as in other NMDAR-focused CNS diseases and disorders. Results on AV-101 transport with adjunctive probenecid were presented by a collaborator of VistaGen at the British Pharmacological Society's Pharmacology 2019 annual conference in Edinburgh, UK, on December 17, 2019.

"During the quarter, we made significant progress across our CNS pipeline, including milestones necessary to advance PH94B, our first-in-class, rapid-onset neuroactive nasal spray, into Phase 3 clinical development for treatment of social anxiety disorder later this year," stated [Shawn Singh, Chief Executive Officer of VistaGen](#). "Social anxiety disorder, or SAD, affects as many as 20 million American adults and adolescents and is the third most common mental health disorder in the U.S. With the alarming prevalence of depression, anxiety, and suicide, driven increasingly by excessive use of social media, and staggering increases in dependency, addiction and even deaths associated with misuse and overuse of benzodiazepines, the urgency for a differentiated, fast-acting, non-addictive, non-sedating treatment for SAD and other anxiety-related disorders is more important now than ever before."

Mr. Singh continued, "During the quarter, we were very pleased that PH94B received the FDA's first ever Fast Track designation for development of a drug candidate for treatment of SAD. We look forward to further advancing our ongoing efforts to meet the needs of millions of individuals with SAD for whom current treatments fall short, while in parallel advancing development of our other first-in-class neuroactive nasal spray, PH10, for major depressive

disorder, and our oral prodrug, AV-101, for treatment of CNS indications involving the NMDA receptor."

Financial Results for the Fiscal Quarter Ended December 31, 2019:

Net loss attributable to common stockholders for the fiscal quarter ended December 31, 2019 decreased to approximately \$6.3 million compared to \$7.5 million for the fiscal quarter ended December 31, 2018, primarily resulting from the \$2.0 million noncash expense associated with the stock-based acquisition of the license to develop and commercialize PH10 in the 2018 quarter.

Research and development expense decreased to \$3.0 million for the fiscal quarter ended December 31, 2019, compared with \$5.3 million for the fiscal quarter ended December 31, 2018, primarily due to the 2018 noncash expense associated with the acquisition of the PH10 license. Expenses related to the Elevate study of AV-101 in MDD and other AV-101 related nonclinical activities decreased in the quarter ended December 31, 2019 compared to 2018, as the Elevate study reached its conclusion following final patient dosing in September 2019. Increased spending for nonclinical activities, including manufacturing expense for PH94B and PH10, generally offset the reduction in AV-101 expenses. In addition to the noncash PH10 license acquisition in the quarter ended December 31, 2018, other noncash expenses, primarily stock-based compensation and depreciation, accounted for approximately \$503,000 and \$297,000 in the quarters ended December 31, 2019 and 2018, respectively.

General and administrative expense increased to approximately \$2.9 million in the fiscal quarter ended December 31, 2019, compared to approximately \$1.9 million in the fiscal quarter ended December 31, 2018. Noncash general and administrative expense, \$2.0 million in the quarter ended December 31, 2019, increased from \$597,000 in the quarter ended December 31, 2018 primarily due to increased noncash stock-based compensation and noncash warrant modification expenses offset by decreased noncash investor and public relations expenses.

At December 31, 2019, VistaGen had cash and cash equivalents of \$1.1 million, compared to \$13.1 million at March 31, 2019. Subsequent to December 31, 2019, on January 24, 2020, the Company received \$2.75 million in gross proceeds from its successful self-placed registered direct offering of common stock and concurrent private placement of warrants.

As of February 12, 2020, there were 47,963,042 shares of common stock outstanding.

VistaGen's Clinical-Stage CNS Pipeline

VistaGen is developing three new generation clinical-stage CNS drug candidates, PH94B, PH10, and AV-101, each with a differentiated mechanism of action, an exceptional safety profile in all clinical studies to date, and therapeutic potential in multiple CNS markets where current treatments are inadequate to meet high unmet patient needs.

PH94B is an investigational first-in-class, odorless, fast-acting synthetic neurosteroid with therapeutic potential in a wide range of neuropsychiatric indications involving anxiety or phobia. VistaGen is initially developing PH94B as a potential fast-acting, non-sedating, non-addictive new generation treatment of social anxiety disorder (SAD). Upon easy self-

administration, a non-systemic microgram-level dose PH94B sprayed into the nose binds to nasal chemosensory receptors that activate neural circuits in the brain that suppress fear and anxiety associated with everyday social and work or performance situations. Following successfully completed Phase 2 development for SAD, VistaGen is now preparing for Phase 3 clinical development of PH94B for SAD. The FDA has granted Fast Track designation for development of PH94B for treatment of SAD, the FDA's first ever Fast Track designation for development of a drug candidate for treatment of SAD.

PH10 is an investigational first-in-class, odorless, fast-acting synthetic neurosteroid with therapeutic potential in a wide range of neuropsychiatric indications involving depression and suicidal ideation. VistaGen is initially developing PH10 as a potential fast-acting, non-sedating, non-addictive new generation treatment of major depressive disorder (MDD) that can be conveniently self-administered at home. Upon self-administration, a non-systemic microgram-level dose of PH10 sprayed into the nose binds to nasal chemosensory receptors that, in turn, activate neural circuits in the brain that lead to rapid-onset antidepressant effects, without side effects, systemic exposure or safety concerns that may be caused by FDA-approved drug treatments for MDD, including oral antidepressants and esketamine. Following successfully completed Phase 2a development for MDD, VistaGen is now preparing for planned Phase 2b clinical development of PH10 for MDD.

AV-101 (4-Cl-KYN) targets the NMDAR (N-methyl-D-aspartate receptor), an ionotropic glutamate receptor in the brain. Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-chlorokynurenic acid (7-Cl-KYNA), which is a potent and selective full antagonist of the glycine co-agonist site of the NMDAR that inhibits the function of the NMDAR. Unlike ketamine and many other NMDAR antagonists, 7-Cl-KYNA is not an ion channel blocker. In all studies to date, AV-101 has exhibited no dissociative or hallucinogenic psychological side effects or safety concerns similar to those that may be caused by drugs such as amantadine, esketamine and ketamine. With its exceptionally few side effects and excellent safety profile, AV-101 has potential to be an oral new generation treatment for multiple large-market CNS indications where current treatments are inadequate to meet high unmet patient needs. Following positive preclinical efficacy studies of AV-101 in multiple CNS indications, as well as recent positive preclinical studies of AV-101 in combination with probenecid, VistaGen is conducting additional AV-101 preclinical studies and assessing opportunities for potential Phase 2a clinical development of AV-101. The FDA has granted Fast Track designation for development of AV-101 as both a potential [adjunctive treatment for MDD](#) and as a [non-opioid treatment for neuropathic pain](#).

About VistaGen

VistaGen Therapeutics is a multi-asset, clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's [pipeline](#) is focused on clinical-stage CNS drug candidates with a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in multiple large and growing CNS markets. 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 three drug candidates for various therapeutic purposes, including (i) PH94B for social anxiety disorder and multiple other anxiety-related disorders; (ii) PH10 for MDD and multiple additional depression-related disorders and suicidal ideation, and (iii) AV-101 for dyskinesia in patients with Parkinson's disease receiving levodopa therapy, epilepsy, major depressive disorder, neuropathic pain and suicidal ideation. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection of each of our drug candidates. Each of these statements 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. Those risks include the following: (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 studies may not be repeated or observed in 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 any of our product candidates; (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 nonclinical and 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.

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

	December 31, 2019	March 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,063,300	\$ 13,100,300

Receivable from supplier	-	300,000
Prepaid expenses and other current assets	319,000	250,900
Total current assets	1,382,300	13,651,200
Property and equipment, net	235,100	312,700
Right of use asset - operating lease	3,665,600	-
Security deposits and other assets	47,800	47,800
Total assets	<u>\$ 5,330,800</u>	<u>\$ 14,011,700</u>

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY

Current liabilities:		
Accounts payable	\$ 1,610,400	\$ 1,055,000
Accrued expenses	951,300	1,685,600
Current notes payable	70,500	57,300
Operating lease obligation	301,400	-
Financing lease obligation	3,200	3,000
Total current liabilities	<u>2,936,800</u>	<u>2,800,900</u>
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	4,686,300	3,748,200
Deferred rent liability	-	381,100
Operating lease obligation	3,798,400	-
Financing lease obligation	3,900	6,300
Total non-current liabilities	<u>8,488,600</u>	<u>4,135,600</u>
Total liabilities	<u>11,425,400</u>	<u>6,936,500</u>

Commitments and contingencies

Stockholders' (deficit) equity:

Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2019 and March 31, 2019:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at December 31, 2019 and March 31, 2019	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2019 and March 31, 2019; 1,160,240 shares issued and outstanding at December 31, 2019 and March 31, 2019	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at December 31, 2019 and March 31, 2019; 2,318,012 shares issued and outstanding at December 31, 2019 and March 31, 2019	2,300	2,300
Common stock, \$0.001 par value; 175,000,000 and 100,000,000 shares authorized at December 31, 2019 and March 31, 2019, respectively; 44,228,630 and 42,758,630 shares issued and outstanding at December 31, 2019 and March 31, 2019, respectively	44,200	42,800
Additional paid-in capital	196,466,000	192,129,900
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2019 and March 31, 2019	(3,968,100)	(3,968,100)
Accumulated deficit	<u>(198,640,700)</u>	<u>(181,133,400)</u>
Total stockholders' (deficit) equity	<u>(6,094,600)</u>	<u>7,075,200</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 5,330,800</u>	<u>\$ 14,011,700</u>

VISTAGEN THERAPEUTICS
STATEMENT OF OPERATIONS
Amounts in Dollars, except share amounts

(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 3,014,500	\$ 5,335,500	\$ 11,533,600	\$ 13,340,300
General and administrative	2,948,300	1,856,800	6,004,500	5,494,100
Total operating expenses	5,962,800	7,192,300	17,538,100	18,834,400
Loss from operations	(5,962,800)	(7,192,300)	(17,538,100)	(18,834,400)
Other income (expenses), net:				
Interest income (expense), net	1,500	(1,800)	33,400	(6,800)
Loss on extinguishment of accounts payable	-	(22,700)	-	(22,700)
Loss before income taxes	(5,961,300)	(7,216,800)	(17,504,700)	(18,863,900)
Income taxes	(200)	-	(2,600)	(2,400)
Net loss and comprehensive loss	\$ (5,961,500)	\$ (7,216,800)	\$ (17,507,300)	\$ (18,866,300)
Accrued dividend on Series B Preferred stock	(321,800)	(290,900)	(938,100)	(848,000)
Net loss attributable to common stockholders	\$ (6,283,300)	\$ (7,507,700)	\$ (18,445,400)	\$ (19,714,300)
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.15)	\$ (0.24)	\$ (0.43)	\$ (0.75)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	43,158,889	30,696,312	42,802,256	26,418,440

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