



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

November 7, 2019

SOUTH SAN FRANCISCO, Calif., Nov. 7, 2019 /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 need, today announced financial results for its fiscal year 2020 second quarter ended September 30, 2019.



VistaGen® Therapeutics

"During the quarter, we achieved several important milestones intended to advance development of each of our three differentiated CNS drug candidates," stated [Shawn Singh, Chief Executive Officer of VistaGen](#). "We recently achieved target enrollment and completed patient dosing in our randomized, double-blind, placebo-controlled Phase 2 ELEVATE study of AV-101, our novel oral NMDA receptor antagonist, in major depressive disorder. In addition, for development of AV-101 in suicidal ideation, with emphasis on U.S. Military Veterans, our collaborators at Baylor University recently completed dosing in their Phase 1b target engagement study in healthy volunteer Veterans, a study funded by the U.S. Department of Veteran's Affairs. We are also encouraged by post-Phase 2 feedback from the FDA earlier this year regarding our Phase 3 development plan for PH94B, our first-in-class, rapid-acting neuroactive nasal spray, in social anxiety disorder. We expect the coming months to be equally active and potentially transformative, as we look forward to topline readouts from two studies involving AV-101 before the end of 2019, and potential regulatory milestones involving PH94B before the end of fiscal 2020."

Financial Results for the Fiscal Quarter Ended September 30, 2019:

Net loss attributable to common stockholders for the fiscal quarter ended September 30, 2019 decreased to approximately \$5.7 million compared to \$7.7 million for the fiscal quarter ended September 30, 2018, primarily attributable to research and development activities relating to the Company's CNS drug development programs.

Research and development expense decreased to \$4.2 million for the fiscal quarter ended September 30, 2019, compared with \$5.3 million for the fiscal quarter ended September 30, 2018. Expense for the quarter ended September 30, 2018 included \$2.25 million noncash expense associated with the Company's acquisition of its exclusive worldwide license to develop and commercialize PH94B and an option to acquire an exclusive worldwide license to develop and commercialize PH10, the Company's first-in-class, rapid-onset neuroactive nasal spray in Phase 2 development for major depressive disorder, which option was subsequently exercised. Offsetting this noncash expense in the quarter ended September 30, 2019 are increased expenses for the ELEVATE study and various nonclinical activities across the Company's CNS pipeline.

General and administrative expense decreased to approximately \$1.1 million in the fiscal quarter ended September 30, 2019, compared to approximately \$2.2 million in the fiscal quarter ended September 30, 2018. Noncash expense of \$272,000 in the quarter ended September 30, 2019, decreased from \$792,000 in the quarter ended September 30, 2018, primarily due to decreases in stock-based compensation and other expenses.

At September 30, 2019, VistaGen had cash and cash equivalents of \$4.1 million, compared to \$13.1 million at March 31, 2019.

As of November 6, 2019, there were 43,222,965 shares of common stock outstanding.

VistaGen's CNS Pipeline

VistaGen is developing three new generation clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, 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.

AV-101 belongs to a new generation of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with numerous CNS diseases and disorders. AV-101 is an oral prodrug of 7-Cl-KYNA, a potent and selective full antagonist of the glycine co-agonist site of the NMDA receptor. Based on several positive preclinical studies and its exceptional safety profile in all preclinical and clinical studies to date, AV-101 has potential to be a new at-home, non-sedating treatment for multiple large market CNS indications, including major depressive disorder, neuropathic pain, suicidal ideation, epilepsy and dyskinesia associated with levodopa therapy for Parkinson's disease. The FDA has granted Fast Track designation for development of AV-101 as both a novel potential [adjunctive treatment for MDD](#) and a [non-opioid treatment for neuropathic pain](#).

PH10 is a first-in-class, odorless, rapid-onset CNS neuroactive nasal spray in development for treatment of major depressive disorder. Administered in microgram doses, PH10 activates nasal chemosensory receptors that, in turn, engage neural circuits that lead to rapid antidepressant effects without psychological side effects, systemic exposure or safety concerns often associated with current oral antidepressants and ketamine-based therapies (intravenous ketamine or esketamine nasal spray). In an exploratory (n=30) randomized, double-blind, placebo-controlled Phase 2a clinical study in major depressive disorder, at microgram doses, rapid-onset antidepressant effects were observed and sustained for 8 weeks, without psychological side effects or systemic exposure. VistaGen is preparing for planned Phase 2b clinical development of PH10 for major depressive disorder.

PH94B is a first-in-class, odorless, rapid-onset (approximately 10 to 15 minutes) CNS neuroactive nasal spray with the potential to be the first FDA-approved, as-needed, on-demand treatment for millions of Americans who suffer from social anxiety disorder, with additional potential in peripartum anxiety, pre/postoperative anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder. Administered at microgram doses, PH94B activates nasal chemosensory receptors that trigger neural circuits in the brain that suppress fear and anxiety associated with everyday social and work or performance situations. Following successful Phase 2 development, VistaGen is preparing for Phase 3 clinical development of PH94B for social anxiety disorder.

About VistaGen

VistaGen Therapeutics is a 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](#) includes three clinical-stage CNS drug candidates, AV-101, PH10 and PH94B, each with a differentiated mechanism of action, an exceptional safety profile in all clinical studies to date, 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: (i) AV-101 for major depressive disorder, neuropathic pain, epilepsy, dyskinesia associated with levodopa therapy for Parkinson's disease and suicidal ideation; (ii) PH94B for social anxiety disorder, peripartum anxiety, pre/postoperative anxiety, post-traumatic stress disorder, panic disorder and generalized anxiety disorder; and (iii) PH10 for major depressive disorder. In addition, statements concerning the Company's future expectations may include statements regarding intellectual property and commercial protection 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 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.

VISTAGEN THERAPEUTICS

Consolidated Balance Sheets

(Amounts in dollars, except share amounts)

(UNAUDITED)

	<u>September 30,</u> <u>2019</u>	<u>March 31,</u> <u>2019</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,072,400	\$ 13,100,300
Receivable from supplier	-	300,000
Prepaid expenses and other current assets	604,500	250,900

Total current assets	4,676,900	13,651,200
Property and equipment, net	260,600	312,700
Right of use asset - operating lease	3,750,200	-
Security deposits and other assets	47,800	47,800
Total assets	<u>\$ 8,735,500</u>	<u>\$ 14,011,700</u>

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY

Current liabilities:		
Accounts payable	\$ 1,449,800	\$ 1,055,000
Accrued expenses	2,215,500	1,685,600
Current notes payable	159,300	57,300
Operating lease obligation	289,600	-
Financing lease obligation	3,100	3,000
Total current liabilities	<u>4,117,300</u>	<u>2,800,900</u>
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	4,364,500	3,748,200
Deferred rent liability	-	381,100
Operating lease obligation	3,879,400	-
Financing lease obligation	4,700	6,300
Total non-current liabilities	<u>8,248,600</u>	<u>4,135,600</u>
Total liabilities	<u>12,365,900</u>	<u>6,936,500</u>

Commitments and contingencies

Stockholders' (deficit) equity:

Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2019 and March 31, 2019:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2019 and March 31, 2019	500	500
Series B Preferred; 4,000,000 shares authorized at September 30, 2019 and March 31, 2019; 1,160,240 shares issued and outstanding at September 30, 2019 and March 31, 2019	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at September 30, 2019 and March 31, 2019; 2,318,012 shares issued and outstanding at September 30, 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 September 30, 2019 and March 31, 2019, respectively; 42,758,630 shares issued and outstanding at September 30, 2019 and March 31, 2019	42,800	42,800
Additional paid-in capital	192,970,100	192,129,900
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2019 and March 31, 2019	(3,968,100)	(3,968,100)
Accumulated deficit	<u>(192,679,200)</u>	<u>(181,133,400)</u>
Total stockholders' (deficit) equity	<u>(3,630,400)</u>	<u>7,075,200</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 8,735,500</u>	<u>\$ 14,011,700</u>

VISTAGEN THERAPEUTICS STATEMENT OF OPERATIONS

Amounts in Dollars, except share amounts

(Unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 4,205,200	\$ 5,261,100	\$ 8,519,100	\$ 8,004,800
General and administrative	1,146,100	2,171,000	3,056,200	3,637,300
Total operating expenses	<u>5,351,300</u>	<u>7,432,100</u>	<u>11,575,300</u>	<u>11,642,100</u>
Loss from operations	(5,351,300)	(7,432,100)	(11,575,300)	(11,642,100)
Other income (expenses), net:				
Interest income (expense), net	15,400	(2,900)	31,900	(5,000)
Loss before income taxes	<u>(5,335,900)</u>	<u>(7,435,000)</u>	<u>(11,543,400)</u>	<u>(11,647,100)</u>
Income taxes	-	-	(2,400)	(2,400)
Net loss and comprehensive loss	<u>\$ (5,335,900)</u>	<u>\$ (7,435,000)</u>	<u>\$ (11,545,800)</u>	<u>\$ (11,649,500)</u>
Accrued dividend on Series B Preferred stock	<u>(313,800)</u>	<u>(283,600)</u>	<u>(616,300)</u>	<u>(557,100)</u>
Net loss attributable to common stockholders	<u>\$ (5,649,700)</u>	<u>\$ (7,718,600)</u>	<u>\$ (12,162,100)</u>	<u>\$ (12,206,600)</u>

Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (0.13)</u>	<u>\$ (0.30)</u>	<u>\$ (0.29)</u>	<u>\$ (0.50)</u>
Weighted average shares used in computing <small>basic and diluted net loss attributable to common stockholders per common share</small>	<u>42,622,965</u>	<u>25,815,245</u>	<u>42,622,965</u>	<u>24,267,816</u>

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