



VistaGen Therapeutics Reports Fiscal 2021 Third Quarter Financial Results and Provides Update on Expected Clinical Studies in Calendar 2021

February 11, 2021

Multiple clinical studies anticipated to launch in Calendar 2021, notably pivotal Phase 3 clinical studies of PH94B as a potential acute treatment of anxiety in adults with social anxiety disorder (SAD)

Strengthened Balance Sheet upon closing of \$100 million underwritten public offering

SOUTH SAN FRANCISCO, Calif., Feb. 11, 2021 (GLOBE NEWSWIRE) -- [VistaGen Therapeutics](#), Inc. (NASDAQ: VTGN), a biopharmaceutical company committed to developing and commercializing a new generation of medicines with the potential to go beyond the current standard of care for anxiety, depression and other central nervous system (CNS) disorders, today reported its financial results for its fiscal 2021 third quarter ended December 31, 2020, and provided an update on planned clinical advancement of its CNS pipeline throughout the remainder of this calendar year.

"Calendar 2020 was transformative, highlighted by closing a PH94B partnership, a positive meeting with the FDA regarding the key aspects of the study design for our upcoming pivotal Phase 3 studies of our PH94B nasal spray in social anxiety disorder and, during the most recent quarter, closing a \$100 million financing which involved significant participation from leading healthcare institutional investors such as Acuta Capital, New Enterprise Associates, OrbiMed and Venrock Healthcare Capital Partners, among others. We are encouraged by these transformative milestones. Together, they have further advanced our tenacious pursuit to bring life-changing medications to the millions affected by anxiety, depression and other mental health challenges worldwide," said [Shawn Singh, Chief Executive Officer of VistaGen](#).

Mr. Singh continued, "We believe we have sufficient capital to fund all of our currently planned nonclinical and clinical studies across our pipeline. As a result, we expect to launch several clinical studies this calendar year, notably our pivotal Phase 3 clinical studies of PH94B as a potential acute treatment of anxiety in adults with social anxiety disorder, as well several small exploratory PH94B Phase 2 studies in adult patients experiencing additional anxiety-related disorders. This year, we will also complete preparations to launch Phase 2B clinical development of PH10 as a potential rapid-onset stand-alone treatment for major depressive disorder in early 2022. Finally, later this year, based on successful preclinical studies involving AV-101 alone and in combination with probenecid, we will launch Phase 1B clinical development of the combination to enable potential exploratory Phase 2 development of in several CNS disorders."

Corporate Highlights in Fiscal Q3 2021:

- [Closed \\$100 million](#) underwritten public offering led by Jefferies Group LLC and William Blair & Company involving significant participation from key healthcare-focused institutional investors, such as Acuta Capital, New Enterprise Associates, OrbiMed and Venrock Healthcare Capital Partners.
- [Expanded R&D team](#) with appointment of Louis Monti, M.D., Ph.D., a pioneer in the development of neuroactive steroids known as pherines, including PH94B and PH10, as Vice President, Translational Medicine.
- [Appointed Senior Vice President, Head of CMC \(Chemistry, Manufacturing and Controls\)](#) with the addition of Mark J. Ginski, Ph.D., an expert with over 25 years of broad CMC leadership experience, spanning preclinical and clinical development.
- [Announced publication](#) in *CNS Spectrums* detailing proposed mechanism of action of investigational neuroactive nasal sprays, PH94B and PH10, for anxiety and depression disorders, respectively.
- [The Korea Intellectual Property Office \(KIPO\)](#) in the Republic of Korea issued a Decision to Grant Patent Application No. 10-2015-7020176 related to methods of treating depressive disorder for PH10.

Financial Results for the Fiscal Quarter Ended December 31, 2020:

Net loss: Net loss attributable to common stockholders for the fiscal quarter ended December 31, 2020 decreased to approximately \$5.65 million compared to \$6.28 million for the fiscal quarter ended December 31, 2019. Net loss for the nine months ended December 31, 2020 and 2019 was approximately \$11.7 million and \$17.5 million, respectively.

Revenue: VistaGen recognized \$313,600 in sublicense revenue pursuant to its PH94B development and commercialization agreement with EverInsight Therapeutics (now AffaMed Therapeutics) for the quarter ended December 31, 2020 compared to none in the quarter ended December 31, 2019. On June 24, 2020, VistaGen entered into the agreement with EverInsight Therapeutics, pursuant to which the Company received a non-dilutive upfront license fee payment of \$5.0 million on August 3, 2020.

Research and development (R&D) expense: Research and development expense increased from \$3.0 million to \$3.5 million for the quarters ended December 31, 2019 and 2020, respectively. Cash compensation for the quarter ended December 31, 2020 increased by approximately \$0.3 million and was offset by a similar decrease in noncash stock-based compensation for the same period compared to expenses in the quarter ended December 31, 2019. PH94B and PH10 development expenses increased by approximately \$1.5 million in the quarter ended December 31, 2020 compared to expense for the quarter ended December 31, 2019 as drug substance and drug product manufacturing preceding clinical trials advanced. AV-101-related expenses decreased primarily due to the completion of the Company's multi-center Phase 2 study of AV-101 for the adjunctive treatment of major depressive disorder in the quarter ended December 31, 2019.

General and administrative (G&A) expense: General and administrative expense decreased to approximately \$2.1 million from approximately \$2.9 million for the quarters ended December 31, 2020 and 2019, respectively. Cash compensation for the quarter ended December 31, 2020 increased by approximately \$0.6 million and was offset by a similar decrease in noncash stock-based compensation for the same period compared to expenses in the quarter ended December 31, 2019. Further, in the quarter ended December 31, 2019, VistaGen completed certain modifications to outstanding warrants and recognized non-cash warrant modification expense of \$826,900.

Cash Position: At December 31, 2020, the Company had cash and cash equivalents of approximately \$104.3 million. The Company believes its current cash position is sufficient to advance an important stream of potential clinical and regulatory catalysts, including, among others: its Phase 3 development program for PH94B for the acute treatment of anxiety in adults with SAD and, upon successful Phase 3 development, submission of its New Drug Application to the U.S. Food and Drug Administration and potential U.S. market approval of PH94B; exploratory Phase 2 clinical development of PH94B in multiple additional anxiety-related disorders; Phase 2B clinical development of PH10 as a potential stand-alone treatment for major depressive disorder; and Phase 1B and potential exploratory Phase 2 clinical development of AV-101 in combination with probenecid for CNS disorders involving the NMDA (N-methyl-D-aspartate) receptor.

As of February 11, 2021, the Company had 141,694,413 shares of common stock outstanding.

About VistaGen

VistaGen Therapeutics is a biopharmaceutical company committed to developing and commercializing innovative medicines with the potential to go beyond the current standard of care for anxiety, depression, and other CNS disorders. Each of VistaGen's three drug candidates has a differentiated potential mechanism of action, has been well-tolerated in all clinical studies to date and has therapeutic potential in multiple CNS markets. For more information, please visit www.vistagen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by us and our management, are inherently uncertain. Our actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching and/or conducting our planned clinical trials, including delays due to the impact of the COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct our planned clinical and non-clinical trials; continued uncertainty with respect to the COVID-19 pandemic; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, including risks related to the COVID-19 pandemic, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of our CNS drug candidates and difficulty in initiating or conducting clinical trials; inadequate and/or untimely supply of one or more of our CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of our CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended March 31, 2020, and in our most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press 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, other than as may be required by law. If we do update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements.

VistaGen Company Contact

Mark McPartland
VistaGen Therapeutics
Phone: (650) 577-3606
Email: IR@vistagen.com

VISTAGEN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	December 31, 2020	March 31, 2020
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 104,331,100	\$ 1,355,100
Prepaid expenses and other current assets	547,500	225,100
Deferred contract acquisition costs - current portion	116,900	-
Total current assets	104,995,500	1,580,200
Property and equipment, net	382,200	209,600
Right of use asset - operating lease	3,312,100	3,579,600
Deferred offering costs	241,300	355,100

Deferred contract acquisitions cost - non-current portion	292,200	-
Security deposits and other assets	47,800	47,800
Total assets	<u>\$ 109,271,100</u>	<u>\$ 5,772,300</u>

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

Current liabilities:		
Accounts payable	\$ 776,400	\$ 1,836,600
Accrued expenses	507,200	561,500
Current notes payable	98,400	56,500
Deferred revenue - current portion	1,244,000	-
Operating lease obligation - current portion	351,500	313,400
Financing lease obligation - current portion	3,600	3,300
Total current liabilities	<u>2,981,100</u>	<u>2,771,300</u>

Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	5,923,700	5,011,800
Deferred revenue - non-current portion	3,108,400	-
Operating lease obligation - non-current portion	3,446,900	3,715,600
Financing lease obligation - non-current portion	300	3,000
Total non-current liabilities	<u>12,479,300</u>	<u>8,730,400</u>
Total liabilities	<u>15,460,400</u>	<u>11,501,700</u>

Commitments and contingencies

Stockholders' equity (deficit):

Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2020 and March 31, 2020:

Series A Preferred, 500,000 shares authorized, issued and outstanding at December 31, 2020 and March 31, 2020	500	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2020 and March 31, 2020; 1,131,669 shares and 1,160,240 shares issued and outstanding at December 31, 2020 and March 31, 2020, respectively	1,100	1,200
Series C Preferred; 3,000,000 shares authorized at December 31, 2020 and March 31, 2020; 2,318,012 shares issued and outstanding at September 30, 2020 and March 31, 2020	2,300	2,300
Series D Preferred; 2,000,000 shares and no shares authorized, issued and outstanding at December 31, 2020 and March 31, 2020, respectively	2,000	-
Common stock, \$0.001 par value; 175,000,000 shares authorized at December 31, 2020 and March 31, 2020; 138,800,137 and 49,348,707 shares issued and outstanding at December 31, 2020 and March 31, 2020, respectively	138,800	49,300
Additional paid-in capital	311,264,800	200,092,800
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2020 and March 31, 2020	(3,968,100)	(3,968,100)
Accumulated deficit	<u>(213,630,700)</u>	<u>(201,907,400)</u>
Total stockholders' equity (deficit)	<u>93,810,700</u>	<u>(5,729,400)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 109,271,100</u>	<u>\$ 5,772,300</u>

VISTAGEN THERAPEUTICS CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Amounts in Dollars, except share amounts)

(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Sublicense revenue	\$ 313,600	\$ -	\$ 647,600	\$ -
Total revenues	<u>313,600</u>	<u>-</u>	<u>647,600</u>	<u>-</u>
Operating expenses:				
Research and development	3,496,100	3,014,500	7,585,500	11,533,600
General and administrative	2,116,800	2,948,300	4,776,900	6,004,500
Total operating expenses	<u>5,612,900</u>	<u>5,962,800</u>	<u>12,362,400</u>	<u>17,538,100</u>
Loss from operations	(5,299,300)	(5,962,800)	(11,714,800)	(17,538,100)
Other income (expenses), net:				

Interest income (expense), net	600	1,500	(6,500)	33,400
Other income	-	-	600	-
Loss before income taxes	(5,298,700)	(5,961,300)	(11,720,700)	(17,504,700)
Income taxes	-	(200)	(2,600)	(2,600)
Net loss and comprehensive loss	\$ (5,298,700)	\$ (5,961,500)	\$ (11,723,300)	\$ (17,507,300)
Accrued dividends on Series B Preferred stock	(353,600)	(321,800)	(1,036,600)	(938,100)
Net loss attributable to common stockholders	\$ (5,652,300)	\$ (6,283,300)	\$ (12,759,900)	\$ (18,445,400)
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.07)	\$ (0.15)	\$ (0.19)	\$ (0.43)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	81,086,105	43,158,889	66,551,962	42,802,256



Source: VistaGen Therapeutics, Inc.

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