VistaGen Therapeutics Reports Fiscal 2021 Second Quarter Financial Results and Provides Highlights on its CNS Pipeline and Business Progress

November 12, 2020

Positive FDA Meeting Sets Key Pathway for Pivotal PH94B Phase 3 Study in the Second Quarter of 2021

Received Over $17.5 Million Net Proceeds from PH94B Upfront License Payment and Public Offering of Common Stock

Positive New Data from Second Preclinical Study of AV-101 in Combination with Probenecid

Positive Preclinical Data Differentiating Mechanism of Action of PH94B from Risk-Ridden Benzodiazepines

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2020 /PRNewswire/ -- VistaGen Therapeutics (NASDAQ: VTGN), a biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) disorders, today reported its financial results for the fiscal 2021 second quarter ended September 30, 2020 and provided an update on its CNS pipeline and business progress.

"We see a significant rise in mental health concerns as the global COVID-19 pandemic continues to impact the daily lives of millions of individuals. We are committed to developing innovative therapies that provide relief to those suffering from anxiety and depression, and we are working diligently towards that goal. We are making significant progress in preparing PH94B for launch of a pivotal Phase 3 study for acute treatment of anxiety in adults with social anxiety disorder in the second quarter of 2021. After reaching consensus with the FDA on the key components of the study design, it will be very similar to the statistically significant Phase 2 study of PH94B in social anxiety disorder. We are also working with the FDA to finalize details for our Phase 2A study of PH94B in adjustment disorder, which we are planning to initiate in early 2021," said Shawn Singh, Chief Executive Officer of VistaGen.

"Millions of people rely on benzodiazepines and other prescription drugs to manage symptoms of stress and anxiety. While some medications are safe and effective treatments, many in the current treatment paradigm have limited therapeutic benefits and potentially serious side effects and safety concerns. In Phase 2 clinical studies, PH94B produced rapid onset anti-anxiety effects without requiring systemic uptake and distribution. With its rapid-onset pharmacology, lack of systemic exposure and sedation, and its excellent safety profile in all studies to date, we believe PH94B has the potential to displace benzodiazepines in the drug treatment paradigm for anxiety disorders. In addition to social anxiety disorder, we believe PH94B also has potential as a novel treatment for adjustment disorder, postpartum anxiety, post-traumatic stress disorder, preprocedural anxiety, panic, and other anxiety-related disorders, and we look forward to assessing its potential in various controlled Phase 2 clinical studies in parallel with our Phase 3 program to assess its potential as an acute treatment of anxiety in adults with social anxiety disorder," concluded Mr. Singh.

CNS Pipeline Highlights and Updates:

PH94B

- VistaGen reached consensus with the FDA on key study design and execution aspects of the Company's initial pivotal

Phase 3 study of PH94B for acute treatment of anxiety in adults with social anxiety disorder (SAD):
    - As in the statistically significant (p=0.002) Phase 2 public speaking study of PH94B in SAD, VistaGen's Phase 3 study will involve a laboratory-simulated anxiety-provoking public speaking challenge.
    - The Phase 3 study will be a randomized, double-blind, placebo-controlled, parallel comparison study conducted at approximately 15 sites in North America.
    - The Subjective Units of Distress Scale (SUDS) will be used to assess the primary efficacy endpoint in the study.
    - Dr. Michael Liebowitz, Professor of Clinical Psychiatry at Columbia University, director of the Medical Research Network in New York City, and creator of the Liebowitz Social Anxiety Scale (LSAS), will be the Principal Investigator of the study.
    - Target enrollment (completed subjects) will be approximately 182 adults with SAD.
    - Study expected to initiate recruitment in 2Q 2021.
- VistaGen is currently preparing for an exploratory Phase 2A clinical study of PH94B for acute treatment of adjustment disorder (AjD), an emotional or behavioral reaction considered excessive or out of proportion to a stressful event or significant life change, occurring within three months of the stressor, and/or significantly impairing a person's social, occupational and/or other important areas of functioning. Given the diverse impact of the COVID-19 pandemic, including, among other things, fear and anxiety about health and safety, economic loss, unemployment, social isolation, disruption of established education and work practices, VistaGen submitted its preliminary protocol for the study to the FDA through the FDA's Coronavirus Treatment Acceleration Program (CTAP). Following that submission, the Company has continued its discussions with the FDA's Division of Psychiatric Products to determine the study's appropriate next steps, including the final study protocol.
    - The Company is planning to conduct the proposed Phase 2A study in New York City and enroll approximately 25 to 30 subjects suffering from adjustment disorder-provoking stressors, including, but not limited to, stressors related to the diverse impact of the COVID-19 pandemic and recent civil unrest in the U.S.
    - The AjD study is expected to initiate patient recruitment in 1Q 2021.
    - The Company is also planning for additional exploratory Phase 2A studies in postpartum anxiety, post-traumatic stress disorder, and pre-procedural anxiety (pre-MRI).
- VistaGen reported new *in vitro* electrophysiology data demonstrating that the mechanism of action of PH94B, does not involve direct activation of GABA-A receptors, in distinct contrast to the mechanism of action of benzodiazepines, which act as direct positive modulators of GABA-A receptors.
    - These studies are significant because they indicate that PH94B has no relevant benzodiazepine-like activity, confirming PH94B's potential to produce rapid-onset benzo-like, anti-anxiety effects, without the risky side effects and safety concerns of benzos.

AV-101

- VistaGen reported positive new data from the Company's second preclinical study of its oral investigational drug, AV-101, combined with probenecid, an FDA-approved drug for treatment of gout used adjunctively to increase the therapeutic benefit of numerous antibacterial, anticancer and antiviral drugs.
    - The results of this new study complement previous preclinical data demonstrating the combination's potential to substantially increase the brain concentration of AV-101's active metabolite, 7-Cl-KYN, a potent and selective full antagonist of the NMDA receptor glycine co-agonist site, thereby reducing, rather than blocking, NMDA receptor signaling.

Partnering Activity

- VistaGen received a $5 million non-dilutive upfront license payment from EverInsight Therapeutics (now AffaMed Therapeutics), the Company's strategic partner for Phase 3 development and commercialization of PH94B for anxiety-related disorders in key markets in Asia.
- Upon successful development and commercialization of PH94B in the licensed territory, VistaGen is eligible to receive up to $172 million in additional development and commercial milestone payments, plus royalties on commercial sales of PH94B.

Capital Resources

- VistaGen completed an underwritten public offering of common stock resulting in gross proceeds of $14.29 million to the Company, before underwriting discounts and commissions and offering expenses.

Financial Results for the Fiscal Quarter Ended September 30, 2020:

Net loss: Net loss attributable to common stockholders for the fiscal quarter ended September 30, 2020 decreased to approximately $3.7 million compared to $5.7 million for the fiscal quarter ended September 30, 2019. For the six-month period ending September 30, 2020, the net loss attributable to common stockholders was approximately $7.1 million, a decrease from approximately $12.2 million reported in the same period last year.

Revenue: Total revenue for the fiscal quarter ended September 30, 2020 was $334,000, representing the revenue recognition related to its agreement with EverInsight Therapeutics (now AffaMed Therapeutics), pursuant to which the Company received a non-dilutive upfront license fee payment of $5.0 million on August 3, 2020. VistaGen recognized $334,000 in sublicense revenue pursuant to this agreement in the six months ended September 30, 2020 compared to no revenue in the six months ended September 30, 2019. The Company expects to continue recognizing revenue pursuant to this payment in future periods during our fiscal year ending March 31, 2021 and thereafter.

Research and development (R&D) expense: Research and development expense decreased from $4.2 million in the quarter ended September 30, 2019 to $2.4 million for the quarter ended September 30, 2020. Research and development expense also decreased from $8.5 million to $4.1 million for the six months ended September 30, 2019 and 2020, respectively, in both cases, primarily due to the completion of the Company's Phase 2 study of AV-101 as a potential adjunctive treatment of major depressive disorder in the fourth calendar quarter of 2019. Expenses related to that study and other nonclinical activities related to AV-101 decreased by $4.8 million for the six months ended September 30, 2020 compared to similar expense in the six months ended September 30, 2019. Noncash research and development expenses, primarily stock-based compensation and depreciation in both periods, accounted for approximately $391,000 and $607,000 in the six months ended September 30, 2020 and 2019, respectively.

General and administrative (G&A) expense: General and administrative expense totaled $1.3 million for the three months ended September 30, 2020 as compared to $1.2 million for the same period in the year prior. General and administrative expense decreased to approximately $2.7 million from approximately $3.1 million for the six months ended September 30, 2020 and 2019, respectively. Noncash general and administrative expense, $804,000 in the six months ended September 30, 2020, decreased from $1,044,000 in the six months ended September 30, 2019 primarily due to decreases in stock-based compensation and the noncash components of investor and public relations expense attributable to the amortization of the fair value of equity securities granted to service providers.

Cash Position: At September 30, 2020, the Company had cash and cash equivalents of approximately $15.4 million. During the quarter ended September 30, 2020, the Company received net proceeds totaling approximately $17.5 million from (i) the $5.0 million gross non-dilutive upfront license fee payment from EverInsight Therapeutics (now AffaMed Therapeutics), and (ii) the gross proceeds of approximately $14.29 million from the sale of shares of its common stock in an underwritten public offering.

As of November 12, 2020, the Company had 73,998,057 shares of common stock outstanding.

About VistaGen

VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative medicines with 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 mechanism of action, an exceptional safety profile in all studies to date, and 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

Various statements in this release are "forward-looking statements" concerning VistaGen's future expectations, plans and prospects. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: successful development, including, but not limited to Phase 3 development, and approval of one or more of the Company's drug candidates may not be achieved in any market for any indication, and, if approved, may not be differentiated from the standard of care; the FDA and other regulatory authorities may decide that the results of one or more of the Company's development programs are not sufficient for regulatory approval; development of the Company's drug candidates may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical studies may not be repeated or observed in future studies; and other adverse events or market conditions may be encountered, at any stage of development, that negatively impact further development, including entry of competitive products or other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's drug candidates. Additional risks are more fully discussed in the section entitled "Risk Factors" in VistaGen's most recent Annual Report on Form 10-K for the year ended March 31, 2020, and in its subsequent quarterly reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

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

	September 30, 2020 (Unaudited)	March 31, 2020 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,399,500	$ 1,355,100
Prepaid expenses and other current assets	455,700	225,100
Deferred contract acquisition costs - current portion	116,900	-
Total current assets	15,972,100	1,580,200
Property and equipment, net	257,600	209,600
Right of use asset - operating lease	3,403,000	3,579,600
Deferred offering costs	268,500	355,100
Deferred contract acquisition cost - non-current portion	321,700	-
Security deposits and other assets	47,800	47,800
Total assets	$ 20,270,700	$ 5,772,300
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		

Current liabilities:		
Accounts payable	$ 1,176,400	$ 1,836,600
Accrued expenses	186,900	561,500
Current notes payable, including accrued interest	352,600	56,500
Deferred revenue - current portion	1,244,000	-
Operating lease obligation - current portion	338,500	313,400
Financing lease obligation - current portion	3,500	3,300
Total current liabilities	3,301,900	2,771,300
Non-current liabilities:		
Non-current portion of notes payable	87,300	-
Accrued dividends on Series B Preferred Stock	5,694,700	5,011,800
Deferred revenue - non-current portion	3,422,000	-
Operating lease obligation - non-current portion	3,540,900	3,715,600
Financing lease obligation - non-current portion	1,300	3,000
Total non-current liabilities	12,746,200	8,730,400
Total liabilities	16,048,100	11,501,700
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2020 and March 31, 2020:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2020 and March 31, 2020	500	500
Series B Preferred; 4,000,000 shares authorized at September 30, 2020 and March 31, 2020; 1,160,240 shares issued and outstanding at September 30, 2020 and March 31, 2020	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at September 30, 2020 and March 31, 2020; 2,318,012 shares issued and outstanding at September 30, 2020 and March 31, 2020	2,300	2,300
Common stock, $0.001 par value; 175,000,000 shares authorized at September 30, 2020 and March 31, 2020; 74,133,722 and 49,348,707 shares issued and outstanding at September 30, 2020 and March 31, 2020, respectively	74,100	49,300
Additional paid-in capital	216,444,600	200,092,800
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2020 and March 31, 2020	(3,968,100)	(3,968,100)
Accumulated deficit	(208,332,000)	(201,907,400)
Total stockholders' equity (deficit)	4,222,600	(5,729,400)
Total liabilities and stockholders' equity (deficit)	$ 20,270,700	$ 5,772,300
Note 1: Derived from audited Consolidated Balance Sheet at March 31, 2020	-	-

VISTAGEN THERAPEUTICS
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in Dollars, except share amounts)
(Unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2020	2019	2020	2019
Sublicense revenue	$ 334,000	$ -	$ 334,000	$ -
Total revenues	334,000	-	334,000	-
Operating expenses:				
Research and development	2,358,200	4,205,200	4,089,400	8,519,100
General and administrative	1,269,500	1,146,100	2,660,100	3,056,200
Total operating expenses	3,627,700	5,351,300	6,749,500	11,575,300
Loss from operations	(3,293,700)	(5,351,300)	(6,415,500)	(11,575,300)
Other income (expenses), net:				
Interest income (expense), net	(3,900)	15,400	(7,100)	31,900
Other income	-	-	600	-
Loss before income taxes	(3,297,600)	(5,335,900)	(6,422,000)	(11,543,400)
Income taxes	(200)	-	(2,600)	(2,400)
Net loss and comprehensive loss	$ (3,297,800)	$ (5,335,900)	$ (6,424,600)	$ (11,545,800)
Accrued dividends on Series B Preferred stock	(347,200)	(313,800)	(683,000)	(616,300)
Net loss attributable to common stockholders	$ (3,645,000)	$ (5,649,700)	$ (7,107,600)	$ (12,162,100)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.05)	$ (0.13)	$ (0.12)	$ (0.29)

Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	67,082,935	42,622,965	59,245,209	42,622,965

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SOURCE VistaGen Therapeutics

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