# VistaGen Therapeutics Reports Fiscal 2021 First Quarter Financial Results and Highlights CNS Pipeline and Business Progress

August 13, 2020

**Company Received Over $17.5 Million Net Proceeds from PH94B Upfront License Payment and Public Offering of Common Stock Subsequent to Quarter-end**

**Positive Meeting with the FDA Sets Key Aspects of Pivotal PH94B Phase 3 Study**

SOUTH SAN FRANCISCO, Calif., Aug. 13, 2020 /PRNewswire/ -- VistaGen Therapeutics, Inc. (Nasdaq: VTGN), a biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) disorders, today reported financial results for its fiscal 2021 first quarter ended June 30, 2020.

"We accomplished several meaningful milestones thus far this fiscal year that positively impact our clinical development programs, including our PH94B Phase 3 program in social anxiety disorder. We reached consensus with the FDA on the key aspects of the design of our pivotal Phase 3 clinical studies of PH94B for acute treatment of anxiety in adults with social anxiety disorder. This design is similar to the design of the highly statistically significant Phase 2 study of PH94B in social anxiety disorder," said Shawn Singh, Chief Executive Officer of VistaGen. "Additionally, we received the $5 million upfront license payment from our partnering arrangement with EverInsight Therapeutics for Phase 3 development and commercialization of PH94B in key markets in Asia. We also completed a successful public offering of our common stock, resulting in gross proceeds to us of $14.29 million. These accomplishments significantly strengthen our go-forward development plans. We believe now more than ever; the global society needs new, safe, fast-acting treatments for anxiety and depression and we remain committed to achieving that goal."

**Financial Highlights During and Subsequent to the Fiscal 2021 First Quarter:**

- VistaGen received a $5 million non-dilutive upfront license payment from EverInsight Therapeutics, the Company's strategic partner for Phase 3 development and commercialization of PH94B for anxiety-related disorders in multiple key markets in Asia.
- 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.

**CNS Pipeline Highlights:**

- VistaGen reached consensus with the FDA on key aspects regarding the Company's initial pivotal Phase 3 study of PH94B for acute treatment of anxiety in adults with social anxiety disorder (SAD) that, among other details, may provide significant time- and cost-efficiencies for its Phase 3 program.
    - As in the highly statistically significant (p=0.002) Phase 2 study of PH94B in SAD, VistaGen's Phase 3 study will

involve a single 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 12 to 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 patients) will be approximately 182 adult patients with SAD.
- Through the FDA's Coronavirus Treatment Acceleration Program (CTAP), VistaGen submitted its preliminary protocol and development plan for an exploratory, open-label Phase 2A study of PH94B for acute treatment of adjustment disorder with anxiety (AjDA), including, but not limited to, anxiety-provoking stressors related to the diverse impact of the COVID-19 pandemic (e.g., fear and anxiety regarding health and safety, economic loss, unemployment, social isolation, distance-learning, etc.) and civil unrest.
    - The Company is currently working closely with the FDA on plans for the Phase 2A study in AjDA, which, when study preparations are completed, will be conducted in New York City by Dr. Michael Liebowitz.

**Financial Results for the Fiscal Quarter Ended June 30, 2020:**

**Net loss:** Net loss attributable to common stockholders for the fiscal quarter ended June 30, 2020 decreased to approximately $3.5 million compared to $6.5 million for the fiscal quarter ended June 30, 2019.

**Research and development (R&D) expense:** R&D expense decreased to approximately $1.7 million from $4.3 million for the quarters ended June 30, 2020 and 2019, respectively, primarily due to the completion of our Phase 2 study of AV-101 in major depressive disorder in the fourth calendar quarter of 2019. Expenses related to that study and other AV-101 related nonclinical activities decreased by $2.5 million in the quarter ended June 30, 2020 compared to expense in the quarter ended June 30, 2019. Noncash research and development expenses, primarily stock-based compensation, and depreciation in both periods, accounted for approximately $249,000 and $416,000 in the quarters ended June 30, 2020 and 2019, respectively.

**General and administrative (G&A) expense:** G&A expense decreased to approximately $1.4 million from approximately $1.9 million for the quarters ended June 30, 2020 and 2019, respectively. Noncash G&A expense, $466,000 in the quarter ended June 30, 2020, decreased from $772,000 in the quarter ended June 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 common stock or warrants granted to service providers.

**Cash Position:** At June 30, 2020, VistaGen had cash and cash equivalents of $1.5 million, compared to $1.4 million at March 31, 2020. After June 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, Inc. pursuant our PH94B strategic collaboration agreement for development and commercialization of PH94B in key markets in Asia, and (ii) the gross proceeds of approximately $14.29 million from the sale of shares of common stock in the underwritten public offering.

As of August 13, 2020, there were 77,998,057 shares of common stock outstanding.

**About PH94B**
PH94B is a rapid-onset (within approximately 15 minutes) synthetic neurosteroid nasal spray with therapeutic potential across a broad range of anxiety-related disorders. Easily self-administered in microgram-level doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects.

VistaGen is preparing for Phase 3 clinical development of PH94B as a potential new generation fast-acting, non-sedating, non-addictive acute treatment of anxiety in adults with social anxiety disorder (SAD). The FDA has granted Fast Track designation for development of PH94B for this indication, believed to be the first such designation by the FDA for a drug candidate for SAD.

With its rapid-onset pharmacology, lack of systemic exposure and excellent safety profile in earlier studies, PH94B has potential as a novel treatment for multiple additional anxiety-related disorders. VistaGen is also preparing for exploratory Phase 2A development of PH94B for acute treatment of adjustment disorder. View more background information on SAD and a video on PH94B's mechanism of action.

**About PH10**
PH10 is an investigational 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 stand-alone treatment of major depressive disorder (MDD). Following successfully completed Phase 2A development for MDD, VistaGen is now preparing for Phase 2B clinical development of PH10 for MDD.

**About AV-101**
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 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 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 CNS indications. 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 Therapeutics, Inc.**
VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and certain CNS disorders where current treatments are believed by VistaGen to be inadequate, resulting in high unmet need. Each of VistaGen's three drug

candidates has a differentiated mechanism of action, an exceptional safety profile, and therapeutic potential in several large global 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, including the potential for successful Phase 3 development of PH94B for acute treatment of anxiety in adults with social anxiety disorder and Phase 2A development for acute treatment of adjustment disorder, as well as ongoing clinical development of PH10 for the potential treatment of MDD and AV-101 as a potential treatment in multiple CNS indications. 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: development and approval of PH94B, PH10 or AV-101 may not be achieved in any market; the FDA may decide that the results of any of the Company's clinical development programs, including its PH94B Phase 3 clinical program for acute treatment of anxiety in adult patients with SAD or any other anxiety-related disorder, are not sufficient for regulatory approval; development of PH94B, PH10 and/or AV-101 may not be successful in any indication; success in nonclinical studies or in earlier-stage clinical trials may not be repeated or observed in future studies which may not support further development or be sufficient to gain regulatory approval to market PH94B, PH10 and/or AV-101; adverse events may be encountered at any stage of development that negatively impact further development. Other risks and uncertainties include, but are not limited to, issues related to: adverse healthcare reforms and changes of laws and regulations; general industry and market conditions; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of PH94B, PH10 and/or AV-101; inadequate and/or untimely supply of PH94B, PH10 and/or AV-101 to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of PH94B, PH10 and/or AV-101, as well as those risks 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 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. In addition, 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.

Tables Follow

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

| | June 30, 2020 | March 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,545,900 | $ 1,355,100 |
| Prepaid expenses and other current assets | 633,000 | 225,100 |
| Total current assets | 2,178,900 | 1,580,200 |
| Property and equipment, net | 184,200 | 209,600 |
| Right of use asset - operating lease | 3,492,100 | 3,579,600 |
| Deferred offering costs | 263,900 | 355,100 |
| Security deposits and other assets | 47,800 | 47,800 |
| Total assets | $ 6,166,900 | $ 5,772,300 |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,307,300 | $ 1,836,600 |
| Accrued expenses | 607,800 | 561,500 |
| Current notes payable, including accrued interest | 428,900 | 56,500 |
| Operating lease obligation - current portion | 325,700 | 313,400 |
| Financing lease obligation - current portion | 3,400 | 3,300 |
| Total current liabilities | 2,673,100 | 2,771,300 |
| Non-current liabilities: | | |
| Non-current portion of notes payable | 124,700 | - |
| Accrued dividends on Series B Preferred Stock | 5,347,600 | 5,011,800 |
| Operating lease obligation - non-current portion | 3,631,100 | 3,715,600 |
| Financing lease obligation - non-current portion | 2,100 | 3,000 |
| Total non-current liabilities | 9,105,500 | 8,730,400 |
| Total liabilities | 11,778,600 | 11,501,700 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2020 and March 31, 2020: | | |
| Series A Preferred, 500,000 shares authorized, issued and outstanding at June 30, 2020 and March 31, 2020 | 500 | 500 |
| Series B Preferred; 4,000,000 shares authorized at June 30, 2020 and March 31, 2020; 1,160,240 shares issued and outstanding at June 30, 2020 and March 31, 2020 | 1,200 | 1,200 |
| Series C Preferred; 3,000,000 shares authorized at June 30, 2020 and March 31, 2020; 2,318,012 shares issued and outstanding at June 30, 2020 and March 31, 2020 | 2,300 | 2,300 |

| | | |
|---|---|---|
| Common stock, $0.001 par value; 175,000,000 shares authorized at June 30, 2020 and March 31, 2020; 55,937,472 and 49,348,707 shares issued and outstanding at June 30, 2020 and March 31, 2020, respectively | 55,900 | 49,300 |
| Additional paid-in capital | 203,330,700 | 200,092,800 |
| Treasury stock, at cost, 135,665 shares of common stock held at June 30, 2020 and March 31, 2020 | (3,968,100) | (3,968,100) |
| Accumulated deficit | (205,034,200) | (201,907,400) |
| Total stockholders' deficit | (5,611,700) | (5,729,400) |
| Total liabilities and stockholders' deficit | $ 6,166,900 | $ 5,772,300 |

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

| | Three Months Ended June 30, | |
|---|---|---|
| | **2020** | **2019** |
| Operating expenses: | | |
| Research and development | $ 1,731,200 | $ 4,313,900 |
| General and administrative | 1,390,600 | 1,910,100 |
| Total operating expenses | 3,121,800 | 6,224,000 |
| Loss from operations | (3,121,800) | (6,224,000) |
| Other income (expenses), net: | | |
| Interest income (expense), net | (3,200) | 16,500 |
| Other income | 600 | - |
| Loss before income taxes | (3,124,400) | (6,207,500) |
| Income taxes | (2,400) | (2,400) |
| Net loss and comprehensive loss | $ (3,126,800) | $ (6,209,900) |
| Accrued dividends on Series B Preferred stock | (335,800) | (302,500) |
| Net loss attributable to common stockholders | $ (3,462,600) | $ (6,512,400) |
| Basic and diluted net loss attributable to common stockholders per common share | $ (0.07) | $ (0.15) |
| Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share | 51,321,355 | 42,622,965 |

View original content to download multimedia:http://www.prnewswire.com/news-releases/vistagen-therapeutics-reports-fiscal-2021-first-quarter-financial-results-and-highlights-cns-pipeline-and-business-progress-301112190.html

SOURCE VistaGen Therapeutics

Released August 13, 2020