



VistaGen Therapeutics Reports Fiscal Year 2020 Results and Provides CNS Pipeline Update

June 29, 2020

VistaGen Eligible to Receive up to \$177 Million, Including Upfront and Potential Milestone Payments, in Addition to Royalties, under PH94B License in Key Asian Markets Announced Subsequent to Fiscal 2020 Year End

SOUTH SAN FRANCISCO, Calif., June 29, 2020 /PRNewswire/ -- [VistaGen Therapeutics](#) (NASDAQ: VTGN), a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and other central nervous system (CNS) diseases and disorders with high unmet need, today reported financial results for its fiscal year ended March 31, 2020.



VistaGen®

Therapeutics

"As these unprecedented times persist, with the chaotic implementation of public safety measures and the civil unrest in the fight for social justice, we continue to live in a world filled with heightened uncertainty and unfamiliarity. The spike in the number of individuals experiencing anxiety and depression is unparalleled and it appears the upward trajectory will continue. While innovative means of providing mental health support have been initiated, many needs are still not being met," stated [Shawn Singh, Chief Executive Officer of VistaGen](#).

Singh continued, "VistaGen is uniquely positioned to develop a robust investigational pipeline of novel treatments for millions of people globally today and for generations to come who are unfortunately suffering due to this heightened mental health pandemic. We have continued to make progress across our CNS pipeline, notably, with PH94B, our first-in-class, rapid-onset neuroactive nasal spray for social anxiety disorder, having recently announced a strategic collaboration with EverInsight for up to \$177 million in upfront and potential milestone payments to develop and commercialize PH94B in key Asian markets. This partnership further highlights the value of this asset, which has global market potential as a rapid-onset and safe, acute anxiety therapy, and provides our company with additional working capital to continue the significant progress we have made in preparation for our Phase 3 program in parallel with emphasis on additional strategic collaborations for development and commercialization of our pipeline in key regional markets outside the U.S."

VistaGen's CNS Pipeline:

VistaGen is developing three differentiated, patent-protected, CNS product candidates for large global markets where current treatments are inadequate to address rising mental health challenges worldwide, as well as need for non-addictive, non-sedating relief from pain, unwanted movement disorders and other neurological conditions besetting increasing numbers of individuals worldwide. VistaGen's CNS product candidates in development are as follows:

PH94B Neuroactive Nasal Spray

PH94B is a first-in-class neuroactive nasal spray with therapeutic potential in a wide range of indications involving anxiety or phobia. Self-administered in microgram doses, PH94B does not require systemic uptake and distribution to produce its rapid-onset anti-anxiety effects and, therefore, has an excellent safety profile.

Strategic Partnership with EverInsight Therapeutics for up to \$177 Million in Upfront and Potential Milestone Payments, in Addition to Royalties

- VistaGen and EverInsight Therapeutics, a company currently funded by the CBC Group (formerly C-Bridge Capital), one of

the largest and most active healthcare-dedicated investment firms in Asia, entered into a strategic partnership for Phase 3 clinical development and commercialization of PH94B, initially for acute treatment of SAD, in multiple key anxiety markets in Asia.

- VistaGen is eligible to receive up to \$177M, including a \$5 million upfront payment and up to \$172 million in potential milestone payments, if Phase 3 development efforts are successful, in addition to royalties.

Social Anxiety Disorder (SAD)

- FDA granted VistaGen Fast Track designation for development of PH94B for on-demand treatment of SAD, the first such designation granted by the FDA for development of a drug candidate for SAD. The Company is currently in final-stage discussions with the FDA regarding key details of its plan for Phase 3 clinical development of PH94B for SAD in the U.S., with the initial objective of developing PH94B as the first FDA-approved on-demand, rapid-onset acute treatment of SAD.
 - Michael Liebowitz, M.D., 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 serve as Principal Investigator of the Company's Phase 3 clinical studies.

Adjustment Disorder with Anxiety related to the COVID-19 Pandemic

- Through the FDA's new Coronavirus Treatment Acceleration Program (CTAP), VistaGen submitted a protocol and development plan for an exploratory open-label Phase 2A study of PH94B for treatment of adjustment disorder with anxiety (AjDA) related to the COVID-19 pandemic.
 - Phase 2A study in AjDA to be conducted in New York City, with Dr. Michael Liebowitz, M.D., serving as Principal Investigator.

Based on its rapid-onset pharmacology, microgram-level dosing, lack of systemic exposure, excellent safety profile and the rapidly rising incidence of anxiety disorders, the Company is also assessing potential exploratory Phase 2A studies of PH94B for treatment of postpartum anxiety, post-traumatic stress disorder (PTSD), preoperative anxiety, and panic disorder.

PH10 Neuroactive Nasal Spray

Major Depressive Disorder (MDD)

PH10 is an odorless, fast-acting synthetic neurosteroid delivered intranasally that has therapeutic potential in a wide range of neuropsychiatric indications involving depression. Self-administered in microgram doses, PH10 does not require systemic uptake and distribution to produce its antidepressant effects. The Company is initially developing PH10 as a potential fast-acting, non-sedating, non-addictive stand-alone treatment of MDD.

- Positive results of exploratory double-blind, randomized, placebo-controlled Phase 2A clinical study of PH10 for treatment of MDD were newly published in peer-reviewed [British Journal of Pharmaceutical and Medical Research](#).
- Following successfully completed Phase 2A development for MDD, the Company is preparing for planned Phase 2B clinical development of PH10 in the U.S. for MDD.
 - Maurizio Fava, M.D., Director of the Clinical Research Program and Executive Vice Chair of the Department of Psychiatry at Massachusetts General Hospital, and Slater Family Professor of Psychiatry at Harvard Medical School, will be the Principal Investigator of the planned Phase 2B study.
- U.S. Patent and Trademark Office (USPTO) granted [U.S. Patent No. 10,322,138](#) related to methods of treating MDD with PH10. Newly granted patent will not expire until at least 2034. Counterpart foreign patents have already been issued in China, Europe, Japan and several other countries.

Considering its rapid-onset pharmacology, microgram-level dosing, lack of systemic exposure, excellent safety profile and the rapidly rising incidence of depression-related disorders, the Company is also assessing potential exploratory Phase 2A studies of PH10 for treatment of postpartum depression, treatment-resistant depression and suicidal ideation.

AV-101

AV-101 is a novel, oral prodrug that targets the NMDAR (N-methyl-D-aspartate receptor). Abnormal NMDAR function is associated with numerous CNS diseases and disorders. AV-101's active metabolite, 7-chloro-kynurenic acid (7-CI-KYNA), is a potent and selective full antagonist of the glycine coagonist site of the NMDAR. Unlike ketamine and other NMDAR antagonists, 7-CI-KYNA is not an ion channel blocker. VistaGen is currently assessing AV-101's potential in combination with probenecid, a safe and well-known oral drug used to treat gout and to increase the therapeutic benefit of numerous antibacterial, anticancer and antiviral drugs, to treat MDD, neuropathic pain, dyskinesia associated with levodopa therapy for Parkinson's disease, epilepsy and suicidal ideation.

- VistaGen reported new positive preclinical data of AV-101 administered with probenecid, demonstrating substantially increased brain concentration effects of AV-101 (7-fold) and its active metabolite, 7-CI-KYNA (35-fold).
- 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
- VistaGen and Nuformix entered strategic agreement to develop novel crystalline forms of AV-101 that may have superior delivery, an enhanced therapeutic profile and additional intellectual property protection.

- The Company reported positive results of preclinical study of AV-101 in widely-used MPTP non-human primate model for reproducing unwanted movement complications of Parkinson's disease (PD). Antidyskinetic activity of AV-101 measured compared favorably with observations with amantadine in parkinsonian monkeys. Better than amantadine, with its known side effects (in humans with PD and in parkinsonian monkeys), no adverse effects with AV-101 were observed. This study supports AV-101's potential to treat dyskinesia associated with levodopa therapy for PD, while maintaining the antiparkinsonian benefits of levodopa therapy and without causing hallucinations or other serious side effects that may be associated with amantadine therapy.
- USPTO issued 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. Patent, once issued, will be in effect until at least 2034.
- FDA authorized Investigational New Drug (IND) application for AV-101 as a potential new treatment of dyskinesia in individuals with PD receiving levodopa therapy.
- The Company announced positive results of preclinical study examining AV-101's analgesic and behavioral profile compared to pregabalin in accepted "gold standard" preclinical model for chronic neuropathic pain caused by nerve damage. AV-101, which does not bind to opioid receptors, demonstrated robust analgesic effects, similar to pregabalin, but with fewer side effects as measured in the rotarod assay, providing complementary support to an earlier preclinical study involving gabapentin, of AV-101's potential to treat debilitating neuropathic pain, without causing the burdensome side effects and safety concerns associated with the medications currently used by millions to treat neuropathic pain, such as risk of abuse, drowsiness, dizziness and sedation.
- Successful results from AV-101 first-step, Phase 1B clinical study with healthy U.S. military Veterans conducted by Baylor University measured NMDAR target engagement of AV-101, supporting potential, with probenecid, for next step AV-101 exploratory Phase 2A study for treatment of suicidal ideation in Veterans.
- Successful Baylor Study and the recent preclinical studies involving AV-101 and adjunctive probenecid suggest AV-101's potential in NMDAR-focused CNS indications for which Company has positive AV-101 preclinical data without probenecid (depression, epilepsy, levodopa-induced dyskinesia and neuropathic pain). Company conducting additional preclinical studies of AV-101 with probenecid to determine most appropriate next-steps to support exploratory Phase 2A clinical studies.

Financial Results for the Fiscal Year Ended March 31, 2020:

Research and development (R&D) expense: R&D expense decreased to \$13.4 million for fiscal 2020, compared with \$17.1 million in fiscal 2019. In fiscal 2019, our acquisition of the PH94B and PH10 licenses through the issuance of our common stock, resulted in an aggregate of \$4.25 million of noncash expense and primarily accounts for the decrease. Other noncash expenses included in research and development expense (excluding the PH94B and PH10 license acquisitions in fiscal 2019), primarily stock compensation and lab equipment depreciation, accounted for approximately \$1.4 million in both fiscal 2020 and fiscal 2019.

General and administrative (G&A) expense: G&A expense totaled \$7.4 million in fiscal 2020 compared to \$7.5 million in fiscal 2019. Increased noncash stock compensation and warrant modification expenses were generally offset by decreases in cash-based salaries and benefits and investor and public relations expenses. Noncash general and administrative expense accounted for approximately \$3,543,000 and \$2,622,000 in fiscal 2020 and fiscal 2019, respectively.

Net loss: Net loss attributable to common stockholders for the fiscal year ended March 31, 2020 decreased to approximately \$22.0 million compared to \$25.7 million for the fiscal year ended March 31, 2019, the decrease resulting primarily from the \$4.25 million noncash expense associated with the stock-based acquisition of the licenses to develop and commercialize PH94B and PH10 in fiscal 2019.

Cash: At March 31, 2020, VistaGen had cash and cash equivalents of \$1.4 million. Subsequent to March 31, 2020, the Company received proceeds of approximately \$3.0 million, including proceeds of approximately \$2.8 million from equity sales and approximately \$200,000 from a potentially forgivable loan under the Paycheck Protection Act. In addition, in June 2020, the Company entered into a strategic licensing and collaboration agreement with EverInsight for the development and commercialization of PH94B for anxiety disorders in multiple key Asian markets. Under the agreement, VistaGen is eligible to receive up to \$177 million in upfront and potential milestone payments, in addition to royalties, including a \$5 million upfront payment.

Shares outstanding: As of June 29, 2020, there were 55,773,682 shares of the Company's common stock outstanding.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for anxiety, depression and certain CNS diseases and disorders where current treatments are inadequate, resulting in high unmet need. VistaGen's [pipeline](#) is focused on three clinical-stage CNS drug candidates, PH94B, PH10 and AV-101, each 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 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, 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, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in dollars, except share amounts)

	March 31, 2020	March 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,355,100	\$ 13,100,300
Receivable from supplier	-	300,000
Prepaid expenses and other current assets	<u>225,100</u>	<u>228,600</u>
Total current assets	1,580,200	13,628,900
Property and equipment, net	209,600	312,700
Right of use asset - operating lease	3,579,600	-
Deferred offering costs	355,100	22,300
Security deposits and other assets	<u>47,800</u>	<u>47,800</u>
Total assets	<u>\$ 5,772,300</u>	<u>\$ 14,011,700</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 1,836,600	\$ 1,055,000
Accrued expenses	561,500	1,685,600
Current note payable	56,500	57,300
Operating lease obligation - current portion	313,400	-
Financing lease obligation - current portion	<u>3,300</u>	<u>3,000</u>
Total current liabilities	<u>2,771,300</u>	<u>2,800,900</u>
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	5,011,800	3,748,200
Deferred rent liability	-	381,100
Operating lease obligation - non-current portion	3,715,600	-
Financing lease obligation - non-current portion	<u>3,000</u>	<u>6,300</u>
Total non-current liabilities	<u>8,730,400</u>	<u>4,135,600</u>
Total liabilities	<u>11,501,700</u>	<u>6,936,500</u>
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2020 and 2019:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at March 31, 2020 and 2019	500	500
Series B Preferred; 4,000,000 shares authorized at March 31, 2020 and 2019; 1,160,240 shares issued and outstanding at March 31, 2020 and 2019	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at March 31, 2020 and 2019; 2,318,012 shares issued and outstanding at March 31, 2020 and 2019	2,300	2,300
Common stock, \$0.001 par value; 175,000,000 and 100,000,000 shares authorized at March 31, 2020 and 2019, respectively; 49,348,707 and 42,758,630 shares issued and outstanding at March 31, 2020 and 2019, respectively	49,300	42,800
Additional paid-in capital	200,092,800	192,129,900
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2020 and 2019	(3,968,100)	(3,968,100)
Accumulated deficit	<u>(201,907,400)</u>	<u>(181,133,400)</u>
Total stockholders' equity (deficit)	<u>(5,729,400)</u>	<u>7,075,200</u>

Total liabilities and stockholders' equity (deficit)

\$ 5,772,300

\$ 14,011,700

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

	Fiscal Years Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 13,374,200	\$ 17,098,500
General and administrative	<u>7,427,300</u>	<u>7,457,800</u>
Total operating expenses	<u>20,801,500</u>	<u>24,556,300</u>
Loss from operations	(20,801,500)	(24,556,300)
Other income (expenses), net:		
Interest income (expense), net	30,100	(8,000)
Loss on extinguishment of debt	=	<u>(22,700)</u>
Loss before income taxes	(20,771,400)	(24,587,000)
Income taxes	<u>(2,600)</u>	<u>(2,600)</u>
Net loss and comprehensive loss	\$ (20,774,000)	\$ (24,589,600)
Accrued dividend on Series B Preferred stock	<u>(1,263,600)</u>	<u>(1,139,900)</u>
Net loss attributable to common stockholders	<u>\$ (22,037,600)</u>	<u>\$ (25,729,500)</u>
Basic and diluted net loss attributable to common stockholders per common share	<u>\$ (0.50)</u>	<u>\$ (0.90)</u>
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	<u>43,869,523</u>	<u>28,562,490</u>

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Released June 29, 2020