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VistaGen Therapeutics Reports Fiscal Year 2019 Results and Provides CNS Pipeline Overview

SOUTH SAN FRANCISCO, CA / ACCESSWIRE / June 25, 2019/ 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 reported financial results for its fiscal year ended March 31, 2019 and provided an overview of operational highlights on its CNS pipeline.

"We are excited about our progress and recent developments involving AV-101, our novel, oral NMDA receptor glycine site antagonist. VistaGen is on track to reach target enrollment in ELEVATE, our Phase 2 study of AV-101 as a new generation treatment of major depressive disorder, during next quarter, with topline results expected in the second half of 2019. In addition, we are delighted with recently reported preclinical data supporting AV-101's potential in two additional large CNS markets with high unmet need, neuropathic pain and levodopa-induced dyskinesia affecting individuals with Parkinson's disease," said Shawn Singh, Chief Executive Officer of VistaGen

"We are also pleased with FDA feedback regarding our plans for pivotal Phase 3 development of PH94B, our novel, rapid-acting neuroactive nasal spray for treatment of social anxiety disorder. With the growing misuse of benzodiazepines already at epidemic levels, we are very optimistic about PH94B's potential to transform the treatment paradigm for social anxiety disorder and reduce significantly or, ideally, eliminate current off-label use and misuse of benzodiazepines to treat this widespread and debilitating disorder. In addition, we believe successful Phase 2a study results support the potential of PH94B as a new treatment for generalized anxiety disorder and PH10, our second novel, rapid-acting, neuroactive nasal spray, as a novel first-line treatment for major depressive disorder. The multiple late-stage opportunities for VistaGen's pipeline to address large CNS market needs are robust, and we look forward to keeping our shareholders informed of our continued progress," added Mr. Singh.

CNS Pipeline Update:

VistaGen's CNS investigational pipeline currently contains three late-stage (in Phase 2 or entering Phase 3) product candidates, AV-101, PH94B, and PH10.

- **AV-101 (4-Cl-KYN):** One of VistaGen's two CNS product candidates in Phase 2 clinical development for major depressive disorder MDD belongs to a new generation

of investigational medicines in neuropsychiatry and neurology known as NMDA (N-methyl-D-aspartate) glutamate receptor modulators. The NMDA receptor is a pivotal receptor in the brain and abnormal NMDA function is associated with multiple CNS diseases and disorders, including MDD, neuropathic pain (NP), epilepsy, and levodopa-induced dyskinesia (LID) in patients with Parkinson's disease (PD). AV-101 is a novel, oral prodrug of 7-chlorokynurenic acid (7-Cl-KYNA), a potent and selective full antagonist of the glycine site of the NMDA receptor, although it does not block the ion channel of the NMDA receptor. Instead, 7-Cl-KYNA is an allosteric antagonist and down-regulates the NMDA receptor which, in part, accounts for AV-101's exceptional safety profile and lack of psychological side effects and safety concerns compared to classic ion-channel blocking NMDA receptor antagonists such as ketamine. AV-101 has potential to be a new generation, oral, at-home treatment for MDD and several other CNS diseases and disorders.

    - **AV-101 for MDD, the ELEVATE Study**: VistaGen's ELEVATE study is a Phase 2 multi-center, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of AV-101 as an add-on treatment (together with an FDA-approved oral antidepressant (AD)) for adult MDD patients with an inadequate therapeutic response to their current AD. VistaGen is also planning a Phase 2a study of AV-101 as an add-on treatment (together with standard ADs) to prevent relapse of MDD following successful ketamine-based therapy. The FDA has granted Fast Track designation for development of AV-101 as a potential add-on treatment of MDD.

    - **AV-101 for Suicidal Ideation, the Baylor/VA Study:** VistaGen is collaborating with Baylor College of Medicine (Baylor) and the U.S. Department of Veterans Affairs (VA) on a small Phase 1b clinical trial of AV-101 in healthy volunteer U.S. military veterans. The Baylor/VA study is a randomized, double-blind, placebo-controlled crossover study designed as a first-step in VistaGen's plans to test potential anti-suicidal effects of AV-101 in U.S. military veterans who respond to ketamine-based therapy. Government funding from the VA is being provided for substantially all study costs.

    - **AV-101 for NP and LID**: VistaGen is planning exploratory Phase 2a studies to assess the efficacy and safety of AV-101 for treatment of chronic NP and LID affecting PD patients.

        - **NP**: In a recently reported preclinical study examining AV-101's analgesic and behavioral profile compared to pregabalin (Lyrica®), AV-101 demonstrated robust analgesic effects, similar to pregabalin, but fewer side effects as measured in the rotarod assay. The FDA has granted Fast Track designation for development of AV-101 as a non-opioid treatment for NP.

        - **LID**: In a recently reported preclinical study in the "gold standard" MPTP monkey model of LID, AV-101 significantly ($p = 0.01$) reduced LID, without affecting the timing, extent or duration of the therapeutic benefits of levodopa therapy for PD, and without adverse events associated with amantadine therapy for LID.

- **PH94B:** VistaGen's PH94B neuroactive nasal spray is fundamentally different from all

current treatments for social anxiety disorder SAD and generalized anxiety disorder (GAD). Administered at microgram doses as an odorless, rapid-onset (10 to 15 minutes) nasal spray, 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.

  - **PH94B for SAD, Published Phase 2 Clinical Trial:** In a 91-patient published, peer-reviewed, randomized, double-blind, placebo-controlled Phase 2 clinical trial, which included both laboratory-based public speaking and social situation challenges, PH94B significantly improved the primary efficacy endpoint, as assessed using the Subjective Units of Distress (SUDS) scale, within 10 to 15 minutes of self-administration. It was not observed to be addictive, sedative or have other adverse events. VistaGen believes that PH94B neuroactive nasal spray is a novel product candidate with potential to become the first FDA-approved on-demand, as-needed treatment for SAD.

  - **PH94B for SAD, Pilot Phase 3 Crossover Study:** In a 22-patient, four-week, randomized, double blind, placebo-controlled pilot Phase 3 crossover study, subjects receiving PH94B had a significantly greater decrease in average peak SUDS scores compared to placebo within one week of treatment. There was also a significantly greater decrease in the Liebowitz Social Anxiety Scale avoidance scores for subjects who received PH94B first, before crossing over to placebo. The data were presented in a poster session at Anxiety and Depression Association of America's 2019 Annual Conference.

  - **PH94B for GAD, Phase 2a Study**: PH94B demonstrated efficacy in an exploratory placebo-controlled Phase 2a study in patients with GAD. Twenty-one patients were randomized to receive PH94B or placebo. Thirty minutes after treatment there was mean reduction of 32.0% for the PH94B group and 19.6% for the placebo group in the total Hamilton Anxiety Rating Scale (HAM-A) score. Electrophysiological changes (respiratory, cardiac, and electrodermal frequency), concordant with the reduction in anxiety, were significantly greater for the PH94B group. We believe these transient anti-anxiety effects of PH94B may warrant further investigation in a Phase 2b GAD trial.

- **PH10 for MDD:** VistaGen's second product candidate for MDD in Phase 2 development is PH10 a novel, rapid-acting CNS neuroactive nasal spray administered in microgram doses. PH10 nasal spray activates nasal chemosensory receptors that, in turn, engage GABA (gamma-aminobutyric acid) and CRH (corticotropin-releasing hormone) neurons in the limbic amygdala system. The activation of these neural circuits is believed to have the potential to lead to rapid antidepressant effects without psychological side effects, systemic exposure or safety concerns often associated with current ADs and ketamine-based therapy.

  - **PH10 for MDD, Phase 2a Study:** In an exploratory 30-patient Phase 2a clinical study, PH10 was well-tolerated and, at microgram doses, demonstrated rapid-onset antidepressant effects, as measured by the Hamilton Depression Rating Scale (HAM-D), without psychological side effects or safety concerns. VistaGen is planning Phase 2b clinical development of PH10 as a first-line treatment for MDD.

Upcoming Clinical Milestones:

- Complete patient enrollment and obtain topline results from the ELEVATE study in the second half of 2019.
- Complete patient enrollment and obtain top line results from the Phase 1b Baylor/VA Study in the second half of 2019.
- Advance preparations for pivotal Phase 3 clinical development of PH94B for treatment of SAD, to begin first half 2020.

Fiscal Year Ended March 31, 2019 Financial Highlights:

Net loss attributable to common stockholders for the fiscal year ended March 31, 2019 was $25.7 million compared to $15.6 million for the fiscal year ended March 31, 2018. Net loss in fiscal 2019 included aggregate noncash expense of approximately $8.2 million, including $4.25 million for the acquisition of exclusive worldwide licenses to develop and commercialize our two novel, late-stage, neuroactive nasal spray product candidates, PH94B and PH10, through the issuance of unregistered shares of VistaGen's common stock.

Research and development expense totaled approximately $17.1 million in fiscal 2019, compared with approximately $7.8 million in fiscal 2018. The increase in fiscal 2019 is primarily attributable to (i) expense related to conducting the ELEVATE study throughout fiscal 2019, (ii) noncash expense of $4.25 million related to acquisition of our licenses to PH94B and PH10 through the issuance of unregistered shares of VistaGen common stock, and (iii) nonclinical activities, including manufacturing expense associated with the production of AV-101 for preclinical and clinical studies.

General and administrative expense was approximately $7.5 million in fiscal 2019, compared to approximately $6.4 million in fiscal 2018, primarily as a result of increased noncash stock-based compensation expense in fiscal 2019.

At March 31, 2019, VistaGen had cash and cash equivalents of approximately $13.1 million.

As of June 24, 2019, there were 42,622,965 shares of common stock outstanding.

About VistaGen

VistaGen Therapeutics is a clinical-stage biopharmaceutical company developing new generation medicines for CNS diseases and disorders with high unmet need. VistaGen's pipeline includes three CNS drug candidates, AV-101, PH10 and PH94B. 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 drug candidates, including AV-101 for MDD, NP, LID and suicidal ideation, PH94B for SAD, and PH10 for MDD, as well as our intellectual property and

commercial protection of our drug candidates, all of which 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, 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.

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VISTAGEN THERAPEUTICS
Consolidated Balance Sheets

(Amounts in dollars, except share amounts)

	March 31, 2019	March 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,100,300	$ 10,378,300
Receivable from supplier	300,000	-
Prepaid expenses and other current assets	250,900	644,800
Total current assets	13,651,200	11,023,100
Property and equipment, net	312,700	207,400
Security deposits and other assets	47,800	47,800
Total assets	$ 14,011,700	$ 11,278,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,055,000	$ 1,195,700
Accrued expenses	1,685,600	206,300
Current notes payable	57,300	53,900
Capital lease obligations	3,000	2,600
Total current liabilities	2,800,900	1,458,500
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	3,748,200	2,608,300
Deferred rent liability	381,100	285,600
Capital lease obligations	6,300	9,300
Total non-current liabilities	4,135,600	2,903,200
Total liabilities	6,936,500	4,361,700
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2019 and 2018:		
Series A Preferred, 500,000 shares authorized, issued and outstanding at March 31, 2019 and 2018	500	500
Series B Preferred; 4,000,000 shares authorized at March 31, 2019 and 2018; 1,160,240 shares issued and outstanding at March 31, 2019 and 2018	1,200	1,200
Series C Preferred; 3,000,000 shares authorized at March 31, 2019 and 2018; 2,318,012 shares issued and outstanding at March 31, 2019 and 2018	2,300	2,300
Common stock, $0.001 par value; 100,000,000 shares authorized at March 31, 2019 and 2018; 42,758,630and 23,068,280 shares issued and outstanding at March 31, 2019 and March 31, 2018, respectively	42,800	23,100
Additional paid-in capital	192,129,900	167,401,400
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2019 and 2018	(3,968,100)	(3,968,100)

Accumulated deficit	(181,133,400)	(156,543,800)
Total stockholders' equity	7,075,200	6,916,600
Total liabilities and stockholders' equity	$ 14,011,700	$ 11,278,300

VISTAGEN THERAPEUTICS
STATEMENT OF OPERATIONS
Amounts in Dollars, except share amounts

	Fiscal Years Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 17,098,500	$ 7,762,500
General and administrative	7,457,800	6,437,100
Total operating expenses	24,556,300	14,199,600
Loss from operations	(24,556,300)	(14,199,600)
Other expenses, net:		
Interest expense, net	(8,000)	(8,900)
Loss on extinguishment of accounts payable	(22,700)	(135,000)
Loss before income taxes	(24,587,000)	(14,343,500)
Income taxes	(2,600)	(2,400)
Net loss and comprehensive loss	(24,589,600)	(14,345,900)
Accrued dividend on Series B Preferred stock	(1,139,900)	(1,030,400)
Deemed dividend from trigger of down round provision feature	-	(199,200)
Net loss attributable to common stockholders	$(25,729,500)	$(15,575,500)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.90)	$ (1.12)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	28,562,490	13,890,041

SOURCE: VistaGen Therapeutics

View source version on accesswire.com:
https://www.accesswire.com/549848/VistaGen-Therapeutics-Reports-Fiscal-Year-2019-Results-and-Provides-CNS-Pipeline-Overview