# VistaGen Therapeutics Reports Fiscal 2019 Second Quarter Financial Results

October 29, 2018

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2018 (GLOBE NEWSWIRE) -- VistaGen Therapeutics, Inc. (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 2019 second quarter ended September 30, 2018.

“During the quarter, we continued to focus our resources on AV-101 development, especially advancement of ELEVATE, our Phase 2 adjunctive treatment study for major depressive disorder, and Phase 3-enabling nonclinical and regulatory activities. ELEVATE is well underway, and we remain confident in our target to deliver topline results in mid-2019,” said Shawn Singh, Chief Executive Officer of VistaGen.

“In addition to advancing our core AV-101 development programs, we also recently enhanced our pipeline with two complementary assets aimed at the treatment of CNS disorders with high unmet need. We signed exclusive license agreements to develop and commercialize these potential first-in-class, intranasally administered, new drug candidates, PH94B for social anxiety disorder and PH10 for major depressive disorder. We believe adding these two potential rapid-onset neuroactive steroid treatments, together with AV-101, which is focused on achieving rapid-onset antidepressant effects through NMDA and AMPA receptors, adds significant pipeline strength and gives us the potential to provide patients with a broad range of potential new generation solutions to treat depression and other CNS disorders with serious unmet need, with the goal of eliminating psychological side effects and safety concerns often associated with current therapies,” concluded Mr. Singh.

***Operational Highlights:***

*Continued Advancements in the Clinical Development of AV-101*

- In connection with our initial collaboration with the U.S. Department of Veteran’s Affairs (VA) and Baylor University (Baylor), Baylor commenced a randomized, double-blind, first-step, cross-over study in healthy volunteer U.S. Military Veterans to define a dose-response relationship between AV-101 and relevant biomarkers related to NMDA function believed to be associated with suicidal ideation. The results of this initial study could lead to a Phase 2 study involving AV-101 and U.S. Military Veterans who are battling suicidal thoughts or behaviors.

- We received FDA Fast Track Designation (FTD) for development of AV-101 as a non-opioid treatment for neuropathic pain, without sedative or psychological side effects. Together with our FTD for development of AV-101 for major depressive disorder (MDD), this is the second FTD we have received from the FDA for AV-101 since December 2017, marking another milestone for our regulatory team.

*License Agreements to Acquire Two First-in-Class CNS Drug Candidates*

- Acquired a license for exclusive worldwide rights to develop and commercialize PH94B, a pivotal Phase 3-ready drug candidate with potential to be the first FDA-approved acute on-demand medication for social anxiety disorder (SAD), a widespread social phobia which, according to the Anxiety and Depression Association of America, affects as many as 15 million American adults.

- Acquired a license for exclusive worldwide rights to develop and commercialize PH10, a potential first-in-class, intranasally administered neuroactive steroid with rapid-onset antidepressant effects for MDD as demonstrated in a Phase 2a study. We believe PH10 is likely to have rapid-onset antidepressant effects within hours, not days or weeks, similar to ketamine-based drug candidates, but potentially without the psychological side effects, safety issues or required in-clinic administration.

***Financial Results for the Fiscal Quarter Ended September 30, 2018:***

Net loss attributable to common stockholders for the fiscal quarter ended September 30, 2018 was approximately $7.7 million, compared to $5.3 million for the fiscal quarter ended September 30, 2017, primarily attributable to increased research and development activities relating to the Company’s AV-101 programs and noncash expense of $2.25 million to acquire the exclusive license to PH94B and exclusive option to license PH10.

Research and development expense totaled approximately $5.3 million for the fiscal quarter ended September 30, 2018, compared with approximately $2.4 million for the fiscal quarter ended September 30, 2017. The increase is primarily attributable to expenses related to conducting ELEVATE and AV-101 Phase 3-enabling nonclinical and regulatory activities, including manufacturing process improvements and production of additional quantities of AV-101 drug substance, coupled with the acquisition of the exclusive license to PH94B and the exclusive option to licensePH10 through the issuance of our common stock, which acquisitions resulted in $2.25 million of noncash expense.

General and administrative expense was approximately $2.2 million in the fiscal quarter ended September 30, 2018, compared to approximately $2.6 million in the fiscal quarter ended September 30, 2017.

At September 30, 2018, the Company had cash and cash equivalents of approximately $7.8 million, compared to approximately $10.4 million at March 31, 2018. Since September 30, 2018, as a result of self-placed private placement transactions of unregistered securities to accredited investors and exercises of outstanding warrants, the Company has received aggregate cash proceeds of approximately $2.4 million.

**About VistaGen**
VistaGen Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing new generation medicines for multiple CNS diseases and disorders with high unmet need. 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, neuropathic pain 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. Among these risks is the possibility that (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, and subsequent quarterly reports on Form 10-Q, 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, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(Amounts in dollars, except share amounts)**

| | September 30, 2018 (Unaudited) | March 31, 2018 (Note 2) |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,831,600 | $ 10,378,300 |
| Prepaid expenses and other current assets | 648,000 | 644,800 |
| Total current assets | 8,479,600 | 11,023,100 |
| Property and equipment, net | 361,800 | 207,400 |
| Security deposits and other assets | 47,800 | 47,800 |

| | | |
|---|---|---|
| Total assets | $ 8,889,200 | $ 11,278,300 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 590,100 | $ 1,195,700 |
| Accrued expenses | 599,700 | 206,300 |
| Current notes payable | 115,600 | 53,900 |
| Capital lease obligations | 2,800 | 2,600 |
| Total current liabilities | 1,308,200 | 1,458,500 |
| Non-current liabilities: | | |
| Accrued dividends on Series B Preferred Stock | 3,165,400 | 2,608,300 |
| Deferred rent liability | 418,500 | 285,600 |
| Capital lease obligations | 7,900 | 9,300 |
| Total non-current liabilities | 3,591,800 | 2,903,200 |
| Total liabilities | 4,900,000 | 4,361,700 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2018 and March 31, 2018: | | |
| Series A Preferred, 500,000 shares authorized, issued and outstanding at September 30, 2018 and March 31, 2018 | 500 | 500 |
| Series B Preferred; 4,000,000 shares authorized at September 30, 2018 and March 31, 2018; 1,160,240 shares issued and outstanding at September 30, 2018 and March 31, 2018 | 1,200 | 1,200 |
| Series C Preferred; 3,000,000 shares authorized at September 30, 2018 and March 31, 2018; 2,318,012 shares issued and outstanding at September 30, 2018 and March 31, 2018 | 2,300 | 2,300 |
| Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2018 and March 31, 2018; 28,676,715 and 23,068,280 shares issued and outstanding at September 30, 2018 and March 31, 2018, respectively | 28,700 | 23,100 |
| Additional paid-in capital | 176,117,900 | 167,401,400 |
| Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2018 and March 31, 2018 | (3,968,100) | (3,968,100) |
| Accumulated deficit | (168,193,300) | (156,543,800) |
| Total stockholders' equity | 3,989,200 | 6,916,600 |
| Total liabilities and stockholders' equity | $ 8,889,200 | $ 11,278,300 |

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(Unaudited)**
**(Amounts in dollars, except share amounts)**

| | Quarters Ended September 30, | | Six Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Operating expenses: | | | | |
| Research and development | $ 5,261,100 | $ 2,426,600 | $ 8,004,800 | $ 3,522,800 |
| General and administrative | 2,171,000 | 2,567,100 | 3,637,300 | 3,731,400 |
| Total operating expenses | 7,432,100 | 4,993,700 | 11,642,100 | 7,254,200 |
| Loss from operations | (7,432,100) | (4,993,700) | (11,642,100) | (7,254,200) |
| Other expenses, net: | | | | |
| Interest expense, net | (2,900) | (3,300) | (5,000) | (5,700) |
| Loss before income taxes | (7,435,000) | (4,997,000) | (11,647,100) | (7,259,900) |
| Income taxes | - | - | (2,400) | (2,400) |
| Net loss and comprehensive loss | (7,435,000) | (4,997,000) | (11,649,500) | (7,262,300) |
| Accrued dividend on Series B Preferred stock | (283,600) | (256,300) | (557,100) | (503,600) |
| Net loss attributable to common stockholders | $ (7,718,600) | $ (5,253,300) | $ (12,206,600) | $ (7,765,900) |
| Basic and diluted net loss attributable to common stockholders per common share | $ (0.30) | $ (0.53) | $ (0.50) | $ (0.82) |
| Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share | 25,815,245 | 9,892,016 | 24,267,816 | 9,465,459 |

VistaGen® Therapeutics

Source: VistaGen Therapeutics, Inc.

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