UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) of the SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 10, 2022

VistaGen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**000-54014**	**20-5093315**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification Number)*

343 Allerton Ave.
South San Francisco, California 94090
(Address of principal executive offices)

(650) 577-3600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	VTGN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2)

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Item 2.02 Results of Operations and Financial Condition.

On February 10, 2022, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its third fiscal quarter ended December 31, 2021. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Disclaimer.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall Exhibit 99.1 filed herewith be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits Index

Exhibit No.	Description
99.1	Press Release issued by VistaGen Therapeutics, Inc., dated February 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VistaGen Therapeutics, Inc.

Date: February 10, 2022

By: */s/ Shawn K. Singh*
Shawn K. Singh
Chief Executive Officer

Exhibit 99.1

VistaGen Therapeutics Reports Third Quarter Financial Results and Provides Corporate Update

- *Advancing late-stage PH94B clinical program, including:*
  - *Progress towards topline data readouts for PALISADE-1 and PALISADE-2 Phase 3 trials designed to evaluate PH94B in social anxiety disorder (SAD) that are expected in mid-2022 and second half 2022, respectively;*
  - *PALISADE Long-term Safety Study and exploratory Phase 2A trial in adjustment disorder with anxiety (AjDA) initiated; and*
  - *Preparation for clinical development in additional anxiety indications underway.*

- *PH10 Phase 2B clinical program in major depressive disorder (MDD) slated to begin in the second half of 2022.*

- *Phase 1B exploratory study for AV-101 in combination with probenecid underway.*

SOUTH SAN FRANCISCO, Calif., February 10, 2022 – VistaGen Therapeutics, Inc. (Nasdaq: VTGN), a company developing therapeutics to transform the treatment paradigm for patients suffering from anxiety, depression and other central nervous system (CNS) disorders, today reported results for its third fiscal quarter ended December 31, 2021 and provided a corporate update.

"Our team is working tirelessly to advance the development of novel therapies to address urgent and growing mental health disorders. Our third quarter results reflect strong execution and progress against our strategy to realize the promise of our differentiated CNS pipeline," stated Shawn Singh, Chief Executive Officer of VistaGen. "As we anticipate Phase 3 data for studies in our PALISADE program for PH94B in social anxiety disorder later this year, we are expanding our clinical programs to explore compelling opportunities to redefine the standard of care for several additional mental health conditions. I am extremely proud of our team and the bold advances we have made toward developing potentially life-changing medicines. Our forward momentum reflects the relentless commitment to our passion and purpose of delivering transformative therapies to address the unmet mental health needs of patients worldwide."

Third Quarter & Recent Business Highlights

VistaGen continued consistent progress across its nasal spray, pherine-based platform and novel oral NMDA (N-methyl-D-aspartate) receptor program.

Ongoing advancement of PALISADE-1 and PALISADE-2 Phase 3 clinical trials in social anxiety disorder (SAD) – The Company's ongoing randomized, multi-center, double-blind, placebo-controlled PALISADE-1 and PALISADE-2 Phase 3 clinical trials in the U.S. are designed to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. PH94B is an odorless, rapid-onset pherine nasal spray with a unique potential mechanism of action (MOA) for the acute treatment of anxiety in adults with SAD, designed to work differently than all therapies approved by the U.S. Food and Drug Administration (FDA) for SAD. Both studies are structured in a manner substantially similar to the public speaking component of a statistically significant peer-reviewed published Phase 2 study of PH94B in which researchers observed a rapid reduction in anxiety in individuals (within 15 minutes) in response to a public speaking challenge (p=0.002). The Company anticipates that topline data will be available in mid-2022 and in the second half of 2022 for PALISADE-1 and PALISADE-2, respectively. The full PALISADE Phase 3 program for PH94B in SAD consists of the two Phase 3 trials, PALISADE-1 and PALISADE-2, as well as the PALISADE Long-term Safety Study and certain small studies designed to support the filing of a U.S. New Drug Application (NDA) to the FDA should the program be successful.

Exploratory clinical evaluation of PH94B expands beyond SAD – During the third quarter, the Company launched the first study in a series of exploratory clinical trials to evaluate PH94B's potential in several anxiety disorders beyond SAD. The initial study in the exploratory program is a Phase 2A clinical trial designed to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of adults with adjustment disorder with anxiety (AjDA). Topline data from this AjDA trial is expected in the second half of 2022. The Company expects to launch additional exploratory clinical studies of PH94B later this year.

New data support PH94B's highly differentiated, non-systemic MOA – The Company reported new preclinical data that support the MOA of PH94B binding to receptors of peripheral neurons in the nasal passages, rather than to neuronal receptors in the CNS, without measurable systemic exposure. These data are important as they further support previous data showing that PH94B does not directly activate GABA-A receptors, which is in distinct contrast to the MOA of benzodiazepines, and are part of the growing body of evidence suggesting that PH94B has the potential to achieve anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns.

PH10 Nasal Spray development continues for multiple depression disorders – PH10 has potential as a novel therapeutic for treatment of multiple depression disorders. Following a positive exploratory Phase 2A study of PH10 in major depressive disorder (MDD), the Company is preparing to initiate a randomized, multi-center, double-blind, placebo-controlled Phase 2B clinical study of PH10 as a potential rapid-onset stand-alone treatment in MDD in the second half of 2022.

AV-101 + probenecid Phase 1B trial initiated -– Following positive preclinical data showing that the combination of AV-101 and probenecid substantially increased the brain concentration of AV-101's active metabolite, thereby demonstrating potential to reduce, rather than block, NMDA receptor signaling, VistaGen initiated a Phase 1B drug-drug interaction study of the combination at the end of the fiscal third quarter. The FDA has granted Fast Track designation for development of AV-101 as a potential adjunctive treatment for MDD and as a non-opioid treatment for neuropathic pain. The Company believes AV-101 in combination with probenecid also may have potential as a treatment for levodopa-induced dyskinesia associated with Parkinson's disease therapy, suicidal ideation, epilepsy, and other neurological disorders involving the NMDA receptor.

Fiscal Year 2022 Third Quarter Financial Results

***Research and development (R&D) expense*:** Research and development expense increased by $4.5 million, from $3.5 million to $8.0 million for the quarters ended December 31, 2020 and 2021, respectively. The increase in R&D expense is primarily related to the initiation and continuation of several clinical trials in the PALISADE Phase 3 program for PH94B in SAD, as well as the addition of new senior management and additional personnel across multiple R&D disciplines.

***General and administrative (G&A) expense*:** General and administrative expense increased to approximately $2.9 million for the quarter ended December 31, 2021 compared to approximately $2.1 million for the quarter ended December 31, 2020. The increase in G&A expense is primarily due to the addition of senior management and other personnel and phase appropriate PH94B pre-launch commercialization activities.

***Net loss*:** Net loss for the quarters ended December 31, 2021 and 2020 was approximately $10.5 million and $5.3 million, respectively.

***Cash position*:** At December 31, 2021, the Company had cash and cash equivalents of approximately $83.7 million.

As of February 9, 2022, the Company had 209,527,955 shares of common stock outstanding.

Conference Call

VistaGen will host a conference call and live audio webcast this afternoon at 5:00 p.m. Eastern Time to provide a corporate update and discuss its financial results for its fiscal year 2022 third quarter ended December 31, 2021.

U.S. Dial-in (Toll-Free): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13726261
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1523673&tp_key=49008240c8

A live audio webcast of the conference call will also be available via this link – https://viavid.webcasts.com/starthere.jsp?ei=1523673&tp_key=49008240c8. Participants should access this webcast site 10 minutes before the start of the call. In addition, a telephone playback of the call will be available after approximately 8:00 p.m. Eastern Time on Thursday, February 10, 2022. To listen to the replay, call toll free 1-844-512-2921 within the United States or 1-412-317-6671 when calling internationally (toll). Please use the replay PIN 13726261.

About VistaGen

VistaGen is a late-stage clinical biopharmaceutical company committed to fundamentally transforming the treatment landscape for many anxiety, depression and other CNS disorders. The Company's leadership is working to improve the lives of those with mental health conditions by advancing a pipeline of innovative programs targeting treatment of multiple forms of anxiety and depression. VistaGen's primary candidates belong to a class of pharmaceuticals administered intranasally known as pherines, which are odorless, synthetic neuroactive steroids that bind to distinct receptors on chemosensory cells in the nasal passages that can impact the limbic amygdala without measurable systemic uptake. VistaGen's lead asset, PH94B, is currently in multiple Phase 3 trials and has the potential to be the first FDA-approved, fast-acting, acute treatment of anxiety for adults with social anxiety disorder. With an experienced leadership team and a steady flow of near- and long-term clinical milestones, VistaGen is passionate about bringing a visionary approach to mental health care. For more information, please visit www.VistaGen.com and connect with VistaGen on Twitter, LinkedIn, and Facebook.

Forward Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by us and our management, are inherently uncertain. Our actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties relating to delays in launching and/or conducting our planned clinical trials, including delays due to the impact of the ongoing COVID-19 pandemic; fluctuating costs of materials and other resources required to conduct our planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; adverse healthcare reforms and changes of laws and regulations; manufacturing and marketing risks, which may include, but are not limited to, unavailability of or delays in delivery of raw materials for manufacture of our CNS drug candidates and difficulty in initiating or conducting clinical trials due to the ongoing COVID-19 pandemic or otherwise; inadequate and/or untimely supply of one or more of our CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of our CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2021 and in our most recent Quarterly Report on Form 10-Q for the quarter ended December 31, 2021, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press 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, other than as may be required by law. If we do update one or more forward-looking statements, no inference should be made that we will make additional updates with respect to those or other forward-looking statements.

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

	December 31, 2021	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,700,200	$ 103,108,300
Receivable from collaboration partner	-	40,600
Prepaid expenses and other current assets	2,936,600	835,100
Deferred contract acquisition costs - current portion	133,500	133,500
Total current assets	86,770,300	104,117,500
Property and equipment, net	452,800	367,400
Right of use asset - operating lease	2,756,800	3,219,600
Deferred offering costs	321,800	294,900
Deferred contract acquisition costs - non-current portion	133,500	234,100
Security deposits	100,900	47,800
Total assets	$ 90,536,100	$ 108,281,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,948,700	$ 838,300
Accrued expenses	2,627,500	1,562,700
Deferred revenue - current portion	1,420,200	1,420,200
Operating lease obligation - current portion	424,100	364,800
Financing lease obligation - current portion	300	3,000
Total current liabilities	6,420,800	4,189,000
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	-	6,272,700
Deferred revenue - non-current portion	1,420,300	2,490,300
Operating lease obligation - non-current portion	2,717,200	3,350,800
Total non-current liabilities	4,137,500	12,113,800
Total liabilities	10,558,300	16,302,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2021 and March 31, 2021:		
Series A Preferred, 500,000 shares authorized at December 31, 2021 and March 31, 2021; no shares and 500,000 shares issued and outstanding at December 31, 2021 and March 31, 2021, respectively	-	500
Series B Preferred; 4,000,000 shares authorized at December 31, 2021 and March 31, 2021; no shares and 1,131,669 shares issued and outstanding at December 31, 2021 and March 31, 2021, respectively	-	1,100
Series C Preferred; 3,000,000 shares authorized at December 31, 2021 and March 31, 2021; no shares and 2,318,012 shares issued and outstanding at December 31, 2021 and March 31, 2021, respectively	-	2,300
Series D Preferred; 2,000,000 shares authorized at December 31, 2021 and March 31, 2021; no shares and 402,149 shares issued and outstanding at December 31, 2021 and March 31, 2021, respectively	-	400
Common stock, $0.001 par value; 325,000,000 shares authorized at December 31, 2021 and March 31, 2021;206,644,870 shares and 180,751,234 shares issued at December 31, 2021 and March 31, 2021, respectively	206,600	180,800
Additional paid-in capital	334,655,000	315,603,100
Treasury stock, at cost, 135,665 shares of common stock held at December 31, 2021 and March 31, 2021	(3,968,100)	(3,968,100)
Accumulated deficit	(250,915,700)	(219,841,600)
Total stockholders' equity	79,977,800	91,978,500
Total liabilities and stockholders' equity	$ 90,536,100	$ 108,281,300

VISTAGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(Amounts in Dollars, except share amounts)
(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Sublicense revenue	$ 357,900	$ 313,600	$ 1,070,000	$ 647,600
Total revenues	357,900	313,600	1,070,000	647,600
Operating expenses:				
Research and development	7,966,800	3,496,100	23,637,100	7,585,500
General and administrative	2,931,300	2,116,800	8,518,800	4,776,900
Total operating expenses	10,898,100	5,612,900	32,155,900	12,362,400
Loss from operations	(10,540,200)	(5,299,300)	(31,085,900)	(11,714,800)
Other income (expenses), net:				
Interest income (expense), net	5,100	600	15,300	(6,500)
Other income	-	-	-	600
Loss before income taxes	(10,535,100)	(5,298,700)	(31,070,600)	(11,720,700)
Income taxes	-	-	(3,400)	(2,600)
Net loss and comprehensive loss	$ (10,535,100)	$ (5,298,700)	(31,074,000)	(11,723,300)
Accrued dividends on Series B Preferred stock	(208,100)	(353,600)	(945,100)	(1,036,600)
Net loss attributable to common stockholders	$ (10,743,200)	$ (5,652,300)	$ (32,019,100)	$ (12,759,900)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.05)	$ (0.07)	$ (0.16)	$ (0.19)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	202,328,683	81,086,105	195,179,267	66,551,962