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): June 23, 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 June 23, 2022, VistaGen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year ended March 31, 2022. 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 June 23, 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: June 23, 2022

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

VistaGen Therapeutics Reports Fiscal Year 2022 Financial Results and Provides Corporate Update

- *Completed last patient out milestone for PALISADE-1 Phase 3 clinical trial of PH94B in social anxiety disorder (SAD). Topline results for PALISADE-1 anticipated mid-2022.*
- *PALISADE-2 on track for topline readout in late 2022.*
- *Received FDA consensus that data from nonclinical and clinical studies of PH94B completed to date provide no signal of abuse potential.*

SOUTH SAN FRANCISCO, Calif., June 23, 2022 – VistaGen Therapeutics, Inc. (Nasdaq: VTGN), a late clinical-stage, central nervous system (CNS)-focused biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders, today reported its financial results for its fiscal year ended March 31, 2022 and provided a corporate update.

"Momentum from our accomplishments throughout our fiscal year 2022 have led us to a position of strength as we await topline results from our PALISADE-1 Phase 3 clinical trial of PH94B in social anxiety disorder. Our progress, most notably recent drug development and regulatory milestones, continues to drive our team forward as we strive to develop much needed innovative medicines for mental health," stated Shawn Singh, Chief Executive Officer of VistaGen.

"We believe individuals should have access to medication that is not only effective, but also safe and without the potential for abuse and other harmful side effects. One of the major reasons we are passionate about developing PH94B is its potential to satisfy that need for the millions of individuals suffering from social anxiety disorder. Our recent consensus with the FDA that a Human Abuse Potential study is not required at this time based on PH94B's demonstrated safety in all studies completed to date adds to a growing body of evidence suggesting that PH94B has potential to achieve rapid-onset anti-anxiety effects without requiring systemic uptake or causing benzodiazepine-like side effects and safety concerns," said Singh.

"At a time when the current drug treatment paradigm for social anxiety disorder is falling far short of delivering necessary relief without worrisome potential consequences, an innovative treatment alternative is imperative. If successfully developed in our ongoing PALISADE Phase 3 Program, PH94B has the potential to fill that void as the first fast-acting, on demand acute treatment of anxiety for the estimated 25 million Americans who suffer from social anxiety disorder. We remain steadfast in pursuit of our mission to improve mental health and well-being for individuals suffering from anxiety, depression and other CNS related disorders worldwide – One Mind at a Time," concluded Singh.

Fiscal Year 2022 & Recent Business Highlights

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

PALISADE Phase 3 Program for PH94B in Social Anxiety Disorder (SAD) reaches Last Patient Out Milestone in PALISADE-1 – VistaGen's PALISADE-1 and PALISADE-2 Phase 3 studies are randomized, multi-center, double-blind, placebo-controlled clinical trials in the U.S. designed to evaluate the efficacy, safety and tolerability of PH94B for the acute treatment of anxiety in adults with SAD. PH94B is an odorless, tasteless, rapid-onset pherine nasal spray with a unique potential mechanism of action (MOA) and no signal of abuse potential in all studies completed to date. PH94B is designed to work differently than all therapies approved by the U.S. Food and Drug Administration (FDA) for SAD. Both Phase 3 studies are structured in a manner substantially similar to the public speaking component of a peer-reviewed Phase 2 study of PH94B in which researchers observed a statistically significant, rapid reduction in anxiety in individuals (within 15 minutes) in response to a public speaking challenge (p=0.002). In June 2022, PALISADE-1 reached the last patient out milestone. Consistent with prior guidance, the Company anticipates topline data for PALISADE-1 in mid-2022. PALISADE-2 is progressing, with topline results anticipated in late 2022. The Company's PALISADE-1 and PALISADE-2 studies are designed to anchor its potential PH94B U.S. New Drug Application (NDA) to the FDA should its PALISADE Phase 3 Program be successful, overall.

Consensus with FDA on abuse potential – No Human Abuse Potential (HAP) study required at this time – The FDA recently indicated that it agrees with the Company that data from nonclinical and clinical studies of PH94B completed to date provide no signal of abuse potential. The FDA also agreed that additional nonclinical studies are not necessary to evaluate the abuse potential of PH94B and, at this time, based on studies completed to date, a HAP study with PH94B is not required. The Company believes that this consensus with the FDA regarding abuse liability is very important as PH94B continues to progress through its Phase 3 development program in SAD.

Nonclinical PH94B data support its differentiated, non-systemic MOA – The Company recently presented preclinical data at the Annual Meeting of the Society of Biological Psychiatry (SOBP), the American Society of Clinical Psychopharmacology (ASCP), and the Medscape LIVE Psych Update Spring Meeting that support the MOA of PH94B binding to receptors of peripheral neurons in the nasal passages, rather than to neuronal receptors in the CNS, and without measurable systemic exposure. These data suggest that anxiolytic activity can be achieved without systemic exposure or transport into the brain, resulting in a lower potential risk for common side effects. As these preclinical data demonstrate, the proposed mechanism of action of PH94B is fundamentally unique from all currently available anti-anxiety therapies.

PALISADE Global Phase 3 Clinical Study in SAD – The Company and AffaMed Therapeutics completed regulatory preparations necessary to initiate PALISADE Global in the U.S. and China in the second half of 2022. Modeled off VistaGen's PALISADE-1 and PALISADE-2 Phase 3 clinical studies, PALISADE Global is a replicate Phase 3 clinical trial designed to evaluate the efficacy, safety, and tolerability of PH94B for the acute treatment of SAD in adults. This study is intended to support the registration and commercialization of PH94B in Greater China and potential other markets outside of the U.S. should PALISADE Global and the Company's PALISADE Phase 3 Program in the U.S. be successful, overall.

Exploratory clinical evaluation of PH94B expands beyond SAD – To evaluate PH94B's potential as a treatment for several distinct anxiety disorders beyond SAD, the Company is preparing to launch a series of Phase 2A exploratory clinical trials in addition to its ongoing 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 are anticipated in late 2022. The Phase 2A clinical trials are expected to include exploratory biomarker studies to assess potential PH94B development opportunities in post-traumatic stress disorder (PTSD), procedural anxiety and post-partum anxiety.

PH10 Nasal Spray development continues for multiple depression disorders – Following positive results from the exploratory Phase 2A program of PH10 in major depressive disorder (MDD), the Company is conducting the necessary nonclinical studies to support the submission of an Investigational New Drug (IND) application to the FDA for further clinical development of PH10 in MDD in the U.S. The Company anticipates submission of the PH10 IND in MDD in 2022, and, if authorized by the FDA, to begin Phase 2B clinical development of PH10 for MDD as soon as practicable thereafter. The Company is considering the evaluation of PH10 as a potential treatment for several distinct depression disorders beyond MDD.

AV-101 + probenecid Phase 1B trial initiated – Following positive preclinical data, VistaGen initiated a Phase 1B drug-drug interaction study of AV-101 in combination with probenecid in late 2021. The Company is considering the evaluation of AV-101 in combination with probenecid as a potential treatment for several distinct neurological disorders.

Fiscal Year 2022 Financial Results

***Research and development (R&D) expense*:** Research and development expense increased by $23.5 million, from $11.9 million to $35.4 million for the fiscal years ended March 31, 2021 and 2022, respectively. The increase in R&D expense is primarily due to the preparation, initiation and continuation of the various clinical trials in the Company's PALISADE Phase 3 Program for PH94B in SAD, as well as the addition of senior management and other personnel across multiple R&D disciplines.

***General and administrative (G&A) expense*:** General and administrative expense increased to approximately $13.5 million for the fiscal year ended March 31, 2022 compared to approximately $7.1 million for the fiscal year ended March 31, 2021. 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 attributable to common stockholders for the fiscal year ended March 31, 2022 and 2021 was approximately $48.7 million and $42.3 million, respectively.

***Cash position*:** At March 31, 2022, the Company had cash and cash equivalents of approximately $68.1 million.

As of June 22, 2022, the Company had 206,640,955 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 ended March 31, 2022.

U.S. Dial-in (Toll-Free): 1-877-407-9716

International Dial-in Number (Toll): 1-201-493-6779
Conference ID: 13729400

Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1544875&tp_key=fd5623fb33

A live audio webcast of the conference call will also be available via the link provided above. 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 pm Eastern Time on Thursday, June 23, 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 number 13729400.

About VistaGen

VistaGen (Nasdaq: VTGN) is a late clinical-stage, CNS-focused biopharmaceutical company striving to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. VistaGen's clinical-stage candidates are targeting multiple forms of anxiety and depression. PH94B and PH10 belong to a new class of drugs known as pherines, which are odorless, neuroactive steroids that bind to distinct receptors on chemosensory neurons in the nasal passages and can impact the limbic amygdala without systemic uptake or direct activity on CNS neurons in the brain. VistaGen's lead candidate, PH94B, is a nasally administered spray currently in multiple Phase 3 trials in the U.S., with topline results anticipated in 2022. Should ongoing Phase 3 studies be successful, PH94B has the potential to be the first FDA-approved, fast-acting, acute treatment of anxiety for adults with social anxiety disorder. VistaGen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression. Connect at www.VistaGen.com.

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 VistaGen and its management, are inherently uncertain. The Company's 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 the completion and results of the Company's PALISADE-1 and PALISADE-2 Phase 3 clinical trials; the Company's ability to submit a NDA to the FDA following the completion of PALISADE-1 and/or PALISADE-2 Phase 3 clinical trials; delays in launching, conducting and/or completing other ongoing and 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 the Company's ongoing and/or 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 the Company's CNS drug candidates due to the ongoing COVID-19 pandemic or otherwise; inadequate and/or untimely supply of one or more of the Company's CNS drug candidates to meet demand; entry of competitive products; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates; and the risks more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2021 and in the Company's 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). The Company's 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 the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, other than as may be required by law. If the Company does update one or more forward-looking statements, no inference should be made that the Company 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)

	March 31, 2022	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 68,135,300	$ 103,108,300
Prepaid expenses and other current assets	2,745,800	875,700
Deferred contract acquisition costs - current portion	116,900	133,500
Total current assets	70,998,000	104,117,500
Property and equipment, net	414,300	367,400
Right-of-use asset - operating lease	2,662,000	3,219,600
Deferred offering costs	321,800	294,900
Deferred contract acquisition costs - non-current portion	146,400	234,100
Security deposits	100,900	47,800
Total assets	$ 74,643,400	$ 108,281,300
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,758,600	$ 838,300
Accrued expenses	1,329,200	1,562,700
Deferred revenue - current portion	1,244,000	1,420,200
Operating lease obligation - current portion	433,300	364,800
Financing lease obligation - current portion	-	3,000
Total current liabilities	5,765,100	4,189,000
Non-current liabilities:		
Accrued dividends on Series B Preferred Stock	-	6,272,700
Deferred revenue - non-current portion	1,557,600	2,490,300
Operating lease obligation - non-current portion	2,605,400	3,350,800
Total non-current liabilities	4,163,000	12,113,800
Total liabilities	9,928,100	16,302,800
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2022 and 2021:		
Series A Preferred, 500,000 shares authorized at March 31, 2022 and 2021; no shares and 500,000 shares issued and outstanding at March 31, 2022 and March 31, 2021, respectively		
Series B Preferred; 4,000,000 shares authorized at March 31, 2022 and 2021; no shares and 1,131,669 shares issued and outstanding at March 31, 2022 and March 31, 2021, respectively	-	1,100
Series C Preferred; 3,000,000 shares authorized at March 31, 2022 and 2021; no shares and 2,318,012 shares issued and outstanding at March 31, 2022 and March 31, 2021, respectively	-	2,300
Series D Preferred; 2,000,000 shares authorized at March 31, 2022 and 2021; no shares and 402,149 shares issued and outstanding at March 31, 2022 and March 31, 2021, respectively	-	400
Common stock, $0.001 par value; 325,000,000 shares authorized at March 31, 2022 and 2021; 206,676,620 shares and 180,751,234 shares issued at March 31, 2022 and March 31, 2021, respectively	206,700	180,800
Additional paid-in capital	336,080,700	315,603,100
Treasury stock, at cost, 135,665 shares of common stock held at March 31, 2022 and 2021	(3,968,100)	(3,968,100)
Accumulated deficit	(267,604,000)	(219,841,600)
Total stockholders' equity	64,715,300	91,978,500
Total liabilities and stockholders' equity	$ 74,643,400	$ 108,281,300

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

	Fiscal Years Ended March 31,	
	2022	**2021**
Sublicense revenue	$ 1,108,900	$ 1,089,500
Total revenues	1,108,900	1,089,500
Operating expenses:		
Research and development	35,407,800	11,925,700
General and administrative	13,480,000	7,097,600
Total operating expenses	48,887,800	19,023,300
Loss from operations	(47,778,900)	(17,933,800)
Other income, net:		
Interest income, net	19,900	1,600
Other income	-	600
Loss before income taxes	(47,759,000)	(17,931,600)
Income taxes	(3,400)	(2,600)
Net loss and comprehensive loss	$ (47,762,400)	$ (17,934,200)
Accrued dividends on Series B Preferred stock	(945,100)	(1,385,600)
Beneficial conversion feature on Series D Preferred	-	(23,000,000)
Net loss attributable to common stockholders	$ (48,707,500)	$ (42,319,800)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.25)	$ (0.49)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	197,978,592	86,133,644