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): November 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 November 10, 2022, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release to announce the Company's financial results for its fiscal year 2023 second quarter ended September 30, 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 November 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: November 10, 2022

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

Vistagen

Vistagen Reports Second Quarter Financial Results and Provides Corporate Update

PALISADE-2 Phase 3 trial with PH94B in social anxiety disorder restart preparations underway after independent interim analysis recommends study continue as planned

Preliminary analysis of nearly 400 subjects in the final data set for the PALISADE Open Label Study demonstrates robust functional improvement in anxiety-provoking social and performance situations in daily life, as measured by the Liebowitz Social Anxiety Scale

Company planning to meet with the U.S. Food and Drug Administration regarding next step in Phase 3 development of PH94B in social anxiety disorder

SOUTH SAN FRANCISCO, Calif., November 10, 2022 – Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other central nervous system (CNS) disorders, today reported financial results for its fiscal year 2023 second quarter ended September 30, 2022 and provided a corporate update.

"During the past quarter, Vistagen achieved several important milestones to advance our CNS pipeline. Recent independent data analysis supports our work to restart our PALISADE-2 Phase 3 study of PH94B in social anxiety disorder, and preliminary data from nearly 400 subjects in our PALISADE Open Label Study demonstrate that PH94B has potential to help millions of individuals suffering from social anxiety disorder, without the side effects and safety concerns often associated with prior FDA approvals in SAD and other off-label treatment options," said Shawn Singh, Chief Executive Officer of Vistagen. "We are focused on optimizing clinical studies for PH94B and we will soon meet with the FDA to pursue a consensus path forward in our Phase 3 program in social anxiety disorder. We are also advancing our second pherine asset, PH10. We recently submitted our U.S. Investigational New Drug application for a small Phase 1 study to facilitate entering Phase 2B development of PH10 in major depressive disorder. Both therapies have the potential to offer novel, fast-acting treatment for millions of patients confronting the effects of debilitating mental health challenges."

Second Quarter Fiscal Year 2023 & Recent Business Highlights

Below is an update on recent development involving the Company's pipeline of CNS product candidates — the pherine-based platform consisting of PH94B and PH10 nasal sprays for anxiety and depression disorders, respectively, and orally available AV-101 for CNS indications involving the NMDA (N-methyl-D-aspartate) receptor.

Independent interim analysis of the Company's PALISADE-2 Phase 3 Study in social anxiety disorder (SAD) recommends continuing the study as planned

In September 2022, based on their review of unblinded data from the 140 subjects who had completed our PALISADE-2 Phase 3 clinical study of PH94B for the acute treatment of anxiety in adults with SAD, independent third-party biostatisticians recommended that the Company continue PALISADE-2 as planned. Although Vistagen did not, and does not, have access to any unblinded data from PALISADE-2, based on the outcome of the interim analysis and the recommendation from the independent biostatisticians, the Company is preparing to restart PALISADE-2 as soon as practicable and then continue the study to the full targeted enrollment of 208 subjects, as originally planned. In parallel with preparing to restart PALISADE-2, the Company is planning to meet with the U.S. Food and Drug Administration (FDA) during the first quarter of calendar 2023 to discuss and reach consensus with the FDA on the next step in the Company's Phase 3 development program for PH94B as a potential treatment for adults with SAD.

Preliminary data from PALISADE Open Label Study

The Company initiated the PALISADE Open Label Study (PALISADE OLS) in October 2021 to evaluate the safety and tolerability of PH94B in adult subjects with SAD taken as needed prior to acute anxiety-provoking social and performance situations in daily life, up to four times per day, over a period of up to 12 months. In addition to assessing safety and tolerability, the Company included several exploratory objectives, including assessment of PH94B's potential to achieve overall symptom reduction and improvement in severity of SAD, as measured by the Liebowitz Social Anxiety Scale (LSAS), the efficacy endpoint required by the FDA for prior SAD approvals. In August 2022, the Company closed recruitment and enrollment in the PALISADE OLS. Preliminary analysis of nearly 400 subjects in the final data set for the PALISADE OLS demonstrates robust functional improvement in anxiety-provoking social and performance situations in daily life, as measured by the LSAS. The Company now has two data sets supporting PH94B's ability to improve LSAS scores – the PALISADE OLS over a period of one month and beyond and a published double-blind, placebo-controlled Phase 2 cross-over study after two weeks of use. These two studies combined demonstrate the potential for PH94B to achieve robust overall reduction in symptoms of SAD and improvement in severity over time as measured by the LSAS. The Company believes LSAS measurements over time may be well-suited for a Phase 3 trial to demonstrate efficacy and the true impact of PH94B on patients' lives given that it measures overall improvement in disease severity by capturing the reduction in fear and anxiety, as well as the avoidance of social and performance situations. These studies reinforce the Company's confidence in the potential of PH94B, used acutely as-needed in daily life, to provide rapid-onset, clinically meaningful, and sustained response with a favorable safety and tolerability profile. A full assessment of the PALISADE OLS is expected during the first quarter of calendar 2023.

Enrollment completed in exploratory Phase 2A trial of PH94B in adjustment disorder with anxiety

The Company has completed enrollment in its ongoing exploratory double-blind, placebo-controlled Phase 2A clinical trial of PH94B to evaluate the efficacy, safety and tolerability of PH94B as a potential treatment of adults with adjustment disorder with anxiety (AjDA). The study protocol involves multiple administration assessments of PH94B, which is administered four times per day for 28 days. Vistagen anticipates topline results from this exploratory Phase 2A AjDA trial during the first quarter of calendar 2023.

Investigational New Drug (IND) application submitted to the FDA to facilitate U.S. Phase 2B clinical development of PH10 for major depressive disorder

In a small (n=30) published exploratory randomized, double-blind, placebo-controlled parallel design Phase 2A study of PH10 in major depressive disorder (MDD) conducted in Mexico, at a 6.4 microgram dose administered intranasally twice daily for 8 weeks, PH10 significantly reduced depressive symptoms as early as one week based on the 17-item Hamilton Depression Scale (HAM-D-17) scores compared to placebo ($p = 0.022$). PH10 was well-tolerated and did not cause psychological side effects (such as dissociation and hallucinations) or other safety concerns that may be associated with rapid-onset ketamine-based therapies. The Company recently submitted its U.S. IND application to enable initiation of a small Phase 1 clinical study of PH10 in the U.S. in healthy volunteers. Should the FDA permit the Company to proceed, the Company plans to initiate the study before the end of calendar 2022. This small and brief Phase 1 study is intended to facilitate Phase 2B development of PH10 in the U.S. as an innovative potential fast-acting stand-alone treatment of MDD. Vistagen may also have potential opportunities to develop PH10 for several other depression-related disorders.

AV-101 + Probenecid Phase 1B trial progressing

Based on observations and findings from preclinical studies, Vistagen believes that AV-101, in combination with FDA-approved oral probenecid, has the potential to become a new oral treatment alternative for certain CNS indications involving the NMDA receptor. The Company is currently conducting an exploratory Phase 1B drug-drug interaction clinical study of AV-101 in combination with probenecid. Upon completion of the study, anticipated during the second quarter of calendar 2023, the Company plans to consider exploratory Phase 2A development of AV-101 in combination with probenecid, on its own or with a collaborator, as a potential oral treatment for CNS disorders involving the NMDA receptor.

Fiscal Year 2023 Second Quarter Financial Results

***Research and development (R&D) expense*:** Research and development expense increased by $2.9 million, from $10.0 million to $12.9 million for the quarters ended September 30, 2021 and 2022, respectively. The increase in R&D expense is primarily due to expenses related to conducting the PALISADE Phase 3 Program for PH94B in SAD, including PALISADE-1, PALISADE-2 and the PALISADE OLS, and the exploratory Phase 2A study of PH94B in AjDA, as well as nonclinical development, regulatory and outsourced manufacturing activities for both PH94B and PH10.

***General and administrative (G&A) expense*:** General and administrative expense increased to approximately $3.7 million for the quarter ended September 30, 2022 compared to approximately $3.2 million for the quarter ended September 30, 2021. The increase in G&A expense was primarily due to costs associated with external legal, accounting and other professional services relating to corporate finance matters as well as expanded corporate initiatives surrounding corporate awareness and investor relations.

***Net loss*:** Net loss attributable to common stockholders for the fiscal quarters ended September 30, 2022 and 2021 was approximately $17.5 million and $13.2 million, respectively.

***Cash position*:** At September 30, 2022, the Company had cash and cash equivalents of approximately $35.3 million. As a result of the conclusion of certain clinical trial activity and deferral of several research and development and pre-commercialization activities, the Company anticipates a decrease in spending over the next few quarters which the Company expects will extend its cash runway through a series of potential key milestones and data readouts in 2023.

As of November 9, 2022, the Company had 206,836,345 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 discuss its financial results for its second quarter fiscal year 2023 ended September 30, 2022 and provide a corporate update.
U.S. Dial-in (Toll-Free): 1-888-599-8686

International Dial-in Number (Toll): 1-929-477-0402
Conference ID: 5975082
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1579342&tp_key=aa33644740

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 p.m. Eastern Time on Thursday, November 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 number 5975082.

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage CNS-focused biopharmaceutical company aiming 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. Candidates include PH94B and PH10, which belong to a new class of drugs known as pherines, which are investigational neuroactive steroids designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic uptake or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression – one mind at a time. 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. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or developments may differ materially from those projected or implied in these forward-looking statements. Among other things, there can be no guarantee that any of the Company's drug candidates will successfully complete ongoing or future clinical trials, receive regulatory approval or be commercially successful. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the results of the Company's interim analysis of data currently available from the PALISADE-2 Phase 3 clinical trial and preliminary data from the PALISADE OLS; resuming enrollment in PALISADE-2; the completion and results of PALISADE-2, as well as the Company's ongoing clinical studies of PH94B, including the Company's Phase 2A clinical trial of PH94B in adults experiencing adjustment disorder with anxiety, and ongoing studies of the Company's other product candidates, PH10 and AV-101; delays in launching, conducting and/or completing other ongoing and planned clinical trials, including delays or other adverse effects due to the 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; and other technical and unexpected hurdles in the development, manufacture and commercialization of the Company's CNS drug candidates. These risks are 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, 2022 and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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)

	September 30, 2022 (unaudited)	March 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,287,200	$ 68,135,300
Prepaid expenses and other current assets	1,559,600	2,745,800
Deferred contract acquisition costs - current portion	67,000	116,900
Total current assets	36,913,800	70,998,000
Property and equipment, net	558,800	414,300
Right-of-use asset - operating lease	2,465,700	2,662,000
Deferred offering costs	411,400	321,800
Deferred contract acquisition costs - non-current portion	251,100	146,400
Security deposits	100,900	100,900
Total assets	$ 40,701,700	$ 74,643,400
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,957,800	$ 2,758,600
Accrued expenses	1,188,300	1,329,200
Notes payable	730,000	-
Deferred revenue - current portion	712,300	1,244,000
Operating lease obligation - current portion	455,500	433,300
Financing lease obligation - current portion	1,500	-
Total current liabilities	6,045,400	5,765,100
Non-current liabilities:		
Deferred revenue - non-current portion	2,671,800	1,557,600
Operating lease obligation - non-current portion	2,371,200	2,605,400
Financing lease obligation - non-current portion	8,300	-
Total non-current liabilities	5,051,300	4,163,000
Total liabilities	11,096,700	9,928,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2022 and March 31, 2022: no shares outstanding at September 30, 2022 and March 31, 2022	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at September 30, 2022 and March 31, 2022; 206,972,010 and 206,676,620 shares issued at September 30, 2022 and March 31, 2022, respectively	207,000	206,700
Additional paid-in capital	338,229,600	336,080,700
Treasury stock, at cost, 135,665 shares of common stock held at September 30, 2022 and March 31, 2022	(3,968,100)	(3,968,100)
Accumulated deficit	(304,863,500)	(267,604,000)
Total stockholders' equity	29,605,000	64,715,300
Total liabilities and stockholders' equity	$ 40,701,700	$ 74,643,400

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Sublicense revenue	$ (892,500)	$ 358,000	$ (582,500)	$ 712,100
Total revenues	(892,500)	358,000	(582,500)	712,100
Operating expenses:				
Research and development	12,894,500	9,936,300	28,185,800	15,393,500
General and administrative	3,702,300	3,221,200	8,494,100	5,864,300
Total operating expenses	16,596,800	13,157,500	36,679,900	21,257,800
Loss from operations	(17,489,300)	(12,799,500)	(37,262,400)	(20,545,700)
Other income, net:				
Interest income, net	6,100	5,100	8,400	10,200
Loss before income taxes	(17,483,200)	(12,794,400)	(37,254,000)	(20,535,500)
Income taxes	-	-	(5,500)	(3,400)
Net loss and comprehensive loss	$ (17,483,200)	$ (12,794,400)	(37,259,500)	(20,538,900)
Accrued dividend on Series B Preferred stock	-	(375,200)	-	(737,000)
Net loss attributable to common stockholders	$ (17,483,200)	$ (13,169,600)	$ (37,259,500)	$ (21,275,900)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.08)	$ (0.07)	$ (0.18)	$ (0.11)
Weighted average shares used in computing basic and diluted net loss attributable to common stockholders per common share	206,811,249	193,227,841	206,704,573	191,585,026