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 13, 2024

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 94080
(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 13, 2024, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release announcing financial results for its fiscal year 2024 third quarter ended December 31, 2023. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Disclaimer.

The information contained in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as 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 13, 2024, furnished herewith.
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 13, 2024

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

Vistagen

Vistagen Reports Fiscal 2024 Third Quarter Financial Results and Provides Corporate Update

Fasedienol PALISADE Phase 3 program for the acute treatment of social anxiety disorder remains on track

PALISADE-3 trial initiation anticipated in 1H 2024; PALISADE-4 trial initiation anticipated in 2H 2024

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)—February 13, 2024-- Vistagen (Nasdaq: VTGN), a late clinical-stage biopharmaceutical company pioneering neuroscience to deliver first-in-class therapies for psychiatric and neurological disorders, today reported financial results for its fiscal year 2024 third quarter ended December 31, 2023 and provided a corporate update.

"Momentum from clinical and corporate milestones achieved through the end of last quarter have significantly advanced our efforts to develop and commercialize fasedienol as a potential first-in-class acute treatment for adults with social anxiety disorder. Building on the positive results of our PALISADE-2 Phase 3 trial in SAD, we remain on track to initiate our PALISADE-3 Phase 3 trial in SAD during the first half of this year," said Shawn Singh, Chief Executive Officer of Vistagen. "In parallel, we continue to make significant progress toward Phase 2B development of two additional clinical-stage neuroscience assets in our pipeline, itruvone for major depressive disorder and hormone-free PH80 for women's health indications, including vasomotor symptoms (hot flashes) due to menopause."

Fasedienol Nasal Spray for Acute Treatment of Social Anxiety Disorder (SAD)

To complement Vistagen’s successful PALISADE-2 Phase 3 trial of fasedienol for the acute treatment of SAD, the Company’s PALISADE-3 trial, anticipated to initiate during the first half of 2024, as well as its PALISADE-4 trial, which is anticipated to be initiated in the second half of 2024, will be U.S. multi-center, randomized, double-blind, placebo-controlled Phase 3 trials designed to evaluate the efficacy, safety, and tolerability of the acute administration of fasedienol to relieve anxiety symptoms in adult patients with SAD, after administration of a single dose of fasedienol during a public speaking challenge in a clinical setting, as measured using the patient-reported Subjective Units of Distress Scale (SUDS) as the primary efficacy endpoint.

Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with the positive results from PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential fasedienol U.S. New Drug Application (NDA) submission for the acute treatment of anxiety in adults with SAD.

Itruvone Nasal Spray for Major Depressive Disorder (MDD)

Leveraging a successful exploratory Phase 2A trial of itruvone for the treatment of MDD, preparations and planning are underway for Phase 2B development.

PH80 Nasal Spray for Vasomotor Symptoms (Hot Flashes) due to Menopause and other Women's Health Indications

Expanding upon successful exploratory Phase 2A trials of PH80 in two women's health indications, preparations and planning are underway for U.S. IND-enabling nonclinical studies to facilitate U.S. Phase 2B development of hormone-free PH80 for the treatment of vasomotor symptoms (hot flashes) due to menopause and, potentially, premenstrual dysphoric disorder (PMDD).

Fiscal Year 2024 Third Quarter Financial Results

***Research and development (R&D) expense*:** R&D expense was $4.5 million and $6.9 million for the three months ended December 31, 2023 and 2022, respectively. The decrease in R&D expense was primarily due to a decrease in clinical and development expenses related to the timing of expenses incurred for the Company's Phase 3 trials of fasedienol in SAD.

***General and administrative (G&A) expense*:** G&A expense was $3.8 million and $3.1 million for the three months ended December 31, 2023 and 2022, respectively. The increase was primarily due to increases in compensation and related expenses.

***Net loss*:** Net loss was $6.3 million and $9.8 million for the three months ended December 31, 2023, and 2022, respectively.

***Cash position*:** At December 31, 2023, the Company had cash and cash equivalents of approximately $126.6 million.

As of February 12, 2024, the Company had 27,029,731 shares of common stock issued and 3,577,240 pre-funded warrants 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.

U.S. Dial-in (Toll-Free): 1-877-407-9716
International Dial-in Number (Toll): 1-201-493-6779

Conference ID: 13743176
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1648110&tp_key=097d964c22

A live audio conference call webcast will also be available via the above link. 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 Tuesday, February 13, 2024. 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 access ID number: 13743176.

Vistagen

About Vistagen

Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company pioneering neuroscience to deliver first-in-class therapies for psychiatric and neurological disorders. Five of Vistagen's six clinical-stage product candidates belong to a new class of drugs known as pherines, which have the potential to rapidly deliver meaningful efficacy with a differentiated safety profile. Pherines are investigational neuroactive nasal sprays with innovative proposed mechanisms of action that activate chemosensory neurons in the nasal passages to impact fundamental neural circuits in the brain without the need for systemic absorption or binding to receptors in the brain. Vistagen's sixth clinical-stage product candidate, AV-101, is an investigational oral drug candidate with the potential to inhibit, but not block, NMDA receptor activity. Vistagen is passionate about transforming what is possible in the treatment of anxiety, depression, and other neuroscience disorders. 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, if initiated, future clinical trials, receive regulatory approval or be commercially successful, or that the Company will be able to successfully replicate the result of past studies of its product candidates, including fasedienol, itruvone, PH80 or its other drug candidates. Other factors that may cause such a difference include, without limitation, risks and uncertainties relating to the Company's submission of an U.S. NDA to the FDA for any product candidate, including fasedienol; the ability of any clinical trial information submitted by the Company to the FDA to support an U.S. NDA; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials, including PALISADE-3 and PALISADE-4 or additional Phase 2 clinical trials of itruvone or PH80; the scope and enforceability of the Company's patents, including patents related to the Company's pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services 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 product 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, 2023, and in the Company's Quarterly Report on Form 10-Q for the period ended December 31, 2023, 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.

Vistagen

VISTAGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2023 (Unaudited)	March 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 126,559,200	$ 16,637,600
Prepaid expenses and other current assets	1,480,300	802,700
Deferred contract acquisition costs - current portion	74,500	67,100
Total current assets	128,114,000	17,507,400
Property and equipment, net	445,100	507,300
Right-of-use asset - operating lease	1,933,600	2,260,300
Deferred offering costs	325,700	495,700
Deferred contract acquisition costs - non-current portion	148,700	217,600
Security deposits	100,900	100,900
Total assets	$ 131,068,000	$ 21,089,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,737,000	$ 2,473,100
Accrued expenses	129,300	787,400
Note payable	-	105,300
Deferred revenue - current portion	1,762,800	714,300
Operating lease obligation - current portion	533,500	485,600
Financing lease obligation - current portion	1,900	1,700
Total current liabilities	4,164,500	4,567,400
Deferred revenue - non-current portion	1,899,400	2,314,600
Operating lease obligation - non-current portion	1,713,300	2,119,800
Financing lease obligation - non-current portion	6,000	7,400
Total liabilities	7,783,200	9,009,200
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and March 31, 2023; no shares outstanding at December 31, 2023 and March 31, 2023	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at December 31, 2023 and March 31, 2023; 27,029,731 and 7,315,583 shares issued at December 31, 2023 and March 31, 2023, respectively	27,000	7,300
Additional paid-in capital	473,918,200	342,892,500
Treasury stock, at cost, 4,522 shares of common stock held at December 31, 2023 and March 31, 2023	(3,968,100)	(3,968,100)
Accumulated deficit	(346,692,300)	(326,851,700)
Total stockholders' equity	123,284,800	12,080,000
Total liabilities and stockholders' equity	$ 131,068,000	$ 21,089,200

VISTAGEN THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Sublicense and other revenue	$ 411,400	$ 179,600	$ 866,700	$ (402,900)
Total revenues	411,400	179,600	866,700	(402,900)
Operating expenses:				
Research and development	4,537,600	6,854,000	12,585,400	35,039,800
General and administrative	3,757,800	3,092,100	9,943,300	11,586,200
Total operating expenses	8,295,400	9,946,100	22,528,700	46,626,000
Loss from operations	(7,884,000)	(9,766,500)	(21,662,000)	(47,028,900)
Other income, net:				
Interest income, net	1,534,200	5,300	1,823,900	13,700
Loss before income taxes	(6,349,800)	(9,761,200)	(19,838,100)	(47,015,200)
Income taxes	-	-	(2,500)	(5,500)
Net loss and comprehensive loss	$ (6,349,800)	$ (9,761,200)	$ (19,840,600)	$ (47,020,700)
Basic and diluted net loss per common share	$ (0.22)	$ (1.42)	$ (1.27)	$ (6.82)
Weighted average common shares outstanding, basic and diluted	29,388,085	6,894,603	15,632,451	6,891,641

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