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): August 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 August 13, 2024, Vistagen Therapeutics, Inc. (the "*Company*") issued a press release announcing financial results for its fiscal year 2025 first quarter ended June 30, 2024. 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 August 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: August 13, 2024

By: */s/ Shawn K. Singh*

Shawn K. Singh
Chief Executive Officer

Exhibit 99.1

Vistagen

Vistagen Reports Fiscal Year 2025 First Quarter Financial Results and Corporate Update

PALISADE Phase 3 Program for the acute treatment of Social Anxiety Disorder progressing on track

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)—August 13, 2024-- Vistagen (Nasdaq: VTGN), a late clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on nose-to-brain neurocircuitry, today reported financial results for its fiscal year 2025 first quarter ended June 30, 2024, and provided a corporate update.

"Building on the success of our PALISADE-2 Phase 3 trial of fasedienol, our rapid-onset, non-systemic pherine nasal spray for the acute treatment of social anxiety disorder, our top priority remains driving forward our U.S. registration-directed PALISADE Phase 3 program for fasedienol. Our PALISADE-3 Phase 3 trial is underway and on track and preparations to initiate our PALISADE-4 Phase 3 trial are progressing as planned," said Shawn Singh, Chief Executive Officer of Vistagen. "In addition to fasedienol, we are excited about the progress in our other two lead pherine development programs, itruvone for major depressive disorder and PH80 for menopausal hot flashes. With novel non-systemic mechanisms of action utilizing nose-to-brain neural circuits, each of our pherine clinical-stage programs has potential to transform current treatment paradigms, set new standards of care, and improve the lives of millions of underserved individuals."

Fasedienol for the Acute Treatment of Social Anxiety Disorder (SAD)

- Vistagen's **PALISADE-3 Phase 3 trial** remains on track to produce top-line results in 2025, in line with previous guidance.
- Vistagen's preparations to initiate its **PALISADE-4 Phase 3** trial as planned in the second half of 2024 and to produce top-line results in 2025 are also on track.
- There is no FDA-approved acute treatment for SAD. Vistagen's PALISADE-3 and PALISADE-4 Phase 3 trials are designed similarly to the Company's positive PALISADE-2 Phase 3 trial of fasedienol for the acute treatment of SAD reported in 2023. With PALISADE-2, Vistagen became the first company to report a positive Phase 3 trial of a new drug candidate for the acute treatment of SAD. 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 to the FDA for the acute treatment of anxiety in adults with SAD.

Itruvone for Major Depressive Disorder (MDD)

- Leveraging positive results from an exploratory Phase 2A trial in MDD previously conducted in Mexico, Vistagen completed its successful U.S. Investigational New Drug (IND)-enabling program to facilitate further Phase 2 development of itruvone in the U.S. Preparations and planning for a Phase 2B trial of itruvone are ongoing, with a primary focus to develop itruvone as a novel, non-systemic, stand-alone treatment for MDD without the sexual side effects, weight gain, and safety concerns associated with current depression therapies.

PH80 for Vasomotor Symptoms (Hot Flashes) due to Menopause

- Following positive results from an exploratory Phase 2A trial conducted in Mexico, similar to its successful U.S. IND-enabling program for itruvone in MDD, Vistagen's ongoing U.S. IND-enabling program is designed to support its planned submission of a U.S. IND to facilitate further Phase 2 clinical development of PH80 in the U.S., with a primary focus on its potential as a novel non-systemic, hormone-free treatment option for millions of women affected by vasomotor symptoms (hot flashes) due to menopause.

Financial Results for Fiscal Year 2025 First Quarter Ended June 30, 2024

Research and development (R&D) expenses

- R&D expenses were $7.6 million for the three months ended June 30, 2024, as compared to $4.2 million for the three months ended June 30, 2023. The increase in R&D expenses was primarily due to an increase in clinical and development expenses related to the commencement of the Company's PALISADE-3 Phase 3 trial, and costs related to preparations for the initiation of its PALISADE-4 Phase 3 trial of fasedienol in SAD, an increase in headcount costs, and an increase in consulting and professional fees.

General and administrative (G&A) expenses

- G&A expenses were $4.6 million for the three months ended June 30, 2024, as compared to $3.0 million for the three months ended June 30, 2023. The increase in G&A expenses was primarily due to an increase in headcount costs and professional service expenses to support the continued expansion of administrative activities.

Net loss

- Net loss was $10.7 million for the three months ended June 30, 2024, as compared to $6.9 million for the three months ended June 30, 2023.

Other financial highlights

- Cash, cash equivalents, and marketable securities were $108.4 million as of June 30, 2024.

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: 13748020
Webcast: **https://viavid.webcasts.com/starthere.jsp?ei=1680978&tp_key=f7af16cbaa**

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, August 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 13748020.

About Fasedienol Nasal Spray for Acute Treatment of Social Anxiety Disorder

Fasedienol is a first-in-class, rapid-onset investigational pherine nasal spray with a novel proposed mechanism of action (MOA) that is differentiated from all currently approved anxiety medications. Fasedienol's proposed MOA regulates the olfactory-amygdala neural circuits of fear and anxiety and attenuates the tone of the sympathetic autonomic nervous system, without systemic distribution, potentiation of GABA-A receptors, or direct activity on neurons in the brain. Vistagen's U.S. registration-directed PALISADE Phase 3 program for fasedienol is focused on the acute treatment of SAD. Fasedienol has not demonstrated any signals of abuse potential or physical dependence in any clinical trial conducted to date. There is no FDA-approved acute treatment for SAD. The FDA has granted Fast Track designation for the investigation of fasedienol for the acute treatment of SAD.

About Itruvone Nasal Spray for Major Depressive Disorder

Itruvone is an investigational pherine nasal spray with a novel, rapid-onset proposed neurocircuitry-focused mechanism of action (MOA) that is fundamentally differentiated from the MOA of all currently approved treatments for depression disorders. Itruvone is administered intranasally at microgram-level doses and is designed to engage and activate chemosensory neurons in the nasal cavity connected to neural circuits in the brain that produce antidepressant effects. Specifically, itruvone's proposed MOA involves the regulation of the olfactory-to-amygdala neural circuitry and is believed to increase the activity of the limbic-hypothalamic sympathetic nervous system and increase the release of catecholamines. Importantly, unlike all currently approved oral antidepressants and ketamine-based therapy (KBT),

including both intravenous ketamine and intranasal ketamine, we believe itruvone has potential to achieve antidepressant effects without systemic absorption or brain penetration and without many of the side effects and safety concerns potentially associated with currently approved antidepressants requiring systemic distribution. The FDA has granted Fast Track designation for the development of itruvone as a potential treatment for major depressive disorder.

About PH80 Nasal Spray for Vasomotor Symptoms (Hot Flashes) Due to Menopause

PH80 is a hormone-free investigational neuroactive pherine nasal spray with a novel neurocircuitry-focused mechanism of action (MOA) that is fundamentally differentiated from all currently approved treatment options for women's health indications. PH80's proposed MOA does not require systemic absorption or direct activity on neurons in the brain. Vistagen is developing PH80 as a potential new non-systemic, hormone-free treatment for the management of vasomotor symptoms (hot flashes) due to menopause.

About Vistagen

Headquartered in South San Francisco, CA, Vistagen (Nasdaq: VTGN) is a late clinical-stage neuroscience-focused biopharmaceutical company dedicated to the development and commercialization of groundbreaking therapies for psychiatric and neurological disorders based on its pioneering approach and deep understanding of nose-to-brain neurocircuitry. Designed exclusively as nasal sprays administered at microgram level doses with novel non-systemic mechanisms of action, Vistagen's diversified pipeline of pherine product candidates rapidly activate chemosensory neurons in the nasal cavity to impact olfactory system and brain neurocircuitry. Favorable safety profiles have been observed in all clinical studies of Vistagen's pherine product candidates completed to date. Vistagen's neuroscience pipeline also includes an oral prodrug with the potential to modulate NMDA receptor activity in multiple neurological conditions, such as levodopa-induced dyskinesia associated with Parkinson's disease therapy and neuropathic pain. At Vistagen, we are passionate about creating novel and differentiated treatments that set new standards of care for millions of people living with anxiety, depression, and other neurological 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 Therapeutics, Inc. (Vistagen or the Company) 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, planned or 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 delays in launching, conducting and/or completing ongoing and planned nonclinical studies and clinical trials, including PALISADE-3 and PALISADE-4 or additional Phase 2 clinical trials of itruvone or PH80; the period over which the Company anticipates its available financial resources will fund its operating expenses; the timing of completion of preclinical studies and clinical trials and related preparatory work required to apply for an maintain regulatory approval for any of the Company's drug candidates; 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 nonclinical 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, 2024, and in the Company's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2024	March 31, 2024
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,918	$ 119,166
Marketable securities	5,446	-
Prepaid expenses and other current assets	2,474	1,506
Total current assets	110,838	120,672
Property and equipment, net	489	435
Right-of-use asset - operating lease	1,703	1,820
Other assets	518	726
Total assets	$ 113,548	$ 123,653
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,209	$ 1,547
Accrued expenses	2,164	2,235
Deferred revenue - current portion	2,296	791
Operating lease obligation - current portion	567	550
Total current liabilities	6,236	5,123
Deferred revenue - non-current portion	1,086	2,674
Operating lease obligation - non-current portion	1,423	1,570
Total liabilities	8,745	9,367
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2024 and March 31, 2024; no shares outstanding at June 30, 2024 and March 31, 2024	-	-
Common stock, $0.001 par value; 325,000,000 shares authorized at June 30, 2024 and March 31, 2024; 27,059,629 and 27,029,731 shares issued at June 30, 2024 and March 31, 2024, respectively	27	27
Additional paid-in capital	475,689	474,441
Treasury stock, at cost, 4,522 shares of common stock held at June 30, 2024 and March 31, 2024	(3,968)	(3,968)
Accumulated other comprehensive income	2	-
Accumulated deficit	(366,947)	(356,214)
Total stockholders' equity	104,803	114,286
Total liabilities and stockholders' equity	$ 113,548	$ 123,653

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VISTAGEN THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended June 30,	
	2024	**2023**
Revenues:		
Sublicense and other revenue	$ 84	$ 177
Total revenues	84	177
Operating expenses:		
Research and development	7,648	4,197
General and administrative	4,567	2,978
Total operating expenses	12,215	7,175
Loss from operations	(12,131)	(6,998)
Other income, net:		
Interest income, net	1,398	98
Loss before income taxes	(10,733)	(6,900)
Income taxes	-	(3)
Net loss	$ (10,733)	$ (6,903)
Unrealized gain on marketable securities	2	—
Comprehensive loss	$ (10,731)	$ (6,903)
Basic and diluted net loss per common share	$ (0.35)	$ (0.94)
Weighted average common shares outstanding, basic and diluted	30,603,435	7,337,005