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 13, 2024 (November 08, 2024)

Kyverna Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41947**	**83-1365441**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
5980 Horton St., STE 550 Emeryville, California		**94608**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (510) 925-2492

N/A

(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 $0.00001 per share	KYTX	The Nasdaq Stock Market LLC

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

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 13, 2024, Kyverna Therapeutics, Inc. (the "Company") issued a press release providing a business update and reporting financial results for the quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

In accordance with General Instructions B.2 of Form 8-K, the information in Item 2.02 of this Current Report and Exhibit 99.1 hereto, 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 liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 8, 2024, James Chung, M.D., Ph.D., Chief Medical Officer of the Company, resigned from the Company, to be effective as of November 22, 2024. Dr. Chung's resignation was not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release issued by Kyverna Therapeutics, Inc. dated November 13, 2024.
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 hereunto duly authorized.

KYVERNA THERAPEUTICS, INC.

Date: November 13, 2024

By: /s/ Warner Biddle
Warner Biddle
Chief Executive Officer

Exhibit 99.1

Kyverna Therapeutics Provides Business Update and Reports Third Quarter 2024 Financial Results

Multiple Key Leadership Appointments, Including Warner Biddle as CEO, Bringing Clinical, Commercial and Strategic Expertise in Cell Therapy

Continuing to Advance Broad KYSA Clinical Development Program: Presented Clinical Data Highlighting Potential for KYV-101 in SPS, MG and MS at ECTRIMS and Plan to Share Updated Clinical Data in LN at Company Symposium at ACR Convergence 2024

Strong Financial Position; Ended the Quarter With $321.6 Million in Cash, Cash Equivalents and Marketable Securities

EMERYVILLE, Calif., November 13, 2024 – Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today reported its business highlights and financial results for the third quarter ended September 30, 2024.

“With KYV-101 advancing towards later stages of development, we are scaling Kyverna to bring the transformative impact of our differentiated CAR T therapies to patients with a range of B cell-driven autoimmune diseases. Since I joined the company in September, we have made significant progress, both clinically and operationally, to maintain Kyverna’s leadership position,” said Warner Biddle, Chief Executive Officer of Kyverna. “At ECTRIMS, we shared promising clinical data highlighting KYV-101’s potential to reset the immune system and durably improve symptoms of neuroinflammatory diseases. At ACR Convergence 2024 later this week, we will share the latest clinical data from lupus nephritis patients demonstrating the potential for durable treatment effect at the target clinical dose.”

Mr. Biddle continued, “In order to deliver on the long-term opportunity for KYV-101, we are working to sharpen our focus, leveraging our clinical datasets and academic partnerships, and continue executing our KYSA clinical trial programs. In 2025 we will share our long-term plan in both neuroinflammatory and rheumatologic diseases.”

Third Quarter 2024 and Recent Business Highlights

KYV-101 Clinical Data Updates:

- **KYV-101 Clinical Data in Neuroinflammatory Indications Presented at ECTRIMS:** In September 2024, in a company-sponsored symposium at the 40th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Kyverna presented data from 11 patients with stiff-person syndrome, myasthenia gravis and multiple sclerosis reinforcing KYV-101's broad potential in B cell-driven neuroinflammatory diseases. Numerous patients demonstrated ongoing durability at one year and beyond.
- **KYV-101 Clinical Data in Lupus Nephritis to be Presented at the American College of Rheumatology (ACR) Convergence 2024:** At a company-sponsored symposium at ACR Convergence 2024, being held in Washington, DC from November 14 - 19, 2024, Kyverna will share clinical data from lupus nephritis patients with at least six months of follow-up after treatment with KYV-101 at its selected target dose. The Company expects to share efficacy, safety and durability data, and highlight KYV-101’s impact on clinically relevant pillars of disease: preservation of kidney function, symptom improvement in underlying disease and elimination of immunosuppressive therapy.

  Also at ACR Convergence 2024, Kyverna will present one oral and two poster presentations outlining its approach to understanding mechanisms of immune reset and detailing Kyverna’s next-generation CAR T-cell therapies, including preclinical data on Ingenui-T, the Company’s 3-day manufacturing process using autologous whole blood as starting material.

KYV-101 Clinical Development Program Updates:

As of November 2024, Kyverna initiated Phase 2 dosing with KYV-101, received RMAT designation in two indications and received Orphan Drug Designation in three indications.

- **Stiff-Person Syndrome:** Kyverna anticipates initiating dosing by end-of-year in KYSA-8, the Company's Phase 2 study in Stiff-Person Syndrome, for which KYV-101 has been granted an RMAT designation and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA).
- **Myasthenia Gravis:** Kyverna initiated dosing in KYSA-6, the Company's Phase 2 study in myasthenia gravis, for which KYV-101 has been granted an RMAT designation and Orphan Drug Designation by the U.S. FDA. Additionally, in November 2024, the European Medicines Association (EMA) granted Orphan Drug Designation to KYV-101 for treatment of myasthenia gravis.
- **Multiple Sclerosis:** Kyverna's academic partners at Stanford and UCSF initiated dosing in Phase 1 investigator-initiated trials (IITs) for the use of KYV-101 in multiple sclerosis. Kyverna intends to leverage these clinical insights and collaborate with FDA to design a potential registration-enabling study for KYSA-7 in multiple sclerosis.
- **Lupus Nephritis:** Kyverna completed the dose-escalation cohort of KYSA-1 and is currently treating patients at the target dose in both KYSA-1 (US) and KYSA-3 (EU), the Company's Phase 1/2 studies in lupus nephritis.
- **Systemic Sclerosis:** Kyverna initiated dosing in KYSA-5, the Company's Phase 1/2 study in systemic sclerosis. In September 2024, KYV-101 was granted Orphan Drug Designation from the U.S. FDA for the treatment of systemic sclerosis.

Corporate, Operational & Manufacturing Updates

- **Kyverna Leadership Updates:** Kyverna strengthened its management team and Board of Directors with key leadership appointments to support the company's evolution in preparation for its next phase of growth, including:
  - Warner Biddle as Chief Executive Officer (CEO) and a member of the Board of Directors, bringing over 30 years of global experience in commercial, product planning and franchise leadership, including successful launches of several CAR-T products.
  - Christi Shaw and Mert Aktar to the Board of Directors, bringing decades of industry leadership in corporate strategy and manufacturing expertise, including for gene and cell therapy.
  - Cara Bauer as Chief Human Resources Officer (CHRO), bringing expertise in human resources strategy, culture building and talent development to support scaling global organizations.

  In addition, Kyverna announced today that James Chung, M.D., Ph.D., the Company's Chief Medical Officer, will step down from his position to pursue external opportunities, effective November 22, 2024. Kyverna has initiated a search for an external candidate to replace Dr. Chung.

- **Expanded Manufacturing Capacity to Support Advancing Clinical Development**: In October 2024, Kyverna signed an agreement with ElevateBio as a second-source supplier for KYV-101.

- **Publication Highlights Manufacturing Capabilities with KYV-101 in Autoimmune Disease:** In October 2024, Kyverna and collaborators published "Successful Generation of Fully Human, Second Generation, Anti-CD19 CAR T Cells for Clinical Use in Patients with Diverse Autoimmune Disorders" in Cytotherapy. The publication details Kyverna's 100% manufacturing success rate for KYV-101 in 20 patients, demonstrating a robust and consistent process for manufacturing and delivering its fully human anti-CD19 CAR T cell therapy across various autoimmune indications.

Financial Results for the Quarter Ended September 30, 2024

For the quarter ended September 30, 2024, the company reported a net loss of $34.3 million, or a net loss per common share of $0.80, compared to a net loss of $15.5 million, or a net loss per common share of $23.27, for the same period in 2023.

During the nine months ended September 30, 2024, net cash used in operating activities was $77.2 million, compared to $33.8 million for the same period in 2023.

Kyverna reported $321.6 million in cash, cash equivalents, and available-for-sale marketable securities as of September 30, 2024.

About Kyverna Therapeutics

Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases.

Our lead CAR T-cell therapy candidate, KYV-101, is advancing through clinical development across two broad areas of autoimmune disease: rheumatology and neurology, including Phase 2 trials for Stiff-Person Syndrome, myasthenia gravis, and multiple sclerosis, a Phase 1/2 trial for systemic sclerosis, and two ongoing multi-center Phase 1/2 trials in the United States and Germany for patients with lupus nephritis.

Kyverna's pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats with properties intended to be well suited for use in B cell-driven autoimmune diseases.

For more information, please visit www.kyvernatx.com.

Forward-looking Statements

This press release contains forward looking statements that are based on management's beliefs and assumptions and on information currently available to management of Kyverna Therapeutics, Inc. ("Kyverna", "we", "our," or the "Company"). All statements other than statements of historical facts contained in this press release are forward looking statements. Forward looking statements include, but are not limited to, statements concerning: the Company's future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies and named patient activities, ongoing clinical trials, research and development costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations. These forward-looking statements are subject to risks and uncertainties, including the factors described under the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 26, 2024 and any subsequent Quarterly Reports on Form 10-Q filed by the Company. Actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. When evaluating Kyverna's business and prospects, careful consideration should be given to these risks and uncertainties. These statements speak only as of the date of this press release, and Kyverna undertakes no obligation to update or revise these statements.

For more information, please contact:

Precision AQ on behalf of Kyverna Therapeutics
Investors: InvestorRelations@kyvernatx.com
Media: media@kyvernatx.com

Kyverna Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 29,193	$ 13,644	$ 78,990	$ 32,760
General and administrative	9,577	2,638	22,573	8,269
Total operating expenses	38,770	16,282	101,563	41,029
Loss from operations	(38,770)	(16,282)	(101,563)	(41,029)
Interest income	4,355	880	11,784	1,493
Interest expense	(32)	(50)	(115)	(140)
Other expense, net	(45)	(13)	(94)	(23)
Total other income, net	4,278	817	11,575	1,330
Net loss	(34,492)	(15,465)	(89,988)	(39,699)
Other comprehensive income				
Unrealized gain on available-for-sale marketable securities, net	190	5	149	31
Total other comprehensive income	190	5	149	31
Net loss and other comprehensive income (loss)	$ (34,302)	$ (15,460)	$ (89,839)	$ (39,668)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.80)	$ (23.27)	$ (2.45)	$ (62.75)
Weighted-average shares of common stock outstanding, basic and diluted	43,155,858	664,656	36,702,183	632,624

Kyverna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 104,663	$ 34,647
Available-for-sale marketable securities	216,924	22,896
Prepaid expenses and other current assets	3,787	3,121
Total current assets	325,374	60,664
Restricted cash	564	565
Property and equipment, net	3,151	2,326
Operating lease right-of-use assets	7,153	6,494
Finance lease right-of-use assets	1,078	1,790
Other non-current assets	1,876	3,356
Total assets	$ 339,196	$ 75,195
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 9,932	$ 4,358
Accrued compensation	4,440	2,812
Accrued license expense – related party	6,250	6,250
Other accrued expenses and current liabilities	6,432	3,519
Operating lease liabilities, short-term portion	3,000	1,964
Finance lease liabilities, short-term portion	931	956
Total current liabilities	30,985	19,859
Operating lease liabilities, net of short-term portion	4,968	5,238
Finance lease liabilities, net of short-term portion	237	921
Other non-current liabilities	296	—
Total liabilities	36,486	26,018
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, no par value; no shares authorized, issued and outstanding as of September 30, 2024; $0.00001 par value, 114,556,997 shares authorized as of December 31, 2023; 114,556,997 shares issued and outstanding as of December 31, 2023; liquidation preference of $181,273 as of December 31, 2023	—	180,574
Stockholders' equity (deficit)		
Preferred stock, 10,000,000 shares authorized, $0.00001 par value, no shares issued and outstanding as of September 30, 2024; no shares authorized, issued, and outstanding as of December 31, 2023	—	—
Common stock, $0.00001 par value; 490,000,000 and 140,492,016 shares authorized as of September 30, 2024 and December 31, 2023, respectively; 43,167,337 and 1,250,103 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	528,588	4,642
Accumulated other comprehensive income	153	4
Accumulated deficit	(226,031)	(136,043)
Total stockholders' equity (deficit)	302,710	(131,397)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 339,196	$ 75,195