

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): May 14, 2024

Kyverna Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41947
(Commission File Number)

83-1365441
(IRS Employer
Identification No.)

5980 Horton St., STE 550
Emeryville, California
(Address of Principal Executive Offices)

94608
(Zip Code)

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

(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 May 14, 2024, Kyverna Therapeutics, Inc. (the “Company”) issued a press release providing a business update and reporting financial results for the first quarter ended March 31, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release issued by Kyverna Therapeutics, Inc., dated May 14, 2024.

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: May 14, 2024

By: /s/ Peter Maag, Ph.D.

Peter Maag, Ph.D.

Chief Executive Officer

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

- *Advanced clinical development in two broad areas of autoimmune disease: rheumatology and neurology*
- *Treated 30 patients cumulatively as of May 14, 2024, including eight patients with myasthenia gravis, seven patients with lupus nephritis, and four patients with multiple sclerosis*
- *Strong balance sheet, bolstered by recent public offering*

EMERYVILLE, Calif., May 14, 2024 – Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today reported its business highlights and financial results for the first quarter ended March 31, 2024.

“We continue to build momentum in the clinical development of our lead product candidate, KYV-101, as we seek to bring autoimmune CAR T-cell therapies to more patients across both the US and Europe,” said Peter Maag, Chief Executive Officer of Kyverna. “We are excited to build on our leadership position in 2024 and continue to execute diligently on our promise to bring hope to patients living with autoimmune disorders.”

First Quarter 2024 and Recent Business Highlights

- Advanced clinical development of KYV-101, our proprietary CD19 chimeric antigen receptor (CAR) T-cell therapy for autoimmunity, in clinical trials and investigator-initiated trials across the US and Europe
- Treated 30 patients cumulatively as of May 14, 2024, including eight patients with myasthenia gravis, seven patients with lupus nephritis, and four patients with multiple sclerosis
- Published early clinical data showing first-in-disease use of KYV-101 in patients with refractory progressive multiple sclerosis
- KYV-101 granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of myasthenia gravis
- Progressed the global KYSA clinical trial program in multiple indications across rheumatology and neurology: Phase 1/2 trials in lupus nephritis (KYSA-1 and KYSA-3), a Phase 1/2 trial in systemic sclerosis (KYSA-5), a Phase 2 trial in myasthenia gravis (KYSA-6), and a Phase 2 trial in multiple sclerosis (KYSA-7)
- Strengthened balance sheet with approximately \$366.9 million in gross proceeds from our initial public offering in February 2024

Upcoming Milestones

- Interim patient data releases and symposia at EULAR in second quarter of 2024, ECTRIMS in third quarter of 2024 and ACR in fourth quarter of 2024
- Regulatory progress in rheumatology and neurology in the US and Europe
- Ongoing progress with Ingenui-T, our manufacturing process designed to improve patient experience and manufacturing efficiencies
- Updates on KYV-201, our allogeneic CD19 CAR T-cell product candidate

Financial Results for the Quarter Ended March 31, 2024

For the quarter ended March 31, 2024, the company reported a net loss of \$26.7 million, or a net loss per common share of \$1.12, compared to a net loss of \$11.1 million, or a net loss per common share of \$12.10, for the same period in 2023.

During the quarter ended March 31, 2024, net cash used in operating activities was \$25.5 million, compared to \$11.5 million for the same period in 2023.

Kyverna reported \$369.8 million in cash, cash equivalents, and available-for-sale marketable securities as of March 31, 2024, inclusive of approximately \$336.2 million in net proceeds raised from its initial public offering that was completed in February 2024, after deducting underwriting discounts and commissions and other offering costs.

About Kyverna Therapeutics

Kyverna 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 with sponsored clinical trials across two broad areas of autoimmune disease: rheumatology and neurology, including Phase 2 trials for multiple sclerosis and myasthenia gravis, a Phase 1/2 trial for systemic sclerosis, and two ongoing multi-center, open-label Phase 1/2 trials in the United States and Germany for patients with lupus nephritis.

Kyverna's pipeline includes next-generation chimeric antigen receptor (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:**Investor Contact:**

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Media Contact:

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kyvernatx@consortpartners.com

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses		
Research and development	\$ 22,476	\$ 8,711
General and administrative	6,882	2,734
Total operating expenses	29,358	11,445
Loss from operations	(29,358)	(11,445)
Interest income	2,735	349
Interest expense	(44)	(44)
Other expense, net	(26)	(3)
Total other income, net	2,665	302
Net loss	(26,693)	(11,143)
Other comprehensive gain (loss)		
Unrealized gain (loss) on available-for-sale marketable securities, net	(5)	18
Total other comprehensive gain (loss)	(5)	18
Net loss and other comprehensive loss	\$ (26,698)	\$ (11,125)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.12)	\$ (12.10)
Weighted-average shares of common stock outstanding, basic and diluted	23,754,062	921,260

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

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 224,287	\$ 34,647
Available-for-sale marketable securities	145,507	22,896
Prepaid expenses and other current assets	5,694	3,121
Total current assets	375,488	60,664
Restricted cash	570	565
Property and equipment, net	2,714	2,326
Operating lease right-of-use assets	8,486	6,494
Finance lease right-of-use assets	1,552	1,790
Other non-current assets	1,174	3,356
Total assets	\$ 389,984	\$ 75,195
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 7,451	\$ 4,358
Accrued compensation	1,363	2,812
Accrued license expense – related party	6,250	6,250
Other accrued expenses and current liabilities	3,083	3,519
Operating lease liabilities, short-term portion	2,739	1,964
Finance lease liabilities, short-term portion	979	956
Total current liabilities	21,865	19,859
Operating lease liabilities, net of short-term portion	6,461	5,238
Finance lease liabilities, net of short-term portion	667	921
Total liabilities	28,993	26,018
Commitments and contingencies		
Redeemable convertible preferred stock, no par value; no shares authorized, issued and outstanding as of March 31, 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 \$181,250 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 March 31, 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 March 31, 2024 and December 31, 2023, respectively; 43,115,244 and 1,250,103 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	523,728	4,642
Accumulated other comprehensive income (loss)	(1)	4
Accumulated deficit	(162,736)	(136,043)
Total stockholders' equity (deficit)	360,991	(131,397)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 389,984	\$ 75,195

