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): July 15, 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 7.01 Regulation FD Disclosure.

On July 15, 2024, Kyverna Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has granted Regenerative Medicine Advanced Therapeutic ("RMAT") designation for KYV-101 for the treatment of stiff-person syndrome ("SPS"). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached 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 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 provided by specific reference in such a filing.

Item 8.01 Other Events.

On July 15, 2024, the Company announced that the FDA granted RMAT designation for KYV-101 for the treatment of SPS.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Kyverna's KYV-101 Receives U.S. FDA RMAT Designation for KYV-101 in the Treatment of Patients With Refractory Stiff-Person Syndrome
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: July 15, 2024

By: /s/ Peter Maag, Ph.D.
Name: Peter Maag, Ph.D.
Title: Chief Executive Officer

Exhibit 99.1

Kyverna's KYV-101 Receives U.S. FDA RMAT Designation for KYV-101 in the Treatment of Patients With Refractory Stiff-Person Syndrome

The application was evaluated based on the positive clinical outcomes of KYV-101 in patients treated in Germany under a named-patient treatment option

The Regenerative Medicine Advanced Therapies designation will allow Kyverna to receive expert guidance on efficient drug development and use of surrogate endpoints from senior FDA officials

EMERYVILLE, Calif**.** July 15, 2024 - Kyverna Therapeutics, Inc. (Kyverna), a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, announced today the designation as Regenerative Medicine Advanced Therapy (RMAT) by the U.S. Food and Drug Administration (FDA) for its autologous, fully human CD19 chimeric antigen receptor (CAR) T-cell product candidate, KYV-101, to be used for the treatment of patients suffering from refractory stiff-person syndrome.

"Stiff-person syndrome has devastating and life-altering effects on patients suffering from this rare autoimmune disease," said Amanda Piquet, M.D., director of the Autoimmune Neurology Program at CU Anschutz Medical Campus, Aurora, CO. "I look forward to the data that will emerge from the KYSA-8 trial as this trial could drastically change the treatment landscape for SPS."

"We are eager to begin generating data from our sponsored trial to advance the knowledge on a potential immunological reset of the patient's immune system," said Peter Maag, Ph.D., chief executive officer at Kyverna. "We are humbled by the resilience of the SPS patients and their hope for a potential paradigm-shifting treatment option that could provide durable, immunosuppressant-free remission."

About Stiff Person Syndrome (SPS)
SPS is a rare, progressive neurological autoimmune disorder causing debilitating muscle stiffness in the torso, arms, and legs, impacting the ability to walk or move. Patients typically present with muscle spasms and stiffness, resulting in difficulty turning and bending. When stiffness is severe, the patients' posture resembles a statue. Muscle spasms and stiffness can be precipitated by unexpected stimuli, including sounds, like a phone ring or a siren, sudden touches or conditions triggering anxiety and emotional upset which, when severe, are misdiagnosed as a primary anxiety disorder[1].

About KYV-101
KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate for use in B cell-driven autoimmune diseases. The CAR in KYV-101 was designed by the National Institutes of Health (NIH) to improve tolerability and tested in a 20-patient Phase 1 trial in oncology. Results were published by the NIH in Nature Medicine[2].

KYV-101 is currently being evaluated in sponsored, open-label, Phase 1/2 and Phase 2 trials of KYV-101 in the United States and Germany across two broad areas of autoimmune disease: rheumatology and neurology.
With 50 patients treated so far with the CAR in KYV-101 in both oncological and autoimmune conditions at more than 15 locations in Europe and the U.S., we believe that the differentiated properties of KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.
KYV-101 is also being evaluated in investigator-initiated trials for multiple indications in multiple geographies.

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 with sponsored clinical trials across two broad areas of autoimmune disease: rheumatology and neurology, including Phase 2 trials for stiff person syndrome, 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 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.

Forward-Looking Statements
Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Forward-looking statements in this press release include, without limitation, those related to: the potential impact of the clinical outcomes from the named-patient activities; the potential that the results of the KYSA-8 trial could drastically change the treatment landscape for SPS; Kyverna's goals to develop certain paradigm-shifting treatment options; the potential for KYV-101 to provide durable, immunosuppressant-free remission for SPS patients; Kyverna's beliefs about the differentiated properties of KYV-101; and Kyverna's clinical trials and named patient activities. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to market conditions, and other factors discussed in the "Risk Factors" section of Kyverna's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that Kyverna has filed or may subsequently file with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release are based on the current expectations of Kyverna's management team and speak only as of the

date hereof, and Kyverna specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

For more information, please visit https://kyvernatx.com.

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[1] Dalakas, M.C., Neurotherapeutics 2022; 19, 832–847.
[2] Brudno et al., *Nature Medicine* 2020; 26:270-280.