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 12, 2026

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., Suite 550 **Emeryville, California**	**94608**
(Address of Principal Executive Offices)	**(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 12, 2026, Kyverna Therapeutics, Inc. (the "Company") issued a press release providing a business update and reporting financial results for the quarter ended March 31, 2026. 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 12, 2026.
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: May 12, 2026

By: /s/ Marc Grasso
Marc Grasso
Chief Financial Officer

Exhibit 99.1

Kyverna Therapeutics Announces Initiation of Rolling SPS BLA Submission and Reports First Quarter 2026 Financial Results

Positive pre-BLA meeting with FDA alignment reached on KYSA-8 single-arm trial in stiff person syndrome (SPS); rolling BLA submission initiated

Miv-cel pivotal trial primary analysis results in SPS demonstrated robust, durable effect in indication with no approved therapies; launch preparations continue with appointment of Nadia Dac as Chief Commercial Officer

Enrollment advances in Phase 3 trial in generalized myasthenia gravis (gMG), further derisked by Phase 2 longer-term follow-up data demonstrating durable efficacy out to one year

EMERYVILLE, Calif., May 12, 2026 -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today reported business and portfolio progress, and financial results for the first quarter ended March 31, 2026.

"As the first company to submit a BLA for an autoimmune CAR T therapy, gaining alignment with the FDA on a single-arm trial and a clear path to submission for miv-cel is a significant milestone for not only Kyverna but also the field," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "This achievement underscores both the hard work and dedication of our entire organization and the promising potential of miv-cel, starting with stiff person syndrome. As we execute our rolling BLA submission and prepare for launch in 2027, we are laying the foundation for a multi-indication neuroimmunology franchise that reinforces our leadership position in autoimmune CAR T. More broadly, we are well positioned to establish a new therapeutic paradigm, delivering durable drug-free, disease-free remission for patients."

Recent Progress in Neuroimmunology CAR T Franchise

- **FDA Alignment on SPS BLA submission:** Kyverna held a positive pre-BLA meeting with the FDA, in which the company gained alignment on its regulatory path for miv-cel in SPS, including a rolling BLA submission and all core components of its BLA package:
    - KYSA-8 single-arm pivotal Phase 2 trial is sufficient to support the BLA submission
    - Primary endpoint measurement is the Timed 25-foot Walk (T2FW) test at 16 weeks
    - Clinical safety package
    - Preclinical package
    - Chemistry, Manufacturing, and Controls (CMC) package

  In addition, the Company will include additional analysis of its completed natural history study presented at the 2026 American Academy of Neurology (AAN) annual meeting and

planned one-year follow-up data from KYSA-8. The natural history data provide context that further reinforces the magnitude of miv-cel's clinical impact in SPS as a progressive, debilitating disease with significant unmet medical need.

The Company has initiated its rolling BLA submission, seeking priority review under the program's Regenerative Medicine Advanced therapy (RMAT) designation, and anticipates completing the submission in Q4 2026.

- **KYSA-8 Primary Analysis Data Demonstrate Robust, Durable Treatment Effect in Patients with SPS:**
  - In April, Kyverna presented findings from the primary analysis of the pivotal KYSA-8 trial of miv-cel in a late-breaking oral presentation at the 2026 AAN annual meeting. The presentation expanded on previously reported positive topline results, demonstrating statistically significant, durable clinical benefit across all primary and secondary endpoints at 16 weeks, with reversal of disability scores following a single dose of miv-cel. In addition, 100% of patients remained free of immunotherapies for SPS as of Week 16 and through last follow-up. Miv-cel was also well tolerated.
  - The Company will share one-year follow-up data in the second half of 2026, which is expected to further demonstrate miv-cel's durable treatment effect. Notably, the first two SPS patients treated with a single dose of miv-cel through the IH pathway in Germany[1] have achieved durable efficacy of over 15 and 26 months, respectively, without the need for chronic immunotherapies.
  - Kyverna also presented outcomes from a large, multicenter, retrospective natural history study examining the impact of SPS on walking speed at AAN, which further contextualizes the transformative clinical data for miv-cel and supports the use of Timed 25-Foot Walk (T25FW) as a valid longitudinal measure of mobility in SPS. The study included 153 patients treated with off-label immunotherapies or symptomatic medications and with T25FW assessments available. The majority of patients showed minimal (<20%) or no improvement in T25FW and required increasing reliance on walking aids over time. Changes in T25FW correlated with changes in disability assessed by Modified Rankin Scale (mRS) over time. These findings further highlight the limited impact of current treatment approaches.

- **Enrollment Ongoing in Phase 3 Portion of KYSA-6 Registrational Trial for gMG:**
  - In April 2026, Kyverna presented longer-term follow-up data from the Phase 2 portion of the KYSA-6 clinical trial of miv-cel in an oral presentation at AAN, supporting miv-cel's potential to deliver durable drug-free, disease-free remission with a well-tolerated safety profile. The updated data demonstrated deep and durable clinical responses across all key outcome measures, with sustained benefit observed through one year following a single dose of miv-cel. Notably, 100% of patients achieved clinically meaningful, rapid and robust reductions in Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores from baseline (the co-primary endpoints of the Phase 3 portion of the trial), regardless of prior biologic exposure, and at deeper

levels observed compared to the interim analysis reported in October 2025. In addition, biomarker and mechanistic data further supported miv-cel's differentiated clinical profile.

- Kyverna expects to share longer-term Phase 2 follow-up data in gMG in the second half of 2026 and continues to enroll patients in its FDA-aligned Phase 3 gMG clinical trial across 15 activated sites globally.

- **Positive Miv-cel Data in Progressive Multiple Sclerosis (PMS):**
  - Updated follow-up data of up to twelve months from Stanford University's Phase 1 investigator-initiated trial (IIT) of miv-cel in PMS were presented at the Stanford Blood and Marrow Transplantation and Cellular Therapy Symposium in May 2026. A total of six patients have been treated receiving either 33M (n=3) or 100M (n=3) CAR T cells, using an alternative bendamustine lymphodepleting (LD) regimen, with four patients having reached 12 months of follow-up. Data showed robust CAR T expansion in blood and cerebrospinal fluid (CSF), and reconstitution of naïve B-cells supportive of immune reset. Of the 5 patients with post-treatment assessments, all achieved improvement or stability in their disability scores at last follow up, as measured by the expanded disability status scale scores (EDSS). Additional biomarker data, including CSF oligoclonal bands and kappa free light chain, continue to support favorable immunological impact. Among patients with available data in fatigue scores, 100% (4/4) showed improvements in scores from baseline. All patients remained off other immunomodulatory therapies and miv-cel was well-tolerated with no high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS).
  - Kyverna expects to provide a development update, including reporting additional data from the Phase 1 IIT study, in the second half of 2026.

Additional Pipeline Opportunities

- Kyverna continues to explore miv-cel with no LD or an alternative LD regimen and the potential for outpatient administration supported by miv-cel's consistent and well-tolerated safety profile.

Recent Business Highlights

- **Appointment of Nadia Dac as Chief Commercial Officer to further strengthen Company's commercial expertise**: Ms. Dac, a seasoned commercial leader in neurology and rare diseases, brings more than 30 years of U.S. and global commercial leadership in the biopharmaceutical industry, executing successful new product launches and building high-performing commercial organizations, including those making the transition to commercial-stage for the first time.
- Kyverna has advanced its SPS launch-readiness activities, including commercial site activation activities, payer engagement, and healthcare professional (HCP) education. The Company's current manufacturing capacity is expected to fully support commercial launch of miv-cel.

Financial Results for the First Quarter Ended March 31, 2026

- Kyverna reported $236.4 million in cash, cash equivalents, and marketable securities as of March 31, 2026. The Company continues to expect to have a cash runway into 2028.
- Research and Development (R&D) expenses were $30.1 million for the first quarter ended March 31, 2026.
- General and Administrative (G&A) expenses were $11.3 million for the first quarter ended March 31, 2026.
- For the quarter ended March 31, 2026, the Company reported a net loss of $39.7 million, or a net loss per common share of $0.66.

About miv-cel (mivocabtagene autoleucel, KYV-101)
Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation, designed for potency and tolerability, which is under investigation for B-cell-driven autoimmune diseases. With a single administration, miv-cel has potential to achieve deep B-cell depletion and immune system reset to deliver durable drug-free, disease-free remission in autoimmune diseases.

About Kyverna Therapeutics
Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a late-stage clinical biopharmaceutical company focused on liberating autoimmune patients through the curative potential of cell therapy. Kyverna's lead autologous CD19-targeting CAR T-cell therapy candidate, miv-cel (mivocabtagene autoleucel, KYV-101), has demonstrated the potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases. Kyverna is advancing its potentially first-in-class neuroimmunology franchise with its recently completed registrational trial in stiff person syndrome and an ongoing registrational trial for generalized myasthenia gravis. The Company is also harnessing other KYSA trials and investigator-initiated trials, including in multiple sclerosis and rheumatoid arthritis, to inform the next priority indications. Additionally, its next generation pipeline includes CAR T-cell therapies deploying novel innovations to improve patient access and experience. For more information, please visit https://kyvernatx.com.

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: Kyverna's regulatory path for SPS, including the rolling BLA submission for SPS, the anticipated information to be included therein and the expected timing for completing such submission, as well as potential for priority review under an RMAT designation; the Phase 3 trial for gMG and status of enrollment in such trial; Kyverna's foundation for a multi-indication neuroimmunology franchise and its potential leadership position in autoimmune CAR-T; Kyverna's potential readiness for commercial launch of miv-cel in SPS, including the sufficiency of its manufacturing capacity and cash runway; Kyverna's potential first-in-class neuroimmunology

CAR T franchise; the potential for outpatient administration of miv-cel in SPS; miv-cel's potential to deliver durable, drug-free, disease-free remission in gMG or other autoimmune diseases; miv-cel's well-tolerated safety profile; the potential that the one-year follow-up data for SPS will further demonstrate miv-cel's durability of treatment effect; and Kyverna's expected upcoming pipeline milestones and anticipated timing for sharing data, including for SPS, gMG, PMS and additional pipeline opportunities. 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, the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; the possibility that the FDA or other regulatory agencies may require additional trials or studies to support its intended BLA submission; intellectual property rights; and other factors discussed in the "Risk Factors" section of Kyverna's previously filed Annual Report on Form 10-K for the year ended December 31, 2025 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 to be filed with the U.S. Securities and Exchange Commission on or about the date hereof. 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 contact:
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[1] Similar to expanded access or compassionate use in the United States, IH or "Individueller Heilversuch," also known as "named-patient basis access," is a regulatory mechanism in Germany that allows for the supply of a treatment that has not received marketing authorization for an individual patient in response to a request by the treating physician on behalf of the named patient. This option can be pursued for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician with the patient's consent. The use of KYV-101 in the IH setting is not a substitute for, nor intended to replace, Kyverna's clinical trials. The goal is not to assess the effectiveness of a potential therapy, but rather to provide an individual patient with a possible efficacious approach when all other treatment options have failed, as determined by the patient's physician.

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

	Three Months Ended March 31,	
	2026	**2025**
Operating expenses		
Research and development	$ 30,073	$ 37,433
General and administrative	11,294	9,975
Total operating expenses	41,367	47,408
Loss from operations	(41,367)	(47,408)
Interest income	2,327	2,825
Interest expense	(667)	(25)
Other expense, net	(21)	(27)
Total other income, net	1,639	2,773
Net loss	(39,728)	(44,635)
Other comprehensive income (loss)		
Unrealized loss on available-for-sale marketable securities, net	(193)	(106)
Total other comprehensive loss	(193)	(106)
Net loss and other comprehensive loss	$ (39,921)	$ (44,741)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (1.03)
Weighted-average shares of common stock outstanding, basic and diluted	60,434,200	43,215,577

Kyverna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands)
(Unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 236,446	$ 279,253
Prepaid expenses and other current assets	5,280	3,700
Total current assets	241,726	282,953
Restricted cash	551	551
Property and equipment, net	1,343	1,546
Operating lease right-of-use assets	8,192	3,568
Finance lease right-of-use assets	198	305
Other non-current assets	5,014	4,903
Total assets	$ 257,024	$ 293,826
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Current liabilities	$ 29,674	$ 36,487
Non-current liabilities	31,770	25,063
Stockholders' equity	195,580	232,276
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 257,024	$ 293,826