Kyverna Therapeutics Provides Business Update and Reports First Quarter 2025 Financial Results

May 13, 2025

Enrollment complete in registrational Phase 2 KYV-101 trial in stiff person syndrome (SPS); on track for topline data in 1H 2026; biologics license application (BLA) filing now anticipated in 1H 2026

Advancing into registrational Phase 3 KYV-101 trial in myasthenia gravis (MG) following successful end-of-Phase 2 meeting with U.S. Food and Drug Administration (FDA); Phase 2 MG data anticipated in 2H 2025

Company to host KOL event in Q3 2025, spotlighting its accelerating neuroinflammation franchise

Strong financial position; cash runway into 2027 supports first BLA filing, MG Phase 3 trial and pre-launch activities

EMERYVILLE, Calif., May 13, 2025 /PRNewswire/ -- 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 quarter ended March 31, 2025.

"We are pleased to report an exceptional start to the year, marked by rapid execution against our focused strategy to advance development of KYV-101 and build Kyverna into a robust clinical and commercial-ready organization," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "Importantly, we have now aligned with the FDA on the registrational pathway for our two lead indications, SPS and MG, laying the foundation for accelerating our potential first-in-class neuroinflammation franchise. Having recently completed enrollment in KYSA-8, our registrational study in SPS, we now anticipate filing our first BLA in the first half of 2026 and are strategically investing in pre-launch activities. We are working with a sense of urgency given SPS is a debilitating and progressive disease with no currently approved therapies."

First Quarter 2025 Highlights and Recent Business Updates

KYV-101: *Autologous, fully human CD19 CAR T-cell product candidate, incorporating highly potent CD28 co-stimulation. KYV-101 is currently being evaluated in company-sponsored KYSA trials and investigator-initiated trials in numerous B cell mediated autoimmune diseases with a prioritized focus in stiff person syndrome, myasthenia gravis and lupus nephritis.*

Stiff Person Syndrome (SPS)

- Kyverna has completed patient enrollment in KYSA-8, its pivotal Phase 2 trial for KYV-101 in SPS. As previously announced, the Company has aligned with the FDA for KYSA-8 to serve as a registrational study in SPS, including its 25-patient trial size and use of the timed 25-foot walk test (T25FW) as the primary endpoint. The Company expects to report topline data from this study and submit its first BLA in the first half of 2026.
- At the American Academy of Neurology (AAN) Annual Meeting in April 2025, Kyverna presented a real-world analysis on functional outcome measures in patients with SPS. In collaboration with the University of Colorado, the study utilized the T25FW and modified Rankin Scale to assess disease severity and progression over time. Findings demonstrated that walking ability in patients with SPS, assessed by T25FW, gets worse over time, validating T25FW as a clinical measure of mobility and disease progression and supporting its utility in monitoring response to therapy.

Myasthenia Gravis (MG)

- Following a positive end-of-Phase 2 meeting with the FDA, Kyverna received written alignment confirming its plans to advance KYV-101 into a Phase 3 clinical trial. The Company plans to share details of the study design mid-year, including trial size and endpoints.

- Kyverna remains on track to report interim data from KYSA-6, its ongoing Phase 2 trial in MG, in the second half of 2025.

Lupus Nephritis (LN)

- Kyverna remains on track to report data from the KYSA-1 and KYSA-3 Phase 1 trials in LN in the second half of 2025.

Additional Indications

- Kyverna is efficiently exploring additional opportunities for KYV-101 beyond the Company's priority indications through sponsored clinical trials and investigator-initiated trials (IITs) across numerous other autoimmune diseases, including multiple sclerosis (MS). Data from these efforts will inform selection of the next priority indication(s) to accelerate into late-stage development.
    - At AAN, researchers presented preliminary KYV-101 data in MS from two IITs, which showed a potentially favorable benefit/risk profile of KYV-101 in patients with progressive MS.

KYV-102: *Next-generation candidate incorporating Kyverna's patented, fully human CD19 CAR T and the Company's proprietary whole-blood rapid manufacturing approach, which aims to improve the CAR T patient experience, eliminate apheresis and broaden CAR T access.*

- Kyverna remains on track to file an investigational new drug application for KYV-102 in the second half of 2025.

Corporate and Manufacturing Updates

- Kyverna advanced chemistry, manufacturing, and controls (CMC) to enhance commercial readiness. In the first quarter:
    - The FDA confirmed the Company's planned CMC package to support commercial manufacturing of KYV-101 for SPS and MG as well as future indications, with extensive CMC experience in autoimmune disease from KYSA studies, IITs and compassionate use cases supporting process characterization.
    - Kyverna successfully initiated clinical manufacturing at Elevate Bio, the Company's second manufacturing partner, for which the FDA accepted comparability data between manufacturing sites.
- Kyverna has streamlined the organization to support the Company's late-stage development and commercialization objectives while preserving cash runway into 2027. This resulted in a workforce reduction of approximately 16% in the first quarter of 2025.

Virtual KOL Neuroinflammation Franchise Event

- Kyverna is planning to host a virtual KOL event in Q3 2025, highlighting its accelerating neuroinflammation franchise and differentiated CD19 asset, KYV-101.

Anticipated Milestones

Kyverna has issued the following guidance on upcoming program milestones:

- **SPS:**
    - Report Topline Pivotal Phase 2 Data 1H 2026
    - BLA filing in 1H 2026 (updated from previous guidance for 2026)
- **MG:**
    - Report Interim Phase 2 Data 2H 2025
- **LN:**

    - Report Phase 1 Data 2H 2025
- **Future Pipeline:**
    - File KYV-102 IND application 2H 2025

Financial Results for the Quarter Ended March 31, 2025

Kyverna reported $242.6 million in cash, cash equivalents, and available-for-sale marketable securities as of March 31, 2025. The Company expects this to provide a cash runway into 2027, which supports its first BLA filing, MG Phase 3 trial and pre-launch activities.

Research and Development (R&D) expenses were $37.4 million for the quarter ended March 31, 2025 compared to $22.5 million for the quarter ended March 31, 2024, which included $0.8 million and $0.6 million of non-cash stock-based compensation expenses, respectively.

General and Administrative (G&A) expenses were $10.0 million for the quarter ended March 31, 2025, compared to $6.9 million for the quarter ended March 31, 2024, which included $1.4 million and $1.7 million of non-cash stock-based compensation expenses, respectively.

For the quarter ended March 31, 2025, the Company reported a net loss of $44.6 million, or a net loss per common share of $1.03, compared to a net loss of $26.7 million, or a net loss per common share of $1.12, for the same period in 2024.

As noted in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 27, 2025, Kyverna's operating cash burn in the first half of 2025 is expected to be higher than its operating cash burn in the second half of 2025. In particular, the Company made certain one-time investments in its CMC readiness, which the Company expects to continue through the first half of 2025 to support commercial readiness for SPS and MG and the filing of its first BLA in 2026. The Company has also accelerated enrollment in certain of its clinical trials, with enrollment completed in its registrational Phase 2 trial in SPS.

About KYV-101

Uniquely designed, KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate with highly potent CD28 co-stimulation and designed for tolerability, which is under investigation for B-cell-driven autoimmune diseases. With KYV-101, Kyverna is pioneering a durable disease-clearing approach aiming for deep B cell depletion, an immune system reset, and long-term remission in autoimmune diseases.

About Kyverna Therapeutics

Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a clinical-stage biopharmaceutical company focused on liberating patients through the curative potential of cell therapy. Kyverna's lead CAR T-cell therapy candidate, KYV-101, is advancing through late-stage clinical development with registrational trials for stiff person syndrome and myasthenia gravis, and two ongoing multi-center Phase 1/2 trials for patients with lupus nephritis. The Company is also harnessing other KYSA trials and investigator-initiated trials, including in multiple sclerosis, to inform the next priority indications for the Company to advance into late-stage development. Its 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 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 strategic priorities and focus; the expected timing for releasing topline data for its Phase 2 trial in stiff person syndrome; the potential for KYV-101 to be a first-in-class neuroinflammation franchise; the potential for KYV-102 to improve the patient experience and broaden CAR T access; anticipated milestones and timing thereof, including anticipated timing for the first intended BLA submission for KYV-101 and timing for reporting data; the speed at which any approvals may be obtained; Kyverna's engagement with regulators; Kyverna's anticipated cash runway; and Kyverna's clinical trials, investigator initiated 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, 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 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.

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	$ 37,433	$ 22,476
General and administrative	9,975	6,882
Total operating expenses	47,408	29,358
Loss from operations	(47,408)	(29,358)
Interest income	2,825	2,735

Interest expense	(25)	(44)
Other expense, net	(27)	(26)
Total other income, net	2,773	2,665
Net loss	(44,635)	(26,693)
Other comprehensive loss		
Unrealized loss on available-for-sale marketable securities, net	(106)	(5)
Total other comprehensive loss	(106)	(5)
Net loss and other comprehensive loss	$ (44,741)	$ (26,698)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.03)	$ (1.12)
Weighted-average shares of common stock outstanding, basic and diluted	43,215,577	23,754,062

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

	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 242,649	$ 285,979
Prepaid expenses and other current assets	5,002	4,622
Total current assets	247,651	290,601
Restricted cash	557	552
Property and equipment, net	2,436	3,347
Operating lease right-of-use assets	5,764	6,468
Finance lease right-of-use assets	603	841
Other non-current assets	3,644	2,836
Total assets	$ 260,655	$ 304,645
Liabilities and stockholders' equity		
Current liabilities	$ 33,292	$ 33,756
Non-current liabilities	3,353	4,302
Stockholders' equity	224,010	266,587
Total liabilities and stockholders' equity	$ 260,655	$ 304,645

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