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

August 12, 2025

Topline data for registrational Phase 2 trial of KYV-101 in stiff person syndrome (SPS) and BLA submission anticipated in 1H 2026

Registrational Phase 3 KYV-101 trial in myasthenia gravis (MG) to include ~60 patients with enrollment to initiate by year-end 2025; interim Phase 2 data expected in Q4 2025

Strong cash position to support upcoming milestones

EMERYVILLE, Calif., Aug. 12, 2025 (GLOBE NEWSWIRE) -- 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 June 30, 2025.

"The second quarter was marked by continued strong execution of our focused strategy, as we achieved key clinical and regulatory milestones to advance our potential first-in-class neuroimmunology CAR T franchise," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "We anticipate this momentum will continue in the second half of the year with the initiation of our Phase 3 registrational trial in MG. We believe this is an efficient and well-powered trial given the substantial clinical effect size that has been observed in this patient population treated with KYV-101. More broadly, we are well-positioned to deliver on multiple near-term value-creating milestones with our interim Phase 2 MG data readout expected in the fourth quarter of this year as well as anticipated topline registrational data for SPS and BLA filing in the first half of next year. We look forward to sharing more details on these programs at our upcoming KOL event, where we will highlight KYV-101's differentiated clinical profile, our Phase 3 trial design for MG and the market opportunity for our neuroimmunology franchise."

Second Quarter 2025 Highlights and Recent Business Updates

KYSA-8 Registrational Phase 2 Trial for Stiff Person Syndrome (SPS)

- Patient enrollment for the registrational trial was completed in the second quarter of 2025. Kyverna remains on track to report topline data from this study and submit its first BLA in the first half of 2026.

KYSA-6 Registrational Phase 2/3 Trial for Myasthenia Gravis (MG)

- Following a successful end-of-Phase 2 meeting with the FDA, Kyverna is expanding its existing KYSA-6 trial to include a Phase 3 portion, which the Company expects to begin enrolling by year-end 2025. The Phase 3 portion of the registrational trial will include approximately 60 patients; further details on the study design will be shared during the Company's virtual KOL event on August 28, 2025.
- Kyverna has completed enrollment of the Phase 2 portion of the KYSA-6 trial and plans to report interim data in the fourth quarter of 2025.

KYSA-1 and KYSA-3 Trials for Lupus Nephritis (LN)

- Kyverna has concluded enrollment for KYSA-1 and KYSA-3 and plans to share the full data set from its Phase 1 LN trials in a peer-reviewed publication in 2026 as the Company continues to prioritize accelerating its late-stage neuroimmunology indications.

Additional Indications: Multiple Sclerosis (MS) and Rheumatoid Arthritis (RA)

- Kyverna is efficiently exploring additional opportunities for KYV-101 through sponsored clinical trials and investigator-initiated trials (IITs) across several other autoimmune diseases, including MS and RA. Data from these efforts will inform the Company's indication expansion strategy.
    - Phase 1 IIT data of KYV-101 in MS to be showcased at the 2025 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in September

2025, including an oral presentation on KYV-101 from Stanford University and a poster presentation from the University of California, San Francisco (UCSF).
    - Phase 1/2 IIT data of KYV-101 in RA from Charité – University of Berlin to be highlighted at the American College of Rheumatology (ACR) Convergence 2025 meeting in October 2025.

KYV-102

- Kyverna expects to file an investigational new drug (IND) application for KYV-102 in the fourth quarter of 2025. KYV-102 is produced with the Company's next-generation proprietary whole blood, rapid manufacturing process, incorporating the same construct as KYV-101. KYV-102 provides the opportunity to broaden access through the elimination of apheresis.

Corporate Updates

- In June 2025, Kyverna Therapeutics announced the appointment of Marc Grasso, M.D., as Chief Financial Officer. Dr. Grasso brings over 25 years of public company, capital markets and investment banking experience. His appointment marks a strategic addition to Kyverna's executive team as the company advances its late-stage clinical and commercial efforts in autoimmune cell therapy.
- Kyverna will host a virtual KOL event, "A Spotlight on Kyverna's Neuroimmunology CAR T Franchise," on Thursday, August 28, 2025, from 11:00 am – 1:30 pm ET. The event will be webcast live and those who intend to join can pre-register for the webcast **here**.

Anticipated Milestones
Kyverna has issued the following guidance on upcoming program milestones:

- **SPS:**
    - Report topline registrational Phase 2 data in 1H 2026
    - BLA filing in 1H 2026
- **MG:**
    - Report interim Phase 2 data in Q4 2025
    - Initiate enrollment for registrational Phase 3 trial by year-end 2025 **(New)**
- **LN:**
    - Report Phase 1 data in a peer-reviewed publication in 2026
- **Additional Indications:**
    - MS: Report Phase 1 IIT data in Q3 2025 **(New)**
    - RA: Report Phase 1/2 IIT data in Q4 2025 **(New)**
- **Future Pipeline:**
    - File KYV-102 IND application in Q4 2025

Financial Results for the Quarter Ended June 30, 2025
Kyverna reported $211.7 million in cash, cash equivalents, and marketable securities as of June 30, 2025, which the Company expects will provide a cash runway into 2027, supporting its first BLA filing for SPS, its MG Phase 3 trial and pre-launch activities.

Research and Development (R&D) expenses were $35.8 million for the quarter ended June 30, 2025, compared to $27.3 million for the quarter ended June 30, 2024, which included $0.9 million and $0.7 million of non-cash stock-based compensation expenses, respectively.

General and Administrative (G&A) expenses were $8.6 million for the quarter ended June 30, 2025, compared to $6.1 million for the quarter ended June 30, 2024, which included $1.6 million and $0.6 million of non-cash stock-based compensation expenses respectively.

For the quarter ended June 30, 2025, the Company reported a net loss of $42.1 million, or a net loss per common share of $0.97, compared to a net loss of $28.8 million, or a net loss per common share of $0.67, for the same period in 2024.

About KYV-101
KYV-101 is a fully human, autologous, CD19 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, KYV-101 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 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 and rheumatoid arthritis, to inform the next priority indications for the Company to advance into late-stage development. Additionally, its pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats, including efficiently expanding into broader autoimmune indications and the potential to increase patient reach with KYV-102 using its proprietary whole blood rapid manufacturing process. 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 and anticipation of continued momentum in the execution of its clinical and regulatory strategy; the expected timing for releasing topline data for its registrational Phase 2 trial in stiff person syndrome; the potential for KYV-101 to be a first-in-class neuroimmunology CAR T franchise; the anticipated number of patients to be enrolled in the registrational Phase 2/3 trial in MG; Kyverna's anticipated milestones and timing thereof, including the anticipated timing for a BLA submission, the anticipated timing for initiating the registrational Phase 2/3 trial in MG, and the anticipated timing for reporting data from clinical trials and IITs; KVY-101's differentiated clinical profile; Kyverna's anticipated cash runway; Kyverna's upcoming KOL event and the topics anticipated to be discussed at such event, including the trial design for the registrational Phase 3 trial in MG; Kyverna's indication expansion strategy and exploration of additional opportunities for KYV-101 in other autoimmune diseases, including in MS and RA; and Kyverna's clinical trials, IITs 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.

For more information, please contact:
Investors: InvestorRelations@kyvernatx.com
Media: Media@kyvernatx.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 35,816	$ 27,321	$ 73,249	$ 49,797
General and administrative	8,594	6,114	18,569	12,996
Total operating expenses	44,410	33,435	91,818	62,793
Loss from operations	(44,410)	(33,435)	(91,818)	(62,793)
Interest income	2,364	4,694	5,189	7,429
Interest expense	(14)	(39)	(38)	(83)
Other expense, net	(21)	(23)	(49)	(49)
Total other income, net	2,329	4,632	5,102	7,297
Net loss	(42,081)	(28,803)	(86,716)	(55,496)
Other comprehensive loss				
Unrealized loss on available-for-sale marketable securities, net	(19)	(36)	(125)	(41)
Total other comprehensive loss	(19)	(36)	(125)	(41)
Net loss and other comprehensive loss	$ (42,100)	$ (28,839)	$ (86,841)	$ (55,537)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (0.67)	$ (2.01)	$ (1.66)
Weighted-average shares of common stock outstanding, basic and diluted	43,225,365	43,125,709	43,220,498	33,439,886

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

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 211,677	$ 285,979

Prepaid expenses and other current assets	2,650	4,622
Total current assets	214,327	290,601
Restricted cash	551	552
Property and equipment, net	2,162	3,347
Operating lease right-of-use assets	5,049	6,468
Finance lease right-of-use assets	366	841
Other non-current assets	4,053	2,836
Total assets	$ 226,508	$ 304,645
Liabilities and stockholders' equity		
Current liabilities	$ 39,789	$ 33,756
Non-current liabilities	2,342	4,302
Stockholders' equity	184,377	266,587
Total liabilities and stockholders' equity	$ 226,508	$ 304,645

Source: Kyverna Therapeutics, Inc.