



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

November 12, 2025

Topline data from registrational trial in stiff person syndrome (SPS) now expected in early 2026; narrowed from previous guidance of first half 2026; BLA submission anticipated in 1H 2026

Positive interim Phase 2 data in generalized myasthenia gravis (gMG); on-track to enroll first patient for registrational Phase 3 portion of trial by year-end 2025

Strengthened financial flexibility with up to \$150M loan facility to support the continued advancement of the Company's late-stage indications in gMG and SPS, while also accelerating pre-launch activities

EMERYVILLE, Calif., Nov. 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 September 30, 2025.

"Kyverna's execution across significant clinical and corporate milestones provides us with strong momentum heading into the new year," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "We are very pleased to have reinforced our market opportunity in generalized myasthenia gravis with unprecedented Phase 2 interim data, demonstrated KYV-101's potential in multiple sclerosis and rheumatoid arthritis with promising IIT data, and strengthened our financial flexibility with non-dilutive financing. Looking ahead, we remain focused on executing our neuroimmunology CAR T-cell franchise strategy, with topline registrational stiff person syndrome data expected ahead of schedule in early 2026."

Third Quarter 2025 Highlights and Recent Business Updates

Neuroimmunology CAR T Franchise: Kyverna is advancing its first-in-class neuroimmunology CAR T franchise for indications with high unmet need, including stiff person syndrome and myasthenia gravis.

- **KYSA-8 Registrational Phase 2 Trial for Stiff Person Syndrome (SPS)**
 - Kyverna narrowed its previously announced guidance for reporting topline data from this trial from the first half of 2026 to early 2026.
 - The Company remains on track to submit its first BLA in the first half of 2026.
- **KYSA-6 Registrational Phase 2/3 Trial for Generalized Myasthenia Gravis (gMG)**
 - Kyverna [presented](#) positive interim data from the Phase 2 portion of its registrational KYSA-6 clinical trial at the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting in October 2025. All primary and secondary endpoints were achieved, demonstrating KYV-101's potential to deliver durable, drug-free, disease-free remission. Notably, 100% of patients (6/6) achieved rapid, robust and sustained reductions from baseline in MG-ADL (mean: -8.0) and QMG (mean: -7.7) at 24 weeks, with significant clinical improvement seen as early as two weeks. Minimal symptom expression (MSE) was achieved in two out of three patients with ≥ 6 months of follow-up. KYV-101 also demonstrated a consistent, manageable, and tolerable safety profile, with no high-grade CRS and no ICANS observed. All patients discontinued immunosuppressant therapies for up to 24 weeks.
 - Kyverna expects to initiate patient enrollment in the Phase 3 portion of the trial by the end of 2025 and share updated data on the Phase 2 portion of the trial in 2026.
- In August 2025, Kyverna hosted a virtual KOL [event](#) focused on its neuroimmunology CAR T franchise. In addition to outlining the design of the Company's registrational Phase 2/3 trial in MG, Kyverna highlighted the unmet need in SPS and MG and shared the initial framework of its neuroimmunology commercial strategy. The event also featured additional follow-up data from compassionate-use patients¹ treated with KYV-101, demonstrating durable drug-free,

disease-free remission beyond 24 months.

Additional Indications: Kyverna is efficiently exploring additional opportunities for KYV-101 through sponsored clinical trials and investigator-initiated trials (IITs) across several other autoimmune diseases. Data from these efforts will inform the Company's indication-expansion strategy.

- **Multiple Sclerosis (MS):** Phase 1 data from IITs evaluating KYV-101 in MS were [presented](#) at the 2025 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in September 2025, including an oral presentation from Stanford University and a poster presentation from the University of California, San Francisco (UCSF). Results showed promising clinical activity, including robust CAR T penetration into the central nervous system and improved expanded disability status scale scores (EDSS).
- **Rheumatoid Arthritis (RA):** Data from the Phase 1 portion of a Phase 1/2 IIT evaluating KYV-101 in treatment-refractory RA were [presented](#) by Charité – University of Berlin at the American College of Rheumatology (ACR) Convergence 2025 meeting in October 2025. Results demonstrated profound reduction in disease-associated autoantibodies and impact on disease activity in patients with difficult-to-treat RA who had failed multiple prior therapies.

KYV-102: KYV-102 is produced with the Company's next-generation proprietary whole blood, rapid manufacturing process, incorporating the same CAR construct as KYV-101. KYV-102 provides the opportunity to broaden access through the elimination of apheresis while reducing the cost of goods.

- Kyverna remains on track to file an investigational new drug (IND) application for KYV-102 in the fourth quarter of 2025.

Corporate Updates

- In November 2025, Kyverna [announced](#) the closing of a loan facility for up to \$150 million with Oxford Finance, providing initial funding of \$25 million. The agreement strengthens Kyverna's financial flexibility, supporting the advancement of its late-stage indications in SPS and gMG, while also accelerating pre-launch activities.

Anticipated Milestones

Kyverna has issued the following guidance on upcoming program milestones:

- **SPS:**
 - Report topline registrational KYSA-8 Phase 2 data in early 2026
 - BLA filing in 1H 2026
- **MG:**
 - Report updated data for the Phase 2 portion of KYSA-6 Phase 2/3 trial data in 2026
 - Initiate enrollment for registrational Phase 3 trial by year-end 2025
- **Additional Indications:**
 - Lupis Nephritis: Report Phase 1 data in a peer-reviewed publication in 2026
- **Future Pipeline:**
 - File IND application in Q4 2025 for KYV-102, Kyverna's whole blood rapid manufacturing process

Financial Results for the Quarter Ended September 30, 2025

Kyverna reported \$171.1 million in cash, cash equivalents, and marketable securities as of September 30, 2025. Including the initial \$25 million drawn from the loan facility in November 2025, the Company expects to have a cash runway into 2027, supporting its BLA filing for SPS and its Phase 3 gMG trial, while also accelerating pre-launch activities.

Research and Development (R&D) expenses were \$30.5 million for the quarter ended September 30, 2025, compared to \$29.2 million for the quarter ended September 30, 2024, which included \$0.9 million and \$1.0 million of non-cash stock-based compensation expenses, respectively.

General and Administrative (G&A) expenses were \$8.3 million for the quarter ended September 30, 2025, compared to \$9.6 million for the quarter ended September 30, 2024, which included \$1.8 million and \$2.4 million of non-cash stock-based compensation expenses, respectively.

For the quarter ended September 30, 2025, the Company reported a net loss of \$36.8 million, or a net loss per common share of \$0.85 compared to a net loss of \$34.5 million, or a net loss per common share of \$0.80, 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 expected timing for releasing topline data for its registrational Phase 2 trial in stiff person syndrome; potential first-in-class opportunities for KYV-101; the anticipated enrollment timing for the Phase 3 portion of its registrational Phase 2/3 trial in gMG and anticipated timing for reporting updated data for the Phase 2 portion of the trial; Kyverna's anticipated milestones and timing thereof, including the anticipated timing for a BLA submission for KYV-101 for SPS and an IND application submission for KYV-102; Kyverna's anticipated cash runway; Kyverna's indication-expansion strategy and exploration of additional opportunities for in other autoimmune diseases, including in MS and RA; and Kyverna's clinical trials, IITs and named-patient access data. 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 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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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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 30,457	\$ 29,193	\$ 103,706	\$ 78,990
General and administrative	8,270	9,577	26,839	22,573
Total operating expenses	38,727	38,770	130,545	101,563
Loss from operations	(38,727)	(38,770)	(130,545)	(101,563)
Interest income	2,000	4,355	7,189	11,784
Interest expense	(7)	(32)	(45)	(115)
Other expense, net	(53)	(45)	(102)	(94)
Total other income, net	1,940	4,278	7,042	11,575
Net loss	(36,787)	(34,492)	(123,503)	(89,988)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities, net	49	190	(76)	149
Total other comprehensive income (loss)	49	190	(76)	149
Net loss and other comprehensive loss	\$ (36,738)	\$ (34,302)	\$ (123,579)	\$ (89,839)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.85)	\$ (0.80)	\$ (2.85)	\$ (2.45)
Weighted-average shares of common stock outstanding, basic and diluted	43,415,367	43,155,858	43,284,111	36,702,183

Condensed Balance Sheets
(in thousands)
(Unaudited)

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	\$ 171,138	\$ 285,979
Prepaid expenses and other current assets	3,787	4,622
Total current assets	174,925	290,601
Restricted cash	551	552
Property and equipment, net	1,793	3,347
Operating lease right-of-use assets	4,317	6,468
Finance lease right-of-use assets	212	841
Other non-current assets	5,358	2,836
Total assets	<u>\$ 187,156</u>	<u>\$ 304,645</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 33,871	\$ 33,756
Non-current liabilities	1,339	4,302
Stockholders' equity	151,946	266,587
Total liabilities and stockholders' equity	<u>\$ 187,156</u>	<u>\$ 304,645</u>