Kyverna Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2025 Financial Results

March 26, 2026

Advancing first-to-market autoimmune CAR T opportunity in stiff person syndrome (SPS) with key launch preparation activities underway; BLA submission anticipated in 1H 2026

Progressing enrollment for FDA-aligned Phase 3 trial in generalized myasthenia gravis (gMG)

Positive progressive multiple sclerosis data underscore valuable pipeline-in-a-product opportunity with miv-cel

Cash and cash equivalents of $279 million provide expected runway into 2028, funding SPS BLA filing, commercial launch, and Phase 3 gMG trial

EMERYVILLE, Calif., March 26, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today reported its business highlights and financial results for the fourth quarter and full year ended December 31, 2025.

“We continue to cement our leadership in autoimmune CAR T supported by our unique construct and a growing body of transformative clinical data that reinforces miv-cel’s differentiated profile,” said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. “We are advancing the first CAR T for stiff person syndrome, a serious and debilitating disease with no FDA-approved treatments, representing a significant unmet need and meaningful commercial opportunity. Our market entry will establish the foundation for our neuroimmunology franchise with expansion into generalized myasthenia gravis and potentially other indications, such as progressive multiple sclerosis, where miv-cel has shown promising clinical benefit.”

Fourth Quarter 2025 Highlights and Recent Business Updates

Neuroimmunology CAR T Franchise

- **KYSA-8 Registrational Phase 2 Clinical Trial for SPS**
  - In December 2025, Kyverna **reported** landmark topline data for miv-cel (mivocabtagene autoleucel, KYV-101) in SPS. Miv-cel achieved highly statistically significant clinical benefit across all primary and secondary endpoints, including reversing disability. It was generally well-tolerated with no high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) observed, supporting the potential for outpatient administration.
  - Kyverna anticipates submitting its first Biologics License Application (BLA) in the first half of 2026.
  - The primary analysis from the Company’s registrational trial will be shared as a late-breaking oral presentation at the 2026 American Academy of Neurology (AAN) meeting on April 21, 2026.
- **KYSA-6 Registrational Phase 2/3 Clinical Trial for gMG**
  - In October 2025, Kyverna **reported** positive interim data from the Phase 2 portion of its KYSA-6 clinical trial. All primary and secondary endpoints were achieved, demonstrating miv-cel’s potential to deliver durable, drug-free, disease-free remission in patients with gMG after a single dose. In addition, miv-cel demonstrated a well-tolerated safety profile with no high-grade CRS or ICANS observed, supporting the potential for outpatient administration.
  - Kyverna is progressing its FDA-aligned Phase 3 gMG clinical trial. The first patient was enrolled in December 2025 and 14 clinical sites across three geographies are active.
  - Additional longer-term follow-up Phase 2 data will be shared in an oral presentation at AAN on April 20, 2026.

Additional Pipeline Opportunities

- **Progressive Multiple Sclerosis (PMS):** Positive updated Phase 1 data from investigator-initiated trials (IITs) evaluating miv-cel in PMS were presented at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) forum in February 2026 by **Stanford University** and the **University of California, San Francisco**. A total of eight patients have been treated across both studies, receiving either 33M (n=5) or 100M (n=3) CAR T cells. The Stanford trial used an alternative bendamustine lymphodepleting regimen.
    - Available follow-up data from six patients showed that 83% (5/6) achieved improvements in their disability scores, as measured by the expanded disability status scale scores (EDSS), with the remaining patient showing stability at last follow up. Among patients with available data in fatigue scores, all (4/4) showed improvements in scores from baseline. All patients remained off other immunomodulatory therapies. Miv-cel was well-tolerated with no high-grade CRS or ICANS.

- **Rheumatoid Arthritis (RA):** Positive data from the Phase 1 portion of a Phase 1/2 IIT evaluating miv-cel in treatment-refractory RA were **presented** by Charité – University of Berlin at the American College of Rheumatology (ACR) Convergence 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. The Phase 2 portion of the study is fully enrolled, and data is expected to be shared in 2026.

- **Additional Updates**: In January 2026, the investigational new drug (IND) application was accepted by the FDA for KYV-102, the Company's proprietary whole blood, rapid manufacturing process. Further, Kyverna will continue to explore miv-cel with no lymphodepletion (LD) or alternative LD regimen as well as outpatient administration.

Corporate Updates

- Advanced SPS launch-readiness activities, including key leadership hires, commercial site activation activities, payer engagement, and healthcare professional (HCP) education. The Company's current manufacturing capacity is expected to fully support commercial launch.
- Expanded the Company's expertise through the following Board of Directors and leadership appointments:
    - Independent director Christi Shaw appointed as Executive Chairperson of the Board; Ian Clark, former Chairperson, remains on the Board
    - Sravan K. Emany and Andrew Miller appointed to the Board
    - Mayo Pujols appointed as Chief Technology Officer
- Strengthened the balance sheet and extended cash runway into 2028 through a combination of financing activities, raising a total of $147.5 million. The Company raised $122.5 million in gross proceeds across a follow-on financing and at-the-market (ATM) program sales. During the fourth quarter, the Company also closed a $150 million milestone-based loan facility with Oxford Finance, providing initial funding of $25 million.

Anticipated Milestones

- **SPS:**
    - Report primary analysis of registrational KYSA-8 trial at AAN in April 2026
    - BLA filing in 1H 2026
    - Launch-ready by year-end 2026

- **gMG:**
  - Report updated data for the Phase 2 portion of KYSA-6 trial at AAN in April 2026

- **Additional Pipeline Opportunities:**
  - Progressive Multiple Sclerosis: Report additional data from Phase 1 IIT in 2026
  - Rheumatoid Arthritis: Report Phase 2 IIT data in 2026
  - Lupus Nephritis: Report Phase 1 data in 2026
  - Share development strategy for KYV-102, Kyverna's whole blood rapid manufacturing process

Financial Results for the Fourth Quarter and Full-Year Ended December 31, 2025
Kyverna reported $279.3 million in cash, cash equivalents, and marketable securities as of December 31, 2025. The Company expects to have a cash runway into 2028, funding its SPS BLA filing and commercial launch and its Phase 3 gMG trial.

Research and Development (R&D) expenses were $30.0 million and $133.7 million for the fourth quarter and full year ended December 31, 2025, respectively, compared to $33.5 million and $112.5 million for the same periods last year. R&D expenses for the fourth quarter and full year ended December 31, 2025 included $1.0 million and $3.6 million of non-cash stock-based compensation expenses, respectively.

General and Administrative (G&A) expenses were $9.3 million and $36.1 million for the fourth quarter and full year ended December 31, 2025, respectively, compared to $7.6 million and $30.1 million for the same periods last year. G&A expenses for the fourth quarter and full year ended December 31, 2025 included $1.7 million and $6.5 million, respectively, of non-cash stock-based compensation expenses.

Net loss for the fourth quarter and full year ended December 31, 2025 was $37.8 million and $161.3 million, respectively, compared to a net loss of $37.5 million and $127.5 million, respectively, for the same periods last year.

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. The Company'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 initial indications in stiff person syndrome and generalized myasthenia gravis. The Company is also advancing additional clinical and investigator-sponsored studies, including in progressive multiple sclerosis and rheumatoid arthritis, to inform future priority indications and develop next-generation CAR T platforms to improve access and patient 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 first-to-market autoimmune CAR T opportunity; the potential for miv-cel to be the first CAR T for SPS; the potential commercial launch of miv-cel in SPS and its potential to be a meaningful commercial opportunity and establish the foundation for expansion into myasthenia gravis and other indications; miv-cel's promise in SPS, myasthenia gravis, progressive multiple sclerosis and potentially other indications; Kyverna's potential readiness for commercial launch of miv-cel in SPS, including the sufficiency of its manufacturing capacity and cash runway and the activities such cash runway is expected to support; Kyverna's anticipated timing for its BLA submission; 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 patients with gMG or other autoimmune disease; and Kyverna's expected upcoming pipeline milestones, including for SPS, gMG 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 Annual Report on Form 10-K for the year ended December 31, 2025 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 30,014	$ 33,483	$ 133,720	$ 112,473
General and administrative	9,268	7,558	36,107	30,131

Total operating expenses	39,282	41,041	169,827	142,604
Loss from operations	(39,282)	(41,041)	(169,827)	(142,604)
Interest income	1,905	3,575	9,094	15,359
Interest expense	(444)	(27)	(489)	(142)
Other expense, net	17	4	(85)	(90)
Total other income, net	1,478	3,552	8,520	15,127
Net loss	(37,804)	(37,489)	(161,307)	(127,477)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities, net	68	(48)	(8)	101
Total other comprehensive income (loss)	68	(48)	(8)	101
Net loss and other comprehensive loss	$ (37,736)	$ (37,537)	$ (161,315)	$ (127,376)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.80)	$ (0.87)	$ (3.64)	$ (3.33)
Weighted-average shares of common stock outstanding, basic and diluted	47,155,840	43,196,247	44,259,999	38,334,571

Kyverna Therapeutics, Inc.
Balance Sheets
(in thousands)

	December 31,	
	2025	**2024**
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 279,253	$ 285,979
Prepaid expenses and other current assets	3,700	4,622
Total current assets	282,953	290,601
Restricted cash	551	552
Property and equipment, net	1,546	3,347
Operating lease right-of-use assets	3,568	6,468
Finance lease right-of-use assets	305	841
Other non-current assets	4,903	2,836
Total assets	$ 293,826	$ 304,645
Liabilities and stockholders' equity		
Current liabilities	$ 36,487	$ 33,756
Non-current liabilities	25,063	4,302
Stockholders' equity	232,276	266,587
Total liabilities and stockholders' equity	$ 293,826	$ 304,645