Kyverna Therapeutics Reports Pipeline Progress and Second Quarter 2026 Financial Results

August 11, 2026

FDA grants RMAT designation for miv-cel in non-active secondary progressive multiple sclerosis (naSPMS) based on compelling clinical data, further expanding the therapy's potential across neuroimmunology

On track to complete rolling BLA submission for miv-cel in stiff person syndrome (SPS) in Q4 2026; KYSA-8 12-month topline data expected in Q3 2026

Enrollment in KYSA-6 Phase 3 trial in generalized myasthenia gravis (gMG) expected to be completed in mid-2027; longer-term follow-up Phase 2 topline data expected in Q3 2026

Reiterates operating runway into 2028

EMERYVILLE, Calif., Aug. 11, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical immunology company pioneering transformative therapies for people with neurologic autoimmune diseases, today reported financial results for the second quarter ended June 30, 2026, and provided a business update.

"Kyverna continues to advance our rolling BLA submission for stiff person syndrome, progress commercial launch readiness activities and accelerate enrollment in our registrational trial in generalized myasthenia gravis, while advancing our pipeline," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "With three RMAT indications and the potential to deliver the first approved CAR T-cell therapy for autoimmune diseases, we are well positioned to achieve our goal of freeing patients from life-long disease burden and chronic immunotherapies with a single dose of miv-cel."

Progress in Miv-cel Neuroimmunology Franchise

- **SPS Rolling Biologic License Application (BLA) Submission Underway and Commercial Readiness Activities On-Track**:
  - Kyverna has initiated its rolling BLA, submitted the Chemistry, Manufacturing and Controls (CMC) module and is on track to complete its submission in the fourth quarter of 2026.
  - The Company plans to seek priority review, under the Regenerative Medicine Advanced therapy (RMAT) designation, positioning miv-cel for potential commercial launch in 2027.
  - Kyverna continues to advance activities to enable a successful rare disease launch in SPS upon approval. These efforts include hiring key commercial leadership roles, commercial site activation, a commercial supply agreement, payer and patient advocacy engagement, and healthcare professional education.
  - The Company plans to report 12-month topline data from KYSA-8 in Q3 2026.

- **Enrollment Ongoing in KYSA-6 Registrational Trial for gMG:**
  - Kyverna continues to advance its Phase 3 gMG trial and expects to complete enrollment by mid-2027. The Company anticipates sharing longer-term follow-up Phase 2 topline data in Q3 2026.

- **Advancing Progressive Multiple Sclerosis (PMS) Strategy with RMAT Designation Granted for Miv-cel for Treatment of Non-active Secondary Progressive Multiple Sclerosis:**
  - RMAT designation has been granted for miv-cel in naSPMS by the FDA based on compelling clinical data from investigator-initiated trials (IIT) at Stanford University and the University of California, San Francisco in patients with PMS. This designation provides the opportunity for increased FDA engagement and eligibility for priority and rolling reviews, as well as accelerated approval pathways, with the goal of bringing transformative innovations to patients more quickly.
  - Kyverna expects to provide an update on its PMS development strategy by early 2027,

as well as additional data from the Stanford Phase 1 IIT in Q4 2026.

“In progressive multiple sclerosis, miv-cel’s potential to stabilize or improve disability status with a single dose could represent a transformative treatment advance given the steady progression patients face despite available therapies. We look forward to sharing our development strategy in progressive multiple sclerosis, leveraging discussions with the FDA through our RMAT designation, by early 2027,” said Naji Gehchan, Chief Medical and Development Officer of Kyverna.

- **Additional Miv-cel Neuroimmunology Franchise Opportunities**
  - Kyverna continues to explore miv-cel with alternative or no preconditioning regimens and the potential for outpatient administration supported by miv-cel's consistent and well-tolerated safety profile.

Leadership Appointments

- In the second quarter, Kyverna strengthened its leadership team with the appointments of Greg Martini as Chief Financial Officer, Nadia Dac as Chief Commercial Officer, and Ritesh Srivastava as Chief Legal and Compliance Officer.

Financial Results for the Second Quarter Ended June 30, 2026

- Kyverna reported $199.4 million in cash, cash equivalents, and marketable securities as of June 30, 2026, which in addition to amounts available for draw from the Oxford Finance amended loan facility, is expected to provide operating runway into 2028.
- Research and Development (R&D) expenses were $24.8 million for the second quarter ended June 30, 2026.
- General and Administrative (G&A) expenses were $14.8 million for the second quarter ended June 30, 2026.
- For the quarter ended June 30, 2026, the Company reported a net loss of $38.3 million, or a net loss per common share of $0.63.

About Miv-cel (mivocabtagene autoleucel, KYV-101)
Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation, uniquely 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 immunology company pioneering differentiated therapies with curative potential for neurologic autoimmune diseases. 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, as well as next generation innovations to expand patient access and evaluate future indications. 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 goal of freeing patients from life-long disease burden and chronic immunotherapies with a single dose of miv-cel; Kyverna’s regulatory path for SPS, including the rolling BLA submission for SPS and the expected timing for completing such submission, as well as potential for priority review under an RMAT designation or any potential first-in-class approval; the Phase 3 trial for gMG and status of enrollment in such trial; miv-cel’s potential to stabilize or improve disability status for PMS patients with a single dose; Kyverna’s transition to a commercial-stage company, clinical execution and significant regulatory progress, and potential readiness for commercial launch of miv-cel in SPS; Kyverna’s operating runway Kyverna’s potential first-in-class neuroimmunology CAR T franchise; the potential for miv-cel to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases; miv-cel’s potential to deliver durable, drug-free, disease-free remission in autoimmune diseases; any potential benefits of RMAT designation for miv-cel in naSPMS by the FDA; Kyverna’s exploration of miv-cel with alternative or no preconditioning and the potential for outpatient administration; and Kyverna’s expected upcoming pipeline milestones, 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 June 30, 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.

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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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 24,788	$ 35,816	$ 54,861	$ 73,249
General and administrative	14,768	8,594	26,062	18,569
Total operating expenses	39,556	44,410	80,923	91,818
Loss from operations	(39,556)	(44,410)	(80,923)	(91,818)
Interest income	1,929	2,364	4,256	5,189
Interest expense	(674)	(14)	(1,341)	(38)
Other expense, net	(18)	(21)	(39)	(49)
Total other income, net	1,237	2,329	2,876	5,102
Net loss	(38,319)	(42,081)	(78,047)	(86,716)
Other comprehensive loss				
Unrealized loss on available-for-sale marketable securities, net	(46)	(19)	(239)	(125)
Total other comprehensive loss	(46)	(19)	(239)	(125)
Net loss and other comprehensive loss	$ (38,365)	$ (42,100)	$ (78,286)	$ (86,841)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.63)	$ (0.97)	$ (1.29)	$ (2.01)
Weighted-average shares of common stock outstanding, basic and diluted	60,896,872	43,225,365	60,666,814	43,220,498

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

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents and available-for-sale marketable securities	$ 199,427	$ 279,253
Prepaid expenses and other current assets	7,115	3,700
Total current assets	206,542	282,953
Restricted cash	551	551
Operating lease right-of-use assets	7,848	3,568
Other non-current assets	4,882	6,754
Total assets	$ 219,823	$ 293,826
Liabilities and stockholders’ equity		
Current liabilities	$ 22,802	$ 36,487
Loan payable, net	24,883	24,743
Other non-current liabilities	6,589	320
Stockholders’ equity	165,549	232,276
Total liabilities and stockholders’ equity	$ 219,823	$ 293,826