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

August 8, 2025

Published results from the 96-Week Phase 2b SYMMETRY trial in the New England Journal of Medicine

Three presentations at the EASL Congress 2025 highlighted data demonstrating statistically significant reversal of compensated cirrhosis (F4) due to MASH and corroborating the anti-fibrotic activity of EFX seen in patients with pre-cirrhotic (F2-F3) MASH

Cash, cash equivalents and short and long-term marketable securities of $1,086.2 million at June 30, 2025

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2025 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, today reported second quarter financial results for the period ending June 30, 2025, and provided business updates.

"In the second quarter of 2025, we continued to build on the strong momentum established with the announcement of statistically significant reversal of cirrhosis due to MASH in the Phase 2b SYMMETRY study, supported by the peer-reviewed publication of 96-week results in the *New England Journal of Medicine* and additional data presentations that reinforce the anti-fibrotic activity of EFX across all stages of MASH," said Andrew Cheng, president and CEO. "We look forward to reporting preliminary results of our first Phase 3 trial, SYNCHRONY *Real-World,* in the first half of 2026 as well as a readout of SYNCHRONY *Histology* in the first half of 2027."

Phase 2b SYMMETRY Data Featured in the *New England Journal of Medicine*

- In a significant milestone for the EFX clinical program, data from the Phase 2b SYMMETRY study evaluating EFX in patients with compensated cirrhosis (F4) due to MASH was published in the *New England Journal of Medicine* on May 9, 2025.
- This peer-reviewed publication reinforces the importance of the SYMMETRY findings and positions EFX as a potential first- and best-in-class therapy with disease-modifying activity in advanced-stage MASH.

New 96-Week SYMMETRY Findings Underscore Broad Potential of EFX in Late-Breaking Oral Presentation at EASL 2025

- Week 96 data presented during a late-breaking oral session at EASL 2025 demonstrated the potential of EFX 50mg to reverse cirrhosis in high-need MASH subgroups, including patients with cryptogenic cirrhosis and type 2 diabetes.
- Data suggest EFX may benefit patients at greater risk of progression toward decompensation and end-stage liver disease, showing reversal of cirrhosis for the first time in these groups with high unmet need.
- The official press program of EASL 2025 highlighted the presentation of SYMMETRY results, underlining the importance of the results within the landscape of liver diseases.

New Analyses from Phase 2b HARMONY Study Presented at EASL 2025 Highlight Consistent Fibrosis Improvement with EFX

- New insights from the Phase 2b HARMONY study demonstrated EFX's ability to improve fibrosis in pre-cirrhotic MASH (F2-F3) using both conventional pathologist scoring and advanced AI-based analysis of biopsy images.
- In an oral presentation, analyses of patients treated with 50mg EFX for 96 weeks showed that a majority of individuals achieved improvements across all three measures of antifibrotic response: qFibrosis® staging of biopsy images, ELF score, and liver stiffness by FibroScan®, in stark contrast to placebo patients, none of whom met all three of the same measures.
- AI-based analysis corroborated the treatment effect observed by conventional pathology scoring.
- A supporting poster provided evidence that qFibrosis® may detect fibrosis improvement earlier than conventional pathology scoring, manifested as statistically significant fibrosis regression in peri-portal and peri-sinusoidal zones.

Second Quarter 2025 Financial Results

- Akero's cash, cash equivalents and short and long-term marketable securities as of June 30, 2025, were $1,086.2 million.
- Akero believes that its cash, cash equivalents and short and long-term marketable securities will be sufficient to fund its current operating plan into 2028.
- Research and development expenses for the three-month period ended June 30, 2025 were $69.3 million, compared to $55.3 million for the comparable period in 2024. These increases were attributable to higher expenses associated with the ongoing Phase 3 SYNCHRONY *Histology*, *Real-World*, and *Outcomes* studies, and manufacture of clinical supplies for Phase 3 and potential marketing applications, as well as higher expenses for personnel.

- General and administrative expenses for the three-month period ended June 30, 2025 were $11.6 million, compared to $10.4 million for the comparable period in 2024. These increases are attributable to higher expenses for personnel, professional services and other costs associated with operating as a public company.
- Total operating expenses were $80.9 million for the three-month period ended June 30, 2025, compared to $65.7 million for the comparable period in 2024.

About MASH
MASH is a serious form of MASLD that is estimated to affect 17 million Americans. MASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. Approximately 20% of patients with MASH are expected to progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for compensated cirrhosis due to MASH, one of the fastest growing causes of liver transplants and liver cancer in the US and Europe.

About Cirrhosis Due to MASH
Cirrhosis due to MASH (metabolic dysfunction-associated steatohepatitis) is a life-threatening disease with high risk of liver failure, cancer, and death. By 2030, an estimated 3 million Americans are projected to have cirrhosis due to MASH.

About EFX
Efruxifermin (EFX), Akero's lead product candidate for MASH, is currently being evaluated in three ongoing Phase 3 studies. In multiple Phase 2 studies, EFX has been observed to reverse fibrosis (including compensated cirrhosis due to MASH), resolve MASH, reduce non-invasive markers of fibrosis and liver injury, and improve insulin sensitivity and lipoprotein profile. This holistic profile offers the potential to address the complex, multi-system disease state of all stages of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death among MASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including metabolic dysfunction-associated steatohepatitis (MASH). Akero's lead product candidate, efruxifermin (EFX), is currently being evaluated in three Phase 3 clinical studies: SYNCHRONY *Histology* in patients with pre-cirrhotic (F2-F3 fibrosis) MASH, SYNCHRONY *Outcomes* in patients with compensated cirrhosis (F4) due to MASH, and SYNCHRONY *Real-World* in patients with MASH or MASLD (metabolic dysfunction-associated steatotic liver disease). The Phase 3 SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic MASH and the SYMMETRY study in patients with compensated cirrhosis due to MASH. Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and X for more information.

Forward Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding Akero's business plans and objectives; the potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX, the future potential of EFX as a therapy with disease-modifying activity in advanced-stage MASH; upcoming milestones, including the results, and expected timing to report results from the SYNCHRONY Phase 3 program; and Akero's growth as a company and expectations regarding its uses of capital, expenses, and financial results, including the expected cash runway. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero's ability to execute on its strategy; positive results from any of its clinical studies may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in Akero's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Akero Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	June 30, 2025	December 31, 2024
Assets		
Cash, cash equivalents and short-term marketable securities	$ 742,315	$ 743,078
Other current assets	22,285	27,302

Non-current assets	344,552	55,506
Total assets	$ 1,109,152	$ 825,886
Liabilities and Stockholders' Equity		
Current liabilities	$ 60,401	$ 39,754
Non-current liabilities	22,932	36,020
Stockholders' equity	1,025,819	750,112
Total liabilities and stockholders' equity	$ 1,109,152	$ 825,886

Akero Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 69,254	$ 55,322	$ 138,821	$ 105,972
General and administrative	11,619	10,419	22,934	19,723
Total operating expenses	80,873	65,741	161,755	125,695
Loss from operations	(80,873)	(65,741)	(161,755)	(125,695)
Interest expense	(1,172)	(1,231)	(2,326)	(2,222)
Interest and other income, net	11,540	10,985	22,851	18,586
Net loss	$ (70,505)	$ (55,987)	$ (141,230)	$ (109,331)
Comprehensive loss	$ (70,602)	$ (56,169)	$ (141,190)	$ (109,862)
Net loss per common share, basic and diluted	$ (0.86)	$ (0.81)	$ (1.76)	$ (1.70)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	81,721,387	69,160,484	80,197,494	64,234,122