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

May 12, 2025

Phase 2b SYMMETRY study preliminary results showed statistically significant reversal of compensated cirrhosis (F4) due to MASH following 96 weeks of treatment with efruxifermin (EFX)

Presented two oral presentations and a poster presentation highlighting the latest data and new analyses from 96-week SYMMETRY and HARMONY clinical studies at EASL Congress 2025

SYMMETRY study results published in New England Journal of Medicine

Raised $402.5 million in gross proceeds in a follow-on public offering in January 2025, resulting in reserves of cash, cash equivalents, and marketable securities of $1,128 million at March 31, 2025

SOUTH SAN FRANCISCO, Calif., May 12, 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 first quarter financial results for the period ending March 31, 2025, and provided business updates.

“In the first quarter of 2025, we reported an unprecedented statistically significant reversal of cirrhosis due to MASH following 96 weeks of treatment with EFX in the Phase 2b SYMMETRY study—a defining moment not only for Akero, but more broadly for the treatment of MASH,” said Andrew Cheng, president and chief executive officer. “Cirrhosis had previously been viewed as an irreversible condition—managed by slowing progression to liver decompensation and treating complications, with effective treatment options limited to liver transplant. We believe the SYMMETRY week 96 results highlight the potential of EFX to transform the treatment of MASH, offering new hope to patients facing a disease with few meaningful treatment options. Publication of the SYMMETRY results in the *New England Journal of Medicine* underscores the importance of these results and strongly supports the continued evaluation of EFX in late-stage MASH—an effort we are currently undertaking as we advance our Phase 3 SYNCHRONY program, supported by more than $1.1 billion in cash, cash equivalents, and short- and long-term marketable securities on hand.”

Week 96 Results of the Phase 2b SYMMETRY Study in Patients with Compensated Cirrhosis (F4) Due to MASH

- EFX is the only known investigational metabolic dysfunction-associated steatohepatitis (MASH) drug evaluated in a randomized, placebo-controlled clinical trial in patients with cirrhosis due to MASH that has been reported to show statistically significant reversal of compensated cirrhosis (F4).
- In January 2025, Akero presented preliminary topline results from the Phase 2b SYMMETRY study evaluating EFX in patients with biopsy-confirmed compensated cirrhosis (F4), Child-Pugh Class A, due to MASH.
- Key biopsy results included:
  - Among patients with baseline and week 96 biopsies, 39% of the 50mg EFX group (p=0.009) demonstrated ≥1-stage improvement in fibrosis with no worsening of MASH, representing a 24% effect size over placebo at 15%.
  - By ITT analysis, with all missing week 96 biopsies treated as failures, 29% of the 50mg EFX group (p=0.031) demonstrated ≥1-stage improvement in fibrosis with no worsening of MASH, representing a 17% effect size over placebo at 12%.
- Additional analyses of non-invasive measures of fibrosis included:
  - A mean reduction in ELF score of 0.53 was observed for the 50mg EFX group. (p<0.001), compared to an increase of 0.22 for placebo.
  - A mean relative reduction in liver stiffness of 24% was observed for the 50mg EFX group (p<0.05), compared to 8% for placebo.

Approximate $402.5M Follow-On Public Offering

- On January 30, 2025, Akero closed an underwritten public offering of 6.427 million common shares at $48.00 per share and 1.958 million pre-funded warrants at $47.9999 per warrant. Gross proceeds from the offering were approximately $402.5 million.

Phase 2b SYMMETRY Results Published in *New England Journal of Medicine (NEJM)*

- On May 9, 2025, results of the Phase 2b SYMMETRY study were published in the *New England Journal of Medicine (NEJM).* Publication in NEJM underscores the importance of the SYMMETRY results and EFX’s potential to be both a first- and best-in-class therapy to treat compensated cirrhosis due to MASH.

Late-Breaking Oral Presentation at EASL 2025 Featured Phase 2b SYMMETRY Results, Including Newly Presented Analyses

- Results from the Phase 2b SYMMETRY study demonstrating EFX’s potential to reverse compensated cirrhosis (F4) due to

MASH were presented at EASL 2025 in Amsterdam on May 9, 2025.
- Newly presented SYMMETRY week 96 analyses showed the potential of 50mg EFX to reverse cirrhosis among patients across key subgroups, including patients with cryptogenic cirrhosis attributed to MASH at baseline and patients with type 2 diabetes at baseline.
- Reversal of cirrhosis across multiple subgroups, including among patients considered to have more advanced cirrhosis or otherwise considered more difficult to treat, suggests that EFX has potential to treat MASH patients with high unmet need.
- SYMMETRY results were selected for inclusion in the EASL meeting's press packet identifying some of the most impactful presentations at the conference.

Oral and Poster Presentations at EASL 2025 Featured Phase 2b HARMONY Results, Including Newly Presented Analyses with AI-Based qFibrosis®

- Results from the Phase 2b HARMONY study demonstrating EFX's potential to reverse fibrosis among patients with pre-cirrhotic MASH (F2-F3) were presented at EASL 2025 in Amsterdam on May 10, 2025.
- An oral presentation featured analyses that combined use of AI-based qFibrosis® with assessment of different correlations across liver histology, ELF score and liver stiffness measurement. Among 21 patients treated with 50mg EFX evaluated with qFibrosis®, 12 (57%) were responders across all three fibrosis endpoints (≥1 qFibrosis® stage without MASH worsening, ≥30% reduction by FibroScan®, and ≥0.5 reduction in ELF Score) and 0 (0%) were non-responders across all three measures, compared to 1 (3%) and 14 (48%), respectively, for 29 placebo patients. The roughly inverse relationship between the 50mg EFX and placebo groups increases confidence in the treatment effect observed by conventional histopathology alone.
- A poster presentation, which included a post-hoc analysis of the 96-week HARMONY study utilizing qFibrosis®, showed the potential for qFibrosis® to detect fibrosis improvement earlier than conventional histopathology. Earlier detection by qFibrosis® included statistically significant regression of fibrosis in the peri-portal (zone 1) and peri-sinusoidal (zone 2) zones of the liver in the EFX-treated groups.

Phase 3 SYNCHRONY Update

- Akero's global Phase 3 SYNCHRONY program (N~3,500) is comprised of three ongoing, randomized, placebo-controlled trials evaluating the safety and tolerability of EFX to support potential marketing applications for both compensated cirrhosis (F4) due to MASH and pre-cirrhotic (F2-F3) MASH.
- In January 2025, Akero completed enrollment of the double-blind portion of the SYNCHRONY *Real-World* study. Preliminary topline results from *Real-World* remain on track to be reported during the first half of 2026. *Real-World* is evaluating the safety and tolerability of 50mg EFX in a double-blind cohort of 601 patients with non-invasively diagnosed metabolic dysfunction-associated steatotic liver disease (MASLD) or MASH (F1-F4).
- The SYNCHRONY *Histology* study, which is evaluating the safety and efficacy of EFX in ~1,650 patients with biopsy confirmed pre-cirrhotic (F2-F3) MASH, remains on track to report 52-week results for primary histology endpoints during the first half of 2027. Patients in *Histology* receive weekly injections of 28mg EFX, 50mg EFX, or placebo. The primary histology endpoint, for Cohort 1 only, to support a potential application for accelerated approval, is the proportion of patients experiencing ≥1-stage fibrosis improvement and resolution of MASH after 52 weeks of treatment. All patients in Cohort 1 and Cohort 2 will be evaluated for long-term clinical outcomes for up to 240 weeks of treatment.
- The SYNCHRONY *Outcomes* study is evaluating the safety and efficacy of 50mg EFX in patients with compensated cirrhosis (F4) Child-Pugh Class A, due to MASH. The primary histology endpoint, for Cohort 1 only, is the proportion of patients experiencing ≥1-stage improvement in fibrosis and no worsening of steatohepatitis after 96 weeks of treatment. The primary clinical outcomes endpoint for all patients enrolled across Cohort 1 and Cohort 2 is the time from randomization to first occurrence of any protocol-specified clinical event.

First Quarter 2025 Financial Results

- Akero's cash, cash equivalents, and short- and long-term marketable securities as of March 31, 2025, were $1,128.3 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 March 31, 2025 were $69.6 million, compared to $50.7 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 March 31, 2025, were $11.3 million, compared to $9.3 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 March 31, 2025, compared to $60.0 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 will progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for the condition and MASH is the fastest-growing cause 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 MASH cirrhosis, which is the fastest growing cause of liver transplants and liver cancer in the United States and Europe.

About Efruxifermin
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), 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 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 ongoing 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 potential impact of EFX as a therapy to treat compensated cirrhosis due to MASH, if approved; the SYNCHRONY Phase 3 program, including the SYNCHRONY *Histology*, SYNCHRONY *Outcomes*, and SYNCHRONY *Real-World* studies and design of trials; the ongoing enrollment of Akero's Phase 3 SYNCHRONY program; and upcoming milestones, including the results, and expected timing to report results from the SYNCHRONY Phase 3 program; 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)

	March 31, 2025	December 31, 2024
Assets		
Cash, cash equivalents and short-term marketable securities	$ 686,293	$ 743,078
Other current assets	26,858	27,302
Non-current assets	442,692	55,506
Total assets	$ 1,155,843	$ 825,886

Liabilities and Stockholders' Equity		
Current liabilities	$ 42,439	$ 39,754
Non-current liabilities	29,558	36,020
Stockholders' equity	1,083,846	750,112
Total liabilities and stockholders' equity	$ 1,155,843	$ 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 March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 69,567	$ 50,650
General and administrative	11,315	9,304
Total operating expenses	80,882	59,954
Loss from operations	(80,882)	(59,954)
Interest expense	(1,154)	(991)
Interest and other income, net	11,311	7,601
Net loss	$ (70,725)	$ (53,344)
Comprehensive loss	$ (70,588)	$ (53,693)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.90)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	78,656,629	59,307,759