Akero Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

November 8, 2024

*— First patients dosed in Phase 3 **SYNCHRONY Outcomes** study of lead candidate efruxifermin (EFX) in patients with compensated cirrhosis (F4) due to MASH —*

*— Phase 3 **SYNCHRONY Real-World** and **Histology** studies on track to report results for their respective primary endpoints in 2026 and the first half of 2027 —*

*— Phase 2b **SYMMETRY** study week 96 results expected to readout in February 2025 —*

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2024 (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, including metabolic dysfunction-associated steatohepatitis (MASH), today reported third quarter financial results for the period ending September 30, 2024 and provided business updates.

"The third quarter of 2024 marked an important milestone for EFX with the first patient dosed in the Phase 3 SYNCHRONY ***Outcomes*** study," said Andrew Cheng, president and CEO. "With this advancement, all three of our Phase 3 studies are actively enrolling — furthering our assessment of the safety and efficacy of EFX and moving us closer to delivering a differentiated treatment option, if approved, to patients living with MASH."

Phase 3 SYNCHRONY Program

- Akero's Phase 3 SYNCHRONY program is comprised of three ongoing, randomized, placebo-controlled trials evaluating the safety and tolerability of EFX to support marketing applications for both pre-cirrhotic MASH (F2-F3) and compensated cirrhosis (F4) due to MASH. The SYNCHRONY program builds on two biopsy-based Phase 2b studies in corresponding patient populations, with a combined total of 300 patients treated for up to 96 weeks.
- SYNCHRONY ***Outcomes*** (F4, compensated)
  - SYNCHRONY ***Outcomes*** is a two-cohort study evaluating EFX in the treatment of patients with compensated cirrhosis (F4) due to MASH. Patients were first dosed in the study in the third quarter of 2024 and are receiving weekly injections of either EFX 50mg or placebo.
  - 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 outcomes endpoint is measured as the time from randomization to first occurrence of any of the protocol-specified clinical events across all patients enrolled in Cohort 1 and Cohort 2.
- SYNCHRONY ***Histology*** (F2-F3)
  - SYNCHRONY ***Histology*** is a two-cohort study evaluating EFX in the treatment of patients with pre-cirrhotic MASH, fibrosis stage 2 or 3 (F2-F3). Patients are receiving weekly injections of EFX 28mg, EFX 50mg, or placebo.
  - The primary histology endpoint (Cohort 1 only), to support an 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.
  - Results for the 52-week primary histology endpoint are expected in the first half of 2027.
- SYNCHRONY ***Real-World*** (F1-F4)
  - SYNCHRONY ***Real-World*** is enrolling patients with MASH or metabolic dysfunction-associated steatotic liver disease (MASLD) to receive weekly injections of EFX 50mg or placebo. The primary endpoint of safety and tolerability will be assessed after 52 weeks of treatment.
  - Results from the SYNCHRONY Real-World study are expected in 2026.

Phase 2b SYMMETRY Study

- The ongoing Phase 2b SYMMETRY study is evaluating the efficacy and safety of EFX in patients with compensated cirrhosis (F4) due to MASH, who were treated with EFX 28mg, EFX 50mg or placebo for up to 96 weeks.
- All planned end-of-treatment biopsies have been collected. Consistent with the protocol, enrolled patients continue in the study through follow-up assessments 30 days after completion of treatment with EFX or placebo.
- Week 96 results are on track to be reported in February 2025.

Third Quarter 2024 Financial Results

- Akero's cash, cash equivalents and short and long-term marketable securities as of September 30, 2024, were $787.1

million.

- Akero believes that its current cash, cash equivalents, and short- and long-term marketable securities will be sufficient to fund its Phase 3 SYNCHRONY ***Histology*** and ***Real-World*** studies through readout of their respective primary endpoints and Akero's current operating plan into the second half of 2027.
- Research and development expenses for the three-month period ended September 30, 2024 were $72.2 million, compared to $38.6 million for the comparable period in 2023. These increases were attributable to higher expenses associated with the ongoing SYMMETRY study, the ongoing Phase 3 SYNCHRONY ***Histology*** and ***Real-World*** studies, initiation of the Phase 3 SYNCHRONY ***Outcomes*** study, 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 September 30, 2024 were $9.5 million, compared to $8.0 million for the comparable period in 2023. 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 $81.7 million for the three-month period ended September 30, 2024, compared to $46.6 million for the comparable period in 2023.

About Efruxifermin

Efruxifermin (EFX), Akero's lead product candidate for MASH, is a differentiated Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. EFX appears to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipid metabolism. This holistic approach offers the potential to address the complex, multi-system disease state of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease — the leading cause of death in MASH patients. EFX is designed to offer convenient once-weekly dosing and has been generally well tolerated in clinical trials to date.

About MASH

MASH is a serious form of MASLD that is estimated to affect more than 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. MASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

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 MASH. Akero's lead product candidate, EFX, is currently being evaluated in three ongoing Phase 3 clinical trials in patients with pre-cirrhotic MASH (F2-F3) or compensated cirrhosis (F4) due to MASH: SYNCHRONY *Histology*, SYNCHRONY *Real-World*, and SYNCHRONY *Outcomes*. The SYNCHRONY program builds on the results of two Phase 2b clinical trials, the completed HARMONY study in patients with pre-cirrhotic MASH (F2-F3) and the ongoing SYMMETRY study in patients with compensated cirrhosis (F4) due to MASH, in which more than 300 patients have been treated for up to 96 weeks. 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, including future plans or expectations for EFX; expectations regarding the SYNCHRONY Phase 3 program, including the anticipated timing to report Phase 3 study results and the program's clinical trial design; the timing to report results of the ongoing Phase 2b SYMMETRY Study; the therapeutic effects of EFX as well as the dosing, safety and tolerability of EFX; 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 a clinical study 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)

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term marketable securities	$ 717,247	$ 550,010
Other current assets	29,641	9,952
Non-current assets	70,659	20,309
Total assets	$ 817,547	$ 580,271
Liabilities and Stockholders' Equity		
Current liabilities	$ 43,291	$ 19,128
Non-current liabilities	35,931	25,837
Stockholders' equity	738,325	535,306
Total liabilities and stockholders' equity	$ 817,547	$ 580,271

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

	Three Months Ended September30,		Nine Months Ended September30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 72,232	$ 38,634	$ 178,204	$ 88,406
General and administrative	9,471	7,981	29,194	22,591
Total operating expenses	81,703	46,615	207,398	110,997
Loss from operations	(81,703)	(46,615)	(207,398)	(110,997)
Interest expense	(1,246)	(888)	(3,468)	(2,202)
Interest and other income, net	10,244	7,844	28,830	16,626
Net loss	$ (72,705)	$ (39,659)	$ (182,036)	$ (96,573)
Comprehensive loss	$ (70,341)	$ (39,914)	$ (180,203)	$ (97,116)
Net loss per common share, basic and diluted	$ (1.05)	$ (0.71)	$ (2.76)	$ (1.87)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	69,442,136	55,613,120	65,982,798	51,506,766