UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 9, 2024

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38944**	**81-5266573**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

601 Gateway Boulevard, Suite 350
South San Francisco, CA **94080**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code (650) 487-6488

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On August 9, 2024, Akero Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on August 9, 2024, furnished herewith.
104	Cover Page Interactive Data File

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 9, 2024

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Name: Andrew Cheng, M.D., Ph.D.
Title: President and Chief Executive Officer

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

-- Initiated Phase 3 SYNCHRONY **Outcomes** *Trial of Lead Candidate Efruxifermin (EFX) in Patients with Compensated Cirrhosis (F4) Due to MASH*

-- Presented Poster and Late-breaking Oral Presentation on EFX at the EASL Congress 2024 --

-- Leadership Team Expanded with Addition of Scott Gangloff as Chief Technical Officer --

SOUTH SAN FRANCISCO, Calif. August 9, 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, today reported second quarter financial results for the period ending June 30, 2024 and provided business updates.

"The second quarter of 2024 brought important progress for EFX with the initiation of the Phase 3 SYNCHRONY ***Outcomes*** trial and appointment of a chief technical officer," said Andrew Cheng, president and CEO. "Initiation of the final planned trial in the Phase 3 SYNCHRONY program and expansion of our leadership team strengthen Akero's position to advance our EFX program, bringing us closer to providing this potentially transformative therapy to patients in need."

Third Phase 3 Clinical Trial Initiated In SYNCHRONY Program

- Akero's global Phase 3 SYNCHRONY clinical trial program consists of three ongoing global, randomized, placebo-controlled trials to support marketing applications for treatment of compensated cirrhosis due to metabolic dysfunction-associated steatohepatitis (MASH) and pre-cirrhotic MASH.
  - SYNCHRONY ***Outcomes*** is a two-cohort trial recruiting patients with compensated cirrhosis (F4) due to MASH to receive weekly injections of EFX 50mg or placebo. The primary histology endpoint (Cohort 1 only) is fibrosis regression without worsening of MASH after 96 weeks of treatment based on histology. Patients will continue treatment as randomized to be evaluated for the primary outcomes endpoint measured as time to first occurrence of any of the pre-defined, adjudicated events across both Cohort 1 and 2.
  - SYNCHRONY ***Histology*** is enrolling patients with pre-cirrhotic MASH, fibrosis stage 2 or 3 (F2-F3) to receive weekly injections of EFX 28mg, EFX 50mg, or placebo. The primary endpoint, to support an application for accelerated approval, is the proportion of patients experiencing ≥ 1-stage fibrosis improvement AND resolution of NASH/MASH after 52 weeks of treatment. After 52 weeks, patients will continue treatment as randomized in SYNCHRONY ***Histology*** to be followed for long-term clinical outcomes.
  - SYNCHRONY ***Real-World*** is enrolling patients with MASH or 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.

- In all EFX Phase 3 studies, patients are using the LyoJect 3S dual chamber syringe, a pre-filled device designed for self-administration and intended for commercial use in the event EFX is approved for marketing.

Phase 2b HARMONY Study Analyses Presented at EASL 2024

- In June 2024, Akero presented analyses of data from the Phase 2b HARMONY study evaluating the efficacy and safety of EFX in patients with pre-cirrhotic MASH, fibrosis stage 2 or 3 (F2-F3), in two presentations at the European Association for the Study of the Liver (EASL) Congress 2024.
- A late-breaking oral presentation featured 96-week data demonstrating that response rates for ≥1-stage improvement in fibrosis with no worsening of MASH were 75% ($p<0.001$) for 50 mg EFX and 46% ($p=0.07$) for 28 mg EFX, vs 24% for placebo.
    - The study also met additional histology endpoints at week 96. Notably 36% ($p<0.01$) and 31% ($p<0.01$) of patients treated with 50 mg EFX and 28 mg EFX, respectively, had a 2-stage improvement in fibrosis without worsening of MASH, more than 10-fold the placebo rate of 3%.
    - Among patients with more advanced F3 fibrosis at baseline, 68% and 40% of patients treated with 50mg EFX and 28mg EFX, respectively, experienced at least a one-stage improvement in fibrosis without worsening of MASH, compared with 14% for placebo.
    - A comparison of week 96 with week 24 results showed that treatment response among EFX-treated patients deepened and expanded with longer treatment, particularly among the 50 mg EFX group, with >80% of all EFX-treated patients with improved fibrosis at week 24 exhibiting sustained improvement through week 96.
    - Treatment with EFX was generally well tolerated, with no drug-induced liver injury or decompensation events, and no deaths. The most frequent adverse events were transient Grade 1 or 2 gastrointestinal events, with an overall event profile between weeks 24 and 96 that was similar to that observed during the first 24 weeks for EFX and comparable to placebo at week 96.
- A poster presentation featured results from a post-hoc analysis of biomarkers associated with collagen synthesis and degradation after 24 weeks treatment with EFX in the HARMONY study. Key observations included:
    - A shift from deposition to degradation of fibrillar (pathological) collagen.
    - Beneficial changes in the extracellular matrix (ECM) with regeneration of structural collagens (basement membrane), and regression of interstitial collagens (fibrils).
    - Correlation of remodeling of ECM biomarkers with reductions in markers of liver injury and regression of fibrosis by histopathology.

Appointment of Scott Gangloff as Chief Technical Officer

- In April 2024, Akero expanded its leadership team with the appointment of Scott Gangloff as Chief Technical Officer, bringing a track record of successful CMC (chemistry, manufacturing and control) development supporting global approvals and launch of several biologics. Scott's extensive knowledge and experience of establishing and optimizing supply chains will support a robust manufacturing capability for EFX at launch, if approved for marketing.

Phase 2b SYMMETRY Study

- The ongoing Phase 2b SYMMETRY study, evaluating the efficacy and safety of EFX in patients with compensated cirrhosis due to MASH (F4), remains on track to report week 96 results in the first quarter of 2025.

Second Quarter 2024 Financial Results

- Akero's cash, cash equivalents and short and long-term marketable securities as of June 30, 2024, were $848.3 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 June 30, 2024 were $55.3 million, compared to $28.0 million for the comparable period in 2023. These increases were attributable to higher expenses associated with completion of the Phase 2b HARMONY study, the ongoing SYMMETRY study, the ongoing Phase 3 SYNCHRONY ***Histology*** and SYNCHRONY ***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 June 30, 2024 were $10.4 million, compared to $7.6 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 $65.7 million for the three-month period ended June 30, 2024, compared to $35.6 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 the ongoing SYMMETRY study, a 96-week Phase 2b clinical trial in patients with compensated cirrhosis due to MASH (F4 fibrosis), as well as three ongoing Phase 3 clinical trials in patients with pre-cirrhotic MASH or compensated cirrhosis 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 HARMONY study in patients with pre-cirrhotic MASH (F2- F3) and the SYMMETRY study in patients with compensated cirrhosis due to MASH (F4). 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; the SYNCHRONY Phase 3 program 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; the anticipated contribution of management to its operations and progress; 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)

	June 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term marketable securities	$ 760,194	$ 550,010
Other current assets	15,816	9,952
Non-current assets	89,033	20,309
Total assets	$ 865,043	$ 580,271
Liabilities and Stockholders' Equity		
Current liabilities	$ 31,174	$ 19,128
Non-current liabilities	35,802	25,837
Stockholders' equity	798,067	535,306
Total liabilities and stockholders' equity	$ 865,043	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 55,322	$ 27,985	$ 105,972	$ 49,772
General and administrative	10,419	7,644	19,723	14,610
Total operating expenses	65,741	35,629	125,695	64,382
Loss from operations	(65,741)	(35,629)	(125,695)	(64,382)
Interest expense	(1,231)	(857)	(2,222)	(1,314)
Interest and other income, net	10,985	5,403	18,586	8,782
Net loss	$ (55,987)	$ (31,083)	$ (109,331)	$ (56,914)
Comprehensive loss	$ (56,169)	$ (31,355)	$ (109,862)	$ (57,202)
Net loss per common share, basic and diluted	$ (0.81)	$ (0.60)	$ (1.70)	$ (1.15)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	69,160,484	51,867,854	64,234,122	49,419,558