# 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): December 18, 2023**

# 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**<br>**South San Francisco, CA**<br>**(Address of principal executive offices)** | **94080**<br>**(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 7.01. Regulation FD Disclosure.**

On December 18, 2023, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Therapeutics Announces First Patients Dosed in Efruxifermin Phase 3 SYNCHRONY Program." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 8.01 Other Events.**

On December 18, 2023, the Company announced that patients have received their first doses of efruxifermin ("EFX") in its Phase 3 clinical study of EFX in the treatment of patients with biopsy-confirmed non-alcoholic fatty liver disease/metabolic dysfunction-associated steatotic liver disease ("NASH/MASH"), fibrosis stage 2 or 3 (F2-F3).

SYNCHRONY Histology will evaluate the efficacy of 28mg and 50mg doses of EFX in patients with biopsy confirmed pre-cirrhotic NASH, F2-F3. The primary endpoint will be ≥ 1-stage fibrosis improvement and resolution of NASH.

SYNCHRONY Real-World will assess safety and tolerability of EFX in patients with non-invasively diagnosed NASH or NAFLD.

Key secondary endpoints in both Phase 3 studies will include changes in biomarkers of liver fibrosis as well as measures of glycemic control and lipids.

**Forward-Looking Statements**

Statements contained under this Item 8.01 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 the potential therapeutic effects of EFX, the SYNCHRONY Phase 3 program, including the SYNCHRONY Histology and SYNCHRONY Real-World studies and design of trials. 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 Current Report on Form 8-K 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by Akero Therapeutics, Inc. on December 18, 2023, 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: December 18, 2023

**AKERO THERAPEUTICS, INC.**

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

**Akero Therapeutics Announces First Patients Dosed in Efruxifermin Phase 3 SYNCHRONY Program**

*Week 96 Phase 2b HARMONY Results for Treatment of Patients with Pre-Cirrhotic NASH/MASH (F2-F3) to be Reported in March 2024*

*End-of-Phase 2 FDA Meeting Scheduled for the first quarter of 2024 to Review Phase 3 Study and Regulatory Path for Treatment of NASH/MASH Patients with Compensated Cirrhosis (F4)*

SOUTH SAN FRANCISCO, Calif. December 18, 2023 /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 patients have received their first doses of efruxifermin (EFX) in the SYNCHRONY Phase 3 program. Two parallel, randomized, placebo-controlled trials have commenced: SYNCHRONY *Histology* evaluating the efficacy and safety of EFX in patients with biopsy-confirmed pre-cirrhotic nonalcoholic steatohepatitis/metabolic dysfunction-associated steatohepatitis (NASH/MASH), and SYNCHRONY *Real-World* assessing safety and tolerability of EFX in patients with non-invasively diagnosed NASH/MASH or non-alcoholic fatty liver disease/metabolic dysfunction-associated steatotic liver disease (NAFLD/MASLD).

“We are thrilled to have dosed the first patients in our Phase 3 program and are delighted with the current level of engagement by clinicians and patients,” said Kitty Yale, chief development officer of Akero. “We look forward to advancing the clinical development of EFX for both pre-cirrhotic and cirrhotic NASH/MASH as we strive to bring meaningful therapies to patients.”

SYNCHRONY *Histology* is expected to enroll approximately 1,000 patients with biopsy-confirmed NASH/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, such as progression to cirrhosis. SYNCHRONY *Real-World* is expected to enroll approximately 600 patients with NASH/MASH or NAFLD/MASLD diagnosed by non-invasive tests to receive weekly injections of EFX 50mg or placebo. The primary endpoint of safety and tolerability will be assessed after 52 weeks of treatment. Key secondary endpoints in both the *Histology* and *Real-World* studies include changes from baseline in markers of liver injury and fibrosis, glycemic control and lipids.

In all EFX Phase 3 studies, patients will self-administer EFX using the LyoJect 3S dual chamber syringe, a pre-filled device intended for commercial use in the event EFX is approved for marketing. This optimized formulation delivers blood levels of EFX comparable to those of the liquid formulation used in prior clinical studies.

**End-of-Phase 2 FDA Meeting to Discuss SYNCHRONY *Outcomes***

An FDA Type B, End-of-Phase-2 meeting has been scheduled for the first quarter of 2024 to review the design of the planned SYNCHRONY *Outcomes* study evaluating EFX in the treatment of NASH/MASH patients with compensated cirrhosis (F4). SYNCHRONY *Outcomes*, as proposed to FDA, will evaluate regression of fibrosis based on histology, with the potential to support applications for accelerated and conditional approval in the United States and Europe, respectively, and follow patients with cirrhosis for long-term clinical outcomes to support full approval.

**Readout of Week 96 Phase 2b HARMONY Results**

All week 96 visits for the Phase 2b HARMONY study, evaluating EFX for the treatment of pre-cirrhotic NASH/MASH (F2-F3), have been completed. Final 30-day follow-up visits are expected to be completed during January 2024 with results expected to be reported in March 2024.

**About Efruxifermin**

Efruxifermin, Akero's lead product candidate for treatment of NASH/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 is designed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipids. This holistic approach offers the potential to address the complex, multi-system disease state of NASH/MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH/MASH patients. EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

**About NASH/MASH**

NASH/MASH is a serious form of NAFLD/MASLD that is estimated to affect 17 million Americans. NASH/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 NASH/MASH will progress to cirrhosis, which has a higher risk of mortality. There are no approved treatments for the condition and NASH/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 NASH/MASH, a disease without any approved therapies. Akero's lead product candidate, EFX, is currently being evaluated in two ongoing, 96-week Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic NASH/MASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH/MASH (F4 fibrosis, compensated), as well as two Phase 3 clinical trials, the SYNCHRONY *Histology* study in patients with pre-cirrhotic NASH/MASH (F2-F3 fibrosis) and the SYNCHRONY *Real-World* study in patients with NASH/MASH or NAFLD/MASLD. Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and Twitter 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 SYNCHRONY Phase 3 program, including the SYNCHRONY Histology and SYNCHRONY Real-World studies and design of trials, the ongoing enrollment of Akero's Phase 3 SYNCHRONY program; expectations regarding communications with the FDA; and upcoming milestones, including the results, and expected timing to report the long-term

follow-up week 96 results of Akero's Phase 2b HARMONY study. 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.

**Investor Contact:**

Austin Murtagh
212.698.8696
IR@akerotx.com

**Media Contact:**

Sarah O'Connell
732.456.0092
soconnell@vergescientific.com