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): March 29, 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 **South San Francisco, CA** **(Address of principal executive offices)**	**94080** **(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 March 29, 2023, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Therapeutics Announces Positive End-of-Phase 2 Meeting with the FDA and SYNCHRONY Phase 3 Program for Efruxifermin in NASH." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On March 30, 2023, the Company announced a positive End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) as well as details of the planned SYNCHRONY Phase 3 efruxifermin (EFX) program for the treatment of nonalcoholic steatohepatitis (NASH).

Based on ongoing discussions with the FDA, the SYNCHRONY Phase 3 program will start enrolling patients into two parallel, randomized, placebo-controlled clinical trials during the second half of 2023.

- SYNCHRONY *Histology* will evaluate the efficacy of 50mg and 28mg doses of EFX in patients with biopsy confirmed pre-cirrhotic NASH, with fibrosis stage 2 or 3 (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 Non-alcoholic fatty liver disease. Key secondary endpoints are to include change in biomarkers of fibrosis and other established non-invasive endpoints.
- The duration of and total number of subjects to be enrolled in the SYNCHRONY *Histology* and *Real-World* trials are subject to confirmation with the FDA.

Following readout of the Phase 2b SYMMETRY trial during the fourth quarter of this year, and subsequent interactions with the FDA, the Company expects to finalize the design of the third Phase 3 clinical trial within the SYNCHRONY program.

- SYNCHRONY *Outcomes* is planned to evaluate the efficacy and safety of EFX in a compensated cirrhotic population, for which the primary endpoint will be clinical outcomes.

As previously indicated and consistent with ICH guidelines, the overall SYNCHRONY program has been designed to comprise a minimum of 1,500 patients exposed to the dose(s) of EFX that are anticipated to be proposed for approval.

Forward-Looking Statements

This Current Report on Form 8-K and certain materials furnished or filed herewith contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding: the Company's business plans and objectives, including future plans or expectations for EFX, the therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the design of trials, rate of enrollment and expected timing thereof, and expected timing to report results of Akero's Phase 2b SYMMETRY study.

Any forward-looking statements 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: risks related to the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, including potential negative impacts on the Company's employees, manufacturers, supply chain and production as well as on global economies and financial markets; the company'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 risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's annual report on Form 10-K filed, with the United States Securities and Exchange Commission (SEC) and subsequent filings with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company 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 March 29, 2023
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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: March 29, 2023

AKERO THERAPEUTICS, INC.

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

Akero Therapeutics Announces Positive End-of-Phase 2 Meeting with the FDA and SYNCHRONY Phase 3 Program for Efruxifermin in NASH

*The planned Phase 3 program consists of three trials, SYNCHRONY **Histology**, SYNCHRONY **Real-World**, and SYNCHRONY **Outcomes** to evaluate the safety and efficacy of efruxifermin (EFX) in patients with NASH*

*SYNCHRONY **Histology** and SYNCHRONY **Real-World** are expected to begin enrollment in the second half of this year*

Consistent with the encouraging clinical profile to date reported for 28mg and 50 mg EFX, Akero will continue to evaluate both doses in the Phase 3 SYNCHRONY program

SOUTH SAN FRANCISCO, Calif., March 29, 2023 – Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease and high unmet medical need, today announced a positive End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) as well as details of the anticipated SYNCHRONY Phase 3 efruxifermin program for the treatment of nonalcoholic steatohepatitis (NASH). There are currently no approved therapies for the treatment of NASH, a serious form of liver disease estimated to affect more than 17 million Americans.

“We are appreciative of the FDA’s support and guidance and are pleased to have aligned on key features of our SYNCHRONY Phase 3 program, with further dialogue envisaged following readout of the Phase 2b SYMMETRY trial evaluating EFX in patients with cirrhosis due to NASH,” said Kitty Yale, chief development officer of Akero. “The strength of EFX’s clinical profile reported to date in our Phase 2 studies gives us confidence in EFX’s potential to be a best-in-class FGF21 analog for treating NASH, if approved, and we look forward to enrolling patients into our first two Phase 3 trials within the SYNCHRONY program later this year.”

Based on ongoing discussions with the FDA, the SYNCHRONY Phase 3 program will start enrolling patients into two parallel, randomized, placebo-controlled clinical trials during the second half of this year.

- SYNCHRONY ***Histology*** will evaluate the efficacy of 28mg and 50mg doses of EFX in patients with biopsy confirmed pre-cirrhotic NASH, with fibrosis stage 2 or 3 (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 are to include change in biomarkers of fibrosis and other established non-invasive endpoints.
- The duration of and total number of subjects to be enrolled in the SYNCHRONY ***Histology*** and ***Real-World*** trials are subject to confirmation with the FDA.

Following readout of the Phase 2b SYMMETRY trial during the fourth quarter of this year, and subsequent interactions with the FDA, Akero expects to finalize the design of the third Phase 3 clinical trial within the SYNCHRONY program.

- SYNCHRONY ***Outcomes*** is planned to evaluate the efficacy and safety of EFX in a compensated cirrhotic population, for which the primary endpoint will be clinical outcomes.

As previously indicated and consistent with ICH guidelines, the overall SYNCHRONY program has been designed to comprise a minimum of 1,500 patients exposed to the dose(s) of EFX that are anticipated to be proposed for approval.

About NASH

Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. An estimated 17.3 million Americans had NASH (fibrosis stages 1-4) in 2016, a number that is predicted to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

About Efruxifermin

Efruxifermin (EFX), formerly known as AKR-001, is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY and SYMMETRY trials, as described in the "About Akero Therapeutics" section below. EFX is designed to reverse fibrosis, reduce liver fat and inflammation, increase insulin sensitivity, and improve lipoproteins. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH 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 non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (EFX), is a differentiated bivalent 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 offer convenient once-weekly subcutaneous dosing. The consistency and magnitude of observed effects to date position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in two Phase 2b clinical trials: the HARMONY trial in patients with pre-cirrhotic NASH (F2-F3 fibrosis), and the SYMMETRY trial in patients with cirrhotic NASH (F4 fibrosis, compensated). EFX is also being evaluated in an expansion cohort of the SYMMETRY trial, comparing safety and tolerability of EFX to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. Akero is headquartered in South San Francisco. Visit 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, including future plans or expectations for efruxifermin (EFX), the therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the design of trials and expected timing thereof; and expected timing to report results of Akero's Phase 2b SYMMETRY 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: risks related to the impact of COVID-19 on Akero's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; 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 subsequent filings 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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