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): June 25, 2021

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 June 25, 2021, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Therapeutics Presents at the American Diabetes Association's 81st Scientific Sessions, Demonstrating that Improvements in Adipose Tissue Metabolism Contributed Substantially to Improved Liver Health and Better Glycemic Control in Efruxifermin (EFX)-treated Pre-Cirrhotic NASH Patients." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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.

The Company today announced additional analyses from its Phase 2a BALANCED study of efruxifermin (EFX) in NASH patients with F1-F3 fibrosis, which are being presented by Juan Frias, MD, medical director of the National Cancer Institute, as two posters at the American Diabetes Association's 81st Scientific Sections (ADA). The posters are available starting at 11:30am ET on June 25, 2021 and will be posted to the company's website. The company's EFX program in NASH is also being featured in a video presentation at the ADA, which can be accessed from the company's website.

In a poster presentation titled "Efruxifermin is associated with improved glucose metabolism in patients with NASH and type 2 diabetes" (Abstract 116-LB), Dr. Frias reports improvements in markers of glucose metabolism, insulin sensitivity and lipoprotein profile, with a trend to reduce body weight, in patients with NASH and type 2 diabetes mellitus after 16 weeks of treatment with EFX. These improvements, including a clinically meaningful and statistically significant reduction in HbA1c, were seen on top of concomitant anti-diabetic medications.

In a second poster presentation titled "Increased adiponectin following efruxifermin treatment is associated with improvements in dyslipidemia, glucose metabolism, and liver health in a 16-week, randomized, placebo-controlled NASH trial" (Abstract 119-LB), Dr. Frias reports the contribution of FGFR1c activation by EFX in adipose tissue, as indicated by increased serum adiponectin, to the beneficial effects observed on liver health and glucose metabolism. These secondary analyses highlight the potential of FGFR1c-mediated reprogramming of adipose metabolism in NASH patients to improve liver health. Insulin-sensitizing therapeutics acting predominantly on adipose tissue, such as pioglitazone, have historically been associated with weight gain. A consistent trend toward weight loss in the BALANCED study suggests that EFX may redirect fat away from the liver to adipose tissue in a weight-neutral manner, contributing to the potentially unique therapeutic profile of EFX.

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 Akero's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; Akero's Phase 2a BALANCED clinical trial, including additional analysis of its data and potential therapeutic benefits; Akero's Phase 2b HARMONY clinical trial; and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials.

Any forward-looking statements in this Current Report on Form 8-K 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, as filed with the Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the 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 June 25, 2021

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: June 25, 2021

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

Akero Therapeutics Presents at the American Diabetes Association's 81st Scientific Sessions, Demonstrating that Improvements in Adipose Tissue Metabolism Contributed Substantially to Improved Liver Health and Better Glycemic Control in Efruxifermin (EFX)-treated Pre-Cirrhotic NASH Patients

Analyses Show that the Magnitude of Reductions in Markers of Liver Injury and Fibrogenesis, as well as HbA1c, Strongly Correlated with Increased Adiponectin Levels, which Specifically Reflect EFX Activity in Adipose Tissue

SOUTH SAN FRANCISCO, June 25, 2021 /GLOBE NEWSWIRE/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today announced additional analyses from its Phase 2a BALANCED study of efruxifermin (EFX) in NASH patients with F1-F3 fibrosis, which are being presented by Juan Frias, MD, medical director of the National Cancer Institute, as two posters at the American Diabetes Association's 81st Scientific Sections (ADA). The posters are available starting at 11:30am ET on June 25, 2021 and will be posted to the company's website. The company's EFX program in NASH is also being featured in a video presentation at the ADA, which can be accessed from the company's website.

In a poster presentation titled "Efruxifermin is associated with improved glucose metabolism in patients with NASH and type 2 diabetes" (Abstract 116-LB), Dr. Frias reports improvements in markers of glucose metabolism, insulin sensitivity and lipoprotein profile, with a trend to reduce body weight, in patients with NASH and type 2 diabetes mellitus after 16 weeks of treatment with EFX. These improvements, including a clinically meaningful and statistically significant reduction in HbA1c, were seen on top of concomitant anti-diabetic medications.

"Improving insulin sensitivity and glucose metabolism is a critical component in the management of NASH because metabolic dysregulation plays a major role in the pathophysiology of this disorder, and because roughly one third of patients with type 2 diabetes also have NASH—often with suboptimal glycemic control," said Dr. Frias. "These preliminary data demonstrating improvements in glucose metabolism with EFX are very encouraging and indicate that EFX may play an important future role in the management of NASH in patients with glucose intolerance."

In a second poster presentation titled "Increased adiponectin following efruxifermin treatment is associated with improvements in dyslipidemia, glucose metabolism, and liver health in a 16-week, randomized, placebo-controlled NASH trial" (Abstract 119-LB), Dr. Frias reports the contribution of FGFR1c activation by EFX in adipose tissue, as indicated by increased serum adiponectin, to the beneficial effects observed on liver health and glucose metabolism. These secondary analyses highlight the potential of FGFR1c-mediated reprogramming of adipose metabolism in NASH patients to improve liver health. Insulin-sensitizing therapeutics acting predominantly on adipose tissue, such as pioglitazone, have historically been associated with weight gain. A consistent trend toward weight loss in the BALANCED study suggests that EFX may redirect fat away from the liver to adipose tissue in a weight-neutral manner, contributing to the potentially unique therapeutic profile of EFX.

"The only way to really treat NASH is to treat the whole body and not just the liver," said Tim Rolph, chief scientific officer of Akero Therapeutics. "The breadth, consistency and magnitude of effects observed following treatment with EFX across clinical trials in patients with metabolic disease appear to derive from EFX's balanced agonism of FGF21's receptors in adipose tissue and liver."

About Akero Therapeutics

Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (EFX) 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. In prior clinical trials, EFX has reversed fibrosis, resolved NASH, reduced liver fat, improved glycemic control, improved lipoprotein profile, and shown a trend to lower body weight. The consistency and magnitude of observed effects position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in a Phase 2b clinical trial in NASH patients with F2/F3 fibrosis, the HARMONY study. Akero is headquartered in South San Francisco. Visit www.akerotx.com 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, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; Akero’s Phase 2a BALANCED clinical trial, including additional analysis of its data and potential therapeutic benefits; Akero’s Phase 2b HARMONY clinical trial; and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical 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: 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, as filed with the Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the 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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