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 21, 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 21, 2021, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Therapeutics Presents Analyses at the 2021 International Liver Congress Showing Normalization of Liver Fat Substantially Reduced Markers of Liver Injury and Fibrosis, and Greatly Increased Probability of Resolving NASH." 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.

On June 21, 2021, the Company announced additional analyses from its Phase 2a BALANCED study of efruxifermin (EFX) in NASH patients with F1-F3 fibrosis, which were presented in two posters at the 2021 International Liver Congress. These analyses show significant correlations between normalization of liver fat (≤ 5% liver fat content (LFC) by MRI-PDFF) and improvements in markers of liver injury and fibrosis, as well as whole-body metabolism. The new analyses also show that combining ALT response of ≥ 17 U/L with normalization of liver fat increases the power to predict resolution of NASH (0- or 1-point for lobular inflammation and 0 points for ballooning component of NAFLD Activity Score) and NASH resolution combined with a 1-stage improvement in fibrosis. Reduction of ALT did not appear to predict regression of fibrosis.

Extent of Reduction of Liver Fat (LFC) at Week 12

Endpoint	Placebo[a]	28mg EFX	50mg EFX	70mg EFX
Relative Reduction in LFC				
≥50%	5%	69%**	100%***	93%***
≥70%	5%	50%*	53%**	80%***
Normalization of LFC				
≤5% at Week 12	5%	25%*	53%**	67%***

*p<0.05, **p<0.01, ***p<0.001

[a] A single placebo responder lost 25 pounds over 16 weeks (11% weight reduction)

Summary of Key Odds Ratios for Liver Fat Normalization[a]

Histologic Endpoint	Odds Ratio (95% CI)[b]	P value[c]
NASH Resolution[1]	4.1 (1.2, 13.2)	0.0365
NAS Reduction by ≥4[2]	6.4 (1.8, 15.6)	0.0068

[a] ≤5% Liver Fat Content at Week 12; [b] Wald 95% Confidence Interval; [c] Fisher's exact test;

[1] 0- or 1-point for lobular inflammation and 0 points for ballooning components of NAFLD Activity Score

[2] At least 2 points in lobular inflammation and/or ballooning components of NAFLD Activity Score

Summary of Key AUROC for Predicting Histological Response Among ALT Responders[a]

Histologic Endpoint	ALT Responders (N=28)	ALT Responders with ≤ 5% Liver Fat Content (N=16)
NASH Resolution	0.74 (0.56, 0.93)	0.83 (0.61, 1)
NASH Resolution and Fibrosis Improvement of ≥1 Stage	0.62 (0.39, 0.86)	0.79 (0.90, 70.2)

[a] *Among Patients with available MRI-PDFF and ALT change at Week 12, and end-of-treatment biopsy (N=54)*

EFX is currently being evaluated in a Phase 2b clinical trial in patients with F2/F3 fibrosis, the HARMONY study. A second Phase 2b clinical trial in patients with Cirrhotic (F4) NASH is planned for the second half of 2021.

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, including expected timing to complete enrollment and report preliminary results; 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. 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 June 21, 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 21, 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 Analyses at the 2021 International Liver Congress Showing Normalization of Liver Fat Substantially Reduced Markers of Liver Injury and Fibrosis, and Greatly Increased Probability of Resolving NASH

Analyses also Show that Combining a Threshold for ALT Reduction of ≥17 U/L with Normalization of Liver Fat Improves Predictive Power for Resolution of NASH with 1-Stage Improvement of Fibrosis

SOUTH SAN FRANCISCO, June 21, 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 were presented in two posters at the 2021 International Liver Congress. These analyses show significant correlations between normalization of liver fat (≤ 5% liver fat content (LFC) by MRI-PDFF) and improvements in markers of liver injury and fibrosis, as well as whole-body metabolism. The new analyses also show that combining ALT response of ≥ 17 U/L with normalization of liver fat increases the power to predict resolution of NASH (0- or 1-point for lobular inflammation and 0 points for ballooning component of NAFLD Activity Score) and NASH resolution combined with a 1-stage improvement in fibrosis.

- Abstract No. 1314: "The role of reduction in liver fat content (MRI-PDFF) and ALT in predicting treatment response in NASH: A secondary analysis of the randomized, controlled BALANCED trial," presented by Rohit Loomba, M.D.
- Abstract No. 1762: "Correlation between changes in liver fat content and improvements in serum markers of liver injury, fibrosis, metabolism, and in histologic parameters following treatment with efruxifermin," presented by Stephen Harrison, M.D.

“These analyses provide evidence that rapid and substantial liver fat reduction was associated with improvements in markers of liver metabolic health and improvement of NASH histopathology following treatment with efruxifermin,” said Kitty Yale, chief development officer of Akero. “These analyses also make an important contribution toward the development of noninvasive markers that can predict histological improvements in NASH. Based on the strength of these correlations, as well as biopsy results from the BALANCED study, we believe treatment with EFX will result in sustained histological improvements in our ongoing and future clinical trials.”

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"EFX is the first therapy to have shown at least a 70 percent relative reduction in liver fat in a majority of all patients evaluated, and normalization of liver fat in approximately half of all patients evaluated," said Stephen Harrison, MD, medical director of Pinnacle Clinical Research. "These analyses showing that large reductions or normalization of liver fat correlate with improvements in multiple non-invasive markers and histopathology of NASH suggest the potential of EFX to set a new threshold for magnitude of liver fat reduction and associated removal of the underlying driver of NASH."

EFX is currently being evaluated in a Phase 2b clinical trial in patients with F2/F3 fibrosis, the HARMONY study. A second Phase 2b clinical trial in patients with Cirrhotic (F4) NASH is planned for the second half of 2021.

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 reduced 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

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