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): February 25, 2022

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 2.02 Results of Operations and Financial Condition

On February 25, 2022, Akero Therapeutics, Inc. announced its financial results for the quarter and full year ended December 31, 2021. 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 February 25, 2022, furnished herewith.
104	Cover Page Interactive Data File (embedded within the 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: February 25, 2022

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

Akero Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results

Akero Remains on Track to Report Phase 2b HARMONY Study Results in the Third Quarter of This Year

SOUTH SAN FRANCISCO, February 25, 2022 /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 fourth quarter and full year financial results for the period ending December 31, 2021.

"Our confidence in efruxifermin's (EFX's) potential to be a best-in-class FGF21 analog for the treatment of NASH continues to grow," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "In 2021 we built on the strong results from our Phase 2a study evaluating EFX in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) by initiating two Phase 2b clinical trials in patients with pre-cirrhotic and cirrhotic NASH. We continue to advance our clinical trials and look forward to reporting our first set of Phase 2b results in the third quarter of this year, consistent with prior guidance."

Phase 2b HARMONY Study Update

- Enrollment for the HARMONY study, a multicenter, randomized, double-blind, placebo-controlled, clinical trial in patients with biopsy-confirmed NASH with fibrosis stage 2 or 3, was completed in February 2022.
- Consistent with initial guidance, Akero remains on track to report HARMONY results in the third quarter of this year.

Manufacturing Update

- Through its drug substance manufacturing partner, Boehringer Ingelheim, Akero recently completed manufacture of EFX drug substance for Phase 3 clinical trials, using the process and scale envisaged for post-approval commercial production.
- Manufacture of a new lyophilized drug product formulation in a pre-filled, dual-chamber syringe device has been established at commercial production scale by Vetter Pharma, Akero's drug product and device manufacturing partner. This dual-chamber device, which is designed to enable convenient, weekly self-administration by patients, is intended to be the commercial presentation for EFX drug product, if approved. Release of clinical batches to support Phase 3 initiation is expected to be completed in 2022.

Full Year and Fourth Quarter 2021 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the year ended December 31, 2021 were $188.3 million.
- Akero believes that its cash, cash equivalents and short-term marketable securities will be sufficient to fund its current operating plan into the third quarter of 2023.
- Research and development expenses for the three-month and twelve-month periods ended December 31, 2021 were $27.7 million and $81.8 million, respectively, compared to $25.7 million and $64.9 million for the comparable periods in 2020. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing, contract research organization costs associated with the HARMONY and SYMMETRY studies and internal personnel costs.

- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2021 were $4.7 million and $19.1 million, respectively, compared to $4.1 million and $15.2 million for the comparable periods in 2020. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with operating as a public company.
- Total operating expenses were $32.4 million and $100.9 million for the three-month and twelve-month periods ended December 31, 2021, respectively, compared to $29.8 million and $80.2 million for the comparable periods in 2020.

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 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 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 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 study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). Akero is headquartered in South San Francisco. Visit us at www.akerotx.com for more information.

About the HARMONY Study

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients have been randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is fibrosis regression after 24 weeks of treatment. To provide additional safety data, patients will continue to receive EFX or placebo for up to 96 weeks of treatment.

About the SYMMETRY Study

The Phase 2b SYMMETRY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in patients with biopsy-confirmed cirrhotic NASH, fibrosis stage 4, compensated. Patients are being randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is fibrosis regression (reversal of cirrhosis) at 36 weeks. To provide additional safety data, patients will continue to receive EFX or placebo for up to 96 weeks of treatment.

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; conduct of Akero's Phase 2b HARMONY study and Phase 2b SYMMETRY study, including expected timing to report results; the timely availability of, and future plans for, a new combination drug product-device to support Phase 3 clinical trials and its potential therapeutic and commercial use; expectations regarding Akero's use of capital, expenses and other future financial results and the potential impact of COVID-19 on strategy, future operations, manufacturing, and clinical trial enrollment and data collection. 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) 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. 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.

Akero Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and short-term marketable securities	$ 188,258	$ 268,387
Other current assets	5,324	2,958
Non-current assets	1,966	1994
Total assets	$ 195,548	$ 273,339
Liabilities and Stockholders' Equity		
Current liabilities	$ 25,128	$ 13,111
Non-current liabilities	1,311	1516
Stockholders' equity	169,109	258,712
Total liabilities and stockholders' equity	$ 195,548	$ 273,339

Akero Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 27,711	$ 25,709	$ 81,759	$ 64,916
General and administrative	4,728	4,074	19,127	15,238
Total operating expenses	32,439	29,783	100,886	80,154
Loss from operations	(32,439)	(29,783)	(100,886)	(80,154)
Other income	15	72	109	947
Net loss	$ (32,424)	$ (29,711)	$ (100,777)	$ (79,207)
Comprehensive loss	$ (32,434)	$ (29,730)	$ (100,801)	$ (79,204)
Net loss per common share, basic and diluted	$ (0.93)	$ (0.86)	$ (2.89)	$ (2.52)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,886,574	34,684,466	34,827,385	31,463,248

Investor Contact:
Christina Tartaglia
212.362.1200
IR@akerotx.com

Media Contact:
650.487.6488
media@akerotx.com