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): November 12, 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 2.02 Results of Operations and Financial Condition

On November 12, 2021, Akero Therapeutics, Inc. announced its financial results for the quarter ended September 30, 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 November 12, 2021, 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: November 12, 2021

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 Third Quarter 2021 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today reported third quarter financial results for the period ending September 30, 2021.

“Our team remains focused on successfully completing two Phase 2b clinical trials, and diligently working with regulators to bring efruxifermin (EFX) to market, potentially as a treatment for patients with more advanced NASH who have the highest medical need,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “We are pleased to have received a Fast Track designation from the FDA, which we believe is a testament to the strength of results we observed in our Phase 2a BALANCED study.”

Third Quarter Business Highlights & Company Updates

- In October, Akero announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to its lead program investigating efruxifermin (EFX) for the treatment of non-alcoholic steatohepatitis (NASH). This designation enables more frequent interactions with the FDA and potential eligibility for priority review if clinical data support it.
- During the third quarter, Akero continued to progress its Phase 2b program comprised of parallel clinical trials in pre-cirrhotic patients with F2/F3 fibrosis (the HARMONY study) and cirrhotic (compensated, F4) NASH (the SYMMETRY study). Akero also continued to make progress towards a successful manufacture of drug product for its Phase 3 program.

Third Quarter 2021 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the period ended September 30, 2021 were $215.1 million.
- Akero believes that its cash, cash equivalents and 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 period ended September 30, 2021 were $19.5 million, compared to $17.4 million for the comparable period in 2020. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing and process development costs, contract research organization costs associated with the HARMONY and SYMMETRY studies and internal personnel costs.
- General and administrative expense for the three-month period ended September 30, 2021 were $4.9 million, compared to $4.2 million for the comparable period in 2020. This increase is 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 $24.4 million for the three-month period ended September 30, 2021, compared to $21.5 million for the corresponding period in 2020.

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. 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 NASH patients with F2/F3 advanced fibrosis and the SYMMETRY study in cirrhotic (compensated, F4) NASH patients. Akero is headquartered in South San Francisco. Visit us at 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 2b HARMONY and Phase 2b SYMMETRY clinical trials; the potential benefits resulting from the Fast Track designation of EFX and related implications; expectations regarding Akero’s use of capital, expenses and other future financial results; 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.

Investor Contact:

Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina.tartaglia@sternir.com

Media Contact:

650.487.6488
media@akerotx.com

Index

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

	September 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and short-term marketable securities	$ 215,081	$ 268,387
Other current assets	6,726	2,958
Non-current assets	1,726	1,994
Total assets	$ 223,533	$ 273,339
Liabilities and Stockholders' Equity		
Current liabilities	$ 23,540	$ 13,111
Non-current liabilities	1,365	1,516
Stockholders' equity	198,628	258,712
Total liabilities and stockholders' equity	$ 223,533	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 19,470	$ 17,379	$ 54,048	$ 39,207
General and administrative	4,883	$ 4,159	14,399	11,164
Total operating expenses	24,353	21,538	68,447	50,371
Loss from operations	(24,353)	(21,538)	(68,447)	(50,371)
Other income	23	135	94	875
Net loss	$ (24,330)	$ (21,403)	$ (68,353)	$ (49,496)
Comprehensive loss	$ (24,338)	$ (21,477)	$ (68,367)	$ (49,474)
Net loss per common share, basic and diluted	$ (0.70)	$ (0.63)	$ (1.96)	$ (1.63)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,862,116	34,002,769	34,807,439	30,381,671