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, 2020

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, 2020, Akero Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2020. 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, 2020, furnished herewith.

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, 2020

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 2020 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif., November 12, 2020 -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic non-alcoholic steatohepatitis (NASH) company developing pioneering medicines designed to restore metabolic balance and improve the overall health of NASH patients, today reported third quarter financial results for the period ending September 30, 2020.

“On the heels of reporting strongly positive histological data from our FGF21 analog, efruxifermin (EFX), we executed a number of important objectives in the third quarter that position us for continued success,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “In addition to raising more than $216 million to enable continued development of EFX, we received feedback from the FDA that enables us to continue to pursue EFX development with our proposed adaptive Phase 2b/3 clinical trial design. EFX also received PRIME designation from EMA for development as a NASH therapy. Each of these milestones represents a large step forward in the development of EFX, which we believe has the potential to be a foundational monotherapy for NASH.”

Third Quarter Business Highlights

- On July 10th, the Company closed an upsized underwritten public offering of 6,012,390 shares of common stock at a price of $36.00 per share. Gross proceeds from the offering, before deducting underwriting discounts, commissions and offering expenses, were approximately $216.4 million.

- On July 21st, the Company announced publication of data in the journal *Cell Reports Medicine* from the Phase 1b clinical trial of EFX, which showed its potential to modulate biomarkers associated with metabolic diseases, including NASH.

- On Sept. 24th, the Company announced that written guidance from the U.S. Food and Drug Administration (FDA) enables implementation of an innovative combined Phase 2b/3 study design for a pivotal EFX clinical trial in NASH patients with F2-F3 fibrosis. Under the planned adaptive trial design, the Company will evaluate the 28 and 50mg EFX doses in a 24-week Phase 2b portion of the trial to inform selection of one of these doses for evaluation in the Phase 3 portion of the study.

- On Sept. 30th, the Company announced enrollment had been completed for a cohort of the BALANCED study (Cohort C), which is investigating the effects of 16 weeks of EFX treatment on patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A. The Company expects results from this study cohort to inform long-term development plans for EFX to treat cirrhotic NASH patients, who are at greatest risk of progressing to end-stage liver disease. The Company expects to report the results of the F4 expansion cohort in the first half of 2021.

- On Oct. 16th, the Company announced that the European Medicines Agency (EMA) granted Priority Medicines (PRIME) designation to EFX for treatment of NASH. The designation was based on the positive efficacy data reported from the Company's Phase 2a BALANCED study. The PRIME program is designed to enhance regulatory support in the EU for the development of promising investigational medicines that target unmet medical need.

Manufacturing Update

- Manufacture of GMP drug substance (API) at commercial scale was completed in April 2020. GMP drug product for the Company's anticipated Phase 2b clinical trial was manufactured from this API in September 2020.

- A new lyophilized formulation is being developed for commercial drug product. This formulation will be used for the Phase 3 portion of the adaptive clinical trial design. Scale-up of manufacturing for this new drug product formulation began during the third quarter of 2020 and is expected to be completed in 2022.

Regulatory Update

- Submission of multiple Investigational New Drug (IND) amendments are ongoing to support the Phase 2b portion of the adaptive Ph2b/3 study design. The Company remains on track to initiate Phase 2b in the first half of 2021.

Financial Highlights

- Akero's cash, cash equivalents and short-term marketable securities at September 30, 2020 were $291.9 million, which includes the net proceeds from the July 10th equity offering.

- Research and development expenses for the three-month and nine-month periods ended September 30, 2020 were $17.4 million and $39.2 million, respectively, compared to $13.9 million and $23.9 million for the comparable periods in 2019. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing and contract research organization costs associated with the BALANCED study and internal personnel costs, including non-cash stock-based compensation.

- General and administrative expenses for the three-month and nine-month periods ended September 30, 2020 were $4.2 million and $11.2 million, respectively, compared to $2.4 million and $5.5 million for the comparable periods in 2019. These increases are attributable to higher internal personnel costs, including non-cash stock-based compensation and professional services and other costs associated with operating as a public company.

- Total operating expenses for the three-month and nine-month periods ended September 30, 2020, were $21.5 million and $50.4 million, respectively, compared to $16.3 million and $29.4 million for the comparable periods in 2019.

About NASH

NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) and is estimated to affect 17 million Americans. NASH is closely linked to the obesity and diabetes epidemics seen around the world. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. As a result, NASH has become a leading cause of liver transplants in the US and Europe.

About Efruxifermin

Efruxifermin (EFX), formerly AKR-001, is Akero's lead product candidate for NASH. EFX has been shown to increase insulin sensitivity, improve lipoproteins, reduce liver fat and inflammation, and reverse fibrosis. The breadth of desirable metabolic effects offers potential to address the complex, multi-organ/tissue pathogenesis of NASH, including risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native human FGF21, EFX offers convenient once-weekly dosing.

About Akero Therapeutics

Akero is a cardio-metabolic NASH company dedicated to reversing the escalating NASH epidemic by developing pioneering medicines designed to restore metabolic balance and improve overall health of NASH patients. The Company’s lead product candidate, efruxifermin, has been evaluated in a 16-week Phase 2a clinical trial, the BALANCED study. Akero Therapeutics is headquartered in South San Francisco, CA. For more information, please visit www.akerotx.com.

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 the Company'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; the potential benefits resulting from the PRIME designation of EFX; Akero’s Phase 2a BALANCED study and Phase 2b/3 study including results and expected timing to complete Cohort C; expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for EFX; expectations regarding successful scale-up of drug substance manufacturing and release of new drug product for use in clinical trials, including new product formulations; expectations regarding the Company’s use of capital, expenses and other future financial results; statements regarding the timing of Company’s efforts regarding the IND amendments; the Company’s planned efforts to prepare for commercialization of EFX, if approved 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 the Company’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 the Company's product candidate development activities and planned clinical trials; 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 foreign countries; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero’s Annual Report on Form 10-K for the year ended December 31, 2019 and most recently filed Quarterly Report on 10-Q, 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. 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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Akero Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents and short-term marketable securities	$ 291,870	$ 136,400
Other current assets	6,163	1,649
Non-current assets	2,003	69
Total assets	$ 300,036	$ 138,118
Liabilities and Stockholders' Equity		
Current liabilities	$ 12,014	$ 9,369
Non-current liabilities	1,564	23
Stockholders' equity	286,458	128,726
Total liabilities and stockholders' equity	$ 300,036	$ 138,118

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 17,379	$ 13,885	$ 39,207	$ 23,908
General and administrative	4,159	2,424	11,164	5,522
Total operating expenses	21,538	16,309	50,371	29,430
Loss from operations	(21,538)	(16,309)	(50,371)	(29,430)
Other income	135	755	875	1,286
Net loss	$ (21,403)	$ (15,554)	$ (49,496)	$ (28,144)
Comprehensive loss	$ (21,477)	$ (15,554)	$ (49,474)	$ (28,144)
Net loss per common share, basic and diluted	$ (0.63)	$ (0.56)	$ (1.63)	$ (2.66)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,002,769	28,024,779	30,381,671	10,589,119