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): August 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	**94080**
(Address of principal executive offices)	**(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 August 12, 2020, Akero Therapeutics, Inc. announced its financial results for the quarter ended June 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 August 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: August 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 SECOND QUARTER 2020 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif., August 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 second quarter financial results for the period ending June 30, 2020.

“During the second quarter of 2020, we reported the first histological results for our FGF21 analog, efruxifermin (EFX), formerly AKR-001. We observed improvements in histological parameters of NASH after only 16 weeks of treatment, the magnitude of which is among the highest observed to date across the NASH field, despite other compounds having been evaluated for 24 to 78 weeks. These results have increased our confidence in EFX’s potential to become a foundational NASH monotherapy,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “We believe positive histological data in biopsy-confirmed NASH patients could be a prerequisite for the FDA to define a registrational development path for any investigational NASH compound. We look forward to discussing our development path with the FDA and advancing a potentially promising therapy for patients, if our development plan is approved.”

Clinically meaningful improvements in glycemic control, weight loss and lipoproteins were also observed in the main BALANCED study. “The significant reductions in HbA1c and body weight we observed in biopsy-confirmed NASH patients following EFX treatment were firsts for an FGF21 analogue,” said Tim Rolph, D.Phil., chief scientific officer of Akero. “Although various preclinical models have shown FGF21 improves glycemic control and weight loss, these improvements have not translated to humans with prior FGF21 analogs. We believe the clinical results observed for EFX can be attributed to EFX’s unique engineering, based on pioneering discoveries that enabled the pharmacology of human FGF21 to be reproduced in a long acting FGF21 analog.”

Second Quarter Business Highlights

- The Company reported secondary and exploratory histology results following 16 weeks of treatment with EFX. Of the 40 biopsy-confirmed NASH patients treated with EFX who had end-of-treatment biopsies:
    - 48% achieved at least a one-stage improvement in fibrosis with no worsening of NASH;
    - 28% achieved at least a two-stage improvement in fibrosis;
    - 48% achieved NASH resolution with no worsening of fibrosis; and
    - 28% achieved both NASH resolution and at least a one-stage improvement in fibrosis.

  These results build on the significant 12-14% absolute reductions (corresponding to 63-72% relative reductions) in liver fat, in each case compared with 0% for placebo. Reductions of 24-32 U/L were observed for ALT, a validated marker of liver damage, compared with 6 U/L for placebo.

- The Company also reported multiple exploratory endpoints for various biomarkers. Results for patients treated with EFX for 16 weeks include:
    - Significant absolute reductions of 0.4% and 0.5% in HbA1c for the 50 and 70mg dose groups, respectively, compared to a 0.1% increase for placebo;
    - Absolute reductions of 2.3kg and 3.7kg in body weight for the 50 and 70mg dose groups, with the latter attaining significance, compared with an increase of 0.1kg for placebo;
    - Significant 37-45% relative reductions in plasma triglycerides, compared with an 8% increase for placebo;
    - Significant 32-40% relative increases in HDL cholesterol, compared with no change for placebo;
    - Significant 13-20% relative reductions in non-HDL cholesterol, compared with no change for placebo; and
    - No increase in LDL cholesterol.
- On June 16th, the Company dosed its first patient in an expansion cohort of the BALANCED study, Cohort C, which is designed to assess safety and tolerability of treatment with EFX in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A. The Company expects the results of Cohort C to inform the long-term development plan for this patient population, which is at greatest risk of progressing to end-stage liver disease.
- 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, which included the exercise in full by the underwriters of their option to purchase an additional 784,224 shares. The gross proceeds, before deducting underwriting discounts and commissions and estimated offering expenses, were approximately $216.4 million. J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Jefferies LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering.

Manufacturing Update

- Manufacture of GMP drug substance (API) at commercial scale was completed in April 2020. This API has been used to manufacture drug product for our anticipated Phase 2b clinical trial. Release of this drug product is expected during the fourth quarter of this year.
- A new formulation of drug product has been developed for use in Phase 3 and commercial launch. Scale up of manufacture for this new drug product will commence during the third quarter of 2020.

Regulatory Update

- FDA's responses to the Company's proposed registrational development plan are expected later this year. The Company has proposed that the 28mg and 50mg doses be evaluated in a Phase 2b clinical trial as part of an adaptive Phase 2b/3 trial design. Submission of Investigational New Drug (IND) amendments to support the Phase 2b clinical trial are expected later this year.

COVID-19 Update

- The COVID-19 pandemic has not materially impacted enrollment or data collection for the BALANCED study or preparations for the Company's upcoming clinical trials.

Financial Highlights

- Akero's cash, cash equivalents and short-term marketable securities at June 30, 2020 were $102.8 million. Following the July 10th equity offering, the Company's cash, cash equivalents and marketable securities were $305.6 million.

- Research and development expenses for the three-month and six-month periods ended June 30, 2020 were $13.0 million and $21.8 million, respectively, compared to $6.0 million and $10.0 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 six-month periods ended June 30, 2020 were $3.4 million and $7.0 million, respectively, compared to $1.6 million and $3.1 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 six-month periods ended June 30, 2020, were $16.5 million and $28.8 million, respectively, compared to $7.6 million and $13.1 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. The progressive damage to the liver associated with NASH resembles the pathology associated with excessive alcohol consumption or viral infections. 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. Efruxifermin was designed to increase insulin sensitivity, improve lipoproteins, reduce liver fat and inflammation, and reverse fibrosis. This holistic approach offers the potential to address the complex, multi-organ/tissue pathogenesis of NASH, including improvements in 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, efruxifermin 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; Akero's Phase 2a BALANCED study, including its results and expected timing to report the analysis of efficacy and safety data; 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; expectations regarding the Company's use of capital, expenses and other future financial results; statements regarding the timing of the FDA's review of the registrational development plan; 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)

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents and short-term marketable securities	$ 102,833	$ 136,400
Other current assets	10,360	1,649
Non-current assets	865	69
Total assets	$ 114,058	$ 138,118
Liabilities and Stockholders' Equity		
Current liabilities	$ 10,393	$ 9,369
Non-current liabilities	2	23
Stockholders' equity	103,663	128,726
Total liabilities and stockholders' equity	$ 114,058	$ 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 13,037	$ 5,960	$ 21,828	$ 10,023
General and administrative	3,417	1,649	7,005	3,098
Total operating expenses	16,454	7,609	28,833	13,121
Loss from operations	(16,454)	(7,609)	(28,833)	(13,121)
Other income, net	247	381	740	531
Net loss	$ (16,207)	$ (7,228)	$ (28,093)	$ (12,590)
Comprehensive loss	$ (16,162)	$ (7,228)	$ (27,997)	$ (12,590)
Net loss per common share, basic and diluted	$ (0.57)	$ (2.21)	$ (0.98)	$ (7.29)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	28,602,976	3,268,390	28,551,227	1,726,795