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): May 13, 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.)**

170 Harbor Way, 3rd Floor 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 May 13, 2020, Akero Therapeutics, Inc. announced its financial results for the quarter ended March 31, 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 May 13, 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: May 13, 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 FIRST QUARTER 2020 FINANCIAL RESULTS

SOUTH SAN FRANCISCO, Calif., May 13, 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 first quarter financial results for the period ending March 31, 2020.

“During the first quarter of 2020 we reported results for the primary endpoint and several secondary efficacy endpoints in our ongoing Phase 2a clinical trial, the BALANCED study, and continued to make important progress toward advancing AKR-001 as a potential cornerstone treatment for NASH,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “The reductions in liver fat and ALT observed with AKR-001 are among the largest reductions reported for NASH clinical studies to date – not only in the FGF21 class, but across all mechanisms in development. We are pleased with our progress and look forward to reporting efficacy and safety data, including biopsy results, toward the end of this quarter when we expect the BALANCED study analysis to be completed. We remain on schedule to initiate our Phase 2b clinical trial in NASH patients in the first half of 2021.”

First Quarter Business Highlights

- Akero reported results for the primary and several secondary efficacy endpoints for the BALANCED study at week 12 of the 16-week dosing period. Each of the three AKR-001 dose groups met the primary endpoint as well as all reported secondary endpoints. These results included highly significant 12-14% absolute reductions in liver fat and 63-72% relative reductions in liver fat (in each case compared with 0% for placebo). Reductions in ALT of 24-32 U/L were observed, compared with 6 U/L for placebo.

- While the study remains blinded, the tolerability profile of the entire study cohort appeared consistent with results from previous clinical trials evaluating AKR-001 in patients with Type 2 diabetes. The adverse events observed most frequently in prior trials were mild/moderate gastrointestinal events and injection site reactions.

- These robust efficacy results are expected to provide flexibility in dose selection for the next study. The Company proposes, pending consultation with FDA, to progress two doses for further evaluation.

COVID-19 and BALANCED Study Update

- The COVID-19 pandemic has not materially impacted data collection for the BALANCED study or preparations for the Company’s upcoming Phase 2b/3 trial.

- The Company has completed all data collection for the BALANCED study. A total of 50 subjects achieved at least a 30% relative reduction of liver fat at week 12 as measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) and therefore were eligible for end-of-study biopsies. Forty-eight of the biopsy-eligible subjects were treated with AKR-001 compared with two subjects on placebo. End-of-study biopsies have been successfully collected for 42 (84%) of the 50 biopsy-eligible subjects.

- Toward the end of this quarter, the Company expects to unblind the BALANCED study data and to report efficacy and safety data, including paired biopsy results. We expect to include results for the proportions of subjects who achieved at least a 2-point reduction in NAFLD activity score (NAS), a 1-point reversal in fibrosis score with no worsening of NASH, and NASH resolution with no worsening of fibrosis. Additional expected analyses include biomarkers of liver injury and fibrosis and other relevant measures for NASH studies, together with safety and tolerability.

- The BALANCED study's Data Monitoring Committee was convened for a review of unblinded safety data following completion of treatment and recommended that a planned expansion cohort (Cohort C) in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A, proceed without any amendments to the protocol.

- After a temporary suspension of enrollment plans, the Company began screening for Cohort C on May 7, 2020 and expects to begin enrollment in the second quarter of this year. Cohort C is designed to inform the long-term development plan in patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A.

- The Company expects to update the AKR-001 IND after completion of the recommended toxicology package for a biopharmaceutical, enabling a longer-term Phase 2b/3 clinical trial to commence during the first half of 2021. These chronic toxicology studies include 26-week dosing followed by a 13-week recovery period off drug in rats and non-human primates. In addition, a standard package of reproductive and developmental toxicology studies has been completed.

- The Company also expects to have drug product available in the fourth quarter of 2020 to supply the Phase 2b portion of an anticipated Phase 2b/3 clinical trial beginning in the first half of 2021. Commercial-scale manufacturing of GMP drug substance (API) was completed in April 2020, without any impact from COVID-19. Manufacture of GMP drug product lots is scheduled for the third quarter of 2020.

Financial Highlights

- Akero's cash, cash equivalents and short-term marketable securities at March 31, 2020 were $125.3 million.

- Research and development expenses for the three-month period ended March 31, 2020 were $8.8 million compared to $4.1 million for the comparable period in 2019. These increases are attributable to higher costs related to Akero's AKR-001 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 period ended March 31, 2020 were $3.6 million compared to $1.4 million for the comparable period 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 were $12.4 million for the three-month period ended March 31, 2020, compared to $5.5 million for the comparable period 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 closely resembles damage caused by excessive alcohol consumption or viral infections, and the disorder is a leading cause of liver transplants in the US and Europe.

About AKR-001

AKR-001 is Akero's lead product candidate for NASH. AKR-001 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-system disease state of NASH, including improvements in physiological parameters linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, AKR-001 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, AKR-001, is currently being evaluated in an ongoing Phase 2a clinical trial. 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 AKR-001, upcoming milestones, and therapeutic effects of AKR-001; 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 AKR-001; expectations for successful completion of nonclinical studies; 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; 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)

	March 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and short-term marketable securities	$ 125,285	$ 136,400
Other current assets	933	1,649
Non-current assets	403	69
Total assets	$ 126,621	$ 138,118
Liabilities and Stockholders' Equity		
Current liabilities	$ 8,286	$ 9,369
Non-current liabilities	12	23
Stockholders' equity	118,323	128,726
Total liabilities and stockholders' equity	$ 126,621	$ 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 March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 8,791	$ 4,063
General and administrative	3,588	1,449
Total operating expenses	12,379	5,512
Loss from operations	(12,379)	(5,512)
Other income, net	493	150
Net loss	$ (11,886)	$ (5,362)
Comprehensive loss	$ (11,835)	$ (5,362)
Net loss per common share - basic and diluted	$ (0.42)	$ (31.90)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	28,499,475	168,071