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, 2019**

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** (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 August 12, 2019, Akero Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2019. 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, 2019, 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, 2019

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

AKERO THERAPEUTICS REPORTS RECENT HIGHLIGHTS AND SECOND QUARTER 2019 FINANCIAL RESULTS

— Advanced AKR-001 into Phase 2a BALANCED clinical study in NASH —
— Raised $98.4 million in aggregate net proceeds from Initial Public Offering —

SAN FRANCISCO, Calif., August 12, 2019 — Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage biotechnology company developing transformational treatments for patients with non-alcoholic steatohepatitis (NASH) and other serious metabolic disorders, today provided a business update and reported second quarter 2019 financial results for the period ending June 30, 2019.

"The second quarter of 2019 was a period of significant growth for Akero marked by the successful completion of our IPO and the initiation of the BALANCED study, our Phase 2a study evaluating our lead candidate AKR-001 for the treatment of NASH," said Andrew Cheng, M.D., Ph.D., President and Chief Executive Officer of Akero. "Our strong cash position provides us with sufficient resources to complete our Phase 2 clinical program. We remain on track to report results of the BALANCED study's primary endpoint in the first quarter of 2020 and full study results in the second quarter of 2020. The progress we've made this year has provided a strong foundation for the continued development of AKR-001, which has the potential to become a cornerstone of NASH treatment that addresses the underlying metabolic drivers of the disease to reduce liver inflammation and fibrosis, while also improving cardiovascular risk factors."

Second Quarter 2019 Business Highlights

- **Completed Upsized Initial Public Offering.** Akero's common stock commenced trading on the Nasdaq Global Select Market under the ticker symbol "AKRO" on June 20, 2019. The IPO was priced at $16.00 per share (the top of its marketing range) and raised $105.8 million in aggregate gross proceeds from the sale of 6,612,500 shares, which reflects the full exercise of the underwriters' overallotment option. Net proceeds to Akero were $98.4 million after deducting underwriting discounts and commissions.

- **Initiated Phase 2a BALANCED trial for AKR-001 in NASH.** Screening for the Phase 2a BALANCED study began on May 28, 2019, following IND clearance on May 24, 2019. The multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial is expected to enroll approximately 80 patients with biopsy-confirmed NASH. Patients will receive weekly subcutaneous dosing of AKR-001 or placebo for up to 16 weeks, with safety and tolerability followed through week 20. The primary efficacy endpoint for the study is absolute change from baseline in hepatic fat fraction measured by Magnetic Resonance Imaging — Proton Density Fat Fraction (MRI-PDFF) at week 12. Collection of data for the primary endpoint is expected to be completed in the first quarter of 2020, and collection of all study data, including repeat liver biopsies, is expected to be completed in the second quarter of 2020.

Second Quarter 2019 Financial Results

- Research and development expenses for the three-month and six-month periods ended June 30, 2019 were $6.0 million and $10.0 million, respectively, compared to $8.4 million and $8.6 million for the comparable periods in 2018. Research and development expenses in 2019 are attributable to direct costs related to our AKR-001 program, including third-party contract manufacturing, CRO

costs associated with the BALANCED trial and internal personnel costs. Research and development expenses in 2018 were primarily attributable to $8.0 million of one-time cash and non-cash product licensing expenses associated with the in-licensing of AKR-001 from Amgen, Inc.

- General and administrative expenses for the three-month and six-month periods ended June 30, 2019 were $1.6 million and $3.1 million, respectively, compared to $0.2 million and $0.4 million for the comparable periods in 2018. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with becoming a public company.

- Total operating expenses were $7.6 million and $13.1 million for the three-month and six-month periods ended June 30, 2019, respectively, compared to $8.7 million and $9.1 million for the comparable periods in 2018.

- Akero's cash and cash equivalents at June 30, 2019 were $162.7 million.

About NASH

NASH is a leading cause of liver failure around the world, driven by the growing global epidemic of obesity. NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) characterized by liver cell (hepatocyte) damage, liver inflammation, and fibrosis that can progress to cirrhosis, liver failure, cancer and death.

About AKR-001

AKR-001 is an engineered human Fc-FGF21 fusion protein designed to harness the inherent benefits of an endogenous hormone called FGF21, with the potential to reduce liver fat, mitigate inflammation, and reverse fibrosis in NASH patients. AKR-001 is uniquely designed to deliver sustained signaling through FGF21's receptors with once-weekly subcutaneous dosing.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage biotechnology company focused on the development and commercialization of transformative treatments for patients with NASH and other serious metabolic diseases with high unmet medical need. The Company's lead program AKR-001 is being evaluated in a Phase 2a clinical trial for the treatment of NASH.

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. Such statements include, but are not limited to, statements regarding the company's business plans and objectives, including future plans or expectations for AKR-001, upcoming milestones, therapeutic effects of AKR-001, expectations regarding the design, implementation, timing, and success of its

current and planned clinical trials for AKR-001 and expectations regarding our uses of capital, expenses and other future financial results and plans related to development of our current and future product candidates. Any forward-looking statements in this statement 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: 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 the final prospectus dated June 19, 2019 and filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the United States Securities and Exchange Commission (SEC) and elsewhere in Akero's 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, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 162,654	$ 75,975
Other current assets	454	1,156
Non-current assets	60	20
Total assets	$ 163,168	$ 77,151
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities	$ 4,740	$ 2,342
Non-current liabilities	39	—
Redeemable convertible preferred stock	—	124,728
Stockholders' equity (deficit)	158,389	(49,919)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 163,168	$ 77,151

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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 5,960	$ 8,420	$ 10,023	$ 8,646
General and administrative	1,649	242	3,098	437
Total operating expenses	7,609	8,662	13,121	9,083
Loss from operations	(7,609)	(8,662)	(13,121)	(9,083)
Other income (expense), net	381	(11)	531	(11)
Net loss and comprehensive loss	$ (7,228)	$ (8,673)	$ (12,590)	$ (9,094)
Net loss attributable to common stockholders	$ (7,228)	$ (8,743)	$ (12,590)	$ (9,164)
Net loss per share attributable to common stockholders - basic and diluted	$ (2.21)	$ (94.86)	$ (7.29)	$ (137.97)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	3,268,390	92,171	1,726,795	66,422