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): March 16, 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** **(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 March 16, 2020, Akero Therapeutics, Inc. announced its financial results for the quarter ended and year ended December 31, 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 March 16, 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: March 16, 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 FOURTH QUARTER AND FULL YEAR 2019 FINANCIAL RESULTS

SAN FRANCISCO, Calif., March 16, 2020 -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic non-alcoholic steatohepatitis (NASH) Company developing pioneering medicines designed to restore metabolic balance and improve overall health of NASH patients, today reported fourth quarter and full year financial results for the period ending December 31, 2019.

“We saw in 2019 a period of continued clinical and manufacturing progress for Akero, driven by precision execution by our team,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “Our rapid progress combined with a strong cash position provide the foundation for the continued development of AKR-001, which we believe has the potential to become a cornerstone of NASH treatment.”

Fourth Quarter Business Highlights

- Enrollment was completed in the Phase 2a BALANCED study in NASH patients. The Company remains on track to report results of the BALANCED study’s primary endpoint in the first quarter of 2020. Top-line results related to secondary endpoints, including safety and tolerability as well as paired biopsies for patients who achieve at least 30% relative reduction in liver fat at week 12, will be reported in the second quarter of 2020.

- The Company has successfully manufactured AKR-001 drug substance at commercial scale as an engineering run at Boehringer Ingelheim. Yield was comparable to the Good Manufacturing Practice (GMP) drug substance originally manufactured by Amgen. Analysis of the drug substance produced by Boehringer Ingelheim confirmed it met the same release specification as previously used for Amgen GMP drug substance. The Company expects to release drug product produced in compliance with current GMP requirements by the fourth quarter of 2020.

Full Year and Fourth Quarter 2019 Financial Results

- Akero’s cash, cash equivalents and short-term marketable securities at December 31, 2019 were $136.4 million.

- Research and development expenses for the three-month and twelve-month periods ended December 31, 2019 were $13.1 million and $37.0 million, respectively, compared to $2.0 million and $11.9 million for the comparable periods in 2018. These increases are attributable to higher costs related to Akero's AKR-001 program, including third-party contract manufacturing, contract research organization costs associated with the BALANCED study and internal personnel costs.

- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2019 were $3.1 million and $8.6 million, respectively, compared to $1.0 million and $1.9 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 $16.2 million and $45.7 million for the three-month and twelve-month periods ended December 31, 2019, respectively, compared to $3.0 million and $13.8 million for the comparable periods in 2018.

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, currently being evaluated in the ongoing Phase 2a BALANCED study. AKR-001 is 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 and has been well-tolerated in clinical studies to date.

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 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 and the BALANCED study, upcoming milestones, and therapeutic effects of AKR-001; 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 plans related to development of the Company's current and future product candidates. 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: 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 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)

	December 31,	
	2019	**2018**
Assets		
Cash, cash equivalents and short-term marketable securities	$ 136,400	$ 75,975
Other current assets	1,649	1,156
Non-current assets	69	20
Total assets	$ 138,118	$ 77,151
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities	$ 9,369	$ 2,342
Non-current liabilities	23	—
Redeemable convertible preferred stock	—	124,728
Stockholders' equity (deficit)	128,726	(49,919)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 138,118	$ 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 December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 13,138	$ 1,983	$ 37,046	$ 11,882
General and administrative	3,083	985	8,605	1,896
Total operating expenses	16,221	2,968	45,651	13,778
Loss from operations	(16,221)	(2,968)	(45,651)	(13,778)
Other income (expense), net	610	(58,504)	1,896	(67,936)
Net loss	$ (15,611)	$ (61,472)	$ (43,755)	$ (81,714)
Comprehensive loss	$ (15,617)	$ (61,472)	$ (43,761)	$ (81,714)
Net loss attributable to common stockholders	$ (15,611)	$ (61,671)	$ (43,755)	$ (82,234)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.55)	$ (449.52)	$ (2.90)	$ (795.28)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	28,335,405	137,194	15,070,728	103,403