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 31, 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 7.01. Regulation FD Disclosure.

On March 31, 2020, Akero Therapeutics, Inc. (the “Company”) issued a press release titled “All AKR-001 Dose Groups Met Week 12 Efficacy Endpoints in NASH Phase 2a BALANCED Study.” A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. A copy of its BALANCED Study slide presentation is being filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

On March 31, 2020, the Company announced that all three AKR-001 dose groups in the BALANCED study met the primary endpoint of absolute change from baseline in liver fat as measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) – at week 12. The BALANCED study is an ongoing randomized, double-blind, placebo-controlled study in NASH patients. While the study remains blinded, the tolerability profile appears 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.

After 12 weeks of treatment, patients who have achieved at least a 30% relative reduction in liver fat are eligible for an end-of-study biopsy. Across the AKR-001 dose groups, 75-85% of patients are eligible for biopsies. As of March 30, 2020, 25 end-of-study biopsies have been collected from a total of 50 eligible patients.

The Company expects to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of this year. The extent to which the COVID-19 pandemic will interfere with collection of the remaining biopsies and data from other scheduled clinical visits, including the safety follow-up visit at week 20, is unclear. The Company is delaying the planned initiation of the BALANCED study cohort C in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A.

Statements contained under this Item 8.01, including Exhibit 99.2, 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: Akero's guidance regarding its business plans and objectives for AKR-001, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of AKR-001; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results and expected timing to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of 2020; and the potential impact of COVID-19 on strategy, future operations and clinical trials.

Any forward-looking statements 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 public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, including potential negative impacts on Akero’s employees, manufacturers, supply chain and production as well as on global economies and financial markets; 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 risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company’s annual report on Form 10-K filed, with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company’s other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on March 31, 2020
99.2	Slide presentation of Akero Therapeutics, Inc.

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 31, 2020

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

All AKR-001 Dose Groups Met Week 12 Efficacy Endpoints in NASH Phase 2a BALANCED Study

All AKR-001 dose groups met the primary endpoint, with statistically significant absolute reductions in liver fat of 12-14%

All AKR-001 dose groups met the secondary endpoint of relative reduction in liver fat, with the 50mg and 70mg dose groups achieving >70% relative reductions

Blinded tolerability profile appears consistent with results from previous clinical trials evaluating AKR-001 in patients with Type 2 diabetes

SAN FRANCISCO, March 31, 2020 - /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO) today announced that all three AKR-001 dose groups in the BALANCED study met the primary endpoint of absolute change from baseline in liver fat as measured by magnetic resonance imaging – proton density fat fraction (MRI-PDFF) – at week 12. Results for the primary endpoint as well as other week 12 efficacy endpoints are summarized in the table below.

Summary of Week 12 Efficacy Endpoints

		AKR-001 (once weekly dose)		
Measure (Mean)	**Placebo (N=21)**	**28 mg (N=19)**	**50 mg (N=20)**	**70 mg (N=20)**
Absolute reduction in liver fat (%)	-0.3	-12.3***	-13.4***	-14.1***
Relative reduction in liver fat (%)	0%	-63***	-71***	-72***
≥30% relative reduction in fat (%)	10	84***	85***	75***
Reduction in ALT (U/L)	-6	-24***	-30***	-32***

***p<0.001, versus placebo

“The magnitude and rate of improvements in liver fat content and ALT observed over 12 weeks in the BALANCED study are among the most robust NASH clinical trial results reported to date,” said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research. “AKR-001 is emerging as one of the most promising drug candidates in development for this serious disease.”

The BALANCED study is an ongoing randomized, double-blind, placebo-controlled study in NASH patients. While the study remains blinded, the tolerability profile appears 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.

After 12 weeks of treatment, patients who have achieved at least a 30% relative reduction in liver fat are eligible for an end-of-study biopsy. Across the AKR-001 dose groups, 75-85% of patients are eligible for biopsies. As of March 30, 2020, 25 end-of-study biopsies have been collected from a total of 50 eligible patients.

We expect to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of this year. The extent to which the COVID-19 pandemic will interfere with collection of the remaining biopsies and data from other scheduled clinical visits, including the safety follow-up visit at week 20, is unclear. We are delaying the planned initiation of the BALANCED study cohort C in NASH patients who have compensated cirrhosis (F4), Child-Pugh Class A.

“We are encouraged by these results, which support continued development of AKR-001 for treatment of NASH,” said Andrew Cheng, M.D., Ph.D., president and CEO of Akero. “AKR-001 has the potential to provide NASH patients with an important treatment option when there are still no approved therapies. We look forward to the full data set with anticipation and are preparing for the next steps in AKR-001’s development.”

Conference Call / Webcast Details

The company will host a conference call and webcast with slide presentation at 8:30 a.m. ET (5:30 a.m. PT) tomorrow morning, March 31. The conference call will be made available on the company's website at www.akerotx.com under the Investors tab in the Events, Presentations & Webcasts section. To access the call via dial-in, please dial 1-866-652-5200 (U.S. toll free) or 1-412-317-6060 (international) five minutes prior to the start time. Following the live audio webcast, a replay will be available on the company's website for 90 days.

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. NASH is a leading cause of liver transplants in the US and Europe.

About the BALANCED Study

The Phase 2a BALANCED study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult patients with NASH. The main study enrolled a total of 80 patients. Participants were randomized to receive weekly subcutaneous doses 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. Secondary measures include change from baseline in ALT at 12 weeks, the number of patients who had a decrease of ≥2 points in the NAFLD activity score (NAS) at 24 weeks and safety and tolerability measures.

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 reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipoproteins. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in lipoprotein risk factors 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 trials 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 to improve overall health. 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. Such statements include, but are not limited to, statements regarding: Akero's guidance regarding its business plans and objectives for AKR-001, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of AKR-001; Akero's Phase 2a BALANCED clinical trial, including its initial primary efficacy results and expected timing to report the top-line safety/tolerability, laboratory measures and paired biopsy data from the BALANCED study in the second quarter of 2020; and the potential impact of COVID-19 on strategy, future operations and clinical trials.

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: risks related to the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, including potential negative impacts on Akero's employees, manufacturers, supply chain and production as well as on global economies and financial markets; 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 risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Akero's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the company's 2019 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Akero's other filings 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.

Media Contact:
Carolyn Hawley
Canale Communications
carolyn@canalecomm.com
619-849-5382

Investor Contact:
Christina Tartaglia
Stern Investor Relations
212-362-1200
akero@sternir.com

Exhibit 99.2

akero

A Global Disease, A Pioneering Treatment

Akero Therapeutics, Inc.

AKR-001 Phase 2a BALANCED Study

Week 12 Efficacy Endpoints

March 31, 2020

SAFE HARBOR

This presentation has been prepared by Akero Therapeutics, Inc. ("we," "us," "our," "Akero" or the "Company") and is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and neither this presentation, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, including but not limited to current beliefs, expectations and assumptions regarding: the future of our business; future plans and strategies, including our expectations around the therapeutic potential and clinical benefits of AKR-001; our development plans for AKR-001; our preclinical and clinical results, including initial primary efficacy results from our Phase 2a BALANCED study; our plan to report the top-line safety/tolerability, laboratory measures and paired biopsy data from our Phase 2a BALANCED study in the second quarter of 2020; and the potential impact of COVID-19 on strategy, future operations and clinical trials. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward- looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

AKR-001 MET ALL WEEK 12 EFFICACY ENDPOINTS

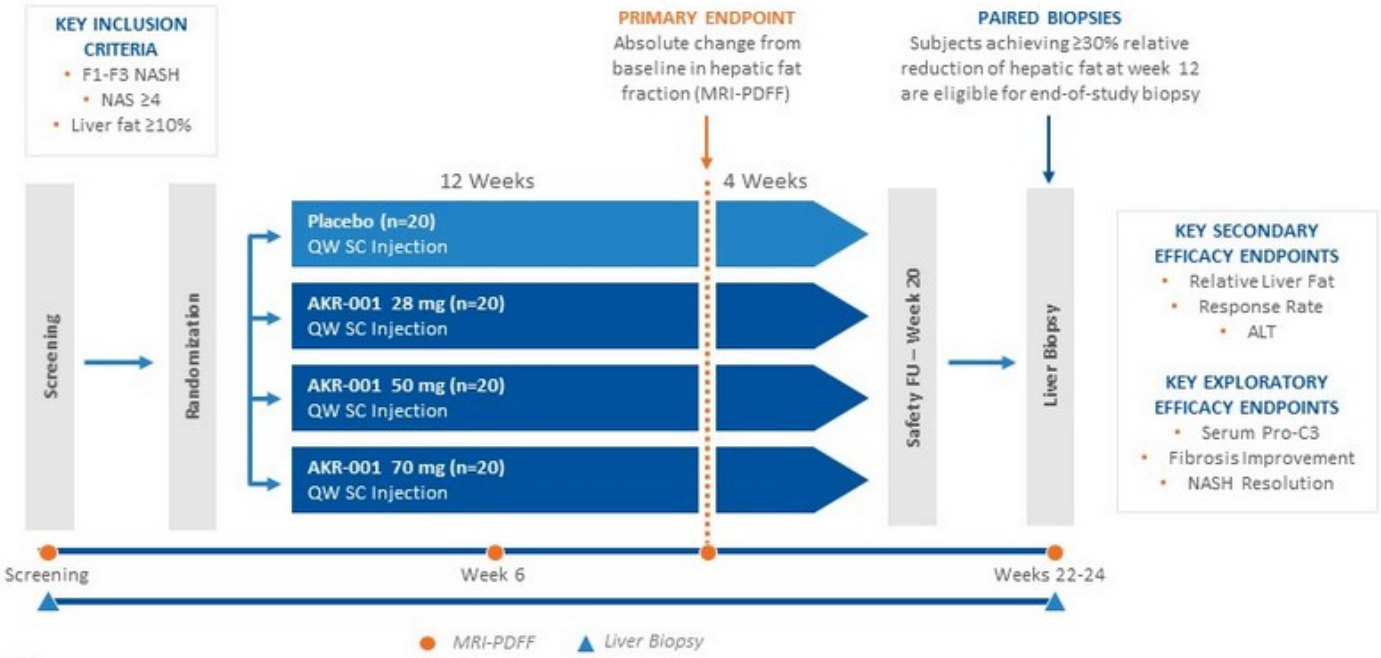
Efficacy Measures

- All AKR-001 dose groups met the primary endpoint, with statistically significant absolute reductions in liver fat of **12-14%**
- Statistically significant relative reductions in liver fat for all AKR-001 dose groups were observed, with **>70%** reductions for the 50 mg and 70 mg dose groups
- Readout of paired biopsy data is expected in 2Q 2020, with **50 subjects** eligible for end-of-study biopsies based on achieving ≥30% relative reductions in liver fat at week 12

Blinded Safety & Tolerability

- Study is ongoing and remains blinded through completion of the study
- Blinded tolerability profile appears generally consistent with results from prior AKR-001 clinical trials
  - Adverse events observed most frequently in prior trials were mild/moderate gastrointestinal events and injection site reactions

THE BALANCED STUDY TRIAL DESIGN



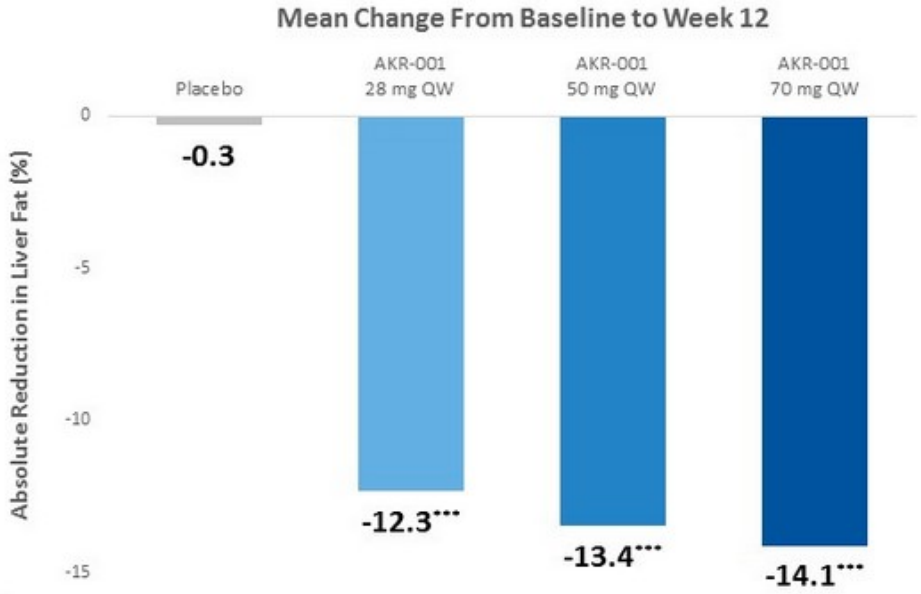
akero

BASELINE DEMOGRAPHICS

Parameter Mean	Placebo (N=21)	AKR-001 28mg (N=19)	AKR-001 50mg (N=20)	AKR-001 70mg (N=20)
Age (Years)	52	50	53	53
Sex (Male/Female)	6/15	9/10	10/10	9/11
Weight (kg)	99.6	108.2	103.5	103.1
BMI (kg/m^2)	37.6	38.8	36.7	37.2
Liver Fat Content (% by MRI-PDFF)	19.3	21.4	18.3	19.4
NAFLD Activity Score (NAS)	5.1	5.6	5.1	5.6
Fibrosis Stage (% F2-F3)	62	63	65	65
Alanine Aminotransferase (ALT) (U/L)	50.7	62.5	53.4	56.8
Aspartate Aminotransferase (AST) (U/L)	38.6	41.1	35.4	44.6
% Type 2 Diabetes	67	37	50	50

Full Analysis Set (FAS) is defined as all subjects who were randomized into the study. All source data: FAS.

ABSOLUTE REDUCTION IN LIVER FAT: All AKR-001 Dose Groups Met Primary Endpoint



Normalization of Liver Fat

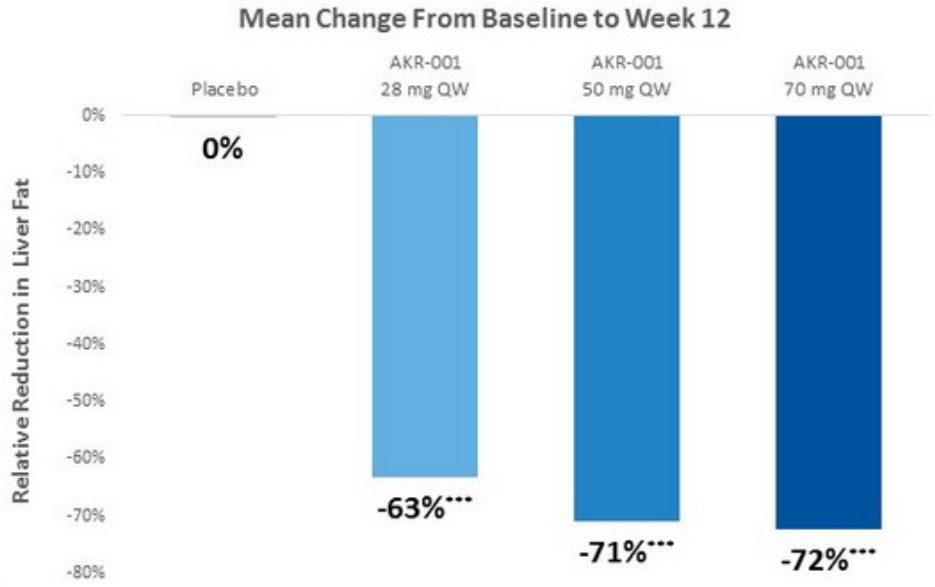
Proportion of subjects with ≤5.0% absolute liver fat at Week 12

Placebo	5%
28 mg	21%
50 mg	45%
70 mg	50%**

** p=0.004, versus placebo
*** p<0.001, versus placebo

akero

RELATIVE REDUCTION IN LIVER FAT: All AKR-001 Dose Groups Met Secondary Endpoint



Response Rate

Proportion of subjects with ≥30% relative reduction at Week 12

Placebo	10%
28 mg	84%***
50 mg	85%***
70 mg	75%***

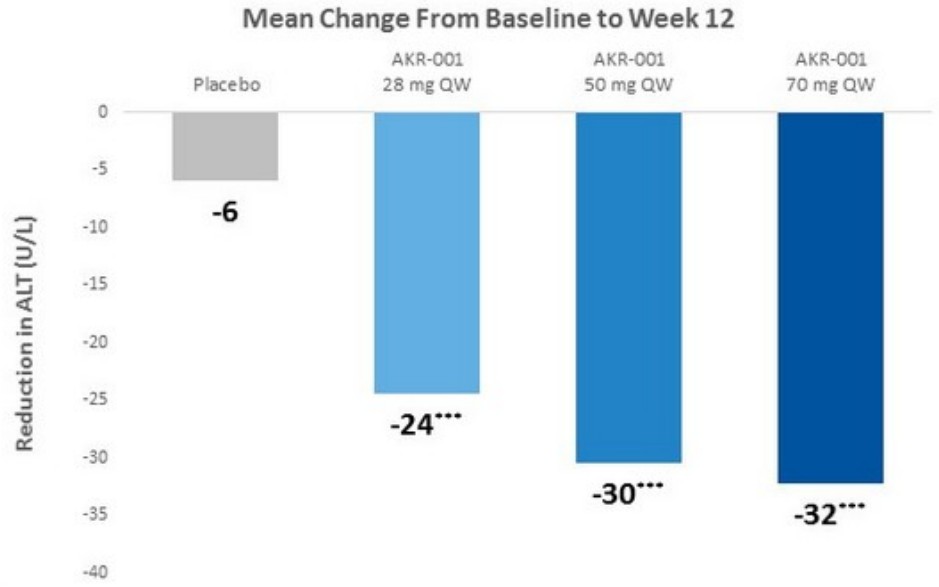
End-of-Study Biopsies

50 subjects eligible

*** p<0.001, versus placebo

akero

REDUCTION IN ALT:
All AKR-001 Dose Groups Met Secondary Endpoint



An ALT unit decrease of ≥17 U/L may correlate with histologic response

Loomba, R (2019) Gastroenterology

*** p<0.001, versus placebo

akero

AKR-001 POTENTIAL AS A CORNERSTONE NASH THERAPY

- ✓ All AKR-001 dose groups met the primary endpoint for absolute reduction in liver fat
- ✓ All AKR-001 dose groups met secondary endpoints for relative reduction in liver fat and ALT reduction
- ✓ Readout of biopsy data is expected in 2Q 2020, with 50 subjects eligible for end-of-study biopsies

akero

A Global Disease, A Pioneering Treatment

NASDAQ: AKRO