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 28, 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 8.01. Other Events.

The Company from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is being filed herewith as Exhibit 99.1 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 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate 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: May 28, 2020

AKERO THERAPEUTICS, INC.

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

Exhibit 99.1

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A Global Disease, A Pioneering Treatment

Akero Therapeutics, Inc.

May 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'S POTENTIAL AS CORNERSTONE NASH THERAPY

Strong Emerging Clinical Profile with Potential to be Leading FGF Compound

- Fc-FGF21 fusion protein licensed from Amgen
- All AKR-001 dose groups met all Week 12 endpoints in ongoing 16-week Phase 2a BALANCED study in adult, biopsy-confirmed NASH patients
  - >70% relative reduction in liver fat in 50mg and 70mg groups at Week 12
- Robust improvements in lipoproteins and insulin sensitivity markers observed in Amgen-sponsored Phase 1b clinical trial in adult patients with Type 2 diabetes

Key Upcoming Milestones

Late June 2020

Ph2a data readout including paired biopsies

1H 2021

Cohort C (F4) readout

Phase 2b/3 initiation

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EXTENSIVE DEVELOPMENT, COMMERCIALIZATION EXPERIENCE INVOLVED IN 20+ MEDICINE APPROVALS

Andrew Cheng, MD, PhD | President & CEO

- 19 years at Gilead
- Chief Medical Officer & HIV Division Head
- Major role in 11 NDA/MAA approvals

Tim Rolph, D.Phil | Founder & CSO

- Over 30 years at Pfizer & Glaxo
- CSO of Pfizer's cardiovascular and metabolic disease unit
- Head of Groton & UK Discovery Research, Pfizer
- Major role in discovery and early clinical evaluation of two medicines: Selzentry (HIV) and Steglatro (Diabetes)

Jonathan Young, PhD, JD | Founder, EVP & COO

- Over 15 years in biotechnology product development, law and regulatory policy
- General Counsel and VP Policy, Braeburn
- Partner and General Counsel, FoxKiser

Kitty Yale | EVP & Chief Development Officer

- Over 25 years at Gilead, Roche, Pfizer
- VP, Gilead Worldwide Clinical Operations
- Major role in 8 global approvals NDA, MAA, JNDA and CFDA

William White | EVP, CFO & Head of Corporate Development

- 18 years in life sciences investment banking at Goldman Sachs, Citigroup and Deutsche Bank
- Most recently, Head of US Life Sciences Investment Banking at Deutsche Bank
- Advised on more than $70bn in M&A and $25bn in financing transactions

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NASH: A SERIOUS AND DEBILITATING MULTI-SYSTEM DISEASE

NASH epidemic fueled by rise in obesity and diabetes
No treatments currently available

An estimated **17 million Americans** have NASH, with expectation that population will **grow >50% by 2030**

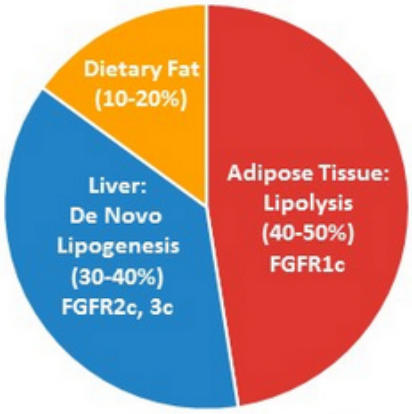
The number of NASH patients with advanced-stage fibrosis and cirrhosis is predicted to **grow to 8 million** in the US by 2030, **an increase of approximately 140% from 2015**

NASH is a **leading cause of liver transplantation** in the US and Europe

The **leading cause of death** for NASH patients is cardiovascular disease

FGF21 ACTS ON TWO MAJOR SOURCES OF LIVER FAT WITH POTENTIAL FOR OPTIMAL REDUCTION

Sources of Fat Flowing into and Through Liver for NASH Patients

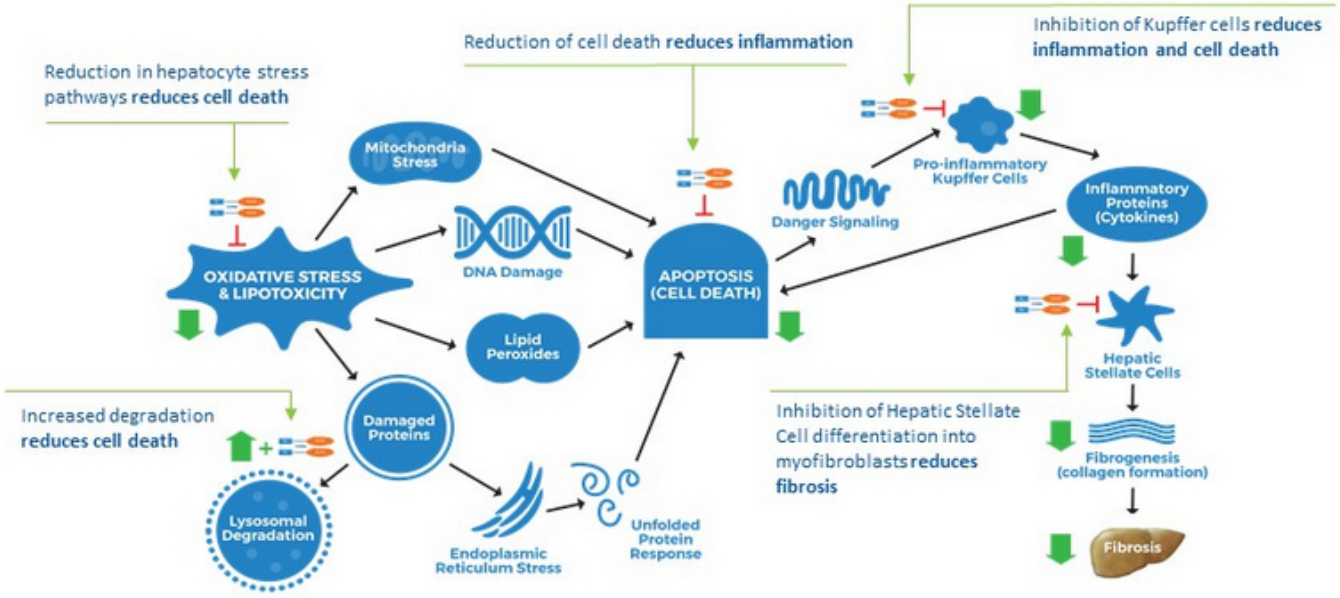


Lambert, JE *et al.* (2014) *Gastroenterology* 146(3): 726-35

Acting on both hepatic and peripheral sources of liver fat is key to optimizing liver fat reduction

Source of Liver Fat	FGF Receptor	FGF21 Activity
Lipolysis	FGFR1c	✓
De Novo Lipogenesis	FGFR2c FGFR3c	✓

FGF21 PROTECTS HEPATOCYTES AND MITIGATES INFLAMMATION & FIBROSIS



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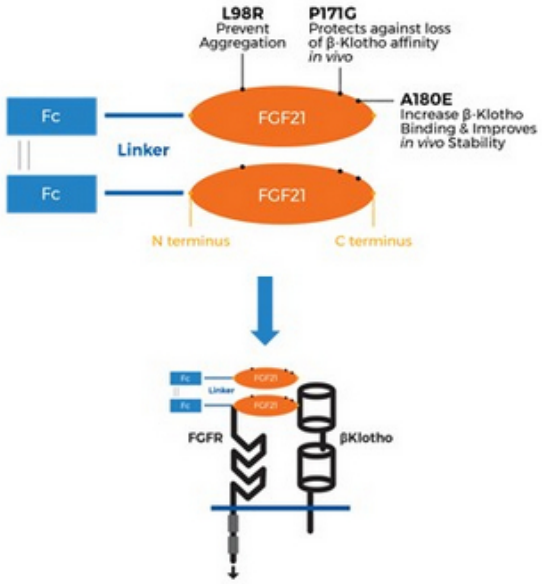
AKR-001 ENGINEERING POTENTIALLY OPTIMAL FOR NASH EFFICACY, WITH CONVENIENT ONCE-WEEKLY DOSING



Key attributes

- Akero proprietary Fc-FGF21, Point mutations
- Increases half-life from < **2 hours** to **3-4 days**
- **High affinity** for β-Klotho
- Better translation to **human** pharmacology
- **Balanced potency** at FGFR1c, 2c, 3c
- **Inactive** at FGFR4

Stanislaus, S *et al.* (2017) *Endocrinology* 158(5): 1314-27; Lee, S *et al.* (2018) *Nature* 553: 501-505; Kharitonenkov, A et al. (2007) Endocrinology 148(2)774-781

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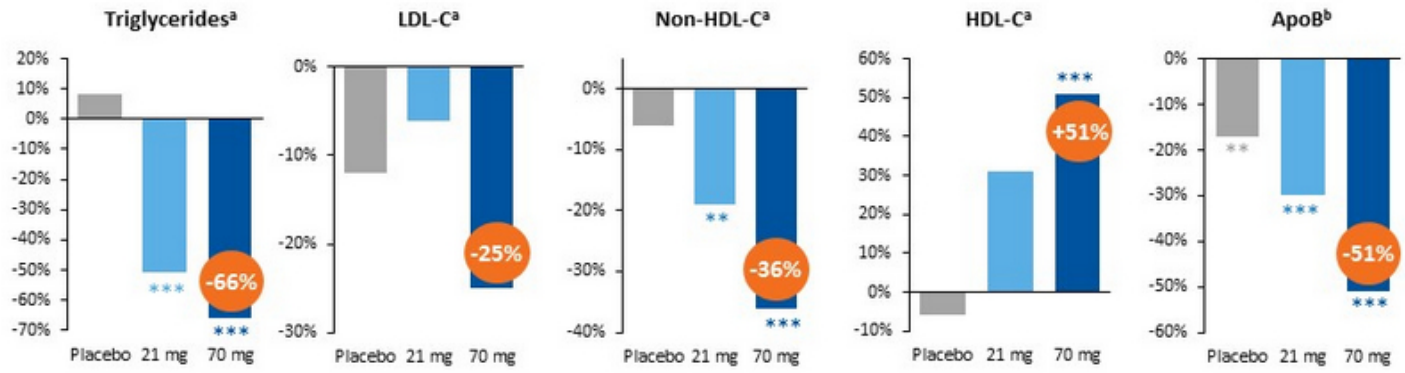
AKR-001 IMPROVED LIPOPROTEIN PROFILE
In Phase 1b Trial in Type 2 Diabetic Patients

AKR-001's significant improvements in lipoproteins and reduction in adipose lipolysis are consistent with effective agonism of FGFR2c and 3c in the liver and FGFR1c in adipose tissue



Percent Change From Baseline, Placebo, 21 mg QW and 70 mg QW [a] Day 25; [b] Day 29 ** = $p<0.01$; *** = $p<0.001$

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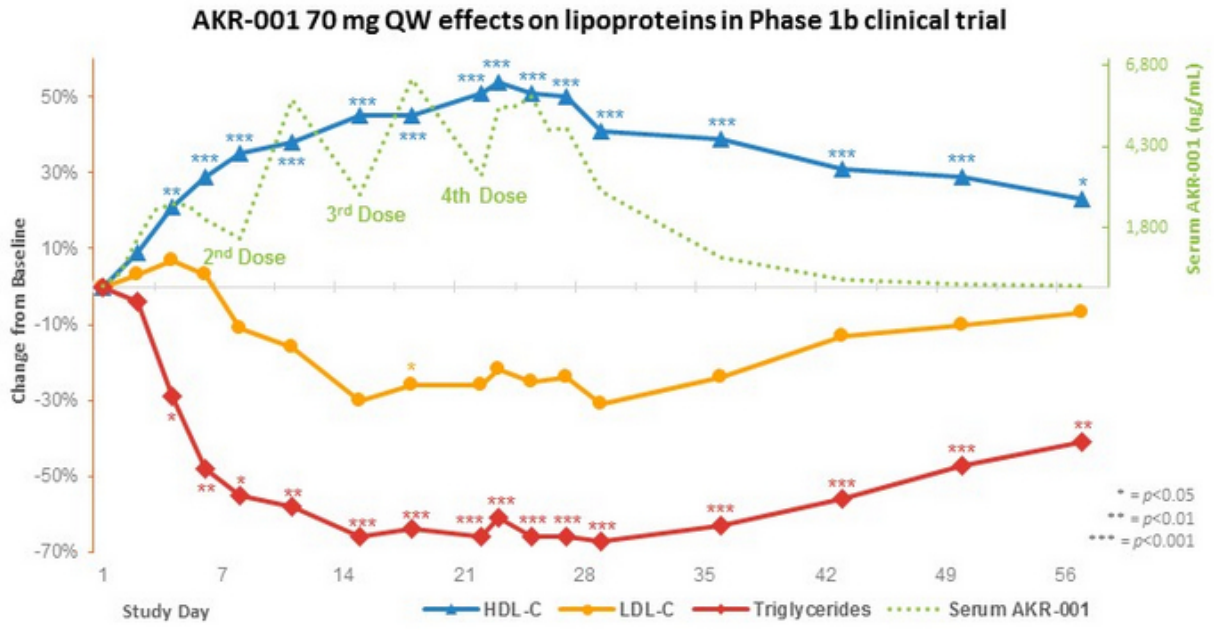
AKR-001 IMPROVED LIPOPROTEINS RAPIDLY AND DURABLY



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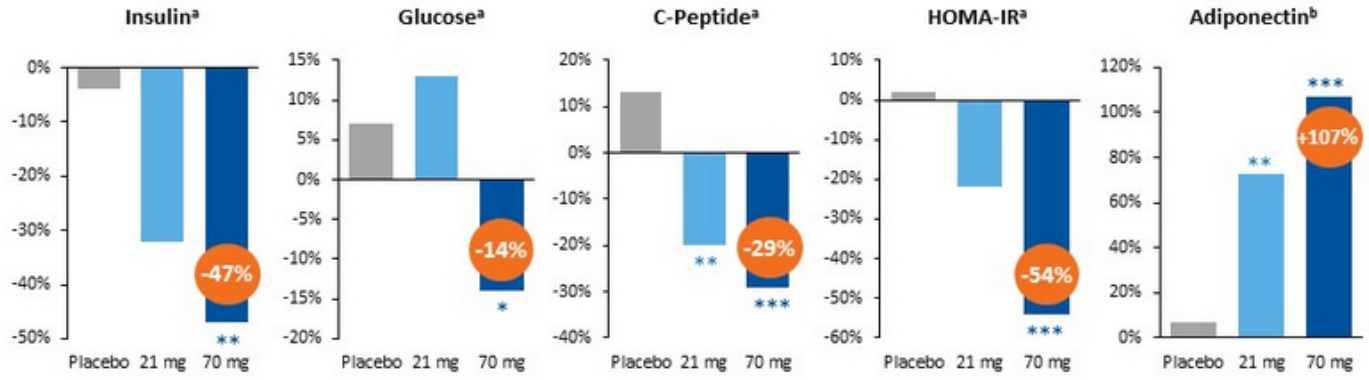
AKR-001 IMPROVED MARKERS OF INSULIN SENSITIVITY
In Phase 1b Trial in Type 2 Diabetic Patients

AKR-001's improvement in markers of insulin sensitivity
is consistent with effective FGFR1c agonism



Percent Change From Baseline, Placebo, 21 mg QW and 70 mg QW [a] Day 25; [b] Day 29 * = $p<0.05$; ** = $p<0.01$; *** = $p<0.001$

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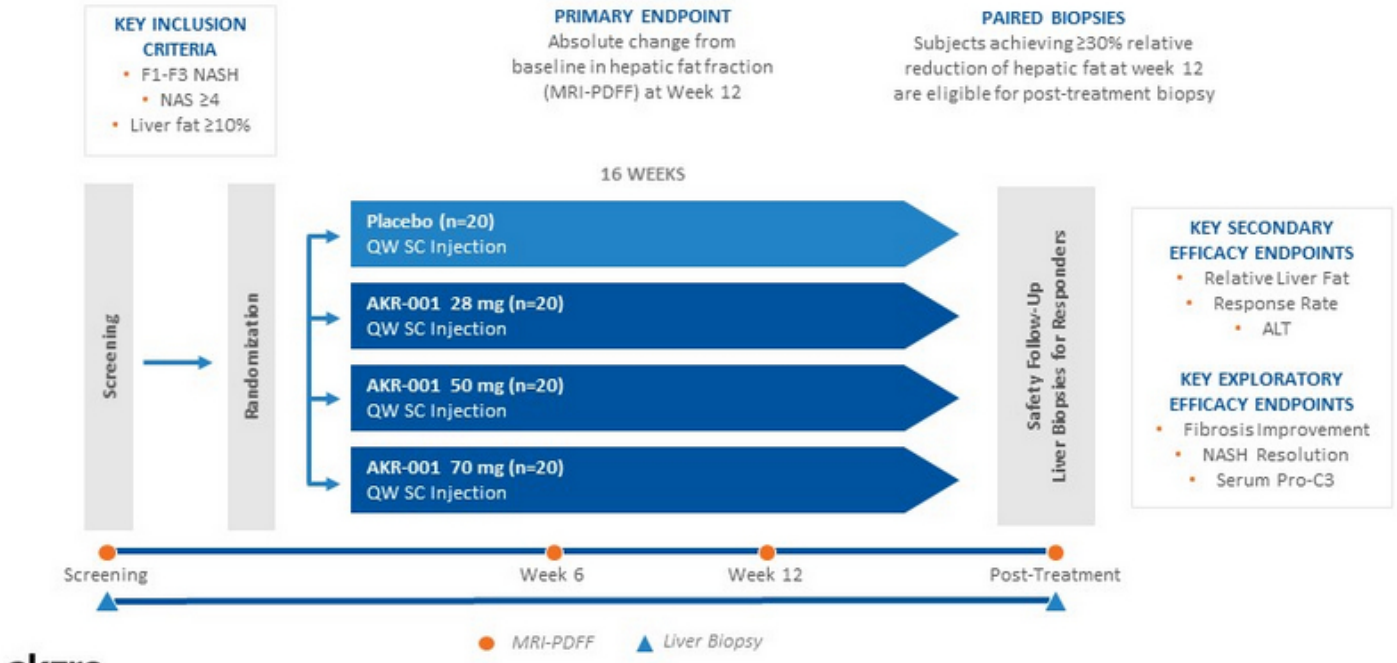
THE PHASE 2a BALANCED STUDY TRIAL DESIGN



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AKR-001 MET ALL WEEK 12 EFFICACY ENDPOINTS In Phase 2a Study in Biopsy-Confirmed Adult NASH Patients

Efficacy Measures

- All AKR-001 dose groups (n=59) 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
- Data Monitoring Committee reviewed unblinded safety data and recommended an expansion cohort proceed without protocol amendment

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

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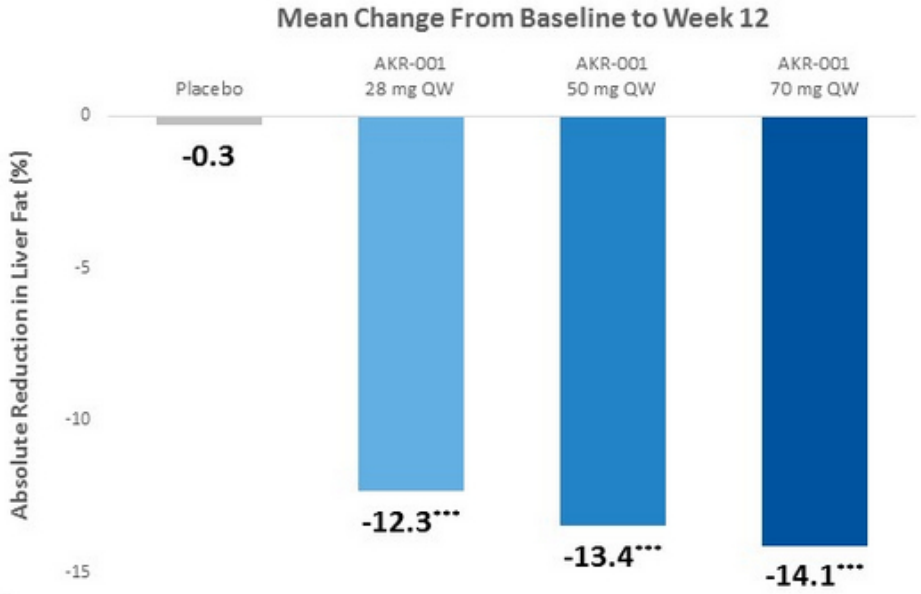
Full Analysis Set (FAS) is defined as all subjects who were randomized into the study. All source data: FAS.

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

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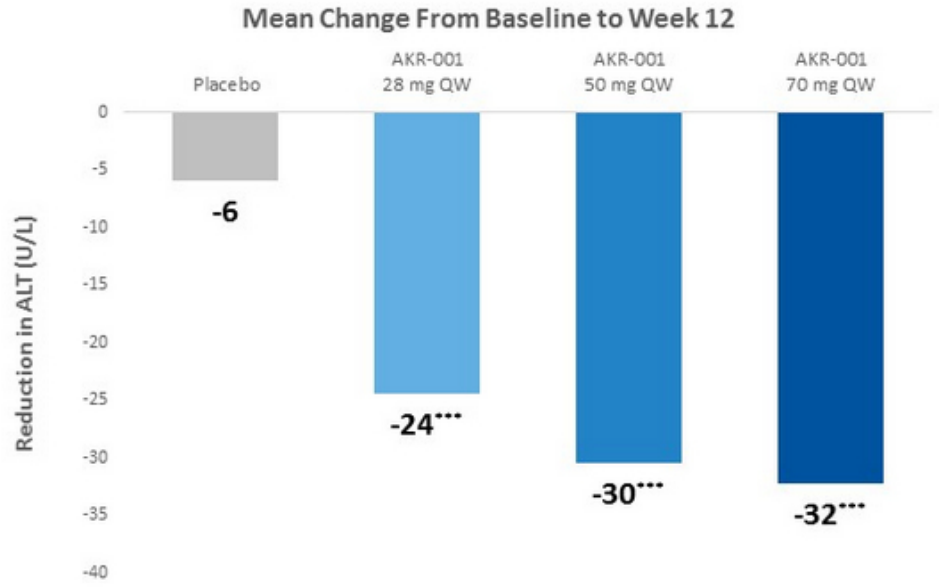
REDUCTION IN ALT:
All AKR-001 Dose Groups Met Secondary Endpoint



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

Loomba, R (2019) Gastroenterology

*** p<0.001, versus placebo

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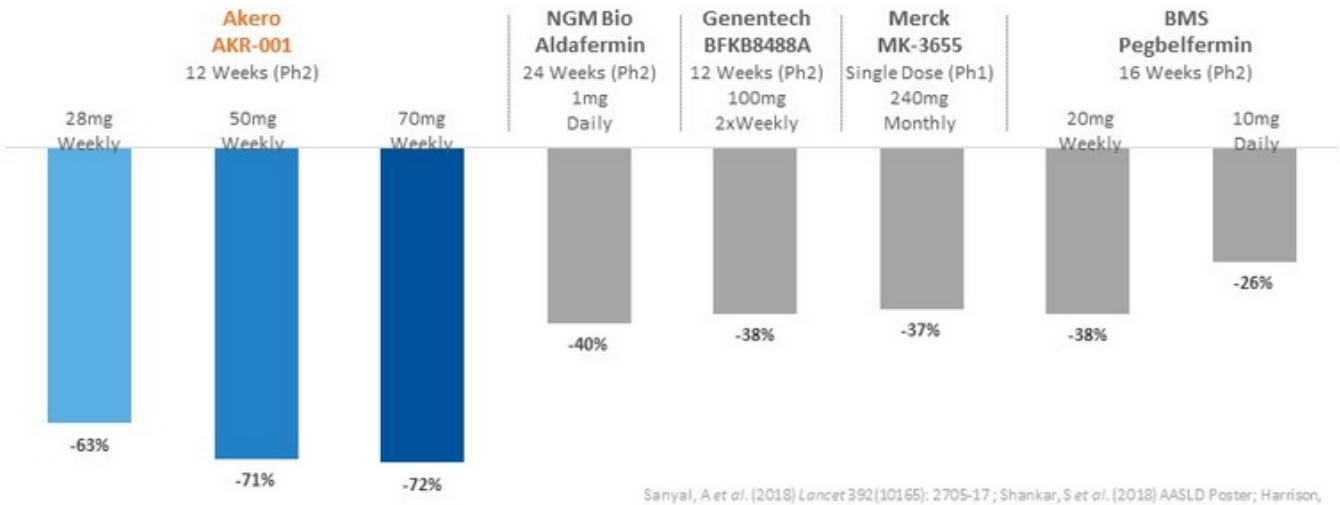
DEVELOPMENT LANDSCAPE FOR RELATIVE REDUCTION IN LIVER FAT

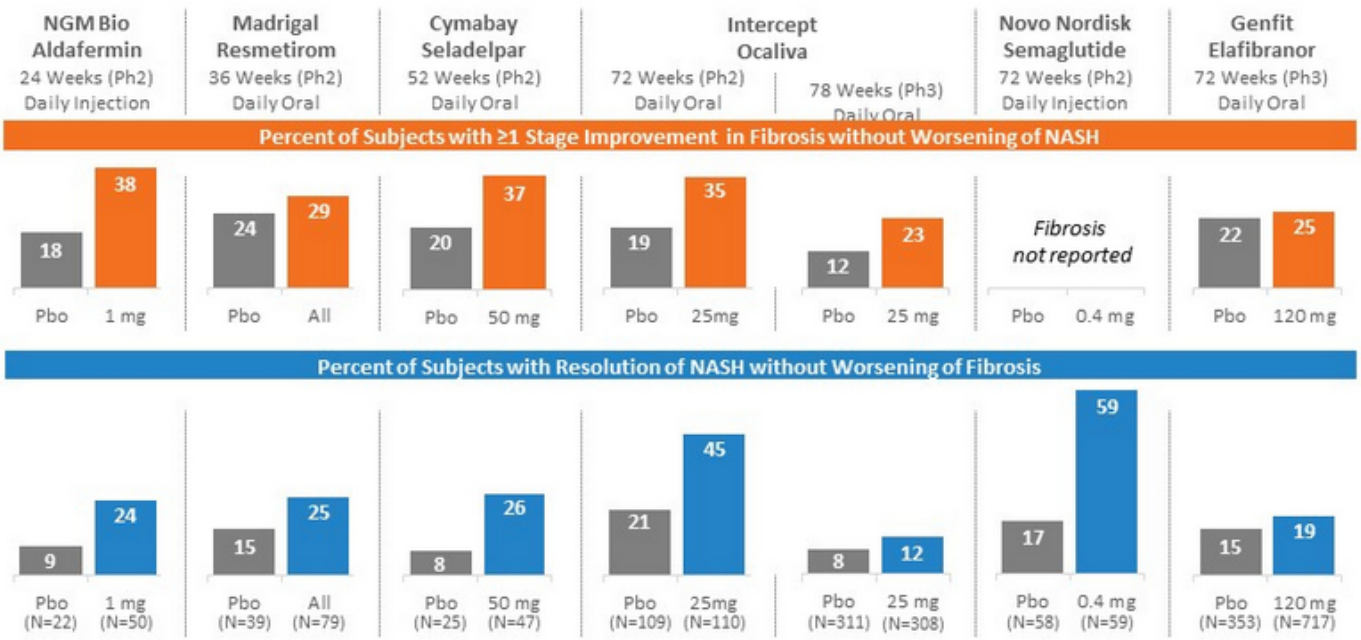
Relative Fat Reduction (MRI-PDFF) of FGFs



Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted

Sanyal, A *et al.* (2018) *Lancet* 392(10165): 2705-17 ; Shankar, S *et al.* (2018) AASLD Poster; Harrison, S *et al.* (2018) EASL Presentation; Ge, H *et al.* (2014) *J Biol Chem* 289(44): 30470-80; Yu, X *et al.* (2013) *PLOS ONE* 8(7): e66923; Wu, X *et al.* (2013) *J Lipid Res* 54(2): 325-32; Wu, A-L *et al.* (2013) *PLOS ONE 6(3): e17868;* Wu, X *et al.* (2009) *Proc Natl Acad Sci* 106(34): 14379-84; Huang, X *et al.* (2007) *Diabetes* 56(10): 2501-10; Kunder et al. (2019) AASLD Poster; NGM (2019) October 7 Corporate Presentation.

DEVELOPMENT LANDSCAPE FOR PHASE 3 HISTOLOGY ENDPOINTS



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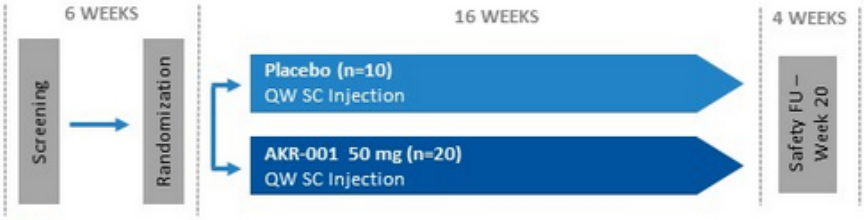
AKR-001: **16 weeks** of **once-weekly** dosing

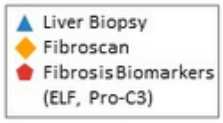
F4 COHORT EXPANSION (COHORT C)

Screening for an additional cohort of patients with compensated cirrhosis (F4), Child-Pugh Class A, began on May 7, 2020, with enrollment expected to begin in 2Q'20

NUMBER OF SUBJECTS
30

PRIMARY ENDPOINT
Safety and tolerability



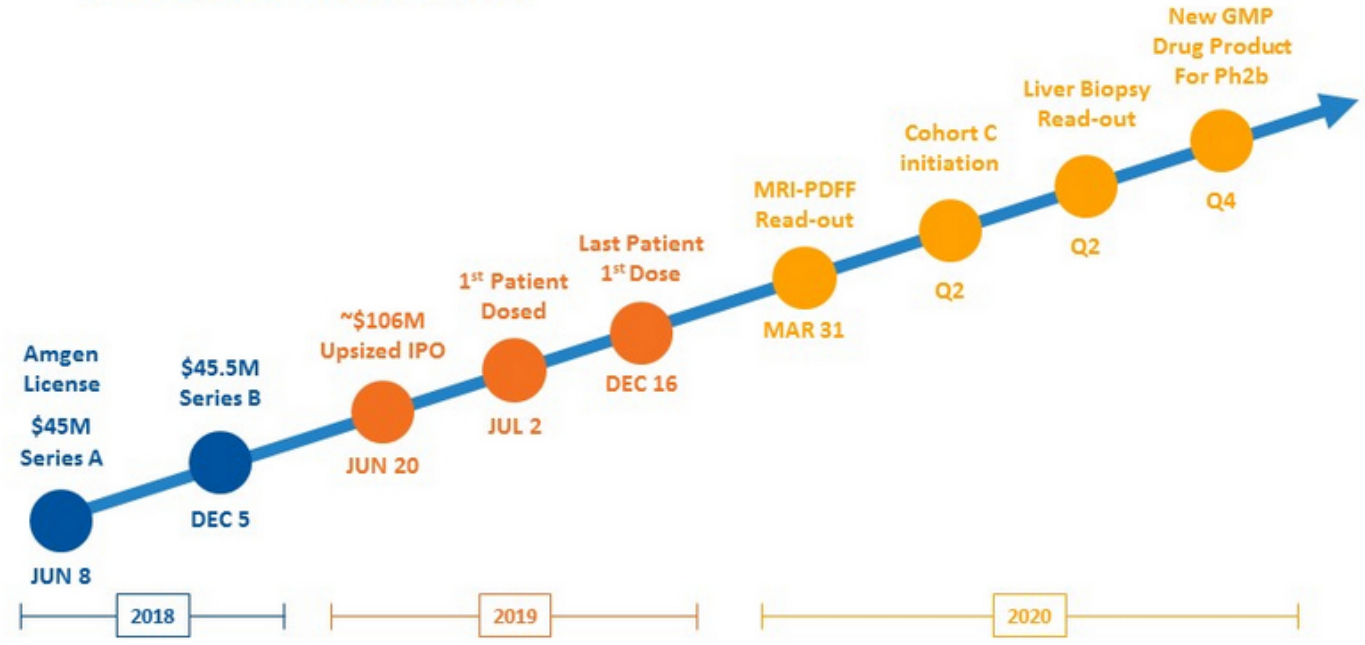


Selection of 50 mg dose based on PK-PD modeling of Phase 1b data, results of BALANCED main study, and availability of drug product

STRONG FINANCIAL POSITION

COMPLETED UPSIZED IPO *June 20, 2019*	Q1 EARNINGS UPDATE *March 31, 2020*	SIGNIFICANT NEAR TERM MILESTONES
~$106M Raised in aggregate gross proceeds	~$125M Cash and cash equivalents	Biopsy Data Readout late Q2 2020
$16 Price upsized IPO at top of marketing range	~$12M Q1 operating expenses	Phase 2b/3 Anticipated initiation 1H 2021

MILESTONES PROJECTED
MILESTONES DELIVERED



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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
- ✓ Data readout expected toward end of 2Q'20
  - Paired biopsy data for 42 subjects (84% of eligible subjects)
  - Biomarkers of liver injury and fibrosis and other relevant measures
  - Safety and tolerability
- ✓ GMP Drug Product expected in Q4'20 ahead of anticipated 1H'21 Ph2b/3 Start

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A Global Disease, A Pioneering Treatment

NASDAQ: AKRO