

**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): January 13, 2020

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38944
(Commission
File Number)

81-5266573
(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 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 Akeru 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: January 13, 2020

AKERO THERAPEUTICS, INC.

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



RESTORING METABOLIC BALANCE. TRANSFORMING LIVES.

Developing medicines to reverse the course
of serious metabolic diseases.

CORPORATE PRESENTATION

SAFE HARBOR

This presentation has been prepared by Akeru Therapeutics, Inc. ("we," "us," "our," "Akeru" 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, our development plans, our preclinical and clinical results and other future conditions. 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.

AKERO

BUILDING VALUE ON A STRONG FOUNDATION

Clinical-Stage FGF Analog

- AKR-001, Fc-FGF21 fusion protein, licensed from **Amgen**
- **3-4 day half-life** for QW dosing
- Robust effects on lipoproteins and markers of insulin sensitivity in 83 T2D patients in two Phase 1 trials
- Well tolerated
- Currently in Phase 2a

Validated Path in NASH

- FGF analogs reduce liver fat; reverse fibrosis in NASH patients
- Phase 1 demonstrated AKR-001's **metabolic effects; anticipated to have anti-fibrotic effects** and target both liver & adipose tissue
- With balanced receptor activity, AKR-001 has potential to be leading FGF analog

Key Upcoming Milestones

1Q20

Ph2a clinical trial primary endpoint (MRI-PDFF)

2Q20

Ph2a clinical trial repeat liver biopsy assessments

NASH

A SERIOUS AND DEBILITATING MULTI-SYSTEM DISEASE

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

A GROWING HEALTH EPIDEMIC



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

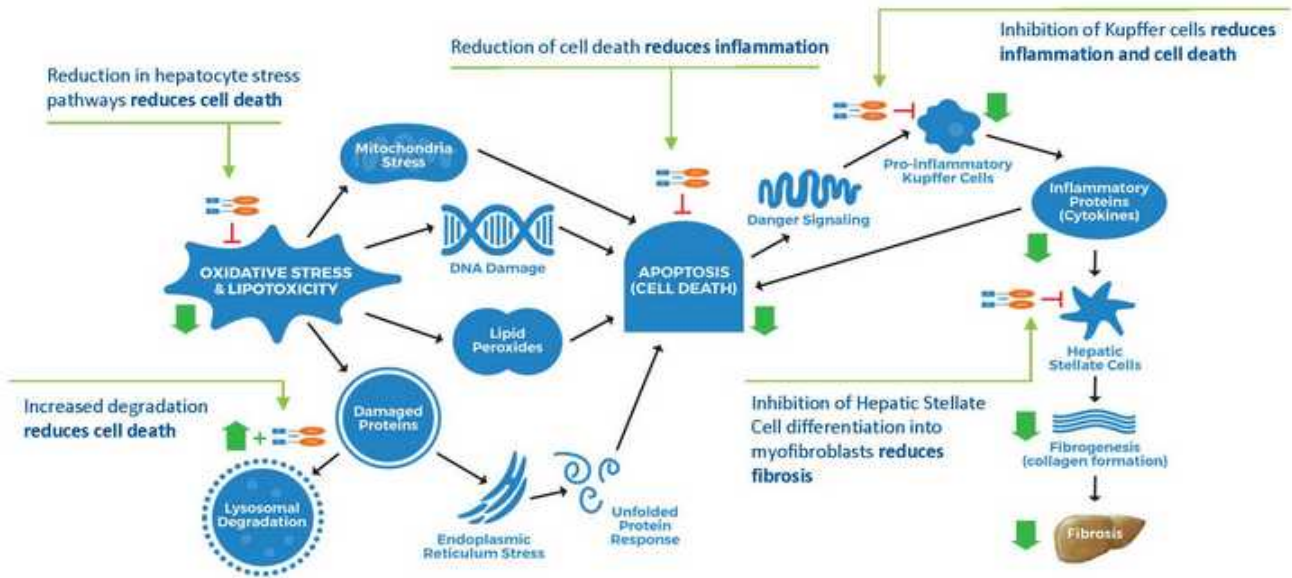


Lambert, JE et al. (2014) *Gastroenterology* 146(3): 726-35

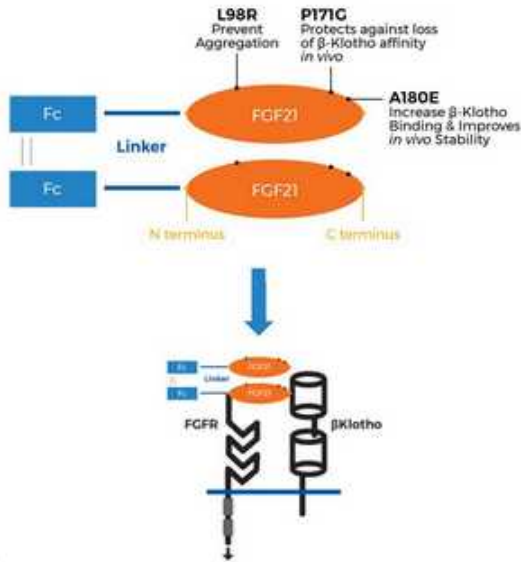
Acting on both hepatic and peripheral sources of liver fat is key to optimizing liver fat reduction

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

FGF21 PROTECTS HEPATOCYTES AND MITIGATES INFLAMMATION & FIBROSIS



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



Key attributes

- Amgen-designed** 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; Kharitonov, A et al. (2007) *Endocrinology* 148(2):774-781

AKR-001 RESTORED METABOLIC BALANCE AND IMPROVED MARKERS OF CARDIOVASCULAR RISK IN PHASE 1

Two Phase 1 clinical trials of AKR-001 studying 83 patients with type 2 diabetes showed



Improved
Lipoproteins



Improved Insulin
Sensitivity



Weight
Neutrality



Favorable
Tolerability

And support AKR-001's potential, in NASH patients, to be

METABOLIC

Redirect calories away from the liver
Reduce liver fat
Reduce hepatocellular stress and cell death

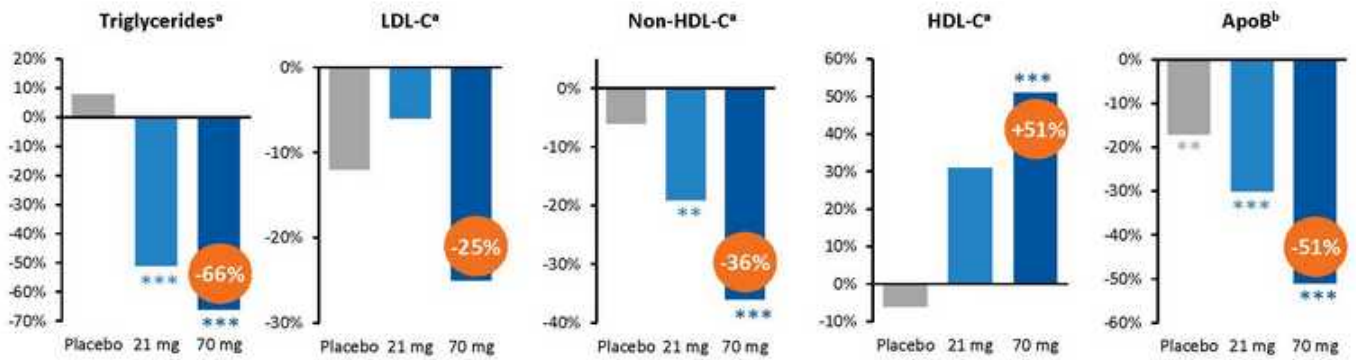
ANTI-FIBROTIC

Suppress inflammation
Reverse fibrosis

CARDIOVASCULAR DISEASE IS LEADING CAUSE OF DEATH IN PEOPLE WITH NASH

AKR-001 IMPROVED LIPOPROTEIN PROFILE

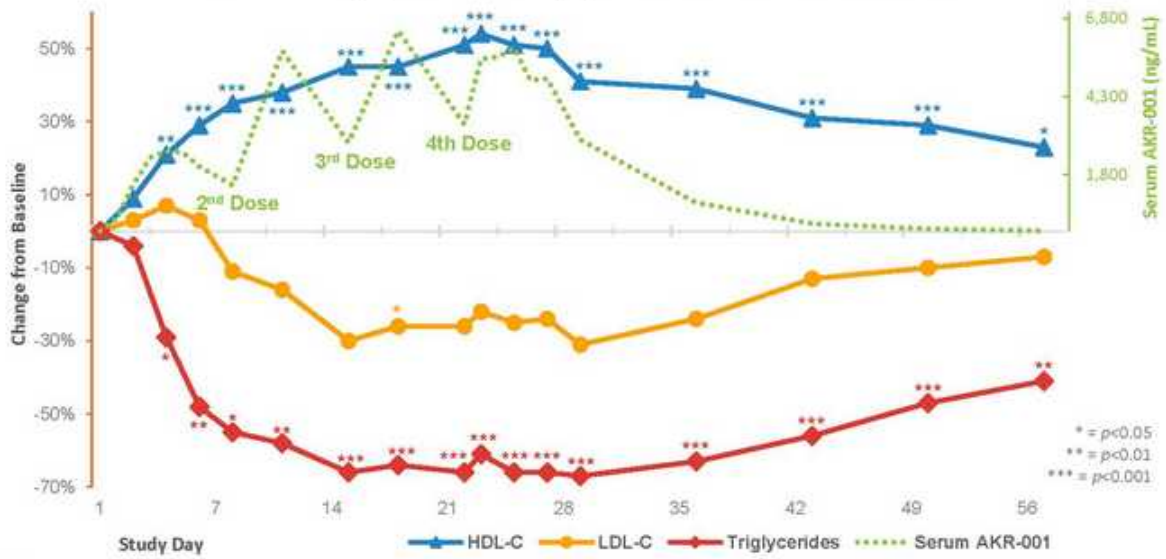
AKR-001's significant improvements in lipoproteins and reduction in adipose lipolysis are consistent with effective agonism of FGFR2c and 3c in the liver and FGFR1c in adipose tissue



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

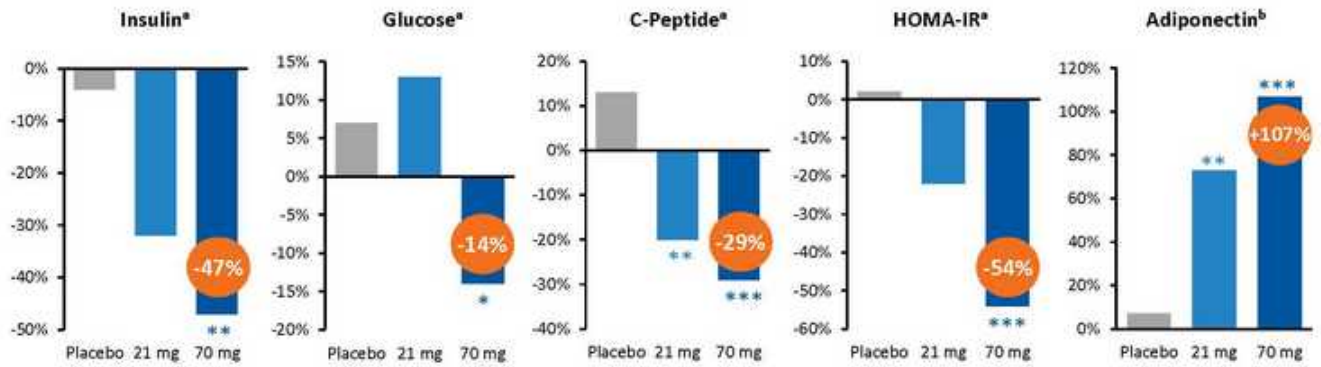
AKR-001 IMPROVED LIPOPROTEINS RAPIDLY AND DURABLY

AKR-001 70 mg QW effects on lipoproteins in Phase 1b clinical trial



AKR-001 IMPROVED INSULIN SENSITIVITY

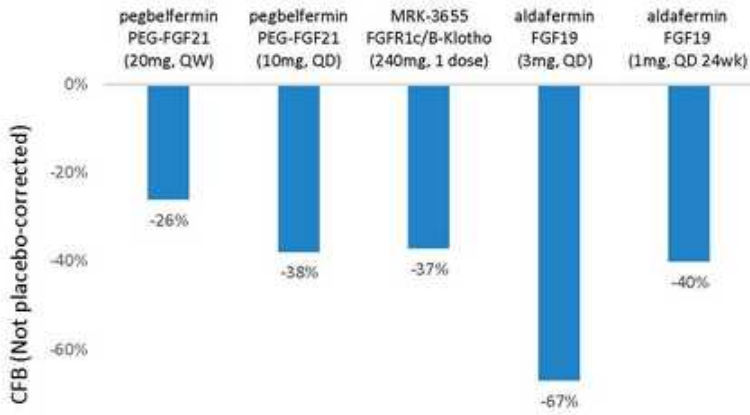
AKR-001's significant improvement in insulin sensitivity is consistent with effective FGFR1c agonism



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

HISTORICAL DATA VALIDATE POTENTIAL FOR BALANCED FGFR AGONISM TO REDUCE 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.

Balanced potency at FGFR1c, 2c, 3c has potential to yield maximum liver fat reduction

Sanyal, A et al. (2018) *Lancet* 392(10165): 2705-17; Shiankai, 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): e66935; Wu, X et al. (2013) *J Lipid Res* 54(2): 325-32; Wu, A-L et al. (2013) *PLOS ONE* 8(3): e78868; Wu, X et al. (2009) *Proc Natl Acad Sci* 106(34): 14379-84; Huang, X et al. (2007) *Diabetes* 56(10): 2501-10; NGM (2019) October 7 Corporate Presentation.

POSITIVE DATA FOR FGFR AGONIST IN LIVER HISTOLOGY UNDERScores POTENTIAL FOR AKR-001

AKR-001 is a balanced agonist of FGFR1c, 2c and 3c, with potential for reduction in hepatocyte stress and apoptosis as well as direct and indirect anti-fibrotic effects

Mean histology change from baseline at W12 (% of patients)	aldafermin 3 mg (n=19)
Fibrosis \geq 1 stage reduction	42%
NAS \geq 1 point reduction	84%

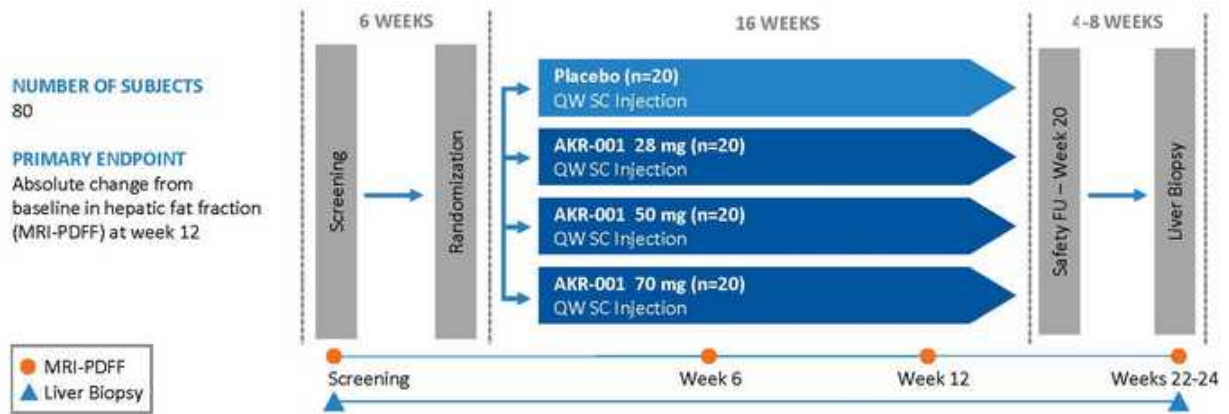
Shankar, S et al. (2018) AASLD Poster

Historical improvements in biopsy-based measures in NASH patients after 12 weeks

- Underscores the capacity of β -Klotho-dependent FGFR agonism to improve NASH and reverse fibrosis
- May open up opportunity to accelerate path to registrational trials, via early demonstration of histological improvement

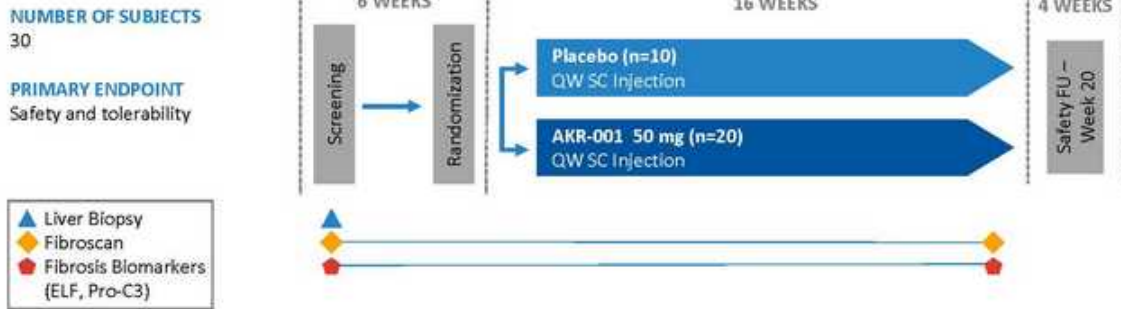
PHASE 2A TRIAL: THE BALANCED STUDY (MAIN STUDY)

Multiple endpoints, including liver fat reduction as well as paired biopsies, designed to provide proof of concept that Akero's FGF21 approach combats major hallmarks of NASH



F4 COHORT EXPANSION (COHORT C)

The BALANCED study is being expanded to include a cohort of patients with compensated cirrhosis (F4), Child-Pugh Class A



Selection of 50 mg dose based on PK-PD Modeling of Phase 1b data and availability of drug product

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

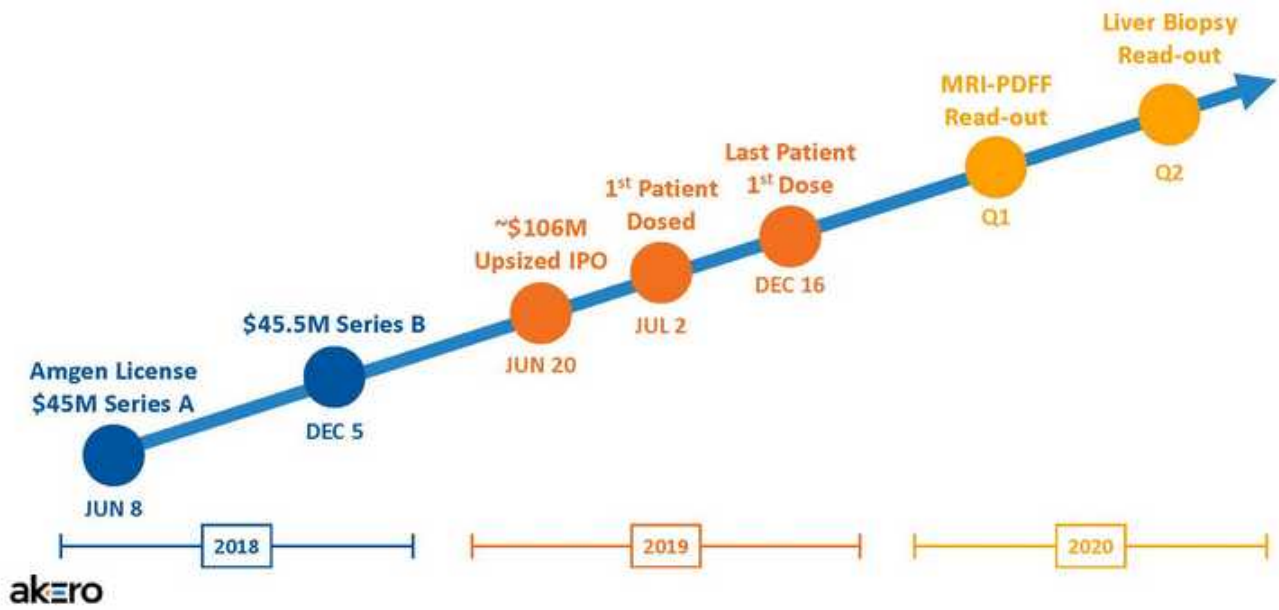
- 18 years in life sciences investment banking at Goldman Sachs, Citigroup and Deutsche Bank
- Most recently, Head of US Life Sciences Investment Banking at Deutsche Bank
- Advised on more than \$70bn in M&A and \$25bn in financing transactions



STRONG FINANCIAL POSITION



MILESTONES PROJECTED MILESTONES DELIVERED



akero

akero

THANK YOU.

CORPORATE PRESENTATION
