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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

_____, Individually and on Behalf of All Others)	Case No. 3:24-cv-02534
Similarly Situated,)	
Plaintiff,)	<u>CLASS ACTION</u>
vs.)	COMPLAINT FOR VIOLATIONS OF THE
AKERO THERAPEUTICS, INC., ANDREW)	FEDERAL SECURITIES LAWS
CHENG, WILLIAM WHITE, and)	
CATRIONA YALE,)	
Defendants.)	
_____)	<u>DEMAND FOR JURY TRIAL</u>

1 Plaintiff ___ (“plaintiff”), individually and on behalf of all other persons similarly situated,
2 by plaintiff’s undersigned attorneys, for plaintiff’s complaint against defendants, alleges the
3 following based upon personal knowledge as to plaintiff and plaintiff’s own acts, and upon
4 information and belief as to all other matters based on the investigation conducted by and through
5 plaintiff’s attorneys, which included, among other things, a review of certain U.S. Securities and
6 Exchange Commission (“SEC”) filings, public statements and press releases by Akeru Therapeutics,
7 Inc. (“Akeru” or the “Company”), as well as media and analyst reports about Akeru and the facts
8 alleged herein.¹ Plaintiff believes that substantial evidentiary support will exist for the allegations
9 set forth herein after a reasonable opportunity for discovery.

10 **NATURE OF THE ACTION**

11 1. This is a securities class action on behalf of all purchasers of Akeru common stock
12 between September 13, 2022 and October 9, 2023, inclusive (the “Class Period”). Plaintiff seeks to
13 pursue remedies against Akeru and certain of Akeru’s current senior executives under §§10(b) and
14 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”), and SEC Rule 10b-5 promulgated
15 thereunder.

16 **JURISDICTION AND VENUE**

17 2. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa. The claims
18 asserted herein arise under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a),
19 and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5. This Court has jurisdiction
20 over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

21 3. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C.
22 §1391(b) because Akeru conducts business and resides in this District, and the events and omissions
23 giving rise to the claims asserted herein occurred in substantial part in this District, including the
24 dissemination of false and misleading statements in and from this District.

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28 ¹ Emphasis has been added unless otherwise noted.

1 4. In connection with the acts alleged in this complaint, defendants, directly or
2 indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to,
3 the mails, interstate telephone communications, and the facilities of the national securities markets.

4 **PARTIES**

5 5. Plaintiff ____, as set forth in the accompanying certification that is
6 incorporated by reference herein, purchased and acquired Akero common stock during the Class
7 Period and has been damaged thereby.

8 6. Defendant Akero is a Delaware corporation with its principal executive offices
9 located in South San Francisco, California. Akero common stock is listed and publicly traded on the
10 NASDAQ Global Select Market (“NASDAQ”) under the ticker symbol “AKRO.” Akero is a
11 clinical stage biopharmaceutical company that was founded to develop transformational medicines
12 for patients with serious metabolic diseases that lack effective treatment options. The Company is
13 currently focused on advancing its lead product candidate efruxifermin (“EFX”), formerly known as
14 AKR-001, to provide a new treatment for patients with nonalcoholic steatohepatitis, a serious liver
15 disease.

16 7. Defendant Andrew Cheng, M.D. (“Cheng”) has served as Akero’s President and
17 Chief Executive Officer (“CEO”) and a member of Akero’s Board of Directors since September
18 2018.

19 8. Defendant William White (“White”) has served as Akero’s Chief Financial Officer
20 since May 2019.

21 9. Defendant Catriona Yale (“Yale”) has served as Akero’s Chief Development Officer
22 since 2018.

23 10. Defendants referenced in ¶¶7-9 above are referred to herein as the “Individual
24 Defendants.” The Individual Defendants and Akero are referred to herein as “defendants.”

25 11. Each of the Individual Defendants was directly involved in the management and day-
26 to-day operations of Akero at the highest levels and was privy to confidential proprietary
27 information concerning Akero and its business, operations, securities offerings, clinical trials, plans,
28 and present and future business prospects. In addition, the Individual Defendants were involved in

1 drafting, producing, reviewing, and/or disseminating the false and misleading statements and
2 information alleged herein, and were aware of, or recklessly disregarded, the false and misleading
3 statements being issued about Akero and its clinical trials of EFX, and approved or ratified these
4 statements, in violation of the federal securities laws.

5 12. As officers and controlling persons of a publicly held company whose securities are
6 registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, which is
7 governed by the provisions of the federal securities laws, the Individual Defendants each had a duty
8 to promptly disseminate accurate, truthful, and complete information with respect to Akero's
9 operations, business, expenditures, and present and future business prospects, including information
10 concerning Akero's clinical trials of EFX. Defendants' false and misleading misrepresentations and
11 omissions during the Class Period violated these specific requirements and obligations.

12 13. The Individual Defendants, because of their positions of control and authority as
13 officers and/or directors of Akero, were able to, and did, control the contents of various SEC filings,
14 press releases, and other public statements pertaining to Akero and its clinical trials of EFX. Each
15 Individual Defendant was provided with copies of the documents alleged herein to be false and
16 misleading before or shortly after their issuance, participated in conference calls with investors
17 during which false and misleading statements were made, and had the ability and opportunity to
18 prevent the statements' issuance or cause them to be corrected. Accordingly, each Individual
19 Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore,
20 primarily liable for the representations contained therein.

21 **BACKGROUND**

22 **Nonalcoholic Steatohepatitis**

23 14. Nonalcoholic steatohepatitis ("NASH") is a serious form of nonalcoholic fatty liver
24 disease ("NAFLD") that is estimated to affect 17 million Americans. According to Akero, NASH is
25 primarily driven by chronic excess caloric intake, or ingesting more energy than the body expends
26 over a sustained period, which results in people becoming overweight and obese. NASH is
27 characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver
28 cells, leading to inflammation and fibrosis (scarring) that can progress to cirrhosis, liver failure,

1 cancer, and death. Approximately 20% of NASH patients will progress to cirrhosis, which has a
2 higher risk of mortality. During the relevant period, no drugs had been approved by the U.S. Food
3 and Drug Administration (“FDA”) for the treatment of NASH, representing a critical unmet need in
4 the field of liver disease.

5 **Efruxifermin (EFX)**

6 15. Akero’s lead product candidate, EFX, is a protein that was engineered to mimic the
7 effect of fibroblast growth factor 21 (“FGF21”), a naturally occurring human hormone that protects
8 against cellular stress and regulates whole-body metabolism and tissue-specific stress responses.
9 Akero asserts that “[b]y delivering sustained and balanced signaling through FGF21’s receptors in
10 liver and adipose tissue, EFX has the potential to treat NASH by addressing all core drivers of
11 disease progression.” EFX was designed to be administered to patients once weekly via
12 subcutaneous injections.

13 **Akero’s Clinical Trials Testing EFX in the Treatment**
14 **of Cirrhotic and Pre-Cirrhotic NASH**

15 16. Over the past several years, Akero has designed and overseen a series of clinical trials
16 to test the efficacy and safety of EFX in treating NASH patients. Akero differentiated its trials, in
17 part, by testing EFX in different NASH populations. Some trials targeted NASH patients with more
18 severe symptoms (*i.e.*, those with NASH-induced cirrhosis), while other trials targeted NASH
19 patients with less severe symptoms (*i.e.*, those who were pre-cirrhotic). Akero’s cirrhotic versus pre-
20 cirrhotic dividing line comports with FDA guidance published in 2018 and 2019 that considers pre-
21 cirrhotic NASH and cirrhotic NASH as two separate indications for treatment purposes.

22 17. Thus, relevant to determining whether a patient was eligible to participate in a
23 particular study (or cohort of a study), Akero first needed to confirm that the patient suffered from
24 NASH and next needed to determine whether the patient was pre-cirrhotic or suffering from NASH-
25 induced cirrhosis.

26 18. The most reliable diagnosis and staging of NASH is achieved by examining a liver
27 biopsy specimen under a microscope. A liver biopsy, however, is an invasive procedure involving
28

1 the extraction of a liver tissue sample. Further complicating matters, liver biopsies have been
2 associated with occasionally causing morbidity (the state of being unhealthy for a particular disease)
3 and, in rare circumstances, mortality. As a result, the use of liver biopsies in clinical trials poses
4 significant logistical challenges (including cost and the availability of pathologists with specific
5 expertise in NASH); and many patients are reluctant or unwilling to undergo the procedure given its
6 invasive nature and attendant risks – concerns that the COVID-19 pandemic only exacerbated.

7 19. Non-invasive biomarkers are sometimes used to diagnose or assess the various grades
8 of NASH and stages of liver fibrosis. For example, a liver elastography through a FibroScan, a
9 special ultrasound technology that measures liver stiffness (hardness) and fat changes in the liver, is
10 sometimes used in conjunction with the following scale:

- 11 • A fibrosis score of F0 to F1 (2 to 7 [kilopascals (“kPa”)]) means there is little
12 or no scarring on the liver.
- 13 • A fibrosis score of F2 (7.5 to 10 kPa) indicates moderate scarring that has
14 spread outside the liver.
- 15 • A fibrosis score of F3 (10 to 14 kPa) indicates severe scarring which has
16 spread and disrupts normal blood flow.
- 17 • A fibrosis score of F4 (14 kPa or higher) means late-stage scarring or
18 cirrhosis, where the scarring is permanent and the damage is irreversible.

19 20. During the Class Period, Akero claimed to be evaluating EFX in two Phase 2 clinical
20 trials in patients with *biopsy-confirmed NASH*: (i) Akero’s “HARMONY” trial that tested EFX in
21 *pre-cirrhotic NASH patients*; and (ii) Akero’s “SYMMETRY” trial that purportedly tested EFX in
22 *patients with NASH-induced cirrhosis*.²

23 21. The HARMONY trial was officially titled “A Phase 2b, Randomized, Double-Blind,
24 Placebo Controlled Study Evaluating the Safety and Efficacy of Efruxifermin *in Non-Cirrhotic*

25 ² Potential new treatments go through several phases of drug trials before they can be approved
26 by the FDA. Each phase has a different purpose. Phase 1 trials test a drug in a small group of
27 people (usually 15-50 patients) for safety and to identify side effects. Phase 2 trials test a drug in a
28 larger group of people (usually fewer than 100 patients) to confirm the drug’s effectiveness and
further study its safety. Phase 3 trials test a drug in a larger group of people (usually hundreds or
thousands of patients) to confirm the drug’s effectiveness, monitor side effects, compare it with
standard or similar treatments (if applicable), and collect information that will allow the new drug to
be used safely.

1 ***Subjects With Nonalcoholic Steatohepatitis (NASH).***” The 96-week Phase 2b HARMONY study
2 was a multicenter, randomized, double-blind, placebo-controlled clinical trial that enrolled 128
3 biopsy-confirmed NASH patients with fibrosis stage 2 or 3 (F2 or F3) who each received once-
4 weekly subcutaneous dosing of 28 milligrams of EFX, 50 milligrams of EFX, or a placebo. On the
5 first day of the Class Period, Akero published a readout of data collected through week 24 of the
6 study. Thereafter, HARMONY trial patients continued to receive EFX or placebo for up to 96
7 weeks to provide additional data.

8 22. The SYMMETRY study was officially titled “A Phase 2b, Randomized, Double-
9 Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Efruxifermin in ***Subjects***
10 ***With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH).***”³ Akero claimed that
11 the 96-week SYMMETRY study was a multicenter, randomized, double-blind, placebo-controlled
12 clinical trial that enrolled 182 patients ***with biopsy-confirmed compensated cirrhosis (F4), Child-***
13 ***Pugh class A, due to NASH,*** each of whom received once-weekly subcutaneous injections of 28
14 milligrams of EFX, 50 milligrams of EFX, or placebo.⁴ The day after the Class Period ended, Akero
15 published a readout of data collected through week 36 of the trial (based on a second liver biopsy).
16 SYMMETRY trial patients continue to receive EFX or placebo for up to 96 weeks to provide
17 additional data, including through a second on-treatment biopsy (third overall) at week 96.

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21 ³ Cirrhosis has two different clinical stages: compensated and decompensated. Compensated
22 cirrhosis is the asymptomatic stage and corresponds to Child-Pugh score A (a scoring system used to
23 determine the degree of liver failure present in patients with cirrhosis). Decompensated cirrhosis is
24 the symptomatic stage that is characterized by the presence or development of overt complications
25 such as ascites, jaundice, variceal hemorrhage, or hepatic encephalopathy and corresponds to Child-
26 Pugh score B (moderate) or C (severe). For compensated cirrhosis patients, non-invasive parameters
27 may all be normal and therefore a liver biopsy is required for the most accurate diagnosis. In clinical
28 practice, however, few patients are given a biopsy with clinicians instead using blood tests and
abdominal ultrasonography.

26 ⁴ The SYMMETRY study added a separate expansion cohort, known as Cohort D, which
27 evaluated the safety and tolerability of EFX compared to placebo when added to an existing GLP-1
28 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes (“Cohort
D”). Unless indicated otherwise, references to the SYMMETRY study herein are to the main
SYMMETRY study and not to Cohort D.

1 **Defendants' Fraudulent Scheme**

2 23. Akero is a clinical stage drug development company with a limited operating history.
3 The Company has yet to generate any revenues because the FDA has not approved any of its drug
4 candidates for sale. Because funding drug development, clinical trials, and commercialization is
5 capital-intensive, Akero has suffered significant recurring losses since its inception, including over
6 \$290 million in losses during the years 2020 to 2022 alone. To finance the Company's operations,
7 Akero conducted two secondary stock offerings and one at-the-market stock offering during the
8 Class Period, raising over \$577 million.

9 24. In order to successfully complete these offerings and raise part of the funding Akero
10 needed to develop and commercialize EFX, defendants repeatedly misled investors as to the true
11 nature of the patient population that was being tested in Akero's SYMMETRY study. Specifically,
12 despite telling investors that the study's patient population was limited to those with NASH-induced
13 cirrhosis (a fact that was key for data integrity and the likelihood of study success), *for*
14 *approximately 20% of those being tested Akero had not confirmed that the patients had NASH*
15 *and that NASH had in fact caused their cirrhosis.*

16 25. Significantly, cirrhosis has multiple etiologies. Cirrhosis can be caused by alcohol
17 abuse, hepatitis, and NAFLD (including its NASH subtype), among other causes. When the cause of
18 a patient's cirrhosis is unknown, however, it is referred to as "cryptogenic" cirrhosis – *i.e.*, cirrhosis
19 "of obscure or unknown origin." Unbeknownst to investors, approximately 20% of the patients in
20 the SYMMETRY study had cryptogenic cirrhosis.

21 26. Cryptogenic cirrhosis is treated differently from NASH cirrhosis by medical experts.
22 For example, in an article titled "Is cryptogenic cirrhosis different from NASH cirrhosis?" written by
23 Paul J. Thuluvath, Sergey Kantsevov, Avesh J. Thuluvath, and Yulia Savva, the authors concluded
24 that "[b]ased on risk perspectives, [cryptogenic cirrhosis] should not be equated with the term
25 'NASH cirrhosis'." Their conclusion was based on a comparison of the clinical characteristics of
26 thousands of adults with cryptogenic cirrhosis (n=7,999) to those with cirrhosis caused by NASH
27 (n=11,302), alcohol (n=21,714), and autoimmune hepatitis (n=3,447). As further explained: "We
28 hypothesized that cryptogenic cirrhosis is a distinct condition from cirrhosis caused by [NASH]. By

1 comparing cryptogenic cirrhosis with cirrhosis of other causes, we found clear clinical differences.
2 Therefore, cryptogenic cirrhosis should not be considered the same as NASH cirrhosis.”

3 27. In the FDA’s 2019 draft guidance for industry titled “Nonalcoholic Steatohepatitis
4 with Compensated Cirrhosis: Developing Drugs for Treatment,” the FDA cautioned sponsors of
5 drugs designed to treat compensated NASH cirrhosis against including cryptogenic cirrhosis patients
6 in trials. The draft guidance stated:

7 Sponsors should be careful to enroll in clinical trials only patients whose cirrhosis is
8 secondary to NASH and not caused by other etiologies. Patients should have
9 histological diagnoses of NASH, and other causes of chronic liver disease should be
10 ruled out (e.g., alcoholic liver disease, viral hepatitis, primary biliary cholangitis,
11 primary sclerosing cholangitis, autoimmune hepatitis, Wilson’s disease,
12 hemochromatosis, alpha-1-antitrypsin deficiency, HIV).

13 28. The distinction between NASH-induced cirrhosis and cryptogenic cirrhosis comes
14 with an important difference. Patients suffering from cryptogenic cirrhosis often have a more
15 advanced (severe) form of cirrhosis and therefore have a different risk profile. Additionally, EFX’s
16 mechanism of action may not work in patients whose cirrhosis was caused by something other than
17 NASH. The inclusion of cryptogenic cirrhotics in the SYMMETRY study therefore introduced a
18 risk of negatively impacting or confounding the trial’s results – risks that were concealed from
19 investors during the Class Period.

20 29. Defendants’ Class Period representations gave the impression that cryptogenic
21 cirrhotics were excluded from the SYMMETRY study. First, defendants represented that enrolled
22 patients had biopsy-confirmed NASH-induced cirrhosis and made no mention of cryptogenic
23 cirrhotics. Indeed, the study itself was titled “*A Study of Efruxifermin in Subjects With
24 Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH).*”

25 30. Second, in March 2021 (before the Class Period), Akero reported results for a similar
26 clinical trial in which the Company tested EFX in patients with cirrhotic NASH (the Cohort C
27 Expansion of Akero’s Phase 2a “BALANCED” study). Akero’s reported results did not include *any*
28 mention of patients with cryptogenic cirrhosis.

1 31. Third, in describing the SYMMETRY study and its endpoints, Akero never disclosed
2 during the Class Period that the Company intended to exclude the results of cryptogenic cirrhotics
3 “who didn’t meet definitive NASH at baseline” when calculating the study’s secondary endpoints for
4 NASH resolution.⁵

5 32. Fourth, when Akero finally did report the SYMMETRY study’s initial results,
6 analysts recognized the inclusion of cryptogenic cirrhotics as important new information, asking
7 questions about their inclusion, and then questioning – based on this new information – whether the
8 inclusion of these patients negatively impacted the trial’s design and results.

9 33. Instead of being forthright with investors about the inclusion of cryptogenic cirrhotics
10 in the SYMMETRY study, defendants hid this information, which prevented investors from
11 accurately pricing the risk that the study would fail to meet its primary endpoint as a result of this
12 concealed fact. It was not until the Company disclosed the study’s 36-week results on October 10,
13 2023 that the market finally began to learn the truth, with investors suffering substantial losses and
14 damages under the federal securities laws as the price of Akero stock plummeted nearly 70% in
15 response.

16 **DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS**
17 **AND OMISSIONS ISSUED DURING THE CLASS PERIOD**

18 34. The Class Period begins on September 13, 2022. On that date, Akero filed with the
19 SEC a Form 8-K signed by defendant Cheng (the “September 13, 2022 Form 8-K”). The September
20 13, 2022 Form 8-K reported the 24-week results for Akero’s Phase 2b HARMONY study of EFX in
21 patients with pre-cirrhotic NASH. The September 13, 2022 Form 8-K and the attached press release
22 stated that both the 50 milligram and 28 milligram doses of EFX had achieved statistical significance
23 on primary and secondary histology endpoints after 24 weeks.

24 35. The September 13, 2022 Form 8-K and the attached press release also discussed
25 Akero’s SYMMETRY study, describing it as “*a Phase 2b trial in biopsy-confirmed NASH patients*”

26 _____
27 ⁵ A clinical study may have one or more primary and secondary endpoints. Primary endpoints
28 serve as the basis for determining whether the study met its objective. Secondary endpoints can
provide additional support for approval of a drug by the FDA.

1 with compensated cirrhosis, Child-Pugh class A” and “the SYMMETRY study in patients with
2 cirrhotic NASH (F4 fibrosis, compensated).”

3 36. On that same day, defendants held an investor call to discuss the results from the
4 HARMONY study (the “September 13, 2022 Call”). During the September 13, 2022 Call,
5 defendants Cheng and Yale both described the SYMMETRY study as “*our ongoing Phase 2b*
6 *SYMMETRY study in patients with cirrhotic NASH.*” Defendant Yale further stated in pertinent
7 part:

8 *On the more immediate horizon, we are encouraged by the strength of our*
9 *histology results and what they mean for our ongoing Phase 2b SYMMETRY study*
10 *in patients with cirrhotic NASH. Based on today’s results, we believe EFX has the*
11 *potential to be the first investigational NASH drug to achieve statistically*
12 *significant histological improvement in patients with cirrhotic NASH.*

13 37. Two days later, on September 15, 2022, Akero filed with the SEC a prospectus
14 supplement (to a prospectus previously filed on May 18, 2021) for a secondary offering of Akero
15 common stock (the “September 2022 Prospectus”). Pursuant to the September 2022 Prospectus, the
16 Company eventually sold over 8.8 million shares of Akero common stock at \$26 per share, raising
17 gross proceeds of approximately \$230 million.

18 38. The September 2022 Prospectus reiterated that the SYMMETRY study was being
19 conducted in patients with NASH-induced cirrhosis, stating in relevant part as follows:

20 We are a clinical-stage company dedicated to developing transformational
21 treatments for patients with serious metabolic diseases marked by high unmet
22 medical need, including non-alcoholic steatohepatitis, or NASH, a disease without
23 any approved therapies. NASH is a severe form of nonalcoholic fatty liver disease,
24 or NAFLD, characterized by inflammation and fibrosis in the liver that can progress
25 to cirrhosis, liver failure, cancer and death. Our lead product candidate,
26 efruxifermin, or EFX, is an analog of fibroblast growth factor 21, or FGF21, which is
27 an endogenously expressed hormone that protects against cellular stress and regulates
28 metabolism of lipids, carbohydrates and proteins throughout the body. *EFX is*
currently being evaluated in two Phase 2b clinical trials in patients with biopsy-
confirmed NASH: the HARMONY study in patients with pre-cirrhotic NASH (F2-
F3 fibrosis) and the SYMMETRY study in patients with cirrhotic NASH (F4
fibrosis, compensated).

39. The September 2022 Prospectus, in a section titled “Our pipeline,” reiterated that the
SYMMETRY study was evaluating EFX in patients with NASH-induced cirrhosis, stating in
pertinent part as follows:

1 Our pipeline is anchored by EFX, a potential best-in-class FGF21 analog for
2 treatment of NASH, if approved. We have one EFX program focused on patients
3 with pre-cirrhotic NASH (F2-F3), which is supported by the HARMONY study, an
4 ongoing Phase 2b clinical trial. ***We have a second EFX program focused on***
5 ***patients with cirrhotic NASH (F4, compensated), which is supported by the***
6 ***SYMMETRY study, an ongoing Phase 2b clinical trial. These two programs align***
7 ***with FDA guidance published in 2018 and 2019, which recommends different***
8 ***regulatory approval pathways for patients with pre-cirrhotic and cirrhotic NASH.***

9 40. On November 4, 2022, Akero filed with the SEC a Form 10-Q signed by defendants
10 Cheng and White (the “3Q22 10-Q”). The 3Q22 10-Q reported the Company’s financial results for
11 the third quarter of 2022 ending September 30, 2022. The 3Q22 10-Q described the SYMMETRY
12 study in pertinent part as follows: “[O]ur ongoing Phase 2b clinical trial of EFX in patients with
13 NASH who have cirrhosis (F4 fibrosis, compensated), known as the SYMMETRY study.”

14 41. The 3Q22 10-Q further stated in relevant part as follows: “EFX is currently being
15 evaluated in two Phase 2b clinical trials in patients with biopsy-confirmed NASH: the
16 HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis) and the SYMMETRY study
17 in patients with cirrhotic NASH (F4 fibrosis, compensated).”

18 42. Two months later, on January 10, 2023, defendant Cheng delivered a presentation at a
19 JPMorgan Healthcare Conference during which Cheng discussed the SYMMETRY study in relevant
20 part as follows:

21 ***[B]ut really the biggest readout this year is in the F4 population. And for us, that’s***
22 ***in the fourth quarter with SYMMETRY, with the patients with compensated***
23 ***cirrhotics. And people, I often get a question is why do we think this is going to be***
24 ***successful? I think the short answer is that we have proof-of-concept data, where we***
25 ***saw 58% of patients in a very, very small proof-of-concept study demonstrated either***
26 ***1-stage improvement of fibrosis or NASH resolution after just 16 weeks of dosing.***
27 ***And I’ll talk about that momentarily. I do want to remind everyone, this may look***
28 ***similar, but this is – like HARMONY, it’s a randomized, double-blind, placebo-***
29 ***controlled trial. SYMMETRY only [involves] patients with biopsy-proven NASH,***
30 ***F4. And the primary endpoint of cirrhosis reversal, that is 1-stage improvement in***
31 ***cirrhotic. The similar secondary markers are being filed in the secondary***
32 ***endpoint, fibrosis markers and other liver injury markers. But the biggest***
33 ***difference is the duration. It’s not a 24-week study, but a 36-week one.***

34 43. On March 17, 2023, Akero filed with the SEC its Form 10-K Annual Report for the
35 year ending December 31, 2022 signed by defendants Cheng and White (the “2022 10-K”). The
36 2022 10-K described the SYMMETRY study in pertinent part as follows: “[O]ur ongoing Phase 2b
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1 ***clinical trial of EFX in patients with NASH who have cirrhosis (F4 fibrosis, compensated), known***
2 ***as the SYMMETRY study.”***

3 44. The 2022 10-K further stated in pertinent part as follows:

4 ***EFX is currently being evaluated in two Phase 2b clinical trials in patients***
5 ***with biopsy-confirmed NASH: a long-term follow-up period for the HARMONY***
6 ***study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), for which we have***
7 ***reported results after 24 weeks of treatment, and the SYMMETRY study in patients***
8 ***with cirrhotic NASH (F4 fibrosis, compensated).***

9 45. The 2022 10-K further stated in a section titled “Our Pipeline” that the study was
10 focused on “patients with cirrhotic NASH,” stating in relevant part as follows:

11 Our pipeline is anchored by EFX, a potential best-in-class FGF21 analog for
12 treatment of NASH, if approved. We have one EFX program focused on patients
13 with pre-cirrhotic NASH (F2-F3), which is supported by the HARMONY study, an
14 ongoing Phase 2b clinical trial. ***We have a second EFX program focused on***
15 ***patients with cirrhotic NASH (F4, compensated), which is supported by the***
16 ***SYMMETRY study, an ongoing Phase 2b clinical trial. These two programs align***
17 ***with FDA guidance published in 2018 and 2019, which recommends different***
18 ***regulatory approval pathways for patients with pre-cirrhotic and cirrhotic NASH.***

19 46. In providing an “Overview of EFX Clinical Development” the 2022 10-K reiterated
20 that the SYMMETRY study was limited to patients with cirrhotic NASH, stating in relevant part
21 that: ***“We have two active EFX programs supported by two ongoing, parallel Phase 2b clinical***
22 ***trials: the HARMONY study in pre-cirrhotic patients with F2-F3 fibrosis and the SYMMETRY***
23 ***study in patients with cirrhosis due to NASH (F4, compensated).”***

24 47. The 2022 10-K further described the ***“Phase 2b clinical trial of EFX in patients with***
25 ***biopsy-confirmed cirrhotic NASH (F4, compensated) for 36 weeks”*** as follows, stating in pertinent
26 part: ***“The Phase 2b SYMMETRY main study is a multicenter, randomized, double-blind, placebo-***
27 ***controlled, clinical trial in biopsy-confirmed NASH patients with compensated cirrhosis (F4,***
28 ***Child-Pugh class A).”***

48. Also on March 17, 2023, Akero filed with the SEC a prospectus supplement (to a
prospectus originally filed May 18, 2021) in connection with an at-the-market stock offering that
ultimately raised at least \$127 million in gross proceeds (the “March 2023 ATM Prospectus”). The

1 March 2023 ATM Prospectus incorporated the 2022 10-K by reference and therefore repeated and
2 reissued the false and misleading statements and omissions contained in the 2022 10-K.

3 49. On May 15, 2023, Akero filed with the SEC a Form 8-K, signed by defendant Cheng,
4 that reported Akero's financial results for the first quarter of 2023 and provided a business update in
5 a press release attached as an exhibit (the "May 15, 2023 Form 8-K"). The May 15, 2023 Form 8-K
6 stated: "***Results from the Phase 2b SYMMETRY study, evaluating treatment of patients with***
7 ***compensated cirrhosis due to NASH, on track to be reported in the fourth quarter of this year.***"

8 50. On May 17, 2023, Akero filed with the SEC a prospectus supplement (to a prospectus
9 originally filed May 18, 2021) in connection with a secondary offering of common stock that
10 ultimately sold over 5.2 million shares at \$42 per share and raised \$220 million in gross proceeds
11 (the "May 2023 Prospectus"). The May 2023 Prospectus incorporated the 2022 10-K by reference
12 and therefore repeated and reissued the false and misleading statements and omissions contained in
13 the 2022 10-K.

14 51. On September 12, 2023, at a Morgan Stanley Global Healthcare Conference,
15 defendant Cheng described the SYMMETRY trial in an investor presentation while again omitting
16 information concerning the inclusion of cryptogenic cirrhotics among the study's patient population,
17 stating in relevant part:

18 ***So this trial is a very straightforward Phase IIb trial. It's 182 patients, randomized***
19 ***1:1:1 to placebo 28 milligrams, of efruxifermin of 50 milligrams. *These are patients****
20 ***with biopsy-confirmed NASH. That is that they have F4 NASH, they're cirrhotic***
21 ***and they're Child-Pugh Class A. These patients, also known as compensated***
22 ***cirrhotics, they're dosed for 36 weeks. And the primary endpoint is one stage***
improvement in fibrosis without worsening of NASH. And we're also looking at
key secondary endpoints such as NASH resolution and a number of other
biomarkers.

23 52. The statements referenced in ¶¶34-51 above were materially false and misleading
24 when made because they failed to disclose the following adverse facts pertaining to Akero's
25 business, operations, and financial condition, which were known to or recklessly disregarded by
26 defendants as follows:

27 (a) that approximately 20% of the patients enrolled in the SYMMETRY study
28 had cryptogenic cirrhosis and did not have definitive NASH at baseline (an NAFLD activity score of

1 greater than or equal to 3, with a score of at least 1 in each of the components of steatosis,
2 ballooning, and inflammation);

3 (b) that the cryptogenic cirrhotic patients included in the SYMMETRY study did
4 not have biopsy-proven compensated cirrhosis due to definitive NASH;

5 (c) that the results from the cryptogenic cirrhosis patients – *i.e.*, those who did not
6 have definitive NASH – were to be excluded from the calculation of the NASH resolution secondary
7 endpoints;

8 (d) that, as a result of the inclusion of cryptogenic cirrhotics in the SYMMETRY
9 study and in the calculation of the study’s primary endpoint, Akero had introduced a confounding
10 factor into the study’s design, materially influencing the study’s potential results and increasing the
11 risks that the study would fail to meet its primary endpoint;

12 (e) that the SYMMETRY study did not align with FDA guidance for testing a
13 drug in treating NASH cirrhotics because Akero had not ruled out potential causes of each patient’s
14 cirrhosis other than NASH; and

15 (f) that, as a result of (a)-(e) above, defendants had materially misrepresented the
16 nature of the SYMMETRY trial, its usefulness in supporting any new drug application filed by
17 Akero in supporting approval for cirrhotic NASH patients, the likelihood that the SYMMETRY trial
18 would be successful as measured by its primary endpoint, and the likelihood that EFX would
19 become a commercial treatment for NASH cirrhotics.

20 53. Before the market opened on October 10, 2023, Akero filed with the SEC a Form 8-
21 K, signed by defendant Cheng, that attached a related press release and slide presentation as exhibits,
22 in which the Company announced the results of the Phase 2b SYMMETRY trial (the “October 10,
23 2023 Form 8-K”). The trial’s primary efficacy endpoint was the proportion of patients who achieved
24 ≥ 1 stage improvement in fibrosis and no worsening of NASH, based on liver biopsies collected at
25 week 36 versus baseline. The press release attached to the October 10, 2023 Form 8-K attempted to
26 gloss over the fact that the SYMMETRY study had failed to meet its primary endpoint (as the results
27 were not statistically significant) by calling the results a “trend” instead. The October 10, 2023
28 Form 8-K stated in relevant part:

1 Akero Therapeutics, Inc., a clinical-stage company developing transformational
2 treatments for patients with serious metabolic disease marked by high unmet medical
3 need, today reported a 36-week analysis of SYMMETRY, a 96-week Phase 2b study
4 evaluating the efficacy and safety of its lead product candidate efruxifermin (EFX) in
5 patients with compensated cirrhosis (F4) due to nonalcoholic steatohepatitis (NASH).

6 ***A trend was observed for the primary endpoint of fibrosis improvement at
7 36 weeks, with 22% and 24% of the 28mg and 50mg EFX-treated groups,
8 respectively, experiencing at least a one-stage improvement in liver fibrosis and no
9 worsening of NASH, compared with 14% for placebo.*** In addition, 4% of patients
10 in each of the EFX-treated groups experienced a three- or two-stage fibrosis
11 improvement without worsening of NASH – from compensated cirrhosis (F4) to F1
12 or F2, compared with 0% for placebo.

13 54. The October 10, 2023 Form 8-K further attempted to minimize the impact of the
14 study’s disappointing primary endpoint results by highlighting the statistically significant results in
15 certain of the trial’s secondary endpoints, most importantly NASH resolution, stating in pertinent
16 part as follows:

17 Statistically significant rates of NASH resolution in 63% and 60% of patients at
18 week 36 were observed for the 28mg and 50mg EFX-treated groups, respectively,
19 compared with 26% for placebo, representing the highest response rates reported to
20 date for NASH resolution in this patient population. Statistically significant
21 improvements were also observed for both EFX groups in non-invasive markers of
22 liver injury and fibrosis, insulin sensitization and lipoproteins.

23 55. Tellingly, when calculating the placebo arm for the primary endpoint, defendants
24 listed 57 patients as being in the placebo arm’s data set, whereas when defendants calculated the
25 number of patients in the placebo arm of the secondary endpoints for NASH resolution, defendants
26 only listed 46 patients as being in the placebo arm. This 11-patient discrepancy in the placebo arm
27 stems from Akero’s exclusion of cryptogenic patients when calculating NASH resolution, as
28 reflected in footnote 1 of the press release, which notes in relevant part: “Source Data: Liver Biopsy
29 Analysis Set (fibrosis improvement); ***Liver Biopsy Analysis Set (definitive NASH only) (resolution
30 of NASH and combined endpoint).***” The slideshow attached to the October 10, 2023 Form 8-K
31 further explained that “***[a]ll patients had biopsy-proven compensated cirrhosis (fibrosis stage 4) due
32 to definitive NASH or cryptogenic cirrhosis presumed secondary to NASH. Subjects with
33 cryptogenic cirrhosis were limited to approximately 20% of the total study population.***”

34 56. Also that morning, Akero held a call with investors to discuss the SYMMETRY
35 trial’s results (the “October 10, 2023 Call”) led by the Individual Defendants. During the October
36

1 10, 2023 Call, defendants confirmed what they previously concealed from investors regarding the
2 makeup of the patient population in the SYMMETRY trial. In her prepared remarks, defendant Yale
3 explained the discrepancy in pertinent part as follows:

4 [G]ood morning, everybody. I'd like to begin with a review of the design of the
5 SYMMETRY study, which is shown on Slide 6.

6 The SYMMETRY study is a Phase IIb randomized, double-blind, placebo-
7 controlled multicenter dose-ranging trial. ***All patients had biopsy-proven
8 compensated cirrhosis fibrosis Stage 4 due to definitive NASH or cryptogenic
9 cirrhosis, presumed secondary to NASH.***

10 ***Subjects with cryptogenic cirrhosis were limited to approximately 20% of
11 the total study population.***

12 * * *

13 ***This study enrolled patients with advanced liver disease, including patients
14 with either cryptogenic cirrhosis or definitive NASH. The analysis set for NASH
15 resolution endpoints excluded those with cryptogenic cirrhosis who didn't meet
16 definitive NASH at baseline. That is the NAFLD activity score of greater than
17 equal to 3, with a score of at least 1 in each of the components of steatosis,
18 ballooning and inflammation.***

19 ***Consequently, the analysis set for NASH resolution is comprised of 126
20 patients, with 46, 38 and 42 patients, respectively, in the placebo, 28 milligram, and
21 50 milligram dose groups.***

22 ***Cryptogenic cirrhosis is sometimes referred to as burn-type NASH, and is
23 associated with advanced fibrosis and a higher level of risk in terms of liver
24 decompensation or death.***

25 57. During the Question-and-Answer session of the October 10, 2023 Call, analysts
26 pressed the Company on the inclusion of cryptogenic cirrhotics in the study, recognizing that the
27 information was new and that the inclusion of these patients was a confounding factor in the results.
28 For example, J.P. Morgan analyst Eric Joseph asked:

And then, this potential for cryptogenic NASH, I think, is a new variable in
thinking about the context of an F4 study. I guess, what's sort of – to the extent there
are – any measures that could be tak[en] in a Phase III program to sort of reduce their
participation and perhaps get a clearer signal?

58. Defendant Cheng replied by acknowledging the different risk profile for cryptogenic
cirrhotics, stating:

In terms of cryptogenic cirrhosis, I think these patients represent a part of the
cirrhotic spectrum. And they have a little more advanced NASH, and I think we've –
and in consultation with the FDA, have chosen to limit the patients to about 20% of

1 the population. And I think that's something we may consider to do. But of course,
2 that's pending discussions with the agency, which we haven't had.

3 59. Defendant Yale thereafter admitted, in response to further analyst questions, that
4 exclusion of the cryptogenic cirrhotics from the secondary endpoint calculations had been pre-
5 specified in the trial's protocol, thus confirming defendants' knowledge or reckless disregard of the
6 true facts concerning the SYMMETRY study's patient population despite the fact that this
7 information was contrary to what defendants had told investors regarding the trial's design.

8 60. In response to this news, the price of Akerio stock closed down \$30.39 per share on
9 October 10, 2023 and \$3.11 per share on October 11, 2023 on higher than average volume – a
10 decline of *nearly 70%* from the stock's closing price of \$48.54 per share on October 9, 2023.

11 61. In the days that immediately followed, analysts cut their price targets on Akerio stock,
12 with Morgan Stanley cutting its price target from \$70 per share to \$33 per share, Cantor Fitzgerald
13 cutting its price target from \$69 per share to \$39 per share, H.C. Wainwright & Co. cutting its price
14 target from \$64 per share to \$40 per share, and UBS cutting its price target from \$83 per share to \$39
15 per share.

16 62. Multiple analysts took particular issue with the previously undisclosed inclusion of
17 cryptogenic cirrhotics in the trial. Cantor Fitzgerald, for instance, noted in an October 10, 2023
18 research report that the inclusion of cryptogenic cirrhotics "*was a surprise to us and most*
19 *investors,*" that "[t]hese patients were included in the primary endpoint but excluded from NASH
20 resolution as they don't have definitive NASH," and that "[t]reatment effect for EFX is a little worse
21 in cryptogenic NASH relative to definitive NASH, which we think *may have negatively affected*
22 *trial results as a few percentage points of efficacy benefit in EFX favor would have led to*
23 *statistical significance.*"

24 63. Similarly, H.C. Wainwright & Co.'s October 11, 2023 research report stated in
25 relevant part:

26 **Here's what we disliked or confused us about SYMMETRY.** Why
27 cryptogenic cirrhotics? Why did the study entry criteria not exclude anyone but
28 definitive NASH cirrhotics (NAS \geq 3 with at least 1 for each of steatosis,
inflammation and ballooning)? If requested by the FDA, why go up to the maximum
20% of study population (placebo was 26%)? *In our view, this feature of the study*

1 *needlessly introduces confounding risk, and may have played a part in missing the*
2 *primary endpoint, in our view.*

3 (Emphasis in original and added.)

4 64. As a result of defendants' wrongful acts and omissions, and the precipitous decline in
5 the market value of Akero stock, plaintiff and other Class members (defined below) have suffered
6 significant losses and damages for which they seek redress through this action.

7 **ADDITIONAL SCIENTER ALLEGATIONS**

8 65. As alleged herein, defendants acted with scienter in that defendants knew, or
9 recklessly disregarded, that the public documents and statements they issued and disseminated to the
10 investing public in the name of Akero, or in their own name, during the Class Period were materially
11 false and misleading. Defendants knowingly and substantially participated or acquiesced in the
12 issuance or dissemination of such statements and documents as primary violations of the federal
13 securities laws. Defendants, by virtue of their receipt of information reflecting the true facts
14 regarding Akero and its clinical trials of EFX, and their control over and/or receipt and/or
15 modification of Akero's materially false and misleading statements, were active and culpable
16 participants in the fraudulent scheme alleged herein.

17 66. Defendants knew and recklessly disregarded the false and misleading nature of the
18 information they caused to be disseminated to the investing public. The fraudulent scheme described
19 herein could not have been perpetuated during the Class Period without the knowledge and
20 complicity of, or at least the reckless disregard by, personnel at the highest levels of Akero,
21 including the Individual Defendants.

22 67. The Individual Defendants, because of their positions with Akero, controlled the
23 contents of Akero's public statements during the Class Period and were intimately involved in
24 Akero's clinical trials of EFX. The Individual Defendants were each provided with or had access to
25 the information alleged herein to be false and misleading prior to or shortly after its issuance and had
26 the ability and opportunity to prevent its issuance or cause it to be corrected. Because of their
27 positions and access to material, non-public information, the Individual Defendants knew or
28 recklessly disregarded that the adverse facts specified herein had not been disclosed to and were

1 being concealed from the public and that the positive representations that were being made were
2 false and misleading.

3 68. A number of additional facts support plaintiff's allegations that defendants had
4 fraudulently concealed Akero's inclusion of cryptogenic cirrhotics in the SYMMETRY study long
5 before the truth was revealed.

6 69. First, defendants had ample financial motive to conceal the truth. Akero had suffered
7 recurring losses since its inception and needed to raise significant capital to fund its clinical trials
8 program and the commercialization of EFX. During the Class Period Akero conducted two
9 secondary offerings of common stock, raising gross proceeds of \$230 million in a September 2022
10 offering of more than 8.8 million shares at \$26 per share (including the underwriters' full exercise of
11 their option to purchase additional shares), and raising gross proceeds of \$220 million in a May 2023
12 offering of more than 5.2 million shares at \$42 per share. During the Class Period, Akero raised an
13 additional \$127 million in an ATM offering of common stock in March and April 2023 by selling
14 over 3 million Akero shares at an average price of \$42.38 per share. In the aggregate, Akero raised
15 at least \$577 million in gross offering proceeds from these 3 offerings over a 13-month period. By
16 concealing the inclusion of cryptogenic cirrhotics when discussing the SYMMETRY study,
17 defendants made it easier for Akero to raise the funding it desperately needed.

18 70. Second, every clinical trial must be conducted according to a clinical trial protocol,
19 which is "[a] document that describes the objective(s), design, methodology, statistical
20 considerations, and organization of a trial. The protocol usually also gives the background and
21 rationale for the trial, but these could be provided in other protocol referenced documents." *E6 (R2)*
22 *Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry* §1.44 (FDA
23 Mar. 2018). The sponsor of the clinical trial, here Akero, is responsible for designing the protocol.
24 *Id.*, §5.4.1. The trial's protocol is to include, *inter alia*, patient inclusion and exclusion criteria, a
25 specific statement of the endpoints to be measured during the trial, and a description of the statistical
26 methods to be employed. *Id.*, §§6.5.1-6.5.2, 6.4, 6.9.1. After the sponsor designs the protocol, the
27 sponsor ultimately provides it to the trial's investigators who agree to be bound by its terms when
28 testing patients. Specifically, "[t]he investigator/institution should conduct the trial in compliance

1 with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and
2 which was given approval/favorable opinion by the IRB/IEC. The investigator/institution and the
3 sponsor should sign the protocol, or an alternative contract, to confirm agreement.” *Id.*, §4.5.1. The
4 Individual Defendants personally oversaw this process. For example, defendant Yale signed the
5 protocol governing Akero’s Phase 2 BALANCED study, which included a representation directly
6 above her signature that “[t]his clinical study protocol was subject to critical review and has been
7 approved by the Sponsor.”

8 71. Based on Akero’s creation of the trial protocol, the Individual Defendants’
9 participation with and access thereto, the fact that defendants have admitted discussing the
10 cryptogenic patient population included in the study with the FDA, and the obvious importance of
11 the protocol to the SYMMETRY study, defendants knew or recklessly disregarded the relevant facts
12 and risks connected to the inclusion of cryptogenic cirrhotics in the SYMMETRY trial.
13 Furthermore, during the October 10, 2023 Call, defendant Yale admitted that the exclusion of
14 cryptogenic cirrhotics from the secondary endpoint calculations was “prespecified,” thereby
15 conceding that the trial’s protocol permitted the inclusion of cryptogenic cirrhotics in the trial as well
16 as their exclusion from certain of the secondary endpoint calculations. Defendants have also
17 admitted that they discussed the inclusion of cryptogenic cirrhotics in the study with the FDA,
18 confirming their knowledge of this patient subset. Furthermore, the protocol’s recognition of the
19 need for separate data sets (via the exclusion of cryptogenic cirrhotics from certain secondary
20 endpoint calculations) itself made clear to defendants that the inclusion of cryptogenic cirrhotics was
21 material information, the omission of which when describing the study was likely to deceive
22 investors.

23 72. Third, as alleged above, defendants repeatedly made statements about the
24 SYMMETRY trial and the patient population EFX was being tested on. These repeated statements
25 demonstrated defendants’ familiarity with the study and its patients.

26 73. Fourth, given Akero’s responsibilities for the trial protocol and the significance of the
27 SYMMETRY study to Akero’s business and prospects, the study’s inclusion and exclusion criteria
28 and basic features of the study’s endpoint calculations were part of the Company’s core operations.

1 As such, a strong inference can be drawn that, based on their positions at the Company, the
2 Individual Defendants, and therefore Akero, were well aware of the true facts concerning the study’s
3 inclusion of cryptogenic cirrhotics and the study’s endpoint calculations, or at the very least that
4 defendants recklessly disregarded this information when making their Class Period statements to
5 investors.

6 **NO SAFE HARBOR**

7 74. Defendants’ “Safe Harbor” warnings accompanying their reportedly forward-looking
8 statements (“FLS”) issued during the Class Period were ineffective to shield those statements from
9 liability. To the extent that projected revenues and earnings were included in Akero’s financial
10 reports prepared in accordance with Generally Accepted Accounting Principles (“GAAP”), including
11 those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe
12 Harbor. 15 U.S.C. §78u-5(b)(2)(A).

13 75. Defendants are also liable for any false or misleading FLS pled because, at the time
14 each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized
15 and approved by an executive officer of Akero who knew that the FLS was false. None of the
16 historic or present tense statements made by defendants were assumptions underlying or relating to
17 any plan, projection, or statement of future economic performance, as they were not stated to be such
18 assumptions underlying or relating to any projection or statement of future economic performance
19 when made, nor were any of the projections or forecasts made by defendants expressly related to or
20 stated to be dependent on those historic or present tense statements when made.

21 **APPLICATION OF PRESUMPTION OF RELIANCE: 22 **FRAUD ON THE MARKET****

23 76. At all relevant times, the market for Akero common stock was an efficient market for
24 the following reasons, among others:

25 (a) Akero common stock met the requirements for listing, and was listed and
26 actively traded on the NASDAQ, a highly efficient and automated market;

27 (b) according to Akero’s Form 10-K for the fiscal year ended December 31, 2022,
28 Akero had more than 46 million shares outstanding as of March 14, 2023;

- 1 (c) as a regulated issuer, Akero filed periodic public reports with the SEC;
- 2 (d) Akero regularly communicated with public investors via established market
- 3 communication mechanisms, including the regular dissemination of press releases on national
- 4 circuits of major newswire services, the internet, and other wide-ranging public disclosures; and
- 5 (e) unexpected material news about Akero was rapidly reflected in and
- 6 incorporated into the price for Akero stock during the Class Period.

7 77. As a result of the foregoing, the market for Akero stock promptly digested current

8 information regarding Akero from publicly available sources and reflected such information in the

9 price of Akero stock. Under these circumstances, all purchasers of Akero stock during the Class

10 Period suffered similar injury through their purchases of Akero stock at artificially inflated prices,

11 and a presumption of reliance applies.

12 78. A presumption of reliance is also appropriate in this action under the Supreme Court's

13 holding in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because plaintiff's claims

14 are based, in significant part, on defendants' material omissions. Because this action involves

15 defendants' failure to disclose material adverse information regarding Akero's business, operations,

16 and guidance, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that

17 the facts withheld be material in the sense that a reasonable investor might have considered them

18 important in making investment decisions. Given the importance of defendants' material

19 misstatements and omissions set forth above, that requirement is satisfied here.

20 **LOSS CAUSATION/ECONOMIC LOSS**

21 79. During the Class Period, as detailed herein, defendants made false and misleading

22 statements and engaged in a scheme to deceive the market and a course of conduct that artificially

23 inflated the price of Akero stock and operated as a fraud or deceit on Class Period purchasers of

24 Akero stock by misrepresenting the value of Akero's business and prospects by concealing Akero's

25 inclusion of patients with cryptogenic cirrhosis in the Company's SYMMETRY trial and its various

26 ramifications. As defendants' misrepresentations and fraudulent conduct became apparent to the

27 market, the price of Akero stock fell precipitously as the prior artificial inflation came out of the

28 stock's price and the concealed risks transpired. As a result of their purchases of Akero stock during

1 the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages,
2 under the federal securities laws.

3 CLASS ACTION ALLEGATIONS

4 80. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil
5 Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of Akero common stock
6 during the Class Period (the “Class”). Excluded from the Class are defendants, the officers and
7 directors of Akero, at all relevant times, members of their immediate families, and their legal
8 representatives, heirs, successors, or assigns, and any entity in which defendants have or had a
9 controlling interest.

10 81. The members of the Class are so numerous that joinder of all members is
11 impracticable. Throughout the Class Period, Akero stock was actively traded on the NASDAQ.
12 While the exact number of Class members is unknown to plaintiff at this time and can only be
13 ascertained through appropriate discovery, plaintiff believes that there could be hundreds or
14 thousands of members in the proposed Class. Record owners and other members of the Class may
15 be identified from records maintained by Akero or its transfer agent and may be notified of the
16 pendency of this action by mail, using the form of notice similar to that customarily used in
17 securities class actions.
18

19 82. Plaintiff’s claims are typical of the claims of the members of the Class as all members
20 of the Class are similarly affected by defendants’ wrongful statements and conduct in violation of
21 federal law that is complained of herein.

22 83. Plaintiff will fairly and adequately protect the interests of the members of the Class
23 and has retained counsel competent and experienced in class and securities litigation.

24 84. Common questions of law and fact exist as to all members of the Class and
25 predominate over any questions solely affecting individual members of the Class. Among the
26 questions of law and fact common to the Class are:

- 27 (a) whether defendants violated the Exchange Act as alleged herein;
28

1 (b) whether statements made by defendants misrepresented or omitted material
2 facts about the business, operations, and prospects of Akero, EFX, and the SYMMETRY trial;

3 (c) whether defendants acted with scienter; and

4 (d) to what extent the members of the Class have sustained damages and the
5 proper measure of damages.

6 85. A class action is superior to all other available methods for the fair and efficient
7 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the
8 damages suffered by individual Class members may be relatively small, the expense and burden of
9 individual litigation make it impossible for members of the Class to individually redress the wrongs
10 done to them. There will be no difficulty in the management of this action as a class action.

11 **COUNT I**

12 **For Violation of §10(b) of the Exchange Act and SEC Rule 10b-5** 13 **Against All Defendants**

14 86. Plaintiff incorporates ¶¶1-85 by reference.

15 87. During the Class Period, defendants disseminated or approved the statements
16 specified above, which they knew or deliberately disregarded were false and misleading in that they
17 contained misrepresentations and failed to disclose material facts necessary in order to make the
18 statements made, in light of the circumstances under which they were made, not misleading.

19 88. Defendants violated §10(b) of the Exchange Act and SEC Rule 10b-5 in that they:

20 (a) employed devices, schemes, and artifices to defraud;

21 (b) made untrue statements of material fact or omitted to state material facts
22 necessary in order to make the statements made, in light of the circumstances under which they were
23 made, not misleading; or

24 (c) engaged in acts, practices, and a course of business that operated as a fraud or
25 deceit upon plaintiff and others similarly situated in connection with their purchases of Akero stock
26 during the Class Period.

27 89. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of
28 the market, they paid artificially inflated prices for Akero stock. Plaintiff and the Class would not

1 have purchased Akero stock at the prices they paid, or at all, if they had been aware that the market
2 prices had been artificially and falsely inflated by defendants' false and misleading statements and
3 fraudulent scheme.

4 **COUNT II**

5 **For Violation of §20(a) of the Exchange Act**
6 **Against All Defendants**

7 90. Plaintiff incorporates ¶¶1-89 by reference.

8 91. Defendants acted as controlling persons of Akero within the meaning of §20(a) of the
9 Exchange Act. By reason of their positions with Akero and/or ownership of Akero stock, the
10 Individual Defendants had the power and authority to cause Akero to engage in the wrongful
11 conduct complained of herein. Akero controlled the Individual Defendants and all of its employees.
12 By reason of such conduct, defendants are liable pursuant to §20(a) of the Exchange Act.

13 **PRAYER FOR RELIEF**

14 WHEREFORE, plaintiff prays for relief and judgment, as follows:

15 A. Determining that this action is a proper class action, designating plaintiff as Lead
16 Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil
17 Procedure and plaintiff's counsel as Lead Counsel;

18 B. Awarding compensatory damages in favor of plaintiff and the other Class members
19 against all defendants, jointly and severally, for all damages sustained as a result of defendants'
20 wrongdoing, in an amount to be proven at trial, including interest thereon;

21 C. Awarding plaintiff and the Class their reasonable costs and expenses incurred in this
22 action, including counsel fees and expert fees; and

23 D. Awarding such equitable, injunctive, or other relief as deemed appropriate by the
24 Court.

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JURY DEMAND

Plaintiff demands a trial by jury.

DATED:
