UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOSEPH KLOBUS, ET AL.,

Plaintiffs,

v.

AKERO THERAPEUTICS, INC., ET AL.,

Defendants.

Case No.: 4:24-CV-02534-YGR

ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND

Re: Dkt. Nos. 39, 40.

Plaintiffs bring this action under federal securities law against defendant Akero Therapeutics, Inc. ("Akero") and three individual defendants: Akero's President and Chief Executive Officer ("CEO") Andrew Cheng, Akero's Chief Development Officer ("CDO") Catriona Yale, and Akero's Chief Financial Officer ("CFO") William White. Plaintiffs allege defendants misled investors about the design of key clinical trials conducted in the process of bringing to market Akero's only asset, a drug called EFX.

Having carefully considered the papers submitted and the pleadings in this action, and for the reasons set forth below, the Court hereby **GRANTS** the motion to dismiss with leave to amend.

I. INTRODUCTION

A. Plaintiffs' Amended Class Action Complaint (Dkt. No. 37, "ACC")

The ACC alleges as follows:

1. Treatment and Study of NASH

Nonalcoholic steatohepatitis ("NASH") is a form of nonalcoholic fatty liver disease.[1] People suffering from NASH face the prospect of "excessive accumulation of fat in the liver that

[1] The scientific literature changed the nomenclature after the class period to refer to the disease as metabolic dysfunction-associated steatohepatitis, or MASH. For the sake of clarity all parties use the prior name, NASH. The Court does so as well.

causes stress and injury to liver cells, leading to inflammation and fibrosis (mild scarring) that can progress to cirrhosis (severe scarring), liver failure, cancer, and death." (ACC ¶ 20.) One of every five NASH patients will "progress to cirrhosis," a condition expected to be fatal within five years for half of patients who do not receive a liver transplant. (*Id.*) At no time through the class period had the Federal Drug Administration ("FDA") approved drug treatment for NASH. (*Id.* ¶ 21.) Thus, defendants' ability to be the first to secure approval for such a drug represented a lucrative business opportunity.

Akero sought to take advantage of this opportunity with its only asset, EFX.[2] FDA approval requires several rounds of drug trials designed to test a new drug's efficacy and safety: Phase 1 trials aim to identify a drug's possible side effects. Phase 2 trials confirm effectiveness and study safety. Phase 3 trials "monitor side effects, compare [the drug] with standard or similar treatments (if applicable), and collect information that will allow the new drug to be used safely." (*Id.* ¶ 37.) Relevant to this action is the design of Akero's EFX clinical trials.

In order to understand the allegations surrounding Akero's trial design, some background information on classifying participants is needed. As stated above, NASH can either be cirrhotic or non-cirrhotic. (*See id.* ¶ 20.) Cirrhosis itself is further subdivided into two relevant sub-categories: compensated and decompensated. (*Id.* ¶ 26.) The former is "the asymptomatic stage and corresponds to Child-Pugh score A."[3] (*Id.*) The latter, by contrast, is "characterized by the presence or development of overt complications . . . and corresponds to Child-Pugh score B or C." (*Id.*) Additionally, cirrhosis has many possible causes, of which NASH is just one. The term used to describe cirrhosis of unknown origin is "cryptogenic" cirrhosis. (*Id.* ¶ 27.) Cryptogenic cirrhosis is "more advanced (severe)" than NASH-induced cirrhosis and therefore carries "a different risk profile." (*Id.* ¶ 30.)

---

[2] EFX stands for efruxifermin. (ACC ¶ 3.)

[3] "The Child-Pugh Score is a scoring system used to determine the degree of liver failure present in patients with cirrhosis. Under the Child-Pugh system, the three classes correlate with one- and two-year patient survival: (i) class A: 100% and 85%; (ii) class B: 80% and 60%; and (iii) class C: 45% and 35%." (ACC at 6 n.3.)

Each of these conditions is diagnosed and treated differently. "Cryptogenic cirrhosis is treated differently from NASH cirrhosis by medical experts." (*Id.* ¶ 37.) Notably, one published medical journal article found "clear clinical differences" between the two and posited that the two "should not be considered the same." (*Id.*) Further, in 2019 the FDA provided draft guidance "caution[ing] sponsors of drugs designed to treat compensated NASH cirrhosis against including cryptogenic cirrhosis patients in trials." (*Id.* ¶ 38.) As quoted, the guidance states: "Sponsors should be careful to enroll in clinical trials only patients whose cirrhosis is secondary to (*i.e.* caused by) NASH and not caused by other etiologies. Patients should have histological diagnoses of NASH, and other causes of chronic liver disease should be ruled out." (*Id.*)

As for diagnoses, the ACC avers that the "most reliable diagnosis and staging of NASH is achieved by examining a liver biopsy specimen under a microscope." (*Id.* ¶ 24.) Many patients, however, are unwilling to undergo a liver biopsy due to several factors including: cost, invasiveness of the procedure, lack of available pathologists with NASH experience, and various safety risks.[4] (*Id.*) A less invasive option is a liver elastography through a FibroScan, defined as "a special ultrasound technology that measures liver stiffness (hardness) and fat changes in the liver." (*Id.* ¶ 25.) The FibroScan can be measured on a scale from F0 to F4, with F4 indicating "late-stage scarring or cirrhosis, where the scarring is permanent and the damage is irreversible." (*Id.*)

2. Market Opportunity

When the class period began, there was a "vast market opportunity for any company that could successfully get a NASH drug approved by the FDA." (*Id.* ¶ 31.) Hence, defendants' stated goal was to design a drug that could: 1) reduce fibrosis amongst the F4 population, and 2) ensure no worsening of NASH. At a May 2022 healthcare conference, Yale stated:

> [I]t's about being reimbursed. And so when we think about payers and insurance, the F4 patient population, we believe, will definitely be prioritized in terms of the market and reimbursed appropriately so. [W]hen I look at the design of our trials, we have been very focused on this fibrosis endpoint [i.e. F4]. So there's two FDA acceptable

[4] The ACC states that "liver biopsies have been associated with occasionally causing morbidity (the state of being unhealthy for a particular disease) and, in rare circumstances, mortality." (ACC ¶ 24.)

> histology endpoints for NASH currently. So you can either [aim] for a NASH resolution with no worsening of fibrosis or you could focus on fibrosis improvement, no worsening of NASH. And we are obviously focused on the latter. And the reason really for that is we really believe that that's where the payers are really focused . . . .

(*Id.* ¶ 32.) In order to accomplish this, Akero conducted three common stock offerings to raise the necessary funds to test EFX. Round 1 raised $230 million by selling more than 8.8 million shares at $26 per share in September 2022. Round 2 raised $220 million by selling more than 5.2 million shares at $42 per share in May 2023. Round 3 raised $127 million by selling more than 3 million shares at an average of $42.38 per share in April 2023.[5] This totaled more than $577 million in proceeds.

3. EFX Clinical Trial Design

Defendants allegedly provided misleading descriptions of the EFX clinical trials. The actual details of the trial design appear to be undisputed. Akero conducted three relevant EFX trials: a Phase 1 trial before the class period named the "BALANCED Study" and two Phase 2 trials conducted during the class period named the "HARMONY"[6] and "SYMMETRY" studies.

Akero announced the results of the BALANCED Study in March 2021 which tested patients with cirrhotic NASH. The "reported results did not include any mention of patients with cryptogenic cirrhosis." (*Id.* ¶ 41.) The HARMONY Study tested EFX in 128 biopsy-confirmed NASH patients with fibrosis stage F2 or F3. (*Id.* at 4 n.4.) The HARMONY study lasted 96 weeks, with a readout of data collected after 24 weeks, specifically on September 13, 2022, the beginning date of the purported class period. (*Id.*)

Relevant here is the SYMMETRY study, which was officially called "A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Efruxifermin in Subjects With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis

[5] Plaintiffs describe the April 2023 round as an at the market ("ATM") offer of common stock. (ACC ¶ 36.)

[6] The HARMONY trial was officially titled "A Phase 2b, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety and Efficacy of Efruxifermin in Non-Cirrhotic Subjects With Nonalcoholic Steatohepatitis (NASH)." (ACC at 10 n.4.)

(NASH)." (*Id*. ¶ 43.) Akero personnel publicly stated that optimistic results from the BALANCED study motivated SYMMETRY. (*See, e.g.*, *id*. ¶¶ 47-48.) SYMMETRY tested EFX in 182 patients over 96 weeks and its primary objective was to evaluate "the proportion of patients who achieved ≥1 stage improvement in fibrosis and no worsening of NASH." (*Id*. ¶¶ 43, 45.) A secondary objective was to see if EFX helps improve NASH itself. (*Id*. ¶ 146.)

By design, 80% of SYMMETRY's participants were patients with "biopsy-proven compensated cirrhosis fibrosis Stage 4 due to definitive NASH," and the remaining 20% were patients with cryptogenic cirrhosis. (*Id*. ¶ 158.) This means one of every five SYMMETRY participants had cirrhosis due to a cause technically unknown but presumed to be due to NASH. The study was designed such that any patient with cryptogenic cirrhosis was excluded from calculations towards the secondary objective. (*Id*. ¶ 55.)

Procedurally, clinical trials must be governed by predetermined protocols laying out the "objective(s), design, methodology, statistical considerations, and organization of a trial." (*Id*. ¶ 44.) As the sponsor all three trials, Akero designed all relevant trial protocols in consultation with the FDA. (*Id*. ¶¶ 44, 161)

B. Defendants' Alleged Misrepresentations and Omissions

In summary, plaintiffs allege that defendants collectively misrepresented the design and population of SYMMETRY by stating or creating the impression that the study contained *only* patients with proven NASH-induced cirrhosis contrary to the relevant medical and FDA guidance at the time for clinical trials such as SYMMETRY. This impression directly caused inflation of Akero's stock price. Moreover, plaintiffs assert that defendants knew Akero needed EFX approval to make the company profitable, that doing so required a "cash runway" to fund multiple clinical trials, and that investors would be less likely to purchase Akero stock if they knew SYMMETRY included cryptogenic patients. The day after the class period, defendants disclosed for the first time the inclusion of patients with cryptogenic cirrhosis, causing an immediate and steep drop in Akero's stock.

Plaintiffs allege misstatements and omissions from five different sources.

1. Representations on Akero and government websites (Statements 1, 2, and 3)

The first category of allegedly misleading statements focuses on those published on Akero's own website and on the government website "ClinicalTrials.gov." (*Id.* ¶¶ 85-87.) The ACC states that information published on the latter was provided by Akero and that Akero's own clinical trial website directs investors to the government site.

On its own website, throughout the entire class period, Akero stated: "The Phase 2b SYMMETRY study is a multicenter, randomized, double-blind, placebo-controlled, clinical ***trial in biopsy-confirmed NASH patients*** with compensated cirrhosis (F4), Child-Pugh class A." (*Id.* ¶ 85 (emphasis in original).) Information about SYMMETRY on the government website could be found throughout the class period under the title: "A Study of Efruxifermin ***in Subjects With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH)*** (Symmetry)." (*Id.* ¶ 86 (emphasis in original).) The government site also contained twelve "study record versions" for SYMMETRY, each of which described the trial as "a multi-center evaluation of efruxifermin (EFX) in a randomized, double-blind, placebo-controlled ***study in cirrhotic subjects with biopsy-proven F4 compensated NASH.*** (*Id.* ¶ 87 (emphasis in original).)[7]

2. SEC filings (Statements 14, 15, 16, 17, 18, 19, 24, 25, 26, 27, 28, 29, 37, 38, 39, 40, 41, 42, 43, 44, 53, 54, 55, 56, 57, and 58)

Plaintiffs identify as false or misleading statements made by Akero on four different forms filed with the SEC throughout the class period: Form 8-K, Form 10-Q, Form 10-K, and Form DEF 14A.

Form 8-K: Akero's May 15, 2023 Form 8-K reported financial results for the first quarter of 2023. Defendant Cheng signed this form which stated: "Results from the ***Phase 2b SYMMETRY study, evaluating treatment of patients with compensated cirrhosis due to NASH***, on track to be reported in the fourth quarter of this year." (*Id.* ¶ 129 (emphasis in original).)

Form 10-Qs: Akero reported quarterly financials on its Form 10-Q, signed by Cheng and White. Three such forms are purported to contain false or misleading statements: the 10-Q for the

[7] Only two of these are dated during the class period. (ACC at 25 n.9.)

third quarter of 2022 and first and second quarters of 2023. The 10-Qs included similar language, touting SYMMETRY participants as: having "biopsy-confirmed NASH," "patients with cirrhotic NASH," and "patients with NASH who have cirrhosis (F4 fibrosis, compensated." (*Id*. ¶¶ 102-03.) Additionally, the 10-Q described the "***inherent difficulties in diagnosing NASH***," telling investors that Akero possibly faced more risk than its competitors because it was "***enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study.***" (*Id*. 103 (emphasis in original).)

The ACC states that the Q1 10-Q for 2023 incorporated by reference the statements made in the 2022 10-K form and 2023 ATM prospectus quoted below, and that the Q2 10-Q for 2023 incorporated by reference all statements made in the Q1 2023 form as well as those made in the May 2023 prospectus described below. (*Id*. ¶¶ 130-31, 141.)

Form 10-K: Akero's 2022 Form 10-K, signed by Cheng and White, made many of the same representations, including describing SYMMETRY participants as: "patients with NASH who have cirrhosis," "patients with biopsy-confirmed NASH," "patients with cirrhotic NASH," and "patients with cirrhosis due to NASH." (*Id*. ¶¶ 115-20.)

Form DEF 14A: Lastly, Akero's proxy statement on Form DEF 14A listed a 2022 performance goal of "[e]nrollment of over 85% of our target enrollment for the Phase 2b SYMMETRY study in patients with ***cirrhosis due to NASH*** (F4, compensated)." (*Id*. ¶ 128. (emphasis in original).) Plaintiffs note that not only did the form make no mention of enrolling patients with cryptogenic cirrhosis, but that Akero's compensation committee determined in December 2022 that the company had met its performance goals, and awarded the three named defendants six-figure bonuses. (*Id*.)

3. Press releases (Statements 4, 5, 20, 21, 36)

Akero press releases stated the same, describing the study participants as "biopsy-confirmed NASH patients with compensated cirrhosis," "patients with cirrhotic NASH," "patients with

compensated cirrhosis (F4) due to NASH,"[8] and "biopsy-confirmed NASH patients." (*Id.* ¶¶ 88, 108, 110, 125.)

This was true for two December 2022 press releases announcing SYMMETRY and the completion of patient enrollment therefor, describing the study the same way. (*See id.* ¶¶ 108, 110.) Akero then released one more such press release quoting Yale as saying the same in March 2023. (*See id.* ¶ 125.)

4. Investor and conference presentations and investor phone calls (Statements 6, 7, 22, 23, 51, 52, 59)

Akero held a call for investors on September 13, 2022 to present the latest data from HARMONY and offer SYMMETRY updates. Here, Cheng and Yale both referred to SYMMETRY participants as "patients with cirrhotic NASH," and Yale stated further that SYMMETRY would be similar to the HARMONY study in that it would include "chronic NASH patients." (*Id.* ¶ 89.)

Then, at a January 10, 2023 healthcare conference, Cheng delivered a presentation. One slide listed "F4 NASH" as the sole "key inclusion criteria" for participating in SYMMETRY. (*Id.* ¶ 113.) Furthermore, Cheng likened SYMMETRY to HARMONY and explained it thusly: "I do want to remind everyone, this may look similar, but this is – like HARMONY, it's a randomized, double-blind, placebo-controlled trial. ***SYMMETRY only [involves] patients with biopsy-proven NASH, F4***." (*Id.* ¶ 112 (emphasis in original).)

Defendants further presented an update to investors on SYMMETRY's progress on June 5, 2023. All named defendants participated, but specific statements here are attributed to Yale ("patients with biopsy-confirmed NASH" and "patients with cirrhosis due to NASH") and Cheng ("patients with compensated cirrhosis due to NASH"). (*Id.* ¶ 138.)

At another conference closer to the end of the class period, Cheng similarly told investors the trial was "straightforward" and participants were "patients with biopsy-confirmed NASH. That is that they have F4 NASH, they're cirrhotic . . . ." (*Id.* ¶ 146.)

[8] For this particular statement the ACC identifies Yale as the specific speaker. All other press release statements are attributed collectively to all defendants.

5. Prospectuses (Statements 8, 9, 10, 11, 12, 13, 30, 31, 32, 33, 34, 35, 45, 46, 47, 48, 49, 50)

The last major category of statements are the prospectuses for SYMMETRY. Plaintiffs describe these as offered "to raise substantial operating funds for Akero." (*Id*. ¶ 57.) Each fundraising round was accompanied by its own prospectus and plaintiffs aver each of the three contained various formulations of the statements alleged above, all implying or stating outright that only NASH-confirmed patients were selected for SYMMETRY, and making no mention of cryptogenic cirrhotic patients. (*See id*. ¶¶ 95-100, 121, 134-135.)

C. Defendants' Disclosure

Akero announced SYMMETRY results on October 10, 2023 in a new 8-K and an investor call. The results were disappointing. The press release attached to the 8-K "attempted to gloss over the fact that the SYMMETRY study had failed to meet its primary endpoint (as the results were not statistically significant)." (*Id*. ¶ 155.)[9] Akero allegedly buried several crucial disclosures within its October 10 statements.

First, because SYMMETRY fared better with regard to its secondary objective than it did with regard to the first, Akero's announced result listed 11 more patients as being part of the placebo group for the first objective compared to the second.[10] According to plaintiffs, "[t]his 11-patient discrepancy in the placebo arm stems from Akero's exclusion of cryptogenic patients when calculating NASH resolution . . . ." (*Id*. ¶ 157.) As support, a footnote in the release stated: "Source Data: ***Liver Biopsy Analysis Set (fibrosis improvement); Liver Biopsy Analysis Set (definitive NASH only) (resolution of NASH*** and combined endpoint)." (*Id*. (emphasis supplied).) This footnote allegedly represents the first time Akero publicly acknowledged that patients with *definitive* NASH did not represent 100% of SYMMETRY participants.

[9] The ACC quotes the 8-K as stating specifically: "A trend was observed for the primary endpoint of fibrosis improvement at 36 weeks, with 22% and 24% of the 28mg and 50mg EFX-treated groups, respectively, experiencing at least a one-stage improvement in liver fibrosis and no worsening of NASH, compared with 14% for placebo." (ACC ¶ 155.)

[10] Recall that the primary objective concerned improvement in fibrosis and no worsening of NASH, and the second concerned NASH resolution.

Second, defendants publicly revealed the inclusion of cryptogenic patients in the investor call. In prepared remarks, Yale stated:

> The SYMMETRY study is a Phase IIb randomized, double-blind, placebo-controlled, multicenter dose-ranging trial. ***All patients had*** biopsy-proven compensated cirrhosis fibrosis Stage 4 due to definitive NASH ***or cryptogenic cirrhosis, presumed secondary to NASH***. ***Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population.*** This study enrolled patients with advanced liver disease, ***including patients with either cryptogenic cirrhosis or definitive NASH. The analysis set for NASH resolution endpoints excluded those with cryptogenic cirrhosis who didn't meet definitive NASH at baseline.***

(*Id*. ¶ 158 (emphasis in original).) Defendants' investor presentation also referenced a slide deck previously shown to investors but which contained two key changes. Whereas during the class period, the SYMMETRY "Key Inclusion Criteria" slide had only listed "F4 NASH," the October 10, 2023 version added both "T2D or 2 or 4 components of metabolic syndrome" as another. It also contained a footnote expressly stating that SYMMETRY included cryptogenic patients. Finally, during the question-and-answer portion of the presentation, Cheng and Yale fielded questions from investors who expressed surprise at the new revelations.

> **J.P. Morgan Analyst**: 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 – are there any measures that could be tak[en] in a Phase III program to sort of reduce their participation and perhaps get a clearer signal?
>
> **Cheng**: In terms of cryptogenic cirrhosis, I think these patients represent a part of the cirrhotic spectrum . . . and I think we've – and in consultation with the FDA, have chosen to limit the patients to about 20% of the population. . . . And I think [removing cryptogenic patients is] something we may consider to do. But of course, that's pending discussions with the agency, which we haven't had.
>
> **Evercore Analyst**: [W]as it prespecified to take out the cryptogenic NASH patients?
>
> **Yale**: Yes, that was all prespecified . . . .

(*Id*. ¶¶ 160-62.)

D. Stock Price Collapse

Immediately after the disclosures, Akero's stock price precipitously dropped.

> Following these disclosures, the price of Akero stock declined 62.6% from a close of $48.54 on October 9, 2023, to a close of $18.15 on October 10, 2023, on 31.9 million shares traded, up from just 631,600 shares traded on October 9, 2023. The stock price fell another 17% on October 11, 2023, to a close of $15.04 on 10.29 million shares traded on October 11, 2023. . . . In the days that immediately followed, analysts cut their price targets on Akero stock, with Morgan Stanley cutting its price target from $70 per share to $33 per share, Cantor Fitzgerald cutting its price target from $69 per share to $39 per share, H.C. Wainwright cutting its price target from $64 per share to $40 per share, J.P. Morgan cutting its price target from $62 per share to $41 per share, Evercore cutting its price target from $60 per share to $36 per share, and UBS cutting its price target from $83 per share to $39 per share.

(*Id*. ¶¶78, 81.)

The ACC offers examples of statements from various analysts and investors tying their decision to cut price targets on Akero to the alleged failure to disclose the material information about cryptogenic patients.

On October 10, 2023, after the publication of the 8-K, but before the investor call, Cantor Fitzgerald stated that despite the disappointing results it remained "bullish" on Akero because it was "positive on the upcoming readout in the F4 NASH population (NASH patients that have compensated cirrhosis)." After the call and on the same day, Cantor Fitzgerald updated its statement:

> **Cryptogenic NASH population vs. Definitive NASH:**
>
> • What's the ***controversy***: SYMMETRY trial included ~15-25% of patients with cryptogenic NASH (rest were definitive NASH), ***which was a surprise to us and most investors***. Cryptogenic NASH patients are more advanced, but don't satisfy typical NASH trial criteria (they score 0 on steatosis).
>
> • These patients were included in the primary endpoint but excluded from NASH resolution as ***they don't have definitive NASH***.
>
> • Treatment effect for EFX is little worse in cryptogenic NASH relative to definitive NASH, which we think ***may have negatively affected trial results as a few percentage points of efficacy benefit in EFX favor would have led to statistical significance.***

> • **Cantor insight**: The baseline liver stiffness by VCTE in the Phase 2B SYMMETRY trial at ~24-25 looks more severe than 20-22 in other F4 trials, ***which may have been driven by cryptogenic NASH patients***.

(*Id*. (emphasis in original).) Similarly, H.C. Wainwright & Co. released the following statement on October 11, 2023:

> ***Here's what we disliked or confused us about*** **SYMMETRY.** ***Why cryptogenic cirrhotics? Why did the study entry criteria not exclude anyone but definitive NASH cirrhotics*** (NAS ≥ 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 needlessly introduces confounding risk, and may have played a part in missing the primary endpoint, in our view.***

(*Id*. ¶ 166 (emphasis in original).)[11]

[11] Defendants request that the Court take judicial notice of or incorporate nine documents. Seven are documents relied on throughout the ACC: a medical journal article and FDA guidance, three investor reports, one investor presentation, and defendants' own Form 8-K. The remaining two are a medical journal article and a November 2024 Akero press release not mentioned in the ACC. (Dkt. No. 40.) Plaintiffs largely oppose these requests.

"In ruling on a [Rule] 12(b)(6) motion, a court may generally consider only allegations [i] contained in the pleadings, [ii] exhibits attached to the complaint, and [iii] matters properly subject to judicial notice." *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). With respect to the first, the doctrine of incorporation by reference "treats certain documents as though they are part of the complaint itself" and may therefore be considered on a motion to dismiss. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002 (9th Cir. 2018). To qualify, plaintiff must "refer[] extensively to the document" in the complaint "or the document [must] form[] the basis of the plaintiff's claim." *Id.* (citation and quotations omitted). Once deemed incorporated by reference, "the entire document is assumed to be true for purposes of [the] motion to dismiss . . . ." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.6 (9th Cir. 2014) (quotation and citation omitted).

Separately, a court may take judicial notice of facts "not subject to reasonable dispute" because they are either "(1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. A court may take judicial notice of a published article proffered "to indicate what was in the public realm at the time" and not for its truth. *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010) (cleaned up).

For this reason, the Court will consider defendants' exhibits 1, 2, 4, 5, 6, 7, and 8 to be incorporated by reference and the request is **GRANTED** as to those documents. The request to take judicial notice of exhibits 3 and 9 is further **GRANTED** for limited purposes: in the case of exhibit 3, in order to note information of which the market was aware during the class period; and in the case of exhibit 9, for the limited purpose of acknowledging the fact that the press release was issued.

E. Procedural History

Plaintiffs filed a complaint on April 26, 2024, which they amended on September 24, 2024. The class action complaint names the class period as September 13, 2022 (the day defendants reported the 24-week HARMONY readout of trial results) through October 9, 2023 (the day before defendants disclosed the information which allegedly caused the stock price to drop). (*Id.* ¶ 2.) The putative class is defined as "all purchasers or acquirers of the common stock of Akero during the Class Period." (*Id.* ¶ 185.)

Plaintiffs bring two claims, both against all defendants: a claim for violation of Section 10(b) of the Exchange Act and Rule 10(b)-5 promulgated thereunder, and a claim for violation of Section 20(a) of the Exchange Act. Defendants move to dismiss both.

II. LEGAL FRAMEWORK

To withstand a motion to dismiss for failure to state a claim under Rule 12(b)(6), a plaintiff must allege sufficient details to give the defendants fair notice of the nature of the claim and the grounds upon which it rests. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007).

Rule 9 establishes a heightened pleading standard for allegations of fraud. Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."); *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997) (to be alleged with particularity under Rule 9(b), a plaintiff must allege "the who, what, when, where, and how" of the alleged fraudulent conduct) (internal citations and quotations omitted).

III. VIOLATION OF § 10(B) OF THE SECURITIES AND EXCHANGE ACT AND RULE 10(B)-5 (COUNT 1)

Section 10(b) of the Securities and Exchange Act, 15 U.S.C. § 78j(b), makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b–5 implements this provision by making

it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b).

To state a claim under Section 10b, a plaintiff must "show that the defendant made a statement which was 'misleading as to a material fact.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988) (emphasis in original). Under the heightened pleading requirement demanded by the Private Securities Litigation Reform Act ("PSLRA"), to state a Section 10(b) claim, plaintiffs must allege facts sufficient to establish: (i) that the defendant made a material misrepresentation or omission of fact; (ii) that the misrepresentation was made with scienter; (iii) a connection between the misrepresentation or omission and the purchase or sale of a security; (iv) reliance on the misrepresentation or omission; (v) loss causation; and (vi) economic loss. *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1061 (9th Cir. 2008). The ACC asserts these claims against all defendants, who challenge the existence of any false or misleading statement, scienter, and loss causation.

A. False or Misleading Statements

1. Statements of Opinion

Defendants first argue that all statements on which the claims rest are opinions, and that plaintiffs have failed to meet the standard for showing that statements of opinion are false or misleading.

In *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, the Supreme Court offered guidance on how to distinguish between statements of fact and opinion. 575 U.S. 175 (2015).

> A fact is "a thing done or existing" or "[a]n actual happening." Webster's New International Dictionary 782 (1927). An opinion is "a belief[,] a view," or a "sentiment which the mind forms of persons or things." *Id.*, at 1509. Most important, a statement of fact ("the coffee is hot") expresses certainty about a thing, whereas a statement of opinion ("I think the coffee is hot") does not. See *ibid.* ("An opinion, in ordinary usage . . . does not imply . . . definiteness . . . or certainty"); 7 Oxford English Dictionary 151 (1933) (an opinion "rests[s] on grounds insufficient for complete demonstration").

Id. at 183.[12] Defendants urge that every statement alleged to be false or misleading is an opinion because diagnosing cirrhotic NASH is a "judgment call" that requires "subjective and uncertain assessments of clinical data." (*See* Dkt. No. 39, Defendants' Motion to Dismiss Amended Complaint ("Mtn.") at 9 (internal cites omitted).) The Court disagrees. That the process of diagnosis involves some judgment calls does not automatically render every diagnostic statement an opinion, especially where the speaker expresses certainty about the diagnosis. Several statements here expressed concrete conclusions about patients' statuses.

Consider, for instance, the unreasonableness of calling Statement 57 an opinion: "The . . . SYMMETRY main study is . . .[a] clinical trial in biopsy-*confirmed* NASH patients with compensated cirrhosis . . . ." (Dkt. No. 38, Chart of False and Misleading Statements ("Statement Chart") at Statement 57 (emphasis supplied).) In addition to defendants' phrasing of certain statements like this one as factual conclusions, plaintiffs allege it is possible to conclusively determine when cirrhosis has been caused by NASH. (*See, e.g.*, ACC ¶ 24.) Defendants' argument that the nature of a diagnostic statement in this context is inherently opinion-based thus rests on a factual determination the Court cannot resolve at this stage. Thus, the claim that the statements are opinions solely because they purported to offer a NASH diagnosis fails.

Defendants' cited cases to the contrary do not compel otherwise. When reviewed, those cases concern statements regarding how defendants *felt* about clinical data, a far cry from the definitive diagnosis defendants here purported to offer. *See Strezsak v. Ardelyx, Inc.*, 2024 WL 1160900, at *5 (N.D. Cal. 2024) (statements that interactions with the FDA "hav[e] gone exceedingly well" and that trials were "successful" were opinions); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (statement that the results of a Phase 2 study "justified" the initiation of a Phase 3 study was an opinion); *Markette v. XOMA Corp.*, 2017 WL 4310759, at *4 (N.D. Cal. 2017) (statements that defendants were "hopeful" and found results "encouraging" were opinions); *Pardi v. Tricida, Inc.*, 2024 WL 1056013, at *6-7 (N.D. Cal. 2024)

[12] *Omnicare* considered the pleading standard for opinions in the context of Section 11 of the Securities and Exchange Act, but the Ninth Circuit adopted the opinion's reasoning in the Section 10 context in *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. V. Align Tech., Inc.* 856 F.3d 605, 616 (9th Cir. 2017).

(statements expressing defendants' optimism about trial results, many of which started with the phrase "we believe," were opinions). *Omnicare* thus dictates that statements purporting to definitively state SYMMETRY participants had NASH are to be treated categorically differently from these true opinions.

That said, the Court finds some other statements do reflect defendants' opinions about the trial or SYMMETRY data and therefore qualify as opinions. One such statement is repeated seven times throughout the statement chart because it appeared in the relevant prospectuses:

> Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with [NASH] [and] significant competition for recruiting such patients in clinical trials. . . . Identifying and qualifying patients to participate in clinical trials is critical to our success. We may be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study. . . . In particular, as a result of the inherent difficulties in diagnosing NASH and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all.

(Statement Chart, Statements 13, 19, 29, 35, 44, 50, 58.)[13]

This statement is an opinion. It told investors that enrolling participants "*could be made more difficult*" by any of several factors including "difficulties in identifying patients" with NASH. (*See, e.g.*, Statement Chart, Statement 13.) Inherent uncertainty accompanies these statements; a listener is put on notice as to the fact that any of several factors may or may not present a difficulty in enrolling participants. Thus, *Omnicare* applies.

So, too, with the following three statements, which expressed an opinion about the data or trial design.

- "On the more immediate horizon, we are encouraged by the strength of our [HARMONY] histology results and what they mean for our ongoing Phase 2b SYMMETRY study in patients with cirrhotic NASH. Based on today's results, we believe EFX has the potential to be the first investigational NASH drug to achieve statistically significant histological improvement in patients with cirrhotic NASH." (Statement 7.)

[13] Statements 13 and 19 only contain the first half of the above.

- "Identifying and qualifying patients to participate in clinical trials is critical to our success. We may encounter delays in enrolling or be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study . . . . In particular, as a result of the inherent difficulties in diagnosing NASH and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study and subsequent clinical trials." (Statements 12, 18.)

- "So this trial is a very straightforward Phase IIb trial. It's 182 patients, randomized 1:1:1 to placebo 28 milligrams, of efruxifermin of 50 milligrams. These are patients with biopsy-confirmed NASH. That is that they have F4 NASH, they're cirrhotic and they're Child-Pugh Class A. These patients, also known as compensated 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." (Statement 59.)

Each of these conveyed defendants' subjective beliefs: in the case of the first statement, that they felt encouraged by the HARMONY data and EFX's potential; in the case of the second, that certain factors present difficulties in administering a clinical trial; and in the case of the third, that the trial was "straightforward." Any facts offered were in support thereof, and therefore the Court finds *Omnicare* applies to Statements 7, 12, 13, 18, 19, 29, 35, 44, 50, 58, and 59.

The Court must therefore apply the pleading standards for opinions enumerated in *Omnicare* to these statements. Three such standards apply:

> First, when a plaintiff relies on a theory of material misrepresentation, the plaintiff must allege both that the speaker did not hold the belief she professed and that the belief is objectively untrue. Second, when a plaintiff relies on a theory that a statement of fact contained within an opinion statement is materially misleading, the plaintiff must allege that the supporting fact [the speaker] supplied [is] untrue. Third, when a plaintiff relies on a theory of omission, the plaintiff must allege facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.

City of Dearborn Heights, 856 F.3d at 615-16 (cleaned up).

Plaintiffs argue they meet all of these pleading requirements. (*See* Dkt. No. 42, Lead Plaintiffs' Opposition to Defendants' Motion to Dismiss Amended Class Action Complaint

("Oppo.") at 12 ("But even if opinions, Defendants' misrepresentations are actionable under *Omnicare* because they omitted material information that contradicted their statements, formed the basis of their statements, and or/contained embedded facts.").)

As to the first statement identified above concerning trial difficulties, plaintiffs fail to show defendants did not hold this belief or that it was objectively false. Indeed, the ACC itself describes the myriad challenges that accompany a NASH diagnosis. (*See* ACC ¶¶ 24-25.) Though the ACC does not say so explicitly, the most obvious inference is that these very complications are the reason why Akero chose to enroll cryptogenic patients in SYMMETRY. Nor does the Court find any embedded fact within this statement: in its entirety, the statement apprises a listener about possible hurdles to completing the trial on time. There is also no omission that renders the statement misleading. Even when read holistically, the fact that SYMMETRY used cryptogenic participants does not render the statement untrue: in all likelihood, it *was* difficult to find patients with confirmed NASH in order to timely complete SYMMETRY. 80% of the participants had confirmed NASH, a fact that presented the challenges of which defendants spoke. As a result, the Court finds statements 13, 19, 29, 35, 44, 50, 58 to be unactionable.

The next three statements, by contrast, each contain embedded facts. Statement 7 described SYMMETRY as a "study in patients with cirrhotic NASH," Statements 12 and 18 stated defendants "enroll[ed] only patients with a biopsy-confirmed diagnosis of NASH" in SYMMETRY, and Statement 59 stated forthrightly: "These are patients with biopsy-confirmed NASH. That is that they have F4 NASH . . . ." The Court must therefore determine if plaintiffs have alleged a supporting fact that is untrue.[14] *See Omnicare*, 575 U.S. at 176.

For the two primary reasons set forth below, the Court finds plaintiffs have plausibly alleged the statement's objective falsity.

One, the ACC alleges that in order to determine eligibility for SYMMETRY, "Akero first needed to *confirm* that the patient suffered from NASH," that "[w]hen the cause of a patient's

[14] In a brief footnote, defendants state: "The [ACC] does not allege a plausible embedded fact argument under Omnicare's second prong because Plaintiffs challenge only Akero's judgment call regarding patient classification." (Mtn. at 11 n.3.) The Court disagrees, for the reason explained above. When phrased conclusively, diagnostic statements are analyzed as facts.

cirrhosis is *unknown*, the condition it is referred to as 'cryptogenic' cirrhosis – i.e., cirrhosis 'of *obscure* or *unknown* origin,'" and that the relevant medical community and the FDA considered NASH and cryptogenic cirrhosis to be distinct conditions. (ACC ¶¶ 23, 27-29 (emphasis supplied).) It follows, then, that including cryptogenic patients, whose cirrhosis is of an unknown origin, in a study touted as exclusively for patients suffering from NASH, involved objectively false statements.

Two, the plausibility of the allegations is corroborated by the documents referenced in the ACC and incorporated by the Court. The medical journal article cited in the ACC itself states: "We hypothesized that cryptogenic cirrhosis is a distinct condition from cirrhosis caused by non-alcoholic steatohepatitis (NASH). By comparing cryptogenic cirrhosis with cirrhosis of other causes, we found clear clinical differences. Therefore, cryptogenic cirrhosis should not be considered the same as NASH cirrhosis." (*Id.* ¶ 28 (quoting Dkt. No. 39-2; Mtn., Ex. 1, at 1).) Defendants argue that the study authors' assertion that "[f]urther investigations are required to identify unknown causes of cirrhosis" renders implausible the assertion that the two conditions are distinct. (*See* Mtn. at 13.) Stating that more research is needed does not fundamentally alter the study's baseline conclusion that cirrhosis caused by NASH and cryptogenic cirrhosis are distinct conditions. Defendants also assert that the study "is in accord with the prevailing view in the scientific community" that "[w]here a sponsor can rule out other potential causes of cirrhosis, and metabolic risk factors are present, patients with cryptogenic cirrhosis can be reasonably presumed to have cirrhosis due to NASH." (*Id.*) The incorporated article and the FDA guidance say no such thing. The study, whose firm conclusion was that the two conditions are and ought to be treated as distinct, noted that "[m]any physicians use [the terms] in a synonymous fashion," but that "this may not be justified." (Dkt. No. 39-2; Mtn., Ex. 1, at 6-7.) That many physicians have a particular practice does not by itself render implausible a factual assertion to the contrary. Similarly, the 2019 FDA draft guidance states: "Sponsors should be careful to enroll in clinical trials only patients whose cirrhosis is secondary to NASH and not caused by other etiologies. Patients should have histological diagnoses of NASH, and other causes of chronic liver disease should be ruled out." (ACC ¶ 29 (quoting Dkt. No. 39-3; Mtn., Ex. 2, at 2).) Nothing in this statement implies the

scientific accuracy of including cryptogenic patients for whom the cause of cirrhosis is unknown within a broader NASH-induced cirrhosis category of patients. In fact, the statement lends itself to the opposite conclusion: that studies designed to treat compensated NASH patients should do their best to enroll *only* those with confirmed NASH.

The Court notes that at this stage, it makes no factual finding on the medical issue animating the dispute. Ultimately, discovery may reveal that defendants' theory of the science at play is correct. The ACC, however, adequately and plausibly alleges an alternative theory and plaintiffs are entitled to have its validity assumed at this juncture.

Defendants do not persuade otherwise. First, defendants argue that the ACC "pleads no facts showing that patients with cryptogenic cirrhotic NASH cannot be considered to have 'NASH cirrhosis,'" and argue statements otherwise are "just Plaintiffs' opinion." (Mtn. at 12.) A holistic reading of the ACC finds the opposite: the medical journal and the draft FDA guidance suggest the two conditions are medically distinct and that clinical trials should treat them as such. Furthermore, the reaction of the investor community to Akero's October 11, 2023 announcement allows for the reasonable inference that investors did not understand Akero to be using an "umbrella term" when describing biopsy-proven or biopsy-confirmed NASH. Finally, as a matter of semantics, even if NASH alone could be considered an umbrella term, adding the modifier "proven" or "confirmed" would conclusively signal to a listener that cryptogenic patients, who by definition can at most be *presumed* to have NASH, fall into a distinct category.[15]

Second, defendants note that the October 10, 2023 investor report mentioned in the ACC "explained that SYMMETRY included two subgroup populations under the umbrella NASH

[15] At argument on the motion, counsel for defendants asserted that because all SYMMETRY participants did in fact have NASH, the terms "biopsy-proven" and "biopsy-confirmed" refer to the *means* of diagnosing the condition, rather than the guarantee patients had the condition in the first place. In other words, defendants assert that these statements indicate the thing being "proven" and "confirmed" is that all patients had a biopsy. Defendants are entitled to present this interpretation to a jury. Plaintiffs, for their part, have alleged facts supporting their interpretation that the statements meant participants' NASH diagnosis had been proven, including: the reactions of the investor community in October 2023, the stark difference in phrasing employed by defendants during versus after the class period, and the understanding of at least some in the scientific community that cryptogenic patients are *not* considered to have NASH.

cirrhotics," which "only underscores that NASH cirrhosis is an umbrella term under which patients with cryptogenic cirrhotic NASH fit." (Mtn. at 12.) In reality, the report describes the revelation that SYMMETRY included cryptogenic patients as a "controversy" and a "surprise to us and most investors" and noted that "[c]ryptogenic NASH patients are more advanced but don't satisfy typical NASH criteria." (Dkt. No. 39-6; Mtn., Ex. 5, at 1.) Despite the use of the term "cryptogenic NASH patients," the document in its totality supports the inference that the conditions were considered distinct by the investor community. Plaintiffs thus adequately plead their theory that the phrase "we are enrolling only patients with a biopsy-confirmed diagnosis of NASH" excludes cryptogenic patients who, by definition, have not had a NASH diagnosis confirmed.

Because plaintiffs have demonstrated that upon a holistic reading of the complaint it is plausible the embedded statements identified above were objectively false, the Court finds Statements 7, 12, 18, and 59 are adequately alleged to be false or misleading.[16]

2. Statements of Fact

For the same reasons identified above, the remaining statements, those of fact, are similarly alleged to be false or misleading. Defendants' own motion acknowledges that where a speaker "affirmatively create(s) an impression of a state of affairs that differs in a material way from the one that actually exists" liability may attach. (Mtn. at 15 (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).) As explained above, just such a dynamic is pled here. Defendants allegedly led investors to believe that all SYMMETRY participants had been diagnosed with NASH when, in fact, some were only presumed to have NASH.

Defendants' argument that "Akero did *not* tell investors that it would include only patients with 'definitive' NASH cirrhosis" demands too much of plaintiffs at the pleading stage. (*See* Mtn. at 15 (emphasis in original).) Plaintiffs' task is to allege defendants "directly contradict[ed] what

[16] Even were the Court to construe these statements under *Omnicare*'s third prong, as omitting a material fact, the analysis above would lead to the same conclusion. Plaintiffs identify "facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *See City of Dearborn Heights*, 856 F.3d at 616. In this case, plaintiffs allege that cryptogenic patients were included in SYMMETRY, and that this omission was misleading to a reasonable person hearing it for the same reasons described above.

[they] knew at that time or omit[ted] material information." *Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 764 (9th Cir. 2023) (internal cites omitted). Plaintiffs need not show, as defendants appear to imply, that defendants formulated the false statement in the most direct, precise, or dishonest manner imaginable.

For the same reasons identified above with regard to embedded facts within statements of opinion, the Court finds the remaining statements are adequately alleged to have been false or misleading.

***

In sum, the Court finds that all statements are adequately alleged to be false and misleading other than Statements 13, 19, 29, 35, 44, 50, 58, which the Court finds do not form the basis of a claim.

B. Scienter

To plead scienter adequately, the complaint must "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A) (emphasis supplied). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking gun' genre, or even the 'most plausible of competing inferences.'" *Tellabs Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007) (citation omitted). Rather, a complaint survives if, when "the allegations are accepted as true and taken collectively . . . a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Id.* at 326. In determining whether this requirement is met, the Court must view the allegations as a whole and determine whether plaintiff has raised an inference of scienter that is "cogent and compelling, thus strong in light of other explanations," to satisfy the PSLRA standard. *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) (quoting *Tellabs*, 551 U.S. at 324). When assessing the allegations holistically, the Court views circumstances that are probative of scienter with a practical and common-sense perspective. *Id.*

The PSLRA also demands "particular allegations which strongly imply Defendants' *contemporaneous* knowledge that the statement was false when made." *Berson v. App. Signal Tech., Inc.*, 527 F.3d 982, 989 (9th Cir. 2008) (emphasis in original). A strong inference of scienter

"must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314. The inference must be that the defendant "made false or misleading statements either *intentionally* or with *deliberate recklessness*." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (emphasis supplied) (internal quotation marks omitted). Deliberate recklessness means that the reckless conduct "reflects some degree of intentional or conscious misconduct." *S. Ferry*, 542 F.3d at 782. "[A]n actor is [deliberately] reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) (quoting *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1064 (9th Cir. 2000)). "[F]acts showing mere recklessness or a motive to commit fraud and opportunity to do so [may] provide some reasonable inference of intent," but are not independently sufficient. *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d at 974, abrogated on other grounds by *S. Ferry*, 542 F.3d at 784.

Plaintiffs' overarching theory is that defendants' motive to hide the true SYMMETRY population involved a gamble:

> Defendants had a motive to overstate the degree of certainty involved in diagnosing patients for the SYMMETRY trial – claiming they had biopsy-proven cirrhotic NASH – in order to raise money from investors. . . . For example, H.C. Wainwright reported that the inclusion of cryptogenic cirrhotics in SYMMETRY introduce[d] a previously undisclosed confounding risk. . . . Where, as here, it is knowledge of the undisclosed risk that is the subject of the material fraudulent statement or omission – not knowledge that the trial would surely fail, scienter is pled. . . . The fact that [d]efendants' "gamble" failed – i.e., that they could achieve statistically significant results in a patient population that is more difficult to reliably diagnose and enroll – is no defense.

(Oppo. at 21 (internal cites omitted).) For their part, defendants counter that plaintiffs' theory is "illogical." (Mtn. at 17.) Defendants wonder why they would "dedicate[] immeasurable time and resources to SYMMETRY, knowing all along that the patient population supposedly signaled doom for the trial, and without any insider seeking to capitalize on this purported lie"? (*Id.*)

Plaintiffs respond that defendants mischaracterize the argument. The argument is not that the trial was always doomed to fail, but rather that defendants hoped it would show success and their "bet" would pay off.

The Court understands plaintiffs' point that there is a difference between taking a risk and knowingly promoting a doomed trial. However, defendants' argument is compelling that troubling gaps persist in plaintiffs' logic: defendants always knew they would ultimately have to report SYMMETRY results in a detailed enough fashion to include the trial design. (*See, e.g.*, Mtn. at 17 ("Courts in this Circuit routinely reject the nonsensical theory that a business would intentionally mislead investors, only to inevitably later disclose some withheld truth to the Company's detriment.").) Nor do plaintiffs answer the looming question of why defendants would accurately and honestly report the inclusion of cryptogenic patients when they did –36 weeks into a 96-week trial– as opposed to keeping it a secret throughout the trial period. (*See* Dkt. No. 44, Defendants' Reply in Support of Motion to Dismiss ("Reply") at 8 (". . . Defendants did not need to include this detail to present the interim results and could have revealed the subgroup later.").)

At argument, the Court asked defense counsel why the FDA-approved study design included cryptogenic patients if their presence was not disclosed until the interim results were announced. Defendants responded as follows:

> . . . often filings [with] the FDA contain a lot more detail that is not disclosed to the general public and certainly not disclosed at the beginning of the announcement of a study, so I don't think that is determinative of anything. And that's sort of our point here; that the public statements were talking about this study at one level and just didn't dive down to the next level of breaking it down into subgroups, which [defendants] did do by the way when they released the interim results. Even there, it is a line drawing thing . . . Even there you can say, okay, once I knew about the two subgroups, maybe I, as an investor, would have liked to know the severity of the disease of the patients within each of those subgroups; and somehow that would have been important to my investing decision and breaking it down into the two big subgroups isn't enough for me. I wanted more detail; right. So, now we are just debating about the level of detail they should have told the market about this study. We are not debating about anything false that was said about this study.

(*See* Dkt. No. 55, Transcript of Proceedings on Apr. 15, 2025 at 23:1-19.) The Court finds this to be an explanation of defendants' behavior that leaves fewer questions than the alternative. Plaintiffs have not, in opposition or at argument, contested the general proposition that study readouts often contain more detailed explanations of a trial's design than comments made beforehand.

Furthermore, while not dispositive by itself, plaintiffs present none of the classic indicia of scienter upon which Courts frequently permit claims to survive. The complaint is devoid, for instance, of whistleblowers or confidential informants or allegations of insider trading. (*See id.* at 16:25-17:14 (plaintiffs' counsel confirming that despite investigation, no confidential informants have come forward).) Absent any such indicator, the Court is left to weigh both parties' respective theories of the case and finds plaintiffs have failed to present one that is "at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314.

Finally, defendants posit that the FDA's approval of SYMMETRY is an indicator that defendants genuinely believed their statements throughout the class period were objectively true. Again, while not dispositive by itself, the fact lends support to a holistic analysis in which defendants present the more compelling argument with regard to scienter.[17]

Because of the above, the Court finds plaintiffs' scienter theory insufficiently pled.

C. Loss Causation

Though the Court finds the complaint fails on grounds of scienter, it provides a loss causation analysis nonetheless.

"A complaint sufficiently alleges loss causation when it contains enough fact to raise a reasonable expectation that discovery will reveal evidence of loss causation. . . . [S]o long as the plaintiff alleges facts to support a theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on

[17] Because the Court finds plaintiffs' scienter theory leaves several questions unanswered, it cannot be saved by applying the core operations theory. Plaintiffs argue this case presents the "quintessential rare circumstance" where the theory applies, (Oppo. at 17 (internal cites omitted)), but offer no satisfactory explanation as to why these defendants would mislead investors when: i) the truth would eventually come out anyway, and ii) they then chose to admit their false and misleading statements well before they were obligated to do so. Even where a corporate officer knows of an omitted material statement, the knowledge itself is insufficient to plead an intent to defraud. *See In re Twitter, Inc. Secs. Litig.*, 506 F. Supp. 3d 867, 889 (N.D. Cal. 2020).

evidentiary grounds." *In re. Splunk, Inc. Secs. Litig.*, 592 F. Supp. 3d 919, 950 (N.D. Cal. 2022) (internal cites omitted).

Defendants argue that the October 10, 2023 statements are perfectly "aligned" with all prior statements and that Akero's stock price dropped because the results of the trial were disappointing, not because of any revelation. (Mtn. at 24-25.)

The first argument is simply a repackaged version of defendants' objective falsity arguments. There can only be alignment between the two sets of statements to the extent NASH can be considered an umbrella term. The Court finds as it does above, that plaintiffs have adequately pled objective falsity.

As to the second, defendants' counterargument explaining the drop in stock price is insufficient to defeat the pleadings. At this stage, plaintiffs need only demonstrate facts evidencing a plausible enough theory of loss causation to permit discovery. Given the reaction of investors to the October 10, 2023 statements, plaintiffs' theory is plausible. (*See* ACC ¶¶ 79-81 (describing the inclusion of cryptogenic patients in SYMMETRY as "a surprise to us and most investors" and a "controversy" before immediately dropping Akero's price target).)

The Court thus finds plaintiffs have adequately pled loss causation.

***

Based on the above, the Court **GRANTS** the motion to dismiss Count 1 with leave to amend.

IV. VIOLATION OF SECTION 20(A) OF THE SECURITIES AND EXCHANGE ACT (COUNT 2)

"[U]nder Section 20(a), a defendant may be liable for securities violations if (1) there is a violation of the Act and (2) the defendant directly or indirectly controls any person liable for the violation." *S.E.C. v. Todd*, 642 F.3d 1207, 1223 (9th Cir. 2011) (citations omitted). Moreover:

> Whether [the defendant] is a controlling person is an intensely factual question, involving scrutiny of the defendant's participation in the day-to-day affairs of the corporation and the defendant's power to control corporate actions. . . . [I]ndicia of control include whether the person managed the company on a day-to-day basis and was involved in the formulation of financial statements, which is sufficient to presume control over the transactions giving rise to the alleged securities violation.

Id. (internal cites omitted).

Here, each named defendant is alleged to have been heavily involved in the day-to-day affairs of the company and, in the case of Cheng and White, to have signed financial statements themselves. As CDO, Yale is alleged to have directly overseen the development of the company's only asset. These activities are sufficient to plead control under Section 20(a). However, this claim rises and falls with the first, which the Court found to be insufficiently pled, and the motion to dismiss it is therefore **GRANTED** with leave to amend.

V. CONCLUSION

For the reasons stated above, the Motion to Dismiss the Amended Class Action Complaint is **GRANTED**. Plaintiff may file an amended complaint within twenty-one (21) days of the date of this Order. Plaintiff shall comply with this Court's Standing Order paragraph 13. Defendants shall file their response within 21 days thereafter.

Parties shall not re-assert grounds which have been resolved or which could have been brought in the first instance. *See* Fed. R. Civ. P. 12(g), (h); *Aetna Life Ins. Co. v. Alla Med. Servs., Inc.*, 855 F.2d 1470, 1475 n.2 (9th Cir. 1988) (generally successive Rule 12 motions on different grounds not permitted); *Albany Ins. Co. v. Almacenadora Somex, S.A.*, 5 F.3d 907, 909 (5th Cir. 1993) (same).

This terminates Docket Nos. 39, 40.

IT IS SO ORDERED.

Date: May 5, 2025

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE

United States District Court
Northern District of California