

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

MICHAEL C. PIZZUTO, Individually)
and on Behalf of All Others Similarly)
Situated,)
Plaintiff,)
v.)
HOMOLOGY MEDICINES, INC.,)
ARTHUR O. TZIANABOS, W.)
BRADFORD SMITH, ALBERT)
SEYMOUR, THERESA MCNEELY,)
and JOHN DOES 1-10,)
Defendants.)

)

Civil Action No. 1:23-CV-10858-AK

**MEMORANDUM AND ORDER ON DEFENDANTS HOMOLOGY MEDICINES, INC.,
ARTHUR O. TZIANABOS, W. BRADFORD SMITH, ALBERT SEYMOUR, AND
THERESA MCNEELY'S MOTION TO DISMISS THE AMENDED CLASS ACTION
COMPLAINT**

ANGEL KELLEY, D.J.

This putative federal securities class action lawsuit challenges statements and omissions concerning a biopharmaceutical company's drug candidate for the treatment of a rare disease. Plaintiffs allege that Homology Medicines, Inc. ("Homology") and individuals Arthur O. Tzianabos, W. Bradford Smith, Albert Seymour, Theresa McNeely, and John Does 1-10 ("Individual Defendants") misled investors about the safety and efficacy of Homology's gene therapy treatment, HMI-102, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. Defendants moved to dismiss for failure to state a claim, arguing that Plaintiffs have failed to plead facts with particularity establishing false or misleading statements, a strong inference of scienter, or loss causation.

After carefully reviewing the record and the briefs as well as hearing oral arguments on these motions, Defendants' Request for Judicial Notice and Incorporation by Reference [Dkt. 92] is **DENIED** in part and **GRANTED** in part, and their Motion to Dismiss the Amended Class Action Complaint [Dkt. 89] is **GRANTED**.

I. PROCEDURAL BACKGROUND

This action was initiated on March 25, 2022, in the Central District of California on behalf of persons or entities who purchased or otherwise acquired publicly traded Homology securities between March 12, 2020, and February 18, 2022 (the "Class Period"). Defendants filed a Motion to Transfer [Dkt. 53], which the court granted. [Dkt. 71].

Following transfer, Defendants filed the pending Motion to Dismiss the Amended Class Action Complaint ("Amended Complaint"). [Dkt. 89]. In support of their motion, Defendants filed the Declaration of Melyn C. N. Grant [Dkt. 91] with sixteen exhibits [Dkts. 91-1 through 91-16], for which they requested judicial notice and incorporation by reference [Dkt. 92]. Plaintiffs opposed four of these exhibits. [Dkt. 94]. The Court heard oral argument on the pending motions on March 4, 2024. [Dkt. 103].

II. REQUEST FOR INCORPORATION BY REFERENCE AND JUDICIAL NOTICE

The Court first addresses Defendants' Request for Incorporation by Reference and Judicial Notice. [Dkt. 92]. Defendants argue that the Court may consider sixteen exhibits in support of their Motion to Dismiss the Amended Complaint. [Id. at 1]. Specifically, Defendants ask the Court to deem Exhibits 2-13 and 15-16 incorporated by reference and Exhibits 1-6 and 8-15 subject to judicial notice. [Id.]. While Plaintiffs take no position regarding most exhibits, they contend that the Court may not consider Exhibits 2, 4, 8, and 14. [Dkt. 94]. According to

Plaintiffs, those exhibits are neither referenced in the Amended Complaint nor are they submitted for any admissible purpose. [Id.]

In ruling on a motion to dismiss, a court can consider “documents incorporated by reference in [the complaint], matters of public record, and other matters susceptible to judicial notice.” Giragosian v. Ryan, 547 F.3d 59, 65 (1st Cir. 2008) (alteration in original) (quoting Colonial Mortg. Bankers Corp. v. Lopez-Stubbe, 324 F.3d 12, 20 (1st Cir. 2003)). When “a complaint’s factual allegations are expressly linked to—and admittedly dependent upon—a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6).” Beddall v. State St. Bank & Tr. Co., 137 F.3d 12, 17 (1st Cir. 1998). Defendants argue that Exhibits 3, 5-7, 9-13, and 15-16 are incorporated by reference because the Amended Complaint extensively refers to these sources [Dkts. 92 at 1; 46 at 54-57, 72-73, 103-105, 113-116, 123-135, 143-145, 152-154, 160, 199-200], and Plaintiffs do not contest this [Dkt. 94 at 2]. The Court finds that Exhibits 3, 5-7, 9-13, and 15-16—Securities and Exchange Commission (“SEC”) filings, materials related to presentations about the pheNIX study, and a Homology press release—are documents sufficiently referred to in the Amended Complaint for the Court’s consideration at the motion to dismiss stage. See Pension Tr. v. J. Jill, Inc., 360 F. Supp. 3d 17, 22 n.1 (D. Mass. 2018) (granting defendants’ request for incorporation by reference where complaint “quote[d] substantial portions” and relied on documents in question). However, the Court does not consider those exhibits to prove the truth of any matters asserted therein. See Leung v. bluebird bio, Inc., 599 F. Supp. 3d 49, 57 (D. Mass. 2022) (noting the existence of SEC filings, analyst conference call transcripts, and an FDA guidance document but not considering

them for the truth of any matter asserted therein). Rather, they address Homology's representations to its investors.

In contrast, the Court will not consider Exhibits 2, 4, 8, and 14. Exhibit 2 consists of materials related to an FDA Advisory Committee meeting, Exhibit 4 is a Homology investor presentation, Exhibit 8 is a publicly available transcript of a Homology investor call, and Exhibit 14 is Homology's Form 8-K that was filed on June 13, 2022. [Dkts. 91-2, 91-4, 91-8, 91-14].

Defendants argue that Exhibits 2, 4, and 8 are incorporated by reference, but they are not. See Clorox Co. Puerto Rico v. Proctor & Gamble Com. Co., 228 F.3d 24, 32 (1st Cir. 2000) (stating that documents are incorporated by reference when they are "integral to or explicitly relied upon in the complaint.") (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996)). The Amended Complaint makes no mention of any November 6, 2020, investor call or transcript thereof—the substance of Exhibits 4 and 8.

Nor does the Amended Complaint depend on Exhibits 4 or 8. Defendants essentially concede that Plaintiffs' claims are not dependent upon Exhibits 4 and 8 when they state that "the call and the accompanying slides reflect the same data and information as the November 6, 2020, press release and slide presentation referenced in the [Amended] Complaint." [Dkt. 63 at 4].

Regarding Exhibit 2, the Amended Complaint does refer to the occurrence of an FDA Advisory Committee Meeting. [Dkt. 46 at ¶ 171]. However, the Amended Complaint mentions nothing about the substance of that meeting. Plaintiffs allege that following that meeting, analysts "noted the tightening regulatory environment for gene therapy treatments, including HMI-102." [Id.]. The occurrence of the FDA Advisory Committee meeting is offered as context, a point in time. Thus, incorporating Exhibit 2 by reference is unnecessary. See Kader v. Sarepta Therapeutics, Inc., No. 1:14-CV-14318-ADB, 2016 WL 1337256, at *10 (D. Mass. Apr.

5, 2016) (“Although these exhibits may have provided helpful [background] context, they are not properly before the Court, nor are they essential to evaluating the sufficiency of the Complaint.”).

Lastly, Defendants request that the Court take judicial notice of Exhibits 1 and 14 because they are public documents. [Dkt. 92 at 4]. Plaintiffs do not dispute that these are public documents. [Dkt. 94 at 8]. However, they argue that Exhibit 14 is irrelevant because the exhibit falls outside the Class Period. [Id.]. The Court agrees. The Class Period runs between March 12, 2020, and February 18, 2022. [Dkt. 46 at ¶ 1]. Exhibit 14 was filed with the SEC on June 13, 2022 [Dkt. 91-14], and thus falls outside the Class Period. Post-Class Period materials are not properly before the Court at the motion to dismiss stage. See Shash v. Biogen Inc., 627 F. Supp. 3d 84, 99 (D. Mass. 2022) (declining to take judicial notice, finding “no basis” to consider information that fell outside the presumptive class period); Hall v. Johnson & Johnson, No. CV 18-1833, 2019 WL 7207491, at *10 (D.N.J. Dec. 27, 2019) (declining to take judicial notice, finding that, “[a]though statements from government entities are typically appropriate for judicial notice,” an exhibit issued three months after the close of the class period “arguably ha[d] minimal relevance to the claims at issue”). Consequently, the Court will not take judicial notice of Exhibit 14.

The Court will, however, take judicial notice of Exhibit 1. While not referenced in the Amended Complaint, this exhibit contains relevant FDA documents proper for consideration at the motion to dismiss stage. Leavitt v. Alnylam Pharm., Inc., 525 F. Supp. 3d 259, 266 n.1 (D. Mass. 2021) (stating that the court “may, in its discretion, take judicial notice of FDA documents”); Kader, 2016 WL 1337256, at *11 (considering FDA statements relevant to, among other things, “the total mix of information available to the market during the Class Period”).

III. FACTUAL BACKGROUND

The following facts are drawn from Plaintiffs' Amended Complaint and from the exhibits filed in support of Defendants' Motion to Dismiss the Amended Complaint, except Exhibits 2, 4, 8, and 14, as discussed above.

A. Homology's Gene Therapy

Homology is a publicly traded biopharmaceutical company incorporated in Delaware with its principal executive offices in Bedford, Massachusetts. [Dkt. 46 at ¶¶ 26-27, 40]. The company specializes in gene therapies, which are treatments designed to cure diseases by changing the underlying genetic cause of the disease. [Id. at ¶ 40]. Instead of applying the most widely used form of gene therapy, commonly known as CRISPR, Homology's gene therapies use adeno-associated virus ("AAV") vectors to deliver their therapeutics. [Id. at ¶ 42]. CRISPR functions by inserting an enzyme into a patient's DNA that then cuts the patient's DNA to eliminate the patient's genetic disorder. [Id. at ¶ 41]. In contrast, AAV vector treatments replicate diseased genes with a functional version that is inserted into a patient using a virus when the patient's cells divide. [Id. at ¶ 42]. FDA Guidance published in 2015 states that because there is a lack of clinical experience with some gene therapy products, "there can be considerable uncertainty about the nature and frequency of safety problems that might be associated with specific types of [gene therapy] products." [Dkt. 91-1 at 6]. Gene therapy, the FDA Guidance states, can therefore "pose substantial risks to subjects." [Id. at 5]. "For some products and conditions, including many uses of [gene therapy] products for serious or life-threatening disease, some toxicities may be expected and acceptable." [Id. at 10]. According to the FDA, "[e]arly-phase studies of [gene therapy] products typically have significant risks and an uncertain potential for benefits." [Id. at 12].

Homology uses proprietary AAV vector technology in its drug candidates with permission from the City of Hope Medical Center and the California Institute of Technology pursuant to exclusive license agreements. [Dkt. 46 at ¶¶ 18, 44]. In exchange, Homology has significant payment obligations on product sales, among other things. [Id. at ¶ 44].

HMI-102 was Homology's lead drug candidate during the Class Period. [Id. at ¶ 45]. HMI-102 was a gene therapy designed to treat phenylketonuria ("PKU"), which is a genetic disorder that causes an amino acid called phenylalanine to build up in the body. [Id.]. PKU is caused by a mutation in the phenylalanine hydroxylase gene that helps create the enzyme needed to metabolize phenylalanine. [Id.]. Too much phenylalanine in the body can result in brain damage. [Id.].

B. The PheNIX Clinical Trial and Related Events

The FDA requires any drug to go through a series of clinical trials before it can be approved for marketing and sales in the United States. Phase 1 clinical trials usually evaluate a drug's safety and appropriate dosage. [Id. at ¶ 48]. Phase 2 clinical trials typically involve a larger number of patients and are designed to identify negative short-term effects and risks as well as provide an initial evaluation of the efficacy of the drug. [Id.]. Phase 3 clinical trials are large-scale trials that are supposed to evaluate the efficacy and safety of the drug to provide an adequate basis for labeling the drug. [Id.].

Homology launched its first ever clinical trial for HMI-102 in June 2019. [Id. at ¶ 49]. The company referred to the two-part trial as the "pheNIX" study. [Id. at ¶ 49-50]. The main goal of the pheNIX study was to meaningfully reduce phenylalanine levels in patients without there being treatment emergent adverse events ("TEAEs"), as AAV vector gene therapies are typically associated with increased liver toxicity. [Id. at ¶ 52]. Thus, immunosuppression with

corticosteroids or steroids are a crucial component of the gene therapy treatment process to increase the success of the therapy without patients rejecting it or having to end treatment because of dangerous levels of toxicity. [Id.].

Part 1 of the study was supposed to evaluate the safety and efficacy of HMI-102 in adults with PKU. [Id. at ¶ 50]. Up to three dose levels of HMI-102 would be investigated with at least two subjects, or cohorts, per dose. [Id.]. After evaluating data from the first two subjects in a cohort, Homology would escalate the next dose level or expand the cohort at the selected dose level. [Id.]. Based on the data from Part 1, Homology could continue to Part 2 of the study, which would evaluate a specific dosage across a larger number of randomized patients who would either receive HMI-102 or a simultaneous treatment control arm. [Id. at ¶ 51].

On June 10, 2019, Homology enrolled its first patient (Patient 1) in the pheNIX study and placed them into the low-dose cohort (Cohort 1). [Id. at ¶ 53]. A second patient (Patient 2) was subsequently also placed into Cohort 1, while the third and fourth patients (Patients 3 and 4) were placed into the mid-dose cohort (Cohort 2). [Id.].

On December 17, 2019, Homology reported initial clinical data, which included the two patients from Cohort 1 and one patient from Cohort 2. [Id. at ¶¶ 54-55]. Homology stated that “Preliminary safety data from Cohorts 1 and 2 showed HMI-102 was well-tolerated. Efficacy data from the first patient in Cohort 2 indicated a dose-response effect with an observed reduction in phenylalanine (“Phe”) levels from baseline” [Id. at ¶ 55]. There were no TEAEs and all of the patients’ alanine aminotransferase and aspartate aminotransferase levels remained normal. [Id.]. Following its initial clinical data, Homology recruited two patients for the high-dose cohort (Cohort 3), totaling the number of patients in the pheNIX study to six. [Id. at ¶ 58].

On March 10, 2020, Patient 5 of Cohort 3 was given a dose of a steroid, prednisone, before receiving a high dose of HMI-102 the following day. [Id. at ¶¶ 59-60]. On April 15, 2020, Patient 5 received her phenylalanine test results, which were significantly higher than the pre-specified endpoint for the pheNIX study. [Id. at ¶ 61]. Patient 5's liver enzymes were also significantly elevated, so she continued steroid treatment but with a more potent and longer-acting steroid, Decadron, than the one she had previously been prescribed. [Id. at ¶¶ 61-62]. The same day, Patient 5 posted about her test results and treatment publicly on Facebook, but the post was removed and/or made private within a few hours. [Id. at ¶¶ 62, 65]. When the market opened on April 15, 2020, Homology's stock traded at \$18.65 per share and closed at \$13.97 per share. [Id. at ¶ 65].

On November 6, 2020, Dr. Olaf Bodamer, Homology's principal investigator for the pheNIX trial, presented additional data (through a new October 19, 2020, data cut) from the pheNIX study at the annual meeting of the New England Consortium of Metabolic Programs. [Id. at ¶ 72; Dkt. 91-7]. The data in the presentation included data from Patient 4, who was in the mid-dose cohort (Cohort 2) and Patients 5 and 6, who were in the high-dose cohort (Cohort 3). [Dkt. 46 at ¶ 72]. The data showed that HMI-102 did not lower Patient 4's phenylalanine levels. [Dkts. 46 at ¶ 72; 91-7 at 11]. HMI-102 was not effective for Patient 5 either. [Dkt. 46 at ¶ 72]. However, Patients 4 and 5 had pre-existing immune conditions, and each experienced elevated alanine aminotransferase ("ALTs"), which Homology believes may have inhibited HMI-102's efficacy. [Dkts. 91-7 at 8; 91-5 at 22]. Homology disclosed that they managed the elevated levels of ALTs with an increase in steroids, as needed. [Dkt. 91-7 at 8]. Based on these results, Homology stated that HMI-102's safety data supported advancing to the dose expansion phase of

the pheNIX study. [Dkt. 46 at ¶ 73]. Between November 5 and 6, 2020, Homology's stock fell from \$12 per share to \$9.50 per share on unusually heavy volume. [Id. at ¶ 77].

The same day as Dr. Bodamer's presentation, Homology announced that based on these results, it would advance to the dose-expansion phase of the pheNIX trial, which would include a mid-dose and a high-dose, combined with a revised steroid regimen. [Id. at ¶ 78, Dkt. 91-8 at 5]. Homology incorporated what it had learned from the dose-expansion findings and modified the steroid regimen to include longer post-infusion steroid treatment. [Dkt. 46 at ¶ 78]. Homology stated they would also exclude patients with preexisting immune conditions in an attempt to mitigate the elevated ALTs observed in Patients 4 and 5. [Dkt. 91-8 at 16-17]. This was a significant announcement, since the dose-expansion phase of the trial could be converted into a registrational trial, which could support a regulatory application, such as a New Drug Application. [Dkt. 46 at ¶ 78].

On November 9, 2020, Homology announced a \$60 million equity investment from Pfizer Inc. [Id. at ¶ 79]. Defendant Tzianabos, then-President and CEO of Homology, stated that "Homology intends to use the net proceeds of the offering to help fund its ongoing and planned PKU clinical trials, as well as the company's central nervous system (CNS) programs." [Id.].

Homology then proceeded with registration for the dose-expansion phase of the pheNIX trial through 2021. [Id. at ¶ 80]. On February 26, 2021, a collaboration agreement between Homology and Novartis Institutes for BioMedical Research, Inc. was terminated. [Id. at ¶ 181]. On April 6, 2021, after market hours, a follow-on offering was announced. [Id. at ¶ 204]. Homology and its underwriter, BITG, priced the offering at \$7.58 per share. [Id.]. Between

April 6, 2021, and April 7, 2021, Homology's stock price declined from \$9.30 per share to \$7.18 per share, respectively, on unusually heavy trading volume. [Id. at ¶ 206].

On October 12, 2021, Homology announced it would delay its initial presentation of data from the dose-expansion phase of the trial from late 2021 to mid-2022 when it expected to have a larger dataset. [Id. at ¶¶ 81, 147]. Homology explained that this decision was made because of slower enrollment than they had expected in part caused by a resurgence in COVID-19. [Id. at ¶ 147]. On January 28, 2022, Homology announced it received \$130 million in funding from Oxford Biomedica plc in exchange for its participation in a joint manufacturing agreement. [Id. at ¶ 85]. This deal extended Homology's operational runway by two years. [Id. at ¶ 86].

C. The FDA Hold

On February 18, 2022, after market close, Homology issued a press release announcing that the FDA had placed a clinical hold on the pheNIX study "due to the need to modify risk mitigation measures in the study in response to observations of elevated liver function tests." [Id. at ¶ 88]. A clinical hold is an FDA order issued to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. [Id. at ¶ 89]. When an ongoing study is placed on a clinical hold, new patients cannot be recruited to the study and given the investigational drug. [Id. at ¶ 91]. Patients already in the study are expected to be taken off therapy involving the investigational drug unless the FDA specifically allows continuing the treatment in the interest of patient safety. [Id.]. Thus, Homology had to immediately suspend the pheNIX clinical trial until further permission from the FDA. [Id. at ¶ 88]. Based on this news, Homology's stock price fell from \$3.86 on February 18, 2022, to \$2.60 per share on February 22, 2022 (the next trading day) on unusually heavy volume. [Id. at ¶ 93].

On March 23, 2022, Homology issued a press release addressing the FDA’s clinical hold, stating that Homology was going to propose a more specific immunosuppressive regimen. [Id. at ¶ 94]. As a result, Homology predicted that they would need additional time “to submit and receive feedback on its proposed clinical risk-mitigation strategy,” and revise the pheNIX study protocol. [Id.]. This also meant that Homology’s efforts to turn the pheNIX study into a registrational trial and to commercialize HMI-102 were delayed. [Id. at ¶ 95]. In the meantime, Homology reported that all of the patients who had experienced elevated ALTs were treated without requiring hospitalization. [Id. at ¶ 94]. Homology subsequently changed its steroid regimen by adding T-cell inhibitors to dampen patients’ immune response after receiving a dose of HMI-102. [Id. at ¶ 96].

On March 25, 2022, Plaintiffs filed this lawsuit. [Dkt. 1].

IV. LEGAL STANDARD

When evaluating a motion to dismiss for failure to state a claim, the Court assumes “the truth of all well-pleaded facts” and draws “all reasonable inferences in the plaintiff’s favor.” Nisselson v. Lernout, 469 F.3d 143, 150 (1st Cir. 2006). To survive dismissal, a complaint must contain sufficient factual material to state a claim for relief that is “plausible on its face.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011). “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . [f]actual allegations must be enough to raise a right to relief above the speculative level” Bell Atl. Corp., 550 U.S. at 555 (internal citation omitted). A court may not disregard properly plead factual allegations even if actual

proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. Rather, the relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13. When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein, and facts susceptible to judicial notice. Haley v. City of Bos., 657 F.3d 39, 46 (1st Cir. 2011).

V. DISCUSSION

A. Count I: Violation of Section 10(b) of the Exchange Act and Rule 10b-5

Section 10(b) of the Exchange Act “forbids the ‘use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device . . .’” Tellabs Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 318 (2007) (alteration in original) (quoting 15 U.S.C. § 78j(b)). SEC Rule 10b-5 implements that prohibition by rendering it unlawful to make “any untrue statement of a material fact” or omission of any “material fact necessary in order to make the statements made . . . not misleading.” 17 C.F.R. § 240.10b-5. To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead the following elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)).

A claim for securities fraud must also comply with Fed. R. Civ. P. 9(b) and satisfy the exacting requirements of the Private Securities Litigation Reform Act of 1995 (“PSLRA”). Rule 9(b) requires a party to state “with particularity the circumstances constituting fraud” including the time, place, and content of the alleged false or fraudulent representations. Fed. R. Civ. P. 9(b). The PSLRA imposes two “[e]xacting” pleading requirements on federal securities fraud

claims beyond those enumerated in the Federal Rules of Civil Procedure. Tellabs, 551 U.S. at 313. First, to support allegations of misleading statements or omissions, Plaintiffs must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1). Second, to adequately plead scienter, Plaintiffs must state “with particularity facts giving rise to a strong inference” that the Defendants acted recklessly or with the intent to deceive, manipulate, or defraud. 15 U.S.C. § 78u-4(b)(2).

1. Materially False Misstatements or Omissions

For a Section 10(b) claim to survive a motion to dismiss, Plaintiffs must show that Defendants made a “false, or misleadingly omitted, statement of [material] fact.” Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 7 (1st Cir. 2021). To plead falsity under the PSLRA, a plaintiff must “specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.” 15 U.S.C. § 78u-4(b)(1). A fact or omission is material where “there is ‘a substantial likelihood’ that a reasonable investor would have viewed it as ‘significantly alter[ing] the total mix of information made available.’” Fire & Police Pension Ass’n v. Simon, 778 F.3d 228, 240 (1st Cir. 2015) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)).

Where a complaint pleads multiple misstatements, falsity is judged statement by statement, not “on the basis of the general flavor derived from an issuer’s collective statements over a long period of time.” In re Bos. Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 56 (D. Mass. 1998). However, the actual language must be considered in “[t]he immediate context of each

statement—namely, the balance of what was said on the particular occasion, and the immediate circumstances in which the particular statement was made.” Id. at 55.

Plaintiffs allege that twenty-five statements from eighteen documents are actionable fraudulent statements. These documents consist of one analyst report, one email, four press releases, four transcripts from conference calls, Homology’s 10-K Forms for 2019 and 2020, and six of Homology’s Form 10-Qs. For each of the statements, Plaintiffs allege one or some subset of the following overlapping reasons why the statements were materially misleading:

- 1) Defendants failed to disclose the negative data about Patients 4 and 5 at the same time they disclosed favorable data from Cohort 2 or referred to the pheNIX data generally, misleading investors as to HMI-102’s safety and efficacy [Dkt. 90-1, Stmt. 1-9, 14-15, 19-21, 24];
- 2) Defendants concealed that the steroid regimen that Homology had initially used was insufficient for patient safety and that the revised steroid regimen still posed safety risks for patients. [Id., Stmt. 10, 12, 17-18, 22, 23, 25]; and
- 3) Defendants created the false impression that the pheNIX data supported advancing into the dose-expansion phase [Id., Stmt. 11, 13, 14-16, 19, 23].

In contesting the adequacy of the complaint vis-à-vis those statements, Defendants advance three basic arguments, each of which would independently support dismissal: (1) the challenged statements were not false or misleading, (2) the Amended Complaint fails to allege facts eliciting a strong inference of scienter, and (3) Plaintiffs have not pleaded facts establishing loss causation. [Dkt. 90 at 9-10]. We address each argument in turn.

In the interest of efficient resolution of the claims and because many of the statements are largely duplicative, the Court will evaluate them categorially. See Urman v. Novelos

Therapeutics, Inc., 796 F. Supp. 2d 277, 282 (D. Mass. 2011) (“statements [that] are closely related [can] be grouped together for consideration without diminishing the individualized attention needed to be given to each”).

a. Statements About Preliminary Data from Phase 1

Plaintiffs challenge fifteen statements Defendants made describing the preliminary data related to the safety and efficacy signs from Phase 1. [Dkt. 90-1, Stmt. 1-9, 14-15, 19-21, 24]. The substance of the challenged statements is exemplified by Homology’s statement in its Form 10-Q filed August 10, 2020:

Preliminary safety data from three subjects in Cohorts 1 and 2 showed HMI-102 was well-tolerated with no treatment-emergent adverse events, or TEAEs, or serious TEAEs, that were related to HMI-102. Efficacy data from the first patient in Cohort 2 suggested a dose response effect with an observed reduction in phenylalanine, or Phe

[Dkt. 90-1, Stmt. 8; Dkt. 46 at ¶ 121]. By choosing to discuss the positive data from Patients 1, 2, and 3, Plaintiffs argue, Homology created a duty to disclose the negative data from Patients 4 and 5. [Dkt. 93 at 7]. However, that is not the case.

Section 10(b) “do[es] not create an affirmative duty to disclose any and all material information.” In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012) (alteration in original) (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)). Even where the omitted “information is material, there is no liability . . . unless there was a duty to disclose it.” Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987); see also SEC v. Johnston, 986 F.3d 63, 72 (1st Cir. 2021) (“[I]t is well-settled that the ‘mere possession of . . . nonpublic information does not create a duty to disclose it’ . . . even when that nonpublic information is material.” quoting In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 72 (1st Cir. 2012)); Basic Inc., 485 U.S. at 239 n.17 (“Silence, absent a duty to disclose, is not misleading under Rule 10b-5.”). Defendants are only required to disclose what is necessary to prevent

affirmative statements from being “so incomplete as to mislead.” In re Bos. Sci. Corp., 686 F.3d at 27 (quoting Matrixx, 563 U.S. at 44); see also Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214, 226 (1st Cir. 2022) (“[A] company is not, by virtue of making some disclosures about its products, obligated to disclose all potentially interesting information.”) (emphasis in original). When assessing whether there is a duty to disclose, a statement should be read “in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information.” Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 190 (2015).

Homology had no duty to disclose data in real time, and it disclosed the Patient 4 and Patient 5 data on November 6, 2020, when it reported the data up to the second cutoff date, October 19, 2020. [Dkt. 46 at ¶¶ 72, 131]. “A company need not immediately disclose all information that ‘might conceivably affect stock prices.’” In re Ocular Therapeutix, Inc. Sec. Litig., No. CV 17-12146-GAO, 2019 WL 1950399, at *7 (D. Mass. Apr. 30, 2019), aff’d sub nom. Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194 (1st Cir. 2020) (quoting In re Bos. Sci. Corp., 686 F.3d at 27). “Why companies do not have to disclose immediately all information that might conceivably affect stock prices is apparent: the burden and risks to management of an unlimited and general obligation would be extreme and could easily disadvantage shareholders in numerous ways” In re Bos. Sci. Corp., 686 F.3d at 27. The fact that the first data cutoff date was before the Class Period is immaterial and does not affect the analysis. As Defendants note, where statements are limited to data before a specified cutoff date, they cannot be considered misleading by “clinical data that occurred after that cut-off date.” [Dkt. 95 at 7 (quoting In re Biogen IDEC, Inc. Sec. Litig., No. 05-10400-WGY, 2007 WL 9602250, at *12 (D. Mass. Oct. 25, 2007))].

Homology repeatedly disclosed—before and during the Class Period—the fact that they were only reporting on the first three subjects because it was data collected before the December 2, 2019, cutoff date. [See, e.g., Dkts. 91-3 at 17; 91-6 at 3; 90-1, Stmt. 1, 6, 8]. Companies reporting on clinical trial data may lawfully disclaim and defend their use of partial data and “cast [their] trial results in a positive light.” Corban v. Sarepta Therapeutics, Inc., No. 14-cv-10201-IT, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2015). Homology also warned of the risk of inferring too much from this “preliminary” data, explaining that the results should be “viewed with caution,” as “outcomes may materially change,” when more data becomes available. [Dkt. 91-6 at 3; see Dkt. 91-3 at 57 (stating that different conclusions or considerations may qualify the preliminary results that Homology reports “once additional data have been received and fully evaluated.”)]. While Plaintiffs take issue with Homology’s decision not to release all patient data available at the time, it was transparent about what data it was withholding from investors. [See e.g., Dkt 90-1, Stmt. 3, 6, 8]. Plaintiffs’ claim, therefore, boils down to their displeasure that the data collected before the predetermined cutoff date was more favorable than the data collected after the first cutoff date. As Homology warned, however, “[a]dverse differences between interim data and final data could significantly harm [Homology’s] business prospects.” [Dkt. 91-3 at 58].

Plaintiffs allege that Defendants’ discussion of only favorable data from Patients 1, 2, and 3, while deliberately concealing the negative data from Patients 4 and 5 is comparable to the situation in Miss. Pub. Emps.’ Ret. Sys. v. Bos. Sci. Corp., in which Boston Scientific’s CEO, LaViolette, stated that a problem with a medical device had been “fixed,” but failed to mention that a third recall would be announced a week later. 523 F.3d 75, 91 (1st Cir. 2008). The other case Plaintiffs point to, In re Ariad Pharm., Inc. Sec. Litig., involves a statement in an

investment bank's report based on a meeting with the Chairman and CEO of Ariad Pharmaceuticals. 842 F.3d 744 (1st Cir. 2016). The report stated that management continued to be optimistic about FDA approval of the drug with a favorable label, and that the most prevalent serious adverse event was pancreatitis. Id. at 753. The First Circuit made similar conclusions in both cases: The companies' failure to disclose recent troubling developments gave rise to a strong inference of scienter, since doing so created an impermissible risk of misleading investors. Miss. Pub. Emps.' Ret. Sys., 523 F.3d at 91; In re Ariad Pharm., 842 F.3d at 753. Both cases are inapposite, however, because the undisclosed information directly contradicted statements the companies had made, assuring investors certain problems were benign or in the past. That is not the case here. Plaintiffs do not allege that any statements Homology made directly contradicted the undisclosed information.

Moreover, most of Defendants' statements regarding the preliminary data from phase 1 constitute a subjective interpretation. [See, e.g., Dkt. 90-1, Stmts. 1, 3, 6, 8, 20, 24 (stating that data from Patients 1-3 showed HMI-102 was "well-tolerated"); Stmts. 14 and 15 (calling the safety and efficacy data "positive")]. Courts have repeatedly held that interpretations of results of clinical studies are opinions. See Harrington v. Tetraphase Pharm. Inc., No. CV 16-10133-LTS, 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) ("[S]cientific opinions are just that: opinions"); Kleinman v. Elan Corp., 706 F.3d 145, 154 (2d Cir. 2013) ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement."); City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014) ("Interpretations of clinical trial data are considered opinions. . . . Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis.") (internal citations omitted).

Interpretations of company data are non-actionable opinions unless Plaintiffs can demonstrate that “Defendants did not subjectively believe them, that self-embedded facts within the opinion were untrue, or that material facts related to Defendants’ inquiry into or knowledge concerning the opinion were omitted.” Corban, 2015 WL 1505693, at *11. Plaintiffs have not made such a showing here. Homology’s statements concerning its opinion of the preliminary data from the dose escalation phase are not actionable. Homology had a reasonable basis for its view that the HMI-102 doses given to Cohorts 1 and 2 in the dose expansion phase were well tolerated. Plaintiffs do not dispute there were no TEAs or serious TEAEs, and the patients’ ALT levels remained within the normal range. [Dkt. 46 at ¶ 55]. Whether the data for subsequent patients was positive or negative is irrelevant, since that does not affect the veracity of Homology’s statements regarding Patients 1, 2, and 3. See Paxton v. Provention Bio, Inc., No. 3:21-CV-11613, 2022 WL 3098236, at *11 (D.N.J. Aug. 4, 2022) (“There is a “reasonable basis” for a company’s interpretation of clinical trial data, for example, when “interim results show[] ‘circumstantial evidence of efficacy’ for one important patient subgroup.” (quoting City of Edinburgh, 754 F.3d at 170)).

Plaintiffs’ allegation that the increased liver toxicity observed in Patients 4 and 5 was caused by HMI-102 and not something else is also an interpretation of the clinical data. In contrast, Defendants believed the elevated ALTs may have been related to the patients’ pre-existing immune conditions. [Dkts. 91-7 at 15 (“Degree of ALT elevation was associated with pre-existing immune conditions”); 91-15 at 3 (“The patients who experienced Grade 3 ALTs had pre-existing underlying immune conditions.”)]. “[R]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.” In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015). There is a key difference between

the parties' different interpretations. Defendants can point to the fact that only the patients with pre-existing immune conditions experienced elevated ALTs as a basis for their theory. In contrast, Plaintiffs do not point to anything to support the claim that HMI-102 caused extremely dangerous levels of liver toxicity.

Plaintiffs also challenge a statement made by Theresa McNeely, Homology's Chief Communications Officer on April 16, 2020. The day after Patient 5 published her Facebook post sharing information about her treatment and test results, Oppenheimer research analyst Michael Biegler emailed McNeely and inquired about the post. [Dkt. 46 at ¶ 66]. McNeely replied, "Some Facebook post. Nothing fundamental changed for [Homology] but unfortunately, our stock price." [Id. at ¶ 106].

Plaintiffs allege that the statement, hereinafter referred to as the "McNeely Email," was affirmatively false or materially misleading because Patient 5's Facebook post represented "a materially adverse development in the pheNIX trial data." [Id. at ¶¶ 63, 108]. Therefore, Plaintiffs contend, things had fundamentally changed "for Homology, the pheNIX study, and HMI-102." [Id. at ¶ 107]. In contrast, Defendants contend this statement is not actionable because it was accurate. [Dkt. 90 at 20]. "No pled facts suggest that the observation of known side effects of AAVs (elevated ALTs) in [Patient 5] changed Homology's development plan; and, it did not." [Id.].

Whether Patient 5's results suggested HMI-102's clinical benefits were substantially less than before Patient 5's results were received is irrelevant as to whether McNeely's email was misleading or false. McNeely's email was a generic expression of corporate optimism, or "puffery" about how Homology was doing. This statement is immaterial as a matter of law. See In re Boston Sci. Sec. Litig., 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011) ("The

corporate puffery rule applies to loose optimism about both a company's current state of affairs and its future prospects." (quoting Fitzer v. Sec. Dynamics Techs., 119 F. Supp. 2d 12, 23 (D. Mass 2000)). "[C]ourts have demonstrated a willingness to find immaterial . . . loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available." Metzler Asset Mgmt. GmbH v. Kingsley, 305 F. Supp. 3d 181, 209 (D. Mass. 2018) (quoting Shaw, 82 F.3d at 1217); see id. at 209-10 (finding statements such as "nothing big on a one time nature," and "Nothing significantly off plan from our standpoint," were corporate puffery and did not materially understate the effect of a participant's death in the clinical study of defendants' multiple sclerosis drug.).

A few days after the Facebook post was published, Senior Research Analyst Madhu S. Kumar at Baird made the following statement in a research report: "We recently addressed market concerns regarding a Facebook post from a potential patient in the Phase1/2 pheNIX trial Having spoken with [Homology] management, we continue to favor the risk/reward dynamic for the mid-20 pheNIX update." [Dkt. 46 at ¶ 110]. The First Circuit applies the "entanglement" test to analyze third-party statements. In re Cabletron Sys., Inc., 311 F.3d 11, 38 (1st Cir. 2002). Under this test, "a defendant may be held primarily liable for misstatements appearing in reports authored by outside analysts when those misrepresentations are based on information provided by the defendant." SEC v. Tambone, 597 F.3d 436, 449 (1st Cir. 2010). Liability may attach when "defendants have expressly or impliedly adopted the statements, placed their imprimatur on the statements, or have otherwise entangled themselves with the analysts to a significant degree." In re Cabletron, 311 F.3d at 37-38 (quoting Schaffer v. Timberland Co., 924 F. Supp. 1298, 1310 (D.N.H. 1996)). Plaintiffs' claims do not satisfy the

entanglement test. Homology did not expressly or impliedly adopt the statement in the Baird research report, nor did they place their imprimatur on the statement.

Here, the Amended Complaint does not state what Homology management even communicated to Dr. Kumar. Plaintiffs have not plead sufficient facts to establish that Defendants intentionally fostered a mistaken belief about Patient 5's data. McNeely's statement that Defendants would speak to (presumably) other analysts later that day, without more, is not enough. Since Plaintiffs do not describe anything that was subsequently said, the Court cannot extrapolate that Defendants fed misleading or false statements to analysts. Thus, Plaintiffs cannot assert that Homology "otherwise entangled themselves with [an] analyst[] to a significant degree." Id.

b. Statements About the Patients' Steroid Regimen

Plaintiffs challenge seven statements Defendants made regarding patients' steroid regimen during the pheNIX study and changes made to it. [Dkt. 90-1, Stmt. 10, 12, 17-18, 22-23, 25]. Homology subsequently framed the elevated liver toxicity in Patients 4 and 5 and the revisions to the steroid regime as a learning process or issue that was being addressed. Defendants made statements such as, "[u]pdates to the expansion phase of the pheNIX trial, including key learnings related to patient selection, monitoring and steroid regimen are being incorporated" [id., Stmt. 10]; "the learnings around the administration of steroids and how we do that and the changes we've made really are paying dividends for us" [id., Stmt. 17]; "one of the key learnings that we came across is really getting the immunosuppression protocol right. And what we understand now is that we need to beef up a little bit at the front end, the prophylactic steroid regimen" [id., Stmt. 18]; and "[w]e have a prophylactic steroid regimen here that's been very successful in mitigating any kind of untoward safety profile" [id., Stmt. 22].

Plaintiffs argue that when discussing the steroid treatment used, Homology failed to sufficiently disclose the risks associated with the steroid regimen by concealing known deficiencies and that the steroid treatment would need to be modified. [Dkt. 46 at ¶ 129; see ¶¶ 126, 139, 142, 151]. Defendants argue that there are no specific allegations to support this claim [Dkt. 90 at 19-20], and the Court agrees.

In their statements regarding the steroid treatment, Homology clearly conveyed the message that they were addressing the elevated ALTs with a modified, increased steroid regimen. [Dkt. 90-1, Stmt. 10, 12; see Dkts. 91-5 at 21; 91-7 at 8; 91-15 at 4]. But managing and mitigating elevated ALTs and other potential side effects of the gene therapy does not mean the steroid treatment would eliminate them. Homology never promised the steroid regimen would completely do away with any side effects, nor could they have.

Plaintiffs do not allege that any of Homology's statements omitted any serious adverse events that had been observed, or that its statements were otherwise untrue. Instead, Plaintiffs make conclusory allegations that the steroid regimen was insufficient and inadequate. Plaintiffs do not provide any facts to explain what made the regimen "unacceptably dangerous" other than the FDA ultimately issuing a clinical hold. [Dkt. 93 at 19]. In other words, Plaintiffs' conclusion relies on the belief that Homology must have concealed some risk if the FDA subsequently decided to issue clinical hold. This is an impermissible fraud by hindsight allegation. See Miss. Pub. Emps.' Ret. Sys., 523 F.3d at 90 ("Fraud by hindsight refers to allegations that assert no more than that because something eventually went wrong, defendants must have known about the problem earlier."). "A complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." ACA Fin. Guar. Corp., 512 F.3d at 62 (quoting Shaw, 82 F.3d at 1223); see In re

Genzyme Corp., No. 09–11267–GAO, 2012 WL 1076124, at *11 (D. Mass. 2012) (concluding that the fact that the FDA later concluded Genzyme did not adequately implement its corrective plans did not make earlier statements about the drug approval process false or misleading.).

Considering Defendants’ statements in the aggregate, Plaintiffs have not adequately alleged that Defendants made any actionable omissions. The “total mix of information” included Homology’s disclosure of the risks at issue. Homology warned about the issue of liver toxicity. For example, Homology warned that they were not certain that their AAV vector therapies would “not cause significant adverse events or toxicities.” [Dkt. 91-5 at 52; see Dkts. 91-5 at 21 (stating that ALT elevations “are common in AAV-based gene therapy trials”); 91-3 at 43 (stating that Homology’s “potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics”)]. This was a known safety risk. The FDA Guidance, published years before the pheNIX study was started, emphasized the risks associated with clinical trials of gene therapy products. [Dkt. 91-1 at 12]. “Early-phase studies of [gene therapy] products typically have significant risks and an uncertain potential for benefits.” [Id.]. In particular, for gene therapy products for serious or life-threatening diseases, “some toxicities may be expected and acceptable.” [Id. at 10]. “In those circumstances,” the FDA notes, “a major trial objective might be to identify the maximum tolerated dose . . . that can be given with acceptable toxicity.” [Id.].

Homology also warned of the possibility of “regulatory headwinds” in their SEC filings. [See, e.g., Dkts. 91-12 at 49 (“undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials.”); 91-3 at 52 (“Our product candidates may cause . . . undesirable side effects . . . which may delay or prevent their regulatory approval”)]. Homology was not required to disclose all the details of the risk

involved when “the overall risk is disclosed and the nature of the future risk remains uncertain.” Hill v. Gozani, 638 F.3d 40, 60 n.5 (1st Cir. 2011); see also Shapiro v. TG Therapeutics, Inc., 652 F. Supp. 3d 416, 426 (S.D.N.Y. 2023) (“Adverse events during clinical trials are raw data. A certain number of such events are to be expected, especially during a clinical trial of a drug candidate . . . that is intended to be used by gravely ill patients.”). Homology sufficiently disclosed the overall risk by communicating the risks associated with AAV vector gene therapy and that they could receive feedback from regulatory authorities to “modify the design of [its] clinical trials.” [Dkt. 91-12 at 43]. Plaintiffs argue that this is not enough because it only speaks to “as-yet-unrealized risks.” [Dkt. 93 at 19]. Nonetheless, Plaintiffs have not pleaded sufficient facts (e.g., clinical trial data or FDA communications) to support their conclusion that Homology knew the steroid regimen was “insufficient” and unsafe” at the time.¹ [Id.].

Most importantly, Homology’s SEC filings explicitly cautioned investors that no conclusion could be drawn about the Phase 1 results until the completion of Phase 2. [See, e.g., Dkts. 91-3 at 58; 91-5 at 66; 91-11 at 60; 91-16 at 53 (stating that “initial, top-line and preliminary data should be viewed with caution until the final data are available.”)]. Plaintiffs’ claims rely on speculation—that Homology must have concealed some risk since the FDA issued a clinical hold. This speculation is not enough. Ganem v. InVivo Therapeutics, 845 F.3d 447, 455 (1st Cir. 2017) (“[S]peculation and conjecture . . . cannot substitute for well-pleaded facts.”). Thus, the Plaintiffs have not adequately pleaded facts sufficient to show there was any actionable omission regarding statements about the steroid treatment.

¹ Homology’s use of a different steroid regimen in the pheEDIT trial is irrelevant here. Plaintiffs do not allege that the other, later trial had even begun at the time the FDA implemented its temporary clinical hold. [Cf. Dkt. 46 ¶ 170 with Dkt. 91-15].

c. Statements About Progressing to the Dose-Expansion Phase

The third category of challenged statements, related to the progression to Phase 2, consists of seven statements. [Dkt. 90-1, Stmt. 11, 13, 14-16, 19, 23]. The statements in Homology's Form 10-Q filed on May 6, 2021, are representative:

In November 2020, we reported positive safety and efficacy clinical data from the dose-escalation phase of the trial. . . . Based on the safety and efficacy results observed in the dose-escalation phase, we have selected and advanced two doses to the randomized, concurrently controlled, dose expansion Phase 2 portion of the pheNIX trial, which has the potential to be converted to a registrational trial.

[Dkt. 90-1, Stmt. 14]. Plaintiffs essentially contend that this statement was misleading because Homology's decision to move to Phase 2 was not "based on" the Phase 1 safety and efficacy results—it was made in spite of those results, which Plaintiffs characterize as negative. [Id. at ¶ 135]. In addition, Plaintiffs argue that given HMI-102's "serious safety risks and questionable clinical benefit," the pheNIX study was unlikely to be converted into a registrational trial. [Id.].

Defendants also made statements such as, "[t]he Company believes the [dose between the doses in Cohorts 2 and 3] has the potential to improve Phe reductions while reducing steroid exposure that was required at the high-dose," [Dkt. 90-1, Stmt. 11]; "[Homology's] progress continues to be on track with the Phase II dose expansion phase of pheNIX," [id., Stmt. 16] and "[Homology has] taken all the learning from [the] dose escalation phase and applied that to the dose expansion phase" [id.].

First, these statements are statements of opinion—they express Homology's interpretation of clinical data and their beliefs about the future rather than presently existing, objective facts. Statements of opinion are often prefaced by phrases like "we think" or "we

believe,” but those phrases are sufficient—not necessary—to make a statement an opinion rather than fact. In Re Philip Morris Int’l Inc. Sec. Litig., 89 F.4th 408, 418 (2d Cir. 2023).

Plaintiffs cite to In re Transkaryotic Therapies, Inc. Sec. Litig., but that case is irrelevant because the opinion statements that did not fall within the PSLRA safe harbor provisions were ones of “present belief” that were material and in direct contradiction to known facts about the FDA’s position with respect to defendants’ data and application for marketing approval. 319 F. Supp. 2d 152, 161 (D. Mass. 2004). Here, there are no opinion statements that directly contradict known facts about HMI-102’s safety and efficacy. “Statements constituting mere puffery, or vague corporate optimism on the current success of a product or its prospects, for example, are not material” In re Bos. Sci. Corp. Sec. Litig., 646 F. Supp. 3d 249, 274 (D. Mass. 2022) (citing Metzler, 305 F. Supp. 3d at 209).

Accordingly, the statements are only actionable if Defendants did not actually believe the statement of opinion and if an embedded statement of fact was not true. Miller Inv. Tr. v. Morgan Stanley & Co., 308 F. Supp. 3d 411, 428 (D. Mass. 2018) (stating that statements of opinion may be actionable when the speaker does not actually hold the stated belief and any embedded statements of fact are untrue). Based on the facts Plaintiffs have pleaded, there is no basis to conclude that Defendants did not genuinely believe that what they were saying at the time they said it was true. Absent concretely pleaded facts, the inference the Plaintiffs ask the Court to draw—that Homology continued to the dose expansion phase while secretly believing that the study was unlikely to be converted into a registrational trial because of the treatment’s severe safety risks and questionable clinical benefits to patients—is implausible and conjectural. The initiation of Phase 2 would be very costly, rendering it improbable that Defendants would have continued if they did not believe the Phase 1 safety and efficacy data supported progression

to the dose expansion phase. [See Dkt. 91-3 at 86 (stating that Homology’s operating expenses were \$111.6 million in 2019, and that they anticipated that their expenses would “increase substantially due to costs associated with [their] Phase 1/2 pheNIX clinical trial with HMI-102.”)].

Second, even assuming Plaintiffs adequately pleaded subjective falsity, the statements in question also have to be objectively false to be actionable. Plaintiffs have not pleaded any facts that contradict any of the contested statements Defendants have made nor have they alleged that Homology’s statements regarding progressing to the dose expansion phase are inaccurate. During a conference call on May 13, 2021, Defendant Arthur Tzianabos, CEO and Director of Homology, stated that the company’s “progress continues to be on track with the Phase II dose expansion” phase of the pheNIX study. [Dkts. 46 at ¶ 137; 90-1, Stmt. 16]. This was true. Homology did not change its development plan based on data from Patients 4 and 5, and Plaintiffs have not plead any facts to establish that Homology did not take into account or dismissed the results of those patients.

The PSLRA safe harbor provisions present the last barrier to sustaining Plaintiffs’ challenge to Homology’s statements that pheNIX trial “ha[d] the potential to be converted to a registrational trial.” [Dkts. 46 at ¶ 131; 90-1, Stmt. 14]. Under certain circumstances, the PSLRA exempts forward-looking statements. See 15 U.S.C. § 78u-5. Forward-looking statements are those “that speak predictively of the future.” In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005). “Forward-looking statements are not actionable if they are 1) identified and accompanied by meaningful cautionary language; 2) immaterial or 3) the plaintiff fails to prove that the statement was made ‘with actual knowledge’ that it was false or misleading.” Leavitt v. Alnylam Pharm., Inc., 451 F. Supp. 3d 176, 183 (D. Mass. 2020)

(quoting 15 U.S.C. § 78u-5(c)(1)). Positing that the pheNIX study could become a registrational trial is a classic forward-looking statement, as it only expresses what Defendants thought was a possibility in the future.

Nearly all of Homology's disclosures included cautionary language noting that they contained forward-looking statements. [Dkt. 91-3 at 4; 91-5 at 4; 91-9 at 5; 91-11 at 3; 91-12 at 3; 91-13 at 3, 6; 91-15 at 5-6; 91-16 at 3]. The Form 10-K Homology filed on March 11, 2021, is illustrative. [Dkt. 91-5]. There, Homology stated, “[b]ased on the safety and efficacy results observed in the dose-escalation phase, [Homology has] selected and advanced two doses to the randomized, concurrently controlled, dose expansion Phase 2 portion of the pheNIX trial, which has the potential to be converted to a registrational trial.” [Id. at 6; Dkt. 90-1, Stmt. 14]. The filing identifies such statements as forward-looking [Dkt. 91-5 at 4] and includes both a brief “Summary Risk Factors” section [id. at 5] as well as an expanded “Risk Factors” section [id. at 42-93]. The “Risk Factors” section explicitly identifies the salient risk that Homology depends “heavily on the successful development, regulatory approval and commercialization of HMI-102, which may never occur if HMI-102 is ultimately shown to not be associated with phenylalanine hydroxylase enzymatic activity and increased Phe metabolism, or if HMI-102 were associated with serious adverse events, or if it were found to not be efficacious.” [Id. at 50]. Therefore, Homology warned, they could not be certain that HMI-102 would be successful in the pheNIX trial or would receive regulatory approval. [Id.]. The same section also identifies important factors that could cause clinical trials to be delayed or terminated, including delays or failures related to “the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of [Homology’s] clinical studies” and “receiv[ing] feedback from regulatory authorities that requires Homology to modify the design of [their] clinical trials.” [Id. at 54].

These statements conveyed substantive information about the risk that ultimately materialized. As such, they were meaningful cautionary language, not mere boilerplate. See In re Ibis Tech. Sec. Litig., 422 F. Supp. 2d 294, 310 (D. Mass. 2006) (“[I]f a statement is accompanied by meaningful cautionary language, the defendants’ state of mind is irrelevant.” (quoting Harris v. Ivax Corp., 182 F.3d 799, 803 (11th Cir. 1999))); In re Bos. Tech., 8 F. Supp. 2d at 53 (“[C]autio[n]ary language must be sufficiently related in subject matter and strong in tone to counter the statement made.”); see also Leavitt, 451 F. Supp. 3d at 186-87 (“[Defendant] warned investors about specific risks including deficient clinical trial results and the prospect of the FDA declining to approve the drug. Such warnings are not mere boilerplate and were sufficient to invoke the safe harbor.”).

In sum, Defendants’ statements about progressing to the dose expansion phase are not materially misleading merely because Plaintiffs “seem[] to take issue with . . . the general ‘rosy’ picture that defendants attempted to paint about the results.” Bristol Pension Fund v. Vertex Pharms. Inc., 12 F. Supp. 3d 225, 237-38 (D. Mass. 2014). “[I]t is not illegal for a company to paint a positive or optimistic picture when disclosing information to investors,” as long as that picture is not materially false or misleading. Id. at 238.

2. Scienter

Liability under section 10(b) and Rule 10b-5 also requires scienter. See 15 U.S.C. § 78u-4(b)(2). Scienter is “a mental state embracing intent to deceive, manipulate, or defraud.” Matrixx, 563 U.S. at 48 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). It requires “a showing of either conscious intent to defraud or ‘a high degree of recklessness.’” ACA Fin. Guar. Corp., 512 F.3d at 58 (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir 2002)). A high degree of recklessness “demands ‘a highly unreasonable omission,’ one

that not only involves ‘an extreme departure from the standards of ordinary care,’ but also ‘presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.’” Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 37 (1st Cir. 2017) (quoting In re Smith & Wesson, 669 F.3d at 77).

Under the PSLRA, a plaintiff must “state with particularity facts giving rise to a strong inference” of scienter. 15 U.S.C. § 78u-4(b)(2). To qualify as “strong,” the Supreme Court has instructed that “an 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 nonfraudulent intent.” Tellabs, 551 U.S. at 324. When there are equally strong inferences for and against scienter, “the draw is awarded to the plaintiff.” City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011). “[W]here a complaint is devoid of any direct-evidence allegations, the indirect-evidence allegations in the complaint will need to do more work to carry the burden of raising a ‘strong inference of scienter’ on their own.” Brennan v. Zafgen, Inc., 853 F.3d 606, 615 n.8 (1st Cir. 2017). Cognizant that “[e]ach individual fact about scienter may provide only a brushstroke,” courts must assess each asserted fact individually before considering “the resulting portrait” and weighing them cumulatively. Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc., 838 F.3d 76, 81 (quoting In re Cabletron, 311 F.3d at 40).

“[A] plaintiff ‘may combine various facts and circumstances indicating fraudulent intent,’ including those demonstrating ‘motive and opportunity,’ to satisfy the scienter requirement.” Brennan, 853 F.3d at 614 (quoting Aldridge, 284 F.3d at 82). However, “‘catch-all allegations’ that merely assert motive and opportunity, without something more, fail to satisfy the PSLRA.”

In re Cabletron, 311 F.3d at 39 (quoting In re Advanta Corp. Secs. Litig., 180 F.3d 525, 535 (3rd Cir. 1999)).

Plaintiffs make a few general allegations of scienter that apply to all of the claims.

Considered as a whole, these allegations fall short of the “strong inference” required under the PSLRA. At best, the allegations are plausible, but not “cogent and compelling.” Tellabs, 551 U.S. at 324.

First, Plaintiffs claim that Defendants possessed material adverse information concerning Patient 4 and 5’s pheNIX trial data throughout the Class Period. [Dkt. 93 at 23]. According to Plaintiffs, while Defendants were in possession of that information, they made contradictory public statements claiming that the pheNIX data demonstrated a clinical benefit for HMI-102. [Id.]. Plaintiffs also allege that Homology was most likely responsible for directing Patient 5 to remove the April 15, 2022, Facebook post describing her treatment. [Id. at 24]. Thus, Defendants’ effort to cover up and subsequently downplay Patient 5’s data demonstrates intent, strengthening the inference of scienter. [Id.]

As previously discussed, Defendants’ statements regarding Phase 1 were true throughout the Class Period. Thus, they cannot be contradictory. Homology characterized its initial disclosures as preliminary data and noted that it only included the results of Patients 1, 2, and 3. [See, e.g., Dkt. 90-1, Stmt. 3, 6, 8 (“[p]reliminary safety data from the first three subjects . . .”)]. Throughout the dose escalation phase, Homology kept investors informed of patient enrollment and dosage, and timely released data from Patients 4 and 5—who received treatment after the initial data cutoff date. [Dkt. 91-7; See Dkt. 46 at ¶ 126]. The Court agrees with Defendants that “[n]o reasonable investor could be misled as to data that was expressly excluded from Homology’s statements.” [Dkt. 95 at 8]. The facts alleged do not support the

inference that Defendants acted with an intent to deceive investors by waiting until November 6, 2020, to disclose Patient 4 and 5 data. It is not evident or inferable from the Amended Complaint that Defendants knew or should have known that their failure to disclose the Patient 4 and 5 data “present[ed] a danger of misleading buyers or sellers as to [HMI-102’s] clinical effect.” Waters, 632 F.3d at 758 (alteration in original) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999)). Defendants’ disclosure of Patients 4 and 5’s results weakens any showing of scienter. As the First Circuit has consistently noted, “attempts to provide investors with warnings of risks generally weaken the inference of scienter.” Ezra Charitable Tr. v. Tyco Int’l, Ltd., 466 F.3d 1, 7 (1st Cir. 2006); see Brennan, 853 F.3d at 617-18 (finding that where defendants disclosed some but not all adverse events and disclosed that they would not report all adverse events as they occurred, a strong competing inference of scienter was that defendants disclosed what they considered to be, at the time, the most relevant information about the clinical trials).

In determining scienter, the Court “must weigh ‘not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged.’” N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008) (quoting Tellabs, 551 U.S. at 314). An alternative and more reasonable inference here is that Defendants were waiting to collect Patient 6’s data in order to analyze and simultaneously disclose the three patients’ results that fell within the second data cut.

Plaintiffs’ allegation that Homology was behind Patient 5’s removal of her Facebook post is completely unsupported by any pleaded facts. In her email reply to research analyst Michael Biegler, McNeely did not take the opportunity to challenge the identity of the Facebook poster or the veracity of the post, which would have helped establish an inference of scienter. Instead, she

acknowledged its existence and replied with a perfunctory opinion statement. Plaintiffs allege that whether McNeely's opinion statement amounts to corporate puffery is a question of materiality, which should be reserved for the trier of fact. [Dkt. 93 at 21]. “[I]f the materiality of a particular fact is in question, that ‘tends to undercut’ an inference that a defendant acted with the requisite scienter.” In re Genzyme Corp., 2012 WL 1076124 at *8 (quoting Waters, 632 F.3d at 757).

Only one day had transpired since Patient 5’s test results had been leaked. It seems highly unlikely that Homology would have had sufficient time to analyze the results by the time analyst Michael Biegler emailed McNeely. Consequently, McNeely was probably not in a position to disclose or comment further. The same is most likely true for Tzainabos’ statement during the conference call a week later. See In re Elan Corp. Sec. Litig., 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008) (“Defendants are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses before a duty to disclose arises.”); see also Biogen IDEC Inc., 537 F.3d at 45 (“A statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it.”).

Next, Plaintiffs argue Defendants knew that the modifications they had made to the steroid regimen for the dose-expansion phase were insufficient to prevent adverse safety events and yet “concealed the risks that it posed to investors in terms of worsening regulatory headwinds.” [Dkt. 93 at 25]. Plaintiffs do not allege that Defendants knew of any statistically significant or causal relationship between the steroid regimen and adverse safety events. Nothing in the Amended Complaint suggests Homology did not take into account the elevated

ALTs in Patients 4 and 5 when they decided to progress to Phase 2 or when they stated that the pheNIX study could become a registrational trial. Therefore, Plaintiffs fail to allege facts supporting Defendants' scienter with respect to the nondisclosure of information regarding the steroid treatment. Moreover, Plaintiffs disclosed the risks to investors. Defendants were transparent about the possibility of regulatory challenges to the pheNIX study at any stage. Homology warned that regulatory agencies might "not accept or agree with [Homology's] assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact . . . the approvability . . . of the particular product candidate and our company in general." [Dkt. 91-16 at 53]; see In re Genzyme Corp., 2012 WL 1076124, at *11 (finding no cogent inference of scienter regarding the FDA's later conclusion that Genzyme did not adequately implement their corrective plans for their drug trial. "[T]he fact that the FDA later made such a conclusion [did] not make earlier statements about the [drug] approval process false or misleading.").

Plaintiffs' argument that Defendants should have known that the initial steroid treatment would be ineffective simply because they and two other companies used a different steroid regimen in a different trial fails. The Court is highly doubtful that this allegation reaches the specialized form of recklessness used in securities fraud cases. See Loc. No. 8 IBEW Ret. Plan & Tr., 838 F.3d at 80 ("This form of recklessness is 'closer to a lesser form of intent' than it is to ordinary negligence." (quoting Greebel, 194 F.3d at 199)). The fact that Homology used a different steroid regimen in different trials for different genetic treatments at different times does not really indicate anything at all. Plaintiffs provided no details whatsoever to establish comparability to the clinical trials conducted by the two companies it named. Even if Plaintiffs

were accurately comparing apples to apples, “scientific opinions are just that: opinions.”

Harrington, 2017 WL 1946305, at *5.

The “opposing inference one could draw from the facts alleged” is stronger than the inference Plaintiffs ask this Court to draw. Tellabs, 551 U.S. at 324. It is improbable that Homology did not honestly believe its positive interpretation of initial preliminary trial data when it subsequently devoted additional resources to conduct the dose expansion phase. Analysts estimated Homology only had sufficient funds to continue operations through the first quarter of 2023 [Dkt. 46 at ¶ 181]. Thus, Homology would have been incentivized to spend judiciously and to focus its efforts on what they thought was their most promising drug trial at the time.

Lastly, Plaintiffs claim that Defendants had “the motive (‘concrete benefits that could be realized by . . . the false statements and wrongful nondisclosures’) and opportunity (‘the means and likely prospect of achieving concrete benefits by the means alleged’)” to knowingly conceal the truth. Aldridge, 284 F.3d at 82 (quoting Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir.)). According to Plaintiffs, Homology made public statements that contradicted the safety of the steroid regimen long enough to raise millions of dollars to make deals with Pfizer and Oxford Biomedica. [Dkt. 93 at 26-27]. These allegations do not support an inference of scienter. Any corporation would be motivated to raise capital, make a profit, avoid bankruptcy, or finance the successful launch of a promising product. See In re Chembio Diagnostics, Inc. Sec. Litig., 586 F. Supp. 3d 199, 220 (E.D.N.Y.) (“[A] motivation of avoiding an event that would ‘threaten the survival of a company’ is . . . ‘too generalized (and generalizable)’” (quoting In re PXRE Grp., Ltd., Sec. Litig., 600 F. Supp. 2d 510, 531-532 (S.D.N.Y. 2009))). The desire to raise capital does not strengthen the inference of an intent to defraud because making deals to extend

the company's financial runway—far from defrauding the shareholders—actually benefits the shareholders. Raising capital to finish developing and launching a product to earn profits for shareholders is the essence of the duty of loyalty; it would be an unusual case where attempts to accomplish this objective constitute the requisite motive to defraud shareholders.

Plaintiffs further contend that a “core operations” theory supports a strong inference of scienter because “Defendants repeatedly discussed the pheNIX trial, demonstrating their familiarity with the data and its implications.” [Dkt. 93 at 25-26]. Under such a theory, “facts critical to a business’s core operations . . . are so apparent that their knowledge may be attributed to the company and its officers.” Epstein v. Itron, Inc., 993 F. Supp. 1314, 1326 (E.D. Wash. 1998), abrogated on other grounds by In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970 (9th Cir. 1999). Courts, however, “have been hesitant to apply significant weight to ‘core operations’ allegations without other significant evidence of a defendant’s intent or recklessness, or a ‘plus factor.’” In re Biogen Inc. Sec. Litig., 193 F. Supp. 3d 5, 51 (D. Mass. 2016), aff’d, 857 F.3d 34 (1st Cir. 2017) (quoting In re A123 Sys., Inc. Sec. Litig., 930 F. Supp. 2d 278, 285 (D. Mass. 2013)). Discussing the pheNIX trial and having familiarity with its data cannot establish fraudulent intent. “[C]orporate management’s general awareness of the day-to-day workings of the company’s business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to the fraud or other allegations supporting scienter.” Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151, 165 (1st Cir. 2019) (quoting S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 784-85 (9th Cir. 2008)) (internal quotations omitted). Here, Plaintiffs again offer merely conclusory allegations and fail to provide the specifics necessary to support a strong inference of scienter where Defendants disclosed HMI-102’s risks and pheNIX trial data to investors.

3. Loss Causation

Defendants contend dismissal is also warranted because the Amended Complaint does not point to a corrective disclosure connecting a stock drop to any of Homology's alleged misstatements. [Dkt. 90 at 31]. To plead loss causation, a plaintiff must allege facts establishing a "causal link between the alleged misconduct and the economic harm ultimately suffered"

In re Alkermes Sec. Litig., No. CIV.A. 03-12091-RCL, 2005 WL 2848341, at *10 (D. Mass. Oct. 6, 2005) (quoting Emergent Cap. Inv. Mgmt., LLC v. Stonepath Grp., Inc., 343 F.3d 189, 197 (2d Cir. 2003)). "A plaintiff may do so by: (1) identifying a 'corrective disclosure' . . . ; (2) showing that the stock price dropped soon after the corrective disclosure; and (3) eliminating other possible explanations for this price drop" Shash v. Biogen, Inc., 84 F.4th 1, 19-20 (1st Cir. 2023) (quoting Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 237-38 (1st Cir. 2013)).

Whether allegations of loss causation must conform to the heightened specificity standard for fraud claims pursuant to Fed. R. Civ. P. 9(b) or the typical plausibility standard under Fed. R. Civ. P. 8 remains an open question in the First Circuit. See Mass. Ret. Sys., 716 F.3d at 239 n.6 (expressly declining to decide the issue because allegations satisfied both standards). Here, similar to Mass. Ret. Sys., the allegations fail under both standards and thus the Court need not determine which one applies.

Plaintiffs cannot show loss causation because they have not alleged any corrective disclosure. That is, Plaintiffs have not adequately alleged that Defendants "reveal[ed] to the market [a] pertinent truth that was previously concealed or obscured by the company's fraud."

Mass. Ret. Sys., 716 F.3d at 237 (quoting FindWhat Inv. Grp. v. FindWhat.com, 658 F.3d 1282, 1311 (11th Cir. 2011)). To support loss causation, corrective disclosures must contain *new* information. See Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Sec. (USA) LLC, 752 F.3d 82, 89 (1st Cir. 2014) (“[A]ny claim that an event moved the stock price when the event was not actually a new disclosure will necessarily fail.”). Plaintiffs offer (1) the April 2020 Facebook Post [Dkt. 46 at ¶¶ 194-95]; (2) the August 2020 disclosure of additional pheNIX trial data [Id. at ¶¶ 196-98]; (3) the November 2020 release of Patient 4 and Patient 5 data [Id. at ¶¶ 199-203]; (4) the April 2021 announcement of a follow-on offering [Id. at ¶¶ 204-06]; and (5) the February 2022 clinical hold issued by the FDA. [Id. at ¶¶ 207-11]. But none are “corrective disclosure[s]” because Plaintiffs have not adequately pleaded scienter. In re Wayfair, Inc. Sec. Litig., 471 F. Supp. 3d 332, 350 (D. Mass. 2020). As such, there is no adequate allegation that the defendants “concealed” or “obscured” any information from the public. Mass. Ret. Sys., 716 F.3d at 237 (quoting FindWhat, 658 F.3d at 1311). Ultimately, Plaintiffs have not adequately pleaded that these disclosures were “connected to a prior false or misleading statement” by the Defendant. In re Wayfair, 471 F. Supp. 3d at 350. Thus, they have not adequately pleaded loss causation. Id.

Even if Plaintiffs had sufficiently plead scienter, the August 2020 Form 10-Q and the April 2021 announcement of a stock offering contain no new information about the pheNIX trial. The financial report did not include any further disclosure about the pheNIX trial data by the Plaintiffs’ own admission. [Dkt. 46 at ¶¶ 196-97 (“Absent from Homology’s quarterly report or accompanying press release was any further disclosure about the pheNIX trial data”)]. The April 2021 stock offerings simply indicated that Homology intended to raise capital but does not

contain any disclosures—let alone *corrective* disclosures—regarding the pheNIX trial. These disclosures necessarily fail to support loss causation.

Even if disclosures contain new information, they must also be corrective to support loss causation. Leung, 599 F. Supp. 3d at 70 (no loss causation where the disclosure “did not correct some untruth” about previously disclosed information); see In re Nektar Therapeutics Sec. Litig., 34 F.4th 828 (9th Cir. 2022) (no loss causation where disclosure “did not correct or revise patient data”). The April 2020 Facebook Post and Homology’s November 2020 announcement of Phase 1 results were limited to new data. The Facebook Post was limited to Patient 5 data [Dkt. 46 at ¶¶ 60-62], and the November 2020 announcement of Phase 1 results provided data from after the new December 2019 cutoff date. [Id. at ¶¶ 72-73]. Neither disclosure corrected, contradicted, or revised previous data. As such, they are insufficient to support loss causation.

Lastly, Plaintiffs point to Homology’s press release announcing the FDA’s clinical hold to support their theory of loss causation. [Id. at ¶¶ 208-09]. However, this was the materialization of a known risk. See Leung, 599 F. Supp. 3d at 70 (no loss causation where “[d]efendants did not conceal the risk” but instead “disclosed [the] risk several times”); Coyne v. Metabolix, Inc., 943 F. Supp. 2d 259, 275 (D. Mass. 2013) (no loss causation where stock price fell “as a result of . . . risk [defendant] repeatedly and regularly disclosed”). Homology warned investors that regulatory authorities might “interrupt, delay or halt clinical trials” because of potential side effects—the exact risk that materialized when the FDA issued a clinical hold. [Dkt. 90-12 at 49; 90-16 at 48]. Defendants did not “conceal” or “obscure” this risk from the public. Mass. Ret. Sys., 716 F.3d at 237 (quoting FindWhat, 658 F.3d at 1311). Therefore, the materialization of this risk cannot support loss causation. See Leung, 599 F. Supp. 3d at 70 (finding that the materialization of the risk that the FDA would require additional comparability

analysis did not support loss causation when Defendants had disclosed that risk several times throughout the Class Period).

Without a corrective disclosure, Plaintiffs are left with a series of events that caused Homology's stock to drop but that are not tethered to any false or misleading statement made by Homology; precisely the kind of untethered events that are "not enough" to support loss causation. Shash, 627 F. Supp. 3d at 113 (quoting Coyne, 943 F. Supp. 2d at 273).

B. COUNT II – Violation of Section 20(a) of the Exchange Act

Finally, Plaintiffs assert claims for control person liability against the individual Defendants pursuant to Section 20(a) of the Exchange Act. Section 20(a) imposes joint and several liability on any person who, "directly or indirectly, controls any person liable" under Section 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a). Because the Amended Complaint fails to allege an underlying violation of federal securities law, the Section 20(b) claims must be dismissed.

VI. CONCLUSION

For the foregoing reasons, Defendants' Request for Judicial Notice [Dkt. 92] is **DENIED** in part and **GRANTED** in part, and Defendants' Motion to Dismiss the Amended Class Action Complaint [Dkt. 89] is **GRANTED**.

SO ORDERED.

Dated: March 31, 2024

/s/ Angel Kelley
Hon. Angel Kelley
United States District Judge