# United States Court of Appeals
## For the First Circuit

No. 23-1393

JULIAN QUINONES, individually and on behalf of all others similarly situated,

Plaintiff, Appellant,

PAUL EVANS, individually and on behalf of all others similarly situated; MICHAEL HINGSTON, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

FREQUENCY THERAPEUTICS, INC.; DAVID L. LUCCHINO; CARL LEBEL,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

Before

Kayatta, Selya, and Howard,
Circuit Judges.

Amanda F. Lawrence, with whom Thomas L. Laughlin, IV and Scott & Scott Attorneys at Law LLP were on brief, for appellant.

Roman Martinez, with whom William J. Trach, Christine C. Smith, Jeff G. Hammel, Kevin M. McDonough, and Latham & Watkins LLP were on brief, for appellees.

July 2, 2024

**KAYATTA, Circuit Judge.** Frequency Therapeutics is a biotechnology start-up that tried to develop a treatment called "FX-322" for individuals suffering from severe sensorineural hearing loss. While initial clinical trials of FX-322 were positive, subsequent testing produced disappointing results. When announced, those results triggered a sharp drop in the price of Frequency's publicly traded stock. That, in turn, led three stockholders to file this putative class action seeking recourse for alleged violations of sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, 15 U.S.C. §§ 78t(a), 78j(b), and Securities and Exchange Commission Rule 10b-5.

Plaintiffs claim that Frequency's Chief Executive Officer, David Lucchino, and its Chief Development Officer, Carl LeBel, knew of problems with the study before the results were announced, yet gave investors assurances to the contrary. The district court dismissed the complaint for failing to allege sufficient facts to support a finding of scienter under the Private Securities Litigation Reform Act ("PSLRA") § 21D(b), 15 U.S.C. § 78u-4(b). We agree and affirm the dismissal.

**I.**

On a motion to dismiss, "we accept the factual allegations set forth" in the complaint, "as 'supplemented by certain materials the defendants filed in the district court in support of their motion to dismiss.'" Constr. Indus. & Laborers

Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 4 (1st Cir. 2021) (quoting Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 198 (1st Cir. 2020)). Initial trials of FX-322 indicated that the treatment was "likely safe and may have a beneficial effect on patients." So in October 2019, Frequency announced that it would be launching a Phase 2a trial of FX-322 with a wider study population. To guard against the possibility of bias in the Phase 2a trial, Frequency kept confidential certain participation eligibility requirements. It made a particular point of not disclosing how poorly a person would need to score on a word-recognition test to qualify for the study. The concern was that persons who knew the qualifying threshold might manipulate their results on the eligibility test to get into the study, and then -- when tested at the end -- show a marked "improvement" in hearing that was not actually a real change.

Frequency's concern was not farfetched. Some tinnitus patients apparently believed that FX-322 could help alleviate their condition. They were therefore eager to gain early access to the treatment through clinical trials even though they might not otherwise have met the study participation criteria. So when a user on Tinnitus Talk -- an online forum for people with tinnitus -- posted in February 2020 that a patient would need to score less than eighty-five percent on a word-recognition test to qualify for the trial, at least some individuals used that information to fake

their way into the study. Thus, plaintiffs allege, by the time Frequency completed its Phase 2a recruitment in September 2020, at least some study participants were fraudulent enrollees.

Subsequent analysis of the Phase 2a trial did not produce statistically significant results. On March 23, 2021, Frequency issued a press release announcing that FX-322 "did not demonstrate improvements in hearing measures versus placebo," and explained that the lackluster results of the Phase 2a study "potentially suggest[ed] bias due to trial design." In the aftermath of the announcement, Frequency stock plummeted from $36.29 per share to $7.99 per share.

Plaintiffs filed their initial complaint on June 3, 2021, and the operative amended complaint on May 16, 2022. They asserted causes of action under sections 10(b) and 20(a) of the Securities and Exchange Act, alleging that defendants knowingly misrepresented the experimental validity of the Phase 2a trial to investors in order to inflate Frequency stock prices. As relevant to this appeal the complaint described two occasions when Frequency officers touted the study design. First on October 29, 2020, Frequency representatives stated in a presentation to investors that Phase 2a was a "double-blind, placebo-controlled, multi-center" study of adults, all of whom "have meaningful word recognition deficits." Second on January 11, 2021, Frequency reiterated in another investor presentation that "all subjects

have meaningful word recognition deficits" as required by the Phase 2a entrance criteria.

The district court agreed that the statements made on October 29, 2020, and January 11, 2021, could be found to be materially false, misleading, incomplete, or inaccurate. See Quinones v. Frequency Therapeutics, Inc., 665 F. Supp. 3d 156, 167-69 (D. Mass. 2023). It therefore viewed the pivotal question as one of scienter: Did defendants know of or recklessly disregard the falsity of the statements when they made them?

To prove scienter, plaintiffs relied on three categories of evidence. First, they pointed to statements from a confidential witness ("CW1") who worked as a Senior Manager of Clinical Operations at Frequency from January 2018 to September 2021. CW1 stated that defendants "must have . . . known" that the confidential Phase 2a participation criteria "were being disseminated online via online posts." CW1 additionally reported that clinicians who helped administer the drug to Phase 2a trial participants told LeBel about a "concerning discrepancy between certain patients' responses during the screening process for admission into Phase 2a and subsequent examinations by the investigators." And so, say plaintiffs, by December 2020, defendants "already knew that Phase 2a was hopelessly biased." Second, plaintiffs highlighted the cadence of CEO Lucchino's stock sales during the pendency of the Phase 2a trial. From December

2020 (when the first batch of study data was collected) through February 2021, Lucchino averaged over 57,000 shares sold per month compared with the 15,000 shares per month he had been selling previously. Third, plaintiffs emphasized that FX-322 was essential to Frequency's commercial success, and as such defendants would have been paying close attention to the Phase 2a trial.

The district court was not persuaded. It concluded that the complaint failed to demonstrate that defendants had made the false statements with the degree of scienter required to state a Securities and Exchange Act claim and dismissed the case. Id. at 162.

Plaintiffs subsequently filed a notice of appeal. About three months later, they filed in the district court a motion for leave to file a second amended complaint. The second amended complaint contained allegations from additional confidential witnesses, which plaintiffs asserted would cure any deficiencies identified in the district court's dismissal order. The district court denied the motion, reasoning that because the case had been appealed, the court "ha[d] no business now volunteering its views about post-decision events."

**II.**

We review de novo a district court's dismissal of a securities fraud complaint for failure to state a claim under

Rule 12(b)(6). Carbonite, Inc., 22 F.4th at 6. To state a claim under section 10(b), a complaint must allege: "(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." In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017) (citing Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015)).

**A.**

Frequency first asks us to backtrack, arguing that the district court was overly generous to plaintiffs in finding that plaintiffs had adequately alleged a false statement. We disagree. The complaint alleges that CW1 "confirmed that multiple patients enrolled in Phase 2a . . . despite not having met the inclusion criteria" by "fak[ing] being deaf." Taking that as true, Frequency's subsequent statements to investors representing that all Phase 2a trial participants had "meaningful word recognition deficits" are necessarily false. Therefore, like the district court, we train our attention on the issue of scienter.

**B.**

To support a finding of scienter under the PSLRA, a complaint must "state with particularity facts giving rise to a strong inference that the defendant . . . either . . . consciously intended to defraud, or that they acted with a high degree of recklessness." Mehta, 955 F.3d at 206 (quoting 15 U.S.C.

§ 78u-4(b)(2)(A) and Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 57 (1st Cir. 2018)). A "strong" inference is "more than merely 'reasonable' or 'permissible' -- it must be cogent and compelling, thus strong in light of other explanations." Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 323-24 (2007). In considering whether a complaint has alleged enough facts to survive a motion to dismiss under these heightened pleading standards, "courts must . . . accept all factual allegations in the complaint as true," but "[a] complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Id. at 322, 324.

Plaintiffs contend that defendants were reckless in ignoring signs that the Phase 2a trial might be infected with bias. First, they point to CW1's allegations that clinicians told LeBel about certain participants who at the beginning of the study reported not being able to hear certain sounds, then at the end told clinicians they could hear those same sounds. This information apparently should have tipped LeBel off to the possibility of bias within the study design. But plaintiffs do not allege when the clinicians conveyed that information to LeBel. Moreover, plaintiffs do not explain why reports of improved hearing would be a concern unless the individuals making the reports were in the placebo group. Given that the study was double-blind, even

the clinicians could not have known which participants were in that group until the end of December. Recall that earlier trials of FX-322 produced promising results. So the minimal allegations in the complaint do not allow us to fault anyone for seeing the initial Phase 2a trial data and thinking that participants with improved hearing were in the treatment group.

That does leave open the possibility that the final study results revealing the problems with the study were conveyed to LeBel prior to his January 11, 2021 investor presentation. But even plaintiffs' confidential witness offers no actual fact that would create a strong inference that defendants knew of the study results by January 11, 2021 (much less by the time of the earlier challenged statements on October 29, 2020). Like Conan Doyle's dog that did not bark, this silence says much. See In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016) (noting that plaintiffs' failure to "allege any specific facts about when the defendants learned of these adverse events" was "a glaring omission"); see also In re Biogen Inc. Sec. Litig., 857 F.3d at 43 (finding that where statements from confidential witnesses do not "go specifically to what the defendants knew at the time they made [the misleading] statements," then they are insufficient to establish scienter).

Plaintiffs respond that because LeBel went on the Tinnitus Talk podcast in July 2020, he must have known about (or

recklessly disregarded) the forum post revealing the study's word-recognition criteria even before the study began. But the complaint is silent as to why LeBel would or should have discovered the post when he participated in the interview. Merely alleging that a person went on a podcast associated with a website does not by itself generate a strong inference that the person reviewed prior posts on that website. As our case law makes clear, "fraud cannot be established by hindsight." Shash v. Biogen, Inc., 84 F.4th 1, 16 (1st Cir. 2023).

The complaint does allege that CW1, a senior manager who helped oversee the Phase 2a study, was in a good position to know about potential issues with the study. But it contains no allegations that CW1 said anything to LeBel -- with whom CW1 worked "hand-in-hand" -- about any concerns.

Nor do any of plaintiffs' other allegations support a finding of scienter. Plaintiffs attempt to rely on the sudden increase in Lucchino's sales of Frequency stocks from December 2020 to February 2021, right before Frequency made its announcement that the Phase 2a trial had been a bust. But all of plaintiffs' claims as to knowledge of the study's flaws are specific only to LeBel -- who is not alleged to have engaged in any inconsistent stock activity during the relevant period. "'[E]ven unusual sales by one insider do not give rise to a strong inference of scienter' when other insiders ha[ve] not engaged in suspicious trading during

the class period." N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 56 (1st Cir. 2008) (quoting Abrams v. Baker Hughes Inc., 292 F.3d 424, 435 (5th Cir. 2002)); see also Local N. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc., 838 F.3d 76, 84-85 (1st Cir. 2016) (finding that an increase in stock sales by some defendants did not prove scienter where other defendants did not engage in inconsistent trading patterns and complaint offered no reason why only certain defendants would know of negative study results).

Moreover, while it is true that Lucchino sold stock, he sold only fifteen percent of his shares, and at the same time received additional shares in the company as part of his compensation. So on the whole, he did not reduce his investment in the company by enough to allow for the strong inference of scienter claimed by plaintiffs. See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 761 (1st Cir. 2011) (noting that a court can "consider[] both shares and vested stock options in determining the significance of a sale" (citation omitted)). When a defendant keeps the "vast majority" of their holdings, the "strength of the insider trading allegations drifts toward the marginal end." Brennan v. Zafgen, Inc., 853 F.3d 606, 615-16 (1st Cir. 2017) (discussing an allegation that defendants had kept at least eighty-five percent of their stock holdings). We agree with plaintiffs that fifteen percent is not

a talismanic number below which any defendant is immune from claims of fraud. But we are also cognizant that "while . . . insider trading may be 'probative of scienter,' it is not sufficient to establish an inference of scienter on its own." In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d at 754 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 197-98 (1st Cir. 1999)).

Plaintiffs additionally point out that because FX-322 was Frequency's "core" product, defendants must have known about the problems with the Phase 2a study population. Certainly the importance of FX-322 to the company makes it reasonable to think that senior management paid attention to what they were told about the study, and would have been curious to know the results. Carbonite, 22 F. 4th at 9. But in this case, that importance provides no sufficient basis for determining when and what senior management were told, at least within the narrow timeframes at issue here. See id. at 9-10 (noting that the complaint must allege facts strongly suggesting that increased attention to a product exposed senior management to any incongruity); see also Auto. Indus. Pension Tr. Fund v. Textron Inc., 682 F.3d 34, 40 (1st Cir. 2012) (observing that plaintiff's allegation that "survival of the company [was] on the line" was "hardly the particularized showing required by the PSLRA").

Plaintiffs insist that the totality of the other evidence supports the conclusion that defendants must have known

about the flaws in the Phase 2a trial before they made the statements at issue. They argue that CW1's allegations coupled with Lucchino's stock sales "strongly suggest" that defendants' close attention to FX-322 "exposed them to information that either rendered their public statements false or necessarily invited further investigation." Carbonite, 22 F.4th at 9-10. But in Carbonite, the complaint alleged that employees had reported problems with the product before the false statements were made. Id. at 10. Moreover, none of the preceding product tests had been successful. Id. In contrast, previous trials of FX-322 had delivered promising results. And critically, none of CW1's allegations are specific as to whether defendants learned of testing discrepancies before they made the statements at issue. Plaintiffs' "core-operations" argument therefore hardly becomes more convincing when coupled only with unspecific claims about when and how defendants learned that the Phase 2a trial might have been contaminated. See Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151, 165 (1st Cir. 2019).

At base, plaintiffs fault the district court for failing to consider whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter." Tellabs, Inc., 551 U.S. at 323. Certainly while "'[e]ach individual fact about scienter may provide only a brushstroke,' . . . our obligation [is] to consider 'the resulting portrait.'" Vertex Pharms., Inc.,

838 F.3d at 81 (first alteration in original) (quoting In re Cabletron Sys., Inc., 311 F.3d 11, 40 (1st Cir. 2002)). At the same time plaintiffs cannot amalgamate a series of sketchy brushstrokes and call it a van Gogh. The PSLRA dictates that to survive a motion to dismiss, "[a]n inference of scienter" must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 40 (1st Cir. 2014) (quoting Tellabs, Inc., 551 U.S. at 324). Viewing the complaint in its totality, we do not conclude that it meets this standard. We accordingly affirm the district court's dismissal of the complaint on its merits.[1]

Finally, plaintiffs contend that they now have the benefit of additional and previously unavailable witnesses whose testimony can make clear that Frequency's senior officers knew of the Phase 2a study's flaw before making the challenged statements. However, any Rule 60 motion, as well as any Rule 15(a) motion, should be presented first to the district court after this appeal is concluded and the case remanded. We express no opinion at all concerning the disposition of any such motion.

[1] Because a section 20(a) claim is "derivative" of a section 10(b) claim, see Textron Inc., 682 F.3d at 36 n.2, it cannot stand where there is no underlying section 10(b) violation, ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 67-68 (1st Cir. 2008).

## III.

We therefore affirm the judgment of the district court.