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United States Court of Appeals, First Circuit.

Nadia SHASH, individually and on behalf of all others similarly situated; Amjad Khan, individually and on behalf of all others similarly situated, Plaintiffs, Appellants,
Victor D. Menashe, individually and on behalf of all others similarly situated, Plaintiff,
v.
BIOGEN, INC.; Michel Vounatsos; Alfred W. Sandrock, Jr.; Samantha Budd Haeberlein, Defendants, Appellees,
Jeffrey D. Capello; Michael R. McDonnell, Defendants.

No. 22-1773
|
October 11, 2023

**Synopsis**

**Background:** Investors brought putative class action against pharmaceutical company and executives alleging that they violated § 10(b) and Rule 10b(5) by making false statements and omissions about clinical-trial results for drug to treat Alzheimer's disease. Following agreed upon transfer of action, the United States District Court for the District of Massachusetts, Indira Talwani, J., 627 F.Supp.3d 84, granted defendants' motion to dismiss for failure to state a claim. Investors appealed.

**Holdings:** The Court of Appeals, Gelpí, Circuit Judge, held that:

investors plausibly alleged statement that all clinical-trial data was consistent with need to get higher dose was misleading;

investors plausibly alleged same statement was material;

investors sufficiently alleged facts giving rise to strong inference of scienter of contradictory subgroup data in connection with same statement;

investors failed to state securities fraud claim based on statements about drug's general efficacy;

investors plausibly alleged loss causation in connection with statement concerning need for higher dose; and

as a matter of apparent first impression, a gap in time separating a stock price drop from the corrective disclosure does not render loss causation allegations per se implausible.

Affirmed in part, reversed in part, vacated in part, and remanded.

**Procedural Posture(s):** On Appeal; Motion to Dismiss for Failure to State a Claim.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS [Hon. Indira Talwani, U.S. District Judge]

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Before Barron, Chief Judge, Howard and Gelpí, Circuit Judges.

**Opinion**

GELPÍ, Circuit Judge.

***1** Following a significant drop in Biogen Inc.'s stock price, Plaintiff-Appellant Nadia Shash and other investors (collectively, "investors") brought a securities fraud class action alleging that Defendants-Appellees [1] ("Defendants") violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Specifically, investors contend that Defendants concealed data that, if revealed, would have established that Defendants' statements about its Alzheimer's disease drug's clinical trials were misleading. Defendants moved to dismiss, and the district court granted the motion, concluding that investors failed to adequately allege a misleading statement or omission, scienter, and loss causation. For the reasons explained herein, we affirm the district court's dismissal of investors' securities fraud claims, except with respect to one

  

particular statement for which we conclude that investors' pleadings adequately stated a claim.

1 The Defendants are Biogen, Inc. ("Biogen") and three of Biogen's then-upper-level executives, Michel Vounatsos, Alfred W. Sandrock, Jr., and Samantha Budd Haeberlein.

## I. Background

When reviewing a motion to dismiss, we recount the underlying facts as alleged in the complaint, "supplemented by certain materials the [D]efendants filed in the district court in support of their motion to dismiss."[2] 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)). Our recitation refers to the investors' second amended complaint and omits any conclusory allegations. See Ponsa-Rabell v. Santander Sec. LLC, 35 F.4th 26, 30 n.2 (1st Cir. 2022).

2 Before the district court, investors moved to exclude certain documents offered by Defendants. Investors did not contest, however, the court's consideration of full transcripts of calls and presentation slides where Defendants made the allegedly misleading statements. Thus, we consider these exhibits when necessary to contextualize the statements at issue. See Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 32 (1st Cir. 2000).

### A. Facts

Biogen is a publicly traded biotechnology company headquartered in Cambridge, Massachusetts, that develops and manufactures products to treat a variety of diseases and disorders. This case revolves around Biogen's Alzheimer's disease treatment, aducanumab.

Alzheimer's disease is a neurodegenerative disease of the brain, characterized by the progressive loss of cognitive function. Although the progression of the disease is well understood, its cause remains unknown. A leading hypothesis theorizes that the protein amyloid beta builds up in the brain and forms into larger structures called plaques, which interfere with synaptic connections, resulting in loss of cognition and other symptoms.

Aducanumab is a monoclonal antibody that specifically targets aggregated amyloid beta. Biogen believed that aducanumab could slow the progression of Alzheimer's disease by removing the amyloid plaque present in patients' brains. Before Biogen could seek approval from the Food and Drug Administration ("FDA") to market the antibody, aducanumab had to go through a series of studies to establish its tolerability, safety, and efficacy. At issue here are the reported results of aducanumab's Phase III trials: ENGAGE and EMERGE.

***2** ENGAGE (Study 301) and EMERGE (Study 302) were identically designed, double-blinded, placebo-controlled studies that were conducted independently, with ENGAGE beginning one month ahead of EMERGE. Each study had three dosage arms: placebo, aducanumab low dose, and aducanumab high dose. Two-thirds of the studies' participants carried the APOE4 gene ("carriers"), which predisposes a carrier to developing both Alzheimer's disease and ARIA,[3] an aducanumab side effect. APOE4 carriers were equally distributed across the studies' three arms. While the studies were ongoing, Biogen amended the dosing protocol for carriers twice. The first amendment, Protocol Version 3 ("PV3"), allowed carriers to titrate (gradually increase) to their target dose following an ARIA event once their symptoms resolved.[4] The second amendment, Protocol Version 4 ("PV4"), increased the maximum high dose of aducanumab for carriers from 6 mg/kg to 10 mg/kg, meaning that, after the amendment, all high dose patients were titrated to 10 mg/kg regardless of carrier status.

3 ARIA is an acronym for Amyloid Related Imaging Abnormalities, which include fluid buildup in the brain and bleeding due to microhemorrhages.

4 Prior to PV3, patients who experienced ARIA could only resume treatment at the next lower dose once ARIA resolved. The amendment also allowed more patients to continue treatment by suspending dosing rather than discontinuing treatment permanently.

To test aducanumab's efficacy over the course of the studies, Biogen selected five assessment tools, which measured a patient's cognition and function, and used biomarker tracking and special imaging to measure amyloid plaque reduction

  

in patients' brains. [5] Patients were evaluated upon entering the study and then again at six months, twelve months, and eighteen months. The studies' protocol required an independent group to perform a futility analysis once 50% of the participants had the opportunity to complete the primary efficacy assessment at the end of eighteen months (Week 78). If the analysis showed that aducanumab was unlikely to prove effective, meaning that the studies had less than a 20% chance of meeting their primary endpoint, the studies were to be terminated early.

5 These assessments are referred to as clinical endpoints. The CDR-SB scale, which measures both cognition and function, was designated as the primary endpoint for both studies.

ENGAGE and EMERGE began in August 2015 and September 2015, respectively. The cutoff date for data used in the futility analysis was December 28, 2018; however, Biogen continued to collect data beyond that point. On March 21, 2019, Biogen publicly announced that the studies met the futility criteria and were being terminated. Subsequently, Biogen's stock price fell over 29%.

Following the termination of aducanumab's Phase III studies, Biogen conducted its own internal review of the clinical data, including the data collected in the interim between the futility cutoff and when the studies ended. Said review revealed that when ENGAGE and EMERGE were analyzed independently -- as opposed to together, with their data being pooled as the futility analysis called for -- EMERGE's high dose arm met the primary and secondary efficacy endpoints. Biogen shared this with the FDA and in June 2019 met with the agency to discuss pathways to approval for aducanumab. The end result was a collaborative Biogen/FDA working group dedicated to analyzing and understanding aducanumab's Phase III clinical data.

On October 22, 2019, [6] seven months after Biogen terminated the ENGAGE and EMERGE studies, Biogen announced, during a third-quarter earnings call, its belief that post hoc analysis (conducted after futility was announced) of the Phase III clinical data supported a regulatory filing for aducanumab. Specifically, Alfred W. Sandrock, Jr. (“Sandrock”), Biogen's then-Chief Medical Officer and Executive Vice President of Research and Development, told investors:

> Our primary learning from these data is that sufficient exposure to high dose aducanumab reduced clinical decline across multiple clinical endpoints. This reduction in clinical decline was statistically significant in EMERGE, and we believe that patients -– that the data from patients who achieved sufficient exposure to high dose aducanumab in ENGAGE support the findings of EMERGE. After consultation with the FDA, we believe that the totality of these data support a regulatory filing.

***3** He explained the changed perspective on aducanumab's futility as follows:

> [P]atients included in the futility analysis were those who had enrolled early in the trials and those early enrolling patients had a lower average exposure to aducanumab in large part due to two protocol amendments that occurred sometime after the start of the trials. These two protocol amendments were put in place precisely to enable more patients to reach high dose aducanumab, and for a longer duration. As a consequence, the larger dataset available after trial cessation included more patients with sufficient exposure to high dose aducanumab.

Sandrock also told investors “that there is a very sort of sharp dose response” and that “you have to get to high dose aducanumab” because “intermediate dosing at least in an 18-month trial is not enough.” During the same call, Samantha Budd Haeberlein (“Budd Haeberlein”), Biogen's then-Vice President of Clinical Development and later Senior Vice President/Head of the Neurodegeneration Development Unit, agreed with Sandrock and stated:

  

> Although the primary and secondary endpoints were not met in ENGAGE in post analysis, the subset of patients who received sufficient exposure to 10 milligram per kilogram aducanumab in this case, at least 10 doses of 10 milligram per kilogram showed similar results to the comparable population from EMERGE, in terms of both amyloid plaque reduction and reduced clinical decline on CDR-SB.... I think what we have learned clearly is that dose is very important, but that if individuals do receive 10 milligrams per kilogram then they do have an efficacious response.

The next day, during an interview on MSNBC, Michel Vounatsos ("Vounatsos"), Biogen's then-Chief Executive Officer, said the following:

> What we demonstrate is that [aducanumab] ... is able to erode and eliminate the plaque leading to the benefits we see in terms of cognition for the patients. It reduces basically the decline and we can see effects such as on memory orientation, language, but also functionally the ability to take care of oneself.

6 This is the first day of the class period for the current litigation.

After Biogen's positive public statements about aducanumab in October 2019, the company presented its topline Phase III results on December 5, 2019, at an Alzheimer's disease conference. During said presentation, Budd Haeberlein stated:

> To summarize, the aducanumab Phase III [topline] results. Following early termination based on futility, we analyzed a larger dataset. And this showed that in EMERGE, the high dose reduced clinical decline as measured by the primary and secondary endpoints. In ENGAGE, aducanumab did not reduce the clinical decline. In a post-hoc analysis, data from a subset of patients exposed to the high dose of aducanumab support the positive findings of EMERGE.

Biogen repeated these aducanumab findings on several subsequent occasions: during a question-and-answer session with investors on December 5, 2019; during a 2019 fourth-quarter earnings call on January 30, 2020; during a presentation of aducanumab's Phase III topline results on April 2, 2020; during a 2020 second-quarter earnings call on July 22, 2020; during a presentation of aducanumab's Phase III topline results at an Alzheimer's disease conference on July 29, 2020; and during a presentation of aducanumab's Phase III topline results at the Chinese National Conference on Neurology on September 19, 2020. During the 2020 second-quarter earnings call, Sandrock took his aducanumab statements further when he said, "[Y]ou really need to get to the higher dose" and "I think our data are all consistent with that."

***4** In July 2020, Biogen applied for FDA approval of aducanumab. The FDA convened an Advisory Committee, whose primary role generally is "to provide independent advice that will contribute to the quality of the agency's regulatory decision-making and lend credibility to the product review process." Given the controversy surrounding the clinical trials, stock analysts believed that the Advisory Committee's decision was critical for aducanumab's future.

Prior to the Advisory Committee meeting, Biogen and the FDA jointly prepared briefing materials, which the FDA published on its website on November 4, 2020. The materials laid out Biogen's position -- largely mirroring its public statements about aducanumab -- followed by the FDA's responses. The FDA's commentary was overwhelmingly favorable, stating, among other things, that "the applicant has provided substantial evidence of effectiveness to support approval." The notable exception was a report prepared by the FDA's statistical reviewer, Tristan Massie ("Massie"). The report's opening summary stated Massie's belief that "the

  

totality of the data does not seem to support the efficacy of the high dose" and that "there is no compelling substantial evidence of treatment effect or disease slowing and that another study is needed to confirm or deny the positive study and the negative study." The report went on to detail subgroup-level analyses supporting Massie's conclusions. [7]

7 Massie's report revealed, among other things, that clinical outcomes for high dose noncarriers, who received the greatest number of 10 mg/kg doses of aducanumab and experienced fewer treatment interruptions, were statistically insignificant when compared to placebo; that carriers achieved better clinical outcomes than noncarriers in EMERGE; that carriers had worse clinical outcomes following the PV4 dose increase; that, in both studies, high dose patients whose treatment was interrupted by ARIA had numerically better outcomes; that more high doses did not result in better clinical outcomes; and that there was no correlation between amyloid plaque reduction and clinical outcomes.

On November 4, 2020 -- the day the briefing materials were released -- Biogen's stock price closed at $355.63 a share. A day later, the stock price fell to $328.90 a share. On November 6, 2020, [8] trading in Biogen stock was halted while the Advisory Committee met to discuss aducanumab. After a full day of review, the Advisory Committee voted almost unanimously that it was unreasonable to consider EMERGE as "primary evidence of effectiveness of aducanumab for the treatment of Alzheimer's disease," even in light of the post hoc analyses from ENGAGE and support from an aducanumab Phase I study. The next trading day, November 9, 2020, Biogen's stock closed at $236.26 a share. The FDA ultimately approved aducanumab under an accelerated approval pathway in June 2021.

8 This is the last day of the class period for the pending litigation.

### B. Procedural History

Investors commenced the current class action seven days after the Advisory Committee meeting, alleging violations of section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), codified at 15 U.S.C. § 78j(b), as implemented by Securities and Exchange Commission ("SEC") Rule 10b-5, codified at 17 C.F.R. § 240.10b-5 ("section 10(b) claim"), and section 20(a) of the Exchange Act, codified at 15 U.S.C. § 78t(a) ("section 20(a) claim"). Specifically, investors claimed that Biogen made misleading statements about aducanumab's dose-response relationship and about the correlation between plaque removal and clinical improvement by concealing subgroup-level clinical data ("subgroup data") that demonstrated that Biogen's statements were false. [9] Following an agreed upon transfer to the District of Massachusetts, [10] Defendants moved to dismiss the investors' second amended complaint, claiming that investors failed to sufficiently plead a materially false or misleading statement or omission, scienter, loss causation, and reliance for their section 10(b) claim. [11] The district court held, in a detailed opinion, that the pleadings were lacking as to a misleading statement or omission, scienter, as well as loss causation, and allowed Defendants' motion to dismiss, extinguishing both of investors' securities fraud claims. This timely appeal followed.

9 Investors' complaint also claimed that Biogen made misleading statements about regional variations in aducanumab's clinical data and about the correlation of EMERGE's secondary clinical endpoints; however, those arguments are not pressed on appeal and are therefore waived. See Vargas-Colón v. Fundación Damas, Inc., 864 F.3d 14, 24 (1st Cir. 2017) (deeming waived arguments that a party fails to develop on appeal).

10 Investors originally filed their complaint in the United States District Court for the Central District of California. The case was transferred pursuant to 28 U.S.C. § 1404(a), which provides that "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented."

11 The Defendants also moved to dismiss investors' section 20(a) claim based on their assertion that the required underlying securities law violation -- investors' section 10(b) claim -- failed.

### II. Standard of Review

***5** "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state

a claim to relief that is plausible on its face.' " Mehta, 955 F.3d at 205 (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). In a securities case, the complaint must also satisfy the Private Securities Litigation Reform Act's ("PSLRA") heightened pleading requirements. Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214, 222 (1st Cir. 2022). We review de novo a Federal Rule of Civil Procedure 12(b)(6) dismissal. Id.

## III. Discussion

Given that investors' section 20(a) claim is dependent on the existence of an underlying securities violation, this appeal turns on whether investors adequately pled their section 10(b) claim. See Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151, 158 n.3 (1st Cir. 2019); Carbonite, Inc., 22 F.4th at 6.

"Section 10(b) of the Securities Exchange Act of 1934 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, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007) (alteration in original) (quoting § 78j(b)). SEC Rule 10b-5, which implements section 10(b), makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." § 240.10b–5.

Accordingly, plaintiffs asserting a section 10(b) claim "must adequately plead '(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.' " Thant, 43 F.4th at 222 (quoting In re Biogen Inc. Sec. Litig., 857 F.3d 34, 41 (1st Cir. 2017)). The first, second, and sixth requirements are at issue here: material misrepresentation or omission, scienter, and loss causation.

In addition to pleading the elements for a section 10(b) claim, the PSLRA requires that plaintiffs "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." Carbonite, Inc., 22 F.4th at 6 (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). The PSLRA further requires that a complaint "state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]," the second element of a section 10(b) claim. Id. at 9 (alteration in original) (quoting § 78u-4(b)(2)(A)). The PSLRA does not specify the pleading standard applicable to the other elements of a section 10(b) claim, such as loss causation, see Katyle v. Penn Nat'l Gaming, Inc., 637 F.3d 462, 471 n.5 (4th Cir. 2011); however, as we explain later, we need not decide that particular issue here. See infra note 15.

Before turning to the case at hand, we pause to chart our analytical course. One of Defendants' allegedly misleading statements -- "So consistent with the findings from ENGAGE and EMERGE, you really need to get to the higher dose. And I think our data are all consistent with that." -- stands out from the rest. As discussed, infra, we conclude that investors adequately alleged a section 10(b) claim as to this particular statement. Because the remainder of Defendants' allegedly misleading statements fail to clear the PSLRA's heightened pleading standard for scienter, we simply assume, without deciding, that those statements are materially misleading before proceeding to our scienter analysis. See Mehta, 955 F.3d at 207; In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744, 750 (1st Cir. 2016). We conclude our analysis by addressing investors' loss causation allegations. Having established these guideposts, we proceed to our analysis.

### A. Material Misrepresentation or Omission

***6** "To survive a motion to dismiss under the securities law, a complaint must adequately plead statements [or omissions] that were 'misleading as to a material fact.' " Thant, 43 F.4th at 222 (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011)). Thus, a violation requires "a false, or misleadingly omitted, statement of fact." Carbonite, Inc., 22 F.4th at 7. Here, the district court found, and the parties do not dispute, that the statements at issue constitute opinions. While the Supreme Court has distinguished opinions from statements of fact, Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 183, 135 S.Ct. 1318, 191 L.Ed.2d 253 (2015) ("[A] statement of fact ('the coffee is hot') expresses certainty about a thing, whereas a statement of opinion ('I think the coffee is hot') does not."), the Court has also explained that couching a statement in terms of an opinion, by using language like "I think" or "I believe," does not automatically render the statement not misleading, id. at 193, 135 S.Ct. 1318. See Carbonite, Inc., 22 F.4th at 7. "[A] reasonable investor may, depending on the circumstances, understand an opinion statement to convey facts about how the speaker has formed the opinion -- or, otherwise put, about the speaker's basis for holding that view." Omnicare, Inc., 575 U.S. at

188, 135 S.Ct. 1318; see Carbonite, Inc., 22 F.4th at 7 ("[A] statement in the form of an opinion ... may convey three facts: that the speaker has such a belief; that the belief fairly aligns with the facts known to the speaker; and ... that the speaker has made the type of inquiry that a reasonable investor would expect given the circumstances."). Thus, "if the real facts are otherwise, but not provided, the opinion statement will mislead its audience." Omnicare, Inc., 575 U.S. at 188, 135 S.Ct. 1318.

The statement that concerns us here is the following: "So consistent with the findings from ENGAGE and EMERGE, you really need to get to the higher dose. And I think our data are all consistent with that." (Emphasis added). We hereinafter refer to this remark as the "all data" statement. Per Carbonite, the "all data" statement plausibly conveyed three facts: that Sandrock genuinely believed all of Biogen's data was "consistent with" needing to get to high dose aducanumab to benefit clinically; that Sandrock's opinion "fairly align[ed] with the facts known" to him when he made the statement; and that Sandrock's opinion was informed by "the type of inquiry that a reasonable investor would expect given the circumstances." See 22 F.4th at 7. Investors point to certain subgroup data as evidence that Sandrock's "all data" statement did not "fairly align[ ]" with the facts known to Biogen at the time.

Specifically, investors allege that subgroup data revealed the following: noncarriers, who received high dose aducanumab from the start and who had fewer treatment interruptions, did not achieve better clinical outcomes, and, when compared to placebo, the benefit for this group was "virtually nil"; carriers, who received high dose aducanumab following PV4, did not experience better clinical outcomes after the dosing protocol change (in EMERGE, carriers' CDR-SB scores got slightly worse); and carriers in ENGAGE are the only subgroup who "did better" on high dose aducanumab. Investors contend that by failing to disclose this subgroup data, Defendants "omitted material information necessary to render [their] statement[ ] not misleading."[12] We agree. Taking these allegations as true, as we must on a motion to dismiss, Brennan v. Zafgen, Inc., 853 F.3d 606, 613 (1st Cir. 2017), the complaint plausibly alleges that not all of Biogen's data was "consistent with" "need[ing] to get to the higher dose" of aducanumab -- some patients did better on a lower dose and others experienced the same lack of clinical benefit whether they were on the higher dose or not. Thus, by failing to disclose the subgroup data, which would have contextualized their "all data" claim, the complaint plausibly alleges that Defendants' omission misled investors.

12 Defendants do not plead ignorance of said subgroup data, and, based on their statements, cited by investors in the complaint, it is reasonable to infer that they knew the results of subgroup analysis. For example, Defendants implicitly referred to the carrier subgroup when discussing PV4's impact on data, given that carriers were the only patient population impacted by PV4.

***7** Nevertheless, to survive a motion to dismiss, the misleading statement must also be material. See Thant, 43 F.4th at 222 (noting "neither factor alone is sufficient"). "A fact is material if it is substantially likely 'that the disclosure of the omitted [or misrepresented] fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.' " Carbonite, Inc., 22 F.4th at 8 (alteration in original) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231–32, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988)).

We conclude that investors met the materiality burden here as to the "all data" statement. Per investors, Defendants premised their explanation of why ENGAGE failed on the importance of reaching high dose aducanumab. And FDA approval of aducanumab was dependent on ENGAGE's data providing some support for EMERGE's positive results or, at the very least, being "understood well enough to be dismissible." It logically follows then that whether all of Biogen's data supported high dose aducanumab, or only some, was "a significant part of the mix of information [a reasonable investor would have] considered in evaluating [Biogen] as an investment," given that FDA approval of aducanumab had not yet occurred when the statement was made. See id. Thus, investors have adequately alleged that Sandrock's "all data" statement was a "material misrepresentation or omission." And, as explained supra, we simply assume arguendo that Defendants' remaining statements are misleading, insofar as they relate to aducanumab's general efficacy, and proceed to investors' next pleading hurdle, scienter.

### B. Scienter

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." Mehta, 955 F.3d at 206 (quoting Tellabs, Inc., 551 U.S. at 319, 127 S.Ct. 2499). "To establish

  

scienter, [a] plaintiff must 'show either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness.' " Carbonite, Inc., 22 F.4th at 8 (quoting Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 57 (1st Cir. 2018)). In this context, recklessness requires more than "simple, or even inexcusable, negligence"; rather, recklessness is "a highly unreasonable omission" amounting to "an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Mehta, 955 F.3d at 206 (quoting Brennan, 853 F.3d at 613).

To determine whether an inference of scienter is "strong," a court must engage in "a comparative evaluation" by weighing the "inferences urged by the plaintiff" against "competing inferences rationally drawn from the facts alleged." Tellabs, Inc., 551 U.S. at 314, 127 S.Ct. 2499. This evaluation must be done holistically, viewing the complaint in its entirety, as opposed to examining individual claims in isolation. Id. at 322-23, 127 S.Ct. 2499. Only where a reasonable person would deem the inference of scienter "cogent and at least as compelling as any opposing inference of nonfraudulent intent," will the pleading survive the PSLRA's exacting standard. Id. at 309, 314, 127 S.Ct. 2499 (explaining that an inference of scienter that is "merely plausible or reasonable" will not suffice). Having laid out some of the basic principles governing section 10(b) claims, we return to the case at hand, beginning with Sandrock's "all data" statement.

### 1. Sandrock's "All Data" Statement

***8** Having concluded, supra, that Sandrock's "all data" statement was misleading given the nature of the statement and the existence of at least some contradictory subgroup data, we next ask whether, as investors claim, Defendants' failure to disclose said subgroup data amounted to "an extreme departure from the standards of ordinary care ... which presents a danger of misleading buyers and sellers that is either known to the [Defendants] or is so obvious that the [Defendants] must have been aware of it." Mehta, 955 F.3d at 206 (quoting Brennan, 853 F.3d at 613). We conclude that it was such a departure.

Here, investors sufficiently alleged facts from which we can infer that Defendants were aware of the contradictory subgroup data and that their failure to disclose said data was "a highly unreasonable omission," giving rise to a strong inference of scienter. Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc., 838 F.3d 76, 80 (1st Cir. 2016) (quoting In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 77 (1st Cir. 2012)). The complaint plausibly claims that Biogen invested tremendous resources into carefully analyzing aducanumab's Phase III data. Moreover, Defendants repeatedly discussed PV4's impact on said data. Since PV4 only impacted carriers of the APOE4 gene, the logical inference is that Biogen analyzed aducanumab's data based on carrier/noncarrier subgroups and therefore knew that at least some data did not support high dose aducanumab. Given Defendants' awareness of the inconsistent subgroup data, it follows that Defendants must have known that their failure to disclose said data risked misleading investors precisely because of what the "all data" statement represented -- that their "data [was] all consistent with" "need[ing] to get to the higher dose" of aducanumab. (Emphasis added); see Mehta, 955 F.3d at 206 (quoting Brennan, 853 F.3d at 613).

It is also clear that Defendants' failure to disclose said subgroup data was "an extreme departure from the standards of ordinary care." Id. (quoting Brennan, 853 F.3d at 613). In December 2019, Defendants explained that they were presenting topline results but were intentionally withholding carrier/noncarrier subgroup data pending regulatory review of aducanumab and that Biogen "look[ed] forward to presenting all the data" "in due time." Months later, in July 2020, Sandrock made the "all data" statement, despite Defendants knowing that at least some contradictory subgroup data existed, which undermined said claim. Defendants then continued to withhold the subgroup data, despite publicly presenting aducanumab's topline results, until November 2020, when the Advisory Committee briefing materials were made public. Taken together, these allegations establish that Defendants knew they had subgroup data inconsistent with the "all data" statement and consciously chose to hold back only the data that was inconsistent with their public claim. Such conduct is akin to the "bad faith misrepresentation of scientific data" that the Third Circuit, in Alaska Electrical Pension Fund v. Pharmacia Corp., held established scienter. 554 F.3d 342, 344, 352 (3d Cir. 2009) (deciding that scienter was sufficiently pled where a company allegedly distorted its drug's clinical results by presenting only six months of favorable data from a thirteen-month study, without revealing that the dataset presented was incomplete). Thus, we similarly hold that investors adequately alleged scienter as to Sandrock's "all data" statement. See id. at 352.

  

**2. Defendants' Remaining Statements**

***9** As we explain, infra, we reach the opposite conclusion for Defendants' other statements pertaining to aducanumab's general efficacy, which we assume are misleading for purposes of our scienter analysis. Said statements could only be made with scienter if Defendants "knew or should have known that their failure to disclose [the subgroup data] 'present[ed] a danger of misleading buyers or sellers' " as to aducanumab's clinical effect. City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 758 (1st Cir. 2011) (second alteration in original) (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 198 (1st Cir. 1999)). Our review leads us to conclude that, even if Defendants were aware of the subgroup data, it is not evident or inferable from the complaint that Defendants knew or believed that said data undermined their statements about aducanumab's general efficacy.

Investors' complaint lacks allegations similar to those that we have previously found sufficient for scienter: "admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d at 751 (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012)). First, despite the resources Defendants allegedly committed to reviewing the clinical data, there is no allegation that Defendants -- or anyone else at Biogen for that matter -- knew that the subgroup data undermined aducanumab's effectiveness when Defendants made their public statements. See Maldonado v. Dominguez, 137 F.3d 1, 9-10 (1st Cir. 1998) (explaining that "scienter 'may not rest on a bare inference that a defendant "must have had" knowledge of the facts' " (quoting Barker v. Henderson, Franklin, Starnes & Holt, 797 F.2d 490, 497 (7th Cir. 1986))). We have previously remarked that a defendant's close attention to clinical data "is only helpful in establishing scienter if that close attention would have revealed an incongruity so glaring as to make the need for further inquiry obvious." Vertex Pharms., Inc., 838 F.3d at 82; see Metzler Asset Mgmt. GmbH, 928 F.3d at 162 (explaining that the fact that leadership monitored data does not alone create a strong inference of scienter). Here, we find it difficult to say that the "incongruity" between the subgroup data and Biogen's conclusion as to aducanumab's efficacy was "glaring" where it involved the interpretation of significant amounts of data through complex statistical analysis. [13]

13 Massie's report, which revealed the allegedly contradictory subgroup data, "contained almost one hundred pages of statistical analyses" and was "dense to the point of being impenetrable."

Second, the complaint does not claim that, at the time Biogen made the efficacy statements at issue, Biogen had been warned that the subgroup data undermined its conclusion about aducanumab's clinical effect. [14] In fact, the complaint is devoid of any allegation about how or when Defendants learned that the subgroup data potentially undermined their conclusion about aducanumab's efficacy. See In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d at 751 (explaining that the complaint failed to create a strong inference of scienter where it lacked specific allegations about when the defendant learned the facts at issue). Massie's report was published, along with the other Advisory Committee briefing material, on November 4, 2020 -- about a month and a half after the last allegedly misleading statement was made. And we have previously made clear that fraud cannot be established by hindsight. See id.

14 Investors' appellate briefs assert that Massie warned Biogen about his concerns, however, the complaint contains no such allegation, so "we do not consider this argument in assessing whether the complaint has stated a claim." See Vertex Pharms., Inc., 838 F.3d at 83-84 (setting aside an argument that the plaintiff raised only in their appellate brief when considering a failure-to-state-a-claim motion).

Investors ask us to take judicial notice of a congressional report detailing the contact between the FDA and Biogen, but, even if we were to do so, said report does little to move the needle. Per the report, the Division of Biometrics (Massie's group) "raised concerns about the analyses" and conveyed to their FDA counterparts and Biogen their belief that "substantial evidence of effectiveness was not met." Staff of H.R. Comm. on Oversight & Reform & Comm. on Energy & Commerce, 117th Cong., Rep. on The High Price of Aduhelm's Approval: An Investigation into FDA's Atypical Review Process and Biogen's Aggressive Launch Plans, at 20 n.80 (Dec. 2022). Even accepting these facts as true, we are still left to guess what specific concerns Massie's group raised and whether the basis for Massie's effectiveness conclusion was

> the subgroup data now at issue. Such "guesswork [is] inconsistent with the PSLRA['s] pleading standard." Vertex Pharms., Inc., 838 F.3d at 86.

***10** Notably, even if the Defendants were on notice of Massie's analyses at the time of their public statements, the complaint lacks any allegation that the Defendants honestly believed Massie's interpretation of the data over their own. See Vertex Pharms., Inc., 838 F.3d at 82 (concluding scienter inadequately pled, in part, because the complaint lacked allegations that the defendants disbelieved their publicly reported study results or viewed the results as contradictory); Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 41 (1st Cir. 2020) (explaining that "mere knowledge" of a fact is insufficient for scienter, absent an "allegation strongly implying that defendants had reason to believe their omission[ ] [of the fact] to be fraudulent"); Metzler Asset Mgmt. GmbH, 928 F.3d at 162 (concluding scienter insufficiently pled, in part, because the complaint's allegations did not reveal whether what was publicly said by defendants was "known by them to be misleading"). The fact that the FDA, minus Massie's group, agreed with Biogen's interpretation of the data -- while not a section 10(b) liability shield -- supports the inference that Biogen sincerely disbelieved Massie's interpretation of the subgroup data as undermining aducanumab's efficacy and that the failure to disclose said data in this context was not made with the requisite "intent to deceive, manipulate, or defraud." Mehta, 955 F.3d at 206 (quoting Tellabs, Inc., 551 U.S. at 319, 127 S.Ct. 2499).

Despite the lack of direct evidence of scienter as to Defendants' efficacy statements, see Brennan, 853 F.3d at 615 n.8, investors contend that the complaint still states facts from which we can infer that Biogen intentionally, or at least recklessly, withheld clinical data to mislead investors about aducanumab's clinical effect. We note that "where 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." Id. Cognizant that "[e]ach individual fact about scienter may provide only a brushstroke," we assess each asserted fact individually before considering "the resulting portrait" and weighing them cumulatively. Vertex Pharms., Inc., 838 F.3d at 81 (alteration in original) (quoting In re Cabletron Sys., Inc., 311 F.3d 11, 40 (1st Cir. 2002)).

First, investors -- citing Pharmacia Corp., 554 F.3d at 344-45, 352 -- allege that Biogen's selective reporting of aducanumab's clinical data contributes to a strong inference of scienter. While we agree with investors' reasoning as to the "all data" statement, we find the case less persuasive when applied to Defendants' general efficacy statements. Biogen explained, during its first public statement about aducanumab after announcing futility, that the "details of subgroups is something that will come ... later." Then, following the company's initial statements in October 2019, Biogen made clear that it was presenting only aducanumab's topline results publicly. While investors take issue with Biogen's decision not to release all patient-level data, unlike the defendant in Pharmacia Corp., Biogen was transparent about what data it was withholding from investors. And in contrast to the "all data" statement, the complaint lacks any indication that Defendants believed the subgroup data undermined their efficacy statements. In that regard, scienter cannot be inferred from the failure to disclose the subgroup results at the time the general statements about aducanumab's efficacy were made because Biogen's own analysis of the data is not fully discredited by the subgroup data. "[A] legitimate disagreement over scientific data does not give rise to a securities fraud claim ...." Id. at 352; see Carbonite, Inc., 22 F.4th at 9-10; Vertex Pharms., Inc., 838 F.3d at 81-83 (finding that the defendants' attention to a drug study would not have revealed any obvious incongruity in the publicly announced study results that turned out to be erroneous, in part, because the complaint did not allege that "scientists in general, much less those at Vertex, regarded the reported results as implausible"). In contrast, as explained supra, Biogen's "all data" statement does not amount to "a legitimate disagreement over scientific data," Pharmacia Corp., 554 F.3d at 352, as that statement is necessarily discredited by Biogen's knowledge that its subgroup data was not all consistent with needing to take a higher dose. Thus, we cannot conclude that Defendants' selective reporting of data amounted to a "bad faith misrepresentation" in the general efficacy context.

***11** Next, investors contend that Biogen's willingness to manipulate its statistical data makes it more likely that the company deliberately or recklessly withheld subgroup data. As support, investors point to the fact that Biogen tasked its statisticians with reviewing the failed Phase III studies to "salvage any data that could support aducanumab's approval." Additionally, investors allege that Biogen diverged from its prespecified analysis plan for evaluating the correlation between clinical outcomes and amyloid beta levels after unblinding the data. These acts, according to investors, allowed Biogen to conceal unfavorable data, which supports an inference of scienter.

  

The negative inference investors urge us to draw from Biogen's alleged data manipulation is undercut, however, by the fact that Biogen disclosed its use of post hoc analyses, which the FDA assisted with and endorsed, following the Phase III studies' failure. See Mehta, 955 F.3d at 208 (explaining that a company's informative disclosure cuts against an inference of scienter). In Biogen's very first statement about pursuing a regulatory filing for aducanumab, the company explained that its team had spent months analyzing the original and expanded dataset following the termination of the studies, including performing "exploratory analysis." Biogen reiterated that its conclusions were based on post hoc analyses on subsequent occasions as well. The mere fact that Biogen engaged in post hoc analysis cannot support a strong inference of scienter where Biogen did not mislead investors about the methodology employed. See Kleinman v. Elan Corp., 706 F.3d 145, 155-56 (2d Cir. 2013) (concluding that a plaintiff's objection to a pharmaceutical company's use of post hoc analysis as methodologically unsound does not give rise to a strong inference of scienter).

Investors next assert that Biogen's departure from its past reporting practices when it came to aducanumab's Phase III data contributes to a strong inference of scienter. Specifically, the complaint alleges that when Biogen presented the results of an earlier aducanumab study (Study 103), the company released the raw data, whereas they declined to do so with the Phase III results. Investors contend that this change gives rise to an inference that Biogen intentionally withheld the data because said data would have otherwise undercut its public statements about aducanumab's efficacy. They further claim that when Biogen stated, "We have nothing to hide," Biogen was falsely reassuring investors that it was withholding subgroup data for regulatory reasons only. This is investors' most compelling argument for scienter. Nevertheless, investors' allegations cannot be viewed in a vacuum and must be compared to the innocent inferences drawn from the same facts. See Tellabs, Inc., 551 U.S. at 314, 127 S.Ct. 2499.

We are not left to wonder why Biogen changed its reporting practices. The company explained its decision during a question-and-answer session with investors on December 5, 2019: "[L]ook, this will soon be under review at regulatory authorities. And so for that reason, we're very sensitive about what we want to present now." There is merit to Defendants' justification for withholding aducanumab's Phase III subgroup data. Unlike when Biogen released the Study 103 results, Biogen was facing an impending regulatory filing for "the first Alzheimer's disease therapy that does more than treat symptoms." And, as investors' complaint mentions, Biogen was not the only company developing Alzheimer's therapies. Further, crediting investors' theory implies that Biogen was more concerned about the public's reaction to the subgroup data than the FDA's, who had access to all of Biogen's data and was ultimately responsible for deciding aducanumab's fate. This defies common sense, even considering investors' claims about collusion between Biogen and the FDA, which we proceed to next. See Nguyen v. Endologix, Inc., 962 F.3d 405, 415 (9th Cir. 2020) (explaining that "the PSLRA neither allows nor requires us to check our disbelief at the door" in concluding that it was illogical for a company to promise FDA approval of a medical device that they knew was really "unapprovable"). Thus, we find the deceitful inference investors urge from Biogen's change in reporting practices less compelling when compared to the competing innocent explanation, particularly given the absence of any allegation that Defendants believed the subgroup data contradicted their efficacy statements.

***12** Investors also point to the many irregularities in aducanumab's FDA approval process as evidence of scienter. They note, for example, that Biogen and the FDA met or communicated almost daily for three months to analyze aducanumab's data, that Biogen and the FDA worked together to prepare "highly atypical joint briefing materials" for the Advisory Committee, that the FDA submitted leading questions designed to support approval to said committee, and that the FDA decided as early as June 2019 to push aducanumab through the approval process. Investors suggest, citing Aldridge v. A.T. Cross Corp., 284 F.3d 72 (1st Cir. 2002), that Biogen's willingness to bend rules makes it more likely that the company intentionally or recklessly concealed the subgroup data to mislead investors about aducanumab's clinical effect. It is not clear from the complaint, however, what rule investors allege Biogen violated. In fact, investors' irregularity allegations focus more on the FDA's conduct throughout the approval process than Biogen's and thus offer little meaningful insight into whether Defendants knew, or recklessly disregarded, that they would mislead investors about aducanumab's efficacy by failing to disclose the subgroup data.

Finally, investors ask us to infer that Biogen's leadership knew about the problematic subgroup data, or were reckless for not investigating it further, given that aducanumab's approval was "critical to Biogen's financial success." Per investors, the fact that aducanumab "would be the most profitable treatment

ever approved by the FDA" and was "make-or-break for the company" indicates that Biogen was paying close attention to the clinical data. But, as we explained supra, "close attention" is not enough where, as here, the "incongruity" between the subgroup data and Defendants' efficacy statements was not obvious. See Vertex Pharms., Inc., 838 F.3d at 82. Scienter requires more than "simple, or even inexcusable, negligence." Mehta, 955 F.3d at 206 (quoting Brennan, 853 F.3d at 613).

Viewed collectively, investors' allegations fail to raise a strong inference that Defendants intentionally or recklessly withheld subgroup data so as to mislead investors about aducanumab's efficacy. The complaint contains no allegation that Defendants knew the subgroup data undermined their efficacy statements; that they were warned that this was so prior to making said statements; that, even if Defendants were aware of Massie's analyses, they credited his conclusion as to aducanumab's clinical effect over their own; or that the inconsistency between the subgroup data and Defendants' efficacy statements was glaringly obvious to Defendants. Additionally, Defendants' explanation for their decision to withhold the subgroup data and public disclosures -- about what data was released and about their use of post hoc analyses -- undercut the negative inferences investors ask us to draw. Investors' scienter allegations with respect to Defendants' general efficacy statements are simply not as compelling as the opposing, innocent inferences drawn from the facts. See Tellabs, Inc., 551 U.S. at 314, 127 S.Ct. 2499.

Nevertheless, having concluded, supra, that investors' claim, pertaining to Sandrock's "all data" statement, cleared the first two section 10(b) pleading hurdles, we proceed to the final leg of our analysis.

### C. Loss Causation

To survive a Rule 12(b)(6) motion as to loss causation, a plaintiff must "provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005); see Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Sec. (USA) LLC, 752 F.3d 82, 86 (1st Cir. 2014) ("To prove loss causation, a plaintiff must show a sufficient connection between the fraudulent conduct and the losses suffered." (cleaned up)). [15] A plaintiff may do so by:

> (1) identifying a "corrective disclosure" (a release of information that reveals to the market the pertinent truth that was previously concealed or obscured by the company's fraud);
>
> (2) showing that the stock price dropped soon after the corrective disclosure; and
>
> (3) eliminating other possible explanations for this price drop, so that the factfinder can infer that it is more probable than not that it was the corrective disclosure -- as opposed to other possible depressive factors -- that caused at least a "substantial" amount of the price drop.

***13** CVS Caremark Corp., 716 F.3d at 237-38 (quoting FindWhat Inv. Grp. v. FindWhat.com, 658 F.3d 1282, 1311-12 (11th Cir. 2011)). Said allegations must be plausible, meaning "supported by 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' " Id. at 237 (quoting Iqbal, 556 U.S. at 678, 129 S.Ct. 1937). With this standard in mind, we proceed to investors' claimed chain of events.

15 While the precise pleading standard for loss causation remains unsettled in our circuit, we need not decide whether "a short and plain statement of the claim showing that the pleader is entitled to relief" suffices, Fed. R. Civ. P. 8(a)(2), or whether "a party must state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), because, here, investors' complaint satisfies either standard. See Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 239 n.6 (1st Cir. 2013).

Investors' complaint alleges the following: Massie's report was released on November 4, 2020, as part of the joint briefing material; the report, which revealed the truth about Biogen's prior fraudulent statements about aducanumab, was "dense," "written for ... world-renowned experts," followed 246 pages of effusive briefing material, and bore a "DRAFT" watermark; investors purchased Biogen stock on the same day that the report was released or, at most, a day later; the stock price did not drop immediately following the release of the report because, for the foregoing reasons, it took time for the market to appreciate the merits of Massie's report; the market's delayed reaction to the report is corroborated by analysts' coverage of the briefing materials; and Biogen's stock price began to drop on November 5, 2020, and "collapsed" on November 9, 2020, the next possible

  

trading day for Biogen stock, when the market fully grasped the significance of Massie's report. The district court declined to credit these allegations, asserting that "causation is not tied to when the market reacts to information, but rather when that information became available to the public." The court then concluded that investors failed to adequately plead loss causation because the alleged corrective disclosure, Massie's report, was published before investors purchased Biogen stock. Implicit in the district court's decision is the presumption that any hit to Biogen's stock price would have immediately followed the Defendants' corrective disclosure and thus was already accounted for in the stock's price when investors purchased shares. Finding no such per se rule in our circuit's loss causation precedent, we conclude otherwise.

At the outset, we pause to note that the district court did not reach the questions of whether the Massie report was a corrective disclosure, insofar as it "reveal[ed] to the market [a] pertinent truth that was previously concealed or obscured by [Biogen]'s [alleged] fraud," or whether investors sufficiently "eliminat[ed] other possible explanations for [Biogen stock's] price drop." Id. (quoting FindWhat.com, 658 F.3d at 1311-12). Because Defendants' arguments as to loss causation largely mirror the district court's decision -- focusing on the timing of the alleged corrective disclosure -- any argument that the Massie report did not otherwise meet the definition of a corrective disclosure by revealing new information to the market or that other "depressive factors" caused the stock price to drop are thus waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990). And because we find that investors' loss causation allegations plausibly indicate that Biogen's stock price dropped after Massie's report revealed the company's misstatements about aducanumab, our loss causation determination turns exclusively on whether a gap in time, between when said misstatements were exposed and the subsequent price drop, nevertheless renders the investors' theory of loss causation per se implausible.

***14** Having reviewed our circuit's loss causation precedent, we find nothing requiring that a stock's price must drop immediately following a corrective disclosure for loss causation to be sufficiently pled. Nor did the district court cite any support for this premise. Investors assert that our decision in In re Xcelera.com Securities Litigation, 430 F.3d 503 (1st Cir. 2005), stands for the proposition that markets may take more than one day to absorb information. But we disagree with their assessment of our holding there. [16] Nevertheless, precedent from other circuits, which we find persuasive, addresses delayed market reactions in the loss causation context.

16 In In re Xcelera.com Securities Litigation, while addressing the reliance element of a securities fraud claim, we credited plaintiffs' expert's event study, which showed "the effect of company-specific information over longer windows of two, three, and five days"; however, we did so "because Plaintiffs' event study capture[d] the same-day reaction of Xcelera's stock price to company-specific events." 430 F.3d at 513 n.11. While we went on to positively cite authority discussing marketplace cause-and-effect relationships over two-day windows, id., such was not essential to our holding. Thus, In re Xcelera.com Securities Litigation does not settle this matter as investors suggest.

The Fifth Circuit, discussing loss causation in Lormand v. US Unwired, Inc., explained that where a "disclosure was followed immediately by a stock price increase rather than a decrease," loss causation could still be adequately pled because "[t]he market could plausibly have had a delayed reaction" and "[t]he actual timing [of a loss] is a factual question," disputes over which are "not enough to dismiss a complaint that alleges a specific causal link." 565 F.3d 228, 267 n.33 (5th Cir. 2009). The Ninth Circuit held similarly, in In re Gilead Sciences Securities Litigation, when the court explained that "[a] limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff's theory of loss causation per se implausible." 536 F.3d 1049, 1058 (9th Cir. 2008); see also Mineworkers' Pension Scheme v. First Solar Inc., 881 F.3d 750, 754 (9th Cir. 2018) ("That a stock price drop comes immediately after the revelation of fraud can help to rule out alternative causes. But that sequence is not a condition of loss causation." (citations omitted)). The Tenth Circuit agreed in Nakkhumpun v. Taylor, 782 F.3d 1142, 1154 (10th Cir. 2015) (concluding that loss causation was adequately pled despite a "concern about the attenuated relationship between the false statement and materialization of the risk ... because the significance of intervening events[,] [if any existed,] created a fact issue that could not be resolved in a motion to dismiss under Rule 12(b)(6)"). And in Singer v. Reali, the Fourth Circuit concluded that plaintiffs had adequately alleged loss causation where the complaint stated that the company's stock price dropped on October 18, 2011, in part, because of a corrective disclosure revealed the day

  

prior in a Form 8-K filing. 883 F.3d 425, 447 (4th Cir. 2018). These cases are instructive.

Here, the issue of when Biogen's stock price actually dropped is a question of fact. See Lormand, 565 F.3d at 266 n.33. Given that such questions are not properly resolved by the court on a motion to dismiss, id.; Nakkhumpun, 782 F.3d at 1154, investors' allegations cannot be per se implausible simply because a gap in time separates the price drop from the corrective disclosure. Thus, dismissal of investors' complaint was not warranted where the allegations contained therein otherwise plausibly established that Biogen's stock price dropped after Massie's report revealed the company's misstatements about aducanumab. See CVS Caremark Corp., 716 F.3d at 242 (concluding that "allegations [we]re sufficiently plausible to foreclose dismissal" where they "indicate[d] that the drop in CVS Caremark's share price was causally related to its misstatements").

## IV. Conclusion

***15** For the foregoing reasons, we **REVERSE** the district court's dismissal of the section 10(b) and section 20(a)[17] claims predicated upon Sandrock's "all data" statement. We otherwise **AFFIRM** the dismissal of investors' remaining fraud claims. The case is remanded for further proceedings consistent with this opinion. No costs are awarded.

17 The district court dismissed the section 20(a) claim without analysis based upon its finding that investors' section 10(b) claim failed. As such, we vacate that dismissal insofar as it pertains to the "all data" statement. See In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d at 753 n.4.

**All Citations**

--- F.4th ----, 2023 WL 6617278

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