United States Court of Appeals
For the First Circuit

Nos. 15-2135, 16-1658

MARK A. CORBAN, individually and on behalf of all others similarly situated; STEVE FLEISCHMANN, individually and on behalf of all others similarly situated;

Plaintiffs, Appellants,

DANIEL BARADARIAN, individually and on behalf of all others similarly situated; BIJESH AMIN, individually and on behalf of all others similarly situated;

Plaintiffs,

v.

SAREPTA THERAPEUTICS, INC.; CHRIS GARABEDIAN; EDWARD KAYE,

Defendants, Appellees,

SANDESH MAHATME,

Defendant.

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

[Hon. Indira Talwani, U.S. District Judge]

Before

Kayatta, Circuit Judge,
Souter, Associate Justice,[*]
and Stahl, Circuit Judge.

[*] David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.

Stuart W. Emmons, with whom William B. Federman, Amanda B. Murphy, and Federman & Sherwood were on brief, for appellants.

Christopher G. Green, with whom Dalila Argaez Wendlandt, Justin G. Florence, Mark D. Vaughn, Alexia R. De Vincentis, and Ropes & Gray LLP were on brief, for appellees.

August 22, 2017

KAYATTA, **Circuit Judge**. The price of the publicly traded securities issued by Sarepta Therapeutics, Inc. dropped sixty-four percent when Sarepta announced that the Food and Drug Administration deemed premature Sarepta's application for approval of a novel gene therapy. Promptly thereafter, several shareholders brought this securities fraud class action against Sarepta as well as former and current Sarepta executives on behalf of those who bought Sarepta stock during the prior four months while Sarepta was expressing conditional optimism that the FDA would accept its application. The district court found that the plaintiffs failed to allege facts creating a strong inference that the defendants intentionally or recklessly deceived the investing public. We agree and affirm.

I.

A.

The district court dismissed the complaint after this action was consolidated and the pleading was once amended. The plaintiffs then brought a motion for leave to file another amended complaint, which the district court denied as futile. The plaintiffs thereafter brought a motion for relief under Rule 60(b)(2) of the Federal Rules of Civil Procedure proposing a fourth version of the complaint, and a motion for reconsideration under Rule 59(e) proposing yet a fifth version. The district court denied all of these motions for the sole reason that it found them

futile because none of the proposed pleadings sufficiently stated a claim under the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u–4(b).[1] Normally we apply a deferential standard of review to decisions denying amendment, relief from judgment, and reconsideration. Here, though, each ruling hinged on a single issue: the sufficiency of the pleading as a matter of law. Hence, our review is de novo. See Mills v. U.S. Bank, NA, 753 F.3d 47, 54 (1st Cir. 2014); Roger Edwards, LLC v. Fiddes & Son Ltd., 427 F.3d 129, 132 (1st Cir. 2005). Because the fifth version of the complaint is the most recent and most complete version of the pleading, we focus our analysis on that iteration and draw the following facts and reasonable inferences from it.

B.

Sarepta is a biopharmaceutical company that works to discover and develop gene therapies for the treatment of rare neuromuscular diseases, including Duchenne muscular dystrophy ("DMD"). DMD is a progressive childhood disease that affects

[1] The district court actually denied the motion for reconsideration through an electronic order that does not furnish the basis for the decision. Although "a short recitation of [the district court's] reasoning" would have been preferable, "this omission alone is not a basis for reversal" because "its reasons are apparent from the record." United States ex rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 10 (1st Cir. 2016). In any event, deeming the denial to have been for futility favors the plaintiffs, who not surprisingly urge us to so regard the order and to resolve the question of the complaint's sufficiency rather than vacating and remanding to the district court for a statement of reasons.

approximately 1 in 3500 boys worldwide. Caused by genetic mutations that hinder or halt production of dystrophin, an essential protein for muscle function, DMD leads to loss of muscle strength and ultimately to respiratory and cardiac failure. Few boys afflicted with this debilitating disease reach adulthood.

Sarepta's lead product candidate during the relevant time period was eteplirsen. Eteplirsen is designed to treat DMD by altering the transcription process to skip the genetic mutation. It thereby enables the body's production of truncated but functional dystrophin, the type of dystrophin associated with less severe forms of muscular dystrophy and longer life expectancies.

To market eteplirsen in the United States, Sarepta needed approval from the FDA. The approval process requires a sponsor like Sarepta to prepare and submit a new drug application ("NDA" or "application"). See 21 U.S.C. § 355(a). When the FDA receives an NDA, it "ma[kes] a threshold determination [whether] the NDA is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). If so, the FDA accepts the application for filing. Id. The agency then assesses the merits of the application, deciding whether to approve the drug. Id. § 314.101(f). Approval generally requires the application's sponsor to demonstrate the drug's clinical benefit. See 21 U.S.C. § 355(d). In certain instances, though, an accelerated approval program permits the FDA to review and approve "a product for a

serious or life-threatening disease or condition . . . upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit." Id. § 356(c)(1)(A). For example, even if a sponsor has not yet shown that a drug reduces the occurrence of stroke, the FDA might fast-track the drug upon a showing that it has a measurable effect on blood pressure. See U.S. Food & Drug Admin., FDA Facts: Biomarkers and Surrogate Endpoints, https://www.fda.gov/aboutfda/innovation/ucm512503.htm (last updated July 22, 2016).

Sarepta set its sights on accelerated FDA approval for eteplirsen, developing and conducting a series of clinical trials to investigate the drug's effect on two endpoints: (1) the percentage change in dystrophin-positive fibers in the patient's muscle, and (2) the distance the patient was able to walk in six minutes. The clinical trials most relevant to this litigation are Sarepta's Phase IIb clinical trials, Study 201 and Study 202. Study 201 enrolled twelve boys in a randomized, double-blind, placebo-controlled trial. Four boys received a placebo, another four received a lower dose of eteplirsen, and four more received a higher dose of the drug. After twenty-four weeks, Study 202 commenced. In this open-label extension, which was neither blind nor placebo-controlled, all twelve participants received the drug in one dosage or the other.

Pointing to the results of these trials, in March 2013, Sarepta informed investors that it would move toward filing an NDA. To that end, Sarepta met with FDA officials that month. During the meeting, the FDA expressed serious concerns regarding the way Sarepta proposed to analyze the results from the Phase IIb trials, cautioning that "the proposed analysis was unreasonable even for hypothesis generation." Sarepta relayed certain information about this meeting to analysts and investors during an April 15, 2013 conference call led by Chris Garabedian, President and Chief Executive Officer of Sarepta at the time, and Edward Kaye, then the company's Senior Vice President and Chief Medical Officer. Garabedian explained that the FDA had "not made a final decision"--and that it was "still too early to draw conclusions" about the FDA's stance--regarding Sarepta's proposed dystrophin endpoint for accelerated approval. He nonetheless conveyed optimism and a sense of positive momentum on this call, stating that the FDA was "approaching the question of [d]ystrophin as a surrogate that is reasonably likely to predict clinical benefit in the thoughtful manner we expected and is requesting more information." Garabedian struck a similar tone at a conference presentation on July 10, 2013.

Approximately two weeks later, on July 23, 2013, Sarepta again met with the FDA regarding eteplirsen. By this time, the FDA had reviewed additional information from Sarepta about its

data. The agency told Sarepta at the July meeting that it was "open to considering an NDA based on these data for filing," subject to a number of conditions. Sarepta quoted that language in a press release it issued the following day, which also stated that Sarepta planned to submit an NDA "in the first half of 2014 for the approval of eteplirsen." The press release went on to say that the FDA "requested additional information related to the methodology and verification of dystrophin quantification," and that the company believed it could address and incorporate the requests into its early 2014 submission. In calls with analysts, investors, and business reporters, Garabedian communicated "excite[ment]," stating that the company was "very encouraged by the FDA feedback" and hopeful that the agency "would accept [an NDA] for filing." He emphasized Sarepta's "belie[f] that dystrophin is a viable surrogate marker," characterizing the company's dystrophin analysis as "robust."

Notwithstanding Garabedian's sanguinity, the company cautioned in its communications that the exact timing of the NDA submission was unknown, that the agency did not yet endorse the dystrophin surrogate endpoint under the accelerated approval pathway, and that in any event "[a] filing would only indicate that the question [of the propriety of Sarepta's dystrophin surrogate endpoint] merits review." Investors apparently paid more attention to those caveats than to the news that the FDA was

open to considering an NDA based on Sarepta's Phase IIb trial data, as Sarepta's stock price dropped nineteen percent on July 24 from its closing price the day before. Nevertheless, as we will describe in greater detail, the plaintiffs contend that Sarepta's July 24 communications were misleadingly rosy and selectively omitted further detail that would have better conveyed a picture of a highly dubious FDA. The plaintiffs therefore point to July 24, 2013, as the beginning of the time period during which class members were defrauded.

During the ensuing months leading up to the November 2013 stock drop, the defendants made several additional comments challenged by the plaintiffs. For example, Garabedian heralded Sarepta's progress toward approval as "a tremendous achievement," described the company's data set as "compelling and favorable," and characterized the FDA's feedback as "particularly encouraging because it recognizes that our Phase IIb study data set is sufficient for the FDA to consider a filing." At another presentation, he called the FDA's response at the July meeting the "type of information that every company hopes for." He subsequently described Sarepta's dystrophin analysis as "a very rigorous, measured approach" which "produced the most robust [dystrophin] data set of any [dystrophin]-producing technology" and was not "questioned or challenged [by the FDA] in terms of [Sarepta's] method for quantifying [dystrophin]." And he opined

that the FDA's request for additional muscle biopsies of the study participants "was not an indication of the lack of strength of [Sarepta's] current biopsy analysis and data."

At the end of September 2013, a competing drug candidate for the treatment of DMD "total[ly] fail[ed]" during a Phase III trial notwithstanding promising Phase II results. Drisapersen, developed by Prosena and GlaxoSmithKline, relied on the "same mechanism of action" as eteplirsen. It had achieved "the coveted 'Breakthrough Designation' from [the] FDA" on account of "its preliminary efficacy and potential." Yet in its "pivotal Phase III trial," it "failed to meet its primary endpoint . . . and all secondary endpoints." This news initially boosted Sarepta stock, as it "essentially g[ave] the entire DMD market to eteplirsen." Yet some investors predicted that drisapersen's failure spelled trouble for Sarepta. Such trouble came to pass on November 12, 2013, when Sarepta divulged the FDA's most recent guidance: Citing the drisapersen failure, the FDA stated that it viewed "an NDA filing for eteplirsen as premature." This news precipitated a sixty-four percent plummet in Sarepta's stock price, and the plaintiffs say it revealed that the defendants' representations since late July had been fraudulent.

After Sarepta announced the FDA's judgment that a filing was premature, the dialogue between Sarepta and the FDA continued. Public disclosures about their back and forth were largely one-

sided: As the FDA later explained, "[b]ecause of laws governing trade secret[s], [the] FDA is generally unable to provide any information to the public about its finding regarding drugs under development and is unable to comment about information provided by the drug developer." On a few occasions, however, FDA officials made public statements about concerns they had communicated to Sarepta (without always specifying when those communications occurred). Sarepta ultimately submitted its NDA in June 2015. The FDA accepted the NDA for filing on August 25, 2015, and it granted accelerated approval for eteplirsen on September 19, 2016. By that time, this litigation was well underway.

C.

Two and a half months after the November stock drop, the plaintiffs filed this putative class action complaint in which they seek relief on behalf of all those who acquired Sarepta stock between July 24, 2013 and November 11, 2013 (the "class period"). According to the relevant complaint, Sarepta and its top executives perpetrated securities fraud under section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. § 78j(b), and the Securities and Exchange Commission's Rule 10b–5, 17 C.F.R. § 240.10b–5. The complaint also charges the individual defendants with liability for the alleged securities fraud under section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a). The complaint avers that the defendants overstated the significance of Sarepta's eteplirsen

data and exaggerated the likelihood that the FDA would accept an NDA for filing, thereby deceiving the investing public and causing the purchase of Sarepta securities at inflated prices.

II.

A.

"To successfully state a securities fraud claim under section 10(b) and Rule 10b-5, a plaintiff must adequately allege, among other things, scienter." Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76, 80 (1st Cir. 2016). Adequately alleging this mental state, which "embrac[es] intent to deceive, manipulate, or defraud," Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)), requires the plaintiff to plead "either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness," id. (citing Greebel v. FTP Software, Inc., 194 F.3d 185, 198-201 (1st Cir. 1999)). That 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." In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 77 (1st Cir. 2012) (quoting Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 649 F.3d 5, 20 (1st Cir. 2011)). Under this strict

recklessness standard, "simple, or even inexcusable negligence" does not suffice. Id. (quoting Miss. Pub. Emps.' Ret. Sys., 649 F.3d at 20).

To decide whether the complaint adequately alleges scienter, "we eschew the ordinary standards of Federal Rule of Civil Procedure 8(a)(2)," Vertex, 838 F.3d at 81, and instead apply the "[e]xacting pleading requirements" imposed by Congress in the PSLRA. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007). "Under the PSLRA's heightened pleading instructions, any private securities complaint alleging that the defendant made a false or misleading statement must . . . 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Id. at 321 (quoting 15 U.S.C. § 78u–4(b)(2)). Although "Congress left the key term 'strong inference' undefined," id. at 314, the Supreme Court has explained that our inquiry is comparative: We must determine whether "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 324.

B.

1.

The complaint focuses much on Sarepta's reports regarding its July 23 meeting with the FDA, including the company's July 24 press release and related comments by its officers.

According to the complaint, these communications constitute the opening salvos of fraud because Sarepta disclosed too little of what FDA officials said at the July and March meetings, and painted too rosy a picture of their reaction to Sarepta's data. The plaintiffs point to statements by Garabedian that he was "encouraged by the feedback from the FDA," that he believed "that data from [Sarepta's] ongoing clinical study . . . will be sufficient for an NDA filing," and that the FDA indicated that it was "open to considering an NDA filing based on the data [Sarepta had] shared with [the FDA] to date." These and similar statements were misleading, the plaintiffs say, because FDA officials also voiced "a number of concerns" to be addressed prior to filing, and articulated "strong reservations" about the type of data upon which Sarepta was relying.

The challenged statements that mark the beginning of the class period provide poor material for building a fraud claim. They convey opinion more than fact. And while opinion that implies false facts may nonetheless suffice, see In re Credit Suisse First Bos. Corp., 431 F.3d 36, 47 (1st Cir. 2005) ("[A] statement of opinion may be considered factual . . . as a statement about the subject matter underlying the opinion."), overruled on other grounds by Tellabs, Inc., 551 U.S. 308, these opinions came replete with caveats. Sarepta made clear that the FDA "requested additional information related to the methodology and verification

of dystrophin quantification" and "would not commit to declaring dystrophin an acceptable surrogate endpoint," and that a decision to allow the filing of an NDA "would not indicate that [the FDA had] accepted dystrophin expression as a biomarker reasonably likely to predict clinical benefit." Garabedian accurately reported that the FDA declined to offer "any guarantee or assurance that an NDA submission would be acceptable for filing." After this mix of optimism and caution was communicated to investors on July 24, Sarepta's stock dropped nineteen percent.

Three weeks later, the company further reminded investors that it had been trying to convince the FDA that its method for quantifying dystrophin was acceptable and preferable. And Kaye acknowledged that the company's data set was "limited." Even if these and other caveats could have been more fulsome, they cut against the inference of scienter. See Geffon v. Micrion Corp., 249 F.3d 29, 37 (1st Cir. 2001) (finding insufficient evidence of scienter where company "sought to provide investors with adequate warnings," even though "[p]erhaps [the company] could have provided still more information about the specifics"). At worst, there was positive spin that put more emphasis in tone and presentation on the real signs of forward movement with the NDA than it did on causes for wondering if the journey would prove successful.

Nor did the class period end in any manner that supports an inference of fraud. Progress toward realizing an optimistic, albeit caveated, prediction markedly slowed, due at least in part to a material development that occurred well after the prediction was proffered--i.e., the failure of the GlaxoSmithKline and Prosena product, drisapersen. While the November announcement demonstrated that the caveated hopes voiced in the time since the July meeting had proven overly optimistic, there is nothing in this chronology to suggest that Sarepta knew prior to November that its efforts would suffer a setback at that time. See Suna v. Bailey Corp., 107 F.3d 64, 68 (1st Cir. 1997) ("[O]ptimistic predictions about the future that prove to be off the mark . . . are immunized unless plaintiffs meet their burden of demonstrating intentional deception." (quoting Serabian v. Amoskeag Bank Shares, Inc., 24 F.3d 357, 361 (1st Cir. 1994), abrogated on other grounds by Greebel, 194 F.3d at 196-97)). Sarepta's hopes, moreover, ultimately proved correct, although on a much slower schedule. The company submitted its NDA in June 2015, and the FDA accepted the NDA for filing in August 2015. In summary, the plaintiffs mine little more than opinions, predictions, caveats, and cramped disclosures in the events bookending the class period.

2.

That leaves the plaintiffs' arguments regarding a pair of statements made by Garabedian in the middle of the class period.

First, on August 15, 2013, Garabedian stated that Sarepta had shared its dystrophin data with the FDA (which is not disputed) and that the data "was not something that was questioned or challenged in terms of [Sarepta's] method for quantifying." Second, on September 9, 2013, he said in reference to the FDA's proposal to conduct additional biopsies of the Phase IIb study participants that the proposal "was not an indication of the lack of strength of [Sarepta's] current biopsy analysis and data."[2] According to the plaintiffs, these statements were "objectively and knowingly false" because the FDA had communicated concerns about the data analysis to Sarepta and Garabedian had knowledge of such communications when he spoke. Specifically, the plaintiffs point to March 2013 communications from the FDA expressing the agency's skepticism about Sarepta's quantification of dystrophin.

Chronology defeats this argument. The March 2013 communications predated Garabedian's August and September statements by several months. In the intervening period, Sarepta submitted additional data to the FDA in compliance with FDA requests, and the agency's skepticism was fairly viewed as having

[2] These are the only two alleged misstatements after the beginning and before the end of the class period that the plaintiffs discuss in support of their argument that the defendants could not have acted negligently and must have acted intentionally or recklessly. They are, accordingly, the only two we consider. See Rodríguez v. Municipality of San Juan, 659 F.3d 168, 175 (1st Cir. 2011).

diminished. As the complaint's allegations show, it was after reviewing the additional data that the FDA declared in July 2013 that it was "open to considering an NDA based on these data for filing." There is nothing in the complaint's allegations to indicate that the strength of the concerns expressed by the FDA in March 2013 persisted or that Garabedian understood the force of those concerns to have survived additional data submissions (much less the later and significantly more specific feedback provided to Sarepta at the July 2013 meeting).

Perhaps sensing this flaw in the timeline, the plaintiffs offer a second reason why Garabedian's statements were "objectively and knowingly false." They claim that the FDA told Sarepta at the July 23 meeting that it doubted the validity of Sarepta's method for quantifying dystrophin. To support this claim, they rely on the FDA's expression of concern that there was possible bias in the dystrophin analysis. This perception of possible bias was based not on any specific indication or allegation of bias, but rather on the general observation that "all muscle biopsies were obtained and processed by a single technician at a single study center." Hence, the FDA felt that another analysis by an independent laboratory was advisable.[3] This

[3] The FDA's suggestion had to do with confirming existing data, rather than generating additional data. For that reason, we see no logical connection between it and Garabedian's September 9, 2013 statement about the FDA's proposal to conduct additional

is far from evidence that the FDA "questioned or challenged" Sarepta's data due to the company's "method for quantifying." At most, it demonstrates that an undifferentiated fear about the latent risk of bias led the FDA to suggest a cautious approach: confirming the results at an independent laboratory. Concerns about reliability are not the same as concerns about methodology, and the plaintiffs' efforts to collapse these concepts in order to demonstrate scienter fall flat. Finally, even if Garabedian's statements may have been misleading (an issue we need not decide), the allegations cited by the plaintiffs do not adequately plead that he intentionally or recklessly misled.

The defendants had no legal obligation to loop the public into each detail of every communication with the FDA. "[M]ere possession of . . . nonpublic information does not create a duty to disclose it," In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d at 74 (first alteration in original) (quoting Hill v. Gozani, 638 F.3d 40, 57 (1st Cir. 2011)), even when that information is "material"--i.e., substantially likely to be viewed by a reasonable investor as "significantly altering the total mix of information made available," id. (citing City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d

biopsies of the Phase IIb study participants. We therefore understand the plaintiffs to offer the FDA's July 2013 concerns about bias only as evidence that Garabedian's August 15, 2013 statement was knowingly false.

751, 756 (1st Cir. 2011)). Of course, a company may not intentionally or recklessly omit facts without which its statements become misleading. Id.; see also 17 C.F.R. § 240.10b-5 (making it unlawful 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"). But simply pointing us to omitted details, as the plaintiffs have done, and failing to explain how the omitted details rendered the particular disclosures misleading, misses the mark. That the defendants neglected to mention specific factors (many of them intricate and technical) contributing to the FDA's position, while nonetheless faithfully representing that position (indeed quoting directly from FDA sources at times), strikes us as more consistent with negligence than reckless or intentional concealment.

In advocating otherwise, the plaintiffs point to Zak v. Chelsea Therapeutics International, Ltd., 780 F.3d 597 (4th Cir. 2015). In Zak, a split panel of the Fourth Circuit vacated the district court's decision that the complaint failed to adequately plead scienter. Id. at 611. The court announced a narrow holding and emphasized that "the scienter inquiry necessarily involves consideration of the facts and of the nature of the alleged omissions or misleading statements within the context of the statements that a defendant affirmatively made." Id. The defendants in Zak had allegedly buried the lede, claiming that the

FDA had "agreed" that the company's new drug application could be submitted based on data from a single study and would not require additional efficacy studies, when in fact FDA officials had told the company "that a single successful study typically was not sufficient to support approval of a new drug." Id. at 602. Even more egregiously, the defendants--while they possessed, but before they made public, an FDA briefing document including recommendations against approval--issued a press release that failed to disclose those recommendations and instead falsely represented the briefing document as surfacing only "lines of inquiry." Id. at 603. In these respects, Zak is less like this case and more like Schueneman v. Arena Pharmaceuticals, Inc., another out-of-circuit decision cited by the plaintiffs in their briefing that is readily distinguishable. See 840 F.3d 698, 702, 708 (9th Cir. 2016) (finding that plaintiff adequately pled scienter where company reported "favorable results on everything" from animal studies and conveyed optimism about FDA approval while concealing strong indications that drug caused cancer in rats).

3.

That brings us to the plaintiffs' argument that Sarepta had a motive to lie, and that its motive supports an inference of scienter. The plaintiffs point to allegations about the company's July 2013 "At the Market" offering, which allowed Sarepta to sell up to $125 million of common stock at market price, as evidence of

motive. The complaint quotes the company's announcement that it "intend[ed] to use any proceeds from this offering for general corporate purposes," some related to eteplirsen and some not. According to the complaint, "[h]ad the market been aware of these undisclosed facts, investors would not have been so willing to participate in the [at-the-market] offering, at least not at the prices they paid." Drawing on these allegations, the plaintiffs argue that the offering provides strong evidence of motive, and therefore scienter, because the defendants "needed the offering to provide Sarepta essential funding."

"[T]he usual concern by executives to improve financial results" does not support an inference of scienter. In re Cabletron Sys., Inc., 311 F.3d 11, 39 (1st Cir. 2002); see also Greebel, 194 F.3d at 197 ("[C]atch-all allegations that defendants stood to benefit from wrongdoing . . . are [not] sufficient." (third alteration in original) (quoting In re Advanta Corp. Sec. Litig., 180 F.3d 525, 535 (3d Cir. 1999))). We require something more than the ever-present desire to improve results, such as allegations that "the very survival of the company w[as] on the line." In re Cabletron Sys., Inc., 311 F.3d at 39. The complaint lacks such allegations, noting only that Sarepta depended heavily on financing activities for capital. Contrary to the district

court cases cited by the plaintiffs,[4] where the companies' finances were in dire straits, the complaint alleges that "Sarepta had $156.2 million in cash and cash equivalents on its balance sheet," and "$80 million in working capital," when it launched the July 2013 at-the-market offering. Lacking are any allegations suggesting that such capital was insufficient for continued operations, much less that Sarepta would shutter its doors unless it padded earnings by deceiving investors.

Beyond the financial motive, the plaintiffs say, Sarepta had reason to spark false hope: It catalyzed families and advocates of boys suffering from DMD to pressure the FDA for accelerated approval. The plaintiffs point to remarks by various FDA officials regarding "[g]reat hope" and "considerable public attention" resulting from Sarepta's teasers about trial results.

[4] In In re Ibis Technology Securities Litigation, the district court found sufficient allegations of scienter in part because the complaint averred that a contemporaneous stock offering "was necessary to ensure that [the company] would not run out of cash and could fund ongoing operations." 422 F. Supp. 2d 294, 317 (D. Mass. 2006). And in Frater v. Hemispherx Biopharma, Inc., the district court held that scienter was adequately pleaded in part because the complaint alleged that the company "was . . . sufficiently short on cash at the time of the alleged misrepresentations that it could not afford to finance an additional clinical trial as the FDA had recommended." 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014). Although the complaint in this case includes allegations that Sarepta limited the size of its Phase IIb trials because it could not afford larger trials, the complaint lacks allegations that the company's financial condition at the time of the alleged misrepresentations was the same as, or worse than, the company's financial condition when it undertook the Phase IIb trials.

But the complaint does not allege that the defendants predicted or intended this result ex ante. After all, "considerable public attention" also means closer scrutiny. And given that outside pressure on the FDA plays no clear or generally acknowledged role in the agency's closely regulated process, as the complaint's allegations themselves reflect, it seems a stretch to infer that the defendants risked closer scrutiny simply to apply indirect pressure on a regulator's data-driven decisionmaking process.

When we consider the totality of the complaint's allegations, and measure the malicious inference against the innocent ones, we do not find "the malicious inference [to be] at least as compelling as any opposing innocent inference." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009) (citing Tellabs, Inc., 551 U.S. at 323)). Sarepta, a biopharmaceutical company navigating the uncertain terrain of accelerated approval for a gene therapy, was energized by clinical trial data, which it shared with the FDA. In the ensuing dialogue between the company and the agency, the initially unwelcoming agency cracked open the door to a possible approval by stating a willingness to consider a new drug application for the therapy while cautioning the company about the importance of more and better data for accelerated approval. The company shared this obviously good news about the FDA's new receptiveness to possible acceptance of a filing while conveying enough caveats so that the

stock price actually dropped. As the company moved toward filing for regulatory approval, a competitor drug candidate with the same mechanism posted disappointing results, and the FDA decided that a new drug application for the company's therapy would be premature, causing a more substantial drop in stock price. The only plausible motive for fraud identified by the plaintiffs is revenue generation, which falls short of pleading a cogent inference of scienter that can carry the day here. More plausible is the opposing innocent inference that the defendants, perhaps negligently, waxed too optimistically about the FDA's expression of a willingness to consider an NDA for eteplirsen while emphasizing too little the FDA's reservations about such an application. This is simply a case in which the complaint focuses too much on nuance rather than false facts or material omissions to support the necessary strong inference of scienter. We therefore affirm dismissal of the section 10(b) and Rule 10b–5 claims as well as the derivative section 20(a) claims.[5]

[5] The plaintiffs have filed two separate appeals from rulings of the district court. The first appeal challenges a ruling that amendment would be futile due to insufficient allegations in the proposed second amended complaint of falsity and materiality. We need not address the sufficiency of allegations as to those elements. The second amended complaint contained even fewer allegations of scienter than its successors, and so our decision today that the most recent and most complete version of the complaint lacks sufficient allegations of scienter resolves both appeals.

III.

Notwithstanding five tries to get it right, the plaintiffs have failed to satisfy the requisite pleading standards. We reject the plaintiffs' appeals and **affirm** the district court's dismissal of this action.