UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

Rulings by summary order do not have precedential effect. Citation to a summary order filed on or after January 1, 2007, is permitted and is governed by Federal Rule of Appellate Procedure 32.1 and this Court's Local Rule 32.1.1. When citing a summary order in a document filed with this Court, a party must cite either the Federal Appendix or an electronic database (with the notation "summary order"). A party citing a summary order must serve a copy of it on any party not represented by counsel.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 16th day of December, two thousand twenty-one.

PRESENT: JOSÉ A. CABRANES,
RAYMOND J. LOHIER, JR.,
BETH ROBINSON,
Circuit Judges.

GEORGE LEHMANN, INSURED BENEFIT PLANS, INC.,

Plaintiffs-Appellants,

20-4185-cv

JEEVESH KHANNA, individually and on behalf of all others similarly situated,

Plaintiff,

v.

OHR PHARMACEUTICAL, INC., JASON SLAKTER, SAM BACKENROTH, IRACH TARAPOREWALA,

Defendants-Appellees.

FOR PLAINTIFFS-APPELLANTS: Richard W. Gonnello (Megan M. Remmel, *on the brief*), Faruqi & Faruqi, LLP, New York, NY.

FOR DEFENDANTS-APPELLEES: Aurora Cassirer (Misha Tseytlin, Mary Weeks, *on the brief*), Troutman Pepper Hamilton Sanders LLP, New York, NY.

Appeal from an order of the United States District Court for the Southern District of New York (Loretta A. Preska, *Judge*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the November 16, 2020, order of the District Court be and hereby is **AFFIRMED**.

George Lehmann and Insured Benefit Plans, Inc. ("Plaintiffs") bring this putative class action against Ohr Pharmaceutical Inc. ("Ohr") and several of its officers (together, "Defendants"). Plaintiffs allege that Defendants committed securities fraud under § 10(b) of the Securities Exchange Act of 1934 (the "1934 Act"), 15 U.S.C. § 78j(b), Rule 10b-5, 17 C.F.R. § 240.10b-5, and § 20(a) of the 1934 Act, 15 U.S.C. § 78t(a). Specifically, Plaintiffs claim that Defendants made misleading statements about the result of a clinical trial evaluating Ohr's drug Squalamine.

The clinical trial in question evaluated whether Squalamine combined with FDA-approved Lucentis would treat "wet" age-related macular degeneration better than Lucentis used by itself. Defendants reported better results for patients receiving Squalamine and Lucentis together than for patients receiving Lucentis alone. Plaintiffs allege that the patients receiving Lucentis alone showed anomalously poor results compared to patients enrolled in prior studies of Lucentis, and that this caused the report of the trial results to exaggerate the benefit of Squalamine. Plaintiffs claim that Defendants, who recognized or should have recognized this anomaly, made false or misleading statements regarding Squalamine's efficacy and the consistency of the Lucentis-only control group results with prior studies of Lucentis as a monotherapy for "wet" age-related macular degeneration patients.

This case is before us for the second time. The first time, we affirmed the District Court's dismissal of the complaint for failure to state a claim upon which relief can be granted, and remanded for the District Court to "determine on the record whether to grant Plaintiffs leave to file a second amended complaint." *Lehmann v. Ohr Pharm., Inc.* (*Lehmann I*), 830 F. App'x 349, 354 (2d Cir. 2020). On remand, Plaintiffs filed pre-motion letters, which the District Court construed collectively as a motion for leave to amend. The District Court denied this motion as futile, and Plaintiffs now appeal. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

While district courts should "freely give leave [to amend] when justice so requires," Fed. R. Civ. P. 15(a)(2), they need not do so where amendment would be futile, *In re Trib. Co. Fraudulent Conv. Litig.*, 10 F.4th 147, 175 (2d Cir. 2021). A finding of futility is a legal conclusion, which we review *de novo*, *id.* at 159, applying the same standard as for a motion to dismiss, *IBEW Loc. Union*

No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC, 783 F.3d 383, 389 (2d Cir. 2015).

We reject Plaintiffs' procedural objection. By ruling on the merits of the arguments presented in Plaintiffs' letter requesting permission to file a motion for leave to amend, the District Court did not improperly prevent Plaintiffs from filing a motion to amend. The District Court's actions were consistent with its "inherent authority to manage [its] docket[ ] . . . with a view toward the efficient and expedient resolution of cases." *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016).[1] We have previously found that so long as a plaintiff's letters are sufficiently detailed and plaintiffs are given an opportunity to respond to a defendant's counterarguments, a district court does not abuse its discretion when it opts to construe plaintiffs' letters as a motion. *See, e.g.*, *In re Best Payphones, Inc.*, 450 F. App'x 8, 15 (2d Cir. 2011) (non-precedential summary order). Here, Plaintiffs' letters sufficiently explained their revised theory, which the District Court considered on the merits. And Plaintiffs were not prejudiced, as they remain entitled to *de novo* review of the District Court's decision. *See id.* (concluding the same while applying a more deferential standard of review).[2] We see no abuse of discretion.

Nor are we persuaded by Plaintiffs' challenge to the District Court's conclusion that any amendment would be futile. To state a claim for securities fraud, Plaintiffs among other things must allege scienter by "stat[ing] with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). As Plaintiffs do not allege conscious misbehavior, the required state of mind is recklessness: "conduct that was highly unreasonable, representing an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *CILP Assocs., L.P. v. PriceWaterhouse Coopers LLP*, 735 F.3d 114, 127 n.11 (2d Cir. 2013) (citation omitted). To create a strong inference, the alleged facts must establish that "it is at least as likely as not that [D]efendants acted" recklessly. *Slayton v. Am. Express Co.*, 604 F.3d 758, 775 (2d Cir. 2010) (citation omitted).

Plaintiffs' theory is that Defendants "knew facts or had access to information suggesting that their public statements were not accurate." *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000). They

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[1] Because the District Court "manage[s] its docket" within "its broad discretion," we review its decision for abuse of discretion, not *de novo*, as Plaintiffs inaccurately suggest. *See Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 87, 98–99 (2d Cir. 2012).

[2] We note separately that we are able to adequately evaluate the futility of amendment without "a proposed amended complaint in the record." Pls.' Br. 27; *see, e.g.*, *Coulter v. Morgan Stanley & Co.*, 753 F.3d 361, 368 (2d Cir. 2014) (affirming finding of futility with no proposed amended complaint in the record where plaintiffs "identified no facts that, if alleged, would establish a valid claim").

seek to allege that Defendants reviewed prior studies of Lucentis and were aware of the results—which Defendants' counsel has described as "all over the map[.]" Pls.' Br. 32. Because Defendants knew or should have known that the reliability of their study's control variable was uncertain, Plaintiffs claim that Defendants were reckless in stating that the Lucentis-only results were consistent with prior studies of Lucentis, and in touting the likely efficacy of Squalamine. Plaintiffs further claim that Defendants wrongly referred to "consistent . . . studies"—plural—when in fact they relied on only one such study. *Id.* at 46–47.

Plaintiffs fail to allege that Defendants were at least as likely as not to have acted with scienter. *See Slayton*, 604 F.3d at 775. While Plaintiffs interpret the results of prior studies of Lucentis, they do not allege facts suggesting that Defendants reached or should have reached the same conclusion. For example, Plaintiffs do not point to any reports concluding that disparate studies of Lucentis had results that were inconsistent with or better than those reported in Defendants' clinical trial. *See Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (holding that plaintiff had not alleged recklessness because its "broad reference to raw data lack[ed] even an allegation that these data had been collected into reports" that reached the conclusion about which defendant was allegedly aware). And Defendants' counsel's description at oral argument of the results presented in the Amended Complaint as "all over the map" does not imply that Defendants themselves were or should have been aware of this variability at the time they made the contested statements.

Instead, Plaintiffs contend, consistent with Defendants' public statements, that "Defendants believed that . . . the CATT study"—one of the studies identified by Plaintiffs—was "comparable." Pls.' Br. 33; *see* App'x 114, 124. Plaintiffs present no reason to doubt the reasonableness of Defendants' view. *See Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 154 (2d Cir. 2013) (holding there is no fraud where "a defendant's competing analysis or interpretation of data is itself reasonable," and identifying "no basis to believe that the [defendants'] statements regarding the control group were unreasonable"). Based on these claims, it is less likely that Defendants were reckless than that they reasonably interpreted prior studies of Lucentis—including the CATT study and other studies with comparable results, such as the MARINA, FUSION, and BRAMD studies—in a way that differed from the interpretation advanced by Plaintiffs.[3] Once again, "Plaintiffs pleaded negligence in the making of some of the allegedly misleading statements, not recklessness approximating actual intent." *Lehmann I*, 830 F. App'x at 353.

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[3] Plaintiffs argue that the significance of the trial results to Ohr's business supports a finding of scienter. However, they do not argue that their "core operations allegations" alone establish scienter, instead claiming only that they "must be considered as part of the holistic inference of scienter." Pls.' Reply 26. As Plaintiffs have alleged no other basis for scienter, we need not consider this argument.

CONCLUSION

We have reviewed all of the arguments raised by Plaintiffs on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the November 16, 2020, order of the District Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk