FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

VICKY NGUYEN, Individually and on behalf of all others similarly situated, *Plaintiff-Appellant*, v. ENDOLOGIX, INC.; JOHN MCDERMOTT; VASEEM MAHBOOB, *Defendants-Appellees*.	No. 18-56322 D.C. No. 2:17-cv-00017-AB-PLA OPINION

Appeal from the United States District Court
for the Central District of California
André Birotte, Jr., District Judge, Presiding

Argued and Submitted February 11, 2020
Pasadena, California

Filed June 10, 2020

Before: Jay S. Bybee, Daniel P. Collins, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Bress

SUMMARY*

Securities Fraud

Affirming the district court's dismissal of a putative securities class action under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, the panel held that the plaintiff failed sufficiently to plead facts giving rise to a strong inference that defendants made false or misleading statements either intentionally or with deliberate recklessness.

Plaintiff alleged that a medical device company misled the investing public about whether the Food and Drug Administration would approve the company's new aneurysm sealing product. Plaintiff's central theory was that company executives knew the device had encountered problems in Europe that would manifest again in U.S. clinical trials, which would in turn lead the FDA to deny premarket approval.

The panel held that allegations that are implausible do not create a strong inference of scienter under the Private Securities Litigation Reform Act. Finding persuasive a decision of the Fourth Circuit, the panel concluded that plaintiff's core theory had no basis in logic or common experience. Based on plaintiff's complaint, the more plausible inference was that the company made optimistic statements about its prospects for FDA approval because its U.S. testing looked promising, not because the company was

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

quixotically seeking FDA approval for a medical device application it knew was destined for defeat.

COUNSEL

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OPINION

BRESS, Circuit Judge:

In this putative securities class action, the plaintiff alleges that a medical device company misled the investing public about whether the Food and Drug Administration (FDA) would approve the company's new aneurysm sealing product. Plaintiff's central theory is that company executives knew the device had encountered problems in Europe that would manifest again in U.S. clinical trials, which would in turn lead the FDA to deny premarket approval. In a securities fraud case, the plaintiff must plead scienter, namely, that defendants made false or misleading statements either intentionally or with deliberate recklessness. In this case, and for all the complaint's girth, it lacks a critical ingredient under the Private Securities Litigation Reform Act (PSLRA): allegations that "state 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) (emphasis added).

Allegations that are implausible do not create a strong inference of scienter. Under the facts alleged, plaintiff's core theory—that the company invested in a U.S. clinical trial and made promising statements about FDA approval, yet knew from its experience in Europe that the FDA would eventually reject the product—has no basis in logic or common experience. Based on plaintiff's complaint, the more plausible inference is that the company made optimistic statements about its prospects for FDA approval because its U.S. testing looked promising, not because the company was quixotically seeking FDA approval for a medical device application it knew was destined for defeat. We therefore affirm the district court's judgment dismissing the complaint and denying leave to amend.

I

The following factual allegations are taken from plaintiff's second amended complaint, which we refer to generally as the "complaint." In the present posture, we treat the complaint's allegations as true and construe them in the light most favorable to the plaintiff. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009).

A

Defendant Endologix is a publicly traded company that manufactures and sells medical devices for the treatment of abdominal aortic aneurysms. The company focuses on treating disorders of the aorta, the largest artery in the body, which runs from the chest to the abdomen. One such disorder is atherosclerosis, a disease that weakens the walls of blood vessels and can cause them to expand outward.

This expansion is known as an aneurysm and results in an unwanted bulge, called an aneurysm sac. An abdominal aortic aneurysm occurs in the abdominal section of the aorta and can result in dangerous internal bleeding if the aneurysm ruptures. Traditional methods of treating abdominal aortic aneurysms include surgery and endovascular repair. A new, more innovative method is endovascular sealing.

Endologix's endovascular sealing product is called Nellix. The device is placed directly into a patient and works somewhat like a stent. But rather than repair the aneurysm like traditional devices, Nellix instead seals the aneurysm sac, reducing the likelihood that the aneurysm will rupture. This method of treatment is thought to reduce post-procedure complications that can occur with the use of aneurysm repair devices. Complications include endoleaks, when blood leaks into the aneurysm sac, and "migration," when a device moves from the location where it was initially placed. Untreated migration can result in blood flow into the aneurysm sac, further aneurysm expansion, and rupture. Remember the term "migration," because it becomes a focal point in plaintiff's allegations.

Endologix first introduced Nellix in Europe in February 2013, after regulators there granted "CE Mark" approval. Plaintiff acknowledges that "[g]enerally, CE marking is thought to be a much quicker, less rigorous process than FDA approval." Beginning in October 2013, Endologix tracked the device's real-world performance through a global registry. The global registry was designed to include 300 patients in up to 30 international centers. By September 2016, Endologix had acquired two years of data from this registry.

So that it could market Nellix in the United States, Endologix sought premarket approval from the FDA.

Premarket approval, or "PMA," is a stringent process in which the FDA determines whether scientific evidence demonstrates that a given device is safe and effective for its intended use. A premarket approval application must include a device's indications for use ("IFU"), which describe "the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended." 21 C.F.R. § 814.20(b)(3)(i). Nellix initially had a broad IFU because it was thought to be compatible with all types of patients, including those with complex anatomies who could not receive treatment using traditional endovascular repair devices.

As part of the FDA process, Endologix in December 2013 received approval from the FDA to conduct a clinical trial for Nellix. *See generally* 21 C.F.R. § 812, *et seq.* This clinical trial, which the complaint refers to as the "EVAS Forward IDE," began in January 2014 and involved 179 patients across 29 centers, approximately 25 of which were in the United States. After one year of monitoring these patients, Endologix submitted the clinical trial results to the FDA. By November 2016, the two-year data were available. The results of the clinical study are discussed below. But first, it is necessary to backtrack a little in time and switch continents to Europe, where Endologix first deployed Nellix.

B

The complaint alleges that device migration in European patients had "implications for FDA approval of Nellix," because "[i]f Nellix was unsafe for European patients it would prove equally unsafe for U.S. patients." The complaint alleges that while the FDA approval process was ongoing, Endologix, its Chief Executive Officer John McDermott, and its Chief Financial Officer Vaseem

Mahboob, became aware that Nellix was migrating in European patients.

The complaint identifies several sources for this allegation. It relies heavily on allegations from Confidential Witness 1, referred to as "CW1," a former Endologix employee who served first as Director of Research and Development and later as the company's head of Aortic Procedure Development. Shortly after plaintiff filed her first amended complaint citing allegations from CW1, CW1 submitted a declaration in the district court disavowing the plaintiff's allegations, denying having "ma[de] many of the statements attributed to me," and stating that "most of the factual assertions attributed to me . . . are contrary to my understandings of fact and my opinions." The district court did not consider this later declaration in granting Endologix's motion to dismiss and neither do we.[1]

The complaint alleges that CW1 was involved with the development of Nellix from the start. According to CW1, European doctors in 2015 began sending Endologix a "stream of complaints and incident reports" claiming that Nellix was migrating in their patients. CW1 alleged that by the fall of 2015, migration was a "serious problem," and McDermott and Mahboob became "very involved." CW1 characterized the European migration issue as the "biggest thing we had going at the company" and stated that McDermott and Mahboob were "given everything" the company put together in an attempt to solve the problem, including "thousands of pages of paper with studies and reports." In December 2015, McDermott held a series of

[1] We therefore deny plaintiff's motion to strike defendant's answering brief and supplemental excerpts of record.

meetings with senior staff to discuss the migration issue. Despite these efforts, Endologix could not find a solution.

Relying still on CW1, the complaint further alleges that the company's investigation into migration issues in Europe revealed that Nellix was dangerous for certain patients, especially those with thrombosis, a condition that causes blood clots in blood vessels. In November 2015, CW1 and two other Endologix employees pushed McDermott to modify the IFU, but McDermott refused.

In early 2016, CW1 and others compiled weekly reports about Nellix migration for McDermott and Mahboob in preparation for Endologix's annual symposium, which was "attended by experts in the field of endovascular aneurysm sealing." McDermott signed off on a presentation for this symposium that documented the scope of the migration problem. This non-public event was held in London on March 10–11, 2016, and CW1 attended the presentations and discussions.

The complaint alleges that, according to CW1, during one presentation at this symposium, an Endologix consultant stated that "[w]e are having some unexplained migrations, a lot of them." Another Endologix representative admitted that the company had no solutions to the problem of Nellix migration. A Latvian vascular surgeon who had used Nellix in his patients also gave a presentation in which he stated that "in a lot of cases" the devices were "slipping" and "moving." This surgeon met with CW1 and others after the presentation and characterized the situation as "urgent," saying "look, I'm telling you now, this is not good." After the symposium, CW1 and others met with McDermott to relay these warnings, but McDermott took no action.

In addition to relying on CW1, the complaint also points to two European reports in alleging that Endologix was aware of Nellix migration in Europe. The complaint alleges that a 2016 United Kingdom case report "warned of the ominous risks of migration" of Nellix and discussed one patient whose Nellix device migrated eleven millimeters. This case report also cited a 2016 University of Liverpool study, which examined thirty-five Nellix devices across eighteen patients. Migration occurred in six of these devices, resulting in a 17% migration rate. As discussed further below, however, the Liverpool study used a definition of migration different than the one used in the FDA clinical trial.

C

Despite the issues in Europe, the complaint alleges that Endologix executives repeatedly assured investors that the FDA would likely approve Nellix. These statements form the basis for plaintiff's allegations of securities fraud.

The statements in question began in May 2016. At a health care conference on May 5, 2016, Mahboob reported that the company expected FDA approval of Nellix in the fourth quarter of 2016 or the first quarter of 2017. On May 9, 2016, Endologix held its first quarter investor conference call, during which Mahboob stated that "Nellix continues to do a fantastic performance outside of the U.S.," and "Nellix is doing as expected. No surprises." CW1 alleges that he and other employees were "disgusted" that migration was not mentioned on this call, which led to "a race to the door." In a press release issued that same day, Endologix stated that it "remain[ed] on track with our timeline for potential FDA approval at the end of 2016 or early 2017." At a health care conference on May 10, 2016, McDermott reiterated that the

company "expect[ed] the [FDA] PMA approval around the end of this year, first part of next year."

On May 26, 2016, Endologix released the data from the first year of the FDA clinical trial. The complaint alleges that the results showed a "100% procedural technical success" and a 94% treatment success rate, achieving the FDA's primary safety and effectiveness endpoints. The device migration rate was 2.3%. Further, the data showed that after one year, endoleaks were present in 3.1% of patients, "the lowest rate ever reported" for a clinical study of an endovascular abdominal aortic aneurysm device.

Endologix submitted these results to the FDA on June 11, 2016. During a conference call that same day to discuss the clinical trial data, McDermott addressed the University of Liverpool study discussed above. Although that study showed a 17% migration rate, McDermott explained that the study defined migration as a movement of four millimeters, which would not qualify as migration under the FDA's ten-millimeter definition.

During Endologix's second quarter investor call on August 2, 2016, McDermott stated "we remain very positive about the likelihood of approval . . . and the significant growth we expect to drive with Nellix." McDermott also addressed the fact that the FDA was considering referring the Nellix premarket approval to an outside panel of experts, which would delay FDA approval by about six months. *See generally* 21 C.F.R. § 814.44. An analyst asked whether the prospect of this referral had been driven by any "sort of red flag raised in terms of data" submitted to the FDA. McDermott responded that while one reason for panel referral was "new clinical issues of safety," in the case of Nellix "everyone has seen the data so we know there aren't any issues there."

In response to another analyst's inquiry about the types of questions Endologix received from the FDA after Endologix submitted its first set of clinical data, McDermott explained:

> [N]one of the questions we got asked are what I would characterize as big surprises. There is clarification on some things, some requests for additional analysis, some additional testing. Nothing that would suggest in our view any question or risk of approvability, just some more blocking and tackling and clarification of the data we submitted. So, we don't see anything in there that's given us heartburn.

Although he was no longer at the company at this point, CW1 stated that McDermott's answer "could not have been further from the truth" because by the time of this call, Endologix had been working for seven or eight months on the migration issue, and McDermott knew about the situation.

Endologix held its third quarter investor call on November 1, 2016. On this call, Endologix revealed that after providing the FDA with an "updated data cut," Endologix had narrowed Nellix's IFU. McDermott stated:

> Regarding Nellix, we've recently ran an updated data cut from the IDE clinical database and noticed an increase in migration in aneurysm enlargement in some patients with two-year follow-up. We're learning that migration can occur in patients with small flow lumens and a lot of thrombus because there isn't enough space to inject sufficient

> polymer to support the stents. Our solution is a simple update to the patient's selection criteria that measures the ratio of aneurysm diameter to the flow lumen to ensure there is enough space for polymer.

McDermott explained that when the company examined the clinical data for patients with this updated selection criteria, it saw "extremely positive safety and durability results out to two years, which gives us confidence that Nellix can be a leading device in the treatment of abdominal aortic aneurysms."

On this November 1, 2016 call, McDermott further explained that the company provided the FDA with its "updated patient selection criteria and have had positive discussion[s] so far." He indicated that the FDA "had some questions about migration," but emphasized that this issue was "a very easy situation to address just by narrowing for those particular anatomies" that did not experience migration. Finally, McDermott represented that "the Nellix PMA approval timelines are unchanged, although we think a panel is more likely now given the updated indications." McDermott estimated that a panel meeting would occur in April or May of 2017, "which would lead to a potential PMA approval in the third quarter of 2017," several months later than Endologix had initially estimated.

On November 16, 2016, however, Endologix issued a press release disclosing that the FDA would not approve Nellix within the timeline the company had previously presented. Instead, the FDA had requested that Endologix provide it with two years of follow-up data for patients in the clinical trial. As a result, PMA approval could not occur until the second quarter of 2018 at the earliest, an eighteen-

month delay from what Endologix originally announced. That day, Endologix's share price fell more than 20.5%, or $2.02 per share.

Endologix held its 2016 investor meeting the next day. There, McDermott explained that, although the clinical trial showed a 2.3% migration rate after year one, the migration rate increased in year two. He noted "[i]t was the increase in the rate from year one to year two" that "drove the discussion" with the FDA and led to the FDA's request for additional data. The complaint alleges that McDermott presented this discovery as new information when, in reality, the company was aware that Nellix experienced increased migration after more than one year in use, based on Endologix's experience with Nellix in the European commercial channel.

On May 17, 2017, Endologix announced that it would not seek FDA approval of Nellix at all. Instead, the company decided to focus its efforts on a second-generation Nellix device, which it estimated would not receive FDA approval until 2020. That same day, Endologix's share price fell more than 36%, or $2.47 per share.

Two months later, the Securities and Exchange Commission (SEC) initiated an investigation into the events surrounding Nellix's FDA approval. After Endologix revealed this investigation in a public filing in August 2017, one of its executives resigned. Plaintiff's complaint does not allege the status of the SEC investigation, but according to Endologix, the SEC has closed it.

D

On January 3, 2017, Vicky Nguyen filed this putative class action against Endologix, McDermott, and Mahboob,

alleging securities fraud. Following her appointment as lead plaintiff, Nguyen filed a first amended complaint. The district court dismissed this complaint for failure to state a claim, but granted Nguyen leave to amend. Nguyen then filed a second amended complaint, the operative complaint here, on behalf of persons who bought or acquired Endologix securities between May 5, 2016 and May 18, 2017.

The complaint alleged violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. *See* 15 U.S.C. §§ 78j(b), 78t(a); 17 C.F.R. § 240.10b-5. The thrust of the complaint is that the defendants made statements about Nellix migration and the prospects of FDA approval that were false and misleading in light of Endologix's knowledge of Nellix migration in Europe.

The district court dismissed the second amended complaint under Federal Rule of Civil Procedure 12(b)(6) because Nguyen had not satisfied the PSLRA's heightened pleading standard for scienter. The district court also denied Nguyen's request for leave to amend to file what would have been her fourth complaint. Nguyen timely appealed.

II

Reviewing de novo and construing the allegations in the complaint in the light most favorable to the plaintiff, *Zucco Partners*, 552 F.3d at 989, we agree with the district court that plaintiff has not adequately alleged a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2)(A). The precedents of the Supreme Court and this court teach that the PSLRA's heightened pleading requirements are meaningful ones, requiring courts carefully to evaluate securities fraud complaints to ensure compliance with the statute's elevated pleading standards. *See, e.g.*, *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007); *Dura Pharm., Inc.*

v. Broudo, 544 U.S. 336, 345–46 (2005); *Zucco Partners*, 552 F.3d at 990–91; *Ronconi v. Larkin*, 253 F.3d 423, 437 (9th Cir. 2001). We hold that in this case, the complaint does not pass muster under the PSLRA.

A

Section 10(b) of the Securities Exchange Act of 1934 provides that it is unlawful for any person "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). The SEC in turn promulgated Rule 10b-5, which provides that it is unlawful for any person:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To 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, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. Section 20(a) of the Act makes certain "controlling person[s]" liable for violations of

§ 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a); *see also Zucco Partners*, 552 F.3d at 990.

To plead a claim under § 10(b) and Rule 10b-5, a plaintiff must allege "(1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 603 (9th Cir. 2014).

This case centers on the critical element of scienter, which in this context is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n.12 (1976)). To allege the required scienter, a complaint must "allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Zucco Partners*, 552 F.3d at 991 (quotations omitted). "[D]eliberate recklessness" is more than "*mere* recklessness or a motive to commit fraud." *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (emphasis in original) (quoting *Zucco Partners*, 552 F.3d at 991). It is instead "an *extreme* departure from the standards of ordinary care," which "presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it." *Id.* (emphasis in original) (quoting *Zucco Partners*, 552 F.3d at 991).

Securities fraud complaints are subject to heightened pleading requirements. One source of these higher standards is Federal Rule of Civil Procedure 9(b), which requires a plaintiff to "state with particularity the circumstances constituting fraud." *See also Schueneman*, 840 F.3d at 705; *Zucco Partners*, 552 F.3d at 990. Another source is the

PSLRA, which was enacted in 1995 as part of Congress's desire to "curb perceived abuses of the § 10(b) private action—'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers.'" *Tellabs*, 551 U.S. at 320 (quoting *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006)).

Under the PSLRA, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Importantly for purposes here, the complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A).

The PSLRA's "strong inference" requirement has teeth. It is an "exacting" pleading obligation, *Zucco Partners*, 552 F.3d at 990, that "present[s] no small hurdle for the securities fraud plaintiff." *Schueneman*, 840 F.3d at 705 (quotations omitted). As the Supreme Court has explained, "[t]he strong inference standard unequivocally raised the bar for pleading scienter." *Tellabs*, 551 U.S. at 321 (quotations omitted) (alteration adopted). Given the substantial costs that securities fraud litigation can impose, the "strong inference" standard reflects Congress's attempt to halt early on securities litigation that lacks merit or is even abusive, while allowing plaintiffs with potentially winning claims to proceed to discovery. *See id.* at 323–24.

Acknowledging these interests, the Supreme Court has held that under the PSLRA's "strong inference" standard, a complaint will survive a motion to dismiss "only if a

reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. It is to this analysis that we now turn.

B

Plaintiff's core theory is that defendants made false and misleading statements about whether the FDA was likely to approve Nellix because defendants knew, based on their experience in Europe, that Nellix would encounter migration issues. The central theory of the complaint is thus that defendants knew the FDA would not approve Nellix, or at least that it would not do so on the timeline defendants were telling the market. That is the theory of falsity on which the complaint attacks defendants' various statements about the prospect of FDA approval: based on Nellix's performance in Europe, defendants "knew that there was absolutely no hope of receiving FDA PMA approval by the end of 2016 or the first part of 2017" and knew "the FDA would not approve [Nellix] for use in the U.S. because of the unacceptable safety risks device migration posed."

These allegations encounter an immediate first-level problem: why would defendants promise the market that the FDA would approve Nellix if defendants knew the FDA would eventually figure out that Nellix could not be approved due to "intractable" and "unresolvable" device migration problems? The theory does not make a whole lot of sense. It depends on the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout once Nellix's "unsolvable" migration problem was revealed. If defendants had sought to profit from this scheme in the interim, such as by selling off their stock or selling the company at a premium, the theory might have more legs. *See, e.g.*, *In re Rigel Pharm.*,

Inc. Sec. Litig., 697 F.3d 869, 884–85 (9th Cir. 2012). There are no factual allegations like that here. Instead, we are asked to accept the theory that defendants were promising FDA approval for a medical device application they knew was "unapprovable," misleading the market all the way up to the point that defendants were "unable to avoid the inevitable."

The allegation does not resonate in common experience. And the PSLRA neither allows nor requires us to check our disbelief at the door. "Plausibility" is a concept more commonly associated with the base-level "non-fraud" pleading standards in Rule 12(b)(6). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556–57 (2007). But plausibility is no less relevant in the context of the heightened pleading standards of Rule 9(b) or the PSLRA. *See In re NVIDIA Corp. Sec. Litig*, 768 F.3d 1046, 1058 (9th Cir. 2014) (rejecting a theory of scienter because of the "implausibility of the timing in CW1's account of events"); *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) ("[C]laims of fraud or mistake . . . must, in addition to pleading with particularity, also plead plausible allegations."). Treating the allegations in the complaint in the light most favorable to the plaintiff, the notion that a company would promise FDA approval that it knew would not materialize does not, without more, create a strong inference of intent to deceive or deliberate recklessness.

The Fourth Circuit addressed a similar claim about prospective FDA approval in *Cozzarelli v. Inspire Pharmaceuticals Inc.*, 549 F.3d 618 (4th Cir. 2008), and its analysis is persuasive here. In *Cozzarelli*, a pharmaceutical company sought FDA approval of a drug for the treatment of dry eye disease. *Id.* at 621. To gain approval, the FDA

required the company to conduct a study on the effectiveness of the product. *Id.* at 622. The study ultimately failed. *Id.* Plaintiffs alleged that, while the study was ongoing, company executives made misleading statements that the study would succeed. *Id.* at 624–25. The Fourth Circuit held that these allegations did not plead a "strong inference" of scienter under the PSLRA. *Id.* at 626.

Underpinning the Fourth Circuit's reasoning in *Cozzarelli* was the point we recognize here: "[i]t is improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure." *Id.* at 627. The plaintiffs' "inference of fraud based on the supposed impossibility of [a successful trial] [wa]s thus not even plausible, much less convincing." *Id.* This was so in *Cozzarelli* even though the defendants there, unlike those here, sold some of their stock in the company while the study was ongoing. *Id.* at 622, 627–28; *see also City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (affirming dismissal of securities fraud complaint because, *inter alia*, "the initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure").

C

Plaintiff does not surmount her plausibility problem, and does not plead a strong inference of scienter, through reliance on confidential witness "CW1." There is, at the outset, reason to question CW1's foundation. He left the company in June 2016, around the time that Endologix reported to the FDA the favorable data from the first year of the U.S. clinical trial, but well before the company narrowed

Nellix's IFU and reported the less favorable second-year data. Many of the statements that plaintiff alleges are false and misleading were made after CW1 left Endologix. There is thus ample basis to question aspects of CW1's claimed knowledge and his effort to impute scienter to the defendants. *See, e.g.*, *Zucco Partners*, 552 F.3d at 995–96.

Even so, CW1 does not get plaintiff where she needs to be under the PSLRA. The central problem with the information attributable to CW1 is that it lacks any detail about the supposed device migration problems that Nellix encountered in the European channel. *See id.* at 995 (explaining that "we look to the level of detail provided by the confidential sources") (quotations omitted).

The allegations sourced to CW1 are high on alarming adjectives—"serious and unsolvable," "dangerous," "urgent," and so on. But they are short on the facts about Nellix migration that would establish a strong inference that defendants' later statements about FDA approval were intentionally false or made with deliberate recklessness. Nowhere does CW1 identify, for example, the number of European patients that experienced device migration, how much Nellix was migrating in these patients, whether the alleged device migration led to any further medical issues, whether the patients had particular conditions that exacerbated the migration, and whether the patients were within or outside either the original or revised IFU. As we have held, "negative characterizations of reports relied on by insiders, without specific reference to the contents of those reports, are insufficient to meet the heightened pleading requirements of the PSLRA." *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002). Strong rhetoric is not a substitute for "particular[] facts giving rise to a strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2)(A).

The same is true of CW1's allegations that Endologix was evaluating Nellix migration in Europe. While CW1 suggests general turmoil within Endologix over an undefined migration issue, much of this is sourced to a March 2016 conference in London, where "experts in the field of endovascular aneurysm sealing" had a "full and honest discussion" with Endologix scientists and directors, who provided "responses to questions concerning migration." The complaint provides no explanation as to why a company supposedly bent on concealment in the United States would have open discussions with numerous company outsiders in Europe on the same underlying issue.

In short, while CW1 references a "stream of complaints and incident reports" and a general concern that these reports supposedly caused, the complaint does not plead any details about these reports that would demonstrate a strong inference of scienter in Endologix's later statements about FDA approval or Nellix migration. *See, e.g.*, *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063 (9th Cir. 2014) (holding that plaintiffs failed to plead scienter by relying on witness accounts that "[did] not detail the actual contents of the reports the executives purportedly referenced or had access to"); *Lipton*, 284 F.3d at 1036; *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) ("We would expect that a proper complaint which purports to rely on the existence of internal reports would contain at least some specifics from those reports."), *abrogated on other grounds by S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008).

The only concrete facts plaintiff alleges from the European channel actually confirm the absence of a strong inference of scienter. The complaint relies most heavily on a 2016 University of Liverpool study that showed device

migration in 6 out of 35 devices studied, a 17% migration rate exceeding the 2.3% migration rate that Endologix observed in the first year of its U.S. clinical trial. But plaintiff is hard-pressed to build a fraud case around the Liverpool study when she admits in her complaint that defendant McDermott acknowledged and discussed this very study on an investor conference call in June 2016. McDermott also explained that the Liverpool study defined migration as four millimeters of movement, whereas the Society for Vascular Surgery and the FDA clinical study treated ten millimeters as the appropriate benchmark for material migration. Plaintiff does not dispute the fact that, as the Liverpool study itself makes clear, applying the ten-millimeter metric there "would have generated a zero rate of migration," because all devices in the study migrated less than ten millimeters. The Liverpool study thus does not demonstrate that defendants' statements about FDA approval were made with wrongful scienter.

The only other data point plaintiff provides is a 2016 United Kingdom case report about a single patient who was reported to have experienced an eleven-millimeter device migration. But once again, the complaint provides no details on the circumstances of this patient or why this case report should have alerted Endologix to a broader problem with Nellix that would have complicated the prospects for FDA approval. A case report is a report about a single person's medical situation. *E.g.*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002). There are understandable limitations associated with building a broad-based fraud claim around the unelaborated experiences of just one patient, given the individualized features of any one person's medical profile. But at the very least, plaintiff here has not pleaded facts showing that the United Kingdom case report creates a strong inference of scienter. Indeed, plaintiff

effectively acknowledges that some amount of device migration may occur, in casting the 2.3% migration rate in the first year of the U.S. clinical trial as favorable, or at least not problematic.[2]

Plaintiff's reliance on *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011), is inapt. *Matrixx* rejected the argument that "reports of adverse events associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product is in fact causing the events." *Id.* at 39 (footnotes omitted). No such "bright-line" rule is being applied here. *Id.*

Matrixx also differs from this case in important ways. *Matrixx* did not involve allegedly false statements about the prospects for FDA approval, but rather, *inter alia*, statements denying reports of adverse events as "completely unfounded and misleading," which contradicted information of which the company was aware. *Id.* at 47 (quotations omitted). Here, by contrast, the plaintiff's own allegations show that Endologix acknowledged the reports of Nellix migration in the Liverpool study and U.S. clinical trial.

In *Matrixx*, moreover, the complaint alleged that the defendant pharmaceutical company was made aware of reports that over ten patients had lost their sense of smell after using the company's drug, and that the company had both followed up on these reports and tried to squelch them, only to then deny there was any issue. *Id.* at 32–33. The

[2] Plaintiff alternatively alleges that the FDA was relying on reports from the European channel or that Endologix failed to provide such reports, contrary to FDA regulations. *See* 21 C.F.R. § 814.20(b)(8)(ii). But plaintiff fails to plead sufficient facts to support either theory.

allegations here, which are based on the Liverpool study, one case report, and CW1's general description of the European commercial experience, lack comparable detail to generate a strong inference of scienter.

Our decision in *Schueneman*, 840 F.3d 698, also provides no assistance to plaintiff. In that case, a company conducted a clinical trial using rats as part of the FDA approval process. *Id.* at 701. Although the rat study revealed that the drug might cause cancer, the company publicly stated that the results of the study made it confident that the FDA would approve the drug. *Id.* at 708. Because the rat studies were "*the* sticking point with the FDA," we held that the complaint adequately alleged scienter. *Id*. (emphasis in original). In this case, by contrast, there are no particularized allegations that FDA approval of Nellix turned on studies or case reports from Europe, as opposed to the U.S. clinical trial.[3]

Where all of this leaves us is that to the extent plaintiff's allegations raise any inference of scienter, we cannot say this inference is "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. The more plausible inference to be drawn

[3] Mahboob's May 9, 2016 statement that "Nellix continues to do a fantastic performance outside of the U.S." also does not create a strong inference of scienter. In context, and based on the analyst question that led to it, Mahboob's statement appears to concern Nellix's sales abroad. Regardless, when considered individually and within the complaint as a whole, Mahboob's statement is too unclear to support a strong inference of scienter. *See, e.g.*, *Police Ret. Sys. of St. Louis*, 759 F.3d at 1063; *Zucco Partners*, 552 F.3d at 1000. Plaintiff also does not plead sufficient facts about the alleged departure of certain Endologix employees, *see Zucco Partners*, 552 F.3d at 1002, or the SEC's investigation, *see Cozzarelli*, 549 F.3d at 628 n.2, to give rise to a strong inference of scienter on these bases.

from the allegations in the complaint is that defendants made promising statements about the timing of FDA approval based on the initial results of the U.S. clinical trial, but then modulated their optimism when the results began to raise more questions.

In late May 2016, at the beginning of the class period and shortly after it first made positive statements about FDA approval, Endologix released the results from the first year of the U.S. clinical trial. By plaintiff's own allegations, the results were favorable: "100% procedural technical success achieved;" "[a]t the year, the treatment success rate was 94%, achieving the primary effectiveness endpoint;" "[f]reedom from device related secondary interventions was 96.6%, the highest rate ever reported for an IDE study of an endovascular AAA device;" and "[e]ndoleaks were present in 3.1% of patients at 1-year, the lowest rate ever reported for an IDE study of an endovascular [abdominal aortic aneurysm] device." The first-year data showed a 2.3% migration rate, which plaintiff does not characterize as unfavorable and which defendants disclosed.

Then, when Endologix obtained two-year data from the clinical trial showing "an increase in migration" in "some patients," defendants disclosed that information and expressed their belief that the issue could be addressed with a narrowed IFU that excluded patients with "particular anatomies" that were more susceptible to device migration. Plaintiff identifies no sufficient factual basis as to why defendants could not have believed that a revised IFU would allow the FDA to approve the product. (And contrary to plaintiff's argument, McDermott did not then say that Endologix had only "recently" learned about Nellix migration; his comment referred to the "updated data cut" Endologix had "recently" run from the clinical trial

database.) Regardless, defendants at this time extended the timeline for estimated FDA approval to the third quarter of 2017. Then, when the FDA requested additional data, Endologix disclosed this development, stating "[i]t was the increase in the rate from year one to year two" that "drove the discussion."

Under the PSLRA, "[a] court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco Partners*, 552 F.3d at 991. The complaint cannot go forward here because the more plausible inference from the facts alleged is that defendants based their statements about FDA approval on the status and progress of the U.S. clinical trial, not that defendants were intentionally or with deliberate recklessness seeking to mislead the market about an FDA approval that they knew would never come through. Viewing the allegations in the complaint both individually and collectively, *id.* at 1006, plaintiff has therefore failed to plead a strong inference of scienter. Because the complaint fails to plead scienter, we have no occasion to address defendants' other arguments as to why the complaint may fail to plead other necessary elements.

We hold that the district court properly dismissed plaintiff's claims under Section 10(b) and Rule 10b-5. Because plaintiff's Section 20(a) "controlling person" claims against McDermott and Mahboob require a violation of Section 10(b) or Rule 10b-5, the Section 20(a) claims necessarily fail as well. *See, e.g.*, *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d at 1052; *Zucco Partners*, 552 F.3d at 990.

III

In the alternative, Nguyen argues that the district court erred in dismissing her second amended complaint with prejudice. Reviewing for abuse of discretion, *Zucco Partners*, 552 F.3d at 989, we hold that the district court did not err.

"[W]here the plaintiff has previously been granted leave to amend and has subsequently failed to add the requisite particularity to its claims, the district court's discretion to deny leave to amend is particularly broad." *Id.* at 1007 (quotations omitted). Here, the district court had already given Nguyen leave to amend. There was thus no abuse of discretion because "it was clear that the plaintiff[] had made [her] best case and had been found wanting." *Id.*

* * *

The judgment of the district court is therefore

AFFIRMED.