United States Court of Appeals
For the First Circuit

No. 19-1614

WANG YAN,

Plaintiff, Appellant,

JOANNE GELLER,

Movant, Appellant,

QIAN DENG; DAVID HERSHLIKOVITZ; JACKIE888, INC.; MICHAEL C. KEMMERLING; NARBEH NATHAN; PAUL SISLIN, individually and on behalf of all other similarly situated parties,

Plaintiffs,

v.

REWALK ROBOTICS LTD.; LARRY JASINSKI; AMI KRAFT; AMIT GOFFER; JEFF DYKAN; HADAR RON; ASAF SHINAR; WAYNE B. WEISMAN; YASUSHI ICHIKI; ARYEH DAN; GLENN MUIR; BARCLAYS CAPITAL INC.; JEFFERIES LLC; CANACCORD GENUITY INC.; KEVIN HERSHBERGER,

Defendants, Appellees.

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

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before

Lynch, Stahl, and Kayatta,
Circuit Judges.

Omar Jafri, with whom Patrick V. Dahlstrom, Pomerantz LLP, Edward F. Haber, Adam M. Steward, and Shapiro Haber & Urmy LLP

were on brief, for appellants.

Douglas P. Baumstein, with whom Susan L. Grace, White & Case LLP, Barry Sher, Anthony Antonelli, Paul Hastings LLP, David S. Godkin, James E. Kruzer, and Birnbaum & Godkin, LLP were on brief, for appellees.

August 25, 2020

KAYATTA, Circuit Judge. On behalf of proposed classes of investors, Wang Yan alleged that ReWalk Robotics, Ltd. ("ReWalk") violated both the Securities Act of 1933 ("Securities Act") and the Securities Exchange Act of 1934 ("Exchange Act") by misrepresenting and omitting details about its dealings with the FDA in its initial public offering (IPO) Registration Statement and in subsequent quarterly and annual disclosures. The district court dismissed the Securities Act claims for failure to state a claim and found that Yan did not have standing to bring the Exchange Act claims. We agree with the district court both that Yan failed to allege a violation of the Securities Act and that he lacked standing to challenge ReWalk's alleged failures to make certain disclosures after his purchases of ReWalk securities. The district court also determined that, because Yan lacked standing, it lacked jurisdiction to consider Yan's request to amend the complaint to add Joanne Geller as a named plaintiff to press the Exchange Act claims on behalf of a putative class. While we disagree with that reasoning, we affirm dismissal of the action because the proposed amendment would have been futile, as it failed to state an Exchange Act claim.

I.

ReWalk (previously Argo Medical Technologies, Inc.) designs and manufactures robotic exoskeletons that allow for upright locomotion by individuals with spinal cord injuries. One

such exoskeleton, ReWalk Personal ("the device"), is intended for long-term use at the user's home and in the community. The device is subject to FDA regulation. ReWalk successfully applied to the FDA for permission to market the device. See 21 U.S.C. § 360e(f). The FDA's order granting that permission labeled the device as a class II medical device, meaning its use carries a medium risk requiring some "special controls," such as training and warning labels, to ensure safe operation. See id. § 360c(a)(1)(B).

The FDA's letter conveying its permission also contained an order pursuant to Section 522 of the Food, Drug, and Cosmetic Act (FDCA), id. § 360*l*(a)(1)(A), that ReWalk conduct a postmarket surveillance study on the device. Section 522 grants the FDA the authority to investigate risks related to class II devices where, as relevant here, the device's failure "would be reasonably likely to have serious adverse health consequences." Id. For such devices, the FDA can order a postmarket surveillance study in order to "understand the nature, severity or frequency of suspected problems," "obtain more information on device performance," "address the long term or infrequent safety and effectiveness issues for implantable and other devices," and "better define the association between problems and devices when unexpected or unexplained serious adverse events occur." Div. of Epidemiology, U.S. Dep't of Health & Hum. Servs., Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act: Guidance

for Industry and Food and Drug Administration Staff (2016). The Section 522 order, central to several issues on this appeal, stated in relevant part as follows:

> [The device's] failure to prevent a fall would be reasonably likely to cause user injury and/or death through fall related sequelae such as traumatic brain injury (TBI), spinal cord injury (SCI), and fractures to the user . . . . In addition, during intervention due to a loss of balance of the patient, the device may potentially harm a "companion".
> . . .
> [The] FDA is concerned with the following: The safety and effectiveness of the ReWalk™ has been demonstrated in an institutional environment (e.g. hospital, rehabilitation institution). However, there is limited information on use outside of the institutional setting (e.g. community and at home use) given that [ReWalk] intends for the product's use in non-institutional settings. [ReWalk] has not provided a complete community and at home use dataset; however, the institutional data provided demonstrate that the benefits outweigh the risks if used in conjunction with a comprehensive training program. A 522 study is ordered to effectively evaluate the training program and long-term safety of the device . . . . Because successful use of the ReWalk™ device requires training and a companion, we believe that a rigorous multi-tiered training program may mitigate the risk of serious injury to the user and companion. Therefore, an assessment that your training regimen is adequate will be required.
>
> Accordingly, under section 522 of the Act, we are ordering you to conduct a postmarket surveillance study of your device to report the rate and nature of all falls and associated injuries which may occur when the device is used in institutional and non-institutional environments such as the clinic, home, and community. Additionally, data

> should be collected to reflect all incidences of injury to a companion in conjunction with the use of the device.
> . . .
> 1. What is the 12-month incidence of serious adverse events in institutional and non-institutional environments . . . ?
> 2. What is the 12-month incidence of falls and companion injuries in institutional or non-institutional environments . . . ?
> 3. What device malfunctions are reported and observed?

The FDA required ReWalk to submit for FDA approval a proposed study plan, which ReWalk did (albeit five days late), and to commence its study within fifteen months. See 21 U.S.C. § 360*l*(b)(1).

Before hearing back from the FDA on its proposed plan, ReWalk issued, on August 26, 2014, a Registration Statement for an IPO. That Statement touted the device's success in clinical studies and "rigorous trials," calling it a "breakthrough product," with "compelling clinical data" "demonstrat[ing] the functionality and utilization" of the device. It further noted that the FDA ordered "performance of a postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain," regarding which "[f]ailure to comply . . . could lead to removal of ReWalk from the market." It did not explicitly state that the FDA ordered this study specifically because the device's failure "would be reasonably likely to have serious adverse health consequences" -- namely, a risk of spinal cord, brain, or skeletal injuries as a result of

falls. But it did state elsewhere that "[i]f any part of [the device]'s hardware or software were to fail, the user could experience death or serious injury" and that "there is no long-term clinical data with respect to the safety or physical effects" of the device. ReWalk went public under this Statement on September 12, 2014, selling 3,450,000 shares and raising over $41 million. Yan was an early purchaser, paying $35,460 for shares on September 15 and 17.

Thereafter, ReWalk and the FDA entered into a lengthy back-and-forth necessitated by ReWalk's halting performance of its obligations under the FDA's grant of marketing permission. ReWalk missed deadlines for submitting plans for the postmarket surveillance study, and the plans it did submit and revise were repeatedly deemed inadequate by the FDA. Eventually, on September 30, 2015, the FDA issued a warning letter stating the device "is currently misbranded under [the FDCA]" and threatening sanctions absent corrective action by ReWalk. See 21 U.S.C. § 352(t)(3). The letter also noted that the company failed to make much progress towards meeting the statutory, fifteen-month deadline by which it was to commence an approved postmarket surveillance study. Labeling a device as misbranded can carry grave consequences, including seizure of the device, injunctions against its manufacture and sale, prosecution, and civil monetary penalties. See, e.g., id. §§ 331, 334(a)(1).

Throughout 2015, ReWalk's management held several quarterly calls with investors, making no mention of the FDA's dissatisfaction with ReWalk's progress toward commencing the required study. It was not until the end of February 2016 that ReWalk disclosed the FDA's warning, right before the FDA published the warning letter on March 1. ReWalk stock had closed the day before at $10.48/share, but it ended March 1 at $9.07/share, a 13% one-day drop. Proposed plaintiff Geller, who had purchased ReWalk securities in late 2015, was among those who suffered a loss when the stock price dropped.

The FDA exercised its discretion to allow ReWalk to continue marketing the device as long as it commenced a postmarket surveillance study by June 1, 2016. It approved ReWalk's study plan on May 5, 2016, although, as of the date of the amended complaint, the FDA still described ReWalk's progress towards completing the study as "inadequate." Nonetheless, plaintiffs do not allege that the FDA has undertaken any enforcement action against ReWalk.

After a number of lawsuits against ReWalk not relevant here had been filed, six individuals (including Yan) and one institution filed this proposed class action on January 31, 2017. The complaint alleged only violations of the Securities Act. Yan successfully moved to be appointed lead plaintiff under the Private

Securities Litigation Reform Act of 1995 (PSLRA).[1] The Securities Act claim focuses exclusively on statements made in (or omitted from) the August 2014 Registration Statement. In a nutshell, it alleges that ReWalk failed to include in the Registration Statement enough information about the reasons the FDA required a postmarket surveillance study.

In August 2017, plaintiffs amended the complaint to add claims under sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934. See 15 U.S.C. §§ 78j(b), 78t(a); 17 C.F.R. § 240.10b-5. These Exchange Act claims primarily train on statements and omissions occurring after the IPO. In brief, they assert that ReWalk with scienter failed to disclose the difficulties it was experiencing with the FDA even as it sought to comfort investors about its progress. In due course, defendants filed an omnibus motion to dismiss the complaint, which the district court granted in part on August 23, 2018.

As to the Securities Act claims, the district court reasoned that the Registration Statement's allegedly misleading statements were true and there were no actionable omissions. See

[1] The PSLRA requires appointment of a lead plaintiff early in class-action securities cases. 15 U.S.C. § 78u-4(a)(3). In making this selection, the district court must consider several factors, one of which is the relative amount of securities purchased, id. § 78u-4(a)(3)(B)(iii)(I)(bb), which favored selecting Yan for this claim.

Wang Yan v. ReWalk Robotics Ltd. (Yan I), 330 F. Supp. 3d 555, 570–72 (D. Mass. 2018). The district court also noted that the complaint failed to mention Regulation S-K, see 17 C.F.R. §§ 229.105, .303, so the court refused to consider whether the complaint stated a plausible theory of liability under the regulation. Yan I, 330 F. Supp. 3d at 569–70.

As to the Exchange Act claims, the district court first determined that the potentially actionable omissions and/or misleading statements all occurred long after Yan made his last purchase of ReWalk securities. Id. at 572. The district court reasoned that Yan would be unable to prosecute the Exchange Act claims unless, perhaps, he could show that the statements made after his purchase were part of a common scheme extending back to the time period during which Yan made his purchases. Id. at 572–74. The court asked for supplemental briefing on these issues. It also suggested Yan might seek a substitute lead plaintiff who might be able to prosecute the claims. Id. at 574. In response, Yan advanced two arguments. First, he claimed to have alleged a common fraudulent scheme tying together the misrepresentations in the Registration Statement and the later alleged omissions and misstatements in the quarterly calls with investors. Second, he argued that, even if he could not pursue the Exchange Act claims, Geller should be added as a named party to replace Yan as lead plaintiff to pursue the Exchange Act claims on behalf of the class.

To further that second argument, Yan moved for leave to file a second amended complaint adding Geller as a named plaintiff.

The district court analyzed these arguments in two steps. First, it determined that the allegations fell well short of tying any allegedly misleading statements made prior to Yan's purchases to the alleged misrepresentations and omissions occurring after Yan's purchases; i.e., the amended complaint failed to allege a common scheme to defraud. Wang Yan v. ReWalk Robotics Ltd. (Yan II), 391 F. Supp. 3d 150, 156–57 (D. Mass. 2019). Second, the district court reasoned that, because all of Yan's own claims failed, he lacked standing to move for an amendment to the complaint that simply added another plaintiff to pursue a claim that Yan himself had no standing to pursue. Id. at 156–61. Accordingly, it dismissed the remaining claims. Yan timely appealed the judgment.

II.

Our review of a judgment dismissing a claim under Rule 12(b)(6) is de novo, and we may affirm the dismissal "on any basis available in the record." Lemelson v. U.S. Bank Nat'l Ass'n, 721 F.3d 18, 21 (1st Cir. 2013). In reviewing the motion, we take as true the facts alleged in the complaint and any reasonable inferences drawn from those facts, disregarding conclusory allegations. O'Brien v. Deutsche Bank Nat'l Tr. Co., 948 F.3d 31, 35 (1st Cir. 2020). We may also consider documents attached to

the complaint and incorporated by reference therein. Id. Although ReWalk argues that we should apply the heightened pleading standards of Federal Rule of Civil Procedure 9(b) because this Securities Act claim "sounds in fraud," Silverstrand Invs. v. AMAG Pharm., Inc., 707 F.3d 95, 102 (1st Cir. 2013), we need not decide whether Rule 9(b) applies because, as we will explain, the complaint fails even under the less-strict requirements of Rule 8. Under those requirements, we ask if the complaint's factual allegations plausibly state a claim that entitles the pleader to relief. Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 237 (1st Cir. 2013).

We consider first whether Yan successfully pleaded a claim that ReWalk violated the Securities Act by misstating or failing to disclose material information in its Registration Statement for its IPO. Relatedly, we also consider Yan's theory of Securities Act liability under Regulation S-K. Third, we consider a procedural objection Yan raises to the district court's reliance on a statutory safe harbor for forward-looking statements.

A.

Section 11 of the Securities Act creates a cause of action based on a registration statement that "contain[s] an untrue statement of a material fact or omit[s] . . . a material fact required to be stated therein or necessary to make the statements

therein not misleading." 15 U.S.C. § 77k(a). It creates a form of "strict liability" for the issuer, in this case ReWalk, for misleading statements, although other defendants can be liable for negligence. Silverstrand Invs., 707 F.3d at 102. An issuer may be liable under the "omissions clause" only where "an issuer's failure to include a material fact has rendered a published statement misleading." Omnicare Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 194 (2015). As discussed below, Regulation S-K also creates a duty to disclose information in certain situations.

1.

The principal theory Yan advances in support of his Securities Act claim focuses on the Registration Statement's description of the FDA's evaluation of the device. While ReWalk disclosed that the FDA ordered a surveillance study, Yan complains that the disclosure was misleading because ReWalk did not reveal that "the FDA specifically determined, in June 2014, that the . . . device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall." Yan asserts that "because the device was reasonably likely to cause serious injury or death, [ReWalk]'s boilerplate recitation of potential adverse regulatory consequences was rendered meaningless."

We disagree. The device as described in the Registration Statement is an exoskeleton upon which a paralyzed user "relies completely . . . to hold him or her upright." The Registration Statement expressly noted that such a "user could experience death or serious injury" were the device to malfunction. Given this context, when ReWalk disclosed that it had to "demonstrate a reasonable assurance of safety" to the FDA through its study, no reader would suspect that the FDA was concerned about mere bumps and bruises.

Nor did the FDA find that the product "was reasonably likely to cause serious injury or death," as Yan claims. The FDA stated only that it had "limited information" on the "rate and nature" of falls during home use but that a "comprehensive training program" may mitigate these risks. Neither the statute nor the FDA's guidance suggests that the FDA need find a reasonable likelihood of injury in order to require a postmarket surveillance study, and Yan does not allege any studies showing such a likelihood of harm. The Registration Statement discloses that the FDA wanted assurances of the device's safety given its incomplete knowledge, and the primary safety issue associated with this device is instability that can lead to serious injury or death -- exactly what the FDA's Section 522 order noted.

2.

Yan also points to the Registration Statement's reference to the study as examining the device's performance in "urban terrain" as potentially misleading. He complains only that the Registration Statement offered no "expla[nation]" or "defin[ition]" of the term. Yan seems to say that the term would be read as excluding rural and suburban non-institutional settings. Even were that so, Yan does not explain how this choice of language made the earlier warning language about death or injury in any setting misleading. Perhaps Yan is saying, without explaining how, that investors would regard a study in "urban terrain" easier to pass than one in suburban (or rural) terrains? Or perhaps, conversely, a test limited to a crowded cityscape may result in a higher percentage of accidents, although we are perplexed as to how describing a test as more difficult to pass than it actually is would induce individuals who would not otherwise invest to do so? In any event, Yan never develops how possible puzzlement over the term would result in materially misleading an investor.

3.

The district court also dismissed claims regarding the Registration Statement's touting of "compelling clinical data" showing the device's success and its assertion that the device is a "breakthrough product," finding them to be unactionable puffery.

Yan assigns error, arguing that these boasts are instead false or misleading "concrete statements of present fact." We again disagree. The district court correctly stated that "upbeat statements of optimism and puffing about [a] company's prospects" are not actionable. Greebel v. FTP Software, Inc., 194 F.3d 185, 207 (1st Cir. 1999). An example of such unactionable puffery found elsewhere includes a claim of "breakthrough drug." City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 173 (3d Cir. 2014) (internal quotation marks omitted). This Registration Statement's "breakthrough" assertion is not materially different. Yan attempts to distinguish Edinburgh on the ground that the defendant there referred to the relevant drug as a "potential" breakthrough. Id. But the drug in Edinburgh was still in the pre-market development stage, Phase 2 trials, at the time the alleged misrepresentations were made. Id. at 163. So while Pfizer's statement could be said to have been more forward looking, i.e., "once the drug fully hits the market, it will be a breakthrough," here ReWalk has a product that is essentially done with the development stage and is post-market, so the Registration Statement is saying that it is a breakthrough. In each instance, the word "breakthrough" is simply a puffed-up qualitative expression of the product's novelty.

Statements of opinion can be actionable if "the real facts are otherwise, but not provided." Omnicare, Inc., 575 U.S.

at 188. But the Registration Statement provides the relevant facts through detailed descriptions of the device and how it works. It explains that the device is "the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking," which Yan does not contest as untrue, effectively conceding that "breakthrough" was hardly beyond the pale of optimistic puffery. Moreover, the FDA's "de novo" classification of the device, meaning the FDA found it to be "not substantially equivalent" to extant devices, 21 C.F.R. § 807.100(a)(2), itself suggests that the device is at least somewhat unique.[2]

Similarly, we find no liability in ReWalk's description of the device's clinical results as "compelling." ReWalk cited and discussed the results to which it was referring and noted the types of studies that the device was yet lacking. A reasonable investor concerned with ReWalk's characterization of the data could easily pick her own preferred qualitative adjective.

[2] The Registration Statement also describes the market for exoskeletons as "new and unproven," providing some of the details about this developing area of medicine, characterizations that Yan does not take exception to. It further describes both the limited number of competitors that were in the market at the time and some competitive products.

B.

As an alternative theory of liability under the Securities Act, Yan points to Items 303 and 503[3] of Regulation S-K. Unlike Section 11 of the Securities Act standing alone, these regulatory requirements do create an affirmative duty to disclose certain information even if the Registration Statement does not itself create the need for a disclosure as a remedy for a half-truth. See 17 C.F.R. §§ 229.105, .303(a)(3)(ii). Item 303 creates liability where "a registrant knew about an uncertainty before an offering," "the known uncertainty is 'reasonably likely to have material effects on the registrant's financial condition or results of operation,'" and "the offering documents failed to disclose the known uncertainty." Silverstrand Invs., 707 F.3d at 103. Similarly, Item 503 creates liability where "the registrant knew, as of the time of the offering, that (1) a risk factor existed; (2) the risk factor could adversely affect the registrant's present or future business expectations; and (3) the offering documents failed to disclose the risk factor." Id.

The district court dismissed any consideration of these theories on the grounds that Yan did not cite the regulations in the complaint. Yan I, 330 F. Supp. 3d at 569-70 (citing In re Hi-

[3] Now recodified as Item 105. FAST Act Modernization and Simplification of Regulation S-K, 84 Fed. Reg. 12,674, 12,716-17 (April 2, 2019).

Crush Partners L.P. Sec. Litig., No. 12 CIV. 8557, 2013 WL 6233561, at *11 n.6 (S.D.N.Y. Dec. 2, 2013)). We need not decide whether Yan adequately pleaded the Regulation S-K claim because we reject this claim on alternate grounds.

Yan's argument, like his Section 11 arguments, is that ReWalk disclosed neither the risk of "instability, falls, and associated injuries" identified by the FDA nor that the device's safety "had not been established outside the controlled institutional environment of a hospital or rehabilitation center." As discussed above, however, this argument fails because the Registration Statement did not omit these risks. It noted, just for example, that "[t]here is no long-term clinical data with respect to the safety or physical effects of [the device]" and that approval for use "beyond the institutional/rehabilitational setting" requires performance of the relevant postmarket study. Indeed, the very requirement to conduct the study, explicitly disclosed, clearly suggested that the FDA perceived a risk that needed to be understood better. In short, ReWalk adequately disclosed the claimed risk or uncertainty, so we affirm the dismissal of the Securities Act claims even as viewed through the lens of Regulation S-K.

C.

As to his Securities Act claims, Yan raises, finally, a procedural objection, complaining that the district court excused

some of the statements challenged in the Registration Statement by "sua sponte" relying on the statutory safe harbor for forward-looking statements. See 15 U.S.C. § 78u-5(c)(1), (i)(1).

It is sometimes inappropriate for a district court to advance on its own a reason to dismiss a claim. See Futura Dev. of P.R., Inc. v. Estado Libre Asociado de P.R., 144 F.3d 7, 13-14 (1st Cir. 1998). Even if that happened here, the reason raised by the district court posed a pure issue of law. Because Yan gets a de novo appeal, and we hold him to no waiver of any type on this issue, he has lost no chance to marshal any supporting arguments. He also points to nothing that he would have added to the record had ReWalk raised the argument itself. In short, he is in no worse a position than he would have been in had ReWalk fully raised and briefed the defense below. See Pediatricians, Inc. v. Provident Life & Accident Ins. Co., 965 F.2d 1164, 1173 (1st Cir. 1992) (repeating the "well settled rule" that we "may affirm the judgment of the district court on any independently sufficient ground," even where that basis was "not briefed or argued" in the district court).

As noted by the district court, a statement is not actionable if it is "a forward-looking statement, and [it] is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C.

§ 78u-5(c)(1)(A)(i). Here, the statements that the district court concluded were protected by the safe harbor, which Yan challenges, are that ReWalk "intend[s] to continue to work with [various entities] to generate additional data regarding functionality and that supports the health and economic benefits of [the device]" and that it will "continue to engage and fund researchers and organizations to conduct clinical studies to demonstrate the functionality and utilization of ReWalk and to highlight economic benefits of reductions in medical complications associated with spinal cord injury." Further, ReWalk "believe[s] that this data will position [ReWalk] to pursue additional third-party reimbursement for [its] products."[4] The verb tense as well as a specific warning about "expectations as to [ReWalk's] clinical research program and clinical results" make clear that these statements are forward looking, and the Registration Statement includes the safe harbor notice regarding the risk factors that could cause the actual clinical results to differ by telling investors they "should consider the risks provided under the 'Risk Factors' in this prospectus" when evaluating these statements. The Registration Statement also disclosed that "future studies or

[4] Although the district court did not clearly reference this last statement in its analysis, it is in the same paragraph of the Registration Statement and complaint. Given its context, it is clear that it should be considered alongside ReWalk's views about the effect of its future clinical studies.

clinical experience may indicate that treatment with [the device] is not superior to treatment with alternative products or therapies" and that insurers may never provide coverage for these devices due in part to their "experimental" nature backed by "limited clinical data." Taken together, we agree with the district court that none of these challenged statements concerning ReWalk's expectancy for the future were actionable.[5]

III.

A.

After dismissing the Securities Act claims, the district court determined that ReWalk made no relevant Exchange Act omissions or misstatements until months after Yan purchased his shares on September 15 and 17, 2014. It found this chronology to be fatal to Yan's standing to bring the Exchange Act claims. Yan II, 391 F. Supp. 3d at 156–57 (citing Gross v. Summa Four, Inc., 93 F.3d 987, 993 (1st Cir. 1996) ("[B]ecause [plaintiff] purchased his stock . . . before the [alleged misrepresentation], he has no standing to complain about the statements . . . ")).

Yan contends that, in so reasoning, the district court overlooked the fact that the complaint alleges that ReWalk repeated after the IPO the same misstatements and omissions that are the

[5] Yan concedes that Securities Act Section 15 claims require a valid Section 11 claim. It follows that dismissal of the Section 15 claims was proper.

subject of Yan's Securities Act claim. Thus, he reasons, ReWalk engaged in a "common scheme" that tied together claimants who purchased in the IPO with claimants who purchased after the IPO.

The problem with this theory is that, as we have explained, the statements and claimed omissions in the Registration Statement (concerning risk, injury, and "urban terrain") were not misleading in any relevant sense. So even if fraud occurred after the IPO, there is no basis for claiming that it commenced before the IPO. The Exchange Act claims of fraud rise or fall instead on consideration of ReWalk's decision not to disclose the difficulties it was having after the IPO in seeking approval by the FDA of a study plan. And all of that difficulty ensued after Yan bought his stock, with the FDA's first response informing ReWalk of its shortcomings arriving on September 29, 2014. So we agree with the district court that there was no basis for any claim of a "common scheme" tying together pre- and post-IPO statements and/or omissions, and to the extent post-IPO omissions and/or statements were actionable under the Exchange Act, Yan had no standing to pursue such claims.

This failure to tie anything misleading in the Registration Statement to later alleged fraudulent omissions dooms Yan's only argument as to why he should be able to continue to pursue the Exchange Act claims of other persons as their class representative under Federal Rule of Civil Procedure 23(b)(3).

Persons who wish to represent a class "must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." Simon v. E. Ky. Welfare Rts. Org., 426 U.S. 26, 40 n.20 (1976) (quoting Warth v. Seldin, 422 U.S. 490, 502 (1975)); see Plumbers Union Loc. No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 769 n.6 (1st Cir. 2011) (citing 5 J. Moore et al., Moore's Federal Practice § 26.63 [1][b], at 23-304 (3d ed. 2010), for the proposition that for each claim there must be a class representative who has standing to raise that claim). Yan identifies no such similar injury without the Registration Statement in play. Even apart from the matter of standing, it would hardly serve the interests of class members who may have valid claims based on their facts to be represented by a person whose facts dictate that he or she will lose the case even if the class members might have won. For these reasons, and likely others, the district court plainly got it right in refusing to allow Yan to proceed as an Exchange Act class representative.

B.

After the district court dismissed Yan's Securities Act claim in Yan I, Yan moved to amend the complaint to add Geller as a named plaintiff to pursue the Exchange Act claim. When the district court took up this motion, it first dismissed Yan's

Exchange Act claim, as just explained. Yan II, 391 F. Supp. 3d at 157. It then reasoned that, bereft of any such claim, Yan had no standing to ask the court to do anything at all, including adding a party. Id. at 158–61.

There are indeed some cases in which courts suggest this formalistic approach is correct. As circuit authority, the district court pointed to Summit Office Park, Inc. v. United States Steel Corp., which stated that, "where a plaintiff never had standing to assert a claim against the defendants, it does not have standing to amend the complaint and control the litigation by substituting new plaintiffs, a new class, and a new cause of action." 639 F.2d 1278, 1282 (5th Cir. 1981); see also, e.g., Lierboe v. State Farm Mut. Auto. Ins. Co., 350 F.3d 1018, 1023 (9th Cir. 2003); Westfield Park Homeowners' Ass'n, Inc. v. NVR, Inc., No. 1:06 CV 00507, 2007 WL 9774486, at *4 (N.D. Ohio Mar. 27, 2007). The better-reasoned authority, though, allows a court to entertain and grant a motion to amend filed by a plaintiff who lacks standing to pursue the claim pleaded.

That authority includes the Supreme Court. In a seminal standing case, Sierra Club v. Morton, the Court held that the Sierra Club lacked standing because any injury would be directly felt only by others. 405 U.S. 727, 735, 741 (1972). The Court nevertheless invited Sierra Club to amend its complaint to better plead standing. Id. at 735 n.8 ("Our decision does not, of course,

bar the Sierra Club from seeking in the district court to amend its complaint by a motion under Rule 15."); see also Mathews v. Diaz, 426 U.S. 67, 75 & n.8 (1976) (recognizing that the plaintiff had not satisfied "a nonwaivable condition of jurisdiction" before filing suit, but concluding that this defect did not void the suit ab initio because "[a] supplemental complaint in the District Court would have eliminated this jurisdictional issue").

Our own circuit has matter-of-factly followed precisely this same approach, reversing the denial of a motion to amend where the amended pleading established Article III standing by adding facts not contained in the prior complaint. Adams v. Watson, 10 F.3d 915, 919-25 (1st Cir. 1993). More recently we observed that "Rule 15(d) has been viewed as an appropriate mechanism for pleading newly arising facts necessary to demonstrate standing." See U.S. ex rel. Gadbois v. PharMerica Corp., 809 F.3d 1, 15 (1st Cir. 2015) (citing Northstar Fin. Advisors, Inc. v. Schwab Invs., 779 F.3d 1036, 1044-45 (9th Cir. 2015)).

Congress has explicitly endorsed this view, even as expanded to cover all jurisdictional defects. See 28 U.S.C. § 1653 ("Defective allegations of jurisdiction may be amended, upon terms, in the trial or appellate courts."); see also Williams v. Lew, 819 F.3d 466, 471 (D.C. Cir. 2016). So too have the better-reasoned circuit court opinions. See, e.g., A.W. v. Tuscaloosa City Schs. Bd. of Educ., 744 F. App'x 668, 672 (11th Cir. 2018)

("[C]ourts may authorize amendment of a complaint under Rule 15 even in the absence of jurisdiction."); Est. of Cornejo ex rel. Solis v. City of Los Angeles, 618 F. App'x 917, 920 n.2 (9th Cir. 2015) (holding in the alternative that even if the plaintiffs did not have standing initially, they properly amended their pleadings under Rule 15 before judgment, "resolv[ing] any standing issues"); Advanced Magnetics, Inc. v. Bayfront Partners, Inc. (AMI), 106 F.3d 11, 13 (2d Cir. 1997) ("Though we uphold the district court's ruling that the assignments were not sufficient to give AMI standing to pursue the shareholders' claims, we conclude that the court should not have dismissed those claims but should have granted AMI's request to amend the complaint to allow the shareholders to pursue their own claims."); Adams, 10 F.3d at 919–25; Nat'l Post Off. Mail Handlers Loc. No. 305 v. U.S. Postal Serv., 594 F.2d 988, 991 (4th Cir. 1979) ("The amendment to allege standing explicitly should be permitted and on remand the district court shall grant leave to amend."); see also, e.g., Nunez v. Saks Inc., 771 F. App'x 401, 402–03 (9th Cir. 2019); Revell v. Port Auth. of N.Y. & N.J., 321 F. App'x 113, 117–18 (3d Cir. 2009).

We also see no reason why this permissiveness does not extend to motions seeking to add a named party asserting the exact same claim that is already pleaded in the complaint. See Allied Int'l, Inc. v. Int'l Longshoremen's Ass'n, 814 F.2d 32, 34–36 (1st Cir. 1987) (citing the advisory committee's note to the 1966

amendment to Federal Rule of Civil Procedure 15, which states that "the attitude taken in revised Rule 15(c) toward change of defendants extends by analogy to amendments changing plaintiffs," and allowing an amendment to substitute the assignee where the original plaintiff had assigned its claims in their entirety, which otherwise would have precluded any recovery).

Federal Rule of Civil Procedure 17 would not make much sense if the district court were correct. The rule expressly anticipates the possibility that a complaint might be brought by someone who turns out not to be the party in interest (i.e., is not the person who has standing to prosecute the claim). See generally Morcelo-Martinez v. Welfare Fund ILA-PRSSA, 972 F.2d 337 (1st Cir. 1992) (affirming dismissal where plaintiffs "lacked standing to bring this action since they were not the real parties in interest"); MHI Shipbuilding, LLC v. Nat'l Fire Ins. Co. of Hartford, 286 B.R. 16, 27-28 (D. Mass. 2002) (discussing the general interaction between standing and Rule 17(a)). The rule expressly admonishes that "[t]he court may not dismiss an action for failure to prosecute in the name of the real party in interest until, after an objection, a reasonable time has been allowed for the real party in interest to ratify, join, or be substituted into the action." Fed. R. Civ. P. 17(a)(3). And the mechanism often used to substitute in the party with standing to press the claim is Rule 15. See Fed. R. Civ. P. 15 advisory committee's note to

1966 amendment (emphasizing that Rule 15(c)(3) "extends by analogy to amendments changing plaintiffs"); see also 6A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1555 (3d ed. 2020) ("Rule 15(c) has been used in conjunction with Rule 17(a) to enable an amendment substituting the real party in interest to relate back to the time the original action was filed.").

Some courts nevertheless seem to think that the foregoing rules somehow do not apply in a class action when the original plaintiff is found to lack standing and timely moves to add a new plaintiff who does have standing. See, e.g., Summit Off. Park, 639 F.2d at 1282. The simplest response to that view is that there is absolutely nothing at all in Rule 23 that even hints at such a bespoke modification of the usual amendment rules in a class action. This is certainly not to say that motions to amend so as to change named plaintiffs must be allowed. It is simply to say that such motions must be evaluated just as they would be under Rule 15 criteria in any other case. Those criteria consist principally of whether there was, per Foman v. Davis, "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of the amendment." 371 U.S. 178, 182 (1962).

The Second Circuit's AMI opinion is especially instructive and is almost directly on point with our present case. AMI brought a class action under the Exchange Act. 106 F.3d at 14. The district court found that AMI had no standing to assert the Exchange Act claim. Id. at 15. AMI moved under Rule 15 to amend the complaint to bring in another party that did have standing to assert the Exchange Act claim, which the district court denied. Id. The Second Circuit then affirmed the dismissal of the original plaintiff's claims for lack of standing, id. at 18, but it reversed the denial of the motion for leave to add a plaintiff to cure the standing defect, id. at 19–21. A contrary approach can claim no justification other than a desire to adhere to a degree of pure formalism that would surprise the drafters of the civil rules, achieve nothing but mischief, and run contrary to our own recognition that Rule 15 "helps courts and litigants to avoid pointless formality." Gadbois, 809 F.3d at 4.

Nothing in the foregoing is contrary to our decision in Pruell v. Caritas Christi, 645 F.3d 81 (1st Cir. 2011). Pruell addressed a question of federal court removal jurisdiction: Whether the case was properly removed turned on whether one of the plaintiffs was, on the day of removal, a party to a collective bargaining agreement. Id. at 83. The court held, quite properly, that it need consider only the named plaintiffs in answering that question, not persons who might or might not become class members

if the case were certified under Rule 23. Id. at 83–84. In so doing, it acted in accord with the view that jurisdiction is based on the claims of only the named class members. Id. at 84. That may no longer be true under CAFA, see Standard Fire Ins. Co. v. Knowles, 568 U.S. 588, 592 (2013) (citing 28 U.S.C. § 1332(d)), but that is beside the point. The point is that Pruell has nothing to say about whether and when a pleading may be amended to add a plaintiff.

This case is especially well suited to the prevailing rules because the district court at all times actually did have Article III subject matter jurisdiction over the action, as Yan had pleaded his own nonfrivolous Securities Act claim, which we today review without any notion that we somehow lack jurisdiction over the case. And while that standing may well be insufficient to allow Yan to serve as a class representative over the Exchange Act claims, nothing in rule or reason says that the district court could not welcome on board another litigant who does have standing to serve as a class representative on that count (assuming all Rule 23 and statute of limitations requirements are satisfied). See Cotton v. Certain Underwriters at Lloyd's of London, 831 F.3d 592, 595 (5th Cir. 2016) (distinguishing Summit and holding that, even if a party lacked constitutional standing over one claim, leave to amend was still proper because there was a separate claim in the suit that the court had jurisdiction to hear). There is

also no contention that dismissal of a claim over which the court has standing precludes a party with standing from seeking leave to amend. See, e.g., O'Boyle v. Real Time Resolutions, Inc., 910 F.3d 338, 347 (7th Cir. 2018).

In sum, the requirements of standing presented no impediment in this case to the granting of the motion to add Geller as a named plaintiff on the Exchange Act claims.[6]

C.

Anticipating the possibility that we might reject the reason given by the district court for denying the motion to amend, ReWalk argues that we can and should affirm the denial of the motion to amend on other grounds not reached by the district court; to wit, the failure of the amended complaint to successfully plead an actionable Exchange Act claim. Although it is often appropriate to leave such a matter for the district court to address in the first instance on remand, especially when the grounds are not fully developed or fairly contested on appeal, see Loftness Specialized Farm Equip., Inc. v. Twiestmeyer, 742 F.3d 845, 851 (8th Cir. 2014), the law is clear that we have the discretion to affirm a decision of the district court on alternative grounds, see Ticketmaster-N.Y., Inc. v. Alioto, 26 F.3d 201, 204 (1st Cir.

[6] Judge Lynch and Judge Stahl limit their joining in this portion of the opinion on the basis that the standing defect in this case may be viewed as a lack of statutory standing.

1994). We exercise that discretion in this case for two reasons. First, we are dealing with issues of law: Whether the amended "complaint adequately alleges facts that would plausibly make out a claim," Abdallah v. Bain Cap. LLC, 752 F.3d 114, 119 (1st Cir. 2014), and similarly, whether the failure of a proposed amended pleading to state a claim is a basis for denying the motion to amend, Rife v. One W. Bank, F.S.B., 873 F.3d 17, 21 (1st Cir. 2017). Second, the parties on this appeal have extensively briefed the adequacy of the Exchange Act allegations, with Yan having anticipated and addressed it in his opening brief, and then furthered his argument in his reply. So we turn our attention to the question whether the amended complaint adequately states a claim under the Exchange Act. For the following reasons, we conclude that it does not.

Under the Exchange Act, plaintiffs need plead a material falsehood or a material omission of a fact that was subject to a duty to disclose. See Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 454 (1st Cir. 2017). A complaint must also "adequately allege, among other things, scienter." Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31, 37 (1st Cir. 2017) (quoting Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76, 80 (1st Cir. 2016)). Scienter can be established by showing a high degree of recklessness in the form of "an extreme departure from the standards of ordinary care, and which 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." Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 649 F.3d 5, 20 (1st Cir. 2011). As Yan correctly argues, he need not plead facts that directly show scienter. See In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005). Rather, he can plead scienter by pleading facts that create a "strong inference" of scienter: "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.'" Corban, 868 F.3d at 37–38 (quoting Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 324 (2007)). "In cases where we have found the pleading standard satisfied, the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012).

There is no claim that ReWalk made any false statement during the relevant period prior to Yan's purchase of ReWalk securities. Rather, the factual basis for the Exchange Act claim is ReWalk's failure to disclose the travel of its pursuit of final FDA approval.

Our case law is clear that a company in ReWalk's position is not in the ordinary case under an affirmative obligation to disclose "each detail of every communication with the FDA." Id. at 40. Relatedly, a failure to "divulge the details of interim 'regulatory back-and-forth' with the FDA . . . when the defendants do provide warnings in broader terms" does not generate a strong inference of scienter. Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 59 (1st Cir. 2018) (quoting Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 244 (1st Cir. 2015)).

The bulk of the omissions to which Yan points concern run-of-the mill regulatory back-and-forths. And in light of the foregoing discussion regarding the adequate risk disclosures in the registration statement, such omissions are inadequate to generate a strong inference of scienter.

The only arguable exception to this run-of-the-mill back-and-forth is the FDA's September 2015 warning letter, where the FDA informed ReWalk that its noncompliance with the postmarket surveillance study deadline rendered the device misbranded. The FDA, however, took no action at that time, instead stating only that "[f]ailure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties." (emphasis added). As we have noted, the registration already disclosed that "[f]ailure to

comply with the [postmarket surveillance study, among other things] could lead to removal of ReWalk from the market" and that "fail[ure] to comply with applicable regulatory requirements . . . may result in" seizures, injunctions, and civil penalties. Furthermore, there is no allegation that ReWalk made any claim concerning its progress with the FDA that was inconsistent with its receipt of the letter. Nor is there any allegation that any defendant regarded the receipt of the letter as anything other than a warning of a need to take action that ReWalk intended to take (and did take).

Of course, it is fair to infer that a written warning noting that a device is currently misbranded for failure to do a satisfactory study is not a common event. So we looked to see if any inference of scienter arising from nondisclosure might be strengthened by context. But ReWalk had already disclosed precisely the regulatory consequences should the FDA not grant the approvals it sought, and here there is no allegation of insider sales, of significant fundraising events between late September 2015 and the FDA's disclosure of the letter, or of claims that executives received some kind of bonus based on stock performance between September 2015 and February 2016 that would otherwise bolster this inference. See generally Greebel, 194 F.3d at 196. Nor is there any allegation that ReWalk expected the FDA would not itself make public its warning.

The amended pleading does contain allegations by so-called confidential witnesses (CW). The CW allegations make clear that executives had knowledge of the back-and-forth with the FDA and of the importance of obtaining regulatory clearance, but mere knowledge of facts is insufficient to support a strong inference of scienter. See Stone & Webster, Inc., 414 F.3d at 205. There must be some allegation strongly implying that defendants had reason to believe their omissions to be fraudulent. And Yan's allegations actually suggest a contrary inference: That even after receiving the warning letter, defendants believed they could still meet the FDA's requirements, as they showed "no sense of urgency" regarding the study until February 2016 -- exactly when they disclosed the warning letter to investors. While this lack of urgency might amount to poor management, such a failing does not amount to securities fraud. See Shaw v. Digit. Equip. Corp., 82 F.3d 1194, 1206 (1st Cir. 1996).

In sum, the complaint alleges no statements by defendants concerning ReWalk's proceedings with the FDA that they had reason to believe were contrary to the facts or previous disclosures, there is no allegation that defendants regarded the warning letter as calling on ReWalk to do what it did not intend to do, and there are no allegations of surrounding circumstances that might cast ReWalk's communications in a more suspicious light. All in all, on the allegations of scienter as presented, we see in

the amended complaint no adequate claim under the Exchange Act. So for that reason the denial of leave for Geller to join the case in order to prosecute that claim was not error.

IV.

We therefore affirm the district court's denial of the motion to add Geller as a party and its dismissal of the amended complaint.