UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IAN GOUCHER, THOMAS L. SULLIVAN, and GERT-PAUL VAN'T HOFF, individually and on behalf of all others similarly situated,	)	21 C 4181
Plaintiffs,	)	Judge Gary Feinerman
vs.	)	
ITERUM THERAPEUTICS PLC, COREY N. FISHMAN, and JUDITH M. MATTHEWS,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Ian Grocher, Thomas Sullivan, and Gert-Paul van't Hoff bring this suit against Iterum Therapeutics plc and two of its officers, Corey Fishman and Judith Matthews, on behalf of themselves and a putative class of others who purchased Iterum stock from November 30, 2020 through July 26, 2021. Doc. 54. Plaintiffs allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. Doc. 54. Defendants move under Civil Rule 12(b)(6) to dismiss the complaint. Doc. 58. The motion is granted, though Plaintiffs will be given a chance to replead.

Background

In resolving Defendants' Rule 12(b)(6) motion, the court assumes the truth of the operative complaint's well-pleaded factual allegations, though not its legal conclusions. *See Zahn v. N. Am. Power & Gas, LLC*, 815 F.3d 1082, 1087 (7th Cir. 2016). The court must also consider "documents attached to the complaint, documents that are critical to the complaint and referred to in it, and information that is subject to proper judicial notice," along with additional facts set forth in Plaintiffs' brief opposing dismissal, so long as those additional facts "are

consistent with the pleadings." *Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1019-20 (7th Cir. 2013) (internal quotation marks omitted). The facts are set forth as favorably to Plaintiffs as those materials allow. *See Pierce v. Zoetis, Inc.*, 818 F.3d 274, 277 (7th Cir. 2016). In setting forth those facts at the pleading stage, the court does not vouch for their accuracy. *See Goldberg v. United States*, 881 F.3d 529, 531 (7th Cir. 2018).

Iterum is a clinical-stage pharmaceutical company focused solely on developing sulopenem, an antibiotic. Doc. 54 at ¶ 2. At all relevant times, Fishman was Iterum's President and CEO, and Matthews was its CFO and Investor Contact. *Id*. at ¶¶ 28-29. Iterum acquired sulopenem from Pfizer in 2015 via an exclusive license. *Id*. at ¶¶ 2, 61.

Pfizer had previously conducted clinical trials for sulopenem but stopped development after failing to generate statistically significant data. *Id*. at ¶ 61. Pfizer had sought to develop sulopenem as a treatment for pneumonia; Iterum, by contrast, seeks to develop it as a treatment for uncomplicated Urinary Tract Infections ("uUTIs"). *Id*. at ¶¶ 63, 51. UTIs are bacterial infections typically treated with antibiotics. *Id*. at ¶ 51. But UTIs have increasingly been caused by antibiotic-resistant bacteria, and Iterum described sulopenem as capable of overcoming that problem. *Id*. at ¶¶ 52-53. As Fishman stated in a 2019 press release: "[I]t has been over 20 years since a new, oral treatment has been developed for urinary tract infections and the existing orals are no longer effective. If approved, oral sulopenem will provide an option to those patients with an elevated risk for treatment failure that currently have no other alternatives." *Id*. at ¶ 53.

The developer (also known as the sponsor) of a new drug must obtain approval from the U.S. Food and Drug Administration ("FDA") before marketing or selling it in the United States. *Id*. at ¶¶ 3, 33. The second stage of the approval process involves clinical trials, which typically occur in three phases. *Id*. at ¶ 35. Phase 1 trials are designed to identify the drug's most

common side effects. *Id*. at ¶ 36. Phase 2 trials focus on the drug's efficacy, while also evaluating safety and short-term side effects. *Id*. at ¶ 37. In Plaintiffs' telling, Phase 3 trials—which are more complex—"can begin" "[i]f Phase 2 clinical trial results demonstrate that the drug is effective." *Id*. at ¶ 38. Specifically, following "a successful Phase 2 clinical trial," a sponsor develops a Phase 3 trial with the FDA. *Ibid*. The principal result measured at the end of a Phase 3 trial, called the "primary endpoint," concerns whether the new drug is more effective than a placebo or comparator, measured by statistical significance. *Id*. at ¶ 39.

Following the clinical trials, a sponsor submits a New Drug Application ("NDA") to the FDA. *Id*. at ¶¶ 3, 40. If the FDA makes "a threshold determination that the NDA is sufficiently complete to permit a substantive review," the FDA files the NDA. 21 C.F.R. § 314.101(a)(1)-(2); *see* Doc. 63 at 20 n.16. The FDA then reviews the NDA and determines whether to approve it in its existing form. Doc. 54 at ¶¶ 41-43.

The Phase 3 clinical trials that Iterum conducted of sulopenem are called SURE-1, SURE-2, and SURE-3. *Id*. at ¶ 65. Most relevant for present purposes is SURE-1, Doc. 63 at 8 n.4, which involved patients with uUTIs and compared sulopenem to ciprofloxacin, a fluoroquinolone. Doc. 54 at ¶¶ 7 n.1, 19. Quinolones and fluoroquinolones are antibiotics effective against a broad range of bacteria. *Id*. at ¶ 7 n.1. Given their risks, "the FDA has advised they are not suitable for common conditions, such as uUTIs, and should only be considered when treatment with other, less toxic antibiotics has failed." *Ibid*.

The putative class period begins on November 30, 2020, when Iterum issued a press release announcing the submission of its NDA to the FDA. *Id*. at ¶ 91; *see* Doc. 58-12. The press release explained that the NDA "include[d] data from the SURE-1, SURE-2 and SURE-3 phase 3 clinical trials," and that "[t]he SURE-1 clinical trial (uUTIs) demonstrated statistical

superiority of oral sulopenem to the widely used comparator, ciprofloxacin, for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with a quinolone non-susceptible pathogen." Doc. 58-12 at 2; *see* Doc. 54 at ¶ 91. The release quoted Fishman as saying: "The submission of the NDA filing for oral sulopenem is a significant step forward in bringing new antibiotics to patients to help address the challenge of antibiotic resistance. … Oral sulopenem, if approved, would mean that physicians and patients have the opportunity to benefit from the proven efficacy and safety of penem antibiotics that, to date in the U.S., have only been available in IV formulations. We are now one step closer to realizing the goal of bringing this much needed medicine to the over six million patients with cipro-resistant UTIs each year in the U.S." Doc. 58-12 at 2; *see* Doc. 54 at ¶ 92.

On January 25, 2021, Iterum issued a press release announcing that the FDA had accepted the NDA for review. Doc. 58-13 at 2; *see* Doc. 54 at ¶ 94. The release explained that the FDA designated the NDA for priority review; planned to hold an advisory committee meeting to discuss it; and assigned a goal date of July 25, 2021 for completing the review. Doc. 58-13 at 2. The release quoted Fishman as stating: "The FDA acceptance of our NDA for review is an important milestone for Iterum. If approved, oral sulopenem would be the first penem available orally in the U.S. with the ability to treat multi-drug resistant infections in the community. … Specifically, this important antibiotic is one step closer to relieving the growing problem of quinolone resistance found in over six million uncomplicated urinary tract infections in the U.S. each year." Doc. 58-13 at 2; *see* Doc. 54 at ¶ 94.

On February 1, 2021, Iterum issued a press release announcing that it had engaged EVERSANA, a commercial services provider, "to immediately initiate pre-launch activities, followed by planned commercialization services upon final agreement." Doc. 58-14 at 2; *see*

Doc. 54 at ¶ 95. The release reiterated that the FDA had designated the NDA for priority review, adding that "[a]head of an anticipated decision by the FDA in July 2021, Iterum [would] utilize EVERSANA's pre-launch activities including U.S. market access, strategic marketing, medical education, and patient services." Doc. 58-14 at 2; *see* Doc. 54 at ¶ 95. The release quoted Fishman as stating: "We are very pleased to partner with EVERSANA and are confident in their ability to provide end-to-end services to ensure oral sulopenem will reach patients and their families efficiently and effectively once oral sulopenem is available for prescribing. … We will be working diligently to ensure we are ready for the potential launch of oral sulopenem in the U.S. in the fourth quarter of 2021." Doc. 58-14 at 2; *see* Doc. 54 at ¶ 95.

In February 2021, Iterum issued three press releases announcing stock offerings expected to generate tens of millions of dollars in proceeds. Doc. 54 at ¶¶ 96-98.

On March 12, 2021, Iterum issued a press release announcing its fourth-quarter and full-year financial results for 2020. *Id*. at ¶ 99. The release quoted Fishman as stating: "Our priorities for the rest of this year are: (1) holding a positive Advisory Committee meeting in June, (2) completion of FDA review of our NDA by the end of July, (3) initiating the commercial launch in the fourth quarter, if approved, and (4) working with the FDA to understand the requirements for potential expansion of our label in uUTI to include all patients, if approved, and to potentially add the complicated urinary tract infection (cUTI) indication. In anticipation of these key milestones, we have raised sufficient capital to support the execution of our strategy as currently planned." *Ibid*. The release added that Iterum had received net proceeds of $74.3 million from the stock offerings announced the previous month. *Id*. at ¶ 100.

Also on March 12, Iterum filed its 2020 10-K with the Securities and Exchange Commission ("SEC"). *Id*. at ¶ 101; *see* Doc. 58-2. The complaint references several statements from the 10-K, including:

- "[I]n the uUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin, in the population of patients with baseline pathogens susceptible to ciprofloxacin driven to a large degree by a greater amount of [asymptomatic bacteriuria] in the sulopenem treated patients at the test of cure visit relative to those receiving ciprofloxacin. However, in the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating superiority to ciprofloxacin, providing evidence of a treatment effect in patients with uUTI." Doc. 58-2 at 5; *see* Doc. 54 at ¶ 101.

- "The FDA currently plans to hold an advisory committee meeting on June 2, 2021 to discuss the NDA." Doc. 58-2 at 5; *see* Doc. 54 at ¶ 102.

- "[W]e believe there is a pressing need for a novel oral antibacterial therapy for UTI, both complicated and uncomplicated … ." Doc. 54 at ¶ 102 (emphasis omitted).

- "[Iterum expected the] commercial opportunity for oral sulopenem to be substantial with initial focus on the treatment of uUTIs caused by a quinolone non-susceptible pathogen in the community." *Id*. at ¶ 103 (emphasis omitted).

- "[This filing] does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." *Id*. at ¶ 104 (emphasis omitted).

That same day, Iterum held a conference call during which Fishman made these statements:

- "With regard to the [FDA Advisory Committee meeting], the review has been ongoing. I would call it a pretty standard review based on the questions we've gotten and in our ability to respond to them. There hasn't been anything flagged by FDA to us as this will be a topic for discussion at the Advisory Committee. I think we feel very good that we have a very robust data package for our indication, and as I mentioned the data that has been provided in other studies and even in places where we didn't hit the endpoint has continued to be highly supportive. … And so I think the overall package is extremely supportive and I think from an AdCom perspective we're going in – we'll be prepared to discuss, of course, the data package and everything around it, but I think we feel good about coming out of

there in good shape." *Id*. at ¶ 105(a) (alteration and omission in original) (emphasis omitted).

- "[W]e haven't gotten any indication that anything is off track. We continue to get indications that we're still on track for everything we've said to-date and the information we provided has been pretty extensive. So, we'll just have to wait and see but as of today, we don't have any indication that anything is different than what we had expected." *Id*. at ¶ 105(b) (alteration in original) (emphasis omitted).

- "[W]e've all sort of kept up to-date on what's happening in other places, but I would say as we sit here today, we feel like this has been a pretty standard kind of review and there's been no shift in the last month or six weeks in terms of tone or anything like that. We're getting information requests, which is very typical. We're responding to those on the timelines were (sic) suggested. And I think we feel like there's been no change in our review at this point and nothing points us in a direction that looks, anything like that as we sit here, as we are talking today." *Ibid*. (alterations in original) (emphasis omitted).

On May 14, 2021, Iterum issued a press release stating that the FDA had postponed its June 2 advisory committee meeting "to allow the FDA more time to review material provided by the Company in support of the NDA." Doc. 54 at ¶ 106 (emphasis omitted). The release said that "[a] new date for such meeting, if required by the FDA, has not yet been confirmed." *Ibid*. The release quoted Fishman as stating: "We continue to prepare for a[n FDA] advisory committee meeting and look forward to clarity from the FDA on timing. In the meantime, the FDA continues its review of [the NDA] and has not advised us of any change to the current [review completion] goal date of July 25, 2021. … With an FDA decision on oral sulopenem expected in the second half of 2021 and a strong cash position, we are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved." *Ibid*. (first and second alterations and omission in original) (emphasis omitted).

Also on May 14, Iterum filed with the SEC its quarterly 10-Q. *Id*. at ¶ 107. The 10-Q "contained substantively the same statements as the 2020 10-K, describing the data supporting the sulopenem NDA, while assuring investors that the Company had made an informed NDA

submission based on prior communications with the FDA." *Ibid*. The 10-Q indicated that, as of March 31, 2021, Iterum had a deficit of $385.9 million and "expect[ed] to continue to incur significant expenses for the foreseeable future as we seek regulatory approval and engage in market preparation and pre-commercialization activities." *Id*. at ¶ 108 (alteration in original). The 10-Q certified that it did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." *Ibid*. (emphasis omitted).

That same day, Defendants held a conference call during which Fishman stated:

- "[T]he FDA review of our new drug application continues, and our interactions to date have progressed well and are typical as to where we expect to be a few months from a potential approval.… In closing, we believe Iterum is in a very solid position with our NDA under review and having about $100 million of cash on the balance sheet." *Id*. at ¶ 109(a) (alternation and omission in original) (emphasis omitted).

- "[W]e've been really upfront about everything that the FDA has told us." *Id*. at ¶ 109(b) (emphasis omitted).

On May 27, 2021, Iterum issued a press release stating that it had participated the previous day in a "late-cycle meeting" with the FDA. *Id*. at ¶ 110. The release added: "During the meeting, the FDA shared issues still under review regarding the [sulopenem NDA] and the Company responded to these issues. The FDA has determined that an Advisory Committee meeting is not currently necessary. The review of the NDA is ongoing and the Company was informed that the FDA continues to work toward the [review completion] goal date of July 25, 2021." *Ibid*. (second alteration in original) (emphasis omitted).

In the wake of that press release, analysts at RBC Capital Markets issued a report stating: "Healthy dialogue between company and agency over path of review continues, including a recent late-cycle meeting. Per the press release and confirmed via our discussion, the company

continues to maintain an open dialogue with FDA on sharing and responding to what we interpret as routine filing issues over the course of the review." Doc. 58-10 at 2; *see* Doc. 54 at ¶ 111. The RBC report "acknowledge[d] the risk for a [rejection] following an AdComm cancellation," adding that "[w]hile our initial take on the AdComm cancellation leans positive, we note past examples have historically led to split outcomes." Doc. 58-10 at 2.

On July 1, 2021, Iterum issued a press release saying that it had "received a letter from the [FDA] stating that, as part of their ongoing review of the Company's [NDA], the agency has identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments at this time. No details with respect to deficiencies were disclosed by the FDA in this notification and the letter further states that the notification does not reflect a final decision on the information under review." Doc. 58-3 at 2; *see* Doc. 54 at ¶ 114. Iterum did not publish the FDA letter. Doc. 54 at ¶ 114. The release quoted Fishman as stating: "While we are disappointed by this news, we continue to believe in the potential of sulopenem to help address the growing challenge of antibiotic resistance. … Our goal now is to work with the FDA to identify and resolve the issues as expeditiously as possible in order to continue advancing this much needed antibiotic." Doc. 58-3 at 2. On this news, Iterum's share price fell 38% by July 2. Doc. 54 at ¶ 115.

Before the market opened on Monday, July 26, 2021, Iterum issued a press release announcing that it had received from the FDA a Complete Response Letter ("CRL") setting forth the agency's determination that it could not approve the NDA in its present form. *Id*. at ¶ 116. Iterum did not publish the CRL and instead described it in the release. *Ibid*. Iterum stated: "In the CRL, the FDA acknowledged that the Phase 3 SURE-1 clinical trial demonstrated statistical significance in difference in overall response rate of oral sulopenem compared to ciprofloxacin

in the ciprofloxacin-resistant population. However, the FDA determined that additional data are necessary to support approval for the treatment of adult women with [uUTIs] caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone. The FDA recommended that Iterum conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that Iterum conduct further nonclinical investigation to determine the optimal dosing regimen, although the FDA stated that this recommendation does not raise an approvability issue. The FDA indicated its willingness to work with Iterum on the design of the clinical trial(s) to address the deficiencies noted." *Ibid*. (alteration in original) (emphasis omitted). On this news, Iterum's stock price fell 44%. *Id*. at ¶ 118.

Discussion

Plaintiffs bring this suit on behalf of a putative class of all purchasers of Iterum common stock from November 30, 2020 through July 26, 2021. *Id*. at ¶ 1. Plaintiffs maintain that they were injured by "Defendants' false and misleading statements and material omissions during the Class Period regarding the development, regulatory approval, and commercialization of sulopenem." *Id*. at ¶¶ 3, 148.

I. Section 10(b) and Rule 10b-5 Claims

As noted, Plaintiffs bring claims under Section 10(b) of the 1934 Act and SEC Rule 10b-5. Section 10(b) makes it

> unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange … [t]o use or employ, in connection with the purchase or sale of any security … any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b). Rule 10b-5, in turn, makes it unlawful

> (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. Rule 10b-5 prohibits only conduct that Section 10(b) itself makes unlawful. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 157 (2008). "In a typical § 10(b) private action a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Ibid*.

Plaintiffs' Section 10(b) and Rule 10b-5 claims are subject to the heightened pleading standards of Civil Rule 9(b), which requires a plaintiff to plead "with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This means that a plaintiff "ordinarily must describe the who, what, when, where, and how of the fraud." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016) (internal quotation marks omitted). "This requirement includes the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *Rocha v. Rudd*, 826 F.3d 905, 911 (7th Cir. 2016) (internal quotation marks omitted). In addition, under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Plaintiffs must (1) "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 … state with

particularity all facts on which that belief is formed," and (2) "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)(1)-(2).

In seeking dismissal of the Section 10(b) and Rule 10b-5 claims, Defendants focus on the material misrepresentation and scienter elements. Doc. 59. To satisfy the material misrepresentation element, a plaintiff must allege that the defendant made a statement that was "*misleading* as to a *material* fact." *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988). "There is no securities fraud by hindsight." *City of Livonia Emps.' Ret. Sys. & Loc. 295/Loc. 851 v. Boeing Co.*, 711 F.3d 754, 758 (7th Cir. 2013) (citation omitted). "The securities laws approach matters from an *ex ante* perspective," and "a statement true when made does not become fraudulent because things unexpectedly go wrong" afterwards. *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992). Although omissions can be misleading, "[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information," *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011), and "[d]isclosure of … information is not required … simply because it may be relevant or of interest to a reasonable investor," *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). An omission is actionable only if disclosure of the omitted information was "necessary 'to make … statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b-5(b)) (omission in original).

In opposing dismissal, Plaintiffs identify several categories of Defendants' statements that they allege were false or misleading. Each category is considered in turn. Because Plaintiffs do not plausibly allege a material misrepresentation or omission, the court need not address Defendants' argument that Plaintiffs fail to satisfy the scienter element of their claims.

A. Statements about the SURE-1 Clinical Trial

As noted, Defendants stated that the SURE-1 clinical trial had "demonstrated statistical superiority of oral sulopenem" to ciprofloxacin for one of the trial's primary endpoints. Doc. 54 at ¶ 91; *see also id*. at ¶ 101 (similar). Plaintiffs "do not allege that the actual top-line results from the SURE-1 trial were false." Doc. 63 at 13. Rather, they allege that "the context in which Defendants presented SURE-1 gave the misleading impression that its results would be sufficient for FDA approval." *Ibid*. (citing, *e.g.*, Fishman's statements that Iterum "ha[d] a very robust data package" and that "the overall data [was] extremely supportive"). Specifically, Plaintiffs maintain that Defendants' statements about SURE-1 "were false and misleading because the FDA's guidelines for a uUTI trial recommended results from two or more studies, the FDA would likely request an additional study with a different comparator, and FDA approval of sulopenem with this deficient clinical trial data was unlikely." *Id*. at 12. "By choosing to speak about the results of SURE-1," Plaintiffs add, "Defendants were required to speak the whole truth to avoid misleading investors about the likelihood of the data's sufficiency to support an NDA." *Ibid*. (internal quotation marks omitted).

Plaintiffs position fails because the information alleged to have rendered Defendants' statements false and misleading was either disclosed by Defendants or otherwise publicly available. As they correctly note, Doc. 59 at 15, Defendants disclosed that SURE-1 had met only one of its two primary endpoints; that ciprofloxacin was the SURE-1 comparator drug; and that the NDA was premised on a single uUTI trial (SURE-1). Doc. 54 at ¶ 70 (alleging that Iterum announced that sulopenem did not meet the primary endpoint in the SURE-2 and SURE-3 trials, which did not involve uUTIs); *id*. at ¶ 72 (alleging that Iterum (a) acknowledged that sulopenem did not meet one of two primary endpoints in the SURE-1 trial and (b) stated that sulopenem met the other primary endpoint by demonstrating superiority to ciprofloxacin); Doc. 58-12 at 2

(November 30, 2020 press release) ("The NDA submission includes data from the SURE-1, SURE-2 and SURE-3 phase 3 clinical trials, in which oral sulopenem was well tolerated with no significant drug related adverse events. The SURE-1 clinical trial (uUTIs) demonstrated statistical superiority of oral sulopenem to the widely used comparator, ciprofloxacin, for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with a quinolone non-susceptible pathogen.").

As for the alleged inadequacies of SURE-1's design, Plaintiffs' position suffers from two flaws. First, Iterum disclosed prior to the putative class period that SURE-2 and SURE-3 did not involve uUTIs and that ciprofloxacin was the SURE-1 comparator. Doc. 54 at ¶¶ 70, 72. Plaintiffs say that the single uUTI study and the use of ciprofloxacin as the comparator "cut against industry standards and conventional wisdom and methods of obtaining FDA approval of a new drug," *id*. at ¶ 69, but they do not allege that the relevant "industry standards" and "conventional wisdom" were not publicly known at the time. *See Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 759 (7th Cir. 2007) ("The securities laws do not require firms to 'disclose' information that is already in the public domain."); *cf. Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 515 (7th Cir. 1989) ("Securities laws require issuers to disclose *firm-specific* information; investors and analysts combine that information with knowledge about the competition, regulatory conditions, and the economy as a whole to produce a value for stock."). Moreover, Defendants disclosed to investors that the Phase 3 trials were conducted under Special Protocol Assessment ("SPA") agreements with the FDA. Doc. 59 at 18; *see* Doc. 58-11 at 4 (2019 10-K) ("[A]lthough we are conducting our Phase 3 clinical trials pursuant to Special Protocol Assessment (SPA) agreements, the FDA or other comparable foreign regulatory authorities may ultimately disagree as to the design or implementation of our Phase 3 clinical

trials or other clinical trials."); Doc. 58-2 at 5, 9 (2020 10-K) ("We conducted the Phase 3 clinical trials under Special Protocol Assessment (SPA) agreements from the FDA. … [A]lthough we conducted our Phase 3 clinical trials pursuant to Special Protocol Assessment (SPA) agreements and the FDA accepted our NDA application for review in January 2021, the FDA or other comparable foreign regulatory authorities may ultimately disagree as to the design or implementation of our Phase 3 clinical trials or other clinical trials."). In a 2018 publication regarding SPA agreements, the FDA explained: "An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval." Doc. 65-2 at 21. The publication cautioned, however, that "an SPA agreement does not indicate FDA concurrence on every protocol detail." *Ibid*. Along similar lines, Plaintiffs at the motion hearing, Doc. 66, acknowledged that although an SPA agreement does not guarantee an NDA's approval, it does signal that the FDA has found acceptable a Phase 3 trial's structure.

Thus, both the FDA's and Plaintiffs' descriptions of SPA agreements—which indicate that the FDA would not enter into such an agreement if it considered a trial's design wholly inadequate—fatally undermine Plaintiffs' submission that SURE-1's design was so deficient that it could not support approval. Emphasizing the same point, Defendants repeatedly warned in Iterum's 10-Ks that, notwithstanding the SPA agreements, "the FDA or other comparable foreign regulatory authorities may ultimately disagree as to the design or implementation of our Phase 3 clinical trials or other clinical trials." Doc. 58-11 at 4 (2019 10-K); Doc. 58-2 at 9 (2020 10-K).

This caveat confirmed for the investing public that the SPA agreements did not guarantee approval of the drug.

Plaintiffs also allege that the NDA relied solely on SURE-1's results, even though "[t]he FDA's guidelines for a uUTI indication recommend results from two or more studies and, while a single trial, like the SURE-1 trial, can be sufficient if it is supported by data from trials in other indications, the Company's SURE-2 and SURE-3 Phase 3 studies in cUTI and intra-abdominal infections were poised to have the opposite effect since both failed to meet their primary endpoints." Doc. 54 at ¶ 112(a). But Defendants observe—and Plaintiffs at the motion hearing acknowledged—that the FDA guidelines cited by Plaintiffs are publicly available. Doc. 65 at 9; *see Higginbotham*, 495 F.3d at 759. So, even if that the NDA "fell short of the FDA's gold standard," "a reasonable investor had reason to know" as much given Defendants' disclosures and the "publicly available information" set forth in the FDA guidelines. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 540 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *cf. Tongue*, 816 F.3d at 213 ("Especially where a complex financial instrument whose value is tied to FDA approval is involved, investors may be expected to keep themselves apprised of the FDA's public positions on testing methodology.").

Plaintiffs' contention that Defendants' descriptions of SURE-1 were rendered false or misleading by Fishman's statements that Iterum "ha[d] a very robust data package" and that "the overall data [was] extremely supportive," Doc. 63 at 13, misses the mark as well. The court will address below whether those statements themselves were false or misleading. But viewed alongside Defendants' other disclosures and caveats—including that sulopenem had not met primary endpoints in SURE-2 and SURE-3 (which did not involve uUTIs); that sulopenem had met only one of its two primary endpoints in SURE-1; that ciprofloxacin was the SURE-1

comparator drug; and that the NDA was premised on a single uUTI trial—those statements did not "g[i]ve the misleading impression that [SURE-1's] results would be sufficient for FDA approval." *Ibid*.

This case is thus much unlike *Skiadas v. Acer Therapeutics Inc.*, 2020 WL 3268495 (S.D.N.Y. June 16, 2020), *reconsideration denied*, 2020 WL 4208442 (S.D.N.Y. July 21, 2020), where the complaint plausibly alleged that the defendants had falsely or misleadingly represented that "the FDA agreed that additional clinical development is not needed" and that "the FDA agreed that an additional clinical trial is not likely needed." *Id*. at *8. Plaintiffs here do not allege that Defendants made any such representations. And in addition to disclosing the above-referenced information about the SURE-1 trial, Iterum's 2019 and 2020 10-Ks cautioned investors: "Even if we believe that the results of our clinical trials warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates." Doc. 58-11 at 4 (2019 10-K); Doc. 58-2 at 8 (2020 10-K). And that precisely is what happened here—Defendants believed their NDA warranted approval, and the FDA disagreed. Moreover, while the FDA's acceptance of an NDA does not guarantee its approval, the FDA's acceptance for priority review of Iterum's NDA—which cited the SURE-1 data—"strongly suggests that," at the time of acceptance, "the FDA had not decided that the trial results doomed or severely damaged the NDA's chances for approval." *Busic v. Orphazyme A/S*, 2022 WL 3299843, at *10 (N.D. Ill. Aug. 11, 2022); *see also id*. at *12 ("[T]he FDA's designation of arimoclomol as a breakthrough therapy and acceptance of its NDA for priority review *after* Orphazyme reported the Phase 2/3 clinical trial results suggest that the agency was optimistic about arimoclomol's chances of approval.").

In sum, Plaintiffs fail to identify any false or misleading statements made by Defendants about SURE-1.

B. Statements About the NDA and Its Chances for FDA Approval

Plaintiffs maintain, Doc. 63 at 13, that the following statements by Defendants were false or misleading regarding the NDA and its chances of approval:

- "I think we feel very good that we have a very robust data package for our indication." Doc. 54 at ¶ 105(a) (emphasis omitted).
- "And so I think the overall package is extremely supportive." *Ibid*. (emphasis omitted).
- "[W]e haven't gotten any indication that anything is off track." *Id*. at ¶ 105(b) (emphasis omitted).
- "[T]he FDA continues its review of [the sulopenem NDA] and has not advised us of any change to the current [review completion] goal date of July 25, 2021." *Id*. at ¶ 106 (second alteration in original) (emphasis omitted).
- "[W]e are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved." *Ibid*. (emphasis omitted).
- "[W]e've been really upfront about everything that the FDA has told us." *Id*. at 109(b) (emphasis omitted).

Plaintiffs maintain that "[t]hese statements were false and misleading because FDA approval of sulopenem was unlikely due to insufficient clinical trial data and Defendants' failure to follow the FDA's guidelines," and they fault Defendants for "fail[ing] to disclose issues and concerns with the NDA itself, communicated by the FDA to Defendants, while continuing to assure investors that the Company was on track and preparing to launch sulopenem" in the fourth quarter of 2021. Doc. 63 at 13-14. The crux of Plaintiffs' submission is that Iterum "designed [its] clinical trials in contravention of FDA guidelines and norms, and then submitted an NDA with that deficient design and statistically insignificant Phase 2 data," *id*. at 17, such that

"Defendants' rosy statements [about the NDA's chances of approval] lacked a reasonable basis," *id*. at 15.

Plaintiffs' arguments regarding the FDA's guidelines and norms and the "deficient design" of Iterum's trials fail for the reasons set forth above. The parties dispute whether Fishman's statements "I think we feel very good that we have a very robust data package for our indication," Doc. 54 at ¶ 105(a) (emphasis omitted), and "I think the overall package is extremely supportive," *ibid*. (emphasis omitted), were false and misleading. Defendants submit that those statements are inactionable "expressions of opinion." Doc. 59 at 24-25. Plaintiffs respond that those statements, "[e]ven if opinions," were plagued by "material omissions that 'conflict with what a reasonable investor would take from the statement itself.'" Doc. 63 at 22 (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015)).

The flaw with Plaintiffs' position is their failure to allege that they did not possess the information that allegedly rendered Iterum's data package deficient. *See In re AnaptysBio, Inc.*, 2021 WL 4267413, at *8 (S.D. Cal. Sept. 20, 2021) ("Plaintiffs … had all the information necessary … to assess the outcome of the clinical trials."). Plaintiffs concede that, months before the putative class period began, Iterum "acknowledged that sulopenem did not meet one primary endpoint compared to ciprofloxacin in the SURE-1 clinical trial." Doc. 54 at ¶ 72 (describing a June 29, 2020 press release). True enough, Plaintiffs allege that "Pfizer ceased development of sulopenem around 2009, and had failed to generate any statistically significant data on sulopenem through its expensive R&D efforts," and that "the Phase 2 data on which Iterum ultimately relied in the sulopenem NDA – and to proceed to Phase 3 – was from a Phase 2 clinical trial conducted by Pfizer around 2009." Doc. 54 at ¶¶ 61, 68. And Plaintiffs further

submit that "this Phase 2 clinical trial did not test sulopenem on patients with uUTIs, but instead tested the drug on patients with pneumonia" and "did not yield statistically significant data." *Id.* at ¶ 68. Yet Plaintiffs do not allege that this information was non-public prior to the putative class period. *See Higginbotham*, 495 F.3d at 759. Indeed, Plaintiffs quote a document they describe as the clinical protocol for SURE-1 (dated March 2018) as stating that "Phase 2 studies in patients with urinary tract infection[s] … have not been conducted in the United States." *Id.* at ¶ 68 n.11 (quoting Iterum Therapeutics US Ltd., *Clinical Trial Protocol: IT001-301*, 19 (Mar. 2018), https://clinicaltrials.gov/ProvidedDocs/98/NCT03354598/Prot_000.pdf). In that same paragraph, the protocol describes a Phase 2 study of patients with pneumonia whose "efficacy results were not statistically significant due to the small numbers enrolled." *Ibid.*

Moreover, Plaintiffs allege that Defendants statements were false or misleading because they relied on Pfizer's Phase 2 clinical trial data "to proceed to Phase 3." *Ibid.* But Plaintiffs' own description of the drug development process indicates that Phase 3 clinical trials begin only after a successful Phase 2 trial and consultation with the FDA: "If Phase 2 clinical trial results demonstrate that the drug is effective, Phase 3 clinical trials can begin. After a successful Phase 2 clinical trial, a drug sponsor meets with the FDA to develop a large-scale Phase 3 clinical trial, which gathers even more data about the drug's safety (*i.e.*, whether the benefits of the drug outweigh the known risks) and efficacy." *Id.* at ¶ 38. So, on Plaintiffs' own understanding of the approval process, the fact that Defendants proceeded to Phase 3 clinical trials after an end-of-Phase 2 meeting, *ibid.*; Doc. 58-2 at 4 ("We designed these Phase 3 clinical trials based on extensive *in vitro* microbiologic surveillance data, Phase 1 pharmacokinetic data from healthy volunteers as well as population pharmacokinetic data from patients, animal models in relevant disease settings, Phase 2 data from a program performed with sulopenem by Pfizer in

Japan in the early 1990s, and regulatory feedback from the FDA at our end-of-Phase 2 meeting, all supported by an advanced commercial manufacturing program which provided clinical supplies."), undermines the notion that their Phase 2 data could not have supported proceeding to Phase 3 trials.

As for Fishman's representation in the March 12, 2021 press release that "[w]e haven't gotten any indication that anything is off track," Doc. 54 at ¶ 105(b) (emphasis omitted), Plaintiffs do not identify any development between the FDA's January 2021 acceptance of Iterum's NDA and Fishman's statement that would have conveyed to Defendants that "anything [was] off track."

Drawing all reasonable inferences in Plaintiffs' favor, such a development occurred around two months after Fishman's statement—on May 14, 2021, Iterum announced that the FDA had postponed the advisory committee meeting planned for June 2, 2021. *Id*. at ¶ 106; Doc. 58-15 at 2. In the press release announcing that setback, Fishman was quoted as stating: "[T]he FDA continues its review of [the sulopenem NDA] and has not advised us of any change to the current [review completion] goal date of July 25, 2021." Doc. 58-15 at 2. Plaintiffs do not maintain that Fishman's statement was literally false, Doc. 63 at 16, and it does not convey the impression that approval was imminent or that Defendants foresaw no potential bumps in the road. And Fishman's statement that Iterum was "preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, *if approved*," does not change the equation because it expressly conveyed that approval was not guaranteed. Doc. 58-15 at 2 (emphasis added).

As for Fishman's statement that "[w]e've been really upfront about everything that the FDA has told us," Doc. 54 at ¶ 109(b) (alteration in original) (emphasis omitted), Plaintiffs fail

to explain how it was misleading or how it "continued to give investors the misleading impression that the NDA was on track for approval," Doc. 63 at 17.

Finally, Plaintiffs argue that Defendants "failed to disclose issues and concerns with the NDA itself, communicated by the FDA to Defendants, while continuing to assure investors that the Company was on track and preparing to launch sulopenem in 4Q2021." Doc. 63 at 13-14. Insofar as Plaintiffs fault Defendants for "fail[ing] to disclose the content and character of Defendants' interactions with the FDA that undermined the NDA's odds of success," *id*. at 15, "[t]he substantial weight of authority reject[s] claims of material omissions where pharmaceutical companies d[o] not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review." *Busic*, 2022 WL 3299843 at *13 (second and third alterations in original) (internal quotation marks omitted); *see In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 541-42 (collecting cases); *Vallabhaneni v. Endocyte, Inc.*, 2016 WL 51260, at *12 & n.2 (S.D. Ind. Jan. 4, 2016) ("[N]umerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology.") (collecting cases); *In re Genzyme Corp.*, 2012 WL 1076124, at *10 (D. Mass. Mar. 30, 2012) ("Because the [FDA's] observations [did] not represent a final agency determination, they [were] necessarily interim statements, subject to revision. … It simply cannot be that every critical comment by a regulatory agency … has to be seen as material for securities law reporting purposes, especially in an industry … where there is constant and close supervision by the FDA.") (internal quotation marks omitted), *aff'd sub nom. In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31 (1st Cir. 2014); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) (holding that the defendants' positive statements about clinical trial results were not misleading even though they

"did not disclose that the FDA had voiced concerns … about the subgroup analysis," because "[t]he fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA"); *In re Alkermes Sec. Litig.*, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) ("Defendants had no duty to disclose that the FDA had requested additional studies because they had never guaranteed FDA approval."); *Anderson v. Abbott Laboratories*, 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001) (holding that the defendant was not obligated to disclose an FDA inspection given that "the agency had not yet decided to sanction Abbott, certainly so far as defendants could tell"), *aff'd sub nom. Gallagher v. Abbott Laboratories*, 269 F.3d 806 (7th Cir. 2001); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Defendants, as a general proposition, had no duty to report its ongoing discussions with FDA during the review process.") (internal quotation marks omitted). Rather, "the law with respect to this issue is clear: a biopharmaceutical corporation need not share a regulatory agency's response or criticism to a trial and its results if it does not constitute a final determination." *Hoey v. Insmed Inc.*, 2018 WL 902266, at *14 (D.N.J. Feb. 15, 2018) (collecting cases). The rationale for the principle that "interim FDA feedback is not material" is that such feedback "does not express a binding agency decision and is subject to change as the FDA and pharmaceutical companies work together to develop viable clinical trials and approvable licensing applications." *Sanofi*, 87 F. Supp. 3d at 54.

At the motion hearing, Doc. 66, Plaintiffs argued that even if Defendants had no duty to disclose interim FDA communications, Defendants' choice to disclose the existence of those communications gave rise to a duty to speak the truth about them. But Plaintiffs do not indicate what more Defendants should have said. Plaintiffs allege that Iterum's May 27, 2021 press

release quoted Fishman as saying that "the FDA [at a late-cycle meeting] shared issues still under review regarding the [NDA] and the Company responded to these issues. The FDA has determined that an Advisory Committee meeting is not currently necessary. The review of the NDA is ongoing and the Company was informed that the FDA continues to work toward the [review completion] goal date of July 25, 2021." Doc. 54 at ¶ 110 (first alteration in original) (emphasis omitted). That statement did not repeat Fishman's suggestion from over two months earlier that everything was on track or otherwise suggest that Defendants believed that approval was likely.

True enough, Plaintiffs allege that analysts at RBC Capital Markets issued a report saying: "Healthy dialogue between [Iterum] and [the FDA] over path of review continues, including a recent late-cycle meeting. Per the press release and confirmed via our discussion [with management], the company continues to maintain an open dialogue with FDA on sharing and responding to *what we interpret as routine filing issues* over the course of the review." *Id*. at ¶ 111 (emphasis added); *see* Doc. 58-10 at 2. Somewhat confusingly, Plaintiffs assert that they "do not allege the statements in the May 2021 RBC Capital Markets report are false." Doc. 63 at 13 n.10. In any event, absent a false or misleading statement by Defendants themselves, *analysts'* interpretation of the issues discussed in the late-cycle meeting does not render *Defendants'* own statements false or misleading. *See Busic*, 2022 WL 3299843, at *5, *14 (noting "numerous reports" indicating that "analysts understood Vadsholt's statement [about labeling talks] to mean that approval for arimoclomol was imminent," but concluding that the statement was not actionable).

C. Statements about Commercialization of Sulopenem

Finally, Plaintiffs argue that Defendants' statements about their commercialization plans, *e.g.*, Doc. 54 at ¶¶ 95, 99, 106, "gave the misleading impression that commercialization of

sulopenem was all but a guarantee," Doc. 63 at 18. Plaintiffs' argument that Defendants' statements about commercialization were false or misleading "because Defendants failed to disclose issues and concerns with the underlying clinical trial data, the NDA, and related FDA communications," *ibid*., fails for the reasons given above.

Nor did the commercialization statements themselves create the impression that approval was all but guaranteed. Iterum's February 1, 2021 press release regarding its collaboration with EVERSANA quoted Fishman as saying: "We will be working diligently to ensure we are ready for the *potential* launch of oral sulopenem in the U.S. in the fourth quarter of 2021." Doc. 58-14 at 2 (emphasis added). Its March 12, 2021 press release outlined priorities that included "initiating the commercial launch in the fourth quarter, *if approved*" and "working with the FDA to understand the requirements for potential expansion of our label in uUTI to include all patients, *if approved*, and to potentially add the complicated urinary tract infection (cUTI) indication." Doc. 54 at ¶ 99 (emphasis altered). Likewise, its March 21, 2021 press release quoted Fishman as stating: "[W]e are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, *if approved*." *Id*. at ¶ 106 (emphasis altered). Those statements—in particular, the "potential" and "if approved" qualifications—do not suggest that approval (and thus commercialization) was a foregone conclusion. *See Busic*, 2022 WL 3299843, at *15 (explaining that, in context, "statements that the company was 'launch-ready' and 'can make a difference for patient[s]' plainly referred to the company's organizational and logistical preparedness and did not misleadingly imply anything about the strength of the company's clinical trial data") (alteration in original).

D. Sarbanes-Oxley Act ("SOX") Certifications

Plaintiffs assert in a footnote that Defendants' SOX certifications were false and misleading because, "[b]y omitting material facts about SURE-1, the NDA, and Iterum's

interactions with the FDA that impacted the odds for commercialization of sulopenem, the 2020 10-K and the 1Q2021 10-Q created the impression for investors that FDA approval was in the bag." Doc. 63 at 18 n.14 (cleaned up). This argument fails for the reasons set forth above.

II. Section 20(a) Claim

Section 20(a) of the 1934 Act extends liability to "[e]very person who, directly or indirectly, controls any person liable" under Section 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a). Plaintiffs argue that their Section 20(a) claim survives because the complaint states a Section 10(b) claim. Doc. 63 at 30. But because Plaintiffs do not state a Section 10(b) claim, their Section 20(a) claim fails as well.

Conclusion

Defendants' motion to dismiss is granted. Although Plaintiffs may be unable to satisfactorily replead the dismissed claims, the court will err on the side of caution and dismiss them without prejudice. *See Runnion ex rel. Runnion v. Girl Scouts of Greater Chi. & Nw. Ind.*, 786 F.3d 510, 519 (7th Cir. 2015) ("Ordinarily, … a plaintiff whose original complaint has been dismissed under Rule 12(b)(6) should be given at least one opportunity to try to amend her complaint before the entire action is dismissed."). Plaintiffs have until January 24, 2023 to file an amended complaint. If Plaintiffs do not amend, the dismissal will convert automatically to a dismissal with prejudice. If Plaintiffs amend, Defendants shall file a responsive pleading by February 21, 2023.

December 28, 2022

United States District Judge