UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 16 Civ. 1691 (RJS)

IN RE ROCKWELL MEDICAL, INC. SECURITIES LITIGATION

MEMORANDUM AND ORDER
March 30, 2018

RICHARD J. SULLIVAN, District Judge:

Lead Plaintiffs Dmitriy Chatskiy, Douglas Benkowski and Earl McCrary ("Plaintiffs") bring this putative class action securities fraud lawsuit against Rockwell Medical, Inc. ("Rockwell"), its Chief Executive Officer, and its Chief Financial Officer (collectively "Defendants"). They allege violations of Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b); Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5; and Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

Now before the Court is Defendants' motion to dismiss the Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 44.) For the reasons set forth below, Defendants' motion is granted.

I. BACKGROUND[1]

A. The Parties

Plaintiffs are investors who purchased Rockwell common stock between November 20, 2014 and February 29, 2016 (the "Class Period") and claim to have suffered damages as a result of false or misleading statements made by Defendants. (Second Amended Complaint ("Compl.") ¶¶ 1, 21–23.)

[1] The facts set forth below are taken from the Second Amended Complaint (Doc. No. 44), statements or documents incorporated into the amended complaint by reference, legally required public disclosure documents filed with the SEC, and documents upon which Plaintiffs relied in bringing the suit. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). In ruling on the instant motion, the Court has also considered Defendants' memorandum of law in support of their motion to dismiss (Doc. No. 46 ("Mem.")), Plaintiffs' opposition (Doc. No. 48 ("Opp'n")), Defendants' reply (Doc. No. 49 ("Reply")), the declarations and exhibits submitted with those briefs, and the transcript of the parties' October 31, 2016 pre-motion conference (Doc. No. 41 ("Tr.")).

Rockwell, whose stock is publicly traded on the NASDAQ stock market under the ticker symbol "RMTI," is a biopharmaceutical company that focuses on developing treatments for patients suffering from end-stage renal disease and chronic kidney disease. (*Id*. ¶¶ 2, 24, 55.) During the Class Period, Defendant Robert L. Chioini served as President, Chief Executive Officer, and Director, while Defendant Thomas E. Klema served as Rockwell's Vice President of Finance, Chief Financial Officer, Treasurer, and Secretary. (*Id*. ¶¶ 25–26.)

B. Facts

Dialysis is a treatment for kidney disease. One side effect of dialysis is that patients lose blood, resulting in iron deficiency. (*Id*. ¶¶ 33, 37.) To counteract iron deficiency, most dialysis patients receive intravenous treatments of iron along with erythropoiesis stimulating agents ("ESA"), which are drugs that increase the production of red blood cells. (*Id*. ¶ 37.) Unfortunately, according to Rockwell, ESAs are "very expensive" and "have serious risks associated with their dosing to dialysis patients." (*Id*. ¶ 37.)

On March 24, 2014, Rockwell issued a press release announcing that it had completed clinical tests on a new drug called Triferic, which was an alternative to existing treatments for dialysis patients. (*Id*. ¶¶ 3, 34.) The announcement also stated that Rockwell had submitted a New Drug Application to the Food and Drug Administration ("FDA") seeking approval to market and sell Triferic in liquid form. (*Id*. ¶ 34.) Rockwell explained that, based on the clinical trials it had conducted, Triferic could "safely and effectively" restore iron levels for dialysis patients while at the same time "significantly reducing [their] ESA dose." (*Id*. ¶ 3.) As a result, Rockwell announced that it expected Triferic "to address an estimated $600M U.S. market." (*Id*. ¶ 35.)

On November 20, 2014, the first day of the Class Period, Rockwell filed a Prospectus Supplement with the SEC in which the company made several statements about its plans to market Triferic upon FDA approval, including:

- "We submitted a New Drug Application . . . to the U.S. Food and Drug Administration . . . in the first quarter of 2014 seeking marketing approval of Triferic. . . . When and if we obtain FDA approval, we intend to market Triferic. We cannot, however, give any assurance that Triferic will be approved by the FDA or, if approved, what will be included in the approved label or whether Triferic once launched will be successfully marketed."

- "[W]e believe the market size in the United States for [this therapy] is between approximately $300 and $600 million per year. Through [a] Distribution Agreement with [another pharmaceutical company], we expect to sell to and service a significant number of dialysis providers in the United States and intend to market Triferic to those dialysis providers."

(*Id*. ¶ 43.)

Two months later, on January 26, 2015, Rockwell issued a press release announcing that the FDA had approved liquid Triferic for commercial sale. (*Id*. ¶ 44.) Chioini "touted" the drug, saying that it had the "potential to become the market-leading iron therapy treatment for hemodialysis patients." (*Id*. ¶ 44.) The press release also stated that Rockwell was "highly confident in executing a successful commercial launch

and penetrating the market [for Triferic]." (*Id.*)

One month later, on February 26, 2015, Rockwell held an earnings call. (*Id.* ¶ 45.) While speaking with securities analysts and investors, Chioini explained that Rockwell's "goal" was "to launch Triferic commercially [within] approximately four to five months." (*Id.*) He also stated that in light of the drug's "clinical and cost saving benefits, a favorable bundled reimbursement structure and a consolidated customer base," Rockwell had "confidence" that it would "have great success selling Triferic in a dialysis market." (*Id.*) During that call, analysts asked Defendants about the marketing strategy for Triferic, and Klema explained that once Rockwell had "adequate inventory," the company would launch the drug and "be profitable shortly after that." (*Id.* ¶ 47.)

On May 7, 2015, Rockwell held another earnings call in which Chioini made similar remarks about the company's plans to launch Triferic. (*Id.* ¶ 49.) In response to an analyst's question about the timeline for Triferic's commercial launch, Chioini stated: "I think the best way to describe it is there's multiple things that are going on and they are all related and they all need to get done at one point and once they're all done then you can launch. . . . Most of it's on the manufacturing . . . side." (*Id.* ¶ 50.)

On June 25, 2015, Rockwell submitted another New Drug Application to the FDA, seeking approval to market and sell Triferic in powder form, packaged similarly to a packet of sugar. (*Id.* ¶¶ 4, 8–9, 52) The powder form had several advantages to liquid Triferic, including that it would entail "lower production costs, greatly decreased susceptibility to contamination during production, cheaper cost of goods, cheaper shipping, lower storage costs, and a longer shelf-life." (*Id.* ¶ 4; *see also id.* ¶¶ 12, 36, 51.) However, Rockwell did not issue a press release or otherwise publicize the filing of its New Drug Application for the powder version of Triferic, and since the FDA does not disclose pending applications, the existence of the second application was unknown to the public. (*Id.* ¶ 36.)

Later that summer, on August 4, 2015, Rockwell held another earnings call during which Defendants discussed the upcoming commercial launch of liquid Triferic. (*Id.* ¶ 53.) In particular, Chioini said, "as we approach commercialization, we are positioned to achieve great success with Triferic." (*Id.*) He added: "[O]ur strong financial position gives us ample resources to launch [Triferic]," and "[Rockwell] continue[s] to invest in . . . manufacturing, final product packaging, inventory, and marketing and sales." (*Id.*)

One month later, on September 9, 2015, Rockwell issued a press release announcing the commercial launch of liquid Triferic and predicting that "Triferic will become the standard of care in iron replacement for dialysis patients." (*Id.* ¶ 55)

On November 9, 2015, the company put out another press release and hosted an earnings call where Defendants made more public statements about Triferic, including:

- "The clinical community has responded favorably to Triferic . . . ." (*Id.* ¶ 57) (press release).
- "We anticipate broad clinical adoption over the next several months of this first-in-class iron maintenance therapy . . . ." (*Id.*) (press release).
- "Just over the first eight weeks [since launch], Triferic has received positive

> feedback from the dialysis community including providers, doctors, nurses, and patient advocacy groups. [Rockwell is] pleased to announce that we have just signed a supply contract with one of the four largest dialysis providers. We have taken orders from other customers as well. We continue to be very busy promoting Triferic to our customer base." (*Id.*) (investor call).

Despite Rockwell's public representations through 2014 and 2015, the reception to Triferic was not universally positive. For example, on August 5, 2015, one month before commercial launch, a market analyst named Jonathan Aschoff wrote an article indicating that because the FDA had not authorized Rockwell to discuss Triferic's ESA-saving effects on the drug's product label, the market should expect "dismal commercial uptake for Triferic." (*Id.* ¶ 40.) Without those effects on the label, he explained, "Triferic is just a substitute for IV iron" and would therefore not improve margins for dialysis centers. (*Id.*) Aschoff also predicted that any adoption of Triferic would be slow because most dialysis centers "currently have IV iron in their protocol," making a switch to Triferic time-consuming. (*Id.*) Similarly, in a September 3, 2015 "editorial collaboration" between the National Kidney Foundation and the publication Medscape, Dr. Jeffrey Berns, a Professor of Medicine at the Hospital of the University of Pennsylvania and editor-in-chief of Medscape, expressed skepticism that Triferic would be "better" or "safer" than existing treatments. (*Id.* ¶¶ 7, 39.) Although Dr. Berns did not "wholly dismiss" the potential for Triferic, he observed that dialysis providers could not "vary dosages of Triferic, something one can do with IV iron." (*Id.* ¶ 39.)

On February 29, 2016, the final day of the Class Period, Defendants held an earnings call regarding the fourth quarter of 2015 during which they told analysts that Triferic had underperformed their previous expectations and that their "net sales of Triferic were immaterial for 2015." (*Id.* ¶ 13.) Defendants also revealed, for the first time, the existence of the New Drug Application for the powder formulation of Triferic, which had been submitted to the FDA in June of 2015 but had not yet been approved. (*Id.* ¶ 14.) Defendant Chioini made several specific statements about the powder formulation, including:

- "Regarding packaging, . . . we created a more efficient and more cost-effective way to package Triferic. Instead of having the active pharmaceutical ingredient . . . manufactured as a powder and packed into a liquid solution in an ampoule, which is what was FDA approved, we determined we could take the manufactured . . . powder straight to finished packaging, with an additional process step in between. So we are able to package Triferic as a powder in a packet, similar to a packet of sugar."

- "This improvement enables the customer to reduce the storage space and number of orders needed to utilize the drug, and it greatly reduces Rockwell's cost of goods compared to the liquid ampoule."

- "This required a separate [application] and we filed that submission with the FDA last year, and we expect to have approval by the end of April. The powder packet will be commercially available immediately thereafter, and it will be the primary product offering."

(*Id.* ¶ 62.)

Defendant Chioini also explained, when prompted by an analyst, that Rockwell would phase out the liquid version of Triferic following the FDA's approval of the powder packet. (*Id.* ¶ 63.) The next day, the share price of Rockwell Medical fell from $9.60 to $6.31 per share. (*Id.* ¶¶ 15, 64.)

C. Procedural History

On March 4, 2016, four days after the February 29 earnings call, Plaintiff Jeremy Schockman, who invested in Rockwell common stock during the Class Period, initiated this action against Rockwell and the individual Defendants. (Doc. No. 1.) On May 3, 2016, Plaintiff Earl McCrary, another individual who invested in Rockwell during the Class Period, filed suit number 16-cv-3304 (RJS), which raised substantially similar claims. (No. 16-cv-3304 (RJS), Doc. No. 1.) On May 20, 2016, all parties entered into a Court-approved stipulation under which: (1) both the instant case and case number 16-cv-3304 (RJS) were consolidated pursuant to Rule 42(a) of the Federal Rules of Civil Procedure; (2) Dmitriy Chatskiy, Douglas Benkowski and Earl McCrary were appointed as Lead Plaintiffs; and (3) the Rosen Law Firm, P.A. and Glancy, Prongay & Murray LLP were appointed Co-Lead Counsel. (Doc. No. 18.) On July 26, 2016, Plaintiffs filed their First Amended Complaint (Doc. No. 26), which they amended again on November 21, 2016 (Doc. No. 44). On January 6, 2017, Defendants filed their motion to dismiss the Second Amended Complaint (Doc. No. 45), which was fully briefed on February 28, 2017 (Doc. No. 49).

II. Legal Standard

To survive a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must "provide the grounds upon which [the] claim rests." *ATSI Commc'ns*, 493 F.3d at 98. Specifically, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and draw all reasonable inferences in favor of the plaintiff. *ATSI Commc'ns*, 493 F.3d at 98. However, that tenet "is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Thus, a pleading that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. If the plaintiff "ha[s] not nudged [its] claims across the line from conceivable to plausible, [its] complaint must be dismissed." *Id.* at 570.

Moreover, securities fraud claims are subject to heightened pleading standards under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (the "PSLRA"), 15 U.S.C. § 78u-4(b). *ATSI Commc'ns*, 493 F.3d at 99. To satisfy Rule 9(b), plaintiffs must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This standard requires that the complaint "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *ATSI Commc'ns*, 493 F.3d at 99.

The PSLRA, in turn, requires plaintiffs to "specify each statement alleged to have

been misleading, [and] the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . [to] state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). As for mental state, the statute demands that plaintiffs "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A) (emphasis added); *see also Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005). A "strong" inference is one that is "more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). Courts "consider both the inferences urged by the plaintiff and any competing inferences rationally drawn from all the facts alleged, taken collectively." *ECA, Local 134 IBEW Jt. Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (citing *Tellabs*). Accordingly, even though courts normally draw reasonable inferences in the non-movant's favor when ruling on a motion to dismiss, the PSLRA creates a more stringent standard for inferences relating to mental state. *Id.* at 196 (citing *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 194 (2d Cir. 2008)).

III. DISCUSSION

Plaintiffs allege that Rockwell and the individual Defendants made a series of material misstatements and omissions during the Class Period. Specifically, Plaintiffs allege that Defendants falsely assured investors of Triferic's market potential and concealed the "real plan" to commercialize the powder form of the drug.

Defendants move to dismiss the Second Amended Complaint, arguing that Plaintiffs fail to allege (1) actionable misstatements or omissions, and (2) scienter. The Court agrees.[2]

A. Securities Fraud: The Exchange Act Section 10(b) and SEC Rule 10b-5

"Section 10(b) of the Exchange Act makes it unlawful '[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 [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" *Emps.' Ret. Sys. of Gov't of the Virgin Is. v. Blanford*, 794 F.3d 297, 304–05 (2d Cir. 2015) (quoting 15 U.S.C. § 78j(b)). "SEC Rule 10b-5 implements this provision of the Exchange Act and explicitly prohibits 'mak[ing] any untrue statement of a material fact'" in connection with the purchase or sale of a security. *Id.* at 305 (quoting 17 C.F.R. § 240.10b-5(b)).

"Judicial interpretation and application, legislative acquiescence, and the passage of time have removed any doubt that a private cause of action exists for a violation of § 10(b) and Rule 10b–5, and constitutes an essential tool for enforcement of the [Exchange Act's] requirements." *Basic Inc. v. Levinson*, 485 U.S. 224, 230–31 (1988). Thus, to establish liability for securities fraud, 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)

[2] Defendants also argue that Plaintiffs have not adequately pleaded loss causation. But because the Court concludes that Plaintiffs' claims must be dismissed on other grounds, the Court declines to address this argument.

reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Dura Pharms.*, 544 U.S. at 341–342 (collecting cases).

1. Misstatements and Omissions

To be actionable, a misstatement or omission must be material. The Supreme Court has explained that materiality "depends on the significance the reasonable investor would place on the withheld or misrepresented information." *Basic*, 485 U.S. at 240. For a misstatement or omission to be material, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* at 240 (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 449 (1976)); *see also ECA*, 553 F.3d at 197. Importantly, the Supreme Court has repeatedly eschewed bright-line rules defining materiality, instead favoring a case-by-case determination. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38–41 (2011). Thus, materiality is a mixed question of law and fact, and in the context of a Fed. R. Civ. P. 12(b)(6) motion, dismissal on materiality grounds is appropriate only when the alleged misstatements or omissions "are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985).

So long as they are material, false statements of fact are actionable under Section 10(b) and Rule 10b-5. *See In re Int'l Bus. Machs. Corp. Secs. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998); *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 812–13 (2d Cir. 1996). In addition, material statements of opinion may also be actionable misstatements where the speaker did not hold the opinion asserted at the time he asserted it, or when the opinion expressed cites a "supporting fact" that is itself untrue. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015); *see also Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016). But, in general, overly optimistic opinion statements about corporate performance do not give rise to securities violations absent those additional showings of disingenuity. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 392 (2d Cir. 2015).

Omissions, by contrast, are actionable only when the speaker has an underlying duty to disclose the omitted information. *Basic*, 485 U.S. at 240 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). There is no freestanding duty to reveal "any and all material information." *Matrixx Initiatives*, 563 U.S. at 44; *see also Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013). As a result, companies may remain silent "[e]ven with respect to information that a reasonable investor might consider material" so long as they do not have an underlying duty to disclose that information. *Matrixx Initiatives*, 563 U.S. at 45; *Kleinman*, 706 F. 3d at 152–53.

A duty to disclose is triggered when a corporate insider trades on confidential information, a statute or regulation requires disclosure, or – as relevant here – the company makes a statement that would otherwise be inaccurate, incomplete, or misleading without the disclosure. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101–02 (2d Cir. 2015). In other words, if a company chooses to speak on a topic, it assumes "a duty to be both accurate and

complete." *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002). Thus, absent insider trading or an affirmative disclosure obligation, companies "can control what they have to disclose under [Section 10(b) and Rule 10b-5] by controlling what they say to the market." *Matrixx Initiatives*, 563 U.S. at 45.[3]

Here, Plaintiffs' fraud allegations are based on both misstatements and omissions. The Court will consider each of these contentions in turn.

a. Alleged Material Misstatements

Plaintiffs argue that Defendants made material misstatements during the Class Period by (1) "falsely assur[ing] investors of the imminent success of Triferic" (Opp'n 3), (2) misprepresenting liquid Triferic's benefits over existing treatments and the clinical community's positive response to liquid Triferic (*id*. at 1), and (3) misrepresenting Rockwell's motivation to commercialize liquid Triferic (*id*. at 3). However, none of these amounts to an actionable misstatement under the securities laws.

i. Statements Regarding Liquid Triferic's "Imminent Success"

As noted above, Defendants made a number of optimistic statements regarding the "commercial viability" of Triferic. For example, on January 26, 2015, when announcing that the FDA had approved the sale of liquid Triferic, Rockwell represented that it was "highly confident in executing a successful commercial launch and penetrating the market." (Compl. ¶ 44.) One month later, on an earnings call, Chioni told investors that Rockwell had "confidence" that it would "have great success selling Triferic in a dialysis market." (*Id*. ¶ 45.) And on November 9, 2015, shortly after launching liquid Triferic, Defendants predicted that there would be "broad clinical adoption over the next several months," and that Triferic would "capture a significant portion of the market." (*Id*. ¶ 57, 58.)[4]

Plaintiffs argue that Defendants' overly optimistic – and ultimately incorrect – projections about Triferic are actionable misstatements. But these statements reflect exactly the kind of "general corporate optimism" that the Second Circuit has recognized to be inactionable "puffery." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) ("companies must be permitted to operate with a hopeful outlook"). "Statements of corporate optimism may be actionable securities violations [only] if 'they are worded as guarantees or are supported by specific statements of fact, or if the speaker does not genuinely or reasonably believe them.'" *IBEW Local*

[3] Moreover, as the Second Circuit recently made clear in *Stratte-McClure*, the *materiality* of an alleged omission must be considered in light of *Basic*'s sliding scale of materiality. 776 F.3d at 103 (holding that *Basic*'s "probability/magnitude test," rather than a regulatory definition, controls the materiality inquiry for claims based on Section 10(b) and Rule 10b-5). Under that test, "the materiality of an allegedly required forward-looking disclosure is determined by 'a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.'" *Id.* (quoting *Basic*, 485 U.S. at 238) (emphasis omitted).

[4] (*See also* Compl. ¶¶ 47 (predicting that Triferic would be "profitable shortly after" its launch); 53 (opining that Rockwell was "positioned to achieve great success with Triferic"); 55 (predicting that Triferic would "become the standard of care in iron replacement for dialysis patients").)

Union No. 58 Pension Tr. Fund & Annuity Fund, 783 F.3d 383 at 392 (quoting *In re Int'l Bus. Machs. Corp. Secs. Litig.*, 163 F.3d at 107).

Here, none of the supposed misstatements about Triferic's potential were worded as guarantees, and Plaintiffs have alleged no concrete evidence to suggest that Defendants did not subjectively believe that Triferic would be successful at the time they made their predictions. Without question, Defendants' upbeat forecast that there would be "broad clinical adoption" of Triferic within "several months" after Triferic's September 2015 launch did not materialize. (Compl. ¶ 57.) But because "[i]t is in the very nature of securities markets that even the most exhaustively researched predictions are fallible," Plaintiffs' allegations are insufficient to state a material misstatement of fact. *Olkey v. Hyperion 1999 Term Trust, Inc.*, 98 F.3d 2, 8 (2d Cir. 1996) (quoting *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 776 (2d Cir. 1991)); *see also*, *id.* ("To show misrepresentation, the complaint must offer more than allegations that the portfolios failed to perform as predicted." (citation omitted)); *Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.) (failure to anticipate unimpressive early performance "does not constitute fraud").

Defendants note, in the alternative, that several of the alleged misrepresentations are not actionable because they are "forward-looking statements" protected under the PSLRA. (Mem. 15–18); *see also Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766–67 (2d Cir. 2010) (noting that the PSLRA protects parties from liability for "forward-looking statement[s]," such as "a statement of future economic performance" under certain conditions, including where "the plaintiff fails to prove that [the statement] was made with actual knowledge that it was false or misleading" or "the forward-looking statement is identified and accompanied by meaningful cautionary language"). Although the Court agrees that at least some of the alleged misrepresentations fit comfortably within the PSLRA's protections (*see, e.g.*, Compl. ¶¶ 44 ("We are highly confident in executing a successful commercial launch [of Triferic] and penetrating the market.")), the Court declines to devote significant ink to this issue, since it is ultimately unnecessary to resolve the current motion.

Perhaps the closest Plaintiffs come to adequately pleading an actionable misstatement regarding the commercial success of liquid Triferic is their allegation that Chioini misrepresented that Rockwell had signed a "supply contract" for Triferic with "one of the four largest dialysis providers." (Compl. ¶ 58.) But the Motley Fool article on which Plaintiffs rely provides no other particularized facts about the supply contract in the excerpted portion of the story, and it is well settled that "[c]onclusory allegations of wrongdoing are no more sufficient if they come from a newspaper article than from plaintiff's counsel." *In re Optionable Sec. Litig.*, 577 F. Supp. 2d 681, 690 (S.D.N.Y. 2008) (citation omitted); *cf. Lopez v. CTPartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 31 (S.D.N.Y. 2016) (quoting *Miller v. Lazard, Ltd.*, 473 F. Supp. 2d 571, 586 (S.D.N.Y. 2007)). In any event, even assuming that the "supply contract" referred to on the November 9, 2015 sales call was, in fact, for a "pilot program," Plaintiffs fail to articulate why Chioini's statement – which speaks generally of a "supply contract" and omits any description of the contract's terms – was misleading. *See In re IAC/InterActiveCorp Sec. Litig.*, 695 F. Supp. 2d 109, 123–24 (S.D.N.Y. 2010) (defendant's statement that

issuer's "agreements with airline[s] are long-term" was not actionable, notwithstanding plaintiffs' allegation that that corporation "lacked good long-term deals with airlines," since defendant "did not say what the price or supply terms of the contracts were").

Ultimately, the Second Amended Complaint contains no specific allegations that support an inference that Defendants did not actually believe their own stated opinions or that they knowingly relied on false statements of fact regarding the imminent success of Triferic. Accordingly, these alleged misstatements are not actionable.

ii. Statements Regarding Liquid Triferic's Superiority and the Clinical Response to Triferic

Plaintiffs next argue that Defendants misstated the benefits of Triferic over alternative therapies and overstated the early clinical response to Triferic. (*See, e.g.*, Compl. ¶¶ 45 (February 26, 2015 statement identifying drug's "clinical and cost saving benefits" as a reason for Rockwell's "confidence" that they would "have great success selling Triferic in a dialysis market"); 49 (May 7, 2015 statement representing that Rockwell's "confidence in [the] commercial launch [of liquid Triferic] [was] based on the strong efficacy and safety profile the drug [had] demonstrated"); 55 (September 9, 2015 press release stating Defendants' belief that "Triferic will become the standard of care in iron replacement for dialysis patients"), 58 (November 9, 2015 statement asserting that "Triferic ha[d] received positive feedback from the dialysis community including providers, doctors, nurses, and patient advocacy groups")).

Plaintiffs contend that these and other similar representations constituted false statements of fact, or opinions based on facts that Defendants knew were false. Specifically, Plaintiffs argue that Rockwell's assurances about cost-effectiveness were misleading because the FDA did not allow Rockwell to include language about Triferic's ESA-saving effects on its product label, thus negating its potential for cost-savings as a replacement for ESA drugs. Plaintiffs also maintain that Rockwell's representations about the superiority of Triferic over conventional IV iron treatments were false, pointing to Aschoff's prediction that "clinical adoption of Triferic" would be "slow" at best because of the prevalence of IV iron treatment at dialysis treatment centers, as well as Berns's skepticism regarding Triferic's benefits over IV iron treatment. (Opp'n 9.)

But once again, Plaintiffs offer only conclusory allegations to support these claims. Thus, while Plaintiffs insist that Defendants knew that Triferic would have "high manufacturing and transportation costs" relative to alternative treatments (Opp'n 9 (citing Compl. ¶¶ 12, 36)), Plaintiffs fail to explain the bases for this assertion. Similarly, Plaintiffs' insistence that there was "no evidence Triferic [was] safer or more effective than IV iron" (Opp'n 9), is belied by Plaintiffs own pleading, which acknowledges that Defendants considered the findings of scientific studies in which Triferic was administered over 100,000 times before publishing their assessments of Triferic's health benefits and cost savings. (Compl. ¶¶ 3 n.1, 37, 48.) Other than the articles by Aschoff and Bern that voiced skepticism about the commercial and clinical attractiveness of Triferic, Plaintiffs offer nothing to suggest that the clinical studies on which Defendants relied were false. But the mere existence of two

articles questioning the prospects and efficacy of Triferic does not support an inference that Defendants' even knew of those criticisms, much less that they lied about the receipt of positive feedback from professionals in the field more generally.

In short, Plaintiffs offer no specific allegations to suggest that Defendants did not actually believe their own stated opinions or that they knowingly relied on false statements of fact regarding the superiority of Triferic to conventional treatments.

iii. Rockwell's Motivation to Launch Liquid Triferic

Plaintiffs next argue that, notwithstanding Defendants' public assertions that they were very motivated to launch Triferic (Compl. ¶¶ 10, 44–45, 55), Defendants secretly intended to have the yet-to-be-approved powder version of Triferic serve as the company's "primary product offering" (*id.* ¶¶ 4, 9, 51–52, 54, 56, 59). Accordingly, Plaintiffs contend that Defendants' public statements gave the false impression that Rockwell was committed to commercializing liquid Triferic when it in fact was not.

But the law is very clear that statements such as these, expressed in relative terms and describing subjective attitudes like intent and motivation, are generally insufficient to support a claim for securities fraud. Rather, "to be actionable, the representation must be one of existing fact, and not merely an expression of opinion, expectation or declaration of intention." *In re Duane Reade Inc. Sec. Litig.*, No. 02-cv-6478 (NRB), 2003 WL 22801416, at *4 (S.D.N.Y. Nov. 25, 2003) (quoting *Greenburg v. Churst*, 282 F. Supp. 2d 112, 121 (S.D.N.Y. 2003)), *aff'd sub nom. Nadoff v. Duane Reade, Inc.*, 107 F. App'x 250 (2d Cir. 2004); *see also In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 565 (S.D.N.Y. 2011) (defining "puffery" as "an 'exaggerated or general statement[] that make[s] no specific claims on which [reasonable persons] can rely'" (quoting *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 528 n.14 (S.D.N.Y. 2003))).

Moreover, Plaintiffs again fail to offer any particularized allegations – such as internal company documents or statements from confidential witnesses – indicating that Defendants were not committed to commercializing the liquid form of Triferic. Nor, as discussed further in the next section, are there any particularized allegations whatsoever that Defendants secretly intended for the powder packet to serve as Triferic's "primary product offering" at the time Rockwell made statements about its intent to market liquid Triferic. Put simply, Plaintiffs have not demonstrated why Defendants' statements that they were "very motivated" to market liquid Triferic were false. (*E.g.*, Compl. ¶ 10.) To state the obvious, vigorously promoting a current product is not at all inconsistent with simultaneously innovating and developing new products. To hold otherwise would risk chilling the development of new products and technologies across all fields. That is certainly not the goal of the federal securities laws. *Cf. In re Apple Computer, Inc.*, 127 Fed. App'x 296, 304 (9th Cir. 2005) (observing that "exposing a company to securities fraud liability for failing accurately to predict demand for a radically new product would chill the innovation essential to the industry's growth").

b. Alleged Material Omissions

Notwithstanding the various alleged misstatements discussed above, this action is primarily about omissions. The crux of

Plaintiffs' case is their allegation that Defendants failed to disclose the real plan for marketing Triferic – *i.e.*, the plan to make the powder form of the drug the company's "primary product offering." Plaintiffs argue that Defendants' public statements regarding Triferic during the Class Period were "materially false and misleading" because Defendants omitted the facts that: (1) they were developing the powder Triferic, (2) they planned for the powder version to serve as the "primary product offering for Triferic," and (3) the successful commercialization of Triferic "hinged on" the FDA's approval of powder Triferic, since the version packaged in liquid ampules was not commercially viable. (Compl. ¶¶ 41, 51, 54 56, 59; Opp'n 9–10, 12–13, 16.)

As noted above, Plaintiffs are correct, as a matter of law, that opinion statements, "though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." (Opp'n 16 (quoting *Tongue*, 816 F.3d at 209–10).) Plaintiffs therefore insist, as they must, that Defendants were "duty-bound," after "having disclosed *something* about Triferic, to disclose *everything* about Triferic." (Tr. 9:1–4 (emphasis added); *see also* Opp'n 10 (asserting that "once Defendants chose to speak about their plans for commercializing Triferic," they had "a duty to disclose" their plans for powder Triferic)). But it is well settled that "a corporation is not required to reveal all facts on a subject just because it reveals a single fact." *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 581–82 (S.D.N.Y. 2013), *aff'd*, 566 F. App'x 93 (2d Cir. 2014); *Christine Asia Co. v. Alibaba Grp. Holding Ltd.*, 192 F. Supp. 3d 456, 471 (S.D.N.Y. 2016) (quoting *Richman v. Goldman Compl. Grp.*, Inc., 868 F. Supp. 2d 261, 274 (S.D.N.Y. 2012))). Indeed, as the Supreme Court has underscored, "[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives*, 563 U.S. at 44. Rather, "[d]isclosure is required under these provisions only when necessary to make . . . statements made, in light of the circumstances under which they were made, not misleading." *Id.*; *see also In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 160 (S.D.N.Y. 2008) ("The requirement to be complete and accurate, however, does not mean that 'by revealing one fact . . . one must reveal all others that . . . would be interesting . . . .'" (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990))); *In re Travelzoo Inc. Sec. Litig.*, Nos. 11-cv-5531 (GBD), 11-cv-6845 (GBD), 2013 WL 1287342, at *6 (S.D.N.Y. Mar. 29, 2013) (concluding Defendant company "had no duty to disclose a *potentially* adverse effect that the launch of one of its products could have on the overall growth and revenue of its other core business" because plaintiffs "must plead with sufficient particularity" that the two products interacted with the company's financial situation "in a way that rendered Defendants' statements about the financial condition of the company misleading at the time they were made").

Here, Defendants spoke about the scientific studies supporting their plans for Triferic and explained in earnings calls and various public filings why they believed that Triferic, in its liquid form, would be successful. (*See, e.g.*, Compl. ¶ 37; *see also* Doc. Nos. 47-3, 47-6, 47-7, 47-8.) They did not mention the possibility of a powder version of the drug or the separate New Drug Application filed in June 2015. Plaintiffs argue, then, that Defendants concealed from public disclosure that

Rockwell's primary product offering would soon be powder Triferic, not liquid Triferic. (Opp'n 9–10; *see also* Compl. ¶¶ 51, 56, 59.) According to Plaintiffs, these omissions regarding powder Triferic made Rockwell's statements about its motivation to promote liquid Triferic and the drug's likely commercial success materially misleading.

In fact, Plaintiffs really have no theory as to why omitting mention of Rockwell's plan to develop and market the powder form of Triferic – in the uncertain event of its approval by the FDA – rendered any of Rockwell's public statements misleading. *See Rudman v. CHC Grp. Ltd.*, 217 F. Supp. 3d 718, 729 (S.D.N.Y. 2016). That failure is not surprising; companies often have new products in development that will eventually update or replace older models, and remaining silent about those still-developing products does not make discussion of the current product offering misleading. Here it bears repeating: simply because an omitted fact would be "interesting" to an investor does not render all other statements on that topic misleading absent disclosure. *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d at 160. Such a broad theory of omissions liability would paralyze corporate spokespersons and likely yield less, rather than more, information for investors – not to mention chill innovation across a range of industries.

Plaintiffs' omissions argument also fails for another reason. As Plaintiffs must acknowledge, Rockwell's ability to market powder Triferic was entirely contingent on approval by the FDA, which, was, of course, no sure thing. *See In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 325 (S.D.N.Y. 2014) (noting that "FDA approval is required before pharmaceuticals and devices may be marketed in the United States"). And the law is clear that "absent an express prior disclosure, a corporation has no affirmative duty to speculate" about future possibilities. *In re UBS AG Sec. Litig.*, No. 07-cv-11225 (RJS), 2012 WL 4471265, at *31 (S.D.N.Y. Sept. 28, 2012), *aff'd sub nom. City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173 (2d Cir. 2014). In other words, a company has "no duty to disclose predictions that are not substantially certain to hold." *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004), *aff'd sub nom. Albert Fadem Tr. v. Citigroup, Inc.*, 165 F. App'x 928 (2d Cir. 2006) (quoting *In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 633 (E.D. Mich. 2001)); *see also Lipow v. Net 1 UEPS Techs., Inc.*, 131 F. Supp. 3d 144, 170 (S.D.N.Y. 2015) (quoting *In re Par Pharm., Inc. Secs. Litig.*, 733 F. Supp. 668, 678 (S.D.N.Y. 1990)); *cf. In re Lions Gate Entm't Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 12 (S.D.N.Y. 2016) ("There is no duty to disclose litigation that is not 'substantially certain to occur.'" (quoting *Richman*, 868 F. Supp. 2d at 273–74)). Indeed, as the Second Circuit has repeatedly instructed, "it would be as serious an infringement of SEC regulations to overstate the definiteness of . . . plans as to understate them." *Dalberth v. Xerox Corp.*, 766 F.3d 172, 187 (2d Cir. 2014) (alteration in original) (quoting *Elec. Specialty Co. v. Int'l Controls Corp.*, 409 F.2d 937, 948 (2d Cir. 1969)).

At bottom, Plaintiffs ask the Court to impose on Defendants a "duty to speculate" that the powder version of Triferic would obtain FDA approval, and once approved would be preferred by customers. (Mem. 2–3.) Since Defendants were clearly not required to speculate about the marketability of the powder packet before knowing that they could, in fact, market the powder packet in the first place, there was no duty to

disclose the existence of the New Drug Application. Although Plaintiffs might have found that information to be "interesting," Defendants cannot be held liable under an omissions theory for leaving discussion of the powder packet out of their public statements during the Class Period. *L.L. Capital Partners, L.P. v. Rockefeller Ctr. Props., Inc.*, 921 F. Supp. 1174, 1179–80 (S.D.N.Y. 1996) ("To be sure, a case can be made for the proposition that the securities laws should require disclosure of an issuer's opinion as to the likelihood of important future contingencies. But that is not now the law." (internal citation omitted)).

* * *

For the foregoing reasons, the Court concludes that Plaintiffs have not pleaded a material misstatement or omission, which alone warrants dismissal of their claim for securities fraud under Section 10(b) and Rule 10b-5. The Court nevertheless turns to scienter, which provides an alternate basis for dismissal.

2. Scienter

Under the PSLRA, a securities fraud complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "The requisite state of mind . . . is an intent 'to deceive, manipulate, or defraud.'" *ECA*, 553 F.3d at 198 (quoting *Tellabs*, 551 U.S. at 313). As noted earlier, to be "strong," an "inference of scienter must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling" to the point where a reasonable person would consider the inference "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. In making this determination, the question is not whether "any individual allegation, scrutinized in isolation, meets th[e] standard"; rather, courts must "collectively" evaluate "*all* of the facts alleged." *Id.* at 323. In the Second Circuit, the requisite strong inference of scienter "can be established by alleging facts to show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198; *accord ATSI Commc'ns*, 493 F.3d at 99.

a. Motive to Commit Fraud

To raise a strong inference of scienter by pleading motive and opportunity to defraud, a plaintiff must allege that the defendant "benefitted in some concrete and personal way from the purported fraud." *ECA*, 553 F.3d at 198 (quoting *Novak v. Kasaks*, 216 F.3d 300, 307–08 (2d Cir. 2000)). By contrast, "[t]he absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders' expense, is inconsistent with an intent to defraud shareholders." *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000). In addition, "it is not sufficient to allege goals that are 'possessed by virtually all corporate insiders,' such as the desire to maintain a high credit rating for the corporation or otherwise sustain the appearance of corporate profitability or the success of an investment, or the desire to maintain a high stock price in order to increase executive compensation." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (quoting *Novak*, 216 F.3d at 307). Because corporate officers and directors often have the power to influence their company's stock prices, *see Philip Morris Cos.*, 75 F.3d at 813, securities fraud allegations typically focus on officer defendants' motives, rather than their opportunity, to commit fraud.

Here, Plaintiffs merely allege that Defendants had a motive to boost the market price of Rockwell's securities and ensure Rockwell had a successful commercial launch of Triferic. (Compl. ¶ 85; *see also* Opp'n 9–10 (asserting that Defendants had the motive to "conceal[ ] their true plans for commercializing Triferic, including the existence of powder Triferic . . . in order to avoid introducing uncertainty into the market and undermining their efforts, albeit poor, to sell liquid Triferic").) But maintaining a high stock price and exuding an image of profitability are goals shared by all corporate insiders, and therefore insufficient to establish scienter. *S. Cherry St., LLC*, 573 F.3d at 109; *see also Teamsters Local 445*, 531 F.3d at 196.

b. Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

Of course, "absence of a motive allegation . . . is not dispositive." (Opp'n 19 (quoting *Matrixx Initiatives, Inc.*, 563 U.S. at 48).); *see also Tellabs*, 551 U.S. at 325. The Second Circuit has long held that the scienter element can be satisfied by "a strong showing of reckless disregard for the truth." *S. Cherry St., LLC*, 573 F.3d at 109. That standard comprises "strong circumstantial evidence" of a defendant's "conscious misbehavior" or "recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 138–39 (2d Cir. 2001) (internal quotation marks omitted). However, in the absence of motive, "the strength of th[ose] circumstantial allegations must be correspondingly greater." *Id.* (internal quotation marks omitted).

"Reckless disregard for the truth" sets a high bar; it is after all a theory of liability based on fraud. "Conscious misbehavior" means "deliberate illegal behavior," such as insider trading or knowingly selling a company's stock at an unwarranted discount. *Novak*, 216 F.3d at 308 (citations omitted). "Recklessness" is a "state of mind approximating *actual intent*," one that is more than "merely a heightened form of negligence"; it is "an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *S. Cherry St., LLC*, 573 F.3d at 109 (quoting *Novak*, 216 F.3d at 312 and *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000)). A plaintiff may plead recklessness by "specifically alleg[ing] defendants' knowledge of facts or access to information contradicting their public statements," or by "alleg[ing] facts demonstrating that defendants failed to review or check information that they had a duty to monitor, or ignored obvious signs of fraud." *Novak*, 216 F.3d at 308. "Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Id.* at 309.[5]

Plaintiffs insist that Defendants knew or recklessly disregarded the facts that liquid Triferic was not commercially viable or more medically effective than existing IV treatments. But as explained earlier, the Second Amended Complaint lacks any

[5] The Court notes that Plaintiffs' brief repeatedly mischaracterizes the applicable standard in the Second Circuit. Specifically, Plaintiffs' submission is littered with assertions that Defendants were "minimally reckless." (Opp'n 22–23.) Tellingly, however, Plaintiffs have not cited a single decision within this Circuit to have ever applied this "minimally reckless" standard. That is not surprising since, as noted above, this Circuit requires plainitffs to raise an inference of "conscious recklessness – *i.e.*, a state of mind *approximating actual intent*, and *not merely a heightened form of negligence*." *S. Cherry St., LLC*, 573 F.3d at 109 (quoting *Novak*, 216 F.3d at 312).

particularized allegations to support an inference that Defendants were aware of any marketing problems with respect to liquid Triferic. For example, the Second Amended Complaint fails to reference a single internal Rockwell document or confidential source that discredits Defendants' public statements about the commercial prospects for Triferic, nor does it include "any dates or time frame in which Defendants were put on notice of contradictory information." *Plumbers & Steamfitters Local 773 Pension Fund v. Can. Imperial Bank of Commerce* (*CIBC*), 694 F. Supp. 2d 287, 300 (S.D.N.Y. 2010). In fact, as to medical efficacy, Plaintiffs themselves acknowledge that Defendants considered an extensive scientific study in which Triferic was administered over 100,000 times before publishing their analyses of Triferic's health benefits and cost savings. (Compl. ¶¶ 3 n.1, 37.) Thus, Plaintiffs' contention that there was "no evidence Triferic [was] safer or more effective than IV iron" (Opp'n 9) is belied by their own pleading. At bottom, "Plaintiffs should, but do not, provide specific instances in which Defendants received information that was contrary to their public declarations" concerning Triferic's imminent success. *CIBC*, 694 F. Supp. 2d at 299. "[W]ithout more to tie the Individual Defendants to specific information contradicting the substance of their statements," these allegations are "insufficient to give rise to a strong inference of scienter." *Shemian v. Research in Motion Ltd.*, No. 11-cv-4068 (RJS), 2013 WL 1285779, at *18 (S.D.N.Y. Mar. 29, 2013), *aff'd*, 570 F. App'x 32 (2d Cir. 2014).

Lacking any concrete evidence that Defendants had information contradicting their public statements about Triferic, Plaintiffs nonetheless insist that Defendants must have been aware of the pitfalls associated with liquid Triferic based on their control over Rockwell's "sales, operations, and its strategic planning." (Opp'n 20.) In other words, Plaintiffs claim that "Defendants had actual knowledge of the materially false and misleading statements and material omissions" concerning liquid Triferic by virtue of their status as "senior managers and/or directors" at the corporation. (Compl. ¶¶ 87–88.) But it is practically hornbook law that "accusations" such as these, which are "founded on nothing more than a defendant's corporate position[,] are entitled to no weight." *Fogel v. Wal-Mart de México SAB de CV*, No. 13-cv-2282 (KPF), 2017 WL 751155, at *16 (S.D.N.Y. Feb. 27, 2017) (quoting *Strougo v. Barclays PLC*, 105 F. Supp. 3d 330, 350 (S.D.N.Y. 2015)); *see also In re PetroChina Co. Ltd. Sec. Litig.*, 120 F. Supp. 3d 340, 366 (S.D.N.Y. 2015).

As a variant on their arguments based on corporate position, Plaintiffs also rely on the so-called "core operations doctrine," asserting that since "[c]ommercializing Triferic was a 'core operation' of [Rockwell]," it was "highly likely that Defendants were actually focused on its commercialization" and therefore aware of these alleged flaws with liquid Triferic. (Opp'n 20.) Under the core operations theory, "if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company." *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004) (citing *Cosmas v. Hassett*, 886 F.2d 8, 13 (2d Cir. 1989)).

Plaintiffs' reliance on the "core operations doctrine" is misplaced for at least

two reasons. First, "[c]ourts applying the core operations doctrine generally 'require[] that the operation in question constitute nearly all of a company's business before finding scienter.'" *Thomas v. Shiloh Indus., Inc.*, No. 15-cv-7449 (KMW), 2017 WL 1102664, at *4 (S.D.N.Y. Mar. 23, 2017) (quoting *Hensley v. IEC Elecs. Corp.*, No. 13-cv-4507 (JMF), 2014 WL 4473373, at *5 (S.D.N.Y. Sept. 11, 2014); *cf. Cosmas*, 886 F.2d at 12 (applying core operations doctrine where misrepresentations related to orders from China, which accounted for over 80% of issuer's backlog orders). Here, although Plaintiffs do allege that Triferic was Defendants' "lead branded drug" (Compl. ¶ 2) and underscore "the importance of Triferic to the Company's profitability" (Opp'n 20 (citing Compl. ¶ 47)), Plaintiffs fail to allege that sales of Triferic ever comprised "nearly all of" Rockwell's business, *cf. Thomas*, 2017 WL 1102664, at *4 (core operations doctrine inapplicable, notwithstanding fact alleged misrepresentations involved facility that was corporation's "crown jewel"). In fact, there are no particularized allegations whatsoever in the Second Amended Complaint regarding what specific portion of Rockwell's business depended on Triferic. Accordingly, Plaintiffs cannot rely on the core operations doctrine to raise an inference of scienter.

Furthermore, the PSLRA, which was enacted in 1995, has significantly limited the salience of the core operations doctrine. As this Court has previously observed, "the plain language of the PSLRA, which requires facts supporting the scienter inference to be 'state[d] with particularity,' would seem to limit the force of general allegations about core company operations." *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 353 (S.D.N.Y. 2011) (alteration in original) (quoting 15 U.S.C. § 78u–4(b)(1)). The Second Circuit has similarly questioned whether the core operation doctrine has survived the enactment of the PSLRA. *See Frederick v. Mechel OAO*, 475 F. App'x 353, 356 (2d Cir. 2012). Tellingly, the only case cited by Plaintiff in support of the applicability of the core operations doctrine relies exclusively on a pre-PSLRA Second Circuit decision. (*See* Opp'n 20; *In re Atlas Air*, 324 F. Supp. 2d at 489–91 (citing *Cosmas*, 886 F.2d at 10–13)).

As a result of these doubts as to the doctrine's continuing import, the core operations inference "may be considered 'as part of [a court's] holistic assessment of the scienter allegations,' [but] it is not 'independently sufficient to raise a strong inference of scienter." *Shemian*, 2013 WL 1285779, at *18 (quoting *Bd. of Trs. of Ft. Lauderdale Gen. Emps'. Ret. Sys v. Mechel OAO*, 811 F. Supp. 2d 853, 872 (S.D.N.Y. 2011)); *accord Cortina v. Anavex Life Scis. Corp.*, 15-cv-10162 (JMF), 2016 WL 7480415, at *7 (S.D.N.Y. Dec. 29, 2016). Therefore, even assuming that the core operations doctrine has continuing vitality as a legal doctrine, it would be far from sufficient, standing alone, to raise a strong inference of scienter in this case.

Ultimately, Plaintiffs rely heavily on Berns and Aschoff's analyses that cast doubt on Triferic's health benefits and ability to "improve dialysis center margins." (Compl. ¶¶ 39–40.) But "[t]here is simply no allegation" in the Second Amended Complaint that Defendants were "confronted with any" of these analyses or other "'red flags'" during the Class Period, as "required to support a strong inference of reckless disregard." *380544 Can., Inc. v. Aspen Tech., Inc.*, 544 F. Supp. 2d 199, 227 (S.D.N.Y. 2008). Furthermore, even assuming Defendants were aware of these

analysts' skepticism concerning Triferic, they were not required to respond to every negative article or to "present an overly gloomy or cautious picture of current performance and future prospects" based on them to avoid liability for securities fraud. *Novak*, 216 F.3d at 309; *see also CIBC*, 694 F. Supp. 2d at 300. While it is true that the FDA did not permit Rockwell to include Triferic's alleged "ESA-sparing benefits" on the product label (Compl. ¶ 41), Defendants' "public statements" need only have been "consistent with reasonably available data" regarding the potential market for Triferic, *Novak*, 216 F.3d at 309, and Plaintiffs fail to offer a single non-conclusory allegation showing that Defendants' public statements were inconsistent with the extensive scientific studies in which Triferic was administered over 100,000 times. Although Defendants "took a more optimistic view of [Triferic's] prospects" than Berns and Aschoff, the law is clear that "misguided optimism is not a cause of action, and does not support an inference of fraud." *Jones v. Perez*, 550 F. App'x 24, 26 (2d Cir. 2013) (quoting *Shields v. Citytrust Bancorp, Inc*., 25 F.3d 1124, 1129 (2d Cir. 1994)). Here, as in *Hershfang v. Citicorp*, Plaintiffs have simply "stitched together a patchwork" of analyst and press reports – if two can even be characterized as a "patchwork" – and "proclaimed the result a tale of securities fraud." 767 F. Supp. 1251, 1259 (S.D.N.Y. 1991). "But by even the modest standards of Rules 9(b) and 12(b)(6), it isn't." *Id.*

Finally, Plaintiffs argue, bizarrely, that "Defendants' failure to disclose their seeking FDA approval for the more cost effective version of Triferic prior to launching liquid Triferic is strong evidence of fraudulent intent." (Opp'n 22.) As an initial matter, that statement is wholly conclusory and circular in its logic. But more than that, it is pernicious and contrary to law. Such a theory of scienter, which would attribute fraudulent intent to any company that fails to publicly count its chickens before they hatch, would effectively create a duty to disclose and a presumption of fraudulent intent that is contradicted by the law of this Circuit. This assertion, coupled with Plaintiffs' misstatements of the law regarding the nonexistent "minimally reckless" standard for scienter, reflects a lack of understanding and care that is troubling.

c. Holistic Assessment

Although the Court has rejected all of Plaintiffs' scienter arguments individually, it must still consider whether the allegations and other proper sources of facts "give rise to a strong inference of scienter" when "taken collectively." *Tellabs*, 551 U.S. at 322–23. "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. Here, two inferences are available: either Defendants knew – or recklessly failed to realize, which amounts to the same thing – that their optimistic statements concerning Triferic's marketability and omissions regarding the powder packet were materially misleading, or, in the alternative, Defendants' statements resulted from misplaced optimism and/or questionable medical and business analyses. Plaintiffs have failed to provide any basis for a conclusion that Defendants had a motive to defraud, and their allegations of conscious misbehavior or recklessness are extraordinarily thin. It is of course true that scienter allegations "need not be irrefutable," or "even the most plausible of competing inferences," to withstand a motion to dismiss. (Opp'n 19 n.16 (quoting *Tellabs*, 551 U.S. at 324).) But the Second

Amended Complaint's highly conclusory and hindsight-driven allegations – which could perhaps not even survive the liberal pleading standard of Rule 8 – are clearly unable to meet the heightned standards of Rule 9(b) and the PSLRA. Put simply, the Court finds that any reasonable person would deem the inference of scienter to be far less compelling than an inference of, at most, non-actionable mismanagement and negligence on the part of Defendants. Accordingly, the Court concludes that Plaintiffs have failed to adequately allege scienter and that their claim under Section 10(b) and Rule 10b-5 must be dismissed.

B. Alleged Violations of Exchange Act Section 20(a)

"Section 20(a) of the Exchange Act provides that individual executives, as 'controlling person[s]' of a company, are secondarily liable for their company's violations of the Exchange Act." *Blanford*, 794 F.3d at 305 (alteration in original) (quoting 15 U.S.C. § 78t(a)). Because Plaintiffs' Section 20(a) claim "is necessarily predicated on a primary violation of securities law," and the Court has determined that Plaintiffs have failed to plead a primary violation, Plaintiffs' Section 20(a) claim must also be dismissed. *See Rombach*, 355 F.3d at 177–78.

C. Required Findings as to the Parties' Compliance with Rule 11

The PSLRA mandates that, at the end of any private securities action, the district court must "include in the record specific findings regarding compliance by each party and each attorney representing any party with each requirement of" Federal Rule of Civil Procedure 11(b). 15 U.S.C. § 78u-4(c)(1); *see also Rombach*, 355 F.3d at 178 (remanding for findings under Rule 11 because the PSLRA "mandates" such findings and "the imposition of sanctions" if "the court finds that any party or lawyer violated Rule 11(b)"). Although the Court finds this to be a close question given (1) the paucity of non-conclusory allegations contained in the Second Amended Complaint (and Plaintiffs' prior complaints), and (2) the serious mischaracterizations of law with respect to scienter in Plaintiffs' brief, the Court ultimately concludes that no party has violated Rule 11(b) and that sanctions are not warranted.

D. Leave to Amend

Finally, the Court considers Plaintiff's request for leave to amend. (Opp'n 26.) "Although Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend 'shall be freely given when justice so requires,' it is within the sound discretion of the [Court] to grant or deny leave to amend." *McCarty v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). In addition, the Second Circuit has consistently stated that district courts may deny leave to amend when plaintiffs request such leave in a cursory sentence on the last page of an opposition to a motion to dismiss, without any justification or an accompanying suggested amended pleading. *See, e.g.*, *City of Pontiac*, 752 F.3d at 188 (affirming denial of leave to amend where plaintiffs already had one opportunity to amend their complaint and had "identified no additional facts or legal theories" to support their request to amend); *Food Holdings Ltd. v. Bank of Am. Corp.*, 423 F. App'x 73, 76 (2d Cir. 2011) (affirming district court's denial of leave to amend where plaintiff requested leave to amend "on the final page of their brief in opposition to defendants' motion to dismiss, in boilerplate language and without any explanation as to why leave to amend was warranted"); *Porat v. Lincoln Towers*

Cmty. Ass'n, 464 F.3d 274, 275–76 (2d Cir. 2006).

Here, on the final page of their opposition to Defendants' motion to dismiss, Plaintiffs, without any legal or other support, state in a single sentence that "if the Court grants any portion of the [motion to dismiss], Plaintiffs respectfully request leave to amend." (Opp'n 26.) Significantly, Plaintiffs offer no basis for their request for leave to amend nor do they attach a proposed amended complaint. *See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015) (noting that a court may deny leave to amend, on notice grounds, "where the request gives no clue as to 'how the complaint's defects would be cured'" (quoting *Porat*, 464 F.3d at 276)). Moreover, this is not Plaintiffs' first attempt at re-pleading in this action. To the contrary, this is the fourth complaint filed in these related cases. It is also worth noting that, on November 14, 2016, after the parties had exchanged pre-motion letters and the Court had held a pre-motion conference concerning Defendants' contemplated motion to dismiss (Doc. Nos. 27, 29, 41), Plaintiffs sought and received leave to amend for the purpose of addressing deficiencies in the first amended complaint that the Court and Defendants addressed at some length (Doc. Nos. 39, 43, 44). Notwithstanding the prior pleadings as well as the benefit of Defendants' pre-motion letter and a colloquy with the Court at the pre-motion conference, in which these very deficiencies were discussed, Plaintiffs' amended pleading *still* fails to allege facts sufficient to withstand a motion to dismiss.

As Judge Lynch aptly noted when he was on the district court, "[w]hile pleading is not a game of skill in which one misstep may be decisive to the outcome, neither is it an interactive game in which plaintiffs file a complaint, and then bat it back and forth with the Court over a rhetorical net until a viable complaint emerges." *In re Refco Capital Mkts., Ltd. Brokerage Customer Sec. Litig.*, Nos. 06-cv-643, 07-cv-8686, 07-cv-8688 (GEL), 2008 WL 4962985, at *2 (S.D.N.Y. Nov. 20, 2008) (citations and internal quotation marks omitted); *see also Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) (noting that courts can deny leave to amend where there has been "repeated failure to cure deficiencies by amendments previously allowed" (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *NRW, Inc. v. Bindra*, No. 12-cv-8555 (RJS), 2015 WL 3763852, at *1 (S.D.N.Y. June 16, 2015) ("To grant leave to amend after a plaintiff has had ample opportunity to amend would be condoning a strategy whereby plaintiffs hedge their bets . . . in the hopes of having another bite at the proverbial apple." (internal quotation marks omitted)). Accordingly, because Plaintiffs have failed to attach a proposed amended complaint or even attempted to explain why an additional opportunity to amend would cure the Complaint's deficiencies, and because Plaintiffs' past attempts provide no comfort in this regard, the Court denies Plaintiffs' request for leave to amend.

IV. CONCLUSION

For the reasons discussed above, the Court finds that Plaintiffs have failed to allege a single misstatement of fact or actionable omission in connection with Defendants' development of Triferic; Plaintiffs have also failed to demonstrate that Defendants acted with fraudulent intent or a reckless disregard for the truth. Indeed, to the extent that any party could be accused of being reckless, it is Plaintiffs, who have essentially embraced a theory of securities fraud that would punish corporations merely

for developing new products on their own timetable. Throughout this country and around the world, there are literally thousands of corporations, large and small, with robust research and development departments. At this very moment, pharmaceutical companies are undoubtedly working tirelessly to develop new drugs and medicines that will make current treatments – including their own offerings – obsolete. That is a good thing, and something that is essential to a dynamic economy and social progress. Plaintiffs' theory of securities fraud – which would compel disclosure of new products whenever a company made required quarterly statements about its existing products – finds no basis in law and smacks of opportunism and cynicism. Litigation is not a sport or a version of the lottery in which plaintiffs are free to launch class action lawsuits simply because a stock dropped from one quarter to the next. More is required, and Plaintiffs have very obviously failed to meet that minimal standard here.

Accordingly, IT IS HEREBY ORDERED THAT Defendants' motion to dismiss the Second Amended Complaint is GRANTED, and this case is dismissed with prejudice. The Clerk of the Court is respectfully directed to terminate the motion pending at docket number 45, and close this case and case number 16-cv-3304 (RJS).

SO ORDERED.

RICHARD J. SULLIVAN
United States District Judge

Dated: March 30, 2018
New York, New York