UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARSHA GILLIS, CARL BAYNEY, and DANIEL REHMSMEYER, *individually and on behalf of all others similarly situated,*

Plaintiffs,

-v-

QRX PHARMA LTD. and JOHN HOLADAY,

Defendants.

15 Civ. 4868 (PAE)

OPINION & ORDER

PAUL A. ENGELMAYER, District Judge:

In this putative class action under the federal securities laws, lead plaintiffs Marsha Gillis, Carl Bayney, and Daniel Rehmsmeyer (collectively, "plaintiffs") claim that the Australian pharmaceutical company QRx Pharma Ltd. ("QRX" or the "Company") and its former CEO John Holaday made false and misleading statements about MoxDuo IR ("MoxDuo"), QRX's leading drug candidate, while it was under review by the U.S. Food and Drug Administration ("FDA").

Plaintiffs bring this lawsuit on behalf of all persons who purchased QRX American Depository Receipts ("ADRs") between December 6, 2010 and April 23, 2014, inclusive (the "Class Period"). They allege violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), and the corresponding rule of the Securities and Exchange Commission, 17 C.F.R. § 240.10b–5 ("Rule 10b–5"). The United States Bankruptcy Court for this District, recognizing QRX's Australian insolvency proceeding

as a foreign main proceeding, has dismissed this case as to QRX pursuant to the resolution of that proceeding, leaving Holaday as the only defendant here.[1]

Pending now is Holaday's motion to dismiss plaintiffs' Second Amended Class Action Complaint ("SAC") for failure to state a claim, under Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the Court grants the motion and dismisses the SAC in its entirety.

I. Background[2]

A. The Parties

QRX is a specialty pharmaceutical company headquartered in Australia that focuses on the development and commercialization of treatments for pain management. SAC ¶ 2. Its ADRs[3] trade over the counter in the United States. *Id.* From April 2007 until May 3, 2014,

[1] For ease of reference, the Court uses "defendants" to collectively refer to QRX and Holaday.

[2] These facts are drawn primarily from the Second Amended Complaint. Dkt. 44 ("SAC"). For the purpose of resolving the motion to dismiss, the Court assumes all well-pled facts to be true and draws all reasonable inferences in favor of plaintiffs. *See Koch v. Christie's Int'l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). The Court also considered the documents attached to the declarations of Peter A. Stokes in support of the motion to dismiss, Dkts. 40, 46 (together, "Stokes Decl."). Because these documents are incorporated into the SAC by reference, or are matters of public record, they are properly considered on a motion to dismiss. *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 179 (2d Cir. 2014) (in resolving motion to dismiss, the court "may consider," *inter alia*, "any statements or documents incorporated in [the complaint] by reference, as well as public disclosure documents required by law to be, and that have been, filed with the SEC, and documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit"); *Fort Worth Emp'rs Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 223 nn.1, 3 (S.D.N.Y. 2009); *In re Regeneron Pharm., Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS), 2005 WL 225288, at *2 n.1 (S.D.N.Y. Feb. 1, 2005).

[3] "The ADR system is the means by which American investors hold and trade equity interests in foreign companies." *Gas Nat. v. E.ON AG*, 468 F. Supp. 2d 595, 596 n.1 (S.D.N.Y. 2006). In order to trade on an American stock exchange, a foreign corporation must issue and deposit American Depository Shares ("ADSs") with an American financial institution. *Id.* The

Holaday was QRX's CEO and Managing Director. *Id.* ¶ 13. Plaintiffs are individuals who purchased QRX ADRs during the Class Period. *Id.* ¶¶ 10–12.

B. MoxDuo and the Combination Rule

Throughout the Class Period, QRX's main focus was advancing MoxDuo, its lead experimental drug candidate, through the FDA approval process, so that it could be marketed and sold in the United States. *See id.* ¶¶ 2–3, 74. MoxDuo is a combination of morphine sulfate and oxycodone hydrochloride. *Id.* ¶ 2. If approved, it would have been the first combination drug product to contain two active opioid ingredients. *Id.* ¶ 15. The intended purpose of the combination was to provide effective analgesia while reducing the frequency and severity of opioid-related side effects, such as nausea, dizziness, oxygen desaturation, and respiratory problems. *Id.* ¶ 2; Stokes Decl., Ex. 2.

Because MoxDuo combined two existing drugs, QRX was required to satisfy the FDA's "Combination Rule" in order to gain approval. *Id.* ¶¶ 3, 15. That rule states that "[t]wo or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component . . . is such that the combination is safe

depository institution issues ADRs to the beneficial owners of the ADSs, who may then sell the ADSs on American securities exchanges. *Id.*

and effective for a significant population requiring such concurrent therapy." 21 C.F.R. § 300.50(a); SAC ¶ 15.

The Combination Rule "does not specifically address the issue of combining two drugs from the same pharmacological class." Stokes Decl., Ex. 24 ("FDA Memo"), at 12. Nor, as of the start of the Class Period, had the FDA publicly opined on how the rule would apply to a prescription dual-opioid like MoxDuo. *See id.* Decades earlier, however, the FDA had set forth a more stringent standard for *non*-prescription drug products that combine two ingredients from the same category. *See id.* at 5, 12. In a 1978 guidance document entitled *OTC Drug Combination General Guidelines*, the FDA stated that "active ingredients from the same therapeutic category that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhanced effectiveness, safety, patient acceptance, or quality of formulation." *Id.*

C. Overview of Plaintiffs' Claims

The SAC's core allegations are that: (1) before the Class Period, the FDA privately articulated to QRX a "Superiority Requirement" that QRX had to meet in order to satisfy the Combination Rule in the novel context of a prescription dual-opioid drug, to wit, that QRX must demonstrate a safety or efficacy benefit of the combination (MoxDuo) compared to "comparable" or "equi-analgesic" doses of its components (morphine and oxycodone);[4] and (2) QRX concealed this information and related setbacks from investors, knowing that QRX could not satisfy the Superiority Requirement. SAC ¶ 3. As result, plaintiffs claim, QRX's optimistic

[4] This meant that QRX was required to show that MoxDuo was superior to doses of morphine and oxycodone that were twice as potent as the respective doses encapsulated in the combination. *See* FDA Memo, at 12. For example, MoxDuo 12/8 mg (12 mg morphine; 8 mg oxycodone) would have to be shown to be superior both to 24 mg morphine and, separately, to 16 mg oxycodone.

statements regarding its clinical studies and the prospect of FDA approval gave investors the "false impression that QRX had a clear path to getting MoxDuo approved," when, in reality, according to plaintiffs, it was at all times virtually certain that QRX's New Drug Application ("NDA") for MoxDuo would be rejected. *Id.*

Plaintiffs claim that QRX's misrepresentations caused QRX ADRs to trade at artificially inflated prices throughout the Class Period. *Id.* ¶ 6. They allege that these misrepresentations were partially dispelled on June 27, 2012, when QRX announced that the FDA had issued a Complete Response Letter declining to approve MoxDuo at that time. *Id.* ¶ 62. Upon that announcement, QRX's ADRs declined 47%, from $7.37 to $3.88 per share. *Id.* However, plaintiffs claim, that was "only a partial disclosure of the true state of affairs and a partial materialization of the concealed risks," because QRX continued to conceal the true basis for the FDA's refusal to approve MoxDuo: that QRX was required, but had failed, to satisfy the Superiority Requirement of the Combination Rule. *Id.*

Plaintiffs allege that the entire truth was not exposed until April 22, 2014, when, during a trading halt on QRX securities, the FDA released a memorandum (the "FDA Memo") recommending against approval of MoxDuo because QRX had not satisfied the Superiority Requirement. *See id.* ¶¶ 4, 64. According to plaintiffs, the FDA Memo also revealed that: (1) long before the Class Period, the FDA had informed QRX of the Superiority Requirement; and (2) throughout the development process, QRX had encountered setbacks stemming from its inability to satisfy that requirement. *See id.* ¶¶ 4, 65. Later that day, QRX announced that an FDA Advisory Committee had voted to recommend against approval of MoxDuo. *Id.* ¶ 67. As a result of these disclosures, plaintiffs allege, when trading resumed on April 23, 2014, the price of QRX ADRs declined more than 83%—from $3.40 to $0.42 per share. *Id.* ¶¶ 5, 68–69.

D. Factual Background

1. Overview of the FDA Review Process

FDA regulations require that drug manufacturers engage in three phases of clinical (*i.e.*, human) trials before presenting a new drug to the FDA for approval. *See* 21 C.F.R. § 312.21. Phase I studies typically involve 20–80 volunteers. *Id.* § 312.21(a). They are designed to ascertain the pharmacology and safety of the drug, and, if possible, to gain early evidence of its effectiveness. *Id.* Phase II trials typically involve groups of "no more than several hundred subjects" and are conducted to "evaluate the effectiveness of the drug for a particular indication . . . and to determine [the drug's] common short-term side effects and risks." *Id.* § 312.21(b). Phase III clinical trials are even larger studies, "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, [which] are intended to gather the additional information about effectiveness and safety that is needed to evaluate" whether the "overall benefit-risk relationship of the drug" supports approval. *Id.* § 312.21(c).

Before commencing a Phase III trial, a drug manufacturer may, but is not required to, request a Special Protocol Assessment ("SPA") from the FDA. An SPA is a written agreement

> which sets out the design and size parameters for clinical trials of a new drug, and the conditions under which the FDA would approve the drug. For the manufacturer, such an agreement minimizes development risk by providing regulatory predictability: Provided that the manufacturer follows the procedure set in the SPA and the drug [ ] meets the benchmarks for effectiveness set in the agreement, the FDA must approve the drug.

Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 210 (S.D.N.Y. 2015) (citing U.S. Food and Drug Admin., *Guidance for Industry: Special Protocol Assessment* (2002), at 2, http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080571.pdf).

Once a pharmaceutical company has completed all three phases of clinical trials, it can submit an NDA to the FDA. *See generally* 21 C.F.R. § 314. The FDA may refuse to accept an

NDA for a variety of technical reasons, such as that the application does not include the requisite components or was not filed in the proper format. *See id.* § 314.101(d). Once the FDA has accepted an NDA, it may refuse to approve it for a variety of substantive reasons, including that "[t]here is a lack of substantial evidence consisting of adequate and well-controlled investigations . . . that the drug product will have the [safety or efficacy] effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling." *Id.* § 314.125(b)(5).

If the FDA determines that it will not approve an NDA in its present form, it will send the applicant a Complete Response Letter ("CRL") that describes the deficiencies in the application and, where possible, provides recommendations for achieving approval. *See id.* § 314.110.

2. QRX's Early Communications with the FDA

In January 2004, QRX met with the FDA in anticipation of filing an Investigational New Drug ("IND") application seeking permission to begin clinical trials for MoxDuo. SAC ¶ 17. At the meeting, QRX explained that the rationale behind MoxDuo was that "the individual components were expected to act synergistically for efficacy" such that "the combination is better than the sum of the parts." FDA Memo, at 9–10; *see also* SAC ¶ 17. The FDA advised that "reduced doses of opioids in combination cannot be assumed to be of clinical benefit alone." FDA Memo, at 10; *see also* SAC ¶ 17.

Sometime thereafter, the FDA authorized QRX to perform clinical trials for MoxDuo, and QRX conducted two Phase II studies, Studies 020 and 021, which it later included in its NDA. *See* SAC ¶ 18; FDA Memo, at 11, 13.

3. Study 008 and the "No Agreement" Letters

On May 1, 2009, QRX requested an SPA for the clinical protocols for Study 008. *See* Stokes Decl., Ex. 17 ("NAL"), at 1. That study was a double-blind Phase III trial comparing the efficacy and safety profiles of MoxDuo 12mg/8mg against component doses of morphine (12 mg) and oxycodone (8 mg), administered alone, for the management of moderate to severe post-operative pain. *See* FDA Memo, at 11. The study's purpose was to "demonstrate that the individual components of Moxduo each made a contribution to the efficacy of the product." *Id.*

On June 19, 2009, the FDA sent QRX a "No Agreement Letter" (the "NAL"), declining to enter into an SPA with QRX because it did not approve of QRX's "proposed efficacy endpoint and statistical approach" for Study 008. *Id.* at 9; *see* NAL. Specifically, the FDA took issue with QRX's proposed primary efficacy endpoint for the trial, SPID24 (*i.e.*, measuring efficacy after 24 hours). NAL, at 1–2. It advised that:

> It is incumbent on you to find a patient population that requires the additional benefit that you anticipate from your proposed formulation and demonstrate superiority of the combination over the individual components in an adequate and well-controlled study. If you cannot demonstrate a difference in treatment response beyond 24 hours, the question becomes whether there is any need for the combination.

Id. at 2. Holaday, who retained a copy of the letter in his personal files, highlighted this passage. *Id.*; SAC ¶ 20.

Notwithstanding this feedback, the FDA affirmed in the NAL that, "[i]n principle, the Combination Rule would be satisfied" if MoxDuo were found to be "statistically significantly superior to each of its individual components on [an appropriate] primary endpoint" for Study 008. NAL, at 3.

On July 10, 2009, QRX submitted a second request for an SPA for Study 008. *See* Stokes Decl., Ex. 18, at 1; SAC ¶ 21. On August 27, 2009, the FDA responded by issuing a

second No Agreement Letter. SAC ¶ 21. In it, the FDA confirmed that QRX's revised proposed primary efficacy endpoint for Study 008, SPID48 (*i.e.*, measuring efficacy after 48 hours), was acceptable, and that QRX had adequately addressed some of the statistical issues raised in the FDA's first letter. Stokes Decl., Ex. 18, at 1–2. It still declined to enter into an SPA with QRX, however, because QRX had not adequately described the primary efficacy analysis. *Id.* at 2.

On September 3, 2009, QRX submitted a third request for an SPA for Study 008. *See* Stokes Decl., Ex. 19, at 1; SAC ¶ 21. On October 5, 2009, the FDA notified QRX that, due to resource constraints, it would not accept the Company's request for a third review cycle. Stokes Decl., Ex. 19, at 1; SAC ¶ 21.

QRX did not publicly disclose that it had requested, or been denied, an SPA for Study 008. *See* SAC ¶ 22. Nor did it disclose any of the interim feedback that it had received in the No Agreement Letters. *See id.*

On November 30, 2009, QRX issued a press release announcing the commencement of Study 008. *Id.* In it, QRX stated that it had "incorporated input from the FDA regarding the design and statistical analysis of [the] study." *Id.*

On December 6, 2010 and January 24, 2011, QRX issued press releases touting the results of Study 008, which it referred to as a "combination rule" study. *See id.* ¶¶ 30, 32. QRX stated that Study 008 had met "both primary and secondary endpoints": MoxDuo "not only demonstrated a statistically superior analgesic effect compared to component doses of morphine (p=0.02) and oxycodone (p=0.02) but, also, a favourable side effect profile despite delivering twice the opioid dose of its individual components." *Id.* ¶ 30; *see also id.* ¶ 32.

On December 6, 2010, QRX issued a press release announcing that it had completed patient enrollment for its third Phase III trial, Study 009.[5] *Id.* ¶ 30. In it, QRX stated that, with the completion of that study and Study 008, the Company "believe[d] it ha[d] met the basic requirements for clinical data to enable NDA filing for MoxDuo [ ] as targeted for the first half CY2011." *Id.* In press releases issued on January 24 and 27, 2011, QRX reiterated this statement. *See id.* ¶¶ 32, 34.

4. Study 022

At an "end of phase 2" meeting with the FDA in 2009, QRX asked "about the requirements to support a claim for a synergistic effect on efficacy and about demonstrating improved safety of MoxDuo compared to equianalgesic doses of morphine sulfate and oxycodone hydrochloride alone." *Id.* ¶ 19; FDA Memo, at 10. The Company later designed a "dedicated [Phase III] safety study," intended to show a safety advantage for MoxDuo. SAC ¶ 19. That study, Study 022, was a double-blind, fixed-dose comparison of MoxDuo (12 mg morphine/8 mg oxycodone) vs. equivalent doses of morphine (24 mg) and, separately, oxycodone (16 mg). *See* Stokes Decl., Ex. 2, at 1.

On January 24, 2011, QRX issued a press release announcing the commencement of Study 022, the purpose of which, QRX stated, was "to compare the tolerability and safety profile of MoxDuo [ ] to equi-analgesic doses of either morphine or oxycodone given alone." *Id.* The press release stated that QRX "expect[ed] to complete dosing in Q2 CY2011" and that the results of the study would be included in its application for marketing approval in Europe. *Id.*

[5] The Company had previously completed Study 008, and Study 007, a double-blind, Phase III study, which compared four dose levels of MoxDuo to placebos. *See* FDA Memo, at 11.

5. QRX's First Submission of the NDA

On July 22, 2011, QRX issued a press release announcing the initiation of its NDA filing with the FDA. *See* SAC ¶ 36. Holaday was quoted as stating that, with this milestone, "[the Company] continue[s] to make significant progress toward commercialising MoxDuo IR." *Id.*

On August 25, 2011, QRX issued a press release announcing its submission of the NDA. *Id.* ¶ 38. The NDA included full reports from two Phase II clinical trials, Studies 020 and 021, and three Phase III clinical trials, Studies 007, 008, and 009. *Id.* ¶ 23. It did not include the full study report for Study 022, because the results were not yet complete. *Id.* In the August 25, 2011 press release, QRX stated that Study 022 would be submitted to the FDA "as part of a 2011 NDA update filing." Stokes Decl., Ex. 6, at 2. Holaday was quoted as saying that QRX was "pleased to have met this significant NDA milestone in just four years, and look[ing] forward to the regulatory approval process that may enable product sales in 2012." *Id.* at 1; SAC ¶ 38.

QRX later, in its 120-day safety update, submitted preliminary analyses from Study 022 to the FDA. *See* FDA Memo, at 13.

6. The FDA's First Complete Response Letter

On June 25, 2012, the FDA sent QRX a CRL (the "June 2012 CRL"), declining to approve the NDA in its present form. *See* SAC ¶ 24; Stokes Decl., Ex. 20 ("6/25/12 CRL"). The FDA identified one deficiency with QRX's application: It had "not provided adequate evidence to support that there is a patient population that requires treatment with Moxduo, as required by the Combination Rule 21 CFR 300.50." 6/25/12 CRL, at 1. To correct this issue, the FDA recommended that QRX submit evidence that MoxDuo has either greater efficacy or superior safety to comparable doses of morphine and oxycodone. *Id.*

The FDA Memo stated that the FDA review team found that Study 008 had met its primary endpoint by demonstrating that MoxDuo was more effective than each of its components. *See* FDA Memo, at 11. Accordingly, the FDA Memo stated, the review team concluded that Study 008 had satisfied the first prong of the Combination Rule, *i.e.*, by showing that "each component makes a contribution to the claimed effects." *Id.* (quoting 21 C.F.R. § 300.50(a)). However, the FDA Memo stated, the review team determined that to satisfy the second prong of the Combination Rule—*i.e.*, that the "dosage of each component . . . is such that the combination is safe and effective for a *significant patient population requiring such concurrent therapy*"—QRX would have to show that MoxDuo offered a safety or efficacy advantage over *comparable doses* of morphine and oxycodone. *See id.* at 12 (quoting 21 C.F.R. § 300.50(a)) (emphasis added). The review team concluded that, because subjects in the morphine and oxycodone arms of Study 008 received roughly half of the amount of opioid that subjects in the MoxDuo arm had received, the results from Study 008 did not satisfy this portion of the rule. *Id.*

As to safety, the FDA Memo stated, the review team found that the available data from Study 022 did not "demonstrate[] either a safety advantage or disadvantage for Moxduo . . . , but rather that Moxduo was comparable to the individual components when taken at . . . equivalent doses." *Id.* at 20.

On June 27, 2012, QRX issued a press release announcing its receipt of the CRL. SAC ¶ 40. It stated that the "Company is presently considering its response to the requests for additional information with regard to the safety and effectiveness of MoxDuo and has been granted a meeting with the FDA to clarify the steps required for approval." *Id.* Later that day, QRX's ADRs declined 47%, from $7.37 to $3.88 per share. *Id.* ¶ 62.

7. QRX's Post-Submission Communications with the FDA

In August and September 2012, QRX issued multiple press releases in which it acknowledged the Company's disappointment as to the CRL, while stating that, based on its post-submission communications with the FDA, it remained optimistic about MoxDuo's prospects for approval. *See id.* ¶¶ 42, 44. A press release issued on August 20, 2012 is representative. In it, QRX reported that:

> [The FDA had] clarified to Company representatives during a post submission review meeting the steps required for approval of immediate release MOXDUO. The FDA requested further information regarding data filed as part of the MOXDUO [NDA] and additional analysis of trials completed to date, including Study 022 which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone at equi-analgesic doses.

Id. ¶ 42. Holaday was quoted there as stating:

> We were encouraged by our reception at the FDA; the Agency confirmed our Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA. . . . Additionally, at the FDA's invitation, we agreed to submit more extensive information on Study 022 and believe the results of this study provide further safety data to support approval of MOXDUO.

Id.

In October 2012, QRX appealed the review team's decision to the FDA Office of Drug Evaluation II ("ODEII"). FDA Memo, at 20; SAC ¶ 27. Along with the appeal, it submitted more complete analyses of Study 022. FDA Memo, at 20; SAC ¶ 27. It argued that (1) the Combination Rule does not require that QRX demonstrate a safety or efficacy advantage for MoxDuo over its components at comparable doses;[6] and (2) even if such an advantage were

[6] In the SAC, plaintiffs state that QRX took the position that MoxDuo should not be subject to the Combination Rule. SAC ¶ 27. However, the FDA Memo, on which plaintiffs rely to support this allegation, indicates that QRX, while challenging the Superiority Requirement that the FDA

required to satisfy the rule, QRX had demonstrated a safety advantage for MoxDuo compared to morphine and oxycodone. FDA Memo, at 20. In response, the ODEII rejected QRX's interpretation of the Combination Rule and concurred with the review team's decision to issue the CRL. FDA Memo, at 20; SAC ¶ 27. It declined to review the new Study 022 analyses, and instead directed QRX to file a revised NDA. FDA Memo, at 20; SAC ¶ 27.

In November 2012, QRX appealed this result to the FDA Office of New Drugs ("OND"). The OND upheld the ODEII's decision on all grounds. FDA Memo, at 20–21; SAC ¶ 27. However, like the ODEII, the OND "recognized the importance of [the Study 022] analyses and strongly recommended that [QRX] submit them as part of [its] response to the CRL." FDA Memo, at 21.

On October 26 and November 7, 2012, QRX issued press releases, in which it reiterated its earlier statements regarding the post-submission feedback it had received from the FDA. *See* SAC ¶¶ 46, 48. QRX did not disclose that it had formally appealed the CRL to the ODEII or the OND. *See id.* ¶¶ 47, 49.

However, in press releases issued on January 16 and 24, 2013, QRX stated that "[d]uring the Company's most recent FDA review meeting, [it] presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for MOXDUO compared to either morphine or oxycodone alone." *Id.* ¶ 52; Stokes Decl., Ex. 12, at 1; *id.*, Ex. 13, at 1. QRX further stated that:

> The FDA also voiced for the first time that no precedent exists for their review of combination products where two drugs in the same category are combined (e.g. morphine and oxycodone as "opioids"). Therefore, despite the Agency previously confirming that there were no safety issues in any of the studies that were part of the original NDA, the resubmitted application, including new results from Study

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had read into the second prong of the rule, did not challenge the applicability of the rule itself. *See* FDA Memo, at 20.

022, will likely undergo review by an Advisory Committee in late Q2 2013.

Stokes Decl., Ex. 12, at 1; *id*., Ex. 13, at 1.

8. QRX's Resubmission of the NDA and the FDA's Second Complete Response Letter

In February 2013, QRX submitted a revised NDA, which, it represented, was intended to show that MoxDuo offered a safety advantage over morphine and oxycodone. SAC ¶ 28. On February 28, 2013, QRX issued a press release announcing its resubmission. *Id.* ¶ 54. In it, Holaday stated:

> We believe the revised documents effectively address the FDA's request for additional data resulting from their review of the initial MOXDUO NDA filed in mid-2011. . . . To this end, and as recommended by the FDA, a comprehensive analysis of Study 022 was included as part of the resubmitted NDA. This study demonstrated the lower risks of respiratory depression for MOXDUO when compared to either morphine or oxycodone.

Id.

In an April 29, 2013 press release, the Company announced that the FDA had formally accepted its resubmission. *Id.* ¶ 56. The press release quoted Holaday as stating that, "[a]ssuming approval, we anticipate product launch . . . before the end of this calendar year." *Id.*

In June 2013, QRX notified the FDA that there were errors in the electronic oxygen saturation data from Study 022. *Id.* ¶ 28; FDA Memo, at 7. Because QRX was unable to correct this data before the FDA's review, the review team could not rely on it in considering the application. SAC ¶ 28; FDA Memo, at 7.

On August 26, 2013, the FDA issued a second CRL, declining to approve the amended NDA. SAC ¶ 28; *see* Stokes Decl., Ex. 21 ("8/26/13 CRL"). According to the FDA Memo, the review team found that the safety data and analyses in the resubmission—including the non-tainted data from Study 022 and pooled analyses from the overall development program—did

not evince a "meaningful safety advantage" for MoxDuo, and thus "did not address the deficiency . . . articulated in the CRL from the first review cycle." FDA Memo, at 7–8.

On November 25, 2013, QRX submitted a second revised NDA, which contained new data-sets and analyses of Study 022's electronic oxygen saturation data. *Id.* at 8, 22; SAC ¶ 29. The next day, QRX issued a press release announcing its resubmission and expressing hope that the FDA would approve it. *See* SAC ¶ 60. As to Study 022, QRX stated that it "believe[s] [that the oxygen desaturation] data demonstrate a significant respiratory safety advantage for MOXDUO over equi-analgesic doses of morphine or oxycodone." *Id*. Holaday was quoted as saying:

> We are confident that our refiled NDA will confirm the validity of the data defining the product's respiratory safety advantages and we are hopeful that the FDA will view them favourably in their consideration of the benefits of immediate release MOXDUO as a therapeutic option for the millions of patients who suffer from acute pain.

Id.

9. The FDA Memo and the AADPAC Meeting

On April 17, 2014, the Australian Stock Exchange and the over-the-counter market in the United States suspended trading in QRX's securities at QRX's request, due to pending news from the Company. *Id.* ¶ 63.

During the trading halt, on April 22, 2014, the FDA published the FDA Memo, which it had prepared as background material for a meeting later that day of its Anesthetic and Analgesic Drug Products Advisory Committee ("AADPAC" or "Committee"). *Id.* ¶ 64; *see* FDA Memo. The SAC claims that the memo, which recommended against approving MoxDuo, "painted a very different picture of MoxDuo's history than QRX had led investors to believe." SAC ¶ 64. Specifically, the SAC alleges, it disclosed that: (1) the FDA had previously advised QRX that

MoxDuo must satisfy the Superiority Requirement of the Combination Rule; (2) the FDA had sent QRX two No Agreement Letters prior to the Company's initiation of Study 008; (3) QRX had twice unsuccessfully appealed the June 2012 CRL; (4) MoxDuo was not found superior to morphine or oxycodone on Study 022's primary endpoint; and (5) the FDA did not find that MoxDuo offered a safety advantage over comparable doses of its components. *See Id.* ¶ 65.

The AADPAC meeting was live-streamed and available to the public. *Id.* ¶ 66. At it, the Committee concluded that MoxDuo presented no efficacy benefit and only an "uncertain safety benefit" over comparable doses of morphine and oxycodone. Stokes Decl., Ex. 23 ("AADPAC Rpt."), at 5. As to the data from Study 022, the meeting minutes state that:

> [s]everal committee members expressed concern about the many post-hoc analyses that were conducted, and described discomfort with relying on the single data point suggesting an improvement in respiratory safety without further supportive data from the other analyses. . . . Overall, members expressed a lack of confidence in the clinical relevance of the respiratory safety data, with one stating that the analysis was sufficient to generate a hypothesis of increased respiratory safety, but was insufficient to confirm this hypothesis.

Id. at 4–5. On this basis, the Committee voted unanimously against approving MoxDuo. *Id.* at 5; SAC ¶ 66. However, "several members expressed interest in further evaluating the potential for [MoxDuo] to improve respiratory safety as compared to single-agent opioids." AADPAC Rpt. 6.

Later that day, QRX issued a press release announcing that the "AADPAC . . . voted to recommend against approval of MoxDuo [because it] . . . found the Company did not provide sufficient evidence to warrant approval . . . at this time." SAC ¶ 67. Holaday then held an investor conference call to discuss the AADPAC's vote. *Id.* ¶ 78. In response to an investor-caller's questions about the NAL, Holaday first denied recollection and then denied receipt of any such letter. *Id.* He stated, however, that:

> there was an issue regarding statistical problems that were minor, but [QRX] asked [the FDA] to review [the] protocol for 008 before [it] began the study. They agreed that it was properly designed and meets the combination rule as applied at that time. Subsequently, prior to our expected approval in 2012, they came back with a Complete Response Letter, wherein they said that [QRX] needed to show a benefit for this product.

Id.

On April 23, 2014, when trading in QRX securities resumed, the price of QRX ADRs dropped from $3.40 to $0.42 per share—a more than 83% drop. *Id.* ¶¶ 68, 69.

10. Aftermath

On May 2, 2014, QRX issued a press release stating that Holaday had stepped down as its Managing Director and CEO. *Id.* ¶ 70. On July 9, 2014, QRX announced that the Chairman and three Directors had resigned from its Board. *Id.* ¶ 72.

On August 14, 2014, QRX issued a press release announcing that it was halting further development work on MoxDuo. *Id.* ¶ 73. The press release stated that the Company believed that the FDA would require additional Phase II and III trials, and that "given specific issues related to the design of these clinical studies, . . . the likelihood of success is now in considerable doubt." *Id.* It stated that QRX had concluded that the significant cost of such a development program was "not commercially justified given the limited residual patent life" of MoxDuo. *Id.*

E. Procedural History

On June 23, 2015, plaintiff Robert Burns Logan filed the first Complaint in this action—a putative class action on behalf of similarly situated investors. Dkt. 1. On August 24, 2015, Logan and the "Gillis Group" (consisting of plaintiffs Gillis, Bayney, and Rehmsmeyer) filed separate motions for appointment as lead plaintiffs and for approval of their respective counsel. Dkts. 13–15 (Logan), 16–18 (Gillis Group). On September 14, 2015, the Court appointed the Gillis Group as lead plaintiffs, and their counsel, the Rosen Law Firm, as class counsel. Dkt. 23.

On October 26, 2016, the Court stayed this case as to QRX, pursuant to an order by the United States Bankruptcy Court recognizing QRX's pending Australian insolvency proceeding as a "foreign main proceeding" under chapter 15 of the Bankruptcy Code. Dkt. 28.

On November 23, 2015, plaintiffs filed an Amended Class Action Complaint ("FAC"). Dkt. 38. On December 11, 2015, Holaday filed a motion to dismiss the FAC, Dkt. 39, and a memorandum of law in support, Dkt. 41. He also submitted a declaration by Peter A. Stokes, Dkt. 40, which attached full copies of certain materials cited in the FAC.

On January 4, 2016, upon leave of court, plaintiffs filed the SAC. Dkt. 44. On January 25, 2016, Holaday filed a motion to dismiss the SAC, Dkt. 45, and a memorandum of law, Dkt. 47 ("Def. Br."), in support. He also submitted a supplemental declaration by Stokes, Dkt. 46, which attached additional materials cited in the SAC. In brief, Holaday argues that plaintiffs' § 10(b) claim must be dismissed because the SAC fails to (1) identify an actionable misstatement or material omission; (2) adequately plead scienter; or (3) adequately plead loss causation regarding any statements made before June 25, 2012. He argues that plaintiffs' § 20(a) claim must be dismissed because the SAC fails to adequately allege a primary violation by QRX.

On February 8, 2016, plaintiffs filed a memorandum of law in opposition to the motion to dismiss. Dkt. 50 ("Pl. Br."). On February 16, 2016, Holaday replied. Dkt. 52 ("Def. Reply Br.").

On February 10, 2016, the Bankruptcy Court entered an order dismissing this case as to QRX. *See* Dkt. 53. It did so pursuant to the "Deed of Company Arrangement of QRX" effectuated in the Australian insolvency proceeding, which brought that proceeding to a close and expunged all shareholder claims existing as of May 22, 2015. *See id.*

II. Applicable Legal Standards

A. Standard for Resolving the Motion to Dismiss

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead "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 will only have "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). A complaint is properly dismissed where, as a matter of law, "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558. Although the court must accept as true all well-pled factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor, *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014), that tenet "is inapplicable to legal conclusions," *Iqbal*, 556 U.S. at 678.

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321–23 (2007).

First, a complaint alleging securities fraud must meet the requirements of Federal Rule of Civil Procedure 9(b). *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *ATSI*, 493 F.3d at 99.

Second, such a complaint must comply with the pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u–4(b). *See ECA*, 553 F.3d at 196. In particular, where a plaintiff's claims depend upon allegations that the defendant has made an untrue statement of material fact or that the defendant omitted a material fact necessary to make a statement not misleading, the plaintiff "shall specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1). Thus, in order to plead a claim of securities fraud, plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). In addition, the plaintiff "shall, with respect to each act or omission . . . 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).

B. Elements of Plaintiffs' Claims

Plaintiffs assert claims under §§ 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. SAC ¶¶ 98–112.

Section 10(b) of the Exchange Act makes it unlawful to "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." 15 U.S.C. § 78j(b). The SEC's implementing rule, Rule 10b–5, provides that it is unlawful "[t]o 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 light of the circumstances under which they were made, not misleading." 17 C.F.R, § 240.10b–5.

To state a claim under § 10(b) of the Exchange Act, a plaintiff must adequately plead "(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." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (internal quotation marks and citation omitted).

To state a claim under § 20(a) of the Exchange Act, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *Carpenters Pension Trust Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (quoting *ATSI*, 493 F.3d at 108) (internal quotation marks omitted). If a plaintiff has not adequately alleged a primary violation, *i.e.*, a viable claim under another provision of the Exchange Act, then the § 20(a) claims must be dismissed. *See id.*

1. False or Misleading Statement or Omission

a. Objective Statements of Fact

To survive a motion to dismiss, the SAC must adequately plead "that the defendant made a statement that was 'misleading as to a material fact.'" *Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis omitted). Significantly, § 10(b) and Rule 10b–5 "do not create an affirmative duty to disclose any and all material information." *Id.* at 44; *see also Basic*, 485 U.S. at 239 n.17 ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5."). "Disclosure of . . . information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Resnick v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). An omission of information not affirmatively required to be disclosed

is, instead, actionable only when disclosure of such information is "necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)) (ellipses in original).

As for the materiality requirement, it "is satisfied when there is '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 38 (quoting *Basic*, 485 U.S. at 231–32). As the Supreme Court has explained, a lower standard—such as defining a "material fact" as any "fact which a reasonable shareholder *might* consider important"—would lead corporations to "bury the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448–49 (1976). The "materiality hurdle" is, therefore, "a meaningful pleading obstacle." *In re ProShares Trust Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013). However, because of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint "on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA*, 553 F.3d at 197 (internal quotation marks and citation omitted).

b. Statements of Opinion

Like objective statements of material fact, subjective statements of opinion can be actionable as fraud. As the Supreme Court has recently clarified, such statements of opinion can give rise to liability in two distinct ways. First, "liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief she professed' or 'the supporting fact she

supplied were untrue.'" *See Tongue v. Sanofi ("Sanofi II")*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015)). "It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d 477, 489 (S.D.N.Y. 2004). "The Second Circuit has firmly rejected this 'fraud by hindsight' approach." *Podany v. Robertson Stephens, Inc.*, 318 F. Supp. 2d 146, 156 (S.D.N.Y. 2004) (citing *Stevelman v. Alias Research, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999)).

Second, "opinions, 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." *Sanofi II*, 816 F.3d at 210 (citing *Omnicare*, 135 S. Ct. at 1332). To adequately allege that a statement of opinion was misleading through the omission of material information, "[t]he investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id.* at 209 (quoting *Omnicare*, 135 S. Ct. at 1332). As the Supreme Court has explained, "a reasonable investor, upon hearing a statement of opinion from an issuer, 'expects not just that the issuer believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at a time.'" *Id.* at 210 (quoting *Omnicare*, 135 S. Ct. at 1329). "The core inquiry," then, "is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329).

The Supreme Court has instructed that its ruling that material omissions of facts may render a statement of opinion actionable should not be given "an overly expansive reading," and that establishing liability on such a theory "is no small task for an investor" to meet. *Id*. (quoting *Omnicare*, 135 S. Ct. at 1332) (internal quotation marks omitted). "Reasonable investors understand that opinions sometimes rest on a weighing of competing facts, . . . [and do] not expect that *every* fact known to an issuer supports its opinion statement." *Id*. (quoting *Omnicare*, 135 S. Ct. at 1329) (alterations and internal quotation marks omitted). "[A] statement of opinion 'is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.'" *Id*. (quoting *Omnicare*, 135 S. Ct. at 1329).

Further, statements of opinion must be considered in the context in which they arise. "'[T]he investor takes into account the customs and practices of the relevant industry,' and . . . 'an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1330).

2. Scienter

To sustain their § 10(b) and § 20(a) claims, plaintiffs must also adequately plead scienter. *See Matrixx Initiatives*, 563 U.S. at 37; *Carpenter Pension Trust Fund*, 750 F.3d at 236. As noted, Rule 9(b) and the PSLRA require plaintiffs to "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). "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.'" *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original).

The requisite mental state is one "embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (internal quotation marks and citation omitted). Plaintiffs "may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99. However, where plaintiffs do not sufficiently allege that defendants had a motive to defraud the public, they "must produce a stronger inference of recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001).

Recklessness is "a state of mind approximating actual intent, and not merely a heightened form of negligence." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (citation and emphasis omitted). To qualify as reckless, defendants' conduct must have been "highly unreasonable" and "an extreme departure from the standards of ordinary care." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000) (quoting *Rolf v. Blyth, Eastman Dillon & Co.*, 570 F.2d 38, 47 (2d Cir. 1978)) (internal quotation marks omitted). An alleged "refusal to see the obvious, or to investigate the doubtful," must be "egregious" to be actionable. *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996) (citation omitted).

Plaintiffs can establish recklessness by adequately alleging that "defendants knew facts or had access to non-public information contradicting their public statements" and therefore "knew or should have known they were misrepresenting material facts." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76 (2d Cir. 2001) (citing *Novak*, 216 F.3d at 308). However, an inference of scienter does not follow from the mere fact of non-disclosure of relevant information. *In re Sanofi Sec. Litig. ("Sanofi I")*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015), *aff'd sub nom. Sanofi II*, 816 F.3d 199. "Instead, to adequately plead scienter, plaintiffs must also provide sufficient factual allegations to indicate that defendants understood that their public statements were

inaccurate, or were 'highly unreasonable' in failing to appreciate that possibility." *Id.* (quoting *Novak*, 216 F.3d at 308). "The key, of course, is the honest belief of the management in the truth of information issued to the public." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd sub nom. State Univ. Ret. Sys. of Ill. v. Astrazeneca PLC*, 334 F. App'x 404 (2d Cir. 2009) (summary order).

In the context of the development and approval process for a new drug, "[i]f the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public, then there is scienter." *Id.* Similarly, there is scienter "if the management is reckless in dealing with such adverse facts." *Id.* If, on the other hand, "the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud." *Id.* (collecting cases).

3. The PSLRA Safe Harbor for Forward-Looking Statements

The PSLRA amended the Exchange Act to provide a safe harbor for forward-looking statements. *See* 15 U.S.C. § 78u-5(c). Forward-looking statements are defined as those that contain, among other things, "a projection of revenues, income, [or] earnings," "plans and objectives of management for future operations," or "a statement of future economic performance." *Id.* § 78u–5(i)(1). A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). Because the statute is written in the disjunctive, statements are protected by the safe harbor if they satisfy any one of these three categories. *Id.* Materiality is defined above; the other two categories are defined as follows:

Meaningful cautionary language: To qualify as "meaningful," cautionary language "must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Id.* at 771 (quoting H.R. Conf. Rep. 104-369, at 43 (1995)). Language that is "vague" or "mere boilerplate" does not suffice. *Id.* at 772. "To determine whether cautionary language is meaningful, courts must first 'identify the allegedly undisclosed risk' and then 'read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.'" *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). Plaintiffs may establish that cautionary language is not meaningful "by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about plaintiffs' loss." *Halperin*, 295 F.3d at 359.

Actual knowledge: The scienter requirement for forward-looking statements—actual knowledge—is "stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity." *Slayton*, 604 F.3d at 773 (quoting *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 274 (3d Cir. 2009)). And, as noted, under the heightened pleading standards, which apply to both scienter requirements, plaintiffs 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).

III. Analysis

By way of overview, the SAC identifies a total of 19 statements[7] that plaintiffs claim are materially misleading. Broadly speaking, these statements can be clustered into four categories: statements addressing (1) Study 008 and QRX's ensuing NDA submission in July 2011; (2) the June 2012 CRL and QRX's later communications with the FDA; (3) QRX's commercialization strategy for MoxDuo; and (4) QRX's submission of the revised NDAs and the prospects for FDA approval.

As to these four categories, the SAC, with very few exceptions, does not claim that the challenged statements therein were themselves false. Rather, it claims that these statements were materially misleading because they did not disclose, *inter alia*, that (1) by the start of the Class Period, the FDA had determined that QRX would be required to demonstrate that MoxDuo was *superior* to *equi-analgesic* doses of its components—a more demanding showing than appeared to be required by the Combination Rule as previously applied; (2) QRX was actively, and unsuccessfully, challenging the FDA's decision to thus apply the Combination Rule; and (3) each of the setbacks that QRX endured in its quest for FDA approval during the Class Period had resulted from its inability to satisfy the Superiority Requirement.[8]

For the reasons that follow, the Court holds that the statements in the first of the four categories—*i.e.*, those relating to Study 008 and QRX's initial NDA application—are not actionable primarily because plaintiffs have not adequately pled that, at the early point in the

[7] Many "statements" challenged in the SAC consist of multi-paragraph excerpts from press releases. For purposes of this analysis, where such paragraphs include multiple representations, the Court addresses each representation as a discrete "statement."

[8] The SAC alleges a number of other omissions, but these are clearly immaterial, as discussed below. The three omissions highlighted here represent plaintiffs' most substantial grievances.

chronology when they were made, the FDA had adopted and articulated its eventual position as to how the Superiority Requirement would apply to MoxDuo. And the other omissions the SAC identifies as to these challenged statements were immaterial and did not render them misleading. Finally, some statements in this category are protected by the PSLRA's safe harbor provision for forward-looking statements.

The statements in the latter three categories were almost all made after the FDA's June 2012 CRL had indisputably informed defendants of the FDA's position as to the Superiority Requirement. However, the Court holds, with one arguable exception, these statements were not made materially misleading by virtue of the omissions upon which plaintiffs seize, including, most centrally, the nondisclosure of the FDA's new Superiority Requirement. That is because, given QRX's other disclosures and the information available to investors, the disclosure of that requirement and the other information plaintiffs fault defendants for not disclosing was not necessary to make QRX's challenged statements non-misleading. Particularly significant, QRX timely revealed: first, that the FDA had declined to approve QRX's original NDA, which included the full study report for Study 008, as inadequate; second, that the FDA had specifically requested additional information from Study 022, which, as QRX publicly explained, was designed to demonstrate MoxDuo's superiority over equi-analgesic doses of morphine and oxycodone; and third, that the Company was submitting further information, at the FDA's invitation, to support approval of MoxDuo. In light of these and other disclosures, which left the public well aware that QRX was trying to clear an FDA hurdle by demonstrating superiority to each of its component drugs, the nuances as to how the agency was proposing to apply the Combination Rule to MoxDuo were not material.

The Court separately holds that many statements in these categories are either immaterial puffery and/or protected by the PSLRA's safe harbor provision for forward-looking statements. Finally, the Court holds that, even if one or more challenged statements were materially misleading, none is actionable because the SAC does not adequately plead scienter. That is, it does not allege that, in failing to disclose the FDA's application of the Combination Rule, defendants either had a motive and opportunity to commit fraud or were reckless in making those statements.

A. Were the Challenged Statements False or Misleading?

1. Statements Regarding Study 008 and the Initial NDA Submission

The first category of statements the SAC challenges consists of five concerning the results of Study 008 and QRX's initial NDA submission. *See* SAC ¶¶ 30, 32, 34, 36, 38. Specifically:

- In a December 6, 2010 press release, which announced the completion of QRX's third Phase 3 clinical trial (Study 009), QRX stated:

  > In April 2010, the company released results from a "combination rule" pivotal study (008) comparing the efficacy and safety profiles of MoxDuo IR against component doses of morphine and oxycodone alone for the management of moderate to severe post-operative pain following bunionectomy surgery. MoxDuo IR not only demonstrated a statistically superior analgesic effect compared to component doses of morphine (p=0.02) and oxycodone (p=0.02) but, also, a favourable side effect profile despite delivering twice the opioid dose of its individual components. This trial met both primary and secondary endpoints.

  Id. ¶ 30. It further stated that, with the successful completion of Study 009, "the company believes it has met the basic requirements for clinical data to enable NDA filing for MoxDuo IR as targeted for the first half of CY2011." *Id.*

- In press releases issued on January 24 and January 27, 2011, the Company made similar statements. *See id.* ¶¶ 32, 34.

- In press releases issued on July 22 and August 25, 2011, QRX reported updates as to the status of its NDA filing. Specifically, it announced that (1) in July 2011, "[c]onsistent with the [CFR] and as agreed with the FDA," QRX had "initiated the NDA review process by filing its completed CMC module"; and (2) in August 2011, it had completed its NDA submission. *Id.* ¶ 38; *see also id.* ¶ 36. The press releases quoted Holaday as stating that such milestones reflected the "significant progress [QRX was making] toward commercialising MoxDuo," *id.* ¶ 36, and that QRX was "look[ing] forward to the regulatory approval process that may enable product sales in 2012," *id.* ¶ 38.

The SAC alleges that these statements were misleading because they did not disclose that in the June 19, 2009 No Agreement Letter, the FDA "had rejected the protocols for Study 008 . . . and had specifically required that QRX demonstrate superiority in safety or efficacy for MoxDuo at comparable doses to Morphine and Oxycodone." *Id.* ¶ 31; *see also id.* ¶¶ 33, 35, 37, 39. The obvious implication of the NAL, plaintiffs argue, was that Study 008—which did not compare MoxDuo to equi-analgesic doses of morphine and oxycodone—was "categorically insufficient" to satisfy the Combination Rule. *Id.* ¶ 31. Rather, Study 022 was the "only study [in the development program] that could possibly satisfy the superiority requirement." *Id.* ¶¶ 31, 33, 37. And, because the study's full results had not been included in the NDA, plaintiffs urge, it was misleading for defendants to state that QRX had met the basic requirements to enable NDA filing and was making progress toward obtaining FDA approval. *See id*. ¶¶ 31, 33, 35, 37, 39.

These statements are not actionable, for several reasons.

First, and most significant, plaintiffs' core premise—that the FDA had stated in the NAL that, to satisfy the Combination Rule, QRX was required to fulfill the Superiority Requirement—is belied by the text of the letter itself. The NAL says nothing of the kind.

Plaintiffs rely solely on the FDA's statement in the NAL that "[i]t is incumbent on you [QRX] to find a patient population that requires the additional benefit you anticipate from your proposed formulation and demonstrate superiority of the combination over the individual

components in an adequate and well-controlled study." *Id.* ¶ 20. Plaintiffs treat that sentence, which was found underlined on a copy of the NAL kept in Holaday's personal files, as a "smoking gun." Pl. Br. 5. Implicit in it, they argue, was a directive that, to satisfy the Combination Rule, QRX was required to show that MoxDuo was superior to its components at *equi-analgesic* doses (something that Study 008 was not designed to test[9]), as opposed to the *actual* doses used in the combination (something that Study 008 was designed to test, and ultimately did show[10]). *See* Pl. Br. 7, 16, 19.

But that construction does not follow. And the surrounding statements in the NAL refute it. First, the quoted language was taken from the FDA's response to a different question altogether: whether SPID24 (*i.e.*, measuring efficacy after 24 hours), rather than SPID48 (*i.e.*, measuring efficacy after 48 hours) was an appropriate primary endpoint for Study 008. *See* NAL, at 1. The FDA's response read, in pertinent part, as follows:

> No, the SPID24 is not acceptable as a primary endpoint for this trial. . . . It is incumbent on you to find a patient population that requires the additional benefit that you anticipate from your proposed formulation and demonstrate superiority of the combination over the individual components in an adequate and well-controlled study. If you cannot demonstrate a difference in treatment response beyond 24 hours, the question becomes whether there is any need for the combination.

Id. at 1–2. Read in context, it is clear that the deficiency which the FDA was addressing—and its stated basis for declining to enter into an SPA for Study 008—was *not* that the study did not

[9] As noted, Study 008 compared the efficacy and safety of MoxDuo (12 mg morphine/8 mg oxycodone) to component, rather than equi-analgesic, doses of morphine and oxycodone. That is, it compared MoxDuo with morphine (12 mg) and oxycodone (8 mg), rather than morphine (24 mg) and oxycodone (16 mg).

[10] *See* FDA Memo, at 11 (noting that the FDA review team "found that Study 008 did demonstrate that Moxduo was superior to each of the components").

compare MoxDuo to equi-analgesic doses of morphine and oxycodone. Rather, the FDA was highlighting a separate problem—one that QRX solved before submitting the NDA: that the FDA did not approve of QRX's proposed 24-hour endpoint.[11]

Moreover, the balance of the NAL, fairly read, *refutes* plaintiffs' view that it articulated the Superiority Requirement as the FDA later set it out. In responding to Question 4, the FDA stated that if MoxDuo were found superior to each of its components on the primary endpoint for Study 008, "the Combination Rule would be satisfied." *Id.* at 3. Critically, the FDA did not state there that only the first prong of the Combination Rule would be satisfied—the position it later adopted. *See* FDA Memo, at 11–12. Rather, it indicated that the Combination Rule would be satisfied in its entirety. Because subjects in the comparison arms of Study 008 received only half the amount of opioid administered to subjects receiving MoxDuo, this statement—far from articulating a Superiority Requirement—is inconsistent with it.

The one document on which plaintiffs rely, therefore, refutes their claim that the FDA notified QRX in the NAL that, to satisfy the Combination Rule, it would be required to meet the Superiority Requirement. This claim is thus not entitled to the usual presumption of truth applicable on a motion to dismiss. *See Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 147 (2d Cir. 2011) ("[W]here a conclusory allegation in the complaint is contradicted by a document attached to the complaint, the document controls and the allegation is not accepted as true."); *Fort Worth Emp'rs Ret. Fund*, 615 F. Supp. 2d at 221 (rejecting plaintiffs' claim that the FDA disclosed risk to defendants because it was based on a "mischaracteriz[ation of] a publicly available letter from the FDA" to defendants); *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d

[11] In the August 27, 2009 No Agreement Letter, the FDA confirmed that it approved of QRX's revised primary endpoint of SPID48. Stokes Decl., Ex. 18, at 1–2.

434, 449 (S.D.N.Y. 2006) (rejecting plaintiffs' characterization of defendant's statement where "[g]iven the full context of the December 1 Release, and the complete transcript of the December 2 conference call provided in the Amended Complaint, plaintiffs' interpretation of the statement is not reasonable, even when viewed in the light most favorable to the plaintiffs"). And, the SAC does not plead any specific facts that support an inference that the FDA had adopted, much less alerted QRX to, this construction of the Combination Rule at any other point before issuing the June 2012 CRL, or that defendants had any reason to anticipate such a construction.[12] Plaintiffs' claims premised on defendants' failure to disclose the Superiority Requirement, or the FDA's purported view that Study 008 could not satisfy it, therefore, necessarily fail as to all statements made before the June 2012 CRL. *See Novak*, 216 F.3d at 309 ("Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them.").

[12] Plaintiffs claim that the FDA Memo disclosed that "since 2004, the FDA had told QRX that in order to satisfy the Combination Rule, QRX must demonstrate that MoxDuo is superior to equivalent doses of morphine and oxycodone alone." SAC ¶ 4; *see also id.* ¶¶ 3, 17. But the FDA Memo says no such thing. Rather, with regard to QRX's pre-NAL communications with the FDA, it states only that: (1) "[a]t the outset of the clinical development program, [QRX] made it clear that the rationale behind developing [MoxDuo] . . . was that the individual components were expected to act synergistically for efficacy"; (2) "[d]uring the January 2004 Pre-IND meeting, [QRX] affirmed that synergy referred to a more than additive effect, i.e., the combination is better than the sum of the parts"; and (3) "[t]he [FDA] went on to say that reduced doses of opioid in combination cannot be assumed to be of clinical benefit alone." FDA Memo, at 9–10. The first two of these statements reflect positions that QRX had presented to the FDA, not vice versa. And the FDA's assertion that "reduced doses of opioid in combination cannot be assumed to be of clinical benefit alone" is not a directive to QRX to demonstrate the superiority of MoxDuo to equi-analgesic doses of its components. *See Corban v. Sarepta Therapeutics, Inc.*, No. 14 Civ. 10201 (IT), 2015 WL 1505693, at *9 (D. Mass. Mar. 31, 2015) (complaint's recitation of vague comment from FDA meeting could not support allegation that FDA had expressed more specific concerns, such that challenged statements were misleading).

Second, to the extent the SAC challenges defendants' failure to disclose in these pre-June 2012 statements either the issuance of the NAL itself or its contents (reporting the FDA's decision not to enter into an SPA with QRX and identifying deficiencies in the protocols for Study 008), those omissions are inactionable as well. *See In re EDAP TMS S.A. Sec. Litig.*, No. 14 Civ. 6069 (LGS), 2015 WL 5326166, at *12 (S.D.N.Y. Sept. 14, 2015) ("Defendants had no duty to disclose the content of the Major Deficiency Letter or [to] trim back their opinions as to the efficacy of the drug." (internal quotation marks and citation omitted)). It is well established that there is no affirmative duty to disclose the substance of interim feedback received from the FDA during the pendency of a drug application.[13] Rather, such feedback must be disclosed only where its omission would render another statement materially misleading. *See Matrixx Initiatives*, 563 U.S. at 44 (where there is no affirmative duty to disclose information, omission is actionable only when disclosure is "necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading'") (quoting 17 C.F.R. § 240.10b-5(b)). That is not the case here: An SPA is an optional preliminary step that is not required for FDA approval; the SAC does not allege that defendants had ever represented that QRX had obtained, or would likely obtain, an SPA; and the SAC does not allege that any issue raised in the NAL was unresolved by the time Study 008 was completed—indeed, the FDA review team

[13] *See, e.g.*, *Sanofi I*, 87 F. Supp. 3d at 534 ("The law did not impose an affirmative duty to disclose the FDA's interim feedback just because it would be of interest to investors.") (citing *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002)); *Vallabhaneni v. Endocyte, Inc.*, No. 114 Civ. 1048 (TWP), 2016 WL 51260, at *12 (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.").

ultimately found that Study 008 met its primary endpoint. The omitted facts relating to the NAL were thus both immaterial and unnecessary to make the challenged statements not misleading.[14]

Third, the PSLRA safe harbor shields defendants' statements that QRX believed it had "met the basic requirements for clinical data to enable NDA filing . . . for the first half of CY2011," SAC ¶ 30, and was "look[ing] forward to the regulatory approval process that may enable product sales in 2012," *id.* ¶ 38.[15] These statements are classically forward-looking, as they address what defendants expected to occur in the future. *See, e.g.*, *Kovtun v. VIVUS, Inc.*, No. 10 Civ. 4957 (PJH), 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012) ("Projections

[14] *See In re MELA Scis., Inc. Sec. Litig.*, No. 10 Civ. 8774 (VB), 2012 WL 4466604, at *14 (S.D.N.Y. Sept. 19, 2012) ("[W]here the FDA eventually approved MelaFind at least in part based on the results of the clinical trial . . . and defendants never guaranteed FDA approval, defendants had no obligation to disclose the purported flaws in the trial."); *Fort Worth Emp'rs Ret. Fund*, 615 F. Supp. 2d at 231 (no duty to disclose that study design did not reflect FDA's preferences where there was no evidence that FDA would delay approval for that reason).

[15] This latter statement is also an inactionable "expression[] of puffery and corporate optimism." *Rombach*, 355 F.3d at 174; *see, e.g.*, *Vallabhaneni*, 2016 WL 51260, at *15 ("Courts frequently consider loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker that no reasonable investor could find them important to the total mix of information available to be immaterial as a matter of law." (internal quotation marks and citation omitted)); *In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 509 (S.D.N.Y. 2009) ("[C]ourts have identified declaration[s] of intention, hope, or projections of future earnings as the hallmarks of inactionable puffery."); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 964 (D. Md. 1995) ("Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable."). The same is true for Holaday's characterization of QRX's initiation and filing of the NDA as "milestone[s]" that reflected the "significant progress" the Company was making toward FDA approval. SAC ¶¶ 36, 38; *see In re EDAP*, 2015 WL 5326166, at *10 (defendants' characterization of the FDA approval process as "on track" was "inactionable puffery and corporate optimism"); *In re S1 Corp. Sec. Litig.*, 173 F. Supp. 2d 1334, 1356 (N.D. Ga. 2001) (company's assertions that it had achieved financial "growth milestones" "constitute[d] vague puffing and immaterial corporate optimism"). These statements are too "broad and nebulous as to not provide any specific or concrete guarantee on which a reasonable investor could have relied." *Lopez v. CTPartners Executive Search Inc.*, No. 15 Civ. 1476 (PAE), 2016 WL 1276457, at *10 (S.D.N.Y. Mar. 29, 2016). They are, therefore, immaterial. *See ECA*, 553 F.3d at 206.

about the likelihood of FDA approval are forward-looking statements."); *Sanofi I*, 87 F. Supp. 3d at 535. Accordingly, they are not actionable if they fall within any of the three disjunctive categories established by the PSLRA safe harbor. *See* 15 U.S.C. § 78u–5(c). Here, they are covered by the third: The SAC does not adequately plead that these statements were "made with actual knowledge . . . that [they were] false or misleading." 15 U.S.C. § 78u-5(c)(1)(B); *Slayton*, 604 F.3d at 766. It alleges only that Holaday "had actual knowledge of the misrepresentations and/or omissions of material facts . . . *or acted with reckless disregard for the truth* in that [he] failed to ascertain and disclose such facts, even though such facts were available to [him]." SAC ¶ 102. That conclusory statement does not remove these statements from the reach of the safe harbor. *See Sanofi I*, 87 F. Supp. 3d at 538 (safe harbor applied where complaint "allege[d] only that defendants were aware of the FDA's concerns and therefore 'knew *or* were severely reckless in disregarding' the misleading nature of their statements") (emphasis in original).

2. Statements Regarding the June 2012 CRL and Ensuing FDA Feedback

The second category of challenged statements consists of nine pertaining to the June 2012 CRL and QRX's ensuing dialogue with the FDA. *See* SAC ¶¶ 40, 42, 44, 46, 48, 50, 52, 54, 58. These fall into three sets: (1) defendants' characterization of the FDA's feedback; (2) defendants' purported reactions to the CRL and the FDA's feedback; and (3) QRX's statement regarding its position on the Superiority Requirement.

a. Defendants' Characterization of the FDA's Feedback

On June 27, 2012, QRX issued a press release announcing that it had received a CRL declining to approve the NDA. *Id.* ¶ 40. The Company stated that it was "presently considering its response to the requests for additional information with regard to the safety and effectiveness of MoxDuo and ha[d] been granted a meeting with the FDA to clarify the steps required for

approval." *Id.* QRX thereafter made a number of statements to the effect that, at post-submission review meetings, the FDA had "clarified to [the] Company . . . the steps required for approval," *id.* ¶ 42; *see also id.* ¶¶ 48, 50, and had specifically requested additional data and analyses from Study 022, *see id*. ¶¶ 42, 54.

Plaintiffs claim that it was misleading for QRX to represent only that the FDA had requested "additional information" regarding "the safety and effectiveness of MoxDuo" and the "data filed as part of the NDA." *Id.* ¶ 41. They argue that QRX should have also disclosed that the FDA had stated that QRX must provide—and had not yet provided—evidence that MoxDuo was superior to its components at comparable doses. *Id.* ¶¶ 41, 43.

This argument is unavailing. To begin with, QRX's statements that it had received the CRL, that it had been granted a meeting with the FDA, and that the FDA had requested additional information regarding Study 022, are all accurate statements of objective historical facts. They are not at all misleading.[16]

That QRX did not disclose the FDA's new application of the Combination Rule—requiring combinations of drugs from the same pharmacological class to meet the Superiority Requirement—did not make these statements misleading. With or without knowledge of the agency's gloss on an existing known requirement, these factual statements were truthful and free of slant. On this point, Judge Briccetti's analysis of a comparable development in *In re MELA*, 2012 WL 4466604, is instructive. There, the drug company MELA received a "non-approval"

[16] *See In re EDAP*, 2015 WL 5326166, at *9–10 (statements regarding evolving status of company's application were "not actionable to the extent they merely recite[d] historical fact"); *In re MELA*, 2012 WL 4466604, at *12 (statement that FDA granted company expedited review was inactionable as recitation of fact); *Fort Worth Emp'rs Ret. Fund*, 615 F. Supp. 2d at 230 (statements about FDA's acceptance of application for review were inactionable recitations of fact).

letter from the FDA on March 19, 2010, stating that the ultimate user market for its experimental drug MelaFind would be limited to dermatologists, as opposed to all physicians, as MELA had sought. *See id.* at *11. MELA did not publicly disclose this feedback. *See id.* However, it: "(1) repeatedly acknowledged 'the [premarket approval application was] not approvable;' (2) informed investors of MELA's belief that it '[could] address all of the agency's outstanding questions in a timely manner and [would] work diligently to do so;' and (3) repeatedly stated MELA's belief that 'MelaFind can be a valuable tool to help dermatologists detect melanoma.'" *Id.* at *11 n.4. In light of those disclosures, Judge Briccetti held, MELA's omission did not make its statements materially misleading. *Id.* Significantly, MELA's post-March 19, 2010 disclosures no longer "expressed optimism that MelaFind would be suited for use by primary care physicians." *Id.* And, given "MELA's candor regarding the FDA's March 19 letter and the non-approvability of MelaFind, defendants' stated belief that MelaFind would still be a valuable tool for dermatologists correct[ed] any misunderstanding that may have resulted from defendants' earlier projections of the user market." *Id.*

Similarly, here, QRX accurately disclosed the fact of non-approval—in this case, of QRX's NDA. *See* SAC ¶¶ 40, 44, 48. And it had already announced that the NDA included the full results from Study 008, which had met both its primary and secondary endpoints. *See id.* ¶¶ 30, 32, 38. These statements, coupled with the Company's disclosure that it planned to respond to the FDA's request for more information regarding MoxDuo's "safety and effectiveness," and that the FDA had requested additional data and analyses for Study 022, allayed any misunderstanding that may have resulted from defendants' pre-CRL expressed views that the Study 008 results could alone support FDA approval. QRX's public statements would not have misled a reasonable investor to believe that, to gain approval, "QRX would only be

required to show that MoxDuo was safe and effective." Pl. Br. 1. Such an investor would have understood that more was needed to satisfy the Combination Rule.

This Court's analysis in *Sanofi I* points to the same result. There, plaintiffs challenged Sanofi's failure to disclose reservations the FDA had repeatedly expressed about a drug trial's single-blind methodology, and the FDA's admonition that, were Sanofi to use that methodology, it would need to show a heightened "treatment effect" to secure approval. 87 F. Supp. 3d at 538–39. In a decision affirmed by the Second Circuit, this Court held that, for two reasons, investors were sufficiently apprised that the FDA might require a heightened showing. First, the public, through FDA regulations and guidance, was already on notice that the FDA preferred a double-blind methodology. *Id.* at 539–40. And second, Sanofi had disclosed that it had used a single-blind study. *Id.* at 540. Sanofi's failure to disclose that the FDA had explicitly stated that its less favored methodology would require Sanofi to make a heightened showing did not, in this context, make its statements misleading to a reasonable investor. *Id.* at 540–41.

Similarly, here, QRX's disclosure of the CRL, and the fact that Study 008 had met its endpoints, put investors on notice that fulfilling the facial requirements of the Combination Rule was not alone enough to secure FDA approval. Indeed, QRX went further. While it did not report the FDA's conceptual vision of the Combination Rule, QRX disclosed that the FDA was particularly interested in "Study 022[,] which evaluated oxygen desaturation levels in patients receiving MOXDUO compared to those administered morphine or oxycodone alone *at equi-analgesic doses*." SAC ¶ 42 (emphasis added). This implicitly alerted investors that the FDA viewed a comparison to equi-analgesic doses—a methodology beyond that required by the Combination Rule on its face—as necessary for approval. For these reasons, that QRX did not explicitly report the FDA's articulation of the Superiority Requirement did not make its

statements misleading. "Rather, the statements served to 'accurately inform rather than mislead prospective [investors],' and the pleadings give the Court no basis on which to infer they were made in bad faith." *Sanofi I*, 87 F. Supp. 3d at 537 (quoting *McMahan v. Wherehouse Ent., Inc.*, 900 F.2d 576, 579 (2d Cir. 1990)) (internal citation omitted).[17]

b. Defendants' Purported Reactions to the CRL and the FDA's Feedback

The SAC separately challenges defendants' optimistic statements at various points in the FDA review process, beginning with the CRL. It faults QRX's statement that it was: (1) "surprise[d]" by the FDA's decision to issue the CRL, SAC ¶ 48; (2) "encouraged" by the feedback it later received from the FDA, including that its "Combination Rule Study (Study 008) satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the MOXDUO NDA," *id.* ¶ 42; *see also id.* ¶¶ 44, 46, 48; and (3) "confident that MOXDUO [would] receive approval," *id.* ¶ 48; *see also id.* ¶ 42 (reporting QRX's statement that it "believe[d] that the review of additional data and subsequent refiling of the NDA could result in a positive decision from the FDA by mid-2013").

The SAC alleges that these statements were misleading because they did not reveal: (1) that the FDA had rejected the protocols for Study 008 in the NAL; (2) that the June 2012 CRL had explained as the basis for the rejection that QRX had not satisfied the Combination Rule; and (3) as to those statements made after QRX's appeals to the ODEII and OND, that QRX had

[17] *See also Corban*, 2015 WL 1505693, at *8 (where defendants informed public that the FDA had requested additional information related to a study, they were "under no duty, at that time, to delve into the FDA's specific concerns over the sufficiency of [the] potential NDA application, at least absent their making of statements that would contradict such concerns"); *Johnson v. Pozen Inc.*, No. 07 Civ. 599 (WWD), 2009 WL 426235, at *19 (M.D.N.C. Feb. 19, 2009) (while defendants "certainly [could] have provided more details when discussing the *in vitro* studies . . . there is no requirement to use any particular words as long as the words [used] are accurate and not misleading").

unsuccessfully appealed the CRL. *See id.* ¶¶ 43, 47, 49. Concretely, plaintiffs posit that the CRL could not have taken QRX by "surprise" because, at the time it submitted the NDA, QRX knew about the Superiority Requirement and that the only study with the potential to satisfy it, Study 022, was not yet complete. Pl. Br. 16. Plaintiffs further claim that QRX could not later have been "encouraged" by the FDA's feedback or "confident" that MoxDuo would receive approval, because QRX (1) disagreed with the FDA's conclusion that, to obtain approval, QRX needed to satisfy the Superiority Requirement; and (2) knew that the FDA had found that the subset of data from Study 022 that was included in the initial NDA had not met that requirement. *See id.* at 17; SAC ¶ 49. Finally, plaintiffs argue, it was misleading to refer to Study 008 as a "Combination [R]ule study," because Study 022 was the "*only* study that was designed and capable of satisfying the superiority component of the combination rule." Pl. Br. 20.

All of the challenged statements in this sub-category are statements of opinion: Rather than addressing existing objective facts, they express QRX's views, either as to the FDA's actions and communications, or as to MoxDuo's prospects. Accordingly, they are actionable only if they (1) were not honestly believed when made; (2) were supported by untrue facts; or (3) omit to mention facts that conflict with what a reasonable investor would take away from the statements themselves. *Sanofi II*, 816 F.3d at 210 (citing *Omnicare*, 135 S. Ct. at 1327–32). For several reasons, the SAC does not plead facts sufficient to meet these standards.

First, the SAC contains no factual allegations which suggest that defendants did not honestly believe the statements they were making—with regard to either their surprise at the CRL or optimism about MoxDuo's prospects—at the time they were made. As discussed, the SAC does not plead facts indicating that, before receiving the CRL, defendants had any reason to expect that the successful results of Study 008 would not be enough to support FDA approval, or

that the FDA would construe the Combination Rule to impose a Superiority Requirement on drugs which, like MoxDuo, combine two drugs from the same pharmacological family. There is thus no basis, on the pleadings, to doubt that defendants were genuinely surprised by these developments.

The SAC similarly supplies no factual basis to conclude that defendants were not actually encouraged by the FDA's interim feedback or confident that MoxDuo would eventually be approved. To the contrary, defendants' continued investment of time and resources into developing MoxDuo—even after receiving the CRL—suggests that they honestly believed approval was still attainable. Also supporting this inference are the pled facts that the FDA had (1) found that the Study 008 results satisfied the first half of the Combination Rule; and (2) expressed keen interest in Study 022, which was designed to satisfy the second half of that rule, as construed by the FDA. Under these circumstances, and "absent concretely pled facts to this effect, the inference that . . . plaintiffs ask the Court to draw—that [QRX] . . . continued to fund [Study 022 and the NDA review process] while secretly believing that FDA approval was unlikely[or] impossible . . . is implausible and conjectural." *Sanofi I*, 87 F. Supp. 3d at 531–32 (citing *City of Edinburgh Council v. Pfizer, Inc*., 754 F.3d 159, 170 (3d Cir. 2014) ("[T]he initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure."); *Davidoff v. Farina*, No. 04 Civ. 7617 (NRB), 2005 WL 2030501, at *11 n.19 (S.D.N.Y. Aug. 22, 2005) ("[I]t would have made no economic sense for defendants to invest literally billions of dollars in a venture that they knew would fail.")).

Second, the SAC does not allege that any facts which defendants cited in stating these views were themselves false. Plaintiffs do not dispute that (1) the FDA issued a CRL declining to approve MoxDuo, while anticipating further study and review; (2) Study 008 showed that MoxDuo satisfied the Combination Rule's efficacy requirement—*i.e.*, that each component makes a contribution to the claimed effects; (3) no unexpected safety issues arose in any of the studies that QRX submitted as part of the initial NDA; and (4) the FDA had requested additional data from Study 022. Indeed, the FDA Memo itself expressly confirms the first, second, and fourth of these propositions. *See* FDA Memo, at 5–7.

Third, the SAC does not plausibly allege that defendants' statements, as reasonably interpreted, were in conflict with facts not volunteered. To be sure, the FDA had articulated a heightened standard—the Superiority Requirement—that MoxDuo would be required to satisfy. However, the FDA had also suggested that that requirement could be satisfied by positive results from Study 022. Indeed, the FDA review team specifically requested that QRX provide additional data from Study 022, and both the ODEII and OND—the arms of the FDA to whom QRX successively, but unsuccessfully, appealed the new standard—"recognized the importance of [those] analyses and strongly recommended that [QRX] submit them as part of [its] response to the CRL." FDA Memo, at 7, 21. And, QRX proceeded to collect and analyze additional data from Study 022 after its initial NDA submission, "believ[ing] that [the data] . . . demonstrated that Moxduo is safer than comparable amounts of both morphine and oxycodone." *Id.* at 22. Based on these pleadings and cognizable materials, defendants' expressions of confidence as to FDA approval, far from being impeached by facts then known to them, "fairly align[ed] with the

information in [their] possession at the time."[18] *Omnicare*, 135 S. Ct. at 1329. As the Second Circuit has explained, "[t]here can be no conflict inferred from a statement of optimism consistent with the FDA's instructions as to the treatment results necessary for approval." *Sanofi II*, 816 F.3d at 211 (FDA's interim feedback did not conflict with defendants' optimistic statements about FDA approval where FDA had indicated that deficiency could be overcome by large treatment effect, which defendants were, in fact, able to produce); *see also id.* at 212 ("Thus, fatal to Plaintiffs' case is the absence of any serious conflict between the FDA's interim, albeit repeated, concerns about methodology and Defendants' optimism about FDA approval.").

The other alleged omissions also do not conflict with defendants' statements of opinion. The NAL's rejection of the proposed protocols for Study 008 is *consistent* with defendants' claimed surprise about the CRL, because, before submitting the NDA, QRX had modified those protocols to incorporate the FDA's feedback. Nor does it impugn defendants' later expressions of optimism about FDA approval, because, by the time those statements were made, the FDA had found that Study 008's results satisfied at least the first prong of the Combination Rule. Accordingly, although they could not alone secure FDA approval, the results from Study 008 lent support to QRX's application.[19]

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[18] Because the FDA, ODEII, and OND had not yet opined on the Superiority Requirement when QRX received the CRL, their positions as to this requirement and QRX's inability to fulfill it could not possibly conflict with QRX's statement that the CRL had taken it by surprise.

[19] It was also not misleading for QRX to continue to refer to Study 008 as a "Combination Rule study." The Company had adopted that shorthand by December 6, 2010, when—based on the FDA's representation in the NAL, and prior to the agency's articulation of the Superiority Requirement—it projected that that study could satisfy the full Combination Rule. *See* SAC ¶ 30 (12/6/10 press release referring to Study 008 as a "'combination rule' pivotal study"). Although the June 2012 CRL indicated that Study 008 would not satisfy the second prong of the rule, it did not undercut the study's ability to satisfy the first. And indeed, the FDA review team found that Study 008 *did* fulfill the first half of the Combination Rule, a finding it presumably conveyed to QRX at its post-submission review meetings. *See* FDA Memo, at 11. Moreover, given QRX's

The SAC also faults QRX for, later, not reporting specifically that the FDA review team had found that the Study 022 data had not demonstrated a safety benefit for MoxDuo. *See* SAC ¶¶ 43, 45, 47, 49. But, significantly, the Study 022 data submitted with the initial NDA was incomplete. *See* FDA Memo, at 13. And QRX subsequently collected and analyzed additional data from that study. *See id.* at 20–21. Because the FDA's negative determination was based only on the first subset of data, it did not foreclose future approval, and thus did not conflict with defendants' optimistic statements.

Finally, QRX's statement that it was "confident that MOXDUO will receive approval," SAC ¶ 48, is, separately, shielded by the PSLRA safe harbor. It is forward-looking and the SAC does not allege that it was "made with actual knowledge . . . that [it was] false or misleading." 15 U.S.C. § 78u-5(c)(1)(B).[20]

c. QRX's Statement Regarding its Position on the Superiority Requirement

The last statement in this category that the SAC challenges is QRX's account of the position it had taken regarding the Superiority Requirement when it met with the FDA. In a January 24, 2013 press release, QRX stated that "[d]uring the Company's most recent review

candid disclosure that the FDA had declined to approve the initial NDA, which included the full study report for Study 008, a reasonable investor would not be misled by QRX's shorthand reference to Study 008 as a "Combination Rule study" into believing that that study's results could alone secure FDA approval. And QRX's statement that the FDA had requested additional information from Study 022 further alerted investors that data from that study would be relevant to the FDA's ultimate decision.

[20] QRX's statement that it "believes that the review of additional data and subsequent refiling of the NDA could result in a positive decision from the FDA by mid-2013," SAC ¶ 42, is similarly protected by the PSLRA safe harbor. And, "[i]t is well recognized that statements that include such cautionary language are usually 'not the stuff of which securities fraud claims are made.'" *Hillson Partners Ltd. P'ship v. Adage, Inc.*, 42 F.3d 204, 218 (4th Cir. 1994) (quoting *Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986)).

meeting, QRxPharma presented a position that although the Combination Rule does not require a demonstration of greater efficacy or safety, the data submitted to date indicate a safety advantage for MoxDuo compared to either morphine or oxycodone alone." SAC ¶ 52. The SAC claims that this statement was misleading because QRX did not also disclose that the FDA review team had already adopted (and the ODEII and OND had affirmed) the construction of the Combination Rule that QRX opposed, under which QRX was required to show that MoxDuo had superior efficacy or safety to equi-analgesic doses of its components. *Id.* ¶ 53. Absent this context, plaintiffs argue, QRX's account of the position it had advocated was misleading. Pl. Br. 17, 20.[21]

Of all the statements recited in the SAC, this one is the most vulnerable to attack. The statement can be read in two ways. First, it can be read to mean that although the Combination Rule definitively does not require a showing of superior safety or efficacy, QRX (gratuitously) presented the position to the FDA that the Study 022 data would satisfy such a requirement. So understood, this statement is problematic, because, of course, the FDA *had* by then interpreted the Combination Rule to require such a showing. The second—and more benign—reading is that QRX had told the FDA that while it did not *believe* that the Combination Rule should be

[21] Plaintiffs claim the same statement was misleading for a separate reason: because QRX did not also disclose that the FDA had rejected the protocols for Study 008 and determined that the Study 022 results submitted with the initial NDA did not prove that MoxDuo had a superior safety profile to morphine or oxycodone. SAC ¶ 53. Substantially for the reasons reviewed above, the Court rejects that theory of liability. QRX's statement of its own view as to how the Combination Rule should apply to combinations of same-class drugs was not made misleading by its failure to report the FDA's statements about these studies. In any event, by the time QRX made the challenged statement, it had publicly disclosed both that (1) the FDA had declined to approve the initial NDA, which included the incomplete data from Study 022; and (2) QRX had agreed to submit additional data from that same study. *See id.* ¶¶ 40, 42; Stokes Decl., Ex. 6, at 2. Therefore, a reasonable investor would not be misled to believe that the FDA had found that the initial subset of Study 022 data had shown a safety advantage for MoxDuo.

construed to require a showing of superiority, Study 022's data would satisfy that requirement. Both parties appear to adopt the latter construction of this statement in their briefs. The Court agrees that, although the statement is no model of clarity, that is the more natural reading.

Read as such, this statement is literally accurate: As plaintiffs do not dispute, QRX presented these positions to the FDA; indeed, the FDA Memo states that these arguments supplied the bases for the Company's appeals. *See* FDA Memo, at 6–7. However, in the Court's judgment, this statement, unlike the others the SAC challenges, was made misleading by QRX's failure to reveal that, by the time of QRX's public statement, the FDA had committed to the very construction of the Combination Rule against which QRX stated that it was advocating. To be sure, by announcing that it had taken a position on the Superiority Requirement, QRX conveyed to investors the *possibility* that the FDA might adopt the opposite view. *See* Def. Br. 9.[22] But nothing in QRX's statement implied, let alone revealed, that the FDA, ODEII, and OND had *already done so*. If anything, a reasonable investor could draw the opposite conclusion: that the agency was still in the process of deciding how to apply the Combination Rule in the novel context presented by MoxDuo. Disclosure of the determination the agency had reached as to the Superiority Requirement was, therefore, "necessary to make" QRX's account of its earlier meeting with the FDA "not misleading." *Matrixx Initiatives*, 563 U.S. at 44 (internal quotation marks and citation omitted).

[22] A contemporaneous disclosure by QRX reinforced that possibility. QRX stated that, at its meeting, "[t]he FDA . . . voiced for the first time that no precedent exists for their review of combination products where two drugs in the same category are combined (e.g. morphine and oxycodone as 'opioids')." Stokes Decl., Ex. 12, at 1; *id.*, Ex. 13, at 1. This statement alerted investors to the possibility that the FDA was considering how to apply the Combination Rule in this novel context, and, therefore, to the possibility that it would demand a more stringent showing for such a combination product, as it had done in the related context of over-the-counter drugs that combine two ingredients from the same category. *See* FDA Memo, at 5, 12.

In order for a misleading statement to be actionable under § 10(b), however, it must be *materially* misleading. *See id.* at 38 ("To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a statement that was '*misleading* as to a *material* fact.'" (quoting *Basic*, 485 U.S. at 238) (emphasis in *Matrixx*)). The issue, then, is whether notice at that time that the FDA had firmly adopted the Superiority Requirement would have "significantly altered the total mix of information made available" to investors. *Id.* (internal quotation marks and citation omitted).

This presents a close question. On the one hand, QRX's disclosures did alert the market to the possibility that the agency would adopt such a construction and apply it to MoxDuo. And, for the reasons stated, QRX's contemporaneous statement that it believed the Study 022 data would satisfy any such requirement was neither false nor misleading. A reasonable investor therefore, arguably, might not have perceived the fact that the FDA had adopted a heightened standard as a significant blow to MoxDuo's prospects for approval. On the other hand, to the extent that an investor may have been skeptical whether QRX could demonstrate MoxDuo's superiority to equi-analgesic doses of its components, news of the heightened standard would have been material, because it would have curtailed the likelihood of approval.

On the pleadings, the Court is not equipped to assess whether reasonable investors would have assumed that MoxDuo would be unlikely or unable to satisfy the heightened standard. The SAC supplies no factual allegations on this point. The Court, therefore, will assume *arguendo* that QRX's statement in the January 24, 2013 press release was materially misleading by virtue of its omission of the FDA's determinate decision to adopt the Superiority Requirement. *See ECA*, 553 F.3d at 197 ("[A] complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance."

(internal quotation marks and citation omitted)). The Court need not, however, resolve this issue, because—as explained below—the SAC fails to adequately plead a separate element: that defendants made this statement with scienter—the "intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319. For that separate reason, this statement is, also, not actionable.

3. Statements Regarding QRX's Commercialization Strategy for MoxDuo

The third category of statements challenged in the SAC consists of two representations by Holaday regarding QRX's commercialization strategy for MoxDuo. *See* SAC ¶¶ 38, 50. First, in an August 25, 2011 press release, Holaday stated that, since QRX's initial public offering, "it ha[d] strived towards an aggressive commercialisation strategy for MoxDuo—one that streamlined development timelines." *Id.* ¶ 38. Second, in a January 16, 2013 press release, he stated that "[t]hroughout the last several years of FDA interactions on MOXDUO, we have followed the Agency's recommendations in designing and implementing clinical trials that demonstrated its effectiveness and safety in acute pain patients." *Id.* ¶ 50.

Plaintiffs argue that the first statement was misleading because it did not disclose that the FDA (in the NAL) had rejected the protocols for Study 008, and that QRX therefore was "not following a streamlined and efficient timeline." *Id.* ¶ 39. They claim the second was misleading because it did not disclose that (1) QRX had gone forward with Study 008 despite the NAL; (2) the CRL had stated that QRX had not satisfied the Combination Rule; and (3) QRX had twice unsuccessfully challenged the FDA's imposition of the Superiority Requirement. *Id.* ¶ 51.

Fairly read, these statements are not actionable. The first merely generally recites QRX's *intention* to pursue an "aggressive commercialisation strategy." *Id.* ¶ 38. As such, it is inactionable as immaterial puffery. "[C]ourts have identified declaration[s] of intention . . . as [a] hallmark[] of inactionable puffery" where they are too broad and nebulous to be material. *In*

re Moody's, 599 F. Supp. 2d at 509.[23] Moreover, the statement is backward-looking—*i.e.*, it describes a broad goal of QRX's up to that point in time. A reasonable investor could not "rely on such a [retrospective] statement as a guarantee of some concrete fact or outcome." *City of Pontiac Policemen's & Firemen's Ret. Sys.*, 752 F.3d at 185. Nor is this an instance where a company so departed from a statement of intention as to make it misleading. *See, e.g.*, *Novak*, 216 F.3d at 315 (defendants' statement that "the inventory situation was 'in good shape' or 'under control'" not puffery where "they allegedly knew that the contrary was true"). On the contrary, the facts pled—including QRX's three attempts to obtain an SPA for Study 008—are consistent with an attempt by the Company, even if ultimately unsuccessful, to pursue an efficient development timeline. In that context, Holaday's failure to mention the Company's receipt of the NAL did not render his broad description of QRX's intended course misleading.

The second statement recites in part that QRX followed the FDA's recommendations in designing and implementing clinical trials. As such, it is neither false nor materially misleading. The cognizable facts show that QRX *did* abide by the FDA's suggestions as to the steps necessary to obtain its approval. First, before submitting the initial NDA, QRX corrected the primary deficiency identified in the NAL as to the protocols for Study 008. *See* Stokes Decl., Ex. 18, at 1–2. With QRX having heeded the FDA's recommendation, the NAL's critique of QRX's earlier deficiency was immaterial by the time of the challenged statement; there was thus no duty to disclose it. Second, after receiving the CRL, QRX complied with the FDA's requests

[23] *Accord In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 283 (3d Cir. 2010) ("[S]tatements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism . . . constitute no more than 'puffery' and are understood by reasonable investors as such." (internal citation omitted)); *see, e.g.*, *In re Royal Cruises Ltd. Secs. Litig.*, 11 Civ. 22955, 2013 WL 3295951, at *12 (S.D. Fla. Apr. 19, 2013) (optimistic statement of "intention to compete successfully" was immaterial puffery).

to provide additional data and analyses for Study 022. *See* FDA Memo, at 20. The fact that the Company was simultaneously challenging the FDA's application of the Combination Rule to the new context presented by MoxDuo, and its determination that QRX had not satisfied that heightened standard, is not inconsistent with Holaday's statement that QRX had tried to heed the FDA's directives, including as to the Superiority Requirement. The nondisclosure of QRX's dissent from the FDA's adoption of that requirement did not make Holaday's statement misleading.

To the extent that the second statement reflects the objective fact that the FDA had recommended that QRX conduct studies demonstrating MoxDuo's effectiveness and safety, it is also inactionable. It was an accurate, if unhelpfully general, characterization of the FDA's recommendation. Holaday certainly could have been more specific—*i.e.*, by stating that the FDA had recommended that QRX implement studies demonstrating the superior efficacy or safety of MoxDuo to equi-analgesic doses of its components. But his failure to be more concrete as to the level of the required showing did not make his general statement materially misleading. Moreover, given the FDA's refusal to approve the initial NDA, which included the full report for Study 008, a reasonable investor would have understood that, whatever the precise showing that was needed, merely demonstrating that MoxDuo was safe and effective (as Study 008 evidently had) was not enough to secure FDA approval.

4. Statements Regarding QRX's Resubmission of the NDA and the Prospects for FDA Approval

Finally, the SAC faults three statements regarding QRX's submission of the revised NDAs and the prospects for FDA approval on the basis of those submissions.

a. Statements Regarding the February 2013 Resubmission

As to the February 2013 resubmission, the SAC challenges Holaday's statements in a February 28, 2013 press release that (1) "as recommended by the FDA," QRX included in its revised NDA a comprehensive analysis of Study 022, which "demonstrated the lower risks of respiratory depression for MOXDUO when compared to either morphine or oxycodone"; and (2) QRX, therefore, "believe[d] the revised documents effectively address[ed] the FDA's request for additional data." SAC ¶ 54. The SAC also challenges Holaday's statement in an April 29, 2013 press release that, "[a]ssuming approval, [QRX] anticipate[d] product launch . . . before the end of [the] calendar year." *Id.* ¶ 56.

Plaintiffs argue that these statements were misleading because they did not disclose that (1) the FDA had rejected the protocols for Study 008 in the NAL; (2) the CRL stated that QRX had not satisfied the Combination Rule because it failed to show superiority; and (3) QRX had twice unsuccessfully appealed the CRL. *Id.* ¶¶ 55, 57. They argue that these statements were also misleading because the FDA review team ultimately concluded that MoxDuo was no safer than morphine or oxycodone. *Id.* ¶ 55.

To the extent that the first statement reflects objective facts—to wit, that the FDA had recommended that QRX submit additional analyses from Study 022, and that QRX had done so—it is neither false nor misleading. As noted, the FDA did, in fact, request additional data and analyses from Study 022. And the FDA Memo reflects that QRX included such data in its resubmission. *See* FDA Memo, at 22.

To the extent the first and second statements reflect defendants' subjective beliefs that (1) Study 022 demonstrated lower risks of respiratory depression for MoxDuo compared to its two component drugs; and (2) QRX had "effectively address[ed] the FDA's request for additional

data," these are statements of opinion. *Sanofi I*, 87 F. Supp. 3d at 543 ("Courts have repeatedly held 'publicly stated interpretations of the results of various clinical studies' to be 'opinions' because '[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.'" (quoting *In re Sanofi–Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 & n.20 (S.D.N.Y. 2011)) (collecting cases). As such, they are actionable only if they (1) were not honestly believed when made; (2) are supported by untrue facts; or (3) omit facts that conflict with what a reasonable investor would take from the statements themselves. *Sanofi II*, 816 F.3d at 210 (citing *Omnicare*, 135 S. Ct. at 1327–32).

The SAC does not come close to pleading facts on which to conclude that defendants disbelieved their own statements. There is no reason to infer that defendants anticipated either that (1) errors in the Study 022 oxygen desaturation data QRX submitted would preclude FDA review of that data; or (2) the FDA would conclude that the remaining Study 022 data did not reflect a "meaningful safety advantage" for MoxDuo. FDA Memo, at 8. And the surrounding circumstances undermine any such inference: The substantial time, money, and effort that QRX continued to invest in Study 022, its appeals to the ODEII and OND, and its revision of the NDA are hard to square with the premise that defendants believed the data from that study was incapable of meeting the FDA's demands. *See Sanofi I*, 87 F. Supp. 3d at 544 ("Defendants' substantial investment of money and personnel in the Lemtrada clinical trials over a several-year period is hard to square with the premise that defendants understood that the study design was fatally flawed or that the results made Lemtrada dead on arrival."). From these facts, the more plausible inference is that defendants sincerely believed that the Study 022 data was valid and demonstrated lower risks of respiratory depression for MoxDuo than its components, and therefore satisfied the Superiority Requirement.

The allegedly omitted facts also did not conflict with what a reasonable investor would have taken away from the statements themselves.[24] The NAL's content is unrelated to the Study 022 results or whether they had the potential to satisfy the FDA's request for additional data. *See Johnson*, 2009 WL 426235, at *22 ("[F]actual statements . . . [that] have nothing to do with genotoxicity . . . cannot create any duty to disclose additional information about preclinical genotoxicity testing."). And the FDA's determination that QRX's *initial* NDA submission (which included only partial results from Study 022) had not satisfied the Superiority Requirement did not undermine defendants' later opinion that the *new* analyses from Study 022 (which had not been included in the initial application) would do so.

Finally, Holaday's projection that "[a]ssuming approval, [QRX] anticipate[s] product launch . . . before the end of [the] calendar year," SAC ¶ 56, is also inactionable. No reasonable investor would interpret it as a "guarantee," or even as suggesting a high likelihood, of FDA approval. It instead assumed such approval *arguendo*. *See In re Medimmune*, 873 F. Supp. at 964 ("Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable. Especially is that so where, as here, virtually every reference made by any Defendant to FDA approval was hedged by variations of the proviso 'if and when approved by FDA.'"). This statement is further shielded by the PSLRA safe harbor: It is forward-looking, and the SAC does not allege that it was made with "actual knowledge . . . that [it was] false or misleading." 15 U.S.C. § 78u-5(c)(1)(B).

[24] The third basis on which a stated opinion can be actionable also does not apply: Because defendants did not recite any objective facts to support their stated opinions, those statements cannot be found actionable on the ground that they were based on untrue factual claims.

b. Statements Regarding the November 2013 Resubmission

As to the November 2013 resubmission, plaintiffs challenge the following statement from QRX's November 26, 2013 press release, entitled *QRxPharma Refiles MoxDuo New Drug Application with the FDA*:

> QRxPharma completed an audit of the more than 30 million data points for oxygen desaturation from Study 022. We believe these data demonstrate a significant respiratory safety advantage for MOXDUO over equi-analgesic doses of morphine or oxycodone. . . .
>
> We expect the FDA to schedule an Advisory Committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following this submission, projected for late May, 2014.

SAC ¶ 60. Plaintiffs also challenge Holaday's statement in the same press release that QRX was "confident that [the] refiled NDA [would] confirm the validity of the data defining the product's respiratory safety advantages and . . . hopeful that the FDA [would] view them favourably in their consideration of the benefits of [MoxDuo]." *Id.*

As to these utterances, plaintiffs do not appear to challenge QRX's factual assertion about its audit of the Study 022 data.[25] Rather, they focus on defendants' stated opinions about what that data showed and whether it could support FDA approval. These statements, too, they argue, were misleading for failure to disclose that (1) the FDA's NAL had rejected the protocols for Study 008; (2) the CRL stated that QRX had not satisfied the Combination Rule because it failed to show superiority; and (3) QRX had twice unsuccessfully appealed the CRL. *Id.* ¶ 61. They further fault the statements for failure "to disclose that Study 022 had failed its primary endpoint, showing MoxDuo to be less safe than morphine or oxycodone with respect to oxygen

[25] In any event, any challenge to this statement of objective fact would fail, as the pleadings do not support an inference that it was false or materially misleading.

desaturation, and that the alleged positive results provided by QRX were based on a post hoc analysis that is of little to no value to the FDA." *Id.*

These challenges fail for several reasons. QRX's statement regarding its "expectation about the FDA's timing is soft and immaterial on its face as a matter of law." *Fort Worth Emp'rs Ret. Fund*, 615 F. Supp. 2d at 230 (holding immaterial statement that "FDA is expected to respond to [defendants'] NDA in late July 2007").[26] Holaday's statement that he was "hopeful" that the FDA would view the revised NDA favorably is immaterial puffery. *See id.* ("mere[] expressions of 'hope' that the FDA would approve [defendants' drug]" were "soft" and "immaterial on their face as a matter of law"); *In re Medimmune*, 873 F. Supp. 964.[27] These statements are not actionable.

So, too, as to the other two statements of opinion. These were that (1) QRX believed the data from Study 022 showed a respiratory safety advantage for MoxDuo compared to equi-analgesic doses of morphine or oxycodone; and (2) Holaday was confident that the refiled NDA would confirm the validity of the data defining the product's respiratory safety advantages. The SAC does not impugn these statements, as it neither pleads contrary facts nor recites facts from which it can be inferred that defendants disbelieved what they were saying. As discussed, the most plausible inference from the facts pled is that defendants genuinely believed that the results from Study 022 demonstrated a safety advantage sufficient to support approval of MoxDuo. And the information which the SAC faults defendants for omitting does not contradict these

[26] Moreover, the AADPAC did, in fact, hold its meeting in April 2014, even earlier than QRX had projected. SAC ¶ 66. Therefore, there was absolutely nothing misleading about this statement.

[27] This statement is also protected by the PSLRA safe harbor because it is forward-looking and the SAC does not allege that it was made with "actual knowledge . . . that [it was] false or misleading." 15 U.S.C. § 78u-5(c)(1)(B).

statements. As noted in connection with the February 2013 resubmission, the undisclosed facts—regarding the NAL, the statement in the CRL construing the Combination Rule to impose a Superiority Requirement on MoxDuo, and the confirmation of that requirement by the ODEII and OND on QRX's internal appeal—did not contradict defendants' stated views. The FDA's in-progress assessments of QRX's studies or its application of the Combination Rule do not make fictive or incredible defendants' statements of optimism about eventual approval.

Plaintiffs also fault QRX for failing to disclose that Study 022 was found not to have met its primary endpoint. SAC ¶ 61. But QRX did not state otherwise. In the statements that plaintiffs challenge, defendants more modestly stated their belief that the study's results showed *certain* respiratory safety advantages for MoxDuo. *See id.* ¶ 60. That the study was found not to meet a particular endpoint—oxygen desaturation rate, defined as the number of desaturations less than 90% divided by the time oxygen saturation was monitored in the treatment period, *see* FDA Memo, at 23—is not inconsistent with these statements. It does not exclude the possibility that MoxDuo demonstrated *other* respiratory advantages over morphine and oxycodone.[28]

Indeed, notwithstanding this shortcoming, the FDA's Memo recited facts that would have lent support to defendants' stated opinion. It stated that MoxDuo had been found "numerically better than both comparators" as to three pre-specified respiratory safety exploratory endpoints: (1) percentage of subjects with oxygen saturation less than 90%; (2) lowest oxygen saturation per subject; and (3) change in respiratory rate from baseline to end of study. *Id*. at 24. And the post

[28] Notably, the AADPAC's assessment that MoxDuo did not satisfy the Superior Requirement did not cite the primary-endpoint failing on which plaintiffs focus. *See Kovtun*, 2012 WL 4477647, at *10 (undisclosed adverse effects revealed by study data did not render defendants' positive statements regarding safety and efficacy misleading where the FDA did not cite those effects as a basis for disapproval).

hoc analyses submitted showed additional respiratory benefits for MoxDuo consistent with QRX's statements: (1) a lower difference in percentage of subjects who had a desaturation; and (2) a smaller percentage of desaturations below 80% in subjects older than 60. *Id.* at 25.

Whether these results reflected a "meaningful" respiratory safety advantage for MoxDuo was a matter on which reasonable minds could differ. Defendants' view that they did was not inconsistent with the data known to them. *See In re Galileo Corp. Shareholders Litig.*, 127 F. Supp. 2d 251, 265–66 (D. Mass. 2001) (rejecting fraud claim challenging subjective "judgments, as to which reasonable persons might disagree").[29] Defendants are "not liable merely because [they] 'kn[ew], but fail[ed] to disclose, some fact cutting the other way.'" *Sanofi II*, 816 F.3d at 214 (quoting *Omnicare*, 135 S. Ct. at 1329). That the FDA and AADPAC ultimately disagreed with defendants' interpretation of the data does not render their subjective assessments false or misleading. *See id.* ("Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data.").[30]

[29] Indeed, the facts that (1) one AADPAC committee member believed the Study 022 oxygen desaturation data supported a "hypothesis of increased respiratory safety"; and (2) "several members expressed interest in further evaluating the potential for this product to improve respiratory safety as compared to single-agent opioids," AADPAC Rpt. 5–6, suggest that defendants' interpretation was neither baseless nor unreasonable.

[30] *See also Davison v. Ventrus Biosciences, Inc.*, No. 13 Civ. 3119 (RMB), 2014 WL 1805242, at *8 (S.D.N.Y. May 5, 2014) ("[W]here, as here, 'a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement.'" (quoting *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013)), *reconsideration denied*, 2014 WL 4460346 (S.D.N.Y. July 2, 2014); *In re Sanofi–Aventis Sec. Litig.*, 774 F. Supp. 2d at 567 ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [defendants] chose to interpret the results."); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04 Civ. 1030 (RPM), 2005 WL 4161977, at *11 (D. Colo. Oct. 20, 2005) ("Interpretations of scientific data are not misleading where the interpretation finds reasonable support in the data.").

Plaintiffs also fault QRX for not disclosing that some data on which it relied in stating that the evidence reflected a significant safety advantage for MoxDuo came from "post hoc" analyses, *i.e.*, analyses not part of Study 022's design. SAC ¶ 61. This challenge, it appears, is based on the fact that "[s]everal [AADPAC] committee members expressed concern about the many post-hoc analyses that were conducted." AADPAC Rpt. 4. At the outset, however, plaintiffs are wrong to imply that *all* positive results on which QRX relied in claiming a safety advantage for MoxDuo fell into the "post-hoc" category. Rather, as noted, MoxDuo also proved superior to its two component drugs on three *pre-specified* respiratory safety exploratory endpoints. *See* FDA Memo, at 24. In any event, in articulating a perceived safety advantage, QRX did not state that it was relying exclusively on findings within the design ambit of Study 022. Nor did it mispresent any data on which it relied. And, the SAC pleads no facts indicating that it was "irrational or unreasonable" to employ modes of analysis exogenous to the study's original design. *Sanofi II*, 816 F.3d at 214. QRX was thus within its bounds to rely on results generated by those analyses in reporting on the study.[31] "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial."

[31] *See, e.g.*, *Kleinman*, 706 F.3d at 154–55 (defendant had no duty to disclose full methodology for calculating data results, even where methodology deviated from original study design and was not the most rigorous available, as long as methodology was reasonable); *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711 (PKC), 2013 WL 2399869, at *14–15 (S.D.N.Y. 2013) (allegations that defendants had not engaged in best practices in design and conduct of study were insufficient to establish material misstatements or omissions); *In re Medimmune*, 873 F. Supp. at 966–67 (because "[m]edical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results," a defendant does not act with reckless disregard to validity of study results simply because a regulatory authority expresses preference for a different methodology); *Padnes v. Scios Nova Inc.*, No. 95 Civ. 1693 (MHP), 1996 WL 539711, at * 5 (N.D. Cal. Sept. 18, 1996) (securities laws do not require "that companies who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data").

In re MELA, 2012 WL 4466604, at *13 (defendants' purported failure to disclose "unsound statistical analysis" and other design flaws in clinical trial did not support securities fraud claim); *cf. In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 879 (9th Cir. 2012) ("Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results.").

Finally, to the extent the SAC challenges Holaday's statement that QRX was "confident that [the] refiled NDA [would] confirm the validity of the data defining the product's respiratory safety advantages," SAC ¶ 60, that statement is shielded by the PSLRA safe harbor. It is forward-looking and the SAC does not adequately allege that it was "made with actual knowledge . . . that [it was] false or misleading." 15 U.S.C. § 78u-5(c)(1)(B).

B. Scienter

Recapping the foregoing discussion, the Court has assumed *arguendo* that just one of QRX's statements (in the January 24, 2013 press release) was materially misleading. The Court has held that all other statements that plaintiffs challenge were not.

As to any challenged statement, to state a claim, plaintiffs would still need to adequately plead scienter. The SAC categorically fails to do so. It does not plausibly allege (or come close to plausibly alleging) that any challenged statement was made with the "intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319.

A plaintiff may plead scienter either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Kalnit*, 264 F.3d at 138 (internal quotations marks and citation omitted).

As to motive, the SAC does not allege that defendants had a motive to defraud the public. And the facts pled do not reveal any incentive to inflate QRX's stock price by pretending, during the period of FDA review, that approval of MoxDuo was likely when (as plaintiffs posit) defendants knew the Superiority Requirement effectively foreclosed approval: There is no allegation that Holaday, or any other high-level official of the Company, sold QRX stock during the Class Period. *See* Pl. Br. 23–24.[32] And there is no allegation that any such person, or the Company itself, otherwise stood to benefit from the inflation in QRX's stock price that was allegedly brought about by defendants' falsely optimistic statements.

Indeed, as pled, the scheme that the SAC imagines lacks a coherent rational objective. The SAC alleges that QRX, with Holaday at its helm, knew for years, long even before the CRL, that MoxDuo would face a heightened proof hurdle (in the form of the Superiority Requirement) which it could not clear. Nevertheless, it alleges, QRX continued to invest substantial time and resources in clinical studies and NDA submissions that it knew were doomed to fail, all the while misrepresenting to the public that approval was likely. That QRX's principals harbored this state of mind is implausible. *See, e.g.*, *Cozzarelli v. Inspire Pharms., Inc*., 549 F.3d 618, 627 (4th Cir. 2008) ("It is improbable that [Defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure."); *Johnson*, 2009 WL 426235, at *25

[32] *See Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) ("The fact that the other defendants did not sell their shares during the relevant class period undermines plaintiffs' claim that defendants delayed notifying the public 'so that they could sell their stock at a huge profit.'" (internal citation omitted)); *Turner v. MagicJack VocalTec, Ltd.*, No. 13 Civ. 0448 (RWS), 2014 WL 406917, at *11 (S.D.N.Y. Feb. 3, 2014) (lack of suspicious stock sales "rebuts an inference of scienter"); *In re eSpeed, Inc. Secs. Litig.*, 457 F. Supp. 2d 266, 289 (S.D.N.Y. 2006) (fact that neither chairman nor CFO sold stock during class period undermined motive allegations against those defendants); *In re N. Telecom Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders . . . is inconsistent with an intent to defraud shareholders.").

(inference of scienter undermined where defendants pointed out that "if they had known in 2006 that the FDA would require an additional study beyond [that included in their application], [they] would have conducted the study then, therefore speeding up FDA approval").

Moreover, by its nature, the purported scheme could not have continued in perpetuity. Defendants would have known that their efforts to prop up QRX stock by feigning likely FDA approval would be revealed, in relatively short order, upon the FDA's rejection of the MoxDuo NDA. *See In re GeoPharma*, 411 F. Supp. 2d at 446–47 ("[T]he tenuous plausibility of the alleged scheme substantially weakene[d] the overall strength of plaintiffs' scienter allegations[,] . . . [where defendants] must have . . . realized that . . . [the public would] quickly uncover the scheme."). For the defendants, including Holaday, this development would likely have generated recriminations—or worse. Absent allegations of insider sales during the period of stock-price inflation, there would be no concrete benefit to defendants to justify these risks. Courts regularly "refuse to infer scienter . . . when confronted with [such] illogical allegations." *In re GeoPharma*, 411 F. Supp. 2d at 446 n.83 (collecting cases).[33] The SAC therefore wholly fails to allege a coherent motive for the fraud scheme it posits.

Where, as here, a motive to defraud is not adequately pled, a plaintiff "must produce a stronger inference of recklessness." *Kalnit*, 264 F.3d at 143. Recklessness is generally

[33] *See, e.g.*, *Davidoff*, 2005 WL 2030501, at *11 n.19 (rejecting scienter allegations as inadequately pled because "it would have made no economic sense for defendants to invest literally billions of dollars in a venture that they knew would fail"); *In re J.P. Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 621–22 (S.D.N.Y. 2005) (motive not adequately pled where "[p]laintiffs [ ] fail[ed] to allege facts explaining why, if it was aware of Enron's problems, [defendant] would have continued to lend Enron billions of dollars"); *Hampshire Equity Partners II, L.P. v. Teradyne, Inc.*, No. 04 Civ. 3318 (LAP), 2005 WL 736217, at *3 (S.D.N.Y. Mar. 30, 2005) (fundamentally illogical and contradictory scienter allegations fail as a matter of law); *In re Merrill Lynch & Co. Inc., Research Reports Sec. Litig.*, 272 F. Supp. 2d 243, 263 (S.D.N.Y. 2003) (complaint's allegations "affirmatively refute[d] scienter" because they contradicted assumption that defendants would act in their own economic self-interest).

established by a showing that "defendants knew facts or had access to non-public information contradicting their public statements," and therefore "knew or should have known they were misrepresenting material facts." *Scholastic*, 252 F.3d at 76 (citing *Novak*, 216 F.3d at 308). The Second Circuit has also noted that "[a]n egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness." *Chill*, 101 F.3d at 269 (internal quotation marks and citations omitted).

Here, plaintiffs base their claim of recklessness on the allegation that defendants knowingly or recklessly disregarded the ostensible falsity of their various statements regarding MoxDuo and its prospects for FDA approval. *See* SAC ¶ 102; Pl. Br. 21–23. Specifically as to Holaday, the remaining defendant, plaintiffs add the allegations that, as a key officer of QRX, he knew that MoxDuo was integral to QRX's success and that, as a person privy to the NAL and the CRL, he was aware, as of June 2012, that the FDA had adopted (and articulated) the Superiority Requirement. *See* SAC ¶¶ 74–76; Pl. Br. 21–22.

Largely for the same reasons that the various statements at issue have been held neither false nor misleading, the facts pled in the SAC fall far short of pleading recklessness, and, thus, scienter. As explained earlier, the SAC does *not* adequately plead that defendants (including Holaday) knew or had access to non-public information contradicting their public statements. Thus, no inference of recklessness fairly arises. The following briefly recaps why, analyzing first the statements made before June 2012 and then those after, with a focus on the January 24, 2013 press release that the Court has identified as QRX's one potentially actionable statement.

As to the statements made before QRX received the June 2012 CRL, the SAC does not adequately plead that defendants knew or should have known that the FDA would later impose a Superiority Requirement on MoxDuo that Study 008 could not satisfy. As noted, the SAC's

claim that the NAL articulated such a requirement is refuted by the NAL's text, which indicated that if QRX met the primary endpoint for that trial, it would satisfy the Combination Rule. On the facts pled, defendants had no other reason to anticipate that the FDA would later interpret the Combination Rule to impose this heightened standard. In this context, there is no basis to plausibly infer that defendants knew or recklessly disregarded that the initial NDA was destined to fail.[34] The alternative inference—that defendants believed that the study results could support FDA approval—is the only plausible one.

As to the statements made after QRX received the June 2012 CRL, the SAC again does not allege facts that are "strong circumstantial evidence of conscious misbehavior or recklessness." *Kalnit*, 264 F.3d at 138. To be sure, the June 2012 CRL (and the ODEII's and OND's decisions affirming it) surely alerted defendants that QRX would have to prove MoxDuo's superiority to comparable doses of its components. But that information did not *contradict* the Company's statements. QRX never thereafter represented that the FDA would *not* impose a Superiority Requirement on MoxDuo. Instead, it informed investors that it believed its

[34] *See Vallabhaneni*, 2016 WL 51260, at *20 ("Plaintiff has insufficiently pleaded that the Phase 2 study was actually fatally flawed or that the Defendants had advance knowledge that the Phase 3 study was futile from the start and Plaintiff cannot establish scienter for this reason."); *Sanofi I*, 87 F. Supp. 3d at 547 (inference of conscious recklessness was "particularly hard to sustain" where plaintiffs did not allege that defendants had access to information about Lemtrada's side-effects that was not made public); *In re MELA*, 2012 WL 4466604, at *7 ("[I]t is insufficient to claim defendants 'should have known' their representations were inaccurate prior to the receipt of the March 19 letter."); *In re SLM Corp. Sec. Litig.*, 740 F. Supp. 2d 542, 559 (S.D.N.Y. 2010) ("An allegation 'that a defendant merely ought to have known is not sufficient to allege recklessness.'") (citation omitted); *Hart v. Internet Wire, Inc.*, 145 F. Supp. 2d 360, 368 (S.D.N.Y. 2001) ("[T]o withstand a motion to dismiss[,] plaintiffs must detail specific contemporaneous data or information known to the defendants that was inconsistent with the representation in question." (internal quotation marks and citation omitted)).

study data would satisfy the agency's Combination Rule, however construed. There was nothing actionable about that statement of belief.[35]

Nor, as pled, did QRX's factual representations about the state and potential of its studies from the date of the CRL forward mislead the public, let alone to an extent that would give rise to an inference of recklessness. To the contrary, the Company accurately disclosed that the data from Study 008 would *not* alone support FDA approval: It reported that the FDA had declined to approve the initial NDA, which included the full report for Study 008, and was interested in receiving more data, specifically from Study 022. *See* SAC ¶¶ 32, 38, 40, 42, 44, 48, 54. This case is thus a far cry from those where scienter could be inferred from the fact that "defendants were consistently representing an intended or expected outcome over time even as new developments adversely effected [sic] the likelihood of that outcome." *In re MELA*, 2012 WL 4466604, at *11 n.4.

The one statement that the Court has held potentially materially misleading is one in the January 24, 2013 press release. In pertinent part, that press release implied that the standard the FDA would apply under the Combination Rule was an open question, without revealing that, by then, the FDA had firmly committed to the Superiority Requirement. *See supra*, pp. 47–51. But

[35] This case is thus easily distinguished from those that have found scienter adequately pled on the ground that defendants' public statements about their pending drug applications were directly contradicted by contrary evidence in their possession. *See, e.g.*, *In re Genta, Inc. Sec. Litig.*, No. 4 Civ. 2123 (JAG), 2005 WL 2416970, at *4–5, *7 (D.N.J. Sept. 30, 2005) (scienter pled where defendants stated that drug "did not appear to be associated with serious . . . adverse reactions," despite knowledge that drug was associated with increased toxicity and adverse reactions); *In re Regeneron*, 2005 WL 225288, at *23–24 ("key allegation" supporting claim of conscious recklessness was that defendants *knew* about problem refuting their statements as to the efficacy of the drug, "rather than being aware of the possibility of the problem"); *In re Cell Pathways, Inc. Sec. Litig.*, No. 99 Civ. 725 (RFK), 2000 WL 805221, at *7 (E.D. Pa. June 20, 2000) (scienter pled where defendants stated that study was proceeding as planned despite knowledge that it was fatally flawed).

even if that statement were held actionable, the facts pled do not support an inference that defendants acted with scienter—that they were "highly unreasonable"—in failing to so disclose. *See Novak*, 216 F.3d at 308. This shortcoming in the press release must be viewed in context. While unclear and thereby misleading, the statement at issue was not false. And the press release implicitly acknowledged the possibility that the FDA would adopt a Superiority Requirement, noting that QRX had presented a contrary "position" in its most recent meeting with the FDA. SAC ¶ 52.

Significant, too, the difference between the two regulatory standards was not one which QRX, at the time of the January 24, 2013 press release, perceived as outcome-determinative. The Company's position instead was that MoxDuo could satisfy either standard, and, as noted, the SAC does not plead facts indicating that that position was not held in good faith.[36] *See Johnson*, 2009 WL 426235, at *22 ("[O]ne may plausibly infer that Defendants did not more specifically discuss the genotoxicity tests because they did not consider them to be impediments to approval.").[37]

[36] That the FDA ultimately held that QRX's data did not satisfy the Superiority Requirement does not mean that QRX's contrary view was wrong or recklessly held. "Medical researchers may well differ over . . . the interpretation of test results." *In re Medimmune*, 873 F. Supp. at 966. And "[p]eople in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129–30 (2d Cir. 1994); *see also In re Medimmune*, 873 F. Supp. at 966–67 ("Simply to aver that the Advisory Committee, based on theoretical (not to say inappropriate) statistical concerns, eventually challenged the company's opinion, is not to say that Defendants should have had knowledge of the theoretical statistical limitations on their assumptions."); *Noble*, 2005 WL 4161977, at *13 (no inference of scienter where "[e]ven [FDA Committee] members who ultimately voted against recommending approval acknowledged [drug company's] data provided some evidence of an increased survival benefit in patients with metastic breast cancer").

[37] *Compare In re MELA*, 2012 WL 4466604, at *8 (inference of scienter is diminished where challenged statements showed that "defendants intended to and did work with the FDA to timely

Under these circumstances, it is not plausible to infer that the author(s) of QRX's press release acted out of deliberation, recklessness, awareness of the release's misleading prose, or to occlude a fatal obstacle to ultimate FDA approval of MoxDuo when they failed to set out with clarity the fact that the FDA had firmly committed to the Superiority Requirement. Any such inference would be based on speculation. *See Kalnit*, 264 F.3d at 143 (defendants' recklessness could not be inferred from failure to disclose letter because "the duty to disclose the [ ] letter was not [ ] clear, especially given that the public was aware" of information that diminished the materiality of the omission); *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d at 447 ("[A] failure to disclose particular information, by itself, can only constitute recklessness if there was an *obvious* duty to disclose that information." (emphasis added)). The more—and only—plausible explanation, on the facts pled, is that the press release's inexact prose was the product of sloppiness, inattention, and/or inartful drafting.

In sum, "even if [d]efendants were less than 'transparent' with regard to the [Superiority Requirement], and even if the failure to disclose was misleading, plaintiffs still cannot establish the essential element of scienter. That is, the more compelling inference here is that [d]efendants acted innocently, or even negligently, with regard to disclosure of the [Superiority Requirement], as opposed to acting recklessly or with fraudulent intent." *Johnson*, 2009 WL 426235, at *24–25.

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address the FDA's concerns"), *and Slayton*, 604 F.3d at 777 (defendants' "prudent course of action . . . weaken[ed] rather than strengthen[ed] an inference of scienter") (internal quotation marks and citation omitted), *with In re Amylin Pharm., Inc., Sec. Litig.*, No. 01 Civ. 1455 (BTM), 2002 WL 31520051, at *5 (S.D. Cal. Oct. 10, 2002) (defendant acted recklessly when it proceeded with Phase II trials, and made statements regarding "completeness" of those trials and the likelihood of FDA approval, despite FDA's warnings that use of the methodology in question may be insufficient to support approval), *order amended on other grounds on denial of reconsideration*, 2003 WL 21500525 (S.D. Cal. May 1, 2003).

Plaintiffs separately seek to base scienter on two actions of Holaday's late in the series of events. First, they argue, scienter can be inferred from "the fact that Holaday attempted to cover up the fraud after being exposed by the FDA." Pl. Br. 22; *see also* SAC ¶ 78. They characterize Holaday as stating, on a conference call with investors on April 22, 2014, shortly after the FDA Memo was released and the penultimate day of the Class Period, that: "(i) he never received a no agreement letter, (ii) [the] FDA never said Study 008 was not properly designed, [and] (iii) [the] FDA sent QRX a letter stating that MoxDuo had met the combination rule." Pl. Br. 22; *see also* SAC ¶ 79. These statements, plaintiffs urge, were each false, and show that Holaday's earlier statements and actions had been accompanied by scienter.[38] Pl. Br. 22; SAC ¶¶ 78–79.

> The transcript of the colloquy in question reflects the following:
>
> Caller: Did you actually receive as the FDA says in its background materials a "no agreement letter" from them on 008, or did you not receive a "no agreement letter"?
>
> Holaday: You know, I don't recall a "no agreement letter", there was an issue regarding statistical problems that were minor, but we asked them to review our protocol for 008 before we began the study. They agreed that it was properly designed and meets the combination rule as applied at that time. Subsequently, prior to our expected approval in 2012, they came back with a Complete Response Letter, wherein they said that we needed to show a benefit for this product.
>
> Caller: So you're saying that Dr. Bob Rappaport is incorrect.
>
> Holaday: Yes. The actual rule states equal to or better than, even this guideline for combination for over the counter products, which was pointed out during today's meeting by the Chairman of the Committee.
>
> Caller: Now I wanna clear up the "no agreement letter". Did QRX receive a letter from the division, from Bob Rappaport, or from any of his staff, saying that they did not agree to the 008 trial?

[38] The SAC does not claim that these statements are themselves actionable. Nor could it. They were made after the FDA Memo was published. And the SAC does not allege that there was a subsequent corrective disclosure, within the Class Period, that caused QRX's stock price to drop.

> Holaday: No.
>
> Caller: So the FDA has published incorrect information in their background letter.
>
> Holaday: David. I do not know of a "no agreement letter". I do know that they had informed us in writing that we had met the combination rule at that time and that they could not further review this product until such time as they, the statistical analysis of this product, until they have decided how best to manage the combination of two drugs in the same category.
>
> Caller: I'll just ask that in a different way, so the FDA have [sic] given you a letter which you've got saying that you have met for the 008 trial the combination rule?
>
> Holaday: That's correct, and they also agreed to that in our pre-NDA meetings as well as our end of phase 2 meetings.

SAC ¶ 78.

By any measure, Holaday's responses in the exchange fell short of the level of punctiliousness and precision that an investor should expect from a CEO. Holaday had received and possessed the FDA's NAL, which marked a material development in the FDA's review of MoxDuo; plaintiffs fairly question his truthfulness in denying recollection of it. Holaday's argument that the FDA's refusal to "grant an SPA does not mean that [it] 'did not agree to the 008 trial,'" Def. Reply Br. 8, is similarly sketchy: The letter is clearly labeled, "*No Agreement* Letter." *See* NAL, at 1 (emphasis added). Although these deficient responses could alternatively be chalked up to more benign causes (*e.g.*, lack of preparation), it is plausible to infer that Holaday dissembled on these two matters on the investor call.

Context, however, is critical. As to the big picture, Holaday's statements on the investor call otherwise accurately conveyed the *substance* of QRX's pre-June 2012 CRL communications with the FDA. He represented, accurately, that the FDA had raised issues in the NAL about the statistical methodology for Study 008, while indicating that if the study were to meet its primary

endpoint it would satisfy the Combination Rule. Moreover, as to the scheme alleged in the SAC, the pre-CRL event that Holaday was, arguably, trying to conceal—that the FDA had declined to enter into an SPA for Study 008—was tangential at best. The core of the alleged scheme was that MoxDuo was (ostensibly) unable to satisfy the new regulatory standard (the Superiority Requirement) the FDA had put in place. The pre-CRL NAL, and the FDA's non-entry into an SPA, were inconsequential to that scheme.[39] If anything, it was the June 2012 CRL, not the NAL, that was the "smoking gun." It was *that letter* which contained the critical information whose concealment, the SAC alleges, made defendants' public statements misleading. And on the investor call, Holaday freely admitted that, in that letter, the FDA had changed its position, notifying QRX that it must satisfy the Superiority Requirement in order to satisfy the Combination Rule. Given Holaday's open discussion of the June 2012 CRL, his errant statements as to the NAL, even if viewed as deliberately misleading, do not supply a basis to infer, retroactively, that his and QRX's statements over the preceding two years were made with scienter.

Separately, plaintiffs seek to derive an inference of scienter from Holaday's "abrupt[] resign[ation]" from QRX in May 2014. Pl. Br. 22; SAC ¶ 77. Courts, however, have consistently held that an officer's resignation, without more, is insufficient to support a strong inference of scienter. *See, e.g.*, *Owens v. Jastrow*, 789 F.3d 529, 541 n.9 (5th Cir. 2015) (noting that district court had rejected scienter allegation on ground that company's "overall decline, rather than securities fraud, was likely the impetus for the resignations"); *In re GeoPharma*, 411 F. Supp. 2d at 451 (resignation was not, without more, probative of scienter); *In re Hertz Global*

[39] As noted, an SPA is not required for FDA approval, and defendants never suggested that QRX had entered into an SPA with the FDA.

Holdings, Inc. Secs. Litig., No. 13 Civ. 7050 (MCA), 2015 WL 4469143, at *21 (D.N.J. July 22, 2015) ("The fact of [defendant's] resignation, without more, adds nothing to Plaintiff's scienter allegations."); *C.D.T.S. v. UBS AG*, No. 12 Civ. 4924 (KBF), 2013 WL 6576031, at *7 (S.D.N.Y. Dec. 13, 2013) (no strong inference of fraud from resignation where "there are a number of other, more plausible reasons why personnel have been demoted and resigned").

The SAC, therefore, fails to allege that any statement recited therein was made with scienter. This holding alone requires dismissal of the SAC.[40]

C. Section 20(a) Claims

Plaintiffs also bring a claim against Holaday under § 20(a) of the Exchange Act in his capacity as a controlling person of QRX. SAC ¶¶ 108–12. To state a claim under § 20(a), however, plaintiffs must adequately allege "a primary violation by the controlled person." *Carpenter Pension Trust Fund*, 750 F.3d at 236 (quoting *ATSI*, 493 F.3d at 108). Because plaintiffs have not done so, their § 20(a) claim must also be dismissed. *See, e.g.*, *In re Lions Gate Entm't Corp. Sec. Litig.*, No. 14 Civ. 5197 (JGK), 2016 WL 297722, at *18 (S.D.N.Y. Jan. 22, 2016) (dismissing § 20(a) claim based on failure to adequately allege a primary violation).

CONCLUSION

For the foregoing reasons, the Court dismisses the SAC in its entirety. The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 39 and 45 and to close this case.

[40] In light of the pleading deficiencies noted, the Court has no occasion to address Holaday's alternative basis for dismissal: that the SAC does not adequately plead loss causation regarding the pre-June 2012 statements. *See* Def. Br. 25.

SO ORDERED.

Paul A. Engelmayer
United States District Judge

Dated: July 6, 2016
New York, New York