UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JONATHAN SCHAEFFER, individually and on behalf of all others similarly situated,	:	
	:	19 Civ. 4183 (VM)
Plaintiff,	:	
- against -	:	**DECISION AND ORDER**
NABRIVA THERAPEUTICS PLC, et al.,	:	
Defendants.	:	

VICTOR MARRERO, United States District Judge.

Lead Plaintiff Jonathan Schaeffer ("Plaintiff") brings this putative securities class action, on behalf of himself and all other persons similarly situated, against defendants Nabriva Therapeutics plc ("Nabriva"), Nabriva's Chief Executive Officer Ted Schroeder ("Schroeder"), Nabriva's Chief Financial Officer Gary Sender ("Sender"), and Nabriva's Chief Medical Officer Jennifer Schranz ("Schranz," and together with Schroeder and Sender, the "Individual Defendants") (collectively, "Defendants"). Plaintiff purports to represent a class consisting of all persons who purchased or otherwise acquired Nabriva common stock between January 4, 2019 through April 30, 2019, both dates inclusive (the "Class Period"). Plaintiff alleges that during the Class Period, Defendants made materially false and misleading statements in violation of Section

10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") ("Section 10(b)") and Securities and Exchange Commission ("SEC") Rule 10b-5 ("Rule 10b-5"). Plaintiff also alleges that the Individual Defendants violated Section 20(a) of the Exchange Act ("Section 20(a)"). (See "Complaint," Dkt. No. 31.)

By letter dated October 21, 2019, Defendants notified Plaintiff of their intent to seek permission to file a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)"). Defendants argue the Complaint is deficient because it fails to plead that Defendants either made misleading statements or did so with scienter. (See "Letter Motion," Dkt. No. 37.) By letter dated November 4, 2019, Plaintiff responded to the Letter Motion and argued that the Complaint is well-pled. (See "Opposition," Dkt. No. 38.) By letter dated November 18, 2019, Defendants replied to the Opposition and reiterated their intent to file a motion to dismiss. (See "Reply," Dkt. No. 39.)

The Court now construes Defendants' Letter Motion as a motion to dismiss.[1] For the reasons set forth below, the Complaint is DISMISSED without prejudice. Plaintiffs are

[1] Kapitalforeningen Lægernes Invest v. United Techs. Corp., 779 F. App'x 69, 70 (2d Cir. 2019) (Mem.) (affirming district court ruling deeming exchange of letters as motion to dismiss).

directed to show cause why the Complaint should not be dismissed with prejudice within twenty days of this Order.

I. BACKGROUND[2]

A. FACTUAL BACKGROUND

Nabriva is a biopharmaceutical company based in Ireland that seeks to develop anti-infective agents to treat serious infections. During the Class Period, Nabriva submitted only two products to the United States Food and Drug Administration ("FDA") for marketing approval. At this time, Nabriva did not generate revenues from product sales and did not expect to generate revenues unless one of its drug candidates obtained marketing approval. The product at issue in this case is CONTEPO™ (fosfomycin) ("CONTEPO"), a drug intended to treat complicated urinary tract infections ("cUTIs").

CONTEPO was first developed by Zavante Therapeutics Inc. ("Zavante"). In 2016, Zavante negotiated multiple contractual agreements with Ercros S.A. ("Ercros"), a company that manufactured CONTEPO on Zavante's behalf at a plant in Aranjuez, Spain. Under these "Ercros Agreements," Zavante was responsible for filing applications with, and

[2] Except as otherwise noted, the factual background below derives from the Complaint and the facts pleaded therein, which the Court accepts as true for the purposes of ruling on a motion to dismiss. See infra Section II.A. Except where specifically quoted, no further citation will be made to the Complaint.

seeking regulatory approvals for CONTEPO from, the FDA. Zavante's responsibilities included obtaining FDA approval of Ercros's manufacturing facilities and quality systems. Ercros was obligated to promptly notify Zavante of any FDA letters or feedback it received, as well as any information indicating CONTEPO was not manufactured in accordance with manufacturing specifications or in compliance with Current Good Manufacturing Practices ("cGMP"). Schroeder, who was then Zavante's Chief Executive Officer, allegedly negotiated this notification obligation because he understood that violations of cGMP could derail any efforts to secure FDA approval of CONTEPO.

In 2017, Zavante announced that CONTEPO had achieved statistically significant results in a clinical trial that enrolled patients with cUTIs. Nabriva acquired Zavante roughly a year later, along with the rights to CONTEPO and the contractual relationships with Ercros. Nabriva subsequently filed a New Drug Application ("NDA") with the FDA to obtain marketing approval for CONTEPO. The ensuing FDA review and Nabriva's public statements regarding the NDA's status form the basis for this action.

1. FDA Review of the CONTEPO NDA

Nabriva filed the CONTEPO NDA with the FDA in October 2018. This prompted FDA review of the NDA, which would conclude with a final decision regarding the NDA by the "PDUFA" date of April 30, 2019. Among other reasons, the FDA may refuse to approve an NDA if the "methods to be used in, and the facilities and controls used for, the manufacture . . . [of] the drug product do not comply with [cGMP] regulations." 21 C.F.R. § 314.125 (13).

After accepting Nabriva's initial NDA filing, the FDA inspected the plant where Ercros manufactured CONTEPO from December 10 through December 14, 2018. On December 14, 2018, the FDA issued a "Form 483" letter containing its inspectional observations to the Director of the Pharmaceutical Division at Ercros, who signed the Ercros Agreements in 2016. While a Form 483 is a form of interim feedback rather than a final FDA decision on an NDA, it lists "significant conditions" that may indicate a drug is being prepared in ways that do not comply with FDA regulations. The FDA discusses its Forms 483 with a company's management at the end of an inspection, and the company is then responsible for taking corrective action to address any significant conditions identified. The Form 483

in this case listed at least ten observations indicating the Aranjuez plant might not comply with cGMP:

- Drug batches of fosfomycin yielded results that were OOS [out of specifications] due to inconsistent peak integrations, and further failed to meet the required reference standard. Although Ercros tested the batches again using a different methodology, the new method did not comply with Ercros' own Standard Operating Procedures ("SOP") or with cGMP.
- A manufacturing investigation to determine why batches of fosfomycin were OOS was purportedly conducted, but the investigation lacked evidence to support the root causes of the discrepancy. Although an attempt was made to process the batches again, Ercros did not implement or document a proper Corrective and Preventive Action Plan ("CAPA").
- Impurities were identified in certain batches of fosfomycin, but an investigation to determine the root cause of the impurities was inadequate. Ercros further failed to implement or document a proper CAPA to prevent the impurities in the future.
- Ercros failed to implement a process validation plan to test intra-batch variability, and thus ensure consistency between batches of fosfomycin.
- Ercros' quality control unit failed to place batches of fosfomycin on long-term stability to ensure longevity of the drug despite multiple attempts because the batches yielded results that were OOS. Moreover, Ercros failed to validate the process for current batch sizes.
- The electronic control system used for manufacturing fosfomycin was not adequately validated to allow batches to be properly tracked and audited. Nor were there adequate written SOP to review the electronic data before batches were recorded and released.
- During production, a series of alarms were triggered that went unaddressed, and Ercros failed to provide documentation on how to address the alarms and specify what actions needed to be taken by an operator in response to the alarms.
- There were no written SOP for storage or the time allowed between collection and testing for samples used to check for contamination. Ercros' quality

control unit also failed to ensure that microorganisms used to test for contamination could be recovered from water samples after a certain specified amount of time.

- Ercros failed to clean, maintain and sanitize equipment and utensils used during the manufacturing process to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug. In fact, the FDA inspector observed visible flaws in the equipment that could alter the purity or the quality of the drug.
- Ercros failed to measure in-process checks of the manufacturing equipment to ensure they were calibrated and documented in accordance with its own SOP.

(Complaint ¶ 40.)

2. Defendants' Alleged Misrepresentations

Defendants made several statements regarding the CONTEPO NDA during the Class Period, none of which mentioned the FDA's Form 483. Plaintiff alleges that the below statements misled investors to believe the FDA would approve the CONTEPO NDA in 2019, even though the Form 483 allegedly demonstrated that approval of the NDA would be delayed beyond that year.

i. January 4, 2019 "Press Release Statements"

On January 4, 2019, Nabriva issued a press release entitled "Nabriva Therapeutics Announces Acceptance of the [NDA] for Intravenous CONTEPO™ to Treat [cUTIs] by FDA." In this press release, Schranz described the NDA submission as "another major milestone" for Nabriva and added that CONTEPO was a "first-in-class" intravenous antibiotic. The

press release claimed that the NDA submission was supported by a "robust data package" and that "the FDA stated that no filing or potential review issue were identified." (Id. at ¶ 46.)

ii. January 23, 2019 "Analyst Meeting Statements"

At a January 23, 2019 corporate analyst meeting, Schroeder said "[w]e've submitted [NDAs] for both lefamulin for community-acquired pneumonia and for CONTEPO or IV fosfomycin for [cUTIs]. . . . And the data are solid for both products, and we think that they will not only win FDA approval but that they will be [] significant additions to the antibiotic armamentarium in the United States." Schroeder added that "[w]e have an April 30 PDUFA date for CONTEPO. We will launch CONTEPO shortly after approval[.]" (Id. at ¶¶ 47-48.)

Plaintiff alleges that both the Press Release Statements and Analyst Meeting Statements "were materially false and misleading when made because they omitted to disclose that (a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, (b) the nature of the cGMP violations at the facility that manufactured CONTEPO could, and ultimately did, result in

the denial of CONTEPO's NDA, and (c) the FDA had identified a 'review issue' for the NDA based on the findings in the Form 483 letter, not the NDA packet the FDA accepted as complete." (Id. at ¶ 49.)

iii. March 12, 2019 "10-K Statements"

Nabriva published its Form 10-K for the year 2018 on March 12, 2019. Each of the Individual Defendants signed and certified the Form 10-K pursuant to the Sarbanes Oxley Act of 2002. The Form 10-K contained the following allegedly misleading statements:

> (A) The success of . . . CONTEPO will depend on a number of factors, including the following: . . . receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities . . . . If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize . . . CONTEPO;
>
> (B) Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which could delay, prevent or impair our development or commercialization efforts;
>
> (C) [R]eliance on third-party manufacturers entails additional risks, including: reliance on the third party for regulatory compliance and quality assurance; an event at one of our manufacturers or suppliers causing an unforeseen disruption of the manufacture or supply of our product candidates . . . . Third-party manufacturers may not be able to comply with [cGMP] regulations . . . . Our failure, or the failure of our third-party manufacturers, to comply with applicable

> regulations could result in sanctions being imposed on us, including . . . delays, suspension or withdrawals of approval . . . which could significantly and adversely affect supplies of our product candidates and products.
>
> (D) Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including: warning or untitled letters; refusal to approve pending applications or supplements to approved applications that we submit.

(Id. at ¶¶ 50, 52, 54, 56.) Plaintiff states that 10-K Statement (A) was materially misleading because Defendants failed to disclose that "(a) the facility where CONTEPO was manufactured had already been subject to a Form 483 letter from the FDA that identified violations of cGMP, and (b) the nature of the cGMP violations at the facility that manufactured CONTEPO *would* cause a significant delay in seeking FDA approval for CONTEPO, and *would* adversely impact Nabriva's ability to successfully commercialize CONTEPO." (Id. at ¶ 51.) 10-K Statement (B) was allegedly misleading because of the Form 483 and because "the nature of the cGMP violations at the facility that manufactured CONTEPO *would* delay, prevent or impair Nabriva's attempt to develop and commercialize CONTEPO." (Id. at ¶ 53.) 10-K Statement (C) was allegedly misleading because "(a) the facility where CONTEPO was manufactured had already been

subject to a Form 483 letter from the FDA that identified violations of cGMP, (b) the nature of the cGMP violations at the facility that manufactured CONTEPO *would* disrupt the production of CONTEPO, (c) a third-party manufacturer, Ercros, had already failed to comply with regulatory and quality assurance requirements, including cGMP, and (d) the failure to comply with cGMP and receipt of the Form 483 letter, as well as the nature of the violations themselves, *would* delay Nabriva's attempt to develop and commercialize CONTEPO." (Id. at ¶ 55.) Finally, 10-K Statement (D) was allegedly misleading because the Form 483 identified cGMP violations and "the failure to comply with cGMP and receipt of the Form 483 letter had already exposed CONTEPO's NDA to FDA refusal." (Id. at ¶ 57.)

3. The FDA's Decision Regarding the CONTEPO NDA

The FDA did not approve the CONTEPO NDA by April 30, 2019. Instead, the FDA issued a Complete Response Letter ("CRL") withholding approval based substantially on the cGMP issues originally identified in the Form 483. Nabriva issued a press release disclosing the FDA's refusal on April 30, 2019. According to the press release, "[t]he CRL request[ed] that Nabriva address issues related to facility inspections and manufacturing deficiencies at one of

Nabriva's contract manufacturers prior to the FDA approving the NDA." On this news, Nabriva's share price declined $0.82 per share, or over 27%, to close at $2.17 on May 1, 2019, on heavy trading volume.

On August 16, 2019, Nabriva announced it would resubmit the CONTEPO NDA after rectifying the cGMP violations. Because resubmission would trigger a six-month review cycle, the FDA likely would not approve CONTEPO in 2019.

B. PROCEDURAL BACKGROUND

Plaintiff Larry Enriquez filed an initial complaint in this putative class action on May 8, 2019. (See Dkt. No. 1.) After the appointment of co-lead counsel and lead plaintiff (see Dkt. No. 20), Plaintiff filed the Complaint on September 23, 2019 (see Dkt. No. 31).

Consistent with the Court's Individual Practices, Defendants notified Plaintiff of perceived deficiencies in the Complaint by letter dated October 21, 2019. (See Letter Motion.) Defendants claimed that the majority of alleged misstatements were inactionable either as puffery or as protected forward-looking statements. (See id. at 1–2.) Defendants added that Forms 483 are interim FDA feedback that need not be disclosed, and that Plaintiff did not

allege supporting facts to demonstrate how the omission of the Form 483 rendered Defendants' statements materially misleading. (See id.) Defendants continued that Plaintiff inadequately pled that any misstatements were made with scienter. (See id. at 2–3.) Defendants concluded that because Plaintiff could not establish primary liability under Section 10(b), any claim for control person liability under Section 20(a) should be dismissed as well. (See id. at 3.)

Plaintiff responded to Defendants' letter on November 4, 2019 and argued that the Complaint adequately pled violations of Sections 10(b) and 20(a). (See Opposition.) Plaintiff argued that the serious nature of the cGMP violations identified in the Form 483 rendered Defendants' statements misleading, because the potential risks they described had already materialized and effectively precluded timely FDA approval. (See id. at 1–3.) Plaintiff also claimed the Complaint raises a strong inference of scienter because Defendants knew of the Form 483, which contradicted their statements. (See id. at 3.) Plaintiff concluded that the Complaint pled liability under Section 20(a) as it pled primary liability and Defendants did not contest their status as control persons. (See id.)

By letter dated November 18, 2019, Defendants reiterated the arguments in the Letter Motion and requested leave to file a motion to dismiss. (See Reply.)

II. LEGAL STANDARDS

A. RULE 12(B)(6) MOTION TO DISMISS

Defendants request leave to file a motion to dismiss the Complaint. (See Letter Motion; Reply.) Rule 12(b)(6) provides for dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). This standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint should be dismissed if the plaintiff has not offered factual allegations sufficient to render the claims facially plausible. See id. However, a court should not dismiss a complaint for failure to state a claim if the

factual allegations sufficiently "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

The requirement that a court accept the factual allegations in the complaint as true does not extend to legal conclusions. See Iqbal, 556 U.S. at 678. In adjudicating a Rule 12(b)(6) motion, a court must confine its consideration "to facts stated on the face of the complaint, in documents appended to the complaint or incorporated in the complaint by reference, and to matters of which judicial notice may be taken." Leonard F. v. Israel Disc. Bank of N.Y., 199 F.3d 99, 107 (2d Cir. 1999) (internal quotation marks omitted). However, plaintiffs claiming fraud -- including securities fraud concerning material misstatements and omissions -- must satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) ("Rule 9(b)") by "stat[ing] with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). "Allegations that are conclusory or unsupported by factual assertions are insufficient." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007).

The Private Securities Litigation Reform Act ("PSLRA") also imposes heightened pleading standards for plaintiffs

alleging securities fraud. When a plaintiff alleges that defendants made misleading statements or omissions, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). 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). To adequately plead scienter, "the complaint shall . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). A court shall grant a motion to dismiss a securities fraud complaint if these requirements are not met.

B. THE EXCHANGE ACT

To state a claim for misrepresentation or omission under Section 10(b) and Rule 10b-5, "a plaintiff must allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4)

upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." ATSI, 493 F.3d at 105; see also Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008). Only the first two elements are at issue here.

Separately, "Section 20(a) of the Exchange Act imposes derivative liability on parties controlling persons who commit Exchange Act violations." In re Vivendi, S.A. Sec. Litig., 838 F.3d 223, 238 n.6 (2d Cir. 2016) (internal quotation marks omitted). "To establish a prima facie case" for Section 20(a) liability, "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." ATSI Commc'ns, 493 F.3d at 108.

1. Materiality

For omitted facts to be material, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426

U.S. 438, 449 (1976)). "[W]hether an alleged misrepresentation or omission is material necessarily depends on all relevant circumstances of the particular case." Ganino v. Citizens Utils. Co., 228 F.3d 154, 162 (2d Cir. 2000). Because materiality is a mixed question of law and fact, "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." Id. (internal quotation marks omitted).

2. Misstatements or Omissions of Material Fact

The PSLRA requires that a complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b); see also Rombach, 355 F.3d at 172 ("To meet the pleading standard of Rule 9(b), this Court has repeatedly required, among other things, that the pleading explain why the statements were fraudulent." (internal quotation marks omitted)). A "pure omission" is actionable

"only when the [defendant] is subject to a duty to disclose the omitted facts." Vivendi, 838 F.3d at 239. Although "Rule 10b-5 imposes no duty to disclose all material, nonpublic information, once a party chooses to speak, it has a 'duty to be both accurate and complete.'" Plumbers' Union Local No. 12 Pension Fund v. Swiss Reinsurance Co., 753 F. Supp. 2d 166, 180 (S.D.N.Y. 2010) (quoting Caiola v. Citibank, N.A., N.Y., 295 F.3d 312, 331 (2d Cir. 2002)). "Disclosure is required . . . only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." Kleinman v. Elan Corp., 706 F.3d 145, 153 (2d Cir. 2013) (internal quotation marks omitted).

3. PSLRA Safe Harbor

The PSLRA contains a safe harbor provision that applies to forward-looking statements, such as "a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management." Slayton v. Am. Express Co., 604 F.3d 758, 766-67 (2d Cir. 2010) (internal quotation marks omitted). Under the PSLRA, a person "shall not be liable with respect to any forward-looking statement," 15 U.S.C. § 77z-2(c), but only to the extent

that: (1) the statements were accompanied by meaningful cautionary language; (2) the statements were immaterial; or (3) the plaintiff failed to prove the statements were made with actual knowledge that they were false or misleading. See Slayton, 604 F.3d at 766.

When evaluating the adequacy of cautionary language, a court must "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 Focus Media Holding Ltd. Litig., 701 F. Supp. 2d 534, 540 (S.D.N.Y. 2010) (internal quotation marks omitted). "Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired." Rombach, 355 F.3d at 173; see also In re Prudential Sec. Inc. P'ships Litig., 930 F. Supp. 68, 72 (S.D.N.Y. 1996) ("To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit.").

4. Inactionable Statements

Certain types of statements, including puffery and opinion statements, are not actionable because they are not materially misleading. "Puffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d 367, 384 (S.D.N.Y. 2012); see also Vivendi, 838 F.3d at 245 ("Puffery encompasses statements [that] are too general to cause a reasonable investor to rely upon them, and thus cannot have misled a reasonable investor.") (internal citations and quotation marks omitted). This rule permits companies "to operate with a hopeful outlook," because corporate officers "are not required to take a gloomy, fearful or defeatist view of the future." Rombach, 355 F.3d at 174 (internal quotation marks omitted). But statements are not puffery when they constitute "misrepresentations of existing facts" that were made even though the speaker "knew that the contrary was true." Novak v. Kasaks, 216 F.3d 300, 315 (2d Cir. 2000) (rejecting a puffery argument where "the defendants stated that the inventory situation was 'in good shape' or 'under control' while they allegedly knew that the contrary was

true"); see also In re Bank of Am. Corp. Sec., Derivatives & ERISA Litig., 757 F. Supp. 2d 260, 310 (S.D.N.Y. 2010) ("[T]here is a difference between enthusiastic statements amounting to general puffery and opinion-based statements that are anchored in 'misrepresentations of existing facts.'" (quoting Novak, 216 F.3d at 315)).

5. Scienter

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007) (internal quotation marks omitted). Under Rule 9(b) and the PSLRA, a plaintiff must "state with particularity [the] facts giving rise to a strong inference that the defendant acted with the required state of mind." Rombach, 355 F.3d at 176. A complaint will survive a motion to dismiss only if "the inference of scienter [is] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Slayton, 604 F.3d at 766 (2d Cir. 2010). When assessing whether a strong inference exists, "the allegations are not to be reviewed independently or in isolation, but the facts alleged must be 'taken collectively.'" Id. (quoting Tellabs, 551 U.S. at 323).

Plaintiffs can satisfy this scienter requirement by alleging facts that either "(1) [show] that the defendants had both motive and opportunity to commit the fraud" or "(2) [constitute] strong circumstantial evidence of conscious misbehavior or recklessness." ATSI, 493 F.3d at 99. "The opportunity to commit fraud is generally assumed where the defendant is a corporation or corporate officer." Dodona I, LLC v. Goldman, Sachs & Co., 847 F. Supp. 2d 624, 638 (S.D.N.Y. 2012). Motive, however, requires Plaintiffs to allege facts showing "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001). Merely alleging "goals that are possessed by virtually all corporate insiders, such as the desire to . . . sustain the appearance of corporate profitability . . . or the desire to maintain a high stock price in order to increase executive compensation" will not suffice. See S. Cherry St., LLC v. Hennessee Grp. LLC, 573 F.3d 98, 109 (2d Cir. 2009) (internal quotation marks omitted).

If a complaint pleads recklessness or conscious misbehavior rather than opportunity and motive, "the strength of the circumstantial allegations must be

correspondingly greater." Kalnit, 264 F.3d at 142 (internal quotation marks omitted). To sufficiently plead recklessness, the complaint must allege conduct which is "highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. (internal quotation marks omitted). In this regard, "a complaint sufficiently pleads scienter where it alleges defendants had knowledge of facts or access to information contradicting their public statements." Sharette v. Credit Suisse Int'l, 127 F. Supp. 3d 60, 80 (S.D.N.Y. 2015) (internal quotation marks omitted).

III. DISCUSSION

A. WHETHER OMISSION OF A FORM 483 MAY BE MATERIAL

Plaintiff's claims rely primarily on Defendants' failure to disclose the Form 483 in the public statements identified above. The materiality of Forms 483 appears to be a matter of first impression in the Second Circuit. However, courts across the country have considered the matter and reached conclusions covering the entire spectrum. See, e.g., Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1129-30 (C.D. Cal. 2005) (finding Form 483

per se material because it contained "facts bearing on possible delays in FDA approval"); City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp., 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012) (finding Form 483 per se immaterial because it was "not the final word on whether [a] facility was in compliance with FDA regulations").

There is also not much Circuit precedent on the subject. The Eighth Circuit has provided the only clear guidance so far, holding that "the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading . . . depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." Pub. Pension Fund Grp. v. KV Pharm. Co., 679 F.3d 972, 982-83 (8th Cir. 2012). The First Circuit has suggested its agreement with the Eighth Circuit's conclusion. See In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42 n.4 (1st Cir. 2014) (noting Eighth Circuit's view that Forms 483 "may or may not be material depending on the circumstances of each case"). The large number of decisions denying motions to dismiss Section 10(b) claims involving Forms 483 bolsters

the conclusion that Forms 483 may be material depending on the circumstances alleged. See, e.g., Wilkof v. Caraco Pharm. Labs, Ltd., No. 09-12830, 2010 WL 4184465, at *6 (E.D. Mich. Oct. 21, 2010); In re Able Labs. Sec. Litig., No. 05-2681, 2008 WL 1967509, at *16, 30 (D.N.J. Mar. 24, 2008).

Under the circumstances of this case, the Court cannot conclude that the Form 483 is "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of [its] importance." Ganino, 228 F.3d at 162. CONTEPO was one of only two drugs being developed by Nabriva and thus represented a substantial share of Nabriva's potential revenues. The Form 483's observations suggested the FDA might deny marketing approval for CONTEPO if Nabriva did not address the cGMP observations in time, which would plainly impact Nabriva's profitability in the eyes of a reasonable investor. See Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 47 (2011) (finding omission material where pharmaceutical product "accounted for 70 percent of Matrixx's sales"). If the Court is to dismiss the Complaint, it will need to be either because Plaintiff fails to plead actionable misrepresentations or a strong inference of scienter.

B. WHETHER THE CHALLENGED STATEMENTS ARE ACTIONABLE

While a Form 483 is likely not per se immaterial, its advisory language indicates it lists only "inspectional observations and do[es] not represent a final agency determination regarding [] compliance." Genzyme, 754 F.3d at 35. Because a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence. See In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 541-42 (S.D.N.Y. 2015). Accordingly, Defendants' failure to disclose the Form 483 will be actionable only if disclosure was necessary to render the statements identified in Section I.A.2. above not misleading. See Kleinman, 706 F.3d at 153.

The Court will first consider whether any of Defendants' statements are inactionable as puffery or protected forward-looking statements and then assess whether any remaining statements might be misleading.

1. Puffery or Safe Harbor Statements

As noted above in Section II.B.4., certain optimistic statements are so vague and general that they would not mislead a reasonable investor, thus rendering them immaterial as a matter of law. The majority of the Press Release Statements fall into this category. Describing the NDA submission as "another major milestone" or CONTEPO as a

"first in class" antibiotic are classic examples of puffery. Both are vaguely optimistic descriptions that make no particularly definite assertions of existing fact and thus provide little basis to mislead a reasonable investor. Numerous courts have deemed either the exact same language or sufficiently similar language puffery. See, e.g., In re EDAP TMS S.A. Sec. Litig., No. 14 Civ. 6069, 2015 WL 5326166, at *4-5, 9-10 (S.D.N.Y. Sept. 14, 2015) (statement that FDA's acceptance of a company's application was a "major milestone"); McClain v. Iradimed Corp., 111 F.Supp.3d 1293, 1305 (S.D. Fla. 2015) (company's description of itself as a "market leader").

The Press Release Statement about the NDA's "robust data package" (and the Analyst Meeting Statement that the NDA's "data are solid") are similarly too vague to be meaningfully misleading. Perhaps more to the point, it is hard to see how withholding information about Ercros's manufacturing conditions affected the truth or falsity of how robust the testing data submitted with the initial NDA filing was. This leaves only one remaining Press Release Statement: "the FDA stated that no filing or potential review issue were identified." Unlike the previous statements, this "Review Issue" statement makes a specific

assertion of a past fact and might have the potential to mislead a reasonable investor. Because it cannot be dismissed as puffery or a forward-looking statement, the Court considers the statement further in Section III.B.2.

The remaining Analyst Meeting Statements are "we think that [CONTEPO] will not only win FDA approval but that [it] will be a significant addition[] to the antibiotic armamentarium in the United States" and "[w]e have an April 30 PDUFA date for CONTEPO. We will launch CONTEPO shortly after approval[.]" Calling CONTEPO a "significant addition to the antibiotic armamentarium in the United States" is also the sort of rosy affirmation that courts consider puffery. See, e.g., City of Sterling Heights Gen. Emps.' Ret. Sys. v. Hospira, Inc., No. 11 C 8332, 2013 WL 566805, at *24 (N.D. Ill. Feb. 13, 2013) (finding statements that company's new project would "transform" its operations and "support further long-term growth" were puffery).

Schroeder's statements that Defendants expected CONTEPO to win FDA approval and intended to launch CONTEPO shortly after approval are both forward-looking. See Kovtun v. VIVUS, Inc., No. C 10-4957, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012) ("Projections about the likelihood of FDA approval are forward-looking

statements."); Gillis v. QRX Pharm. Ltd., 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016) (statements about the NDA approval process "are classically forward-looking, as they address what defendants expected to occur in the future"). These forward-looking statements will be protected under the PSLRA's safe harbor if they are "identified and accompanied by meaningful cautionary language *or* [are] immaterial *or* the plaintiff fails to prove that [they were] made with actual knowledge that [they were] false or misleading." Slayton, 604 F.3d at 766 (emphasis in original). In this case, Plaintiff has failed to prove the statements were made with actual knowledge that they were false or misleading. As will be explained further below in Section III.C., Plaintiff's arguments regarding scienter turn primarily on the notion that the Form 483 contained information that contradicted Defendants' public statements, and that Defendants were thus reckless in failing to disclose it. While this might suffice to require denial of Defendants' motion to dismiss as to some statements, forward-looking statements are held to a higher pleading standard. The Complaint simply does not allege that Defendants actually knew their statements about CONTEPO's likelihood of approval or their intentions to

launch CONTEPO shortly after approval were false and misleading when made. For this reason alone, Defendants' forward-looking statements are protected by the PSLRA's safe harbor provision.

This leaves only the "Review Issue" statement and the 10-K Statements. Because none of these statements are forward-looking or puffery, the Court considers them separately below.

2. Otherwise Misleading Statements

The 10-K Statements list risk factors regarding CONTEPO, and they might serve as the type of meaningful cautionary language that would insulate forward-looking statements in Nabriva's 2018 Form 10-K under the PLSRA's safe harbor provision. Plaintiff focuses on factors concerning Ercros's ability to comply with cGMP requirements, which affect the risk that the FDA will delay or deny marketing approval to CONTEPO, or at least issue warning letters to similar effect. Plaintiff claims the 10-K statements are misleading because they present the risk of delayed FDA approval as a possibility, rather than as a certainty in light of the Form 483's observations. See Complaint ¶¶ 51, 53, 55 (each noting the Form 483 and asserting "the nature of the cGMP violations at the

facility that manufactured CONTEPO *would*" lead to delayed approval); see also Rombach, 355 F.3d at 173 ("Cautionary words about future risk cannot insulate from liability the failure to disclose the risk has transpired.").

Plaintiff's assertions raise one key issue: whether the Form 483's observations regarding potential cGMP violations substantially indicated the Aranjuez plant could not comply with FDA regulations by April 30, 2019, such that the risk of delayed FDA approval had effectively materialized. The Complaint suggests this was evident from the nature of the violations listed in the Form 483. The Form 483's observations do seem concerning at first glance. But a review of similar case law concerning Forms 483 suggests to the Court that the Form 483's observations alone are likely insufficient to render 10-K Statements (A)-(C) misleading. See, e.g., In re Discovery Labs. Sec. Litig., No. 06-1820, 2007 WL 789432, at *4 (E.D. Pa. Mar. 15, 2007) (stating that Form 483 noting cGMP violations including "failure properly to control conditions, failure to investigate variations from those controls, and failure to keep proper documentation" raised issues that "while they may be expensive or time-consuming to remedy, are eminently correctable"); McClain, 111 F. Supp. 3d at 1304-

05 (describing a Form 483 identifying eight potential violations as "an inspector's observations during a routine inspection," and that defendants "were not required to prematurely disclose that the FDA might take action").

The potential violations at the Ercros facility may have been quite serious, and perhaps serious enough that commercialization of CONTEPO in 2019 was no longer realistic. However, the Form 483's observations alone do not provide a sufficient basis to draw this inference and thus render 10-K Statements (A)-(C) misleading. Because the PDUFA date for CONTEPO was still over four months away from the issuance of the Form 483, Plaintiff needs to plead something that suggests why these violations could not be remedied within that timeframe, rather than conclusorily stating it was so. Absent that, it is unclear why the risks identified in 10-K Statements (A)-(C) had already materialized. It is similarly possible that Ercros and Nabriva were attempting to remedy the issues identified in December, and that the cGMP violations seemed "eminently correctable" by April 30, 2019. Unless Plaintiff can plead extra facts to render their account regarding the extent of the cGMP issues plausible, the descriptions of possible risks in 10-K Statements (A)-(C) are not misleading.

While the Form 483 itself is insufficient to render 10-K Statements (A)-(C) misleading, the issuance of a Form 483 may be enough to render other statements misleading. For example, failing to disclose a recent Form 483 that lists numerous potential cGMP violations could render misleading a company's statements that it is presently substantially in compliance with cGMP regulations. See, e.g., KV Pharm., 679 F.3d at 982 ("The issuance of a Form 483 represents a risk that the FDA may take corrective action against a company, and thus a company is obligated to assess the seriousness of the risk and disclose such information to potential investors if it also represents it is in compliance with FDA regulations and cGMP."); Wilkof, 2010 WL 4184465, at *2 (finding misleading company's statement that it was "substantially cGMP compliant"). Similarly, if the FDA issued a Form 483 listing various concerns regarding a manufacturing facility, describing that as a "good inspection" would probably mislead reasonable investors even if the concerns were ultimately remediable. See McGuire v. Dendreon Corp., No. C07-800MJP, 2008 WL 5130042, at *5 (W.D. Wash. Dec. 5, 2008).

In this regard, 10-K Statement (D) might mislead a reasonable investor. Unlike the other 10-K Statements,

which discussed the risk that Nabriva could not timely commercialize CONTEPO, 10-K Statement (D) states that Nabriva's "failure to comply with all regulatory requirements" might result in its receipt of "warning or untitled letters." Even if a Form 483 letter is technically not the same as a warning or untitled letter, its contents might be serious enough that a reasonable investor would consider it a substantially equivalent FDA warning. See Plumbers, 753 F. Supp. 2d at 180 ("[E]ven an entirely truthful statement may provide a basis for liability if material omissions related to the content of the statement make it ... materially misleading."); In re Am. Int'l Grp. 2008 Sec. Litig., 741 F. Supp. 2d 511, 531 (S.D.N.Y. 2010) ("[W]arnings of specific risks . . . do not shelter defendants from liability if they fail to disclose hard facts critical to appreciating the magnitude of the risks described."). A Form 483 lists "significant conditions" that may require corrective action, and under the totality of the circumstances it might be more akin to a warning than a routine inspectional observation. Drawing all reasonable inferences in favor of Plaintiff, as the Court must at this stage, 10-K Statement (D) could plausibly

mislead a reasonable investor as to the status of Nabriva's interactions with the FDA up to that point.

The Review Issue statement could similarly mislead a reasonable investor. Again, the statement might be literally true. But the Review Issue statement was made in January of 2019, roughly two months after the NDA filing, and it specifically mentioned "no filing *or* potential review issue were identified." Investors might construe the phrase "review issue" to refer to the FDA's ongoing substantive review, rather than the FDA's review of the initial NDA filing itself. A reasonable investor might thus infer that there had been no review issues as of January 4, 2019, even though they might just as reasonably consider the Form 483 at least a potential review issue. Drawing all reasonable inferences in favor of the Plaintiff, the Review Issue statement could also be materially misleading.

Accordingly, the Court is persuaded that the Review Issue statement and 10-K Statement (D) could mislead a reasonable investor. However, the Court must further consider whether Defendants made these potentially misleading statements with the requisite scienter.

C. SCIENTER

As noted above in Section II.B.5., a pleading raises a strong inference of scienter if it alleges facts that either "(1) [show] that the defendants had both motive and opportunity to commit the fraud" or "(2) [constitute] strong circumstantial evidence of conscious misbehavior or recklessness." ATSI, 493 F.3d at 99. This strong inference must be cogent and at least as compelling as an inference that the potentially misleading statements were made either innocently or even negligently, upon a holistic review of the complaint's allegations. Slayton, 604 F.3d at 766. In cases regarding public statements about FDA approval, a complaint will adequately plead scienter if it alleges "the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public," or "if the management is reckless in dealing with such adverse facts." In re AstraZeneca Sec. Litig., 559 F.Supp.2d 453, 470 (S.D.N.Y. 2008).

As an initial matter, the Complaint plausibly pleads that Nabriva knew about the Form 483. It alleges that Nabriva's CEO negotiated the Ercros Agreements and saw to the inclusion of clauses requiring Ercros to notify Nabriva

of any Forms 483 or evidence that CONTEPO was not being manufactured in accordance with cGMP regulations. The Ercros employee who signed those agreements was also the same employee to receive the Form 483 and discuss it with the FDA. Considering also that CONTEPO represented one of only two potential sources of revenue for Nabriva, it is entirely plausible that Nabriva would have learned of the Form 483 before January 4, 2019.

However, the Complaint does not plead enough to show that Defendants knew or recklessly disregarded that their statements were misleading in light of the Form 483. The Complaint certainly does not plead any motive for the alleged misrepresentations. While the Court might attempt to infer reasons that the Defendants would knowingly misstate FDA approval by April 30, 2019 was likely, such as the desire to maintain the appearance of profitability, all of those reasons would be ones shared by virtually all corporate speakers. Absent some additional allegations, such as corporate officers' sales of stock during the same period, the Court has no basis to conclude that the Complaint pleads motive. See S. Cherry, 573 F.3d at 109.

As for recklessness, Plaintiff seems to view Defendants' awareness of the Form 483 as "knowledge of

facts or access to information contradicting their public statements." Sharette, 127 F. Supp. 3d at 80. However, it is unclear that the Form 483 actually contradicts Defendants' public statements. The statements might remain true even in light of the Form 483. While the issuance of the Form 483 might render the Review Issue statement and 10-K Statement (D) misleading to reasonable investors, it does not necessarily follow that Defendants were reckless in disregarding that possibility. Put differently, it might have been reasonable for Defendants to believe the Form 483 did not contradict their public statements given the circumstances known to them, even if a reasonable investor might have otherwise thought it did. Plaintiff needs to plead something more to indicate why Defendants' failure to mention the Form 483 was "highly unreasonable." See Kalnit, 264 F.3d at 142. That could be additional information indicating the Form 483 substantially contradicted Defendants' public statements, or it could be another kind of information otherwise bearing on Defendants' state of mind. But as currently pled, the Complaint provides little to suggest why Defendants' failure to recognize the potentially misleading nature of their statements was

reckless instead of negligent, or based on a reasonable belief that potential violations could be timely remedied.

Taken collectively, the Complaint's allegations amount to the assertions that Defendants knew about the Form 483 and that "the nature of the cGMP violations at the facility that manufactured CONTEPO" was so serious that the FDA would not approve CONTEPO by the PDUFA date. Based on these two assertions alone, the inference that Defendants recklessly disregarded the potentially misleading nature of some statements is not cogent or at least as compelling as an inference that they made the statements either negligently or reasonably believing their accuracy.

This conclusion is consistent with the general weight of Form 483 cases across the country. While knowledge of a Form 483 alone might be enough to render certain statements both misleading and made with scienter, in those cases the Form 483 more clearly contradicts the statement being made (for example, that the company is currently in substantial compliance with cGMP regulations). Otherwise, the majority of Form 483 cases usually rely on additional factual matter to corroborate the allegedly serious nature of the omitted Form 483, thus raising a strong inference that defendants

recklessly disregarded the materially misleading nature of a failure to mention the form.

This is not an unduly high pleading requirement, particularly bearing in mind that plaintiffs may have limited access to facts bearing on defendants' knowledge at this early stage of the proceedings. There is a wide variety of ways that a plaintiff might adequately allege a defendant's failure to mention a Form 483 was reckless. For example, a pattern of FDA feedback reflecting the same unresolved concerns might demonstrate defendants' failure to mention the form was unreasonable. See, e.g., KV Pharm., 679 F.3d at 980–983 (noting defendant's knowledge of repeated Form 483s in context of determining whether Form 483s might be materially misleading); Gov't of Guam Ret. Fund v. Invacare Corp., No. 13 Civ. 1165, 2014 WL 4064256, at *5 (N.D. Oh. Aug. 18, 2014) (inference of recklessness compelling where defendants knew they received five Forms 483 that "presented the near certainty that the FDA would take corrective action"). A pattern of Forms 483 is not strictly necessary, of course; other forms of regulatory feedback could similarly suggest that a reasonable defendant would have appreciated the gravity of the concerns raised. See In re Cryolife, Inc., No.

Civ.A.1:02CV1868, 2003 WL 24015055, at *12-13 (N.D. Ga. May 27, 2003) (scienter adequately alleged where FDA, Centers for Disease Control and Prevention, and New York state agencies all repeatedly raised the same concerns during the class period).

Statements by company employees may also help strengthen an inference of scienter. A complaint might adequately plead scienter if it "contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016). Many Form 483 cases feature statements by confidential former employees reflecting that the problems identified in the Forms 483 were pervasive enough that they could not be readily remedied. See, e.g., Sterling Heights, 2013 WL 566805, at *18-21, *26-28 (scienter alleged where defendants participated in various remediation meetings aimed at addressing FDA concerns, which were not routine given allegations including former employees' discussion of pervasive cGMP violations).

The Second Circuit has also recognized that "egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness." Novak, 216 F.3d at 308 (citing Chill v. Gen. Elec. Co., 101 F.3d 263, 269 (2d Cir. 1996)). Multiple courts have found recklessness adequately pled based on alleged failures to investigate issues identified by the FDA. See, e.g., Able, 2008 WL 1967509, at *15 (finding scienter adequately pled where defendants "were reckless in not knowing of the problems in [the company's] manufacturing process . . . [by virtue of] not adequately investigating or following up on the 2004 FDA Form 483"); In re Dr. Reddy's Lab. Ltd. Sec. Litig., No. 17 Civ. 6436, 2019 WL 1299673, at *16 (D.N.J. Mar. 21, 2019) ("Defendants' alleged failure to investigate FDA warnings weighs further in favor of finding scienter and falsity.").

There are many ways that plaintiffs can raise a strong inference that defendants knew or recklessly disregarded that omission of a Form 483 might render their public statements misleading, and the list given above is not exhaustive. Plaintiff here pleads no such additional facts, instead relying on the conclusory allegation that the Form

483's observations alone rendered Defendants' public statements knowingly or recklessly misleading.

"The inquiry regarding scienter is necessarily case-specific, and the conclusion rests on a practical judgment about whether, taking all of the allegations collectively, it is at least as likely that Defendants acted with scienter." City of Providence v. Aeropostale, Inc., No. 11 Civ. 7132, 2013 WL 1197755, at *16 (S.D.N.Y. Mar. 25, 2013). Taking the Complaint's allegations collectively, the Court is not persuaded that the inference of scienter here is strong, cogent, or at least as compelling as an inference that any potentially misleading statements were made either negligently or innocently. As currently pled, the Complaint more closely resembles that in Genzyme than those in cases denying motions to dismiss: the FDA issued a Form 483 to a company, which proceeded to make optimistic statements at analyst meetings omitting the Form 483's existence, and which received a CRL letter a few months later refusing FDA approval based on concerns cited in the Form 483. Genzyme, 754 F.3d at 35–37. The Genzyme court's summary of the complaint in that case largely tracks the Court's conclusion in this one:

> [P]laintiffs' account is plausible. However, their allegations do not muster sufficient strength to meet

> the formidable pleading standard set by Congress for securities fraud claims under Section 10(b). The element of materiality is wanting as to some allegations, as is the element of falsity as to others. But more importantly, the complaint as a whole, as well as the allegations individually, fail to compel a strong inference of scienter on the part of defendants.

Id. at 46. Because Plaintiff has failed to plead a primary violation under Section 10(b), his Section 20(a) claims must be dismissed as well. See ATSI, 493 F.3d at 108. As it is unclear whether an amended complaint might adequately state a claim in this case, the Court hereby directs plaintiff to show cause within 20 days of this Order why the case should not be dismissed with prejudice.

IV. ORDER

For the reasons discussed above, it is hereby

ORDERED that the motion so deemed by the Court as filed by defendants Nabriva Therapeutics plc, Ted Schroeder, Gary Sender, and Jennifer Schranz to dismiss (Dkt. Nos. 37, 39) the complaint of Plaintiff Jonathan Schaeffer ("Complaint," Dkt. No. 31) is **GRANTED**, and that the Complaint is dismissed without prejudice.

It is further **ORDERED** that Plaintiff Jonathan Schaeffer show cause why this case should not be dismissed with prejudice within twenty days from the entry of this Order.

SO ORDERED.

Dated: New York, New York
28 April 2020

Victor Marrero
U.S.D.J.