UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TONYA HILLS and OKLAHOMA LAW ENFORCEMENT RETIREMENT SYSTEM, individually and on behalf of all others similarly situated, *Plaintiffs*, v. BIOXCEL THERAPEUTICS, INC., VIMAL MEHTA, RICHARD STEINHART, and ROBERT RISINGER, *Defendants*.	)	3:23-CV-00915 (SVN) July 11, 2024

RULING ON DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT AND PLAINTIFFS' MOTION TO STRIKE

Sarala V. Nagala, United States District Judge.

Plaintiffs Tonya Hills and Oklahoma Law Enforcement Retirement System, on behalf of themselves and all others similarly situated, bring this securities fraud action against Defendants BioXcel Therapeutics, Inc. ("BioXcel" or the "Company"), Vimal Mehta (BioXcel's Chief Executive Officer), Richard Steinhart (BioXcel's Chief Financial Officer), and Robert Risinger (BioXcel's Chief Medical Officer) (together, the "Individual Defendants," and, with BioXcel, "Defendants"), claiming that, between December 7, 2022, and August 11, 2023, Defendants made materially misleading disclosures which caused the artificial inflation of BioXcel's stock value. Specifically, Plaintiffs contend that Defendants did not disclose to investors that the Food and Drug Administration ("FDA") had inspected BioXcel's pivotal clinical trial and provided unfavorable observations regarding the trial's compliance with internal and FDA regulatory standards.

Based on Plaintiffs' allegations, the Court agrees Defendants made material misrepresentations with respect to two statements. However, as Plaintiffs have not adequately

pleaded scienter as to those statements, their amended complaint fails to state a claim for securities fraud. Accordingly, and for the reasons that follow, Defendants' motion to dismiss is granted, and Plaintiffs shall be afforded leave to amend. In addition, as Defendants improperly rely on two exhibits submitted with their motion, the Court will not consider those exhibits for the purposes Defendants offer them, although it denies Plaintiffs' motion to strike as the improper procedural mechanism for seeking such relief.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs' amended complaint, ECF No. 90, alleges the following facts, which are taken as true for purposes of a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

BioXcel is a biotechnology company that focuses on finding new therapeutic uses for pre-existing chemicals. Am. Compl. ¶ 1. Although its repertoire includes four chemical compounds, its most advanced research and development plans relate to BXCL501, which is a chemical compound that can be used to treat agitation in various patient populations. *Id.* BXCL501 is approved to treat agitation in patients with schizophrenia and bipolar disorders, and is marketed as IGALMI to those populations. *Id.* ¶ 2.

In December of 2021, BioXcel announced that it was embarking on two Phase 3 clinical trials (TRANQUILITY II and TRANQUILITY III, respectively) in its quest to secure FDA approval for BXCL501 to be used to treat agitation in patients with dementia and Alzheimer's disease. *Id.* ¶¶ 2–3. In April of 2022, BioXcel announced it had entered into a financing agreement with Oaktree Capital Management, L.P. ("Oaktree") and Qatar Investment Authority ("QIA"), which would provide private loans intended to fund BioXcel's commercial and developmental efforts. *Id.* ¶¶ 73, 74. Under the terms of the agreements with Oaktree and QIA, as disclosed in the April 2022 Form 8-K, certain tranches of funding were available to BioXcel prior to December

31, 2024, only "upon satisfaction of certain conditions," including "certain" regulatory, financial, and patent-related milestones not specified in the amended complaint. *Id.* ¶¶ 79, 82. Due to limited revenue from IGALMI sales and a need to meet regulatory approval benchmarks in order to pay back Oaktree and QIA and access additional financing, the TRANQUILITY trials were essential to BioXcel's overall success. *Id.* ¶ 4.

BioXcel engaged Segal Trials, a "second-rate clinical trial company," to conduct the trials because it believed Segal Trials could speed them up—allowing BioXcel to meet its benchmarks. *Id.* ¶ 90. The principal investigator at the Segal Trials site where the TRANQUILITY II trial was conducted was Dr. Caitlin Meyer, who was inexperienced and had never before overseen a clinical trial. *Id.* ¶ 91. Dr. Meyer was in charge of enrolling and overseeing 40% of the patients in the TRANQUILITY II study. *Id.*

Between December 5, 2022, and December 21, 2022, the FDA conducted a site inspection of the TRANQUILITY II clinical trial. *Id.* ¶ 7. Site inspections like this one allow the FDA to protect the rights, safety, and welfare of human research subjects in clinical trials; verify the accuracy, reliability, and integrity of clinical trial data submitted to the FDA; and evaluate compliance with FDA regulations governing clinical trials. *Id.* ¶ 102. In "rare instances," after the FDA has conducted an investigation, it will issue a Form 483. *Id.* ¶ 104. These are issued when an inspector has observed conditions that may constitute violations of statutes or regulations. *Id.*

On December 21, 2022, the FDA issued a Form 483 to Dr. Meyer, which outlined flaws in the trial. *Id.* ¶ 8. The Form 483 listed three "observations" by the FDA: (1) four out of thirty-seven subjects had not provided consent using consent forms approved by the Institutional Review Board; (2) Dr. Meyer had failed to prepare or maintain adequate case histories for twenty-five of

thirty-seven subjects reviewed, such that there was not sufficient documentation to show that those subjects met all criteria for inclusion in the study; and (3) Dr. Meyer had not followed dosing protocol with respect to four of the subjects and failed to report one Serious Adverse Event ("SAE") within a 24-hour time period, as required by the trial protocol. Form 483, Defs.' Mot. to Dismiss, Ex. 5, ECF No. 106-8 at 2–6[1]; *see also* Am. Compl. ¶¶ 118–22. The Form 483 provides that it contains "inspectional observations, and do[es] not represent a final Agency determination regarding . . . compliance." ECF No. 106-8 at 2. The Form further provides that, if the receiving entity has an objection to the observation or plans to implement a corrective action in response to the observation, it can discuss those measures with the FDA. *Id.*

Typically, when a study sponsor like BioXcel engages a principal investigator, there is a contract in place that states that the investigator must notify the sponsor directly and promptly when a Form 483 is issued. Am. Compl. ¶ 112. FDA regulations also require that the sponsor be notified. *Id.*; *see also id.* ¶ 182.

BioXcel first disclosed the existence of the Form 483 publicly on June 29, 2023, in a Form 8-K filed with the Securities and Exchange Commission ("SEC"). *Id.* ¶ 10. This Form 8-K also disclosed the release of positive topline data from the TRANQUILITY II trial. *Id.* With respect to the Form 483, the Form 8-K disclosed that the FDA had performed an inspection and issued a Form 483 with observations "related to the principal investigator's failure to adhere to the informed consent form . . ., maintain adequate case histories for certain patients . . ., and adhere to the investigational plan in certain instances." *Id.* ¶ 124. It further disclosed that the principal investigator "responded to the FDA observations within the time period requested," but that the FDA inspection "remain[ed] open . . . as the FDA has not issued an Establishment Inspection

[1] The Court finds that the Form 483 is incorporated by reference into the amended complaint, given its heavy reliance on its content. *See Chambers v. Time Warner, Inc.,* 282 F.3d 147,153 (2d Cir. 2002).

Report." *Id.* On an analyst call later that day, Defendant Risinger acknowledged BioXcel had known of the Form 483 since December of 2022: "The FDA did the audit back in December. We were aware of it, and we've been monitoring that site even more closely." *Id.* ¶ 126.

The June 2023 Form 8-K also disclosed that in May of 2023, it came to the Company's attention that Dr. Meyer may have fabricated correspondence to the FDA in order to appear compliant with SAE protocol (on a separate occasion than the SAE violation detailed in the Form 483). *Id.* ¶¶ 10, 122, 124. Specifically, it seemed she had fabricated an email which made it appear she had reported an SAE in a timely manner when she had not. *Id.* ¶ 94. BioXcel initiated an investigation, and, as of June 29, 2023, had "recently received confirmation" that in fact Dr. Meyer had fabricated the email, and that this fabricated email had been provided to the FDA during the December 2022 inspection. *Id.* ¶ 124. The Company stated that it was "currently in the process of conducting an investigation into protocol adherence and data integrity at the principal investigator's trial site," and was "in the process of retaining an independent third party to audit the data collected at the site." *Id.* It had notified the FDA of all findings and intended corrective measures to "validate the integrity of the data generated by this investigator for the TRANQUILITY II trial." *Id.* Lastly, it disclosed that these developments could "impact the timing of the Company's development plans for, and prospects for regulatory approval of, BXCL501 for the acute treatment of agitation associated with dementia in patients with probable Alzheimer's disease." *Id.* ¶ 125. Analyst reports noted that these disclosures "overshadowed" the positive study data released that same day. *Id.* ¶ 128. The price of BioXcel stock immediately fell, from $17.67 per share to $6.39 per share in a single day, on unusually heavy trading volume. *Id.* ¶ 127.

On August 14, 2023, BioXcel announced that, based on recent events, it would likely be unable to meet the "milestones required to access the additional capital under the financing

agreements" with Oaktree and QIA, and that there was "substantial doubt" about its ability to continue as a going concern for at least one year. *Id.* ¶¶ 17, 135, 136. It also announced that it had requested a meeting with the FDA to discuss the TRANQUILITY program (including the TRANQUILITY II and III trials and the data audit) and what would be required to seek a supplemental New Drug Application ("sNDA") for BXCL501 to treat dementia and Alzheimer's patients; that it was pausing its TRANQUILITY III clinical trial due to early enrollment data; and that it planned to implement a company reorganization that would reduce the workforce by more than 50%. *Id.* ¶¶ 137–39. Again, the stock price declined—from $7.40 per share at the close of market on August 11, 2023, to $4.33 per share on August 14, 2023. *Id.* ¶ 18.

During the time between the initiation of the FDA inspection and the allegedly corrective disclosures on June 29 and August 14, 2023, Defendants also made other disclosures about TRANQUILITY II and BioXcel's financial health. *Id.* ¶¶ 142, 143. Plaintiffs allege that eighteen of these statements, made during presentations, earnings calls, and in financial disclosures, *see id.* ¶¶ 144–176, were false and/or materially misleading, largely because they expressed positivity and optimism about BioXcel's future, BioXcel's liquidity, and the TRANQUILITY II trials, while concealing the Form 483 letter which suggested that a "material portion of the study data was potentially invalid." *E.g.*, *id.* ¶ 157. The particular statements are discussed further below.

Plaintiffs further allege that Defendants Mehta, Steinhart, and Risinger acted with scienter in making these statements because they knew, or recklessly disregarded, that these statements were false or misleading. *Id.* ¶ 177. Defendants were aware that BioXcel's loan agreements depended on its ability to get FDA approval for BXCL501 in Alzheimer's and dementia patients, and that investors were especially interested in the TRANQUILITY II trials and its progress. *Id.* ¶¶ 190, 192. Further, confidential witnesses reported that Defendants Mehta and Risinger were

very involved in the daily affairs of BioXcel and the progress of BXCL501. *Id.* ¶¶ 195–98; *see also id.* ¶¶ 29–56.

Plaintiffs also claim that the Individual Defendants had the motive and opportunity to mislead investors, in support of their scienter allegations. First, Defendants allegedly had an incentive to mislead investors regarding the efficacy of the trials because their critical funding from Oaktree and QIA was contingent on the success of the TRANQUILITY II trials. *Id.* ¶ 201. Second, certain defendants engaged in lucrative insider trading that occurred during the class period. *Id.* Specifically, between December of 2022 and August of 2023, Defendant Mehta realized profits of $3,750,379 based on his sales of BioXcel common stock, disposing of approximately 91.8% of the total shares he had available; and Defendant Steinhart realized profits of $176,502 based on sales of common stock that disposed of approximately 93.1% of his available shares. *Id.* ¶¶ 16, 210–11, 218–19. In addition, Krishnan Nandabalan, a director and co-founder of BioXcel, who is not a defendant, sold 180,000 shares of BioXcel during this period (100% of the shares he owned), yielding a net profit of $3,186,271.89. *Id.* ¶¶ 16, 214–16. These sales were made pursuant to 10b5-1 trading plans entered into in August and June of 2022, respectively. *Id.* ¶ 220.

Plaintiffs originally filed suit on July 7, 2023, and their amended complaint was filed December 5, 2023. Their purported class consists of all investors who purchased the allegedly artificially inflated common stock of BioXcel between December 7, 2022, and August 11, 2023. *Id.* at ¶ 223. They bring two counts: (1) for violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), against all Defendants; and (2) for violation of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against the Individual Defendants.

Because Plaintiffs' motion to strike impacts which exhibits the Court considers for Defendants' motion to dismiss, the Court discusses the motion to strike first.

II. PLAINTIFFS' MOTION TO STRIKE

In support of their motion to dismiss, Defendants attached seventeen exhibits consisting primarily of BioXcel's filings with the SEC; the FDA Form 483 delivered to Dr. Meyer and material from the FDA's website about Forms 483; transcripts of various calls and presentations referenced in the amended complaint; and excerpts of the agreements between BioXcel and Oaktree and QIA. *See* Grant Decl., ECF No. 106-3 (describing exhibits). Plaintiffs moved to strike two specific exhibits: Exhibit 7, a document from the FDA website presenting the total number of Form 483s issued for fiscal years 2013 through 2023; and Exhibit 12, BioXcel's Form 10-Q filed with the SEC for the period ending September 30, 2023. *See* Defs.' Mot. to Dismiss Ex. 7, ECF No. 106-10; Defs.' Mot. to Dismiss Ex. 12, ECF No. 106-15.[2] While a motion to strike is not the proper procedural method for achieving Plaintiffs' objective—that the Court not consider these exhibits in deciding Defendants' motion to dismiss—the Court agrees with Plaintiffs that it would be improper to consider Exhibits 7 and 12 for the purposes requested by Defendants. Therefore, although it denies Plaintiffs' motion to strike, the Court will not consider either exhibit for the purposes Defendants request in deciding Defendants' motion to dismiss.

A. Legal Standard

Pursuant to Rule 12(f) of the Federal Rules of Civil Procedure, a court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."

[2] Plaintiffs also suggest that *none* of Defendants' exhibits should be considered because Defendants failed to meaningfully argue in their briefing why any of the included exhibits warrant consideration. Pls.' Mot. to Strike, ECF No. 107 at 5. The Court agrees that Defendants should have provided more analysis as to why each particular exhibit is appropriate for the Court to consider on a motion to dismiss. Nonetheless, at oral argument, Plaintiffs clarified that they are only seeking the exclusion of the two disputed exhibits—Exhibits 7 and 12—so the Court need not address any of the other exhibits specifically in this ruling.

Striking a pleading is a "drastic remedy;" thus, motions to strike are generally disfavored and require the moving party to "clearly show that the challenged matter has no bearing on the subject matter of the litigation." *Lamoureux v AnazaoHealth Corp.,* 250 F.R.D. 100, 102–03 (D. Conn. 2008) (citation omitted); *see also* Wright & Miller, Fed. Practice and Procedure §1380 ("[M]otions under Rule 12(f) are viewed with disfavor by the federal courts and are infrequently granted.").

B. Discussion

As a preliminary matter, the Court agrees with Defendants that a motion to strike pursuant to Federal Rule of Civil Procedure 12(f) is not technically the proper avenue to obtain the relief sought by Plaintiffs. "Federal Rule of Civil Procedure 12(f) permits a district court to strike a 'pleading' for various reasons." *D'Alessandro v. Arrow Pharmacy Holdings, LLC*, No. 3:20-CV-536 (SVN), 2023 WL 1967245, at *6 (D. Conn. Feb. 13, 2023). Federal Rule of Civil Procedure 7(a) designates as pleadings: "a complaint, an answer, a reply to a counterclaim, an answer to a cross-claim, a third-party complaint, a third-party answer, and a reply to an answer or third-party answer if ordered by the court." *See Monroe v. Board of Ed. of Town of Wolcott, Conn.,* 65 F.R.D. 641, 645 (D. Conn. 1975) (citing Fed. R. Civ. P. 7(a)). The exhibits challenged by the Plaintiffs do not constitute a pleading under Rule 7(a). *See id.* Thus, a motion to strike is an improper procedure for the relief sought by the Plaintiffs, as "it is inappropriate [for the Court] to strike material contained in exhibits to motions." *O'Brien v. Wisniewski,* No. 3:10-CV-120 CSH, 2012 WL 1118076, at *3 (D. Conn. Apr. 3, 2012). Nonetheless, the Court will construe Plaintiffs' motion as "an invitation by [Plaintiffs] to consider" whether the Court may properly rely upon Defendants' Exhibits 7 and 12 when ruling on Defendants' motion to dismiss. *See Monroe*, 65 F.R.D. at 645.

When deciding on a motion to dismiss, "courts ordinarily examine . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs Inc. v. Makor Issues & Rts. Ltd.,* 551 U.S. 308, 322 (2007). A prerequisite to the Court considering a document to be incorporated by reference is the "plaintiff's *reliance* on the terms and effect of a document in drafting the complaint . . . mere notice or possession is not enough." *Chambers,* 282 F.3d at 153 (emphasis in original). Federal Rule of Evidence 201(b) permits courts to take judicial notice of facts that are not "subject to reasonable dispute because [they] . . . can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned."

1. Exhibit 7

Exhibit 7, which contains excerpts of the FDA Inspectional Observation Data Sets for fiscal years 2014 to 2023, provides that the number of Form 483s issued by the FDA in those years ranged from a low of 2,430 (in 2021) to a high of 5,045 (in 2017). *See generally* ECF No. 106-10. It is undisputed that Exhibit 7 was not incorporated into the complaint by reference. The Court can, however, take judicial notice of the statistics listed in Exhibit 7 because the number of Forms 483 issued in these years and the authenticity of Exhibit 7 are not reasonably in dispute. The material in Exhibit 7 is therefore a proper subject of judicial notice. *See Rynasko v. New York Univ.*, 63 F.4th 186, 191 n.4 (2d Cir. 2023) (noting the court can take judicial notice of documents from official government websites).

Nonetheless, consideration of this data to refute Plaintiffs' claim that the issuance of Form 483 was so "serious" and "rare" that it would cause delays in BioXcel's research, as Defendants urge, would be improper. *See* Am. Compl. ¶¶ 7, 104; Defs.' Br. in Supp. of Mot. to Dismiss, ECF No. 106-1 at 18 (citing Exhibit 7 and stating that Form 483s are issued for minor documentation

issues and more serious conditions); *id.* at 34 n.13 (arguing that the Form 483 here reflected "common issues"). For one, the data presented in Exhibit 7 may not be the full picture—for instance, the Court has no information about the total number of inspections conducted by the FDA each year in the particular category of center Dr. Meyer's trial falls into, which would be necessary to understand the alleged rarity of Form 483s. And, regardless of the value of Exhibit 7 as a general matter, resolving this factual dispute between the parties or drawing the inference suggested by Defendants would be wholly inappropriate at the motion to dismiss stage. *See Wade v. Kay Jewelers Inc.,* No. 3:17-CV-990 (MPS), 2018 WL 4440532, at *3 (D. Conn. Sept. 17, 2018) (noting that it is improper for a court to consider documents "to contravene a statement in the amended complaint"); *see also In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 (RRM) (RLM), 2013 WL 4647512, at *4 (E.D.N.Y. Aug. 29, 2013) (noting that the inquiry of whether to take judicial notice is "separate and distinct" from the inquiry of "what inferences or conclusions to draw from the noticed material"). As Defendants have not put forth another theory of relevance for Exhibit 7, the Court takes judicial notice of the existence of the FDA statistics but declines to consider Exhibit 7 for purposes of concluding, as Defendants urge, that Forms 483 are not rare.

2. Exhibit 12

Exhibit 12 is the Company's 10-Q for the third quarter of 2023. In pertinent part in this filing, the Company reported that the investigation it had begun in June of 2023 concerning the TRANQUILITY II trial was ongoing but that, based on the investigation to date, it believed "there [had] been no further instances of misconduct or fraud or other findings that adversely impact[ed] the data integrity or reliability of the eligibility, safety, and efficacy data generated" at the trial site operated by Dr. Meyer. *See* ECF No. 106-15 at 5, 9.

First, the Court finds that Exhibit 12 is not incorporated by reference into the amended complaint. Although the amended complaint references a 10-Q filing in the "third quarter" of 2023 in one paragraph, *see* Am. Compl. ¶ 135, this paragraph actually describes the 10-Q filing for the *second* quarter of 2023—the August 14, 2023, allegedly corrective disclosure. When queried on this issue at oral argument, Plaintiffs confirmed the reference to a "third quarter" filing was a typographical error. The Court therefore declines to find that Exhibit 12 was incorporated by reference into the amended complaint.

With respect to judicial notice, the Second Circuit has held that a district court may "take judicial notice of the contents of relevant public disclosure[s]," including "documents required by law to be filed, and actually filed, with the SEC." *Kramer v. Time Warner Inc.*, 937 F.2d 767,774 (2d Cir. 1991); *see also Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (noting that a court can take judicial notice of public records integral to a fraud complaint). As the authenticity of documents required to be filed with the SEC cannot be seriously questioned, taking judicial notice of SEC filings is generally proper. *See Kramer*, 937 F.2d at 774 ("a district court may take judicial notice of the contents of relevant public disclosure documents required to be filed with the SEC as facts capable of accurate and ready determination by resort to sources who accuracy cannot reasonably be questioned"); *see also Finn v. Barney*, 471 F. App'x. 30, 32 (2d Cir. 2012) (summary order) (holding that the district court did not abuse its discretion in taking judicial notice of publicly filed documents).

Here, Form 10-Q is a legally required public disclosure form that must be filed and was filed with the SEC; thus, the Court can and does take judicial notice of the contents of the document for the purpose of establishing that BioXcel made the representations therein. However, to the extent that Defendants seek to use the filing to dispute Plaintiffs' allegations of falsity, *i.e.*, by

attempting to demonstrate that its statements throughout the class period regarding its confidence in BioXcel's clinical trial were accurate because its investigation uncovered no data issues, *see* ECF No. 106-1 at 27, the Court rejects Defendants' invitation to draw the inference that the representations made were factually true. *See In re Frito-Lay*, 2013 WL 4647512, at *4; *see also Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (noting that courts can take judicial notice of the fact of a regulatory filing, without "regard to the truth of [its] contents").

For the reasons described herein, Plaintiffs' motion to strike is denied as a technical matter. The Court will take judicial notice of both Exhibits 7 and 12, but for only the limited purposes described above.

III. DEFENDANTS' MOTION TO DISMISS

Defendants move to dismiss Plaintiffs' amended complaint in its entirety, arguing that it fails to state a claim upon which relief can be granted. For the reasons described herein, Defendants' motion is granted, and Plaintiffs will be given leave to amend.

A. Legal Standard

1. Rule 12(b)(6)

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss a case or cause of action for failure to state a claim upon which relief can be granted. When determining whether a complaint states a claim upon which relief can be granted, highly detailed allegations are not required, but the complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In undertaking this analysis, the Court must

"draw all reasonable inferences in [the plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted).

2. Private Securities Litigation Reform Act of 1995 (PSLRA) and Rule 9(b)

To state a claim for securities fraud, a plaintiff must "satisfy the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b)." *Employees' Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 304 (2d Cir. 2015) (citation omitted). Federal Rule of Civil Procedure 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." In the context of securities fraud, this means a plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) (quoting *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004)).

B. Discussion

Plaintiffs have advanced two causes of action: a Section 10(b) claim brought against all Defendants (Count I) and a Section 20(a) claim brought against the Individual Defendants only (Count II). Section 10(b), codified at 15 U.S.C. § 78j, provides that it is unlawful for any person, directly or indirectly, by the use of interstate commerce or mail, to "use or employ . . . any manipulative or deceptive device or contrivance" in violation of SEC rules. Section 20(a), codified at 15 U.S.C. § 78t, provides that every person who controls a company that or another person who violates SEC rules shall be jointly and severally liable with the company or other person.

As Plaintiffs' Section 20(a) claim rises and falls with their Section 10(b) claim, the Court focuses on the latter claim. To state a claim for securities fraud under Section 10(b) of the

Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), a plaintiff must plead "(1) a misstatement or omission of material fact; (2) scienter; (3) a connection with the purchase or sale of securities; (4) reliance; (5) economic loss; and (6) loss causation." *Plumber & Steamfitters Loc. 773 Pension Fund v. Danske Bank A/S*, 11 F.4th 90, 98 (2d Cir. 2021) (citation omitted).

Defendants dispute whether Plaintiffs have adequately pleaded the first, second, and sixth elements of their Section 10(b) claim—misstatements, scienter, and loss causation.

1. Actionable Misstatements or Omissions

Securities and Exchange Commission Rule 10b-5, which implements Section 10(b), makes it unlawful to, among other things "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). For an omitted fact to rise to the requisite level of materiality, 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." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (citations omitted). Disclosure of *all* material information is not required; rather, disclosure of omitted information is required only when it is necessary to make a statement not misleading. *Id.* at 44. Whether a statement is misleading is evaluated not only by its literal truth, but by its "context and manner of presentation." *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (citation omitted). Ultimately, then, the "test for whether a statement is materially misleading is not whether the statement is misleading in and of itself, but whether the defendants' representations, *taken together and in context*, would have misled a reasonable investor." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016) (internal quotation marks and citation omitted) (emphasis in original).

Certain types of statements cannot be materially misleading. For example, "expressions of puffery and corporate optimism do not give rise to securities violations." *Rombach*, 355 F.3d at 174. A statement of "puffery" is an "optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it." *Villare v. Abiomed, Inc.*, No. 19 Civ. 7319 (ER), 2021 WL 4311749, at *13 (S.D.N.Y. Sept. 21, 2021) (citation omitted); *see also Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 173 (2d Cir. 2020) ("Generic, indefinite statements of corporate optimism typically are not actionable.").

In addition, the PSLRA provides a safe harbor for forward-looking statements. A forward-looking statement is defined as, among other things, "a statement containing a projection of revenues . . . a statement of the plans and objectives of management for future operations," or a "statement of future economic performance." 15 U.S.C. § 78u-5(i)(1). A forward-looking statement is not actionable if "(1) it is identified and accompanied by meaningful cautionary language, (2) it is immaterial, or (3) the plaintiff fails to prove that the statement was made with actual knowledge that it was false or misleading." *Villare*, 2021 WL 4311749, at *16; *see also Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010) (noting that a defendant need only establish one of these conditions to take advantage of the safe harbor).

As Plaintiffs contend that all of the challenged disclosures were false because of the Company's failure to disclose the Form 483, the Court first discusses the duty to disclose Form 483 letters, before turning to an analysis of each of Defendants' allegedly false or misleading statements.[3]

[3] Although there is some repetition in the sections that follow, as some arguments apply equally to multiple statements, the Court finds this method of proceeding statement-by-statement appropriate for the sake of clarity and completeness.

a. Form 483

The thrust of Plaintiffs' claim is that Defendants' disclosures between December of 2022 and June of 2023 were misleading because they omitted the fact that Defendants had received a Form 483 for a clinical trial site that covered 40% of patients enrolled in the TRANQUILITY II clinical trial. In Plaintiffs' view, because the receipt of the Form 483 seriously called into question (a) the validity of the clinical trial, (b) the timing and ultimate approval of the drug for dementia and Alzheimer's patients, and (c) BioXcel's ability to meet milestones required to obtain additional financing, Defendants' disclosures—which, at a high level, expressed confidence in the progress of the trial and the ultimate success of any sNDA—were misleading. Defendants do not dispute the allegation that they were aware of the Form 483 as early as its issuance on December 21, 2022. They argue primarily that they had no duty to disclose the Form 483 and that, in any event, Plaintiffs have not alleged how any of their statements were inconsistent with the existence of the Form 483 or how the Form 483 carried the weight Plaintiffs seek to attribute to it. *See* ECF No. 106-1 at 32–35.

Although the "case law is not well developed on the materiality of 483 letters, particularly within the Second Circuit," *see Oklahoma Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, No. 19 Civ. 3354 (VM), 2020 WL 3268531, at *16 (S.D.N.Y. June 17, 2020), the Court agrees with Defendants that there is no "standalone duty" to disclose a Form 483 in and of itself. *See, e.g.*, *Schaeffer v. Nabriva Therapeutics plc*, No. 19 Civ. 4183 (VM), 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020). Nonetheless, it is equally clear that the failure to disclose a Form 483 can render a statement materially misleading, depending on the circumstances of the statement at issue. *See, e.g.*, *id.* at *11 (finding statement that failure to comply with regulation "might result" in receipt of "warning or untitled letters" misleading where company had already received Form

483); *Teligent*, 2020 WL 3268531, at *13–14 (finding statement that company could receive warning letter for compliance issues misleading in light of receipt of Form 483); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1132 (C.D. Cal. 2005) (finding actionable failure to mention Form 483 issues in response to questions regarding potential obstacles to FDA approval); *see also Pub. Pension Fund Grp. V. KV Pharm. Co.*, 679 F.3d 972, 983 (8th Cir. 2012) (materiality of Form 483 may depend on 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"). As the *Schaeffer* court noted, the "general weight" of cases in which the omission of a Form 483 renders a statement misleading falls into two buckets—cases in which the Form 483 "clearly contradicts the statement being made (for example, that the company is currently in substantial compliance with . . . regulations);" and cases in which there is "additional factual matter to corroborate the allegedly serious nature of the omitted Form 483," such that a "strong inference" can be drawn of the misleading nature of the statement. *See Schaeffer*, 2020 WL 7701463, at *12.

With this background in mind, the Court discusses the impact of the omission of the Form 483 on the alleged misstatements.

b. Paragraph 144: December 7, 2022, Statement

Plaintiffs first challenge Defendant Mehta's statement to investors during a presentation that "TRANQUILITY [II] is in advanced stages of enrollment, and it's progressing well." Am. Compl. ¶ 144. They argue this statement is false because on December 5, 2022, the FDA initiated its investigation into Dr. Meyer and the violations that would later form the basis of the Form 483 had already occurred. *Id.* ¶ 145.

The Court agrees with Defendants that this statement is not actionable. On December 7, the Form 483 had not been issued and Plaintiffs have not pleaded any facts suggesting that, as of this date, Defendants were aware of any specific issues with Dr. Meyer's site that would render this statement false or misleading. *Cf. Todd v. STAAR Surgical Co.*, No. CV-14-05263-MWF-RZ, 2016 WL 6699284, at *12 (C.D. Cal. Apr. 12, 2016) (finding statement actionable where complaint alleged facts demonstrating defendants' awareness of "adverse observations . . . well before" receipt of Form 483). That the investigation had been initiated, and that BioXcel had hired an "inexperienced principal investigator employed by a disreputable clinical trial company," Am. Compl. ¶ 145, does not itself suggest that anything about this statement is fraudulent. *See Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) ("Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them."). Moreover, the statement that the trial was "progressing well," even in the context of projecting that the data readout would be ready in the first half of 2023, is "too general" for a reasonable investor to rely on, and therefore inactionable for that additional reason as well. *See Kusnier v. Virgin Galactic Holdings, Inc.*, 639 F. Supp. 3d 350, 373 (E.D.N.Y. 2022) ("Courts generally find that present tense statements of optimism describing things as 'going well,' 'progressing well,' 'just amazing,' and the like are puffery because they are too general to be relied upon.").[4]

c. Paragraphs 146 and 147: January 11, 2023, Statements

Plaintiffs next challenge several statements made in a PowerPoint and during a presentation to investors at a healthcare conference. Specifically, the PowerPoint stated that the TRANQUILITY II trial was "on track in 1H 2023," and had "progressed" on a "strong

[4] Having found that this statement is not actionable for these reasons, the Court declines to address Defendants' argument that this statement, and others discussed below appearing in paragraphs 146, 147, 149, 156, 162, 164, 167, 169, 171, 173, and 175 of the amended complaint, are forward-looking statements protected by the PLSRA's safe harbor.

foundation," and during the presentation Defendant Mehta stated that the company was "excited about" the trial data that was expected in the first half of 2023. Am. Compl. ¶¶ 146, 147. Plaintiffs again claim these statements were false essentially due to the fact that the Company had at this point received the Form 483 which "called into question the integrity of the [trial] data and materially increased the risk of further adverse regulatory action." *Id.* ¶ 148.

The Court does not find that the mere fact that by this time Defendants were aware of the Form 483 is sufficient to render these statements false. None of the statements speak to FDA compliance or otherwise contradict the Form 483 itself, nor is there any indication that the Form 483 violations were so severe that, only a month after receiving the letter, the trial could not be "on track." Further, none of these statements are concrete enough to be anything more than inactionable puffery. That the TRANQUILITY II trial was "pivotal," "on track," had "progressed" on a "strong foundation," and that the Company was "very excited" about the data are typical "[g]eneric, indefinite statements of corporate optimism." *See Abramson*, 965 F.3d at 173; *Kusnier*, 639 F. Supp. 3d at 373; *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757–58 (S.D.N.Y. 2018) (recognizing that statements a company is "on track" or only putting a "positive spin on developments in the FDA approval process" are puffery) (cleaned up); *Shemian v. Rsch. In Motion Ltd.*, No. 11 Civ. 4068 (RJS), 2013 WL 1285779, at *23 (S.D.N.Y. Mar. 29, 2013), *aff'd*, 570 F. App'x 32 (2d Cir. 2014) (statements about "exciting growth" and a "strong foundation" for market expansion were "too vague to be considered misleading," and were therefore "non-actionable corporate puffery").

d. Paragraph 149: February 21, 2023, Statement

Third, Plaintiffs claim that Defendant Mehta's statements at a Key Opinion Leader ("KOL") event were false or misleading. In relevant part, Mehta stated that there were "multiple

opportunities to expand the market potential for [IGALMI]," including "Alzheimer's-related agitation [and] TRANQUILITY II," and that the company's "data readouts [including for TRANQUILITY II] [were] on track" to be announced in the first half of 2023. Am. Compl. ¶ 149.

Contrary to Defendants' suggestion, the literal truth of at least part of this statement—the data readouts did in fact occur in the first half of 2023—is insufficient to protect it from the securities laws. *See, e.g.*, *Greco v. Qudian Inc.*, No. 1:20-CV-577-GHW, 2022 WL 4226022, at *8 (S.D.N.Y. Sept. 13, 2022) (noting that literally true statements can be actionable if they create a materially misleading impression). Nonetheless, the Court once again agrees with Defendants that this statement is too vague to be actionable, as it generally expresses BioXcel's optimism about potential market expansion in indefinite terms. *See, e.g.*, *Shemian*, 2013 WL 1285779, at *23.

Although the Form 483 related to the data produced at Dr. Meyer's clinical trial site, the Court finds once again that it is not sufficient, alone, to render false or misleading Defendant Mehta's opinion that the data readouts were "on track," or that TRANQUILITY II presented a market expansion opportunity for BioXcel. In other words, Plaintiffs have not pleaded particularized facts connecting the observations in the Form 483—which itself says nothing regarding the future of the TRANQUILITY II trial and does not even explicitly require corrective action—to their contention that "BioXcel's clinical trial and commercialization would be delayed significantly" and the "expanded commercialization of BXCL501 would be delayed or abandoned," *see* Am. Compl. ¶ 150, which is the required linkage to render this statement false or misleading. *See Schaeffer*, 2020 WL 7701463, at *10 (finding that, while the "potential violations" "may have been quite serious, and perhaps serious enough that commercialization of [drug] in 2019 was no longer realistic," the Form 483's observations "alone do not provide a sufficient basis

to draw this inference and thus render" certain statements misleading); *Teligent*, 2020 WL 3268531, at *12 (finding statement that company was "on track" not actionable, and noting that receipt of Form 483 letter "[did] not change this conclusion, as a review of the issues described therein suggests the violations were correctable, at least with sufficient dedicated resources and time").

e. Paragraph 151: March 16, 2023, Risk Disclosure Statement

The Court concludes, on the other hand, that Plaintiffs have plausibly demonstrated that one risk disclosure or risk-factor statement in BioXcel's Form 10-K for the year ending December 31, 2022, was materially misleading due to the omission of information regarding the Form 483.

In this10-K, BioXcel stated, in relevant part:

> We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
>
> […]
>
> If we or any of our CROs [clinical research organizations] fail to comply with applicable GCPs [good clinical practices], the clinical data generated in our clinical trials may be deemed unreliable and the FDA . . . may require us to perform additional clinical trials before approving our marketing applications.

Am. Compl. ¶ 151; Defs.' Mot. to Dismiss Ex. 1, ECF No. 106-4 at 47.

The Court agrees with Plaintiffs that, although presented in a hypothetical form, a reasonable investor may have concluded that the risk disclosed by this statement had already materialized based on the issuance of the Form 483 letter, which specifically details compliance issues with the clinical protocols and potential data integrity issues with Dr. Meyer's clinical trial site. While the statement may be literally true, presenting this information as a risk disclosure—when there was evidence that these risks had actually materialized by the time the disclosure was

made—was misleading. *See Teligent*, 2020 WL 3268531, at *12 (noting that it is "deceitful to warn that it was merely possible for the unfavorable events to happen when they have already occurred" (citation and internal quotation marks omitted) (cleaned up)); *Odeh v. Immunomedics, Inc.*, No. CV 18-17645, 2020 WL 4381924, at *6 (D.N.J. July 31, 2020) (finding a reasonable shareholder could have found disclosures misleading where they "framed a data breach as a potential risk when such a risk had already materialized").

Although a Form 483 is not a final finding of non-compliance by the FDA, *see* ECF No. 106-8 at 2, and thus Defendants argue that no risk of non-compliance by third parties had *fully* materialized, the Court finds that a reasonable investor might have plausibly believed that Defendants' risk disclosure suggested that no third party's compliance had even been called into question. *See Schaeffer*, 2020 WL 7701463, at *11 (disclosure regarding risk of receiving a warning letter was misleading, although a Form 483 letter was "technically not the same as a warning" letter, as investors may have considered it "substantially equivalent" depending on its contents). Despite that Defendants may have been able to correct the Form 483 violations at issue, the Court finds this statement misleading since it inherently suggests that no third-party compliance and data issues had yet arisen. *See Salzman v. ImmunityBio, Inc.*, No. 23-CV-01216-GPC-VET, 2024 WL 3100274, at *9 (S.D. Cal. June 20, 2024) (arguments about "correctability" did not render compliance-related statements not misleading where defendants "never disclosed *any* negative news relating to their manufacturing capacity") (emphasis in original).

The Court rejects Defendants' attempt to frame this risk disclosure as targeted at the risk of *delayed FDA approval*, rather than the risk of third-party noncompliance (which would lead to delayed approval). *See* ECF No. 106-1 at 28. The disclosure clearly connects the two events and, although the delay in FDA approval is the downstream and more serious risk, both events

(compliance failures *and* delayed approval) are framed as risks in the if-then statement at issue. The Court finds this sufficient to render the statement materially misleading. *See ImmunityBio*, 2024 WL 3100274, at *10 ("Defendants' argument fails because it confuses the risk for its consequence.").

Defendants urged for the first time at oral argument that the Second Circuit requires the consequence of the risk to have materialized in order for a risk disclosure to be actionable, citing to the court's decision in *Set Capital LLC v. Credit Suisse Group AG*, 996 F.3d 64 (2d Cir. 2021). While it is true that in *Set Capital* the court appears to have focused on the materialization of the consequence of the risk (negative price impact) in finding warning statements materially misleading, *id.* at 85–86, the decision does not dictate the outcome Defendants suggest, as it does not draw a clear distinction between risk and risk consequence. In any event, courts in the Second Circuit regularly find that the ultimate risk, alternatively framed as the consequence of the risk, need not have materialized for a risk disclosure to be actionable. *See, e.g.*, *Sec. & Exch. Comm'n v. DeFrancesco*, 683 F. Supp. 3d 367, 373–74 (S.D.N.Y. 2023) (finding statement that "[i]f we fail to manage new store openings in a timely and cost-efficient manner, our growth or profits may decrease" misleading because the risk of "fail[ing] to open new stores as rapidly as expected" was "couched as if [it was] a future possibilit[y]," rather than a "realized fact[]"); *In re Tenaris S.A. Sec. Litig.*, 493 F. Supp. 3d 143, 161 (E.D.N.Y. 2020) ("The risk factor disclosures may mislead a reasonable investor because they use the hypothetical qualifier 'if' to warn that a Tenaris employee could fail to comply with the law, when, according to the Amended Complaint, [an employee] had already broken the law.").

The Court recognizes that *Schaeffer* found a very similar risk disclosure not misleading because the ultimate consequence of the risk of third-party noncompliance (failure to

commercialize the drug) had not materialized. *See* 2020 WL 7701463, at *4, *10 (discussing 10-K Statement (C), which stated that "[R]eliance on third-party manufacturers entails additional risks" and that "Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed upon us, including . . . delays, suspension or withdrawals of approval . . . which could significantly and adversely affect supplies of our product candidates and products."). The statement at issue in *Schaffer*, however, did not attach the "hypothetical qualifier 'if'" to the risk of third-party noncompliance, making it less misleading than the statement here. *See Tenaris*, 493 F. Supp. 3d at 161. In any event, although the Court finds *Schaeffer* a helpful persuasive authority, it is not binding on this Court.

Overall, the Court finds this statement misleading, and materially so, in that a reasonable investor would have found that the issuance of the Form 483 would have significantly altered the "total mix" of information available regarding compliance issues of third-party clinical partners. *See Matrixx*, 563 U.S. at 38. Although Defendants were under no obligation to disclose the Form 483, once they chose to discuss issues relating to the Form 483, they had an obligation to provide complete information in a manner that was not misleading. *See Aramic LLC v. Revance Therapeutics, Inc.*, No. 21-CV-09585-AMO, 2024 WL 1354503, at *12 (N.D. Cal. Apr. 2, 2024) (finding that defendant's statement regarding the risk of receiving FDA response "put the Form 483 itself 'in play,'" and noting that "once [defendants] chose to discuss the [FDA] process, they were required to do so in a way that was not misleading"). By framing the risk of third-party noncompliance as a mere possibility when they knew the FDA had issued a Form 483 observing such noncompliance at its audit, Defendants did not provide complete information to reasonable investors; thus, the statement was misleading and is actionable.

f. Paragraph 154: March 16, 2023, Cash Flow Statement

Plaintiffs challenge a further portion of the March 16, 2023, 10-K: BioXcel's statement that it expected it would have sufficient funding for at least twelve months. Am. Compl. ¶ 154.

Plaintiffs have not pleaded sufficient facts to demonstrate why the statement regarding Defendants' cash availability was false or misleading when it was made. They claim that the Form 483 letter had "affected Defendants' ability to meet regulatory milestones required by the Company's financing agreements." *Id.* ¶ 155. However, Plaintiffs have not alleged what these milestones were, and therefore cannot demonstrate the requisite connection between the observations in the Form 483 letter and the inability to comply with the financing agreements, as they need to do to demonstrate why this statement is fraudulent. The agreements, as alleged by Plaintiffs, required BioXcel to reach "certain" unspecified milestones by December 31, 2024. *Id.* ¶¶ 79, 82; *see also* Defs.' Mot. to Dismiss Ex. 8, ECF No. 106-11 at 15 (contract requiring FDA approval of BXCL501 for Alzheimer's by December 31, 2024). Plaintiffs also allege in their confidential witness allegations that there was internal pressure at BioXcel to get the study "'wrapped up' by the end of 2023," as there were "significant milestones" that had to be met for clinical studies. Am. Compl. ¶ 30, 85. That there were potential issues with the study data as of March 2023 does not, as Plaintiffs suggest, plausibly lend itself to the conclusion that Defendants were not in a position to comply with their financing agreements (especially given Plaintiffs provide only vague allegations about what was required by the end of 2023), despite that Defendants updated their position a few months later.

In addition, to the extent this statement is a statement of opinion, the Court finds it nonactionable, as Plaintiffs have not demonstrated it was insincerely or unreasonably held. *See Malin v. XL Cap. Ltd.*, 499 F. Supp. 2d 117, 144–45 (D. Conn. 2007), *aff'd*, 312 F. App'x 400 (2d

Cir. 2009) (noting that "[o]ptimistic statements concerning the future of a company" are generally opinion and puffery, and that, with respect to opinions, falsity analysis "collapses into the scienter requirement") (citations omitted).

Lastly, as the statement is forward-looking and accompanied by meaningful cautionary language, including language that the funding projection was based on assumptions that "may prove to be wrong" such as "the scope, progress, timing, costs, and results of clinical trials," *see* ECF No. 106-4 at 18, it is protected by the PSLRA safe harbor. *See Gissin v. Endres*, 739 F. Supp. 2d 488, 508–11 (S.D.N.Y. 2010) (finding financial projection protected by safe harbor).

g. Paragraphs 156, 158, and 160: March 9, 2023, Statements

Plaintiffs next challenge three statements from a March 9, 2023, earnings call: (1) Defendant Mehta's statement that "the upcoming quarter may represent a watershed moment for [BioXcel]," given the expected release of clinical data from the TRANQUILITY II trial, and that the trial was "fully enrolled" the "data cleaning and verification process has begun"; (2) Defendant Steinhart's statement that "full execution of our strategic financing with Oaktree and Qatar Investment Authority would result in a cash runway into 2025"; and (3) Defendant Risinger's statement that verification of trial data would take eight to ten weeks of daily work to "make sure our data is accurate, correct and precise." Am. Compl. ¶¶ 156, 158, 160.

The Court does not find these statements actionable. First, the description of the upcoming quarter as a potential "watershed moment for the company" due to the announcement of "pivotal clinical data that potentially supports significant market expansion opportunities" for BXCL501 is a clear expression of corporate optimism or puffery, *see, e.g.*, *Shemian*, 2013 WL 1285779, at *23, despite that it is connected to the description of the trial as "fully enrolled" and the commencement of the data cleaning process. Plaintiffs do not allege that the trial was not "fully enrolled" or that

Defendants were not engaged in the process of cleaning and verifying the data. Instead, they again rely on the fact that the Form 483 called into question whether certain patients were properly enrolled, leading to a material risk that the trial data would be inaccurate, and approval and commercialization would be delayed. Am. Compl. ¶ 157. However, as discussed above, this fact does not render the statement about verification of the trial data and excitement for the trial data misleading—if anything, the statement clearly suggests that there were risks the data might not be as-expected, since it needed to undergo a cleaning and verification process. Moreover, Plaintiffs seem to draw too strong an inference from the Form 483 itself, which observes only that Dr. Meyer's site did not have "adequate case histories" or "sufficient documentation" regarding enrollment criteria. ECF No. 106-8 at 3. The Form 483 does not appear to be a determination that the subjects of the investigation were, in fact, not properly enrolled. *Cf. Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 483–85 (S.D.N.Y. 2018), *aff'd in part, vacated in part and on other grounds, remanded sub nom. Abramson v. Newlink Genetics Corp.*, 965 F.3d 165 (2d Cir. 2020) (statements that trial had successfully achieved first milestone of patient enrollment were misleading where confidential witness had observed the acceptance of unqualified patients)). Indeed, the Form 483 itself provides that corrective action to remedy the observations was possible—suggesting the enrollment issues were not a death knell for the trial. *See* ECF No. 106-8 at 2.

Second, Defendant Steinhart's statement that the Company "believes that full execution of our strategic financing with Oaktree and Qatar Investment Authority would result in a cash runway into 2025" is also not actionable. This financial projection is an inherently forward-looking statement. *See Gissin*, 739 F. Supp. 2d at 505–06 (finding similar statement forward-looking). It is also a statement of opinion. *See Malin*, 499 F. Supp. 2d at 144 (noting that the language of

"believes" indicates a statement's "status as opinion[], rather than guarantee[]"). As of March 2023, Plaintiffs have only demonstrated that Defendants were aware of the Form 483 letter—again, and as discussed with respect to the statement in paragraph 154, this is insufficient to suggest, on its own, that Defendants reasonably did not believe the Company would not be able to take advantage of the financing agreements such that they would have known this statement was false or misleading when it was made.

Third, the failure to disclose the Form 483 letter likewise does not render Defendant Risinger's statement that it takes significant work to ensure the data is accurate, correct, and precise misleading. If anything, like Defendant Mehta's statement, this statement suggests that the Company could *not* assume the data it received from the clinical sites was entirely accurate, correct, and precise before going through its own process. That the Company, at this time, had some information that some data may have been compromised by Dr. Meyer's compliance failures does not make a statement about the cautionary measures the Company planned to take to verify and clean the data false or misleading. *See Cohen v. Kitov Pharms. Holdings, Ltd.*, No. 17 CIV. 0917 (LGS), 2018 WL 1406619, at *5 (S.D.N.Y. Mar. 20, 2018) (finding statement not misleading because "there was nothing inaccurate or incomplete about the description of the [] process without the omitted facts").

h. Paragraphs 162 and 164: May 8, 2023, Statements

Likewise, Defendants' statements during a May 8, 2023, earnings call are not actionable. Plaintiffs challenge two statements: (1) Defendant Mehta's statement that the company was "on track to report top line data [from TRANQUILITY II] in June," and that these results were "expected to enable significant potential market expansion"; and (2) Defendant Steinhart's statement that the company expected a "notable uptick in revenue in the second half of the year"

due to "more formulary approvals," and that full execution of the agreements with Oaktree and QIA would "result in a cash runway into 2025." Am. Compl. ¶¶ 162, 164.

Given Plaintiffs' position that the statements are false or misleading due to the concealment of the receipt of the Form 483, and not "because they misled investors about the timing or completion of the TRANQUILITY II trial," *see* Pls.' Opp. Br., ECF No. 108 at 32, the Court does not find these statements actionable. Defendant Mehta's statement that the Company was on track to report the top line data in June was not false, as BioXcel did just that. As for the statements regarding market expansion, an uptick in revenue, and a cash runway into 2025, Plaintiffs do not dispute the accuracy of Defendants' financial projection or other financial metrics. Thus, their allegations appear to largely amount to a fraud by hindsight claim: because Defendants eventually walked back their projections, there must have been something fraudulent about their earlier disclosures. This approach has been rejected in the Second Circuit. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) (noting that Second Circuit has "firmly rejected" fraud by hindsight approach of proving an opinion was not borne out by subsequent events). And, again, more fundamentally, "fatal to Plaintiffs' case" is the absence of a "serious conflict" between the FDA's Form 483 feedback and "Defendants' optimism about FDA approval" with respect to these opinion statements. *See Tongue*, 816 F.3d at 211–12 (finding statement that there was 90% likelihood of achieving milestone and projecting timeline for FDA approval not misleading despite "FDA's interim, albeit repeated, concerns about methodology" of clinical study).

i. Paragraphs 166 and 167: May 9, 2023, Presentation Statements

Plaintiffs next challenge two of Defendant Risinger's statements made during a presentation the next day. First, Defendant Risinger stated that the TRANQUILITY II trial was

"completed," that the last patient had "completed," and the data was locked and undergoing verification, and that the Company was confident in being able to demonstrate efficacy and safety. Am. Compl. ¶ 166. Second, in response to an analyst question about what "the bar" was for a "successful trial," as far as efficacy, he stated that BioXcel was "demonstrating in [the TRANQUILITY II] study whether or not it's safe," and had confidence in being able to "take this package." *Id.* ¶ 167.

The Court finds that the representation in paragraph 166 that the trial was "completed" is a materially misleading statement. Less than two months later in June of 2023, when BioXcel disclosed the investigation and the Form 483 of Dr. Meyer's site, it also disclosed that the FDA "inspection remain[ed] open," as the FDA had not "issued an Establishment Inspection Report." *Id.* ¶ 124. Given that the inspection remained open in June, it stands to reason that the investigation was open at the time of Defendant Risinger's statement in May. *See Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 251 (2d Cir. 2014) (June 2010 report described problems from which one could draw the inference that problems existed one month earlier when statements were made). Although the inspection being open may not be technically the same as the trial being "complete," the Court finds that a reasonable investor may have understood the statement to indicate that there were no outstanding issues with the trial or loose ends for the Company to tie up. *Cf. Schaeffer*, 2020 WL 7701463, at *11 (disclosure regarding risk of receiving a warning letter was misleading, although a Form 483 letter was "technically not the same as a warning" letter, as investors may have considered it "substantially equivalent" depending on its contents); *see also Meyer*, 761 F.3d at 251 (noting a "technically true" statement regarding compliance was nonetheless misleading due to omission regarding existing problems). That such loose ends existed would also have significantly altered the "total mix" of information available regarding the status of the clinical

trial, and investor expectations therefrom. *See Matrixx*, 563 U.S. at 38. Further, as the statement that the trial was complete is a concrete representation of an existing fact, the Court does not find that it is puffery or a forward-looking statement protected by the safe harbor, as Defendants urge.

On the other hand, Defendant Risinger's statement that BioXcel had "high confidence" in demonstrating efficacy and safety is a generic expression of corporate optimism that is not actionable. *See In re Mylan N.V. Sec. Litig.*, No. 2:20-CV-955-NR, 2023 WL 3539371, at *10 (W.D. Pa. May 18, 2023) (statements "too vague to be verified" were corporate puffery, as a reasonable investor would not put stock in these "corporate platitudes"). In addition, there are insufficient facts alleged from which the Court could infer that the Form 483 alone suggested to Defendants that the data from the TRANQUILITY II trial could not demonstrate the efficacy and safety of BXCL501, thus making the subject of the omission and the subject of the statement "too attenuated" to be actionable. *See Cohen*, 2018 WL 1406619, at *5.[5]

j. Paragraph 169: May 9, 2023, 10-Q Statement

On the same day as the presentation, BioXcel disclosed in its Form 10-Q that it "believe[d] that its existing cash and cash equivalents [would] be sufficient to cover its cash flow requirements" for the next 12 months. Am. Compl. ¶ 169.

Plaintiffs allege that Defendants' statement regarding cash availability was misleading in light of the Form 483 and the fact that, just three months later, Defendants walked back this projection. However, as discussed above with respect to paragraph 154 and 164, the Court does not find that the Form 483 alone is sufficient to demonstrate that these financial projections were

[5] Plaintiffs also suggest that the statement is false due to the failure to disclose Dr. Meyer's fabricated email. *See* Am. Compl. ¶ 168. Although BioXcel later disclosed that at some point in May of 2023 it found evidence that Dr. Meyer may have fabricated an email, Plaintiffs do not plead when this discovery occurred. Thus, Plaintiffs have not pleaded with the requisite particularity how the discovery of (and failure to disclose) the fabricated email rendered this statement misleading.

false and misleading, and any reliance on the August 2023 disclosure to prove the falsity of the earlier disclosure is classic fraud by hindsight, which does not make this opinion statement actionable. *See In re Sanofi*, 87 F. Supp. 3d at 528.

k. Paragraph 171: May 25, 2023, Statement

Plaintiffs next challenge Defendant Mehta's statement, on a call to investors, that BioXcel was "excited about BXCL501's recent and upcoming data readout," which "showcases its pipeline within a product potential," and was "confident in the TRANQUILITY II design and plan." Am. Compl. ¶ 171. They allege this statement is false or misleading because Dr. Meyer had violated the TRANQUILITY II design and plan, contrary to Defendant Mehta's assurances of confidence. *See id.* ¶ 172.

The Court agrees with Defendants that this statement is too vague to be anything but inactionable puffery. *See Villare*, 2021 WL 4311749, at *13 (defining puffery as a statement that is so "vague, broad, and non-specific that a reasonable investor would not rely on it") (citation omitted); *In re Mylan*, 2023 WL 3539371, at *10 (statements "too vague to be verified" were corporate puffery, as reasonable investor would not put stock in these "corporate platitudes"). The fact that Dr. Meyer may have violated the design and plan, as described in the Form 483, does not change this conclusion, as this does not provide a reason for BioXcel to be less confident in the design and plan itself.

l. Paragraph 173: June 8, 2023, Statement

A few weeks later, during a presentation at a conference, an analyst asked Defendant Mehta what, hypothetically, the "regulatory expectations" would be after receiving "stupendous data" from TRANQUILITY II at the end of the month. Am. Compl. ¶ 173. Mehta responded that BioXcel's ability to file a sNDA with the FDA would "depend[] on the data" from the

TRANQUILITY II trial and that, after conversation with the FDA, if the FDA "allow[ed] us to file [the sNDA] with TRANQUILITY II, we'll be ready to go, basically, if we don't need to generate anything." *Id.*

The Court does not find that this statement is false or misleading due to the omission of the Form 483. This statement is not a "misrepresentation of existing facts," but rather a "vague and non-specific," but optimistic, assertion about what might occur, on an unspecified timeline. *See Teligent*, 2020 WL 3268531, at *12. Although Defendant Mehta's optimism that there might be a world in which the FDA allowed the Company to submit an sNDA with the TRANQUILITY II data was, "in retrospect . . . misguided," that does not render this statement a misrepresentation of fact. *See id.*; *see also Tongue*, 816 F.3d at 212. In addition, the statement is embedded with cautionary language—that the ability to submit an sNDA depended on the data, and on conversations with the FDA—that would not lead a reasonable investor to believe that no possible obstacle stood between BioXcel and FDA approval. Thus, the Court does not find this statement to be a material misrepresentation.

m. Paragraph 175: June 14, 2023, Statement

Last, Plaintiffs challenge Defendant Risinger's statement to investors during a conference that BioXcel had "a lot of confidence in being able to demonstrate both efficacy and safety" through the TRANQUILITY II trials. Am. Compl. ¶ 175.

For the same reasons as discussed above with respect to paragraph 167, the Court finds that this statement is too vague, and too attenuated from the Form 483, for this statement to be not actionable.

n. In Sum

In sum, the Court finds that Plaintiffs have sufficiently alleged that only the statements contained in paragraphs 151 and 166 discussed above are materially false or misleading due to the failure to disclose the receipt of the Form 483.

2. Scienter

The Court concludes, however, that Plaintiffs have not adequately pleaded Defendants acted with scienter in making those two statements.

Under the PSLRA, plaintiffs must state with particularity the "facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs*, 551 U.S. at 313 (citation omitted). There must be a "strong inference that the defendant acted with the required state of mind." *Id.* at 314 (citing 15 U.S.C. § 78u-4(b)(2)). In the Second Circuit, a plaintiff can plead scienter 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." *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 212 (2d Cir. 2020). The Supreme Court has held that, in order for an inference of scienter to qualify as "strong," it "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The appropriate inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322–23 (emphasis in original). Plaintiffs argue they have met their burden of alleging scienter both because Defendants had the motive and opportunity to commit the fraud and because there is strong circumstantial evidence Defendants consciously misbehaved or acted recklessly. *See* ECF No. 108 at 36, 44–45.

a. Motive and Opportunity

Plaintiffs allege that Defendants' motive to commit fraud is demonstrated by their need to obtain outside funding under the Oaktree and QIA agreements and their suspiciously timed stock sales. Am. Compl. ¶¶ 201–222. The Court does not find Plaintiffs' allegations sufficient to plead scienter with particularity.

With respect to the need to reach milestones to access funding under the financing agreements with Oaktree and QIA, Plaintiffs have not alleged how the "false statements and wrongful disclosures" concerning the concealment of the Form 483 could have helped Defendants to realize the "concrete benefits" available under the financing agreements. *See Malin*, 499 F. Supp. 2d at 150. As alleged by Plaintiffs, BioXcel's goal was to file a sNDA application by the end of 2023 in order to reach financing milestones. *See* Am. Compl. ¶ 206. There is no allegation that there was any financing milestone other than receiving FDA approval for BXCL501 for the treatment of Alzheimer's. Yet, none of the challenged statements, and certainly none of the actionable statements, involve BioXcel or the Individual Defendants misrepresenting that BioXcel had met that milestone, so as to suggest they were positioned to unlock the additional funding. *Cf. Skiadas v. Acer Therapeutics Inc.*, No. 1:19-CV-6137-GHW, 2020 WL 3268495, at *11 (S.D.N.Y. June 16, 2020) (finding motive sufficiently alleged where defendants had incentive to misrepresent FDA's position on approval, in order to obtain further investment to keep the company viable). Thus, it is difficult to see how the motive to receive funding from Oaktree or QIA could have incentivized the statements, since the statements themselves could not help BioXcel meet the alleged milestones—only FDA approval could. The fact that BioXcel may have been anxious about meeting its milestones as a general matter, *see, e.g.*, Am. Compl. ¶ 45 (describing constant projecting of financing), does not suffice to plead a motive to commit fraud with particularity.

The stock sales are a closer call, but are not sufficiently suspicious to create a strong inference of scienter. A plaintiff can demonstrate motive to commit fraud by showing that corporate insiders made misrepresentations "in order to sell their own shares at a profit." *In re Weight Watchers Int'l Inc. Sec. Litig.*, 504 F. Supp. 3d 224, 256 (S.D.N.Y. 2020) (citation omitted).[6] The simple fact that stock was sold is not enough, however—a plaintiff must also demonstrate that the sales were unusual or suspicious. *Id.* This inquiry can turn on a number of factors, including: "(1) the amount of net profits realized from the sales; (2) the percentages of holdings sold; (3) the change in volume of insider defendant's sales; (4) the number of insider defendants selling; (5) whether sales occurred soon after statements defendants are alleged to have known were misleading; (6) whether sales occurred shortly before corrective disclosures or materialization of the alleged risk; and (7) whether sales were made pursuant to trading plans such as Rule 10b5-1 plans." *Id.*; *see also In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74–75 (2d Cir. 2001).

A Rule 10b5-1 trading plan can provide a defense to a securities fraud action. Such plans, among other things, specify the amount of stock to be sold and the date of sale; include a written formula or algorithm for determining the amount of stock to be sold and the date of sale; and do not permit the seller to exercise any subsequent influence over "how, when, or whether to effect purchases or sales." 17 C.F.R. § 240.10b5-1. In securities fraud cases, it is "well established that, ordinarily, trades pursuant to 10b5-1 plans do not raise a strong inference of scienter." *See Villare*, 2021 WL 4311749, at *21. If a 10b5-1 trading plan is entered into "during the Class Period and the Complaint sufficiently alleges that the purpose of the plan was to take advantage of an inflated

[6] The opportunity to commit fraud is usually presumed when individual defendants are high-level corporate insiders, and is not challenged here. *See Oklahoma Firefighters Pension & Ret. Sys. v. Lexmark Int'l, Inc.*, 367 F. Supp. 3d 16, 36 (S.D.N.Y. 2019).

stock price," however, the plan provides no defense to scienter allegations." *Blanford*, 794 F.3d at 309.

The plans at issue here were entered into approximately six and four months *before* the start of the class period, respectively, reducing their value for purposes of pleading scienter. All stock sales made by Defendants Mehta and non-party Nandabalan during the class period were made pursuant to 10b5-1 trading plans entered into on August 31, 2022; all stock sales made by Defendant Steinhart were made pursuant to a 10b5-1 trading plan entered into on June 23, 2022. Am. Compl. ¶ 220. Plaintiffs only conclusorily suggest that Defendants Mehta and Nandabalan entered into trading plans when they were "well-aware of adverse material nonpublic information," *see id.*, without providing any detail as to what such information might be. Of course, it could not have been the existence of the Form 483, as that was not issued until December of 2022. Plaintiffs' conclusory allegation does not sufficiently allege that the purpose of the 10b5-1 plan was to take advantage of an inflated stock price. *See Blanford*, 794 F.3d at 309. The plans therefore provide a defense to Plaintiffs' allegations. *See id.*; *see also In re Aratana*, 315 F. Supp. 3d at 764 (rejecting plaintiffs' scienter argument where complaint did not raise inference that trading "plans were themselves suspect").

Plaintiffs contend the sales are nonetheless suspicious because Defendant Mehta sold on December 15 and 16, 2022, during the FDA inspection, and on June 15 and June 16, 2023, about two weeks before the Company's corrective disclosure regarding the Form 483. *See* Am. Compl. ¶ 210. However, as these too were pursuant to trading plans, they "could not be timed suspiciously." *See Arkansas Pub. Emps. Ret. Sys. V. Bristol-Myers Squibb Co.*, 28 F.4th 343, 355–56 (2d Cir. 2022); *see also City of Coral Springs Police Officers' Ret. Plan v. Farfetch Ltd.*, 565 F. Supp. 3d 478, 489 (S.D.N.Y. 2021) (noting that trades executed in the weeks preceding

corrective disclosures had "in reality been scheduled" well before, pursuant to trading plan, and finding no scienter where plaintiffs failed to allege scienter with respect to the time trading plan was entered into). And the sales of the other insiders who traded, Director Nandabalan and Defendant Steinhart, occurred at least one month prior to the negative announcement. *See Sun v. TAL Educ. Grp.*, No. 22-CV-01015 (ALC), 2023 WL 6394413, at *29 (S.D.N.Y. Sept. 29, 2023) (declining to find sales that took place more than a month before corrective disclosures "inherently suspicious") (citation omitted). That these trades were made pursuant to plans also undercuts any inference to be drawn from the fact that the three insiders did not engage in any trading prior to the class period. *See* Am. Compl. ¶¶ 211, 215, 219. In addition, that the sales are "fairly evenly distributed throughout the Class Period," with some regularity in trading patterns (e.g., Defendant Mehta selling 30,000 shares about every three months, *see* Am. Compl. ¶ 210) suggests the trades were not unusual or suspicious. *See Malin*, 499 F. Supp. 2d at 151–52.

With respect to the proportion of holdings sold, Plaintiffs allege that Defendants Mehta and Steinhart sold over 90% of the shares they "had available during the Class Period," *see* Am. Compl. ¶¶ 211, 219, while Director Nandabalan sold "all of the shares he directly owned," *see id.* ¶ 215. Although Defendants Mehta and Steinhart sold more than 90% of the call options and Restricted Stock Units (RSUs) they exercised during the Class Period, there are no allegations regarding the percentage of these sales in relation to their stockholdings as a whole, as there are for Director Nandabalan. *See Sun*, 2023 WL 6394413, at *29 (failure to allege portion or percentage of holdings did not support inference of suspicious or unusual trading); *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 271, 271 n. 5 (S.D.N.Y. 2009) (comparing sales to overall ownership and total holdings, rather than available units, and finding sale volume not unusual). And, while Director Nandabalan's trading might be the most suspicious in terms of

proportion, he is not alleged to have any involvement in the day-to-day business, nor to have made any of the misstatements at issue. Thus, his sales do not give rise to an inference of scienter. *See Malin*, 499 F. Supp. 2d at 153–54. Overall, then, given the totality of circumstances and the fact that all sales were made pursuant to trading plans, the Court does not find that the insider stock sales raise a strong inference of scienter.

Nor does Plaintiffs' brief allegation that Defendant Mehta and "other executive officers" stood to receive annual bonuses which were tied to performance goals which "generally related to clinical trial performance," among other things, save their scienter allegations. Am. Compl. ¶ 222. As a general matter, performance-based bonuses are insufficient to create an inference of scienter. *See In re CRM Holdings, Ltd. Sec. Litig.*, No. 10 CIV. 975 RPP, 2012 WL 1646888, at *25 (S.D.N.Y. May 10, 2012) (citing *Kalnit v. Eichler*, 264 F.3d 131, 140 (2d Cir. 2000)); *see also Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) ("[if] scienter could be pleaded on [the basis of incentive to increase executive compensation] alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions")). Moreover, Plaintiffs' allegations regarding the bonuses, which do not clearly tie any one metric to the annual bonus, are too vague to meet the pleading standard under Rule 9(b). *See Woolgar v. Kingstone Companies, Inc.*, 477 F. Supp. 3d 193, 234 (S.D.N.Y. 2020) (rejecting plaintiff's motive theory where plaintiff did not explain the connection between compensation or bonuses and alleged misstatements).

b. Circumstantial Evidence

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant." *Kalnit*, 264 F.3d at 142 (citation omitted). However, the "strength of the circumstantial allegations must be correspondingly

greater." *Id.* (citation omitted). Courts may look to circumstances such as whether defendants "(1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to monitor." *Blanford*, 794 F.3d at 306 (citation omitted).

As circumstantial evidence here, Plaintiffs point to Defendants' knowledge of the Form 483 letter, the importance of the TRANQUILITY II trials to BioXcel's business and to analysts, the hands-on involvement of Defendants Mehta and Risinger, and the fact that Defendants Mehta and Steinhart signed Sarbanes-Oxley certifications. Am. Compl. ¶¶ 177–200.

The Court agrees with Defendants that their awareness of the Form 483 does not demonstrate recklessness. Even if, in hindsight, two of Defendants' statements were misleading by omission due to the failure to disclose the Form 483, this alone does not support an inference that they were intentionally or recklessly so. *Cf. Schaeffer*, 2020 WL 7701463, at *12 (knowledge of Form 483 may not have been "knowledge of facts" contradicting public statements, as even if statement could have been misleading, it "does not necessarily follow that Defendants were reckless in disregarding that possibility"). With respect to the statement regarding trial completion specifically, the Court has noted that there may be technical distinctions between what the Form 483 meant and what the statements represented—for instance, that the inspection remaining open may not be directly inconsistent with the trial being complete. While these differences may not be salient to the reasonable investor, they are also not necessarily consistent with an inference that Defendants were deliberately hiding the Form 483. And with respect to the risk disclosure, the fact that Defendants "intentionally put the public on notice" of the risk of noncompliance, "[e]ven if those statements in hindsight were incomplete and misleading . . . strongly negates an inference

that [Defendants] were acting recklessly or consciously" in making the misstatements. *See City of Coral Springs*, 565 F. Supp. 3d at 490. Although the importance of the TRANQUILITY II trials to BioXcel's business provides support for an inference of scienter as a general matter, *see ImmunityBio*, 2024 WL 3100274, at *11, the Court does not find it creates a strong inference of scienter in this case, where Defendants did not directly make false representations about their FDA compliance or ability to secure FDA approval on a specific timeline.

This conclusion is not undermined by the information from the confidential witnesses. The majority of the confidential witness allegations are quite vague and conclusory, and generally untethered from the Individual Defendants and the statements at issue. For instance, Plaintiffs allege, through CW7, that Defendant Mehta was "very involved" and a "hands-on CEO," Am. Compl. ¶ 195. And through CW5, who worked directly with Defendant Risinger, Plaintiffs allege that Defendant Risinger was "kind of monolithic," and made "all the development decisions . . . on a microscopic level"). *Id.* ¶ 197. However, both confidential witnesses left BioXcel in April and March of 2022—between eight and nine months before the start of the FDA inspection and the first of the alleged misstatements. *Id.* ¶¶ 46, 50. Thus, the Court does not find this information "probative of [Defendants'] mental state" when they made the alleged misstatements. *See Sun*, 2023 WL 6394413, at *31. The confidential witness allegations, as a whole, largely provide "generic and conclusory allegations based upon rumor or conjecture." *Woolgar*, 477 F. Supp. 3d at 218–19 (citation omitted). Moreover, no information provided by the confidential witnesses is inconsistent with the challenged statements. *Id.* at 221.

Thus, viewing the allegations as a whole, Plaintiffs do not adequately allege scienter. The Court cannot find that the inference of scienter is "at least as compelling" as the non-culpable inference urged by Defendants. *See Tellabs*, 551 U.S. at 324.

3. Loss Causation

"Loss causation is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005) (internal quotation marks and citation omitted). To establish loss causation, a plaintiff must allege that the "misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Id.* at 173.

Since Plaintiffs' failure to adequately plead scienter is "dispositive," the Court "need not reach the issue of loss causation." *See In re Plug Power, Inc. Sec. Litig.*, No. 21 Civ. 2004 (ER), 2022 WL 4631892, at *20 (S.D.N.Y. Sept. 29, 2022) (collecting cases).

4. Section 20(a) Claim

Section 20(a) of the Exchange Act "imposes derivative liability on parties controlling persons who commit Exchange Act violations." *In re Vivendi*, 838 F.3d at 238 n.6 (internal quotation marks and citation omitted). To establish a claim under Section 20(a), 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, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

Because the Court has found that Plaintiffs fail to state a claim under Section 10(b), their Section 20(a) claim necessarily also fails. Defendants' motion to dismiss Plaintiff's Section 20(a) claim is therefore granted.

IV. CONCLUSION

For the reasons described herein, Plaintiffs' motion to strike is DENIED, and Defendants' motion to dismiss is GRANTED. Although Defendants argue in a footnote that Plaintiffs should

not be granted leave to amend due to the futility of amendment, *see* ECF No. 106-1 at 47 n.19, the Court will grant Plaintiffs leave to amend to attempt to cure any pleading deficiencies identified herein. *See Sun*, 2023 WL 6394413, at *34 (S.D.N.Y. Sept. 29, 2023) (noting it is the "usual practice" in the Second Circuit to provide leave to amend upon granting a motion to dismiss).

Plaintiffs may file a Second Amended Complaint to attempt to remedy the deficiencies identified herein by **August 1, 2024**.

SO ORDERED at Hartford, Connecticut, this 11th day of July, 2024.

/s/ Sarala V. Nagala
SARALA V. NAGALA
UNITED STATES DISTRICT JUDGE