UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STEVEN B. CHRISTIANSEN, on behalf of himself and a class of similarly situated investors, Plaintiff, -against- SPECTRUM PHARMACEUTICALS, INC., THOMAS J. RIGA, FRANCOIS J. LEBEL, and NORA E. BRENNAN, Defendants.	22-CV-10292 (VEC) OPINION & ORDER

VALERIE CAPRONI, United States District Judge:

Plaintiff in this putative securities fraud class action alleges that Spectrum Pharmaceuticals, Inc. ("Spectrum" or the "Company") and its executives (together, "Defendants") made false or misleading statements about Spectrum's progress securing accelerated U.S. Food and Drug Administration ("FDA") approval of a new drug to treat lung cancer. Plaintiff brings claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a) (the "Exchange Act"), and related regulations. *See generally* Consolidated Class Action Complaint (the "CCAC"), Dkt. 67.[1] On July 25, 2023, Defendants moved to dismiss the action for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). *See* Defs. Not. of Mot., Dkt. 69. For the following reasons, Defendants' motion is DENIED in part and GRANTED in part.

[1] On January 12, 2023, the Court consolidated this action with *Cummings v. Spectrum Pharms., Inc.*, 22-CV-10677 (VEC) (S.D.N.Y.). *See* Order, Dkt. 18. On February 15, 2023, the Court consolidated this action with *Carneiro v. Spectrum Pharms., Inc.*, 23-CV-00767 (S.D.N.Y.). *See* Order, Dkt. 39. On March 21, 2023, the Court appointed Steven Christiansen as lead plaintiff for the putative class. *See* Opinion & Order, Dkt. 63.

BACKGROUND[2]

Spectrum is a publicly traded biopharmaceutical company that develops drugs to treat cancer. CCAC ¶ 46. Thomas Riga ("Riga") is Spectrum's Chief Executive Officer ("CEO"). *Id.* ¶¶ 1, 47. Francois Lebel ("Lebel") formerly was Spectrum's Executive Vice President ("EVP") and Chief Medical Officer ("CMO"). *Id.* ¶¶ 1, 48. Nora Brennan ("Brennan") is currently Spectrum's EVP and Chief Financial Officer ("CFO"). *Id.* ¶¶ 1, 49.

Plaintiff Steven Christiansen purchased Spectrum common stock between March 17, 2022, and September 22, 2022 (the "Class Period"). *Id.* ¶¶ 1, 45. Defendants' conduct during the Class Period allegedly fraudulently inflated Spectrum's share price, causing Plaintiff damages. *Id.* ¶¶ 45, 148–51.

I. Spectrum's Development of Poziotinib

Over the past several years, Spectrum has conducted clinical trials with the goal of achieving FDA approval of poziotinib ("pozi") — a drug intended to treat certain lung cancer patients. *Id.* ¶¶ 2, 3, 66.[3] From 2017 to 2020, Spectrum conducted studies of the drug's efficacy and safety, including by administering 16 mg of pozi once per day to patients in Cohort 2 (the "Cohort 2 Study"). *Id.* ¶¶ 5, 67–68, 72.[4] In November 2021, despite the FDA's concerns that Spectrum did not have adequate data to justify the dosage used in the Cohort 2 Study, but with

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[2] For the purposes of this Opinion, the Court assumes the truth of the facts alleged in the CCAC. The Court also considers materials incorporated into the CCAC by reference, documents that are integral to the CCAC, and materials subject to judicial notice. *See Colbert v. Rio Tinto PLC*, 824 F. App'x 5, 10 n.5 (2d Cir. 2020); *Cohen v. Rosicki, Rosicki & Assocs., P.C.*, 897 F.3d 75, 80 (2d Cir. 2018).

[3] As of May 26, 2023, pozi had not been approved by the FDA, and Spectrum had deprioritized its development. CCAC ¶ 38. FDA approval, which requires three phases of clinical trials, is necessary for the drug to be marketed to the public. *Id.* ¶¶ 38, 52.

[4] Clinical trials are designed, in part, to determine an "optimized" dosage regime. That is achieved when efficacy is maximized and toxicity is minimized. *Id.* ¶ 9. In or around July 2017, the FDA expressed concerns to Spectrum that 16 mg of pozi once per day was not an "optimized" dosage regimen. *Id.* ¶ 70; *see also* FDA Briefing, Dkt. 71-1, at 13. The FDA expressed similar concerns in subsequent years, as discussed *infra*. *See, e.g.*, CCAC ¶¶ 75, 77.

the FDA's "agree[ment]," Spectrum applied for accelerated FDA approval of pozi using data from that study. *Id.* ¶¶ 4–6, 80; FDA Briefing, Dkt. 71-1, at 14.[5]

For the FDA to grant accelerated approval of pozi, Spectrum needed promptly to launch an additional, confirmatory clinical trial (the "Pinnacle Study"). CCAC ¶¶ 4, 6, 8, 58, 60.[6] Spectrum announced to investors in November 2021 that it intended to confirm the methodology for the Pinnacle Study with the FDA soon. *Id.* ¶¶ 7–8, 79.

In December 2021, Spectrum discussed the design of the Pinnacle Study with the FDA. *Id.* ¶ 83. Spectrum disagreed with FDA officials about the appropriate dosage for the Pinnacle Study; at least some FDA officials told Spectrum that it should conduct additional trials to collect more dosage optimization data before moving forward with the Pinnacle Study.[7] *Id.* ¶ 84.

In February 2022, Spectrum again discussed the design of the Pinnacle Study with the FDA. *Id.* ¶ 85. FDA again expressed concerns about: Spectrum's delays in initiating the Pinnacle Study; Spectrum's lack of dosage optimization data for pozi; and the drug's safety profile. *Id.*; *see also* FDA Briefing at 15.

That same month, Spectrum issued a press release indicating that, by November 24, 2022, the FDA would act on Spectrum's application for accelerated approval of pozi, and that the agency had "reiterated the importance of having [the Pinnacle Study] substantially enrolled" at the time of approval. CCAC ¶¶ 8, 86.

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[5] Data from the Cohort 2 Study was the "[p]rimary" data that supported Spectrum's application. FDA Briefing at 16. Spectrum also submitted "[s]upportive" data from Cohorts 1, 3, 4, 5, 6, and 7. *Id.* Spectrum's supportive data included data using different dosage regimens. *Id.* at 16–17.

[6] FDA guidance states that confirmatory clinical trials should "usually be already underway" at the time of a drug sponsor's application for accelerated FDA approval. CCAC ¶ 59; *see also* FDA Briefing at 10.

[7] According to the September 22, 2022, FDA briefing (the "FDA Briefing") cited in the CCAC, Spectrum and the FDA "agreed" that 8 mg of pozi twice daily "was preferable" to the dosage regimen Spectrum had initially proposed. *See* FDA Briefing at 14.

II. Defendants' Allegedly Fraudulent Conduct

Plaintiff asserts that, during the Class Period, Defendants made false or misleading representations and omissions primarily to the effect that (1) Spectrum had optimized pozi's dosage; (2) Spectrum and the FDA were aligned on the Pinnacle Study's dosage regimen; (3) patients had enrolled in the Pinnacle Study; and (4) the FDA would likely approve pozi. *Id.* ¶¶ 87–104, 122–47. According to Plaintiff, Defendants were motivated to rush the Pinnacle Study and mislead investors about their progress and interactions with the FDA because Spectrum was financially distressed and needed cash and because Spectrum's executives wanted to sell their Company shares at artificially inflated prices. *Id.* ¶¶ 18, 152–57.[8]

A. The March 17, 2022 Investor Call

On March 17, 2022, during a conference call with Spectrum investors and analysts, Spectrum stated, "[O]ver time, we have learned to optimize some of the tolerability and abate some of the [adverse events] here with [pozi's clinical trial] dosage." *Id.* ¶¶ 9, 87, 123. According to Plaintiff, Spectrum thereby misrepresented that it had identified the optimal pozi dosage regimen to balance efficacy and safety, creating the false impression that Spectrum had adequate optimization data. *Id.* ¶¶ 9, 124. According to Plaintiff, that representation was false and misleading because, unbeknownst to investors, the FDA had by that time told Spectrum repeatedly that its dosing data were inadequate for FDA approval. *Id.* ¶¶ 10–11, 87, 124. During

[8] From April 2022 through May 12, 2022, Spectrum sold 1.4 million shares of its common stock for $1.4 million. CCAC ¶ 19. From May 13, 2022, through June 30, 2022, Spectrum sold over 4 million shares of its common stock for approximately $3.5 million. *Id.* ¶¶ 21, 95. From July 2022 through August 12, 2022, Spectrum sold 5.1 million shares of its common stock for approximately $4.5 million. *Id.* ¶¶ 23, 97. From August 13, 2022, through September 30, 2022, Spectrum sold close to 14 million shares of its common stock for approximately $17 million. *Id.* ¶¶ 28, 103.

During the Class Period, Lebel sold 15,335 shares of Spectrum common stock for approximately $14,000, and Brennan sold 3,569 shares of Spectrum common stock for approximately $3,000. *Id.* ¶¶ 48, 49, 88, 97. None of the individual Defendants purchased Spectrum common stock on the open market during that time. *Id.* ¶ 157. Plaintiff does not allege that Riga sold any Spectrum common stock.

the same conference call, Spectrum stated that it would disclose the Pinnacle Study's design and details after the first patient was enrolled in the trial. *Id.* ¶ 12.

B. The May 12, 2022 Disclosures

On May 12, 2022, Spectrum issued a press release stating that the Pinnacle Study had been "initiated" and that patients were "being randomized 2-to-1" into treatment groups receiving either 8 mg of pozi twice daily or a different drug. *Id.* ¶¶ 13, 89, 125; *see also* May 12, 2022 Press Release, Dkt. 71-6, at 2.

During a conference call with investors that day, Spectrum discussed the design of the Pinnacle Study. CCAC ¶ 126. When asked how Spectrum planned to reconcile the difference in dosage regimens between the Cohort 2 Study (16 mg per day in a single dose) and the Pinnacle Study (16 mg per day in two doses, also known as 8 mg "BID"), Spectrum stated, "[W]e believe that [16 mg per day] is a safe and effective dose and obviously aligned with [the] FDA on [the Pinnacle Study] to go with [the 8 mg BID dose]." *Id.* ¶¶ 14, 89, 128. These representations were false and misleading, Plaintiff claims, because they created the false impression (1) that the Pinnacle Study was enrolling patients, even though no patients had enrolled in the study; and (2) that Defendants and the FDA were aligned on the Pinnacle Study's dosage regimen, even though the FDA had previously warned Defendants that "it would be at their own risk to move forward" without adequate optimization data. *Id.* ¶¶ 15–16, 89–91, 127, 129, 132.

Spectrum stated during the conference call that it was "very logical that the FDA could have additional questions on dosing" in light of the Company's decision to use different dosing for the Pinnacle Study than for the Cohort 2 Study. *Id.* ¶ 130. That representation was false and misleading, Plaintiff claims, because Spectrum knew that dosage data was a "sticking point" for the FDA, that the agency had unanswered questions and ongoing concerns about the Company's

dosage data, and that it did not agree with the Company's anticipated design for the Pinnacle Study. *Id.* ¶ 131.

Following these disclosures, some analysts reported that Spectrum had "noted that it ha[d] started enrolling patients" in the Pinnacle Study, that the Pinnacle Study "bode[d] well for the potential [FDA] approval," and that Spectrum had "announced alignment w/FDA on confirmatory [study] design . . . ." *Id.* ¶¶ 17, 92–94, 132.

Spectrum filed its March 2022 Form 10-Q with the SEC that day. *Id.* ¶ 133. According to Plaintiff, the 10-Q identified as a risk factor that clinical trials could be delayed due to various issues including "difficulties in identifying and enrolling patients," "slower than anticipated patient enrollment," and Spectrum's "inability to recruit and enroll patients to participate in clinical trials . . . ." *Id.*; *see also* March 2021 Form 10-K, Dkt. 71-2, at 16 (incorporated by reference into the March 2022 Form 10-Q, Dkt. 71-7).[9] According to Plaintiff, these warnings were false and misleading because the risk of delayed studies had already materialized; Spectrum had already failed to enroll patients in the Pinnacle Study, and the FDA had already expressed concerns to Spectrum about delays in enrolling patients. CCAC ¶ 134. Plaintiff alleges that Spectrum also failed to disclose known uncertainties about whether pozi would be approved in the management discussion and analysis section ("MD&A") of the Form 10-Q. *Id.* ¶ 135.[10]

On May 18, 2022, FDA officials again expressed concerns to Spectrum about pozi's safety profile, delayed enrollment in the Pinnacle Study, and Spectrum's inadequate dosage optimization data. *Id.* ¶¶ 20, 96; *see also* FDA Briefing at 15.

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[9] Although the March 2021 Form 10-K, incorporated into the CCAC by reference, discusses those issues in connection with a risk factor, the identified risk factor is that "[c]linical trials may fail to demonstrate the safety and efficacy of our drug products, which could prevent or significantly delay obtaining regulatory approval." March 2021 Form 10-K, Dkt. 71-2, at 16.

[10] Spectrum made the same alleged misrepresentations and omissions in its June 2022 Form 10-Q filed on August 12, 2022. *Id.* ¶¶ 145–47; *see also* June 2022 Form 10-Q, Dkt. 71-8.

C. The June 16, 2022 Statement

On June 16, 2022, Spectrum said during a conference that it was on "the cusp of not just one, but two FDA approvals with the action dates in the next five months." CCAC ¶ 136. Spectrum's statement was false and misleading, Plaintiff claims, because no patients had enrolled in the Pinnacle Study and because the FDA had recently reiterated its concerns about pozi's efficacy, Spectrum's lack of optimization data, and delays in the Pinnacle Study. *Id.* ¶ 137.

On July 28, 2022, in meetings with Spectrum, FDA officials again expressed concerns about pozi's safety profile, delayed enrollment in the Pinnacle Study, and Spectrum's inadequate dosage optimization data. *Id.* ¶¶ 22, 98; *see also* FDA Briefing at 15.

D. The August 11, 2022 Representations

On August 11, 2022, Spectrum issued a press release stating that the Pinnacle Study was "in progress" and that patients were "being randomized 2-to-1" into treatment groups receiving either 8 mg of pozi BID or a different drug. CCAC ¶¶ 24, 138. That same day, an analyst asked Spectrum during an investor call how many "sites" were "active" on the Pinnacle Study, what percentage of target patients had been enrolled in the Pinnacle Study, and the necessary enrollment for Spectrum to meet the FDA's November 24, 2022 deadline for review of its application. *Id.* ¶¶ 25, 99. In response, Spectrum said, "[W]e're very active in opening site[s]. But as I'm sure you know, it takes a long time to open sites. We have some site[s] open. I'm not going to give you numbers today. I'm not going to speak directly to enrollment today. And so we're moving as fast as we can internationally as well as in North America." *Id.* ¶¶ 26, 100, 142. Spectrum also represented that the FDA had indicated that no particular number of patients was required to be enrolled in the Pinnacle Study by the time the FDA acted on its application. *Id.* ¶

142. Spectrum indicated on the same investor call that it was aware of the FDA's guidance on the accelerated approval process. *Id*. ¶ 102.

According to Plaintiff, as reflected in a contemporaneous analyst report, these representations "reaffirmed investors' impression" of the status of the Pinnacle Study and the likelihood of FDA approval. The analyst report relied on by Plaintiff noted that the Pinnacle Study's dosage regimen "bode[d] well for the potential [FDA] approval." *Id.* ¶¶ 27, 101, 144.

These representations were false and misleading, Plaintiff claims, because no patients had enrolled in the Pinnacle Study and because the FDA had recently reiterated its concerns about pozi's efficacy, Spectrum's lack of optimization data, and delays in the Pinnacle Study. *Id.* ¶¶ 141, 143.

III. The FDA Speaks and Spectrum's Stock Price Declines

Before the market opened on September 20, 2022,[11] the FDA released a briefing report (the "FDA Briefing") in advance of its meeting with Spectrum to review pozi. *Id.* ¶ 30. The FDA Briefing disclosed that FDA officials had repeatedly expressed concerns to Defendants about pozi's safety profile, delayed enrollment in the Pinnacle Study, and Spectrum's inadequate dosage data. *Id.* ¶¶ 31, 105. The FDA Briefing revealed that no patients had been enrolled in the Pinnacle Study and that initial results from the study were not anticipated for another four to five years. *Id.* ¶ 105.

Spectrum's share price declined that day by $0.40 per share, or more than 37%. *Id.* ¶¶ 32, 106. Analysts issued reports stating that the FDA's announcements were "[n]egative" for the drug's approval and that the FDA's upcoming meeting with Defendants "could be more

[11] On September 8, 2022, in meetings with Spectrum, FDA officials had reiterated concerns about pozi's safety profile, delayed enrollment in the Pinnacle Study, and Spectrum's inadequate dosage data for the drug. CCAC ¶¶ 29, 104; *see also* FDA Briefing at 15.

argumentative than [analysts] initially thought" because the Pinnacle Study had not yet started; the FDA's "focus on dosing optimization" gave analysts "some pause." *Id.* ¶ 33.

The FDA's Oncologic Drugs Advisory Committee (the "FDA Committee") met with Spectrum to discuss pozi's approval on September 22, 2022. *Id.* ¶¶ 35, 108. FDA Committee members stated that the agency had repeatedly informed Spectrum (from 2017 to 2021) that its plans for dosage optimization were not adequate; that Spectrum had failed to address the FDA's concerns about optimization; that no patients had been enrolled in the Pinnacle Study despite ongoing discussions with the FDA about the need for prompt enrollment; that the FDA had not reached agreement with Spectrum on the Pinnacle Study's dosage regimen; that the FDA had warned Defendants that they could only move forward with the Pinnacle Study "at their own risk" given inadequate dosage data; and that Spectrum's failure adequately to optimize pozi's dosage in time was the "fatal [] flaw" in its drug development program. *Id.* ¶¶ 35, 108–13.

When asked by a member of the FDA Committee whether the Pinnacle Study was "really underway" even though patients were not yet enrolled, Spectrum said that the Pinnacle Study was "very much underway." *Id.* ¶¶ 35, 115. "[W]e never expected patients at this stage, and we're on track." *Id.* In response, an FDA Committee member stated that agency guidance for accelerated approvals "clearly states that it is anticipated that these trials should be ongoing, and by ongoing, we mean accrual of patients to the study at the time of the accelerated approvals . . . ." *Id.* ¶ 117.

At the end of the meeting, the FDA Committee voted nine to four to recommend that the FDA not approve Spectrum's application for accelerated approval because pozi's benefits did not outweigh its risks. *Id.* ¶¶ 35, 118. Spectrum issued a press release to that effect. *Id.* ¶ 118.

The next day, Spectrum's share price declined by $0.20 per share, or more than 31%. *Id.* ¶¶ 36, 119. Analysts issued reports stating that the vote of the FDA Committee was "negative for potential approval of poziotinib," that views expressed during the meeting "[did] not bode well" for FDA approval, and that the negative vote followed "an excruciating FDA review that had been previously evident in [Spectrum's] correspondence with the agency," going back to February 2022. *Id.* ¶ 37.

On November 25, 2022, Spectrum disclosed that it had received a letter from the FDA indicating that it would not approve the pending application for pozi; Spectrum announced that it would "de-prioritize" the drug's development. *Id.* ¶¶ 38, 120.

On January 4, 2023, Spectrum disclosed that Lebel had resigned from the company as EVP and CMO, effective December 31, 2022. *Id.* ¶¶ 39, 121.

DISCUSSION

To survive a motion to dismiss for failure to state a claim upon which relief can be granted, "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)). In general, "a complaint does not need to contain detailed or elaborate factual allegations, but only allegations sufficient to raise an entitlement to relief above the speculative level." *Keiler v. Harlequin Enters. Ltd.*, 751 F.3d 64, 70 (2d Cir. 2014) (citation omitted). When considering a Rule 12(b)(6) motion to dismiss, the Court draws all reasonable inferences in the light most favorable to the plaintiff. *See Gibbons v. Malone*, 703 F.3d 595, 599 (2d Cir. 2013) (citation omitted). The Court is not required, however, to "accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

Section 10(b) of the Securities Exchange Act ("Section 10(b)") makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe. . . ." 15 U.S.C. § 78j(b). The SEC's implementing rule, Rule 10b–5, makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5. To state a claim under these provisions, a plaintiff must plausibly plead six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Pac. Inv. Mgmt. Co. v. Mayer Brown LLP*, 603 F.3d 144, 151 (2d Cir. 2010) (quoting *Stoneridge Inv. Partners v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Only the first and second elements — a material misrepresentation or omission and scienter — are at issue in Defendants' motion to dismiss.

Because claims under Section 10(b) and Rule 10b–5 sound in fraud, a heightened pleading standard applies. Pursuant to Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"), the complaint 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." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007) (citing *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000)); *see also* 15 U.S.C. § 78u–4(b)(1)(B).

I. Plaintiff Adequately Alleges That Certain Statements or Omissions by Spectrum Were Actionably False or Misleading

Plaintiff adequately alleges that (1) Spectrum's statement that the Company and the FDA were aligned on the dosage regimen for the Pinnacle Study, CCAC ¶ 128; and (2) Spectrum's statements that Spectrum had begun to enroll patients in the Pinnacle Study, *id.* ¶¶ 125–27, 138–43, were actionably false or misleading. Plaintiff has not adequately alleged that Spectrum's statements regarding (1) pozi's dosage optimization, *id.* ¶¶ 123, 130; (2) the FDA's patient enrollment threshold for approval, *id.* ¶ 142; (3) the risks of achieving approval for pozi, *id.* ¶ 133; and (4) the likelihood of pozi being approved by the FDA, *id.* ¶ 136, were false or misleading under the Exchange Act.[12]

A. Legal Standard

False or misleading statements and omissions are actionable under the Exchange Act. Whether a statement is false or misleading is "evaluated not only by 'literal truth,' but by 'context and manner of presentation.'" *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (quoting *Operating Loc. 469 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 92 (2d Cir. 2010)). To base a claim on an omission — such as failing to disclose a material business risk — a plaintiff must also plead that the defendant had a duty to disclose the omitted fact. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015). Under Rule 10b–5, it is unlawful, *inter alia*, to "omit to state a material fact necessary in order to make the statements made . . . not misleading." 17 C.F.R. § 240.10b–5(b). Thus, "once a company speaks on an issue or topic, there is a duty to tell the whole truth." *Meyer v. Jinkosolar Holdings Co.*,

[12] As discussed *infra* n.24, the Court does not address Plaintiff's allegations regarding the MD&A section of Spectrum's Forms 10-Q, *see* CCAC ¶¶ 135, 147, because Defendants did not move to dismiss Plaintiff's claims based on statements in the MD&A.

761 F.3d 245, 250 (2d Cir. 2014). "[S]o-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." *S.E.C. v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011), *rev'd on other grounds*, 568 U.S. 442 (2013); *see also In re Vivendi, S.A. Secs. Litig.*, 838 F.3d 223, 240 (2d Cir. 2016) ("The rule against half-truths, or statements that are misleading by omission, comports with the common-law tort of fraudulent misrepresentation, according to which a statement that contains only favorable matters and omits all reference to unfavorable matters is as much a false representation as if all the facts stated were untrue." (internal quotation marks and citation omitted)).

Risk disclosures are actionable half-truths when the company warns about a risk that could have an impact on its business when, in fact, that risk has already materialized. *In re Facebook, Inc. IPO Secs. & Derivative Litig.*, 986 F. Supp. 2d 487, 516 (S.D.N.Y. 2013); *see also Plumbers & Pipefitters Nat'l Pension Fund v. Tableau Software, Inc.*, No. 17-CV-5753 (JGK), 2019 WL 2360942, at *4 (S.D.N.Y. Mar. 4, 2019) (holding that risk disclosures were misleading where "the company was already experiencing significant setbacks [from the disclosed risk] . . . at the time the 10-K was issued" without also disclosing that the setback had occurred).

An opinion statement is not actionable unless the speaker disbelieved the statement at the time it was made, the opinion contained "one or more embedded factual statements that can be proven false," or the opinion "implie[d] facts or the absence of contrary facts" and the speaker knows or reasonably should know of different material facts that were omitted. *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 175 (2d Cir. 2020) (citing *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 188 (2015) (explaining that a speaker

who expresses belief that his conduct is lawful implies that he has consulted the law — which would be an actionable factual statement if untrue)).

Statements that are too vague or general to be relied upon — puffery — are actionable only when the speaker "knew that the contrary was true." *Abramson*, 965 F.3d 165 at 173–74; *see also ECA, Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009). "Whether a representation is 'mere puffery' depends, in part, on the context in which it is made." *In re Petrobras Secs. Litig.*, 116 F. Supp. 3d 368, 381 (S.D.N.Y. 2015) (citation omitted). "People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) (internal quotation marks and citation omitted).

Forward-looking statements are not actionable if (1) they are "identified and accompanied by meaningful cautionary language," (2) they are "immaterial," or (3) "the plaintiff fails to prove that [the forward-looking statement at issue] was made with actual knowledge that it was false or misleading." *Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010) (citation omitted).

B. Application

1. Actionable Statements

i. Alignment with the FDA on the Pinnacle Study's Dosage

According to Plaintiff, Spectrum's May 12, 2022 statement, "[W]e believe that [16 mg per day] is a safe and effective dose and obviously aligned with [the] FDA on [the Pinnacle Study] to go with [the 8 mg BID dose]," was materially false and misleading because Spectrum

and the FDA never agreed on the Pinnacle Study's design. CCAC ¶ 128.[13] Plaintiff adequately alleges that Spectrum's statement was false or misleading because FDA officials had allegedly told Defendants that Spectrum did not have adequate data for the agency to approve Spectrum's dosing regimen for the Pinnacle Study.

The parties do not dispute that Spectrum's May 12, 2022 statement communicated that there was an agreement between Spectrum and the FDA that 8 mg BID was an appropriate dosage regimen for the Pinnacle Study.[14] Plaintiff adequately alleges that Spectrum's statement is actionable because FDA officials had allegedly communicated to Defendants weeks prior that Spectrum needed more data before the FDA could determine that the proposed dosage for Pinnacle Study participants was optimized.[15] *See id.* ¶¶ 84–85; FDA Briefing at 14. Spectrum's statement that the FDA had agreed to the 8 mg BID dosing regime was, therefore, false. *See Shanawaz v. Intellipharmaceutics Int'l Inc.*, 348 F. Supp. 3d 313, 324 (S.D.N.Y. 2018)

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[13] Defendants primarily argue that Spectrum's statement was not false or misleading because (1) Spectrum and the FDA had agreed that 8 mg BID was an appropriate dosage regimen for the Pinnacle Study; (2) Spectrum's statement did not embed a material falsity, which is necessary for an opinion to be actionable; and (3) Spectrum's statement did not trigger a duty to disclose the FDA's concerns about the Pinnacle Study. *See* Defs. Mem., Dkt. 70, at 10–13.

In response, Plaintiff primarily argues that (1) the FDA warned Defendants that additional data were necessary before it would sign off on Spectrum's plan to administer 8 mg BID for the Pinnacle Study; (2) Spectrum's statement was not one of opinion, but one of present fact; (3) even assuming that Spectrum's statement was an opinion, it embedded the falsity that Spectrum and the FDA had an agreement about the Pinnacle Study, thus triggering an obligation to disclose conflicting facts. *See* Pl. Mem., Dkt. 75, at 14–18.

[14] *See* Pl. Mem. at 7, 14–16; Defs. Reply Mem., Dkt. 84, at 5. The Court is not convinced that the parties' reading of the statement is necessarily correct. A reasonable investor may have understood Spectrum to be communicating that its anticipated use of a dosing regimen for the Pinnacle Study that was different from the dosing regimen it had used for the Cohort 2 Study — as opposed to the 8 mg BID dosage regimen specifically — aligned with FDA guidance. At the motion-to-dismiss stage, however, the Court adopts the parties' interpretation of the statement, which is more favorable to Plaintiff. *See IWA Forest Indus. Pension Plan v. Textron Inc.*, 14 F.4th 141, 147 (2d Cir. 2021) (concluding that the district court's "alternative interpretation of the challenged statements [under the Exchange Act] was not unreasonable" but "premature" at the motion-to-dismiss stage and reversing the district court's dismissal).

[15] Plaintiff argues that the statement is one of fact, not one of opinion. *See* Pl. Mem. at 16. This distinction is not "significan[t]" at this stage in light of *Omnicare*, which renders opinions actionable if they embed false statements of fact. *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 176 (2d Cir. 2020).

(concluding that defendants' public statements about an application for expedited FDA approval were actionable misrepresentations under the Exchange Act because defendants' statements were "false when made" in light of FDA officials' contrary contemporaneous views of the application); *In re OSI Pharms., Inc. Secs. Litig.*, No. 04-CV-5505 (JS) (WDW), 2007 WL 9672541, at *8–9 (E.D.N.Y. Mar. 31, 2007) (concluding that defendants' statements about a clinical trial were false or misleading under the Exchange Act because defendants' statements were allegedly contradicted by clinical trial results at their disposal).

Defendants urge the Court to conclude otherwise because the FDA Briefing states that, on December 13, 2021, Spectrum and FDA officials had discussed the Pinnacle Study's design and "agreed that the 8 mg BID regimen as the starting dosage was preferable in the [Pinnacle Study]." Defs. Reply Mem., Dkt. 84, at 5. That argument is unpersuasive because Defendants omit crucial context. As Plaintiff explains, *see* CCAC ¶¶ 83–84, the FDA Briefing reflects that FDA officials urged Spectrum to develop more data before determining the dosage regimen it would use in the Pinnacle Study. Although the parties agreed that 8 mg BID was preferable "*compared to [Spectrum's] [initial] proposal*," the FDA Briefing does not reflect that the FDA signed off on the proposed dosage regimen. FDA Briefing at 14 (emphasis added).

For all of those reasons, Plaintiff has adequately alleged that Spectrum's statement about the FDA's approval of the Pinnacle Study's dosage regimen was false or misleading in violation of the Exchange Act.

ii. Enrollment in the Pinnacle Study

Plaintiff alleges that, on May 12, 2022, and on August 11, 2022, Spectrum fraudulently represented that patients were enrolled in the Pinnacle Study when it stated that "[p]atients are being randomized 2-to-1" into treatment groups receiving either 8 mg of pozi BID or a different

drug. CCAC ¶¶ 125–27; 138–41. Plaintiff also takes issue with Spectrum's August 11, 2022 statement that it could not provide enrollment numbers but was "very active in opening [clinical testing] site[s]," and that the FDA had said that no particular number of patients were required to be enrolled in the Pinnacle Study by the time the FDA acted on Spectrum's application. *Id.* ¶¶ 142–43.[16]

Most of these statements are actionable. Spectrum's repeated statements in May and August 2022 that patients were "being randomized" in the Pinnacle Study, *see* CCAC ¶¶ 125–27, 138–41, are actionable at this stage because a reasonable investor could have construed these statements as indicating that at least *some* patients had been enrolled in the Pinnacle Study when, in fact, none had. Although Spectrum discussed patient randomization in the context of describing the Pinnacle Study's design, which arguably suggests that the design had not yet been implemented, Spectrum also stated that the Pinnacle Study had been "initiated" and was "underway," suggesting that the study was not still on the drawing board.[17] A reasonable

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[16] Defendants primarily argue that (1) Defendants merely described the Pinnacle Study's design and how it would operate prospectively rather than reporting on current progress; (2) Plaintiff ignores key context; (3) certain analysts correctly understood Defendants' representations; (4) Spectrum represented only that clinical testing sites were open, not that patients had been enrolled in the Pinnacle Study; and (5) the FDA did not, in fact, require a specific number of patients to be enrolled by the time it acted on Spectrum's application. *See* Defs. Mem. at 14–18.

In response, Plaintiff primarily argues that (1) Defendants improperly rely on extraneous documents and disputed facts; (2) Defendants ignore key context; (3) at least one analyst reported that Spectrum had started enrolling patients in the Pinnacle Study; (4) Defendants' forward-looking statements were not inconsistent with a reasonable investor's understanding Spectrum's statements to mean that patients had been enrolled; and (5) Defendants' misleading half-truths are actionable. *See* Pl. Mem. at 10–14.

[17] *See* May 12, 2022 Press Release, Dkt. 71-6, at 2; May 12, 2022 Earnings Call Tr., Dkt. 71-11, at 4; August 11, 2022 Earnings Call Tr., Dkt. 71-10, at 4–5. Defendants make much of the fact that, during the earnings calls, Spectrum made statements about the Pinnacle Study in the future tense or suggesting future action. *See* Defs. Mem. at 15–16. Representations that Spectrum was "*actively engaged in opening* [clinical testing] *sites*[,]" and that patients "*will be* evaluated" and "*will be* allowed" to receive pozi treatment, *id.*, however, did not foreclose a reasonable investor's understanding that at least some patients had enrolled in the Pinnacle Study, even if they had not significantly progressed through the study.

investor may, therefore, have construed Spectrum's statements as indicating that patients had enrolled in the Pinnacle Study even though none had. *See Micholle v. Ophthotech Corp.*, No. 17-CV-210 (VSB), 2019 WL 4464802, at *11–13 (S.D.N.Y. Sept. 17, 2019) (concluding that defendants' statements about changes to a clinical trial's enrollment criteria may have been materially false or misleading under the Exchange Act given the contextual interplay between two statements in a Form 10-K); *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 483–84 (S.D.N.Y. 2018) (concluding that defendants' statements about patient enrollment in a clinical trial may have been materially false or misleading under the Exchange Act because defendants were allegedly pressured to expedite patient enrollment and "downplayed" enrollment issues), *aff'd in part, vacated in part sub nom. Abramson*, 965 F.3d at 178–79 (affirming the district court's conclusion that plaintiffs adequately alleged the falsity of defendants' statements regarding patient enrollment); *Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc.*, 22 F.4th 1, 10–11 (1st Cir. 2021) (concluding that defendants' statements may have been materially false or misleading under the Exchange Act because they were in context "flat-out claims about [defendants' product] as it then stood").

The parties also dispute how a reasonable investor would have viewed Spectrum's statements in light of the broader context of the Company's past statements. Plaintiff highlights Spectrum's statement on a March 17, 2022 earnings call in response to a question about patient enrollment in the Pinnacle study: "Our practice has been that we make announcement [sic] about [sic] design and details of a trial once we enroll the first patient." Mar. 17, 2022 Call Tr., Dkt. 85-1, at 9; *see also* CCAC ¶ 12. Spectrum's subsequent statements suggest that, by discussing the Pinnacle Study's design and details, the Company implicitly represented that at least one patient had been enrolled in the study. Although not dispositive to the Court's analysis, this allegation reinforces it.

In response, Defendants point out that Spectrum expressly announced when it "enrolled its first patient" in other clinical studies, *see* Defs. Mem. at 15 (citing Dkts. 71-12–71:15), which it did not do for the Pinnacle Study. But the only pozi press release Defendants cite discloses that Spectrum "dose[d]" its first patient in a given study, not that a patient was first enrolled. Sept. 12, 2018 Press Release, Dkt. 71-12; *see also* Remaining Press Releases, Dkts. 71:13–71:15 (discussing bladder cancer, breast cancer, and prostate cancer treatments). Moreover, the Court is not persuaded that a press release issued almost four years before the statements at issue would have any meaningful impact on how a reasonable investor would understand the statements that were made.

Indeed, at least one analyst allegedly reported a few days after Spectrum's May 12, 2022 statements that "Spectrum noted that it has started enrolling patients" in the Pinnacle Study. CCAC ¶ 132. *See Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 303 (S.D.N.Y. 2018) (concluding that the plaintiff adequately alleged misleading statements and omissions under the Exchange Act in part because an analyst report reflected the plaintiff's theory of how defendants' statements were understood); *In re Bristol Myers Squibb Co. Secs. Litig.*, 586 F. Supp. 2d 148, 161–62 (S.D.N.Y. 2008) (same with respect to multiple analyst reports).[18]

Spectrum's August 11, 2022 statement that Spectrum could not provide enrollment "numbers" but was "very active" in opening clinical testing sites is also actionable at this stage. That statement falsely implied that the Pinnacle Study was sufficiently underway for there to be patient enrollment "numbers," even if the Company declined to provide those numbers. *See Micholle*, 2019 WL 4464802, at *11–13; *Nguyen*, 297 F. Supp. 3d at 483–84. Moreover, the statement was made in response to an analyst's question regarding the "percentage" of target patients who had been enrolled. *See* CCAC ¶ 142. Instead of correcting the analyst's apparent misconception that some non-zero fraction of patients were already participating in the Pinnacle Study, Spectrum gave the misleading impression that an unspecified number of patients *had* enrolled. *See Cohen v. Kitov Pharms. Holdings, Ltd.*, No. 17-CV-0917 (LGS), 2018 WL 1406619, at *5 (S.D.N.Y. Mar. 20, 2018) (finding alleged material omissions regarding clinical trial results adequate to state a claim under the Exchange Act because defendants' omission "created [the false] impression" that the study showed statistically significant efficacy); *In re*

[18] Defendants point out that other analysts did not report that Spectrum had begun enrolling patients in the Pinnacle Study. *See* Defs. Mem. at 16. Although the Court takes judicial notice of these reports, they do not defeat Plaintiff's claim at this stage because a reasonable investor could have understood Spectrum's statements as the analyst did to mean that at least some patients had been enrolled in the Pinnacle Study.

Delcath Sys., Inc. Secs. Litig., 36 F. Supp. 3d 320, 331–32 (S.D.N.Y. 2014) (same because defendants' failure to disclose certain data, "combined with" misleading statements, gave a false impression of the drug's safety).

For all of those reasons, Plaintiff adequately alleges that Spectrum's statements regarding enrollment in the Pinnacle Study,[19] aside from the Company's statement about the necessary enrollment threshold for FDA approval, were false or misleading under the Exchange Act.

2. Non-Actionable Statements

i. Dosage Optimization

Plaintiff alleges that Spectrum's March 17, 2022 statement, "I think over time, we have learned to optimize some of the tolerability and abate some of the [adverse events] here with [pozi's 8 mg BID clinical trial] dosage," CCAC ¶ 123, and Spectrum's May 12, 2022 statement that it was "very logical that the FDA could have additional questions on dosing," *id.* ¶ 130, were materially false and misleading because of the FDA's concerns about Spectrum's dosage data.[20]

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[19] By contrast, Spectrum's statement that the FDA had told the Company that no particular number of patients were required to be enrolled in the Pinnacle Study by the time the FDA acted on Spectrum's application is not actionable. *See* CCAC ¶ 142. Plaintiff does not specifically address this statement in his papers, apparently conceding that it is not actionable. *See* Pl. Mem. Spectrum explained that the adequacy of patient enrollment in the Pinnacle Study would be subject to a "multifactorial judgment" by the agency, and that Spectrum would need to "demonstrate a true active program" to obtain FDA signoff. CCAC ¶ 142. Spectrum's statement does not conflict with the FDA's alleged instructions to secure "substantial," although otherwise unspecified, enrollment in the Pinnacle Study. *See Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 353–54 (2d Cir. 2022) (concluding that plaintiffs failed to allege that defendants' descriptions of a clinical trial were false or misleading in part because there was "no general understanding" of a specific statistical threshold required to achieve a particular clinical designation).

[20] Defendants primarily argue that Plaintiff does not adequately allege any false or misleading statements because (1) Plaintiff does not allege facts contradicting Spectrum's statement that "some" of the drug's tolerability had been optimized; (2) Plaintiff invokes nonactionable expressions of opinion; (3) contrary opinions expressed by certain FDA staff or FDA Committee members do not render Spectrum's statements false or misleading; (4) Spectrum acknowledged that it had not determined an optimal dose; and (5) Spectrum had no affirmative duty to disclose FDA concerns or questions regarding dose optimization. *See* Defs. Mem. at 10–14.

In response, Plaintiff primarily argues that (1) Spectrum's statement embedded the materially false fact that it *had* data showing dose optimization and thus triggered a duty to disclose material facts that were necessary to avoid misleading investors; (2) Spectrum had been told at the time the statement was made that it lacked the necessary data for dosage optimization in the Pinnacle Study; (3) the FDA staff did not just offer a contrary

The parties do not dispute that Spectrum's statements were opinions. At issue is whether the opinions embedded falsity and whether, to avoid misleading investors, Spectrum had an affirmative duty to disclose that FDA officials had, by that point, expressed concerns about the adequacy of Spectrum's optimization data.

Spectrum's statements did not embed falsity. To the contrary, Spectrum represented that only "some" of pozi's tolerability had been optimized, *see* CCAC ¶ 123, an equivocation that, if anything, embedded the fact that Spectrum had not yet fully optimized the drug's dosage, *see In re Eastman Kodak Co. Secs. Litig.*, 632 F. Supp. 3d 169, 185–86 (W.D.N.Y. 2022) (concluding that a defendant's "vague" statement conveyed a "lack of certainty" and was therefore not actionable under the Exchange Act); *City of Sterling Heights Police & Fire Ret. Sys. v. Vodafone Grp. Pub. Ltd.*, 655 F. Supp. 2d 262, 273 (S.D.N.Y. 2009) (concluding that, "[f]ar from constituting a fraudulent statement by [the defendant]" under the Exchange Act, the defendant's remarks "acknowledge[d] uncertainties"). Spectrum's acknowledgement that it was "very logical" for FDA officials to have further questions about dosage, and that Spectrum would gain more "clarity" on the issue as its meeting with the FDA Committee approached, *see* CCAC ¶ 130, similarly insinuated that dosage optimization was ongoing, *see In re Fairway Grp. Holdings Corp. Secs. Litig.*, No. 14-CV-0950 (LAK) (AJP), 2015 WL 4931357, at *21–22 (S.D.N.Y. Aug. 19, 2015) (concluding that the plaintiff did not adequately allege that the defendant made actionable statements of embedded falsity under the Exchange Act because the statements were

interpretation of clinical data but affirmatively told Spectrum that necessary optimization data did not exist; and (4) Spectrum did have an affirmative duty to disclose feedback from the FDA. *See* Pl. Mem. at 18–21.

neither "determinate or verifiable" nor "actually . . . false"), *report & recommendation adopted*, 2015 WL 5255469 (S.D.N.Y. Sept. 9, 2015).[21]

Spectrum's statements also did not trigger an affirmative duty to disclose the FDA's reservations about Spectrum's optimization data. A defendant's omission when expressing an opinion is only actionable if the omitted fact "conflict[s] with what a reasonable investor would take from the statement itself." *Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016) (quoting *Omnicare*, 575 U.S. at 189)). Spectrum's statement that it had only partially achieved dosage optimization and that the FDA would surely have more questions about dosage as pozi's development progressed did not conflict with the FDA's view that there was work to be done before the drug's dosage could be deemed optimized.

The Second Circuit's decision in *Sanofi* is instructive. In that case, the Circuit concluded that defendants' statements of "optimism about FDA approval" were not misleading even though they failed to disclose that the FDA had expressed "interim, albeit repeated, concerns about [defendants' drug study methodology]." *Id.* at 212. The Circuit agreed with the district court that there was no "serious conflict" between defendants' statements and the FDA's concerns. *Id.* at 211–12. The defendants were not required to disclose FDA feedback "merely because it

[21] The Court's conclusion is buttressed by other statements Spectrum made regarding pozi's dosage data around this time. On June 9, 2022, Spectrum stated during a publicized fireside chat with an investment bank that one of the two "main issues" Spectrum was preparing to address ahead of its meeting with the FDA Committee was dosage; the FDA "had some concerns regarding dosing," particularly because Spectrum had applied for approval using 16 mg per day dosage data even though the data "seem[ed] to show some improved tolerance" at the 8 mg BID dosage. Fireside Chat Tr., Dkt. 71-9, at 3. Spectrum concluded, "So I think there are dosing questions that exist." *Id.* *Cf. Colbert*, 824 F. App'x at 10 n.5 (concluding that the defendant's statements were not materially misleading under the Exchange Act in part because "there was at least one" analyst report "publicly stating" the "very fact that [the plaintiff] assert[ed] was concealed"). Plaintiff argues that documents "not mentioned or relied upon in the Complaint" may not be considered at the motion-to-dismiss stage. Pl. Mem. at 10 n.4. It is well established, however, that "it is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents." *Colbert*, 824 F. App'x at 10 n.5 (considering a public report for the fact that the report had been published, without noticing the report for the truth of what it stated, when resolving a motion to dismiss claims under the Exchange Act) (quoting *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008)).

tended to cut against" their optimistic statements, even if the plaintiffs "would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise" had they known. *Id.* at 212. The same reasoning applies here. Spectrum's vaguely optimistic view that it was gradually optimizing pozi's dosage, subject to ongoing FDA feedback, fell far short of contradicting the agency's position that Spectrum needed more data to achieve its approval.[22] *See also Omnicare*, 575 U.S. at 189–90 (noting that "[a]n opinion statement . . . is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way"); *In re Philip Morris Int'l Inc. Secs. Litig.*, 437 F. Supp. 3d 329 (S.D.N.Y. 2020) (concluding that defendants' opinion statements about their clinical studies were not misleading under the Exchange Act because a corporate defendant "need not disclose all concerns about its research methodology" so long as omitted facts do not conflict with a reasonable investor's understanding of the statement made (citations omitted)), *aff'd*, 89 F.4th 408 (2d Cir. 2023).

For all of those reasons, Plaintiff does not adequately allege that Spectrum's statements regarding pozi's dosage optimization were false or misleading in violation of the Exchange Act.

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[22] Plaintiff argues in a footnote that *Sanofi* is inapposite because, in that case, there was no "sharp conflict" between the defendants' statements and the FDA's views. Pl. Mem. at 19 n.13. For the reasons discussed *supra*, however, the same is true here.

Plaintiff also maintains that he adequately stated a claim because analysts were "surprise[d]" that the FDA Briefing focused on dose optimization. Pl. Mem. at 21 (citing CCAC ¶ 33). The mere fact that the FDA's "focus on dosing optimization" gave one analyst "some pause" does not suggest that Spectrum's prior statements, which acknowledged uncertainties about the FDA's eventual position, are actionable. *Cf. City of Sterling Heights Police & Fire Ret. Sys. v. Vodafone Grp. Public Ltd. Co.*, 655 F. Supp. 2d 262, 273 (S.D.N.Y. 2009) ("Many of the statements cited in the [c]omplaint reflect surprise by third parties concerning the announcement of [the defendant company's] tax obligations, but none can be construed as a fraudulent statement by the Company . . . .").

ii. Risk Warnings

Plaintiff alleges that Spectrum's Forms 10-Q filed in May and August 2022 were false and misleading because they identified a possible delay in clinical trials due to, among other factors, "difficulties in identifying and enrolling patients," "slower than anticipated patient enrollment," and Spectrum's "inability to recruit and enroll patients," even though those risks had already materialized. CCAC ¶¶ 133, 145; *see also* March 2021 Form 10-K at 16 (incorporated by reference into the Forms 10-Q, *see* Dkts. 71-7, 71-8).[23]

Read in context, Spectrum's disclosures were not false or misleading because the overarching risk they identified — that "[c]linical trials may fail to demonstrate the safety and efficacy of [Spectrum's] drug products, which could prevent or significantly delay obtaining regulatory approval" — had not yet materialized. *See* March 2021 Form 10-K at 16. Although Spectrum disclosed that regulatory approval requires "substantial evidence from well-controlled clinical trials," and that such trials could be delayed, Spectrum did not identify delayed clinical trials as a risk in and of itself. This distinction is crucial. Spectrum was allegedly aware that the Pinnacle Study would be delayed at the time it made these disclosures, but it was *not* allegedly aware that pozi's regulatory approval would be delayed. Because that risk had not yet

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[23] Defendants primarily argue that these statements are not false or misleading because the statements (1) were not made by a person with actual knowledge of their falsity; and (2) the risk Spectrum disclosed had not yet materialized. *See* Defs. Mem. at 18–19; Defs. Reply Mem. at 6–7.

In response, Plaintiff primarily argues that (1) the risk identified in Spectrum's disclosures had in fact materialized; and (2) Defendants improperly recast the CCAC as alleging that Spectrum merely warned investors about the risks of pozi not receiving accelerated approval, rather than warning about patient enrollment in the Pinnacle Study. *See* Pl. Mem. at 20–21.

Plaintiff also alleges that Spectrum failed to disclose known uncertainties about whether pozi would be approved in the MD&A section of its Forms 10-Q in violation of Item 303 of SEC Regulation S-K, 17 C.F.R. 929.303. CCAC ¶¶ 135, 147. Defendants did not challenge the adequacy of these allegations to support a claim under the Exchange Act, even after Plaintiff flagged the allegations in his response memorandum. *See* Pl. Mem. at 22 n.15. Because Defendants have not moved to dismiss the CCAC to the extent it is predicated on those allegedly false statements, the Court does not consider whether these unchallenged allegations adequately state a claim under the Exchange Act.

materialized, Spectrum's statements are not actionable. *See Rosi v. Aclaris Therapeutics, Inc.*, No. 19-CV-7118 (LJL), 2021 WL 1177505, at *20 (S.D.N.Y. Mar. 29, 2021) (concluding that a company's risk factors, which stated that the company's drugs "could be subject to post-marketing restrictions" and that the company "may be subject to penalties if [it] fail[ed] to comply with regulatory requirements," were not actionable under the Exchange Act even though the FDA had notified the company that it had failed to comply with regulatory requirements because post-marketing restrictions or penalties had not yet materialized); *Schaeffer v. Nabriva Therapeutics PLC*, No. 19-CV-4183 (VM), 2020 WL 7701463, at *10–11 (S.D.N.Y. Apr. 28, 2020) (concluding that a company's risk factors, which flagged the defendant company's ability to comply with regulatory requirements because noncompliance could prevent or delay FDA approval of the company's drug, were not actionable in relevant part under the Exchange Act even though Defendants were aware of "quite serious" regulatory violations because the company still had four months to address the violations and obtain FDA approval; the risk that the FDA would not approve the drug had not yet materialized).

For all of those reasons, Spectrum's risk warnings are not actionable under the Exchange Act.

iii. FDA Approval

Finally, Plaintiff alleges that Spectrum's statement on June 16, 2022, that Spectrum was "on the cusp of . . . two FDA approvals with the action dates in the next five months" was false or misleading because the Pinnacle Study was still not underway, and the FDA had recently reiterated its concerns about Spectrum's drug development. CCAC ¶¶ 136–37.[24] Spectrum's

[24] Defendants primarily argue that Spectrum's statement is not actionable because (1) it was forward-looking and therefore subject to the PSLRA's safe harbor protections; and (2) it was an expression of corporate optimism. *See* Defs. Mem. at 18–20.

statement is not actionable because it was forward-looking, and Plaintiff has not adequately alleged that the Company knew it was false or misleading. The PSLRA's safe harbor (the "Safe Harbor"), therefore, applies.

Courts have repeatedly recognized that "[p]rojections about the likelihood of FDA approval are forward-looking statements." *Schaeffer*, 2020 WL 7701463, at *10 (collecting cases and concluding that defendants' statements that they expected their drug to secure FDA approval was forward-looking and subject to the PSLRA's safe harbor provision) (internal quotation marks and citation omitted); *see also In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015) (concluding same). Contrary to Plaintiff's assertion, the fact that Spectrum's statement was in the present tense does not mean it loses protection of the Safe Harbor. Spectrum effectively communicated that pozi would soon be approved by the FDA, a message about the drug's future. *See Kusnier v. Virgin Galactic Holdings, Inc.*, 639 F. Supp. 3d 350, 371–72 (E.D.N.Y. 2022) (stating that "[c]ourts in this circuit have often held that statements that refer to a company being 'presently on track' with goals are forward-looking" and concluding that the present-tense statements at issue were forward-looking); *Villare v. Abiomed, Inc.*, No. 19-CV-7319 (ER), 2021 WL 4311749, at *16–17 (S.D.N.Y. Sept. 21, 2021) (concluding same about present-tense statements).

Unless Plaintiff has adequately alleged that Spectrum knew at the time that pozi would not be approved by the FDA, the Safe Harbor applies.[25] Plaintiff has not done so. As further

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In response, Plaintiff primarily argues that (1) the PSLRA's safe harbor does not apply because Spectrum's statement was not identified as forward-looking and was not accompanied by a cautionary statement; and (2) the PSLRA's safe harbor does not apply because Spectrum's statement was a mix of present and future events. *See* Pl. Mem. at 21–22.

[25] Spectrum's statement would also be within the Safe Harbor if it included meaningful cautionary language or if the statement were not material. *See Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010). Because the Court finds that Plaintiff failed to allege the requisite scienter, it need not address these alternative grounds for protection by the Safe Harbor.

discussed*infra*, Plaintiff alleges with specificity that Defendants knew about the slow progress of the Pinnacle Study and knew that Spectrum had inadequate dosage data but alleges in only a conclusory fashion that Defendants knew that pozi would not be approved by the FDA. *See* CCAC ¶ 137. Plaintiff concedes this very point in his briefing. *See* Pl. Mem. at 3 n.2 (stating that Plaintiff has "not alleged" that Defendants "knew in advance that the [pozi application] would not be approved or that they failed to predict the outcome of the [FDA Committee meeting]"). The FDA Committee's split vote further supports this conclusion. *See* CCAC ¶ 35. The Safe Harbor, therefore, applies. *See Schaeffer*, 2020 WL 7701463, at *10 (concluding that the Safe Harbor applied to defendants' statements that they expected FDA approval of a drug because the plaintiff merely alleged that defendants were "reckless in failing to disclose" information in an FDA feedback letter, not that defendants knew the drug would not be approved); *Villaire*, 2021 WL 4311749, at *17 (explaining that the scienter requirement for forward-looking statements under the PSLRA requires "actual knowledge," not mere recklessness, and that the Safe Harbor applied because the plaintiff's knowledge allegations were "conclusory").

For all of those reasons, Spectrum's statement about the likelihood of FDA approval is not actionable.

II. Plaintiff Adequately Alleges Scienter For the Potentially Actionable False or Misleading Statements Except as to Brennan

Plaintiff has adequately alleged circumstantial evidence that Spectrum, Riga and Lebel consciously or recklessly made the false or misleading statements that the Court finds are

potentially actionable[26]: (1) that Spectrum and the FDA were aligned on the dosage for the Pinnacle Study; and (2) that patients were enrolled in the Pinnacle Study.[27]

A. Legal Standard

To plead scienter under the Exchange Act, a plaintiff must "state with particularity the facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). The "required state of mind" is an "intent to deceive, manipulate, or defraud," or recklessness. *Emps. Ret. Sys. of Gov't of the Virgin Is. v. Blanford*, 794 F.3d 297, 305 (2d Cir. 2015) (internal quotation marks and citations omitted). The Court must "take into account plausible opposing inferences" and consider "plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 323–24 (2007). The inference "must be more than merely

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[26] As discussed *supra* n.24, the Court does not address Plaintiff's allegations regarding the MD&A section of Spectrum's Forms 10-Q.

[27] Plaintiff does not adequately allege motive and opportunity scienter because a corporation's alleged need for cash and executives' share sales, without more, *see* CCAC ¶¶ 21, 23, 28, 95, 97, 103, 152–57, are not sufficiently suspicious or unusual. *See Chill v. General Elec. Co.*, 101 F.3d 263, 268 (2d Cir. 1996) (concluding that a company's alleged desire to "maintain the appearance of corporate profitability, or of the success of [its] investment," even though such positive publicity would "naturally involve benefit" to the company, was not sufficiently "concrete" for scienter under the Exchange Act); *Reilly v. U.S. Physical Therapy, Inc.*, No. 17-CV-2347 (NRB), 2018 WL 3559089, at *15 (S.D.N.Y. July 23, 2018) (finding that executives' sales of over 40% of their shares was not inherently "suspicious" and did not give rise to an inference of motive under the Exchange Act); *In re Gentiva Secs. Litig.*, 971 F. Supp. 2d 305, 324–26 (E.D.N.Y. 2013) (finding allegations of share sales inadequate evidence of motive scienter under the Exchange Act because the plaintiff failed to allege the defendant's net profits); *In re CRM Holdings, Ltd. Secs. Litig.*, No. 10-CV-975 (RPP), 2012 WL 1646888, at *23 (S.D.N.Y. May 10, 2012) (finding sales of 100%, 36%, and 26% of defendants' shares for proceeds in excess of $37.3 million, standing alone, to be inadequate to give rise to an inference of scienter under the Exchange Act); *In re PXRE Grp., Ltd., Secs. Litig.*, 600 F. Supp. 2d 510, 532 (S.D.N.Y. 2009) (holding that allegations that a company committed fraud because it "desperately needed" to raise capital "to protect [its] very survival" were inadequate to allege scienter under the Exchange Act); *In re Emex Corp. Secs. Litig*., No 01-CV-4886 (SWK), 2002 WL 31093612, at *6 (S.D.N.Y. Sept. 18, 2002) (holding that a company's alleged "desire to raise much needed capital" was inadequate to allege scienter under the Exchange Act).

The parties spend much of their briefing disputing the extent to which Spectrum's executives *increased* their Spectrum holdings during the Class Period. *See* Defs. Reply at 7–9; Pl. Surreply, Dkt. 88, at 1–3. The Court need not resolve this dispute because, even assuming that Spectrum's executives did not increase their Spectrum holdings, Plaintiff has not adequately alleged motive and opportunity scienter. The Court notes, however, that the Form 4s Defendants cite in support of their analysis, *see* Reply Mem. at 8 (citing Dkts. 71-22, 71-23, 85-4), appear to have been filed before the end of the Class Period, and therefore do not fully substantiate Defendants' assertions.

'reasonable' or 'permissible'—it must be . . . cogent and at least as compelling as any opposing inference [of nonfraudulent intent]." *Id.* at 324. "The plaintiff may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns, Inc.*, 493 F.3d at 99 (citation omitted).

A motive and opportunity to defraud may be inferred from "unusual insider trading activity," *Rothman v. Gregor*, 220 F.3d 81, 94 (2d Cir. 2000) (internal quotation marks and citation omitted), but "[t]he mere fact that insider stock sales occurred does not suffice to establish scienter," *In re Gildan Activewear, Inc. Secs. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009) (internal quotation marks and citation omitted). For trades to be evidence of scienter, the plaintiff must allege "that the sales were 'unusual' or 'suspicious.'" *Id.* (collecting cases). "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *In re Scholastic Corp. Secs. Litig.*, 252 F.3d 63, 74–75 (2d Cir. 2001).

In the context of private securities fraud actions, recklessness means "conscious recklessness—i.e., a state of mind approximating actual intent, and not merely a heightened form of negligence." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (quoting *Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000) (emphasis omitted)). Examples of recklessness are "highly unreasonable" conduct that "represents an extreme departure from the standards of ordinary care," failing to review or check information one had a duty to monitor, or ignoring obvious signs of fraud. *Id.* "Circumstantial evidence can support an inference of scienter in a variety of ways, including where 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 (quoting *ECA, Local 134 IBEW*, 553 F.3d at 199). "Where motive is not apparent . . . the strength of the circumstantial allegations must be correspondingly greater." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (internal quotation marks and citation omitted).

B. Application

Plaintiff adequately alleges circumstantial evidence of conscious misbehavior or recklessness with respect to the two categories of statements that are actionable: Spectrum's statement about the Company and the FDA's alignment with respect to the dosage plan for the Pinnacle Study, CCAC ¶ 128; and Spectrum's statements that patients were enrolled in the Pinnacle Study, *id.* ¶¶ 125–27, 138–43.[28]

Plaintiff alleges that Riga falsely stated during a call with investors that the FDA had signed off on the Pinnacle Study's dosage regimen mere months after Lebel, who was on the call, had met with the FDA and learned that the agency did not agree with the dosage regimen Spectrum planned to use for the Pinnacle Study. CCAC ¶¶ 84, 128, 129. Riga repeatedly spoke to investors about pozi's development and the FDA review process, suggesting that he was

[28] Defendants primarily argue that Plaintiff has not adequately alleged circumstantial evidence of conscious misbehavior or recklessness because (1) Plaintiff alleges scienter in a conclusory fashion; (2) Plaintiff has not alleged that Defendants were "on notice" that pozi would not secure FDA approval such that their statements would be misleading; (3) Plaintiff engages in impermissible group pleading; (4) the FDA Briefing does not contradict Spectrum's statements; and (5) Lebel's resignation does not establish scienter. *See* Defs. Mem. at 23–25; Defs. Reply Mem. at 9–10.

In response, Plaintiff primarily argues that (1) Lebel and Riga were specifically informed of or had access to facts that sharply contradicted their statements to investors, as corroborated by the FDA Briefing and statements by the FDA Committee; (2) Lebel and Riga were intimately involved in meetings and communications with FDA officials regarding pozi, as reflected by their knowledge on the subject at investor calls; (3) Lebel and Riga acknowledged their awareness of FDA guidance; (4) Lebel's resignation after Spectrum deprioritized pozi was suspicious; and (5) Spectrum was a small company with only two drug product candidates, meaning that Defendants likely knew about any FDA developments. *See* Pl. Mem. at 22–24.

aware of relevant FDA meetings and communications. *See, e.g.*, *id.* ¶¶ 102, 128, 130. Moreover, the FDA Briefing and comments from members of the FDA Committee reflect that Spectrum representatives had been repeatedly told that the FDA had not signed off on the dosage regimen for the Pinnacle Study, and that Spectrum could only proceed with the Pinnacle Study at its own risk. *See id.* ¶¶ 16, 111–12. During the Class Period, pozi was one of only two drugs in late-stage development at the Company. *See id.* ¶¶ 2, 46. All of those facts, according to Plaintiff, adequately demonstrate that Riga knew or recklessly disregarded the fact that the FDA believed that Spectrum had not adequately optimized dosing. *See id.* ¶ 131.

These allegations give rise to an inference that Riga, Spectrum's CEO and one of two executives who repeatedly discussed pozi's development with investors, was aware of the FDA's position but decided to communicate to investors that the Company and the FDA were aligned on the Pinnacle Study's dosage regimen anyway. *See Rosi*, 2021 WL 1177505, at *22 (concluding that the plaintiff adequately alleged scienter under the Exchange Act through circumstantial evidence because defendants, who were company executives, had allegedly attended meetings regarding the FDA's concerns about their company's pharmaceutical product); *Okla. Firefighters Pension & Ret. Sys.*, 367 F. Supp. 3d 16, 36–37 (S.D.N.Y. 2019) (same in part because the defendants had "attended meetings" with other executives to discuss the topic); *In re Salix Pharms., Ltd.*, No. 14-CV-8925 (KMW), 2016 WL 1629341, at *14 (S.D.N.Y. Apr. 22, 2016) (same in part because the defendant company's CFO had allegedly discussed the disputed topic with analysts); *In re Delcath Sys., Inc. Secs. Litig.*, 36 F. Supp. 3d 320, 335–36 (S.D.N.Y. 2014) (same because the defendant company was "focused on the production of just one [pharmaceutical] product," a defendant executive's public statements

"evinced a familiarity" with the clinical trial at issue, and because an FDA committee was "extreme[ly] negative[e]" about the prospect of approving the defendants' drug).

Plaintiff also adequately alleged that Riga and Lebel consciously or recklessly misrepresented that patients were enrolled in the Pinnacle Study. Riga and Lebel — the two executives who repeatedly discussed the Pinnacle Study's design, implementation, and enrollment with investors — allegedly met with FDA officials in 2021 and multiple times in 2022 to discuss the Pinnacle Study, including the FDA's concerns about its delayed launch and lack of patients and the need for Spectrum to ensure substantial enrollment by November 2022. CCAC ¶¶ 83–84, 98, 137; FDA Briefing at 14–15. Moreover, Riga and Lebel were both aware of the FDA's requirement that the Pinnacle Study be well underway as a prerequisite to accelerated approval of pozi. *See* CCAC ¶¶ 35, 102, 115. These allegations give rise to the inference that Riga and Lebel had to have known that no patients had been enrolled in the Pinnacle Study, yet decided to suggest otherwise.[29] *See Rosi*, 2021 WL 1177505, at *22; *In re Okla. Firefighters Pension & Ret. Sys.*, 367 F. Supp. 3d at 36–37; *Salix Pharms., Ltd.*, 2016 WL 1629341, at *14; *In re Delcath Sys., Inc. Secs. Litig.*, 36 F. Supp. 3d at 335.

By contrast, Brennan barely appears in the CCAC. Apart from Brennan's leadership role, Plaintiff does not allege any facts tending to show that she had knowledge of or access to facts contradicting Spectrum's representations that patients had been enrolled in the Pinnacle Study. Plaintiff has, therefore, not adequately alleged that Brennan knew or recklessly disregarded facts about patient enrollment. *See Venkataraman v. Kandi Techs. Grp., Inc.*, No. 20-CV-8082 (LGS), 2022 WL 4225562, at *7 (S.D.N.Y. Sept. 13, 2022) (concluding that the plaintiff did not

[29] Lebel's resignation does not weigh in favor of scienter because Plaintiff has not adequately alleged that it was "highly unusual and suspicious." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 598 (S.D.N.Y. 2011) (collecting cases) (internal quotation marks and citation omitted).

adequately allege scienter with respect to a defendant because the complaint "contain[ed] no substantive allegations about [the defendant] whatsoever").

For all of those reasons, except as to Brennan, because Riga and Lebel's scienter is imputed to Spectrum, *see Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008); *City of Sterling Heights Police & Fire Ret. Sys. v. Reckitt Benckiser Grp. PLC*, 587 F. Supp. 3d 56, 99–110 (S.D.N.Y. 2022), Plaintiff has adequately alleged scienter with respect to Spectrum, Lebel, and Riga in connection with Defendants' statements that the FDA approved of the Pinnacle Study's dosage and that patients were enrolled in the Pinnacle Study.

III. Plaintiff's Claims Under Section 20(a) of the Exchange Act Survive to the Extent His Claims Under Section 10(b) of the Exchange Act Survive

Plaintiff alleges that Riga, Lebel, and Brennan are liable for violating Section 20(a) of the Exchange Act by virtue of their senior positions at Spectrum and their power to control Spectrum's public statements to investors throughout the Class Period. *See* CCAC ¶¶ 177–79.

Defendants moved to dismiss Plaintiff's claims under Section 20(a) solely on the grounds that Plaintiff failed to state claims under Section 10(b). *See* Defs. Mem. at 25. To the extent Plaintiff's claims under Section 10(b) survive, so do his claims under Section 20(a). *See Venkataraman*, 2022 WL 4225562, at *9 (concluding that because the complaint alleged a primary violation under Section 10(b) of the Exchange Act as to certain individual defendants, Section 20(a) claims against those defendants also survived).[30]

[30] Because Defendants did not move to dismiss the CCAC as to statements contained in the MD&A sections of Spectrum's Forms 10-Q, Brennan remains a defendant in this action.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is DENIED with respect to Plaintiff's claims under Sections 10(b) and 20(a) of the Exchange Act based on Spectrum's statements that (1) the Company and the FDA were aligned with respect to the dosage regimen for the Pinnacle Study; and (2) patients were enrolled in the Pinnacle Study. Defendants' motion to dismiss is GRANTED with respect to Plaintiff's claims based on Spectrum's statements (1) regarding pozi's dosage optimization; (2) about the FDA's patient enrollment threshold in the Pinnacle Study; (3) of material risk; (4) regarding pozi's likely approval by the FDA; and (5) any claim against Brennan other than those based on the MD&A sections of Spectrum's Forms 10-Q.[31]

The parties must appear for a status conference on **Friday, February 23, 2024 at 10:00 A.M.,** in Courtroom 443, Thurgood Marshall Courthouse, 40 Foley Square, New York, New York, 10007.

Not later than **Thursday, February 15, 2024**, the parties must file a joint proposed case management plan, which may be found on the Court's website: https://nysd.uscourts.gov/hon-valerie-e-caproni. In addition to their proposed case management plan, the parties must file a letter of no more than five pages addressing each of the following in separate paragraphs:

a) a brief description of the case, including the factual and legal bases for the claim(s) and defense(s);

b) any contemplated motions;

c) the basis for subject matter jurisdiction;

[31] Plaintiff's request for leave to amend, *see* Pl. Mem. at 25 n.17, is denied because he does not indicate how amendment would cure the deficiencies in the CCAC, *see Attestor Value Master Fund v. Republic of Arg.*, 940 F.3d 825, 833 (2d Cir. 2019).

d) the prospect for settlement; and

e) whether the parties believe a status conference would be helpful or whether they believe it is unnecessary and that their proposed Case Management Plan be so ordered.

The Clerk of Court is respectfully directed to close the open motion at Docket Entry 69.

Date: January 23, 2024
New York, New York

VALERIE CAPRONI
United States District Judge