UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re ASTRAZENECA PLC SECURITIES LITIGATION	21-CV-722 (JPO) OPINION AND ORDER

J. PAUL OETKEN, District Judge:

In this putative securities class action, Lead Plaintiff Nuggehalli Balmukund Nandkumar, Lead Plaintiff Wayne County Employees' Retirement System, and Plaintiff Vladimir Zhukov sue Defendants AstraZeneca plc, Pascal Soriot, Marc Dunoyer, and Menelas Pangalos under Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 ("the Exchange Act"), and Rule 10b-5 promulgated thereunder. Defendants move to dismiss the amended complaint for failure to state a claim. For the reasons that follow, Defendants' motion to dismiss is granted.

I. Background

The following background comes from the allegations in the amended complaint, which "are assumed to be true." *Hamilton v. Westchester Cnty.*, 3 F.4th 86, 90-91 (2d Cir. 2021).

A. Factual Background

1. Background and Phase I/II Trials

Defendant AstraZeneca plc is a biopharmaceutical company. (*See* Dkt. No. 42 ("Am. Compl.") ¶ 19.) In April 2020, AstraZeneca partnered with Oxford to develop a potential recombinant adenovirus vaccine to combat COVID-19. (*See* Am. Compl. ¶ 30.) This vaccine candidate, known as AZD1222, was based on "tried and tested vaccine approaches," not "novel mRNA technology." (Am. Compl. ¶ 32.) It was "made from a weakened version of a common

cold virus (known as an adenovirus) from chimpanzees" and "modified to contain genetic material shared by the coronavirus." (Am. Compl. ¶ 33.) By introducing this material into the body, AZD1222 "train[ed] the body to recognize and respond to the proteins produced by" COVID-19, and "provoke[d] the immune system into mounting a response." (Am. Compl. ¶ 33.)

In May 2020, the United States "made what was at the time its biggest investment in Covid vaccine development, awarding AstraZeneca up to $1.2 billion for the development and manufacturing of the vaccine in exchange for 300 million doses." (Am. Compl. ¶ 35.) "AstraZeneca announced that it would manufacture the vaccine at no profit during the course of the pandemic." (Am. Compl. ¶ 36.) Analysts noted, however, that "there may be a future commercial opportunity if re-vaccination is required post-pandemic." (Am. Compl. ¶ 36.)

AstraZeneca and Oxford began Phase I/II trials. (*See* Am. Compl. ¶ 38.) On May 21, 2020, AstraZeneca stated: "A Phase I/II clinical trial of AZD1222 began last month to assess safety, immunogenicity and efficacy in over 1,000 healthy volunteers aged 18 to 55 years across several trial centres in Southern England." (Am. Compl. ¶ 38.) On June 4, 2020, AstraZeneca stated in a press release that the vaccines had "been given to more than 320 people to date and have been shown to be safe and well tolerated, although they can cause temporary side effects such as a temperature, influenza-like symptoms, headache or a sore arm." (Am. Compl. ¶ 38.)

2. Statements on Phase II/III Trials

AstraZeneca and Oxford then conducted "a larger Phase II/III study, involving thousands of participants, to assess how well the vaccine worked." (Am. Compl. ¶ 40.) On June 13, 2020, AstraZeneca highlighted "the start of a Phase II/III UK trial of AZD1222 in about 10,000 adult volunteers." (Am. Compl. ¶ 44.) On July 20, 2020, AstraZeneca reported the interim results for the ongoing Phase I/II and II/III trials. The release stated that "[l]ate-stage Phase II/III trials are currently underway in the UK, Brazil and South Africa and are due to start in the US. Trials will

determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses in different age ranges and at various doses." (Am. Compl. ¶ 47.)

On July 30, 2020, AstraZeneca filed a Form 6-K with the United States Securities and Exchange Commission ("SEC"), which reported its financials for the six months prior to June 30, 2020, with similar information about the Phase II/III trial. (*See* Am. Compl. ¶ 49.) The Form 6-K stated that the Phase I/II trial resulted in "the COV002 Phase II/III trial in the UK, with over 10,000 participants." (Am. Compl. ¶ 49.) It further stated that "COV002 has launched and has recruited almost 9,000 participants in the UK; late-stage development has begun in Brazil and South Africa." (Am. Compl. ¶ 49.) The Form 6-K reiterated that "[l]ate stage trials are currently underway in the UK, Brazil and South Africa and are due to start in the US. These trials will determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses in different age ranges, at various doses." (Am. Compl. ¶ 50.)

Also on July 30, 2020, AstraZeneca hosted a conference call with analysts and investors that was led by Individual Defendants Pascal Soriot, Marc Dunoyer, and Menelas Pangalos. (*See* Am. Compl. ¶ 51.) During the call, Pangalos stated that "[l]ate-stage trials are currently ongoing in the U.K., in Brazil in South Africa and are about to start in the United States." (Am. Compl. ¶ 51.) He reported that "our data shows that we're getting a good level of neutralizing antibody presentation in the patients that are vaccinated with the 2 doses as well as a good T cell response." (Am. Compl. ¶ 51.) Pangalos further stated that "[t]he study remains on track . . . we've dosed now nearly 12,000 patients around the world, in the U.K., Brazil and South Africa, and we're about to start the Phase III program in the U.S." (Am. Compl. 52.)

During the call, an analyst asked, "Is there something about the trial design, the single dose or lack of elderly patients that might constrain you there?" (Am. Compl. ¶ 53.) Pangalos

responded that "the studies that we have running in the U.K., Brazil, South Africa and soon to start in the U.S. will all be 2-dose studies." (Am. Compl. ¶ 53.) Another analyst asked if Pangalos could "give us timing at all when you may have some data on elderly and also pediatric and other at-risk patients." (Am. Compl. ¶ 54.) Pangalos responded that "data on different age groups is coming from the Phase I study and from the Phase II part and the Phase II study we're running in the U.K., and we're getting that data in on a weekly basis." (Am. Compl. ¶ 54.). On August 14, 2020, AstraZeneca issued a press release again reporting that "[c]linical development of AZD1222 is progressing globally with late-stage Phase II/III trials ongoing in the UK and Brazil." (Am. Compl. ¶ 57.)

3. Statements Reflecting Public Commitments

During the clinical trials, AstraZeneca expressed various commitments to public safety and equitable access. On August 31, 2020, for example, AstraZeneca issued a press release affirming that one of its "core values is to 'follow the science' and to adhere to the highest scientific and clinical standards, making the safety and efficacy of the vaccine of paramount importance." (Am. Compl. ¶ 60.) It further stated that its "submissions for market authorization will meet the stringent requirements established by regulators everywhere around the world." (Am. Compl. ¶ 60.) AstraZeneca CEO Pascal Soriot also stated: "I want to reiterate my commitment that we are putting science and the interest of society at the heart of our work. We are moving quickly but without cutting corners, and regulators have clear and stringent efficacy and safety standards for the approval of any new medicine, and that includes this potential COVID-19 vaccine." (Am. Compl. ¶ 60.) Also on August 31, 2020, AstraZeneca released another press release noting that it was "today issuing a commitment to the highest safety standards and to broad and equitable access," reiterating its core values to 'follow the science' and 'put patients first.'" (Am. Compl. ¶ 61.) On September 8, 2020, AstraZeneca CEO Pascal

Soriot signed a pledge to "[a]lways make the safety and well-being of vaccinated individuals our top priority"; "[c]ontinue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes"; "[o]nly submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA"; and "[w]ork to ensure a sufficient supply and range of vaccine options, including those suitable for global access." (Am. Compl. ¶ 63.) On September 8, 2020, during a conference call, AstraZeneca CEO Pascal Soriot again "expressed his confidence in the design of the trials, safety protocols, and [data safety monitoring.]" (Am. Compl. ¶ 67.)

4. Statements on Clinical Results

AstraZeneca began to report on the clinical results as they came in. On October 26, 2020, a spokesman for AstraZeneca told CNBC by email that it was "encouraging to see immunogenicity responses were similar between older and younger adults and that reactogenicity was lower in older adults, where the COVID-19 disease severity is higher." (Am. Compl. ¶ 70.) Immunogenicity reflects the type of immune responses that a vaccine generates and their magnitude over time. (*See* Am. Compl. ¶ 70 n.2.) Reactogenicity reflects the physical manifestation of the inflammatory response to vaccination. (*See* Am. Compl. ¶ 70 n.2.)

On November 5, 2020, AstraZeneca filed a Form 6-K with the SEC, which reported its financials for the nine months prior to September 30, 2020. (*See* Am. Compl. ¶ 72.) The Form 6-K reported that data showed that "AZD1222 has an acceptable tolerability profile and is immunogenic in adults above 18 years of age, including older adults. Stronger immune responses were shown after a second dose given one month apart, across all adult age ranges. Local and systemic reactions were lower in older adults than younger adults (<55 years) and reactions were lessened after the second dose." (Am. Compl. ¶ 72.)

Also on November 5, 2020, AstraZeneca hosted a conference call with analysts and investors that was led by Individual Defendants Pascal Soriot, Marc Dunoyer, and Menelas Pangalos. (*See* Am. Compl. ¶ 74.) AstraZeneca CEO Pacal Soriot stated that "[t]he efforts against the COVID-19 pandemic include advancing the vaccine candidate and more importantly initiating Phase III trials for our long-acting antibody combination, which is incredibly promising." (Am. Compl. ¶ 74.) Menelas Pangalos further stated that "[p]rogress has been made with our vaccine, AZD1222." (Am. Compl. ¶ 74.) During the call, an analyst asked, "to what extent . . . is there likely to be data on elderly patients?" (Am. Compl. ¶ 74.) Pangalos responded that "Andy Pollard has just presented a few weeks ago . . . at an infection conference actually data . . . [that] showed that the immune response in the 56 to 69 year olds and 69 and 70 and above looks very similar to the response of the 18 to 55 year olds. In that regard, we're feeling good about the immunogenicity in all the age groups that we're testing. And we think we will have data from those age groups for the readout." (Am. Compl. ¶ 76.)

5. Alleged Omissions

Throughout this time, the amended complaint alleges, AstraZeneca omitted an "[u]ndisclosed [d]osing [e]rror" affecting its Phase II/III clinical trial. (Am. Compl. ¶ 40.) As alleged, "Oxford hired an outside manufacturer to produce large quantities of the vaccine for the trial." (Am. Compl. ¶ 40.) But the manufacturer produced a "half-strength dose." (Am. Compl. ¶ 41.) Oxford researchers decided to give some participants in the trial "two injections." (Am. Compl. ¶ 41.) Those participants would receive a "lower dose" for the first dose and a "standard dose" for the second dose. (Am. Compl. ¶ 42.) Other participants would receive a "standard dose" for the first dose and a "standard dose" for the second dose. (Am. Compl. ¶ 42.)

AstraZeneca and Oxford "informed health regulators about the half-dose followed by the full-dose error, and it was concluded that the study protocol should be amended to include

recipients of" both regimens. (Am. Compl. ¶ 42.) "The protocol was amended on June 5, 2020." (Am. Compl. ¶ 42.) Accordingly, there were "two distinct groups with different dosing regimens with no pause in enrollment." (Am. Compl. ¶ 42.) As also relevant, there were no "subjects older than 55 years of age" in the "lower-dose" / "standard-dose" cohort. (Am. Compl. ¶ 42.) But AstraZeneca allegedly did not inform investors of this. (*See* Am. Compl. ¶ 42.)

The amended complaint alleges that AstraZeneca's statements throughout this period were misleading on the basis of the following omissions relating to the purported dosing error: (i) "the Phase II/III clinical trials for AZD1222 had suffered from a critical manufacturing error, resulting in a portion of trial participants receiving half the designed dosage"; (ii) "the Phase II/III clinical trials for AZD1222 consisted of a patchwork of disparate patient subgroups, each with subtly different treatments, undermining the validity and important of the conclusions that could be drawn from the clinical data across these disparate patient populations." (*See, e.g.*, Am. Compl. ¶ 48.) The amended complaint further alleges that (iii) "certain Phase II/III clinical trial participants AZD1222 had not received a second dose at the designated time points, but rather received the second dose up to several weeks after the dose had been scheduled to be delivered according to the original trial design." (*See, e.g.*, Am. Compl. ¶ 48.)

The amended complaint also alleges that AstraZeneca's statements throughout this period were misleading on the basis of omissions relating to the number of patients over 55 in its trials: (iv) "AstraZeneca had failed to include a substantial number of patients over 55 years of age in its Phase II/III clinical trials for AZD1222, and no patients over 55 in the half-dose regimen, despite this patient population being particularly vulnerable to the effects of Covid and thus a high priority target market for the drug." (*See, e.g.*, Am. Compl. ¶ 48.)

More generally, the amended complaint alleges that AstraZeneca's statements throughout this period were misleading because it failed to disclose that: (v) "AstraZeneca's Phase II/III clinical trials for AZD1222 had been hamstrung by widespread flaws in design, errors in execution, and a failure to properly coordinate and communicate with regulatory authorities and the general public"; (vi) "the Phase II/III clinical trials for AZD1222 failed to follow relevant and applicable protocols and guidelines, including, without limitation, the guidelines for Good Clinical Practice"; (vii) "as a result . . . , the Phase II/III clinical trials for AZD1222 had not been conducted in accordance with industry best practices and acceptable standards, and the data and conclusions that could be derived from the Phase II/III clinical trials was of limited utility"; and (viii) "as a result . . . , AZD1222 was unlikely to be approved for commercial use in the U.S. in the short term, one of the largest potential markets for the drug." (*See, e.g.*, Am. Compl. ¶ 48.)

B. Alleged Corrective Disclosures

The amended complaint alleges that these omissions reached the market over time. (*See* Am. Compl. ¶¶ 78-123.) The first alleged price drop occurred from November 20, 2020, to November 25, 2020. (*See* Am. Compl. ¶ 92.) On November 23, 2020, AstraZeneca released an interim analysis of its ongoing trial for AZD1222, and in doing so, "disclosed that the interim analysis involved two smaller-scale trials in disparate locales (the United Kingdom and Brazil) that, for unexplained reasons, employed two different dosing regimens." (Am. Compl. ¶ 78.) "One clinical trial, involving 2,741 subjects, provided patients a half dose of AZD1222 followed by a full dose." (Am. Compl. ¶ 78.) "The other trial, involving 8,895 subjects, provided two full doses." (Am. Compl. ¶ 78.) In a subsequent call, AstraZeneca "revealed that the half-dosing regimen was not a part of the original trial design, but rather . . . a contract manufacturer had under-predicted the dose of the vaccine by half in the UK trial." (Am. Compl. ¶ 81.)

On November 24, 2020, Dr. Moncef Slaoui, the head of the United States's Operation Warp Speed — a public-private partnership to facilitate the development of a vaccine targeting COVID-19 — "told reporters that AstraZeneca's half-strength dose had not been initially tested in people over the age of 55." (Am. Compl. ¶ 82.) Further, Dr. Slauoi revealed that "certain trial participants received their second dose weeks later than originally planned." (Am. Compl. ¶ 82.) Finally, Dr. Slaoui revealed that the trials amalgamated an array of groups and subgroups. (*See* Am. Compl. ¶ 82.) As a result, the price of AstraZeneca allegedly fell 5% from $55.30 on November 20, 2020, to $52.60 by market close on November 25, 2020. (*See* Am. Compl. ¶ 92.)

The second alleged price drop occurred on December 14, 2020. (*See* Am. Compl. ¶ 114.) On December 8, 2020, AstraZeneca and Oxford published the full data from the Phase II/III trials in the British medical journal *The Lancet*. (*See* Am. Compl. ¶ 101.) The *Lancet* article stated that the trial protocol "was amended on June 5, 2020, resulting in [enrollment] of two distinct groups with different dosing regimens with no pause in enrollment." (Am. Compl. ¶ 103.) A half-dose / standard-dose cohort "(aged 18-55 years) was enrolled over 11 days between May 31 and June 10, 2020." (Am. Compl. ¶ 103.) A standard-dose / standard-dose "cohort (aged 18-55 years) was enrolled from June 9 to July 20, 2020." (Am. Compl. ¶ 103.) "Subsequently, [enrollment] of older age cohorts began (from Aug 8, 2020, for participants aged 56-69 years and from Aug 13, 2020, for participants aged ≥ 70 years), all of whom were assigned to two standard doses." (Am. Compl. ¶ 103.) The *Lancet* article noted that some "doses could not be administered at a 4-week interval." (Am. Compl. 104.) It concluded that "[v]accine efficacy in older age groups could not be assessed but will be determined, if sufficient data are available, in a future analysis after more cases have accrued." (Am. Compl. ¶ 105.) On December 14, the *Daily Mail* published an article in which Menelas Pangalos said: "There is no doubt I think that we would have

run the study a little bit differently if we had been doing it from scratch." (Am. Compl. ¶ 114.) In response, AstraZeneca's stock fell by approximately 8%. (*See* Am. Compl. ¶ 114.)

The third alleged price drop occurred from January 26, 2021, to January 29, 2021. (*See* Am. Compl. ¶¶ 118-123.) On January 26, 2021, a German financial newspaper quoted sources in the German federal government stating that the AstraZeneca vaccine was less than 10 percent effective in people over 65 years old. (*See* Am. Compl. ¶ 118.) On January 28, 2021, Germany's vaccine commission advised against using AstraZeneca's coronavirus vaccines on older people; the interior ministry concluded that "no conclusion can be made regarding efficacy and safety in the elderly" due to "the small number of study participants in the age group ≥ 65 years." (Am. Compl. ¶ 119.) On January 29, 2021, a committee of the European Medicines Agency recommend AstraZeneca's Covid vaccine for approval in patients above 18 years of age but noted that "[e]fficacy could not be demonstrated in subjects older than 55 [years of age] due to the low number of COVID-19 cases in this age group." (Am. Compl. ¶ 120.) Further, their report noted that "[t]he conduct of studies was sub-optimal with regards to substantial changes to the protocol made after the start of studies, errors in dosing and an unplanned varying dose interval between 4 and 26 weeks." (Am. Compl. ¶ 121.) That day, French President Emmanual Macron stated, "everything seems to indicate that it's quasi ineffective for people older than 65 years old, some say 60 years and above." (Am. Compl. ¶ 122.) In response, the price of AstraZeneca declined by 7% from January 26, 2021, to January 29, 2021. (*See* Am. Compl. ¶ 123.)

C. Procedural History

Lead Plaintiffs Nuggehalli Balmukund Nandkumar and Wayne County Employees' Retirement System and Plaintiff Vladimir Zhukov bring an amended class action complaint against Defendants AstraZeneca plc; AstraZeneca CEO Pascal Soriot; AstraZeneca CFO Marc Dunoyer; and Menelas Pangalos, who was Executive Vice President of Biopharmaceuticals

Research & Development at AstraZeneca. (*See* Am. Compl. ¶¶ 11-18.) The amended complaint asserts that Defendants violated Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and the SEC's Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. (*See* Am. Compl. ¶¶ 150-155.) It further asserts that the Individual Defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), as controlling persons of AstraZeneca. (*See* Am. Compl. ¶¶ 156-160.)

Defendants move to dismiss the amended complaint under Federal Rules of Civil Procedure 8, 9(b), and 12(b)(6), as well as the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4 *et seq*. (*See* Dkt. No. 45.)

II. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) directs a court to dismiss a complaint "for failure to state a claim upon which relief can be granted." To survive a motion to dismiss for failure to state a claim, a complaint must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This means that a complaint is properly dismissed where "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S at 558. A complaint is also properly dismissed "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679.

Securities fraud claims, however, demand more: To survive a motion to dismiss, plaintiffs must satisfy "heightened pleading requirements." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). "[A] party must state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). Similarly, the Private Securities Litigation Reform Act ("PSLRA") sets forth that when a plaintiff alleges securities fraud for an untrue statement or

omission of a material fact, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). To satisfy these requirements, a 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." *Charles Schwab Corp. v. Bank of Am. Corp.*, 883 F.3d 68, 94 (2d Cir. 2018) (quoting *Emps.' Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 305 (2d Cir. 2015)) (internal marks omitted). The PSLRA further requires that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005). "To qualify as 'strong' . . . an inference of scienter 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, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

III. Discussion

The amended complaint asserts that Defendants violated Section 10(b) and Rule 10b-5, but it fails to identify any misleading statement from AstraZeneca and to adequately allege scienter. Absent a primary violation of the Exchange Act, Plaintiffs' Section 20(a) claim also fails.

A. Section 10(b) and Rule 10b-5 Claims

Section 10(b) makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules or regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). Rule 10b-5 makes it unlawful "for any person, directly or indirectly . . . [t]o make any untrue statement of material

fact or to omit a material fact necessary in order to make the statements made, in the light of the circumstances under which they are made, not misleading." 17 C.F.R. § 240.10b-5. To state a claim under these provisions, "a plaintiff must allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." *Seltzer v. Omega Healthcare Inv'rs, Inc.*, 968 F.3d 204, 212 (2d Cir. 2020) (quoting *ATSI Commc'ns, Inc.*, 493 F.3d at 105) (marks omitted).

In general, the amended complaint must be dismissed under the PSLRA because it falls short of the PSLRA's "particularity threshold." *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 38 (2d Cir. 2012); (*see* Dkt. No. 46 ("Defs.' Memo") at 16 n.13.) When a plaintiff alleges securities fraud for a misleading statement or material omission, the PSLRA obligates the plaintiff to "demonstrate with specificity why and how" each statement is materially false or misleading. *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004); *see* 15 U.S.C. § 78u-4(b)(1). The amended complaint does not adequately do so. Rather, in boilerplate fashion, the amended complaint identifies statements throughout the class period, italicizes them within long block quotes, and then, after each one, repeats a copy-and-pasted list of omissions. (*See, e.g.*, Am. Compl. ¶¶ 48, 56, 58, 62, 64, 68, 71, 77.) To satisfy the PSLRA, a pleading must do more than identify statements and then "provide[] a bullet-point list (running over a page) of 'true facts, which were then known to or recklessly disregarded by each of the Defendants.'" *Boca Raton Firefighters & Police Pension Fund*, 506 F. App'x at 38. Such allegations do not specify why and how each statement is misleading because they do not specify what understanding each statement left investors, and how that understanding was inconsistent with alleged omissions. *See In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2019)

(dismissing complaint where plaintiffs did not explain "which statements link up with which issues in the laundry list"). Rather, they "leav[e] the District Court to search the long quotations in the complaint for particular false statements, and then determine on its own initiative how and why the statements were false and how other facts might show a strong inference of scienter." *Boca Raton Firefighters & Police Pension Fund*, 506 F. App'x at 38.

1. AZ1222 Dosing Omissions (Alleged Omissions #1, #2, and #3)

Read generously, the amended complaint does not state a claim because it does not identify any statement made misleading by any alleged omission. Plaintiffs first protest that Defendants failed to disclose in a timely manner that some participants in the Phase II/III clinical trials for AZ1222 received "half the designed dosage"; that some participants "received the second dose up to several weeks after the dose had been scheduled to be delivered"; and that the trial reflected "a patchwork of disparate patient subgroups, each with subtly different treatments." (*See, e.g.*, Am. Compl. ¶ 48.) "[A]n omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100-01 (2d Cir. 2015) (quoting *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993)). "[T]here is no generalized duty to 'disclose negative facts.'" *In re Philip Morris Int'l Inc. Sec. Litig.*, No. 18-CV-8049, 2021 WL 4135059, at *10 (S.D.N.Y. Sept. 10, 2021) (quoting *Barilli v. Sky Solar Holdings, Ltd.*, 389 F. Supp. 3d 232, 252 (S.D.N.Y. 2019)). Rather, a duty arises only if there is "a corporate insider trad[ing] on confidential information," a "statute or regulation requiring disclosure," or a corporate statement that would otherwise be "inaccurate, incomplete, or misleading." *Stratte-McClure*, 776 F.3d at 101 (quoting *Glazer v. Formica Corp.*, 964 F.2d 149, 157 (2d Cir. 1992)). Plaintiffs here attempt to demonstrate that Defendants made statements rendered misleading by the alleged omissions.

Plaintiffs have not identified any inaccurate, misleading, or incomplete statement relating to AZ1222's dosing during AstraZeneca and Oxford's Phase II/III clinical trials for AZ1222. "The veracity of a statement or omission is measured . . . by its ability to accurately inform rather than mislead prospective buyers." *Operating Loc. 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86, 89 (2d Cir. 2010). Plaintiffs have identified only accurate statements describing the launch and historical progression of the Phase II/III clinical trials. For example, Plaintiffs highlight statements that note "the start of a Phase II/III UK trial of AZD1222 in about 10,000 adult volunteers" (Am. Compl. ¶ 44); that "COV002 has launched and has recruited almost 9,000 participants in the UK" (Am. Compl. ¶ 49); and that "[l]ate-stage Phase II/III trials are currently underway in the UK, Brazil and South Africa" (Am. Compl. ¶ 50). Such statements are not actionable; they "merely recite historical fact." *In re EDAP TMS S.A. Sec. Litig.*, No. 14-CV-6069, 2015 WL 5326166, at *10 (S.D.N.Y. Sept. 14, 2015); *see Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 230 (S.D.N.Y. 2009) (same).

Plaintiffs argue that these statements, if literally truthful, were still misleading. To be sure, whether a statement is misleading is "evaluated not only by 'literal truth,' but [also] by 'context and manner of presentation.'" *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019). But Plaintiffs have not alleged any relevant context to create a misleading impression. Plaintiffs argue only that the statements alone "created the misleading impression that their trials were proceeding as expected, [and] producing positive results, . . . with no significant setbacks or unusual issues," (Dkt. No. 51 ("Pls.' Opp'n") at 14-15.) But that is akin to saying that the absence of a negative disclosure gave the impression that there were no negative facts. Were that the standard, every omission would be actionable. Instead, there is "no generalized duty to 'disclose negative facts.'" *In re Phillip Morris Int'l Inc. Sec. Litig.*, 2021 WL 4135059, at *10.

Lastly, Plaintiffs allege that Defendants put the "conduct of the trials at issue" when they mentioned the Phase II/III UK trials. (*See* Pls.' Opp'n at 19.) "[O]nce a company speaks on an issue or topic, there is a duty to tell the whole truth." *In re Vivendi Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016). But the statements that Plaintiffs have identified are at such a high level of generality, and the alleged omitted facts so granular, that there is no violation of that principle here. "There is no boundless duty to reveal all facts on [a] subject just because a company or its officers speak on a subject." *City of Riviera Beach Gen. Emps. Ret. Sys. v. Macquarie Infrastructure Corp.*, No. 18-CV-3608, 2021 WL 4084572, at *6 (S.D.N.Y. Sept. 7, 2021) (internal quotation marks omitted). Instead, "the statement made and the fact that allegedly should have been disclosed must share a reasonable level of specificity." *Id.*; *see Diehl v. Omega Protein Corp.*, 339 F. Supp. 3d 153, 163 (S.D.N.Y. 2018) ("[I]t is the specificity" of a statement that may require a defendant to speak more fully.) That specificity is lacking here. Plaintiffs protest that Defendants failed to disclose the strength and timing of the dosage received by participants in the Phase II/III UK trials, but they have not identified any statements from Defendants at all about the strength and timing of that dosage. Instead, they have identified statements merely reciting the historical progression of the clinical trial. Such statements do not trigger an obligation to disclose the granular information sought in the amended complaint. *Cf. In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-CV-1307, 2014 WL 585658, at *11 (S.D.N.Y. Feb. 14, 2014) ("There is . . . no rule requiring this type of 'deep dive' disclosure.").

2. AZ1222 Elderly Omissions (Alleged Omission #4)

Plaintiffs also suggest that Defendants violated Section 10(b) and Rule 10b-5 because Defendants did not disclose that the Phase II/III trial for AZ1222 "failed to include a substantial number of patients over 55 years of age . . . , and no patients over 55 in the half-dose regimen." (*e.g.*, Am. Compl. ¶ 48.) Again, such allegations do not state a claim because Plaintiffs have not

identified any statement made inaccurate, misleading, or incomplete by that omission. For example, Plaintiffs emphasize that Defendants repeatedly stated that the Phase II/III trial would measure immune responses "in different age ranges." (Am. Compl. ¶¶ 47, 50.) But there is no dispute that the Phase II/III in fact measured immune responses in different age ranges. Acknowledging that, Plaintiffs argue that various statements "created the misleading impression that the number of 55+ subjects was sufficient to be studied" (Pls.' Memo at 16), where in fact the trial lacked a "substantial number of patients over 55 years of age" (*e.g.*, Am. Compl. ¶ 48). But that dispute — over the number of patients adequate to make findings legitimate — is "little more than a dispute about the proper interpretation of data." *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016). The Second Circuit has rejected such disputes "as a basis for liability" under the securities laws. *Id.* (citing *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013)).

3. AZ1222 General Omissions (Alleged Omission #5)

Plaintiffs next assert that Defendants violated Section 10(b) of the Exchange Act because AstraZeneca CEO Pascal Soriot stated that AstraZeneca was "moving quickly but without cutting corners" (Am. Compl. ¶ 60), and Individual Defendant Menelas Pangalos stated that the Phase II/III trial remained "on track" (Am. Compl. ¶ 52), but failed to disclose that "AstraZeneca's Phase II/III clinical trials for AZD1222 had been hamstrung by widespread flaws in design, errors in execution, and a failure to properly coordinate and communicate with regulatory authorities and the general public" (*see, e.g.*, Am. Compl. ¶ 56). Statements like working "without cutting corners" or staying "on track" are not actionable under Section 10(b). Mere puffery, *see Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000), they do no more than reflect "statements that are loosely optimistic regarding a company's well-being," *In re Lulumon Sec. Litig.*, 14 F. Supp. 3d 553, 572 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015), and they are "so vague, broad, and non-specific that a reasonable investor would not rely on [them],"

Galestan v. OneMain Holdings, Inc., 348 F. Supp. 3d 282, 297-98 (S.D.N.Y. 2018). Accordingly, such allegations do not state a claim. *Cf. In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757-58 (S.D.N.Y. 2018) (finding statement that company was "proud" to be "on track to have these products reach the market in 2016" was puffery); *In re EDAP TMS S.A. Sec. Litig.* No. 14-CV-6069, 2015 WL 5326166, at *9 (S.D.N.Y. Sept. 14, 2015) (finding statements that FDA approval process was "on track" and making "progress" to be puffery because they did no more than place a "positive spin on developments").

4. AZ1222 Guidelines Omissions (Alleged Omissions #6 and #7)

The amended complaint also has not stated a claim from allegations that AstraZeneca expressed various commitments to public safety and equitable access. Plaintiffs emphasize, among other things, that AstraZeneca stated that its "core values" were to "follow the science" and "put patients first" (Am. Compl. ¶¶ 60-61); that AstraZeneca made a "commitment to the highest safety standards and to broad and equitable access" (Am. Compl. ¶ 61); that it pledged to "make the safety and well-being of vaccinated individuals our top priority" (Am. Compl. ¶ 63); and that it pledged to "adhere to high scientific and ethical standards regarding the conduct of clinicial trials and the rigor of manufacturing processes" (Am. Compl. ¶63). Those statements are also inactionable "puffery" because they "are too general to cause a reasonable investor to rely upon them." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009). Accordingly, even if the statements are in tension with any omissions in some abstract sense, they cannot support a claim. *Cf. City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 183 (2d Cir. 2014) (declaring "general statements about reputation, integrity, and compliance with ethical norms" to be "inactionable 'puffery'"); *In re AT&T/DirecTV Now Sec. Litig.*, No. 19-CV-2892, 2020 WL 4909718 (S.D.N.Y. Aug. 18, 2020) (finding statements about company's "core set of values," set forth in

its "Code of Business Conduct," and its commitment to "the highest standards" to be "puffery"); *In re Philip Morris Int'l Inc. Sec. Litig.*, 437 F. Supp. 3d 329, 350-51 (S.D.N.Y. 2020) (finding statements that company was "conducting extensive and rigorous scientific studies" and conducting "research [that] meets rigorous standards" to be "puffery").

5. AZ1222 Approval Omission (Alleged Omission #8)

Finally, the amended complaint does not state a claim from allegations that Defendants failed to disclose that "AZD1222 was unlikely to be approved for commercial use in the U.S. in the short term." (*See, e.g.*, Am. Compl. ¶ 48.) The amended complaint does not clearly identify what statements are in tension with that omitted fact, but any statements about the likelihood of regulatory approval are protected under the PSLRA's safe harbor for forward-looking statements. *See* 15 U.S.C. § 78u-5(c). Statements about the likelihood of regulatory approval are "classically forward-looking, as they address what defendants expect[] to occur in the future." *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016). Under the PSLRA's safe harbor, "a defendant is not liable if the forward-looking statement is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). All statements here relating to the likelihood of regulatory approval were accompanied by adequate cautionary language. (*See* Defs. Memo at 26-27; Dkt. No. 46-1 ("Defs.' Memo Annex B.").) Accordingly, they cannot support a claim. *Cf. Schaeffer v. Nabriva Therapeutics plc*, No. 19-CV-4183, 2020 WL 7701463, at *10 (S.D.N.Y. Apr. 28,

2020) (finding "statements that Defendants expected CONTEPO to win FDA approval and intended to launch CONTEPO shortly after approval" to be within safe harbor).[1]

* * *

Separately, Plaintiffs fail to state a claim under Section 10(a) and 10b-5 because the amended complaint does not raise a "strong inference" of fraudulent intent. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005). Plaintiffs argue that Defendants had a "motive and opportunity" to commit fraud. *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000). But to plead a motive to commit fraud, a plaintiff must allege "that the individual defendants received a 'concrete and personal benefit' from making their alleged misrepresentations" or actionable omissions. *Sfiraiala v. Deutsche Bank Aktiengesellschaft*, 729 F. App'x 55, 57 (2d Cir. 2018) (summary order). Plaintiffs have not done so. The closest Plaintiffs come is alleging that Defendants had a motive to inflate stocks so that AstraZeneca could fund the "December 2020 acquisition of Alexion Pharmaceuticals." (Am. Compl. ¶ 140.) But Plaintiffs have not alleged any "unique connection between the fraud and the acquisition," *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 201 n.6 (2d Cir. 2009), such as "misstatements directly relating to the acquisition of [the] company," and the "generalized desire to achieve a lucrative acquisition proposal" is otherwise insufficient, *id.* at 201. Plaintiffs also suggest that Defendants were motivated to "develop a viable Covid

[1] Plaintiffs do suggest that Defendants made a statement based on then-known omitted facts when AstraZeneca CEO Pascal Soriot signed a pledge stating that AstraZeneca would "[o]nly submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA." (Am. Compl. ¶ 63; *see* Pls.' Opp'n at 25 n.22.) Plaintiffs argue that this statement misled investors into thinking that AstraZeneca and Oxford would conduct a "single" Phase III trial rather than multiple trials. (*See* Pls.' Opp'n 5 n.2.) An investor would not understand the statement to commit AstraZeneca to conduct only a single trial.

vaccine in order to obtain the prestige that would come with it and avoid reputational or financial harm." (Pls.' Opp'n at 32.) These motives are "common to most corporate officers," so they are insufficient. *ECA*, 553 F.3d at 198; *cf. In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 735 (S.D.N.Y. 2018) (finding no motive even where drug was a company's "only drug product candidate, so the success of the Company hinged on the clinical success of this product").

Nor have Plaintiffs alleged facts reflecting "strong circumstantial evidence of conscious misbehavior or recklessness." *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d at 39. To raise an inference of fraudulent intent, alleged behavior must be "highly unreasonable" and "an extreme departure from the standards of ordinary care," *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001), *i.e.*, "a state of mind approximating actual intent," *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009). Plaintiffs have not alleged such behavior. Plaintiffs argue that Defendants had access to "contrary facts" in tension with various public statements. (*See* Pls.' Opp'n at 28-29.) But it is settled in this Circuit that "[w]here plaintiffs contend defendants had access to contrary facts" to public statements, "they must specifically identify the reports or statements containing this information." *Shetty v. Trivago N.V.*, 796 F. App'x 31, 35 (2d Cir. 2019) (summary order). Plaintiffs' "failure to do so is sufficient to end the inquiry." *Id.* At most, Plaintiffs have identified an "amend[ment] [to] the study protocol on June 5, 2020" for the Phase II/III trial, in which AstraZeneca and Oxford "informed health regulators about the half-dose followed by the full-dose error." (Am. Compl. ¶ 139.) Aside from such dosing material, Plaintiffs have not adequately alleged that Defendants had access to any omitted facts.

Even if Defendants had access to the omitted facts, the nondisclosures here do not raise a strong inference of conscious misbehavior or recklessness. For one, Defendants disclosed the facts contained in that report to the FDA, which undermines an inference of fraudulent intent.

See Borochoff v. GlaxoSmithKline PLC, No. 07-CV-5574, 2008 WL 2073421, at *8 (S.D.N.Y. May 9, 2008), *aff'd sub nom. Avon Pension Fund v. GlaxoSmithKline PLC*, 343 F. App'x 671 (2d Cir. 2009). For another, the omitted facts are not so contrary that they raise an inference of conscious misbehavior or recklessness. For example, Plaintiffs fault Defendants for not immediately disclosing the half-dose subgroup, and Plaintiffs fault Defendants making statements relating to elderly participation in the Part II/III clinical trial without disclosing that the company had "failed to include a substantial number of patients over 55 years of age" in the trial. (*E.g.,* Am. Compl. ¶ 48.) Because there is room for disagreement over whether the half-dose subgroup would undermine any trial results, and there is room for disagreement over how many elderly patients are enough to assess an immune response, Defendants' disclosures and nondisclosures here were not "highly unreasonable." *Kalnit*, 264 F.3d at 142; *see In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d at 41 (concluding that it was not reckless for company to "tout[] Felbatol's safety" despite "actual awareness of adverse reports"). Accordingly, Plaintiffs have not made out any claims under Section 10(b) of the Exchange Act or the SEC's Rule 10b-5.

B. Section 20(a) Claims

Plaintiffs' claims of control-person liability under Section 20(a) of the Exchange Act against the individual defendants must also be dismissed. Section 20(a) establishes liability for those who control persons or entities who violate provisions of the Exchange Act. *See* 15 U.S.C. § 78t(a). "To establish a prima facie case of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSA Commc'ns, Inc.*, 493 F.3d at 108. Because Plaintiffs have not stated a primary violation, they also have not stated a claim of control-person liability.

IV. Conclusion

For the foregoing reasons, Defendants' motion dismiss (Dkt. No. 45) is GRANTED. Plaintiffs' motion for leave a file a sur-reply (Dkt. No. 55) is denied as moot. The Court declines to grant leave to amend because (1) Plaintiffs have not complied with paragraph 3(D)(ii) of the Court's Individual Rules despite the opportunity to do so, (2) Plaintiffs have not suggested how they would amend the already-amended complaint to remedy the grounds for dismissal identified in this opinion, and (3) the Court concludes that amendment would be futile under the circumstances.

The Clerk of Court is directed to enter final judgment dismissing the amended complaint with prejudice.

The Clerk of Court is directed to close the motions at Docket Number 45 and 55 and to close this case.

SO ORDERED.

Dated: September 12, 2022
New York, New York

J. PAUL OETKEN
United States District Judge