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United States District Court, D. New Jersey.

IN RE NOVO NORDISK A/S SECURITIES LITIGATION

Civil Action No. 25-713 (RK) (JBD)
|
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Attorneys and Law Firms

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OPINION

Robert Kirsch United States District Judge

***1 THIS MATTER** comes before the Court upon a Motion to Dismiss filed by Defendants Novo Nordisk A/S ("Novo" or the "Company"), Lars Fruergaard Jørgensen ("Jørgensen"), and Martin Holst Lange ("Lange") (collectively, "Defendants"). (ECF No. 69.)[1] Defendants seek to dismiss co-lead Plaintiffs New York Hotel Trades Council & Hotel Association of New York City, Inc. Pension Fund, Pavers & Road Builders District Council Pension Fund, and City of Kissimmee General Employees' Retirement Plan's (collectively, "Plaintiffs") Consolidated Complaint. ("CC," ECF No. 41.) Plaintiffs filed a brief in opposition, ("Opp.," ECF No. 70), and Defendants replied, ("Reply," ECF No. 71). The Court has considered the parties' submissions and resolves the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, Defendants' Motion to Dismiss is **GRANTED IN PART** and **DENIED IN PART**.

[1] The Court will refer to Defendants' brief in support of their Motion to Dismiss, (ECF No. 69-1), as "MTD." The Court also refers to Jørgensen and Lange together as the "Individual Defendants."

I. BACKGROUND[2]

[2] The facts below are taken from the CC and assumed to be true solely for the purposes of deciding the subject Motion. All references throughout this Opinion to "Exhibit" or "Ex." refer to the exhibits to Audra Soloway's Declarations. (ECF Nos. 69-2, 71-1.) Although Defendants' Motion initially included 37 exhibits, their Reply brief included an additional exhibit for which Defendants sought incorporation by reference. (ECF No. 71-2; ECF No. 71 at 10 n.8 (seeking incorporation by reference of Novo's Analyst/Investor Day Call transcript).) To avoid confusion, the Court cites these exhibits throughout by their PDF page number as they appear on the Court's electronic docket.

Clinical trials are complicated and nuanced, and investor calls are not scientific conferences. Nonetheless, under federal securities law, pharmaceutical companies may not mischaracterize or withhold material aspects of those trials in a deceitful or misleading way. In the highly lucrative marketplace of glucagon-like peptide-1 ("GLP-1") drugs, drug efficacy and tolerability appear to be a critical focus of manufacturer and investor alike. Efficacy matters to ensure that the drug works. Tolerability, as the word suggests, matters to ensure that patients can take the drug as prescribed. The person-to-person differences in human physiology will lead to varying results among participants of pharmacological clinical trials, including an individual's inability to tolerate a GLP-1. In other words, as likely in any clinical trial of a new drug, there are those whose side effects or reactions have compelled them to withdraw or to substantially de-escalate a tested dosage. That is different from the fundamental restructuring of a clinical protocol to allow for "flexible" dosing. Conflating these two forms of dose modification—one resulting from absolute intolerance to a drug and the other from more open-ended flexibility—whitewashes, as Plaintiffs allege here, serious questions about drug tolerability.

***2** This putative class action brought by purchasers of Novo American Depository Receipts ("ADRs") between and including November 2, 2022 and December 19, 2024 ("the Class Period") against Novo and two key officers asserts claims for securities fraud under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78a et seq. and Rule 10b-5 promulgated thereunder (CC ¶ 1.) Plaintiffs allege that Defendants—Novo, its former CEO, and its Executive Vice

President of Development—made material misstatements or omitted material information relating to a clinical trial Novo conducted of its weight loss and diabetes-treating drug, CagriSema. Throughout the Class Period, Defendants allegedly represented that the clinical trial, REDEFINE 1, would adhere to Novo's clinical trial status quo; that the various clinical protocols were materially unchanged from earlier phases. When the truth was revealed to investors —essentially, that REDEFINE 1 had instead, without the public's knowledge, allowed participants to flexibly control their own CagriSema dosage—Plaintiffs contend that Novo ADRs plummeted and shareholders lost money. As detailed below, Defendants contest these allegations. For the vast majority of these alleged misstatements, Plaintiffs have failed to state a securities claim. But for a specific category of statements relating to CagriSema's "tolerability" and REDEFINE 1's related clinical protocols, Plaintiffs have adequately pleaded a claim.

A. THE PARTIES

The three co-lead Plaintiffs, various multi-employer pension plans and defined benefit funds, purchased Novo ADRs at alleged "artificially inflated prices" during the Class Period, suffering losses when the shares tumbled. (CC ¶¶ 14–16.) Novo, a Danish corporation with its United States principal place of business in Plainsboro, New Jersey, is a global pharmaceutical company known for its production of GLP-1 prescription drugs, Ozempic and Wegovy. (*Id.* ¶¶ 2–3, 17.) The Company's sponsored ADRs trade publicly on the New York Stock Exchange under the ticker "NVO." (*Id.* ¶ 17.) Defendant Jørgensen was the CEO of Novo and a member of the Company's Management Board during the Class Period. (*Id.* ¶ 18.) Also throughout the Class Period, Defendant Lange served the Company as Executive Vice President of Development "and as a member of Novo's Management Board, Research Portfolio, and Product Development Committees." (*Id.* ¶ 19.) Per the CC, Lange was the person Novo held out "to investors as the person who was most capable of answering all 'key' questions regarding the design of Novo's clinical studies." (*Id.*; *see also id.* ¶ 94 ("Novo and its senior management team identified Lange as the 'key person' authorized on Novo's behalf to answer important questions regarding the Company's clinical trial designs and outcomes.").)

B. NOVO'S DEVELOPMENT OF CAGRISEMA

Plaintiffs' allegations go hand in hand with the meteoric rise of GLP-1 drugs to treat obesity and diabetes. Novo initially added GLP-1 medications, designed to simulate the body's insulin secretion, to their portfolio of diabetes-treating medications in 2010. (*Id.* ¶ 23.) In 2017, Novo launched its new GLP-1 drug, semaglutide—better known as Ozempic—to treat diabetes. (*Id.* ¶ 26.) Following Ozempic's success in stimulating weight loss and treating obesity, Novo launched a clinical trial, STEP 1, to test semaglutide's effectiveness in reducing obesity. (*Id.*) STEP 1 confirmed the efficacy of Ozempic for weight loss—resulting in 14% weight loss on average—and the FDA approved Novo's application to market semaglutide for obesity, branded as Wegovy. (*Id.*)

Billions of dollars in GLP-1 drug sales drove Novo to become the largest company in Europe by market capitalization. (*Id.* ¶¶ 28–29.) Attempting to enter the lucrative GLP-1 market itself, rival pharmaceutical company Eli Lilly began to develop its own GLP-1 drug, tirzepatide, branded as Mounjaro.[3] (*Id.* ¶ 30.) In June 2022, Eli Lilly published a study demonstrating Mounjaro's "improvement over Novo's Ozempic and Wegovy"—the highest dose of tirzepatide generated 22.5% weight loss on average with higher tolerability than Novo's drugs. (*Id.*) In June 2023, Eli Lilly announced even better clinical trial results from another experimental GLP-1 drug, retatrutide, which produced 24.2% weight loss in its Phase II study. (*Id.* ¶ 31.)

[3] Eli Lilly is not a party to this litigation.

Plaintiffs allege that, in an effort to maintain its market share in the face of growing competition, Novo pointed investors to the next drug in its development pipeline, CagriSema. (*Id.* ¶ 33.) CagriSema is a combination drug of cagrilintide, "an amylin analogue that increases satiety," and semaglutide, "the Ozempic and Wegovy GLP-1 drug." (*Id.*) Novo—and various market analysts—hoped that the combination of the two drugs would not only promote greater weight loss than semaglutide alone but also would have improved "tolerability"—i.e., "the ability to maintain patient adherence" to a GLP-1 drug regimen. (*Id.* ¶¶ 34–35.)

***3** Phase I of the CagriSema trial began in July 2018. (*Id.* ¶ 37.) The study used a "multiple-ascending dose" of cagrilintide, where participants were randomly assigned a dose of either 0.16 mg, 0.3 mg, 0.6 mg, 1.2 mg, 2.4 mg, or 4.5 mg of cagrilintide and a 2.4 mg dose of semaglutide. (*Id.*) These doses escalated incrementally over the first 16 weeks of the trial, with participants receiving the final target dose for the final four weeks. (*Id.*) On June 18, 2020, Novo announced

a successful Phase I trial, with participants on the highest dose losing an average of 17.1% body weight. (*Id.*)

Novo began its Phase II trial for CagriSema in 2021. (*Id.* ¶ 38; Ex. 17.) Phase II assessed the "efficacy and safety of a fixed dose combination of CagriSema (2.4 mg cagrilintide and 2.4 mg semaglutide) relative to the individual components" of cagrilintide and semaglutide. (CC ¶ 38; Ex. 17 at 8.) Trial participants gradually increased their dosage of CagriSema until they reached a target dose of 2.4 mg per drug, then maintained that dose for 32 weeks. (CC ¶ 38.) As is relevant to the present litigation, Novo's Phase II clinical trial protocols contained a provision related to "Dose modification." (Ex. 17 at 32.) This provision stated that investigators should "consider" delaying participant dose escalation, reducing the dose during dose escalation, or reducing the participant's maintenance dose. (*Id.*) However, such modifications could occur "only ... if the subject would otherwise discontinue the trial products completely and only if considered safe to continue on any trial products dose." [4]

6.6 Dose modification

Consider delaying dose escalation or reducing the dose during dose escalation if:

- The current dose is not tolerated by the subject. This should only be allowed if the subject would otherwise discontinue trial products completely and only if considered safe to continue on any trial products dose, as per investigator's discretion

Consider reducing the maintenance dose if;

- The maintenance dose is not tolerated by the subject. The subject may stay at a lower dose level but only if the subject would otherwise discontinue trial products completely and only if considered safe to continue on any trial products dose, as per investigator's discretion.

- The subject achieves a BMI of <22.5 kg/m^2 and continues losing weight, per investigator's discretion

Dose modifications must be applied to both trial products. In case of deviations from the planned dose escalation regimen, it is recommended that the subject makes at least one attempt to re-escalate to the maintenance dose, as per the investigator's discretion. It is recommended that the investigator consults Novo Nordisk in case of persistent deviations from the planned escalation regimen.

(*Id.*)

4 The Court notes that the earlier STEP trials for Ozempic contained similar language that the dose reduction or maintaining a lower dose "should only be allowed if the subject would otherwise discontinue trial product completely and if considered safe to continue on trial product, as per the investigator's discretion." (Ex. 5 at 30 (STEP 1); Ex. 6 at 32 (STEP 2); Ex. 7 at 29 (STEP 3).)

In August 2022, Novo announced completion of the Phase II CagriSema trial, stating that CagriSema achieved 15.6% weight reduction. (*Id.* ¶ 39.) Novo also announced that it expected to begin its Phase III CagriSema trial later that year: the "REDEFINE 1" study. (*Id.*)

C. ALLEGED FALSE AND MISLEADING STATEMENTS

In connection with REDEFINE 1, Plaintiffs allege that Defendants made 44 total false or misleading statements within three general categories, regarding (1) the REDEFINE 1 dosing protocol, (2) CagriSema's tolerability and weight-loss potential, and (3) statements regarding potential future CagriSema trials. [5] Within these three groups, the CC breaks down the allegedly problematic statements into seven sets.

5 These three categories are only slightly different from the CC's prescribed categories of statements, (CC ¶ 42), and Defendants' own categories, (MTD at 10).

***4** The first challenged statement occurred on November 2, 2022, the first day of the asserted Class Period, in Novo's published SEC Form 6-K. (*Id.* ¶ 43.) Novo stated that "REDEFINE 1 is a 68-week trial comparing the efficacy and safety of once-weekly CagriSema (2.4 mg semaglutide and 2.4 mg cagrilintide) with semaglutide 2.4 mg, cagrilintide 2.4 mg and placebo. The trial is expected to enrol[l] approximately 3,400 people with overweight [sic] or obesity. REDEFINE 1 is the first pivotal trial in the REDEFINE program[ ]." [6] (*Id.* (alterations in original [7]).)

6 This same day, Plaintiffs allege that Defendant Lange sold 1,000 Novo Class B shares for $110,834 in proceeds. (CC ¶ 122.)

[7] Unless indicated otherwise, the Court omits the CC's italicization and bolding on each of the alleged misstatements.

The second set of statements occurred as part of an investor presentation slide deck Defendants initially prepared for a November 2, 2022 earnings call. (CC ¶ 44; Ex. 16 at 36.) The slide deck represented that REDEFINE 1 would include a "2.4 mg/2.4mg" dosing protocol of cagrilintide and semaglutide:

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(Ex. 16 at 36.) Defendants included this same slide in other earnings call presentations over the next fourteen months on February 1, 2023, May 4, 2023, August 10, 2023, November 2, 2023, and January 31, 2024.[8] (CC ¶¶ 52–56.)

[8] Plaintiffs allege that several of these presentation dates coincide with, or were in close proximity to, the Individual Defendants selling thousands of their Novo shares. On February 1, 2023, Plaintiffs allege that Jørgensen sold 36,260 Class B Novo shares for $5,054,879. (CC ¶ 119.) On November 13, 2023, Plaintiffs allege that Lange sold 7,000 shares for $706,860. (*Id.* ¶ 122.) On February 5, 2024, Plaintiffs allege that Jørgensen sold 179,930 shares for more than $20 million and Lange sold 16,000 shares for more than $1.5 million. (*Id.* ¶¶ 120–23.)

The third set of challenged statements occurred in Novo's publication of the REDEFINE 1 study record on the publicly available ClinicalTrials.gov. (*Id.* ¶ 45.) Initially published on the first day of the Class Period November 2, 2022, the study record update stated that the experimental dose of CagriSema would be "2.4mg/2.4mg," explaining that study "[p]articipants will receive 2.4 mg cagrilintide and 2.4 mg semaglutide once-weekly after a dose escalation period of 16 weeks ... during the maintenance period for 52 weeks in the main phase." (*Id.*) Novo published assorted updates to the REDEFINE 1 study entry that reiterated this language 29 additional times during the Class Period. (*Id.* ¶ 51 (listing nearly monthly updates to ClinicalTrials.gov study entry for REDEFINE 1 from November 10, 2022 to December 15, 2024).)

The fourth set of challenged statements occurred on November 3, 2022, at a second Novo third-quarter 2022 earnings call the day after the start of the Class Period. (*Id.* ¶ 48.) In response to an investor question about what Novo was planning to do to "get better tolerability" among participants in REDEFINE 1—particularly given Eli Lilly's ability to improve its own drug tolerability—Defendant Lange stated:

> Specifically on going to higher doses, we're actually following our normal step of more or less doubling the dose. We've shown that we can do that without introducing more tolerability issues. And based on what we know already now, we feel confident that these call them step increases will not introduce more tolerability issues than what we've seen.

(*Id.*)

The fifth set of challenged statements occurred on March 7, 2024 at the Novo Capital Markets Day presentation for analysts and investors. (*Id.* ¶ 59.) In his opening statement, Lange discussed CagriSema and the REDEFINE I study:

> ***5** My next [love] is obviously CagriSema. You've seen the data a couple of times in obesity. We know that it holds great potential. ***At least 25% weight loss with a safety and tolerability profile that in Phase I/II was similar to that [of Wegovy.] So we get more bang for the buck, so to speak, without having to compromise on safety and tolerability.*** If we can show that in Phase III, that's really going to be a game changer.[9]

(*Id.* (alterations in original).) On the same Capital Markets Day conference call, a securities analyst from Morgan Stanley asked about a comment Lange had made about "looking at lower doses of CagriSema"—below the 2.4 mg/2.4 mg ratio planned for the REDEFINE 1 maintenance dose—and the effect such lower dosing would have on REDEFINE 1 participants. (*Id.* ¶ 62.) Lange responded: "So I don't think I said lower doses for CagriSema. Currently, we are investigating 2.4 milligram plus 2.4 milligram," and that

although Novo would be investigating different dosing in the future, Lange stated that "currently, we see the maximum benefit on weight loss on, glycemic control, but certainly also on the cardiovascular biomarkers on the doses that we picked for [REDEFINE 1], so 2.4 milligram and 2.4 milligram." (*Id.*)

9 Plaintiffs only allege that the bold and italicized portion of this quote is false or misleading.

Also during the March 7, 2024 Capital Markets Day, Novo presented slides on "diabetes care" discussing various drugs in the Novo "[d]evelopment pipeline," representing that CagriSema would be an "FDC" of "sema and cagri." (*Id.* ¶ 65; Ex. 29 at 17.) As clearly illustrated hereinbelow, an almost unreadable-font-size footnote on the slide defines FDC as "fixed dose combination."

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(*Id.*)

The sixth set of statements are based on a slide Novo first presented on March 7, 2024 at its Capital Markets Day. (CC ¶ 68.) In a slide deck about "Obesity care," Novo stated in a slide that in "[p]otential future trials" Novo would "[e]valuate lower doses for personali[z]ed treatment."

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(*Id.*; Ex. 30 at 7.) Novo would present this same slide at additional earnings call presentations during the Class Period, including on May 2, 2024, August 7, 2024, and November 6, 2024. [10] (CC ¶¶ 69–70, 75.)

10 Plaintiffs allege that on May 14, 2024, in close proximity to the first of these subsequent presentations, Lange sold 9,000 Class B Novo shares for more than $1 million in proceeds. (CC ¶ 123.)

The seventh set of statements concern statements Defendant Lange made on conference calls to discuss Novo's third-quarter 2024 earnings. (*Id.* ¶ 73.) First, on November 6, 2024, in response to a Bernstein analyst's question about CagriSema's "increased efficacy on weight loss" but increasing tolerability problems in patients, Lange stated:

> We are still basing all of our assumptions on data derived from Phases I and II. Based on what we know and based on how we understand the biology, as you said yourself, we expect to see really unsurpassed weight loss.... And based on what we've seen so far, that will come with a safety and tolerability profile broadly in line with what we see with GLP-1 treatment.

***6** (*Id.*) The next day, on a second earnings conference call, in response to a Redburn Atlantic analyst's questions about "antidrug antibodies" and how those would affect Novo's model projecting 25% weight loss, Lange responded that he was not worried about the effect of those antibodies on the efficacy or safety of CagriSema based on current data. [11] (*Id.* ¶ 77.) Furthermore, Lange stated that "[t]hat also means then when we look at our model, that has actually been factored in, because the model is based on the clinical response in Phases 1 and 2, and that lands us nicely at the 25% mark." (*Id.*)

11 Plaintiffs do not allege that Lange's specific statements about the effect of antidrug antibodies on REDEFINE 1 or CagriSema generally were false or misleading, only his above statement that Novo's "model" suggested 25% weight loss from REDEFINE 1. (CC ¶ 77.)

D. DISCLOSURE AND MARKET REACTION

On December 20, 2024, Novo issued a "company announcement" regarding REDEFINE 1. (*Id.* ¶ 79; Ex. 21 at 2.) According to the Consolidated Complaint, Novo informed the public, for the first time, that "[t]he REDEFINE 1 trial was based on a *flexible* protocol, allowing patients to modify their dosing throughout the trial." (CC ¶ 79 (emphasis added); Ex. 21 at 2.) Apparently, the REDEFINE 1 dosing protocol —reproduced below—had allowed participants "who [were] unable to reach the target maintenance dose of 2.4mg/2.4mg due to intolerability ... to continue at the maximum tolerated dose."

Dose modifications

> Consider delaying the dose escalation or reducing the dose if the current dose is not tolerated. It is recommended that the participant makes ad least one attempt to re-escalate to the maintenance dose during the study, as per the investigator's discretion. Participants who are unable to reach the target maintenance dose of 2.4 mg/2.4 mg due to intolerability will be permitted to continue at the maximum tolerated dose.
>
> During dose escalation and - dose maintenance, efforts should be made by the investigator to support participants in escalating and maintaining the corresponding IMP dose. To mitigate and manage GI symptoms the investigator can advise participants to eat more slowly, eat smaller meals, and stop eating when feeling full. In cases of intolerable GI AEs, the investigator may consider use of symptomatic medication (e.g. antiemetic or antidiarrheal).

(Ex. 19 at 51.)

Novo's announcement explained that after the 68-week trial, only 57.3% of all participants were taking the highest dose —a once weekly "fixed dose combination of cagrilintide 2.4 mg and semaglutide 2.4 mg." (Ex. 21 at 2.) This means, mathematically, that some 42.7% of the more than 3,400 participants either withdrew from the study completely or did not maintain the 2.4 mg maintenance dose. (*Id.*) The announcement also revealed the weight loss results of REDEFINE 1, indicating 20.4% weight loss in practice. [12] (CC ¶ 80.) Subsequent reporting and securities analysis focused on these "weak" weight loss results, the clear tolerability problems, and the "flexible trial protocol." (*Id.* ¶¶ 81–82.)

12 The announcement also indicated that the "hypothetical" weight loss if "all people adhered to treatment" was 22.7%. (CC ¶ 80.) The distinction between these two percentages—one practical and one theoretical—is not relevant to the disposition of the instant Motion.

A little over a month later, on February 5, 2025, Novo discussed the REDEFINE 1 dosing protocol further in their 2024 earnings call presentation to investors. (*Id.* ¶ 83.) In a slide presented to investors, Novo stated that "[b]ased on the observed weight loss in CagriSema phase 1 and 2 trials, a flexible protocol was incorporated in the REDEFINE 1 trial." (*Id.*) This dosing regimen would allow trial participants to "modify [their] dose" and allowed them "to stay at a tolerated dose" throughout the trial:

***7** Tabular or graphical material not displayable at this time.

(*Id.*) On the earnings call that same day, Defendant Lange explained that Novo "permitted dose modifications" in REDEFINE 1 "[b]ased on the CagriSema weight loss data observed in Phase 1 and 2 trials," and that this form of "individual dose titration" was intended "to balance efficacy, tolerability, and trial dropout" of participants. (*Id.* ¶¶ 84–85.) Because of this flexibility, a number of investors and analysts commented that the REDEFINE 1 trial results did not provide clear data about CagriSema's tolerability; that because so many participants failed to maintain the final maintenance dose of 2.4 mg of each drug, the actual tolerability of CagriSema remained "unanswered." (*Id.* ¶¶ 87–89 (analysis from TD Cowen, Barclays, and Deutsche Bank), 129–32 (analysis and reporting from DNB Markets, BMO Capital Markets, William Blair, and Reuters).)

Following the initial December 20, 2024 announcement, the price of Novo ADRs "collapsed $18.15 per share, or 17.83% [of their value], in a single day" with "abnormally high volume of over 53 million ADRs traded." [13] (*Id.* ¶ 127.) Subsequent analyst and media reports emphasized the flexible dosing protocols in REDEFINE 1 "and [those protocols'] implications on CagriSema's efficacy and tolerability." (*Id.* ¶¶ 128–32 (noting analysis and reporting from DNB Markets, BMO Capital Markets, William Blair, and Reuters).) Plaintiffs contend that Defendants' alleged misrepresentations "about CagriSema, REDEFINE 1, and Novo's business prospects" caused them to suffer damage based on the "artificially inflated prices for Novo ADRs." (*Id.* ¶¶ 148–53.)

13 Plaintiffs allege that in contrast to this collapse, "the S&P 500 Index *increased* 1.1% and Novo's peer group index ... increased 0.77%." (CC ¶ 127.)

E. ADDITIONAL SCIENTER ALLEGATIONS

The Consolidated Complaint also outlines additional facts related to Defendants' scienter. [14] First, Plaintiffs point to extensive public statements to investors that allegedly indicate that Defendant Lange was the " 'key person' authorized on Novo's behalf to answer important questions regarding the Company's clinical trial designs and outcomes." (*Id.* ¶ 94.) In particular, Plaintiffs note instances

of Novo executives deferring to Lange's experience with CagriSema. These include (1) Novo's CFO deferring a question to Lange about CagriSema dosing on Novo's first-quarter 2021 earnings call, (2) Novo's CFO introducing Lange as the corporate representative most involved in a June 2022 American Diabetes Association presentation and the person "able to [answer] all the key questions around our clinical trial outcomes, design, ... and so on[,]" (3) Defendant Jørgensen deferring a question about CagriSema's "competitiveness" to Lange on the first-quarter 2023 earnings call, (4) a Novo Vice President deferring various investor inquiries about CagriSema's dosage considerations and clinical trials to Lange on two third-quarter 2023 earnings calls, (5) a Novo Vice President introducing Lange as the "key person in terms of running the clinical trials" at a November 2023 American Heart Association Conference, (6) a Novo Vice President deferring investor questions about CagriSema's expectations and tolerability to Lange on the third-quarter 2024 earnings call, (7) a Novo Vice President deferring investor questions to Lange regarding the REDEFINE 1 results data, and (8) various statements from Lange himself about the dosing plans in CagriSema trials. (*Id.* ¶¶ 95–101, 103–04 (alterations in original).) In this same vein, Plaintiffs point to Lange's allegedly false statements themselves as indicating that Lange "held himself out as an expert on the dosing protocol of REDEFINE 1." (*Id.* ¶ 102, 105–06.)

14 These scienter-related allegations are in addition to those already discussed above, notably the Individual Defendants' various Novo Class B share sales. (CC ¶¶ 117–23.)

***8** Second, Plaintiffs allege that CagriSema was "Novo's next big weight loss drug" and "*needed*" it to be successful to compete in a competitive GLP-1 market following Eli Lilly's entry. (*Id.* ¶¶ 107–08; *see also id.* ¶ 109 (various securities analysts commenting that CagriSema was "critical" to Novo's future).) Plaintiffs point to statements from Novo from both before and during the Class Period in which Lange called CagriSema "a very important product in our pipeline" and having the "huge potential" for broad GLP-1 adoption. (*Id.* ¶ 108.) Relatedly, Plaintiffs point to Lange's statement at the March 7, 2024 Capital Markets Day that REDEFINE 1 was Novo's "pivotal study" for CagriSema. (*Id.*)

Third, Plaintiffs point to Defendant Jørgensen's departure following the end of the Class Period as further evidence of scienter. (*Id.* ¶¶ 110–11.) Novo fired Jørgensen as CEO on May 16, 2025. (*Id.* ¶ 110.) Novo gave limited details on the departure, stating that it was "made in light of the recent market challenges Novo Nordisk has been facing, and the development of the company's share price since mid-2024." (*Id.*) Plaintiffs allege that one market analyst surmised that "misses on trials like CagriSema could have contributed" to the termination. (*Id.* ¶ 111.) Albeit somewhat attenuated, Plaintiffs further allege that this departure was evidence of the Novo Nordisk Foundation's ("NNF") influence on Novo as its majority shareholder. (*Id.* ¶ 116.) Because of this pressure from NNF, Plaintiffs allege that Defendants were incentivized to keep share prices as high as possible. (*Id.*) Following the disappointing REDEFINE 1 results, Plaintiffs allege that "NNF used its influence to oust Jørgensen as CEO." (*Id.*)

Finally, Plaintiffs allege that Novo's need for financing in connection with the acquisition of a manufacturer further incentivized inflated stock prices. (*Id.* ¶¶ 112–15.) In May 2024, Novo announced plans to sell $5 billion worth of Eurobonds in order to help finance purchase of Catalent, Inc., an American drug manufacturer. (*Id.* ¶ 113.) Because Novo's "strategy of concealment" successfully withheld the truth about REDEFINE 1, Plaintiffs allege, Novo was able to raise the necessary funding. (*Id.* ¶¶ 114–15.)

F. PROCEDURAL HISTORY

On January 24, 2025, in the instant action, Plaintiff Changyeon Moon filed a putative class action complaint. (ECF No. 1.) On April 9, 2025, the Court appointed New York Hotel Trades Council & Hotel Association of New York City, Inc. Pension Fund, Pavers & Road Builders District Council Pension Fund, and City of Kissimmee General Employees' Retirement Plan as co-lead Plaintiffs. (ECF No. 28.) The co-lead Plaintiffs filed the Consolidated Complaint on July 2, 2025. (CC.) The Consolidated Complaint asserts against all Defendants one claim for violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder (Count One) and one claim for a violation of Section 20(a) of the Exchange Act (Count Two). (CC ¶¶ 146–59.) In lieu of answering, Defendants filed the instant Motion. (ECF No. 69.) Plaintiffs opposed the Motion, (Opp.), and Defendants replied, (Reply). The Motion is now ripe for decision.

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), the court may dismiss a complaint for "failure to state a claim upon which relief can be granted." For a complaint to survive dismissal under this rule, it "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 evaluating the sufficiency of a complaint, "[a]ll allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom." *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) (citations omitted). A pleading that "offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678 (citations and quotation marks omitted). In short, the pleading's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

***9** For fraud claims, a complaint is subject to Rule 9(b)'s heightened pleading standard "[i]ndependent of the standard applicable to Rule 12(b)(6) motions." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A party alleging fraud must therefore support its allegations with "the who, what, when, where and how of the events at issue." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (citations omitted); *see also Feingold v. Graff*, 516 F. App'x 223, 226 (3d Cir. 2013) ("[T]he plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007))). Rule 9(b)'s heightened pleading standard "ensure[s] that defendants are placed on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of fraud." *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (citations and quotations omitted). Rule 9(b)'s requirements are "rigorously applied in securities fraud cases," including those brought under the Exchange Act. *Cal. Pub. Emps' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997)).

In addition to satisfying Rule 9(b), plaintiffs alleging securities fraud pursuant to the Exchange Act must also comply with the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u–4, *et seq.* The PSLRA "imposes another layer of factual particularity to allegations of securities fraud." *In re Rockefeller Ctr.*, 311 F.3d at 217. To allege fraud under the PSLRA, the plaintiff must "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.' " *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313, 321 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12 (1976)).

III. DISCUSSION

Defendants argue that Plaintiffs' Section 10(b) claim fails because Plaintiffs do not allege the falsity of the above statements or the requisite strong scienter inference of the listed Defendants. Defendants further contend that the Section 20(a) claim must be dismissed based on the failure of Plaintiffs' Section 10(b) claim. Prior to addressing the merits of Defendants' arguments, the Court first turns to the parties' threshold dispute regarding the documents the Court may consider in connection with the subject Motion.

A. JUDICIALLY NOTICEABLE DOCUMENTS

Defendants request the Court to take judicial notice of 38 exhibits that were submitted with their Motion, or to find those exhibits incorporated by reference in the Consolidated Complaint. (*See* Exs. to Decl. of Audra Soloway, ECF Nos. 69-3 to 69-39; ECF No. 71-2.) These exhibits, described in greater detail below, include, *inter alia*, SEC filings, conference call transcripts, and publicly available clinical trials. (*See id.*) Plaintiffs do not contest that eleven of Defendants' requested exhibits are incorporated by reference into the CC. (ECF No. 70-2 at 3.)[15] Plaintiffs, however, oppose the Court considering the other 27 exhibits, contending that Defendants are using them "to create a counter narrative to Plaintiffs' well-pleaded Complaint." (*Id.* at 5.) Defendants respond that these remaining 27 exhibits are (1) "*integral to or explicitly* relied upon in the complaint" such that they are incorporated by reference, and/or (2) subject to proper judicial notice under Federal Rule of Evidence 201(b). (ECF No. 71-3 at 2–3 (quoting *In re Burlington*, 114 F.3d at 1426 (emphasis in original)).)

15 Specifically, Plaintiffs concede that Exhibits 15–16, 18, 20–25, 29, and 30 are incorporated by reference and the Court may consider them. (ECF No. 70-2 at 3.)

***10** While normally the Court may "not consider matters extraneous to the pleadings" at the motion to dismiss stage, the Court may rely on documents that are "*integral to or explicitly relied* upon in the complaint" without converting the motion into one for summary judgment. *In re Burlington*, 114 F.3d at 1426 (emphasis in original) (internal quotation marks omitted). The exception's applicability turns on "whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *Id.* at 1426. The purpose of this approach is to prevent a plaintiff from "maintain[ing] a claim of fraud by extracting an isolated statement from a document and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement was not fraudulent." *Id.* at 1426.

The Court may also consider documents subject to judicial notice, containing facts that are "not subject to reasonable dispute in that [they are] either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (alteration in original) (quoting Fed. R. Evid. 201(b)). As the Third Circuit cautioned, "[o]nly in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case" at the motion to dismiss stage. *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007). Defendants' exhibits fall into the following categories:

(1) SEC Filings, Conference Call Transcripts, and Earnings Presentations: Exhibits 1, 4, 15–16, 18, 20, 29–32, 36–38;

(2) FDA Review of STEP 1 Trial: Exhibit 3;

(3) Novo's Clinical Trial Study Records and Protocols: Exhibits 2, 5–7, 13–14, 17, 19, 33;

(4) Documents Related to Eli Lilly's SURMOUNT-1 Clinical Trial: Exhibits 8–12;

(5) Articles and Reports: Exhibits 21, 23–28; and

(6) Charts Prepared by Defendants: Exhibits 22, 34–35.

The Court discusses each category in turn.

1. SEC Filings, Conference Call Transcripts, and Earnings Presentations: Exhibits 1, 4, 15–16, 18, 20, 29–32, 36–38

Defendants submit thirteen exhibits for the Court's consideration from Novo's SEC filings, conference call transcripts, and earnings presentations. These exhibits contain many of the alleged misstatements from the CC, as well as various representations Novo made about its clinical trials. Plaintiffs concede that Exhibits 15, 16, 18, 20, 29, and 30—various SEC 6-K forms, conference call transcripts, quarterly presentations, and earnings calls—are appropriately incorporated by reference in the Consolidated Complaint. (ECF No. 70-2 at 3.) The parties disagree, however, as to the judicial noticeability of (1) other SEC 6-K forms from outside the Class Period discussing other clinical trials and (2) various SEC 20-F forms. (*Contrast* ECF No. 70-2 *with* ECF No. 71-3 (disagreeing as to the noticeability and permissible uses for Exhibits 1, 4, 31, 32, 36, and 37).) A court may "tak[e] judicial notice of properly-authenticated public disclosure documents filed with SEC." *In re NAHC*, 306 F.3d at 1331 (citing *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000)). This may include documents not relied upon in the complaint. *Id.* (finding no abuse of discretion for judicial notice of SEC filings "not relied upon in the Complaint"). However, these documents "cannot be offered 'to prove the truth of their contents but only to determine what the documents stated.' " *Id.* (quoting *Oran*, 226 F.3d at 289). Accordingly, the Court takes judicial notice of Exhibits 1, 4, 31, 32, 36, and 37, but only to determine what those documents stated. [16]

16 The Court declines to consider Exhibit 38, Novo's Investor Day call transcript from June 2023, which Defendants did not provide with the Court until their Reply. *In re Niaspan Antitrust Litig.*, 67 F.4th 118, 135 (3d Cir. 2023).

2. FDA Review of Novo's STEP 1 trial: Exhibit 3

***11** Defendants submit as Exhibit 3 the U.S. Food and Drug Administration ("FDA") Center for Drug Evaluation and Research's "Clinical Review" of Novo's STEP 1 clinical trial relating to the 2.4 mg dose of Ozempic. Defendants use this exhibit in their Motion to indicate how Novo had previously described the STEP 1 Ozempic trial. (*See* MTD at 4 n.2.) Courts regularly take judicial notice of publicly available and authentic documents from the FDA. *See, e.g.*,

Sneed v. Procter & Gamble Co., 779 F. Supp. 3d 1025, 1031–32 (N.D. Cal. 2025) (compiling cases). Although Plaintiffs contest that Exhibit 3 is not incorporated by reference into the Consolidated Complaint, they do not appear to contest that the document is authentic or the kind of document subject to judicial notice. (ECF No. 70-2 at 6–8.) Accordingly, the Court takes judicial notice of Exhibit 3, but only to determine what the document stated.

3. Novo's Clinical Trial Study Records and Protocols: Exhibits 2, 5–7, 13–14, 17, 19, 33

Defendants request that the Court consider, whether by judicial notice or incorporation by reference, nine exhibits related to various clinical trials Novo conducted for Ozempic and CagriSema. Defendants utilize these exhibits to discuss the protocols and practices of REDEFINE 1 and Novo's other GLP-1 clinical studies, particularly in contrast to each other. (*See generally* MTD.)

For Exhibits 2, 5, 6, and 7—study details and clinical trial protocols for STEP 1, 2, and 3 trials of Ozempic published on ClinicalTrials.gov—Defendants request only that the Court take judicial notice of these exhibits. (ECF No. 71-3 at 7.) Plaintiffs contest only that the exhibits are not incorporated by reference, making no argument about the Court taking judicial notice. (ECF No. 70-2 at 6–8 (only contesting incorporation by reference).) These clinical trials, publicly available at ClinicalTrials.gov, are properly subject to judicial notice. *See Abely v. Aeterna Zentaris Inc.*, No. 12-4711, 2013 WL 2399869, at *22 (S.D.N.Y. May 29, 2013). Accordingly, the Court takes judicial notice of Exhibits 2, 5, 6, and 7, but only to determine what those documents stated.

With respect to Exhibit 13—study records from Novo's Phase I clinical trial for CagriSema published on ClinicalTrials.gov in 2018—Plaintiffs object to the Court taking judicial notice of this Exhibit because this clinical trial occurred before the Class Period and does not relate to any of its alleged misrepresentations. (ECF No. 70-2 at 11–12.) However, Plaintiffs do not contest the authenticity or accuracy of this Exhibit, and Courts may take judicial notice of documents not relied upon in the complaint. *In re NAHC*, 306 F.3d at 1331; *see also In re Amarin Corp. PLC Sec. Litig.*, No. 19-6601, 2021 WL 1171669, at *8 (D.N.J. Mar. 29, 2021), *aff'd* No. 21-2071, 2022 WL 2128560 (3d Cir. June 14, 2022). Accordingly, the Court takes judicial notice of Exhibit 13. *See Abely*, 2013 WL 2399869, at *22 (taking judicial notice of ClinicalTrials.gov exhibits).

For Exhibit 14, the "Supplementary appendix" of Novo's clinical protocol for its Phase I trial of CagriSema as published by *The Lancet* in 2021, Plaintiffs oppose its consideration by, *inter alia*, contesting the Exhibit's authenticity. (ECF No. 70-2 at 10–12.) Defendants argue that the Phase I protocols are referenced extensively in the Consolidated Complaint, and that Plaintiffs' allegations specifically contrast the REDEFINE 1 trial at issue with the supposedly "fixed dose" protocol of the Phase I trial. (ECF No. 71-3 at 5–7.) However, Defendants do not in any way explain how this "Supplementary appendix"—not mentioned anywhere in the Consolidated Complaint—is an indisputably authentic or accurate version of the Phase I clinical protocols, nor do they explain how *The Lancet* is a publication of which courts may generally take judicial notice. (*Id.*) Accordingly, the Court declines to incorporate by reference or take judicial notice of Exhibit 14. *In re Burlington*, 114 F.3d at 1426; *Victaulic Co.*, 499 F.3d at 236.

***12** Exhibit 17 is the clinical protocol for Novo's Phase II trial of CagriSema, available publicly on ClinicalTrials.gov. Plaintiffs extensively reference this clinical trial throughout the Consolidated Complaint, including descriptions of the dosing protocols. (CC ¶¶ 4, 38–39, 46, 48, 57, 59–60, 63, 66, 74, 77–78, 83, 86, 102.) Because the alleged falsity of Defendants' various misrepresentations about REDEFINE 1 depends, in part, on the "fundamentally different dosing protocols" of the Phase II clinical trial, (*id.* ¶ 74), these protocols are "integral" to Plaintiffs' allegations, *In re Burlington*, 114 F.3d at 1426. Accordingly, the Court determines that Exhibit 17 is incorporated by reference.

Exhibit 19 is Novo's clinical trial protocol for REDEFINE 1, as published by the *New England Journal of Medicine* in June 2025. Because Plaintiffs' case relies on Defendants' alleged misrepresentations about the nature of these REDEFINE 1 protocols, the protocols are integral to the Consolidated Complaint and the Court deems them incorporated by reference. *Id.* However, given Plaintiffs' observations about incompleteness as the Exhibit did not include the abstract, the Court will nonetheless incorporate the complete article—including its abstract—as it is published on *The New England Journal of Medicine* website.[17] (ECF No. 70-2 at 15); *Simon v. Taylor*, 252 F. Supp. 3d 1196, 1260 n.33 (D.N.M. 2017) (explaining that "the Court may consider medical and scientific reports and journals among the sources which the

Court deems reliable" and compiling cases), *aff'd*, 794 F. App'x 703 (10th Cir. 2019).

17 Notwithstanding the missing abstract, the Court notes that Exhibit 19 is otherwise identical to the final September 26, 2023 *protocols* published online. Accordingly, for the sake of clarity, the Opinion cites to Exhibit 19 throughout when citing to or quoting the REDEFINE 1 protocols.

Exhibit 33 is the REDEFINE 9 study record—a Phase III clinical trial for CagriSema following the REDEFINE 1 trial—as published on ClinicalTrials.gov in April 2024. The Court did not consider this document to reach its decision and therefore need not resolve the parties' dispute over its noticeability. *Cf In re PTC Therapeutics, Inc. Sec. Litig.*, No. 16-1124, 2017 WL 3705801, at *3 n.5 (D.N.J. Aug. 28, 2017).

4. Documents Related to Eli Lilly's SURMOUNT-1 Clinical Trial: Exhibits 8–12

Defendants request that the Court consider five Exhibits related to Eli Lilly's SURMOUNT-1 clinical trials, including a publicly available conference transcript (Exhibit 8), background and protocols for the SURMOUNT-1 clinical trial published in *The New England Journal of Medicine* (Exhibits 9, 11), Eli Lilly's earnings presentation for the first quarter of 2022 (Exhibit 10), and the FDA's review of the SURMOUNT-1 trial (Exhibit 12). Defendants rely on these exhibits to show—with respect to clinical trials of a GLP-1 competitor—that clinical trials typically include language allowing for some form of dose modification. (MTD at 5.) Plaintiffs argue that their allegations are not based on these documents, Eli Lilly's conduct, or the SURMOUNT-1 clinical trials such that incorporation by reference is unwarranted. (ECF No. 70-2 at 8–10.)

However, Plaintiffs do not contest the judicial noticeability of these Exhibits, each of which is properly subject to judicial notice. (*Id.* at 10); *Simon*, 252 F. Supp. 3d at 1260 n.33 (credible medical journal articles); *Sneed*, 779 F. Supp. 3d at 1031–32 (FDA documents); *In re Lucid Grp., Inc. Sec. Litig.*, No. 22-2094, 2025 WL 1474494, at *2 (N.D. Cal. May 22, 2025). Accordingly, the Court takes judicial notice of Exhibits 8 through 12, but only for the limited purpose to determine what the documents stated. [18] *In re Lucid*, 2025 WL 1474494, at *2.

18 Of these five exhibits, Defendants only seek incorporation by reference of Exhibit 11, the protocol for Eli Lilly's SURMOUNT-1 clinical trial. (ECF No. 71-3 at 6–7.) Although the Consolidated Complaint references this clinical trial in passing, (CC ¶¶ 34, 81), the allegations—relating to *Novo's* CagriSema clinical trials and *Defendants'* alleged misrepresentations—do not explicitly rely on *Eli Lilly's* conduct. *In re Burlington*, 114 F.3d at 1426. Accordingly, although the Court will take judicial notice of Exhibit 11, it declines to find the Exhibit incorporated by reference.

5. Articles and Reports: Exhibits 21, 23–28

***13** The parties agree that Exhibits 21, 23, 24, and 25—various Novo press releases, investor reports, and news articles—are incorporated by reference in the Consolidated Complaint. (ECF No. 70-2 at 3.) However, the parties disagree as to whether Exhibits 26, 27, and 28, three articles that discuss "fixed-dose combinations," are properly subject to judicial notice to provide the pharmaceutical industry's definition of "fixed dose." (*Contrast* ECF No. 70-2 at 16–17 *with* ECF No. 71-3 at 8.) Defendants seek judicial notice of these articles in an attempt to support their preferred definition of "fixed dose." (MTD at 16.) Where a document is "subject to varying interpretations" such that there is "a reasonable dispute" as to what it means, the facts identified in that document "do[ ] not qualify for judicial notice under Rule 201(b)." *Khoja*, 899 F.3d at 1000; *Doe v. Princeton Univ.*, 30 F.4th 335, 343 (3d Cir. 2022) (declining to take judicial notice of "facts challenged by the plaintiff" in otherwise noticeable document). Because Plaintiffs' Consolidated Complaint asserts a differing definition of "fixed dose" to that offered by the cited articles, the Court will not "credit[ ] the [articles'] assertion over the Complaint's." *Doe*, 30 F.4th at 343; (*see* CC ¶ 7 (contrasting "fixed dose" to "flexible dosing")); *see also Victaulic Co.*, 499 F.3d at 237 (holding that district court's decision to credit "a bare 'fact' that is reflected not in the pleadings, but" in an extraneous document, "and then drawing inferences *against* the non-moving party" was improper at motion to dismiss stage (emphasis in original)). Accordingly, the Court will not consider Exhibits 26, 27, or 28.

6. Defendants' Charts: Exhibits 22, 34–35.

Finally, Defendants have prepared charts at Exhibits 22, 34, and 35 which it seeks the Court to consider. Plaintiffs do not oppose consideration of Exhibit 22, a chart organizing the various alleged misrepresentations from Defendants at issue. [19] (ECF No. 70-2 at 3); *In re PTC Therapeutics*, 2017 WL 3705801, at *3 n.5. However, Plaintiffs object to the Court's taking judicial notice of Exhibits 34 and 35, charts "setting forth all transactions in Novo common stock" by Defendants Jørgensen and Lange during the Class Period. (ECF No. 70-2 at 19–20.) While the contents of the chart may have been pulled from publicly available information, the Court does not find that these charts created by counsel are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." *In re NAHC*, 306 F.3d at 1331 (citing Fed. R. Evid. 201(b)). Even if the Court could have taken judicial notice of the more than 350 appendix pages included with these exhibits, the charts include no citations or references to these documents to support their lawyer-made representations about the Individual Defendants' stock sales. [20] *See Doeblers' Pa. Hybrids, Inc. v. Doebler*, 442 F.3d 812, 820 n.8 (3d Cir. 2006) ("Judges are not like pigs, hunting for truffles buried in the record." (cleaned up)). Further, Defendants do not provide a complete list of documents on which the charts rely to allow the Court to confirm their noticeability. Therefore, the Court will not take judicial notice of Exhibits 34 and 35.

19 Although the Court will utilize Defendants' helpful organizational tool, it will not consider any of the legal conclusions or arguments included throughout Exhibit 22. Moreover, because the CC itself does not specifically reference or rely on the lawyer-made chart, the Court will take judicial notice of the Exhibit, not find it incorporated by reference.

20 Defendants' only reference to these Exhibits in their Motion refers to their counsel-created *chart*, not the underlying appendices of documents submitted with the exhibits. (*See* MTD at 23.) Therefore, even if those underlying documents were judicially noticeable, the inability of the Court to "readily determin[e]" the accuracy of the Exhibits precludes judicial notice. *In re NAHC*, 306 F.3d at 1331 (citing Fed. R. Evid. 201(b)).

* * *

In summary, in deciding Defendants' Motion to Dismiss, the following documents are deemed incorporated by reference into the CC:

i. Exhibits 15–16, 18, 20, and 29–30 from Novo's SEC filings, conference call transcripts, and earnings presentations

ii. Exhibits 17 and 19 related to Novo's clinical trial study records and protocols

iii. Exhibits 21 and 23–25 from the various articles and reports

The Court will take judicial notice of:

i. Exhibits 1, 4, 31–32, and 36–37 from Novo's SEC filings, conference call transcripts, and earnings presentations

***14** ii. Exhibit 3 related to the FDA review of the STEP 1 Trial

iii. Exhibits 2, 5–7, 13 related to Novo's clinical trial study records and protocols

iv. Exhibits 8–12 related to Eli Lilly's SURMOUNT-1 clinical trial

v. Exhibit 22 containing Defendants' alleged misrepresentations

However, the Court will not consider: [21]

i. Exhibit 14 containing the "Supplementary appendix" published in *The Lancet*

ii. Exhibits 26–28 containing articles Defendants assert define the phrase "fixed-dose combination"

iii. Exhibit 33 containing the REDEFINE 9 study record

iv. Exhibits 34–35 depicting the Jørgensen and Lange stock transaction histories

v. Exhibit 38 containing Novo's investor day call transcript from June 2023

21 To the extent Defendants make factual distinctions on the basis of these excluded exhibits, the Court will not consider them. *See Malleus*, 641 F.3d at 563 (explaining that the Court must accept all allegations in the complaint as true and draw all

inferences in favor of the non-movant the motion to dismiss stage).

B. SECTION 10(B) CLAIM

In Count One, Plaintiffs assert a claim under Section 10(b) and Rule 10b-5. Section 10(b) of the Exchange Act authorizes a private cause of action for the "use or employ, in connection with the purchase or sale of any security ... [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b-5, which implements § 10(b), makes it unlawful, in connection with the purchase or sale of any security:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) 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 the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b-5. In asserting a claim for securities fraud under Section 10(b) and Rule 10b-5, a plaintiff must allege "(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." *Handal v. Innovative Indus. Props., Inc.*, 157 F.4th 279, 292 (3d Cir. 2025) (quoting *Matrixx Initiatives v. Siracusano*, 563 U.S. 27, 37–38 (2011)). In a securities fraud case, "[a] corporation is liable for statements by employees who have apparent authority to make them." *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (alteration in original) (quoting *Makor Issues & Rts., Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 708 (7th Cir. 2008)).

1. Material Misrepresentation or Omission

To make out a Section 10(b) claim, a plaintiff must "identify a false representation of material fact or omission that makes a disclosed statement materially misleading." *In re NAHC*, 306 F.3d at 1330 (citing *In re Burlington Coat Factory*, 114 F.3d at 1419). A statement or omission of fact is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (internal quotation marks omitted); *see also In re Newell Brands, Inc. Sec. Litig.*, 837 F. App'x 869, 874 (3d Cir. 2020) (statements or omissions viewed "in light of all the information then available to the market" (internal quotation marks omitted)). Further, a statement or omission only gives rise to liability if it was "misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *In re NAHC*, 306 F.3d at 1330. Even where a plaintiff has adequately pleaded falsity with requisite particularity, "those factual allegations must still satisfy the plausibility standard, which requires a 'reasonable expectation that discovery will reveal evidence' of the necessary elements of the claim." *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 681 (3d Cir. 2023) (quoting *Twombly*, 550 U.S. at 556.)

***15** The contours of what qualifies as an actionable misstatement are well articulated. An opinion is actionable under the securities laws if it "(i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits appropriate qualifying language." *Id.* at 686. The PSLRA also creates a "safe harbor" for forward-looking statements. 15 U.S.C. § 78u–5(c). Alleged misrepresentations are not actionable if the statements "are (1) identified as [forward-looking], and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 278–79 (3d Cir. 2010). Finally, the Court must distinguish material misrepresentations from statements of opinions that "constitute no more than 'puffery' and are understood by reasonable investors as such." *In re Newell Brands*, 837 F. App'x at 874 (quoting *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 872 (3d Cir. 2000)). Material misrepresentations are actionable while puffery is not.

In addition, while omissions may lead to liability, "Section 10(b) and Rule 10b-5 'do not create an affirmative duty to disclose any and all material information.' " *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, No. 16-6509, 2018 WL 3772675, at *15 (D.N.J. Aug. 8, 2018) (quoting *Matrixx Initiatives, Inc.*, 563 U.S. at 44). "Disclosure is required 'only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading.'

" *Id.* (cleaned up) (quoting *Matrixx Initiatives, Inc.*, 563 U.S. at 44). If a defendant "makes an affirmative statement or characterization about its business, it puts that subject 'in play' and assumes a duty, under the securities laws, to speak truthfully about that subject." *In re Merck & Co., Inc. Sec., Derivative, & "ERISA" Litig.*, No. 05-1151, 2011 WL 3444199, at *9 (D.N.J. Aug. 8, 2011) (citing *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 282 (3d Cir. 1992)).

The first element is subject to the PSLRA's "[e]xacting pleading requirements." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 168 (3d Cir. 2014) (alteration in original) (quoting *Tellabs, Inc.*, 551 U.S. at 313). Thus, "[a] complaint involving securities fraud must 'specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation ... is made on information and belief ... all facts on which that belief is formed.' " *In re Newell Brands*, 837 F. App'x at 874 (omissions in original) (quoting 15 U.S.C. § 78u-4(b)(1)). "The purpose of the heightened pleading requirements is to ensure that private securities actions do not become a partial downside insurance policy against the vicissitudes of the market." *Id.* at 874 (internal quotation marks omitted).

As described above, Plaintiffs' claims are based on the 44 alleged false or misleading statements grouped into three categories: (1) statements describing the CagriSema dosing protocol in REDEFINE 1; (2) statements discussing the REDEFINE 1 trial and CagriSema's tolerability and weight loss results; and (3) statements discussing "potential future trials" of CagriSema.[22] Defendants argue that Plaintiffs fail to allege any material misrepresentation or omission, or that any alleged false statements are nonactionable or protected by the PSLRA's safe harbor for forward-looking statements. (*See generally* MTD 9–21.) With this as the backdrop, the Court analyzes the alleged false and misleading statements to determine whether Plaintiffs have satisfied the high bar of the PLSRA's "[e]xacting pleading requirements." *City of Edinburgh Council*, 754 F.3d at 168 (alteration in original).

22 As noted, these categories are substantially similar to the parties' own categories. *See supra* note 5. Like the parties, the Court will not examine each statement individually, but—consistent with the parties' approach—will assess the allegedly false and misleading statements by category and identify specific statements as examples where necessary.

a. REDEFINE 1's Structure & Dosing Protocol

***16** Plaintiffs allege that throughout the Class Period, Defendants made numerous false and misleading statements regarding the REDEFINE 1 study in general and its dosing protocol for CagriSema. (*See, e.g.*, CC ¶¶ 43–45, 51–56, 62, 65.) For example, Plaintiffs point to numerous statements and slides from Novo and Defendant Lange during the Class Period regarding the trial design for REDEFINE 1 as "comparing" and "investigating" the efficacy of a 2.4 mg cagrilintide and 2.4 mg semaglutide combination of CagriSema. (*Id.* ¶¶ 43–45, 51–56, 62.) Plaintiffs argue that these statements were false and misleading because, in reality, "no patients were required to take a fixed dose [of] 2.4 mg cagrilintide and 2.4 mg semaglutide of CagriSema," (*id.* ¶ 7), because REDEFINE 1 was subject to a "flexible dosing" protocol that "allowed study participants to modify their CagriSema dosage at any time during the 52-week main phase of the trial," (*id.* ¶ 46(a)). Thus, Plaintiffs allege these statements were misleading by omission: Plaintiffs assert that Defendants were obligated to disclose this flexible dosing protocol alongside these general descriptions of the REDEFINE 1 study. (Opp. at 8–12.) Because this change in protocol affected a topic investors cared to ask about—tolerability—Plaintiffs argue that the omission of information about the flexible protocol was material. (*Id.* at 19–22 (citing *Kendall v. Odonate Therapeutics, Inc.*, No. 20-1828, 2021 WL 3406271, at *5 (S.D. Cal. Aug. 4, 2021)).)

These various statements about the general aims of the REDEFINE 1 study were not false or misleading, whether by omission or otherwise. As an initial matter, the statements are literally true: Defendants *were* "comparing" and "investigating" the safety and efficacy of a combination 2.4 mg dose of CagriSema in the REDEFINE 1 study, even if it was subject to a flexible dosing protocol. (CC ¶¶ 43, 62.) These various anodyne statements also make no representations regarding CagriSema's safety or tolerability, and do not raise any impression about REDEFINE 1's dosing protocol. Defendants never disclose in their benign descriptions of the anticipated structure of the REDEFINE 1 study that a 2.4 mg cagrilintide and 2.4 mg semaglutide combination of CagriSema would be required—inalterably—for the duration of the 52-week maintenance phase of the trial.

Furthermore, such statements would not mislead a reasonable investor that a combination 2.4 mg dose would be "required" of trial participants such that further disclosure was necessary.

(*Id.* ¶ 7); *In re Cognizant*, 2018 WL 3772675, at *15. Instead, given how pharmaceutical companies "typically use[ ]" language regarding an investigated dose—at least with those clinical trials referenced throughout the CC—Defendants' statements about REDEFINE 1's structure imply that dosing flexibility was expected. *Ortiz v. Canopy Growth Corp.*, 537 F. Supp. 3d 621, 654 (D.N.J. 2021). Many of the clinical trial exhibits the Court is considering with the instant Motion show that both Novo and rival pharmaceutical company Eli Lilly (1) stated some investigated dosage of GLP-1 drugs, but (2) allowed dosage modification in certain circumstances. (*See* Ex. 2 at 18 (stating that "target dose of Novo's STEP 1 semaglutide trial was 2.4 mg "once-weekly"), Ex. 5 at 30 (allowing participants to "stay at [a] lower dose level of 1.7 mg" if "subject would otherwise discontinue trial product completely")); Ex. 17 at 9, 32 (stating that Novo's Phase II CagriSema trial was designed to test 2.4 mg of cagrilintide and semaglutide but allowed subjects to maintain lower dose level if they would otherwise discontinue trial); Exs. 8 at 7, 11 at 147 (stating that Eli Lilly's SURMOUNT-1 trial was designed to evaluate "5-, 10- and 15-milligram doses of tirzepatide," but allowed modifications for management of "intolerable GI symptoms" and "excessive weight loss").)

In short, when a reader "takes into account the customs and practices of the relevant industry," strict adherence to a target dose is not generally expected of GLP-1 clinical trial participants. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 190 (2015). Plaintiffs do not allege how—when viewed in this broader context—Defendants' various statements would reasonably mislead investors that, somehow, REDEFINE 1 *would* require such an inflexible protocol, unlike all other clinical trials discussed in the CC. Not only is Plaintiffs' argument here contrary to these accepted customs, but also defies common sense—of course REDEFINE 1 would provide trial participants some way to discontinue or de-escalate their dosage if circumstances required it. Thus, Defendants' purported omission of one of the many protocols used in the REDEFINE 1 trial does not give rise to Section 10(b) liability. *See Winer Fam. Tr. v. Queen*, 503 F.3d 319, 330 (3d Cir. 2007) ("The duty to disclose rule does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise, but means only such others, if any, that are needed so that what was revealed would not be so incomplete as to mislead." (cleaned up) (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc))). The prior quoted holding is on point here.

***17** Plaintiffs suggest that they did not allege that Defendants' various statements above implied that REDEFINE 1 "*required*" participants "to adhere to the target dose, irrespective of any possible side effect." (Opp. at 10 (emphasis added).) Instead, Plaintiffs assert in their Opposition that Defendants' statements were misleading because they "led investors to believe that REDEFINE 1 utilized a *typical* dosing protocol of 2.4 mg cagrilintide and 2.4 mg semaglutide." (*Id.* at 10–11 (emphasis added).) Plaintiffs' argument in their brief is contradicted by the CC's plain allegations. *Frederico*, 507 F.3d at 202 ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." (cleaned up).) The CC clearly alleges that Defendants implied that the full dose was *required*, not simply that the dosing protocol was *different* from previous trials. (*See, e.g.*, CC ¶¶ 7 ("But the truth was that no patients were *required* to take a fixed dose 2.4 mg cagrilintide and 2.4 mg semaglutide of CagriSema." (emphasis added)), 46(a) ("REDEFINE 1 did not *require* a once-weekly dose of CagriSema at 2.4 mg of cagrilintide and 2.4 mg of semaglutide, as participants were allowed to personalize their dose of CagriSema." (emphasis added)), 57(a) (same); 63(a) (same).) To the extent Plaintiffs now argue in opposition that the statements were false or misleading for some other reason, this is inconsistent with the strict pleading requirements of the PSLRA. *In re Newell Brands*, 837 F. App'x at 874 (explaining that the PSLRA requires the complaint to state the "reason or reasons" why the alleged statements misleading (quoting 15 USCA § 78u-4(b)(1)(B))).

Also within this category of alleged misstatements about the structure of REDEFINE 1 is the March 7, 2024 slide in Novo's "Diabetes care" deck stating that CagriSema would be an "FDC" of "sema and cagri" during its Phase III trials (which include REDEFINE 1), with a footnote on that slide defining FDC as "fixed dose combination." (CC ¶ 65.) Plaintiffs allege that because the REDEFINE 1 trial incorporated a *flexible* dosing protocol, Defendants' statement that CagriSema would be a *fixed* dose combination was false and misleading. (*Id.* ¶ 66.)

Tabular or graphical material not displayable at this time.

(*Id.* ¶ 65; Ex. 29 at 17.)

However, this statement is not false or misleading. As an initial matter, the slide makes no reference to the REDEFINE 1 dosing protocol *at all*; it does not mention the 2.4 mg

combination dose Novo intended to investigate or even define what "fixed dose combination" means. (CC ¶ 65.) When viewed in context—even less so than the above misstatements in this same category—this single, barely discernable footnote within a dense, 25-slide pharmaceutical presentation does not imply anything about the REDEFINE 1 trial protocols, let alone that Novo intended to study a particular dosage of CagriSema. *Gluck v. Hecla Mining Co.*, 657 F. Supp. 3d 471, 489 (S.D.N.Y. 2023); (Ex. 29); *see In re Donald J. Trump Casino Sec. Litig.*, 793 F. Supp. 543, 556 (D.N.J. 1992) ("Solitary statements alone cannot support a federal securities law claim when read out of context."), *aff'd* 7 F.3d 357 (3d Cir. 1993).

Moreover, Plaintiffs' alleged interpretation of "fixed dose combination" does not appear correct when considered alongside the REDEFINE 1 trial protocol the Court determined was incorporated by reference. (Ex. 19.) The REDEFINE 1 clinical trial protocol never references patients taking CagriSema as a "fixed dose" anywhere in the dosing protocols. (*See generally id.*) Instead, REDEFINE 1 defines CagriSema "as a new fixed-dose combination *product*," and as a "[f]ixed *combination* of cagrilintide and semaglutide." (*Id.* at 12 (emphases added), 128; *see also id.* at 129 (defining "FDC" as "Fixed Dose Combination").) These various usages suggest that the reference to "fixed dose combination" on the above slide, as it is used throughout the actual protocols, refer not to an unchanging *dosage* of CagriSema trial participants were expected to take, but to a set *ratio* of cagrilintide and semaglutide; that CagriSema is a fixed, unchanging ratio of equal parts of cagrilintide and semaglutide. Because it is clear from properly considered exhibits that Plaintiffs "completely mischaracterize[ ] the nature of [Defendants'] alleged statement"—and such a statement would not be misleading even if interpreted as Plaintiffs request—this statement cannot be considered materially false or misleading. *In re Amarin Corp. PLC Sec. Litig.*, No. 13-6663, 2016 WL 1644623, at *19 (D.N.J. Apr. 26, 2016), *aff'd*, 689 F. App'x 124 (3d Cir. 2017). Accordingly, all statements in this category are dismissed. (CC ¶¶ 43–45, 51–56, 62, 65.)

b. Statements Discussing Weight Loss & Tolerability in REDEFINE 1

***18** Plaintiffs' second category of alleged misstatements relate to four statements made by Defendant Lange regarding CagriSema's tolerability and projected weight loss in the REDEFINE 1 trial. (*Id.* ¶¶ 48, 59, 73, 77.) The first of these statements, made the second day of the Class Period November 3, 2022 on Novo's third-quarter 2022 earnings call, was responding to a UBS Investment Bank analyst question about how Novo could "get a better tolerability" for CagriSema in the REDEFINE 1 trial, particularly in light of Eli Lilly's own success. (*Id.* ¶ 48.) As recounted above, Lange responded:

> Specifically on going to higher doses, we're actually following our normal step of more or less doubling the dose. We've shown that we can do that without introducing more tolerability issues. And based on what we know already now, we feel confident that these call them step increases will not introduce more tolerability issues than what we've seen.

(*Id.*) The second of these statements, made by Lange on March 7, 2024 in his opening statement at Novo Capital Markets Day, predicted "[a]t least 25% weight loss" from CagriSema in the REDEFINE 1 study, allowing Novo to "get more bang for the buck, so to speak, *without having to compromise on safety and tolerability*." (*Id.* ¶ 59 (emphasis altered).) Similarly, on November 6, 2024—in response to an analyst question about balancing weight loss efficacy with increased tolerability issues—Lange stated:

> We are still basing all of our assumptions on data derived from Phases I and II. Based on what we know and based on how we understand the biology, as you said yourself, we expect to see really unsurpassed weight loss.... And based on what we've seen so far, that will come with a safety and tolerability profile broadly in line with what we see with GLP-1 treatment.

(*Id.* ¶ 73.) Finally, Plaintiffs point to Lange's statement on November 7, 2024, where he responded to a question about "antidrug antibodies" by suggesting that Novo had already

"factored in" the effect of such antibodies into REDEFINE 1, and that "because the model is based on the clinical response in Phases 1 and 2, and that lands us nicely at the 25% mark [in REDEFINE 1 weight loss.]" (*Id.* 77.)

Plaintiffs allege that these statements were misleading because Lange failed to disclose "that Novo had designed REDEFINE 1 to include flexible dosing from its outset to address tolerability issues observed in CagriSema's Phases I and II trials." (*Id.* ¶¶ 49(a), 60(a) (similar), 74(a) (similar), 78(a) (similar).) Thus, Plaintiffs argue, Lange's statements about CagriSema's expected (1) "tolerability profile" and (2) 25% weight loss following REDEFINE 1 were false and misleading because of REDEFINE 1's "fundamentally different" flexible dosing structure. (*Id.* ¶¶ 60(b), 74(b) (same), 78(a) (same).) Because investors specifically asked how Novo intended to address potential tolerability problems and weight loss efficacy—especially when compared to Eli Lilly's success—Plaintiffs assert that these statements were material. (Opp. at 19–22.)

At this preliminary posture, to the extent Lange represented that the "tolerability" of CagriSema in the first three of these statements—while failing to disclose the flexible dosing protocol incorporated in REDEFINE 1—Plaintiffs have adequately pleaded that these statements were materially misleading.[23] Although Section 10(b) does not impose an affirmative duty to disclose, defendants that "make[ ] an affirmative statement or characterization about [their] business, [put] that subject 'in play' and assume[ ] a duty, under the securities laws, to speak truthfully about that subject." *In re Merck*, 2011 WL 3444199, at *9 (quoting *Shapiro*, 964 F.2d at 282). Even where such a statement is an opinion, the Third Circuit has explained that such statements are "misleadingly incomplete" where the speaker does not disclose known material facts about his "basis for holding that view." *In re Maiden Holdings, Ltd. Sec. Litig.*, 153 F.4th 354, 358 (3d Cir. 2025) (quoting *Omnicare*, 575 U.S. at 188).

23 Defendants do not contest the materiality of the withheld information about the flexible dosing protocol. (*See generally* MTD.) The Court is otherwise satisfied—given specific investor questions about the issue—that Plaintiffs have sufficiently pleaded Lange's statements about the tolerability of CagriSema and Novo's approach to REDEFINE 1 would be material to a reasonable investor. (*See, e.g.*, CC ¶ 48); *In re Burlington*, 114 F.3d at 1425 ("Ordinarily, the law defines 'material' information as information that would be important to a reasonable investor in making his or her investment decision."); *Bauer v. Prudential Fin., Inc.*, Nos. 09-1120 & 09-1771, 2010 WL 2710443, at *6 (D.N.J. June 29, 2010) ("Typically, materiality is a question of fact for the fact-finder." (citing *In re Adams Golf Inc. Sec. Litig.*, 381 F.3d 267, 274 (3d Cir. 2004))).

***19** Here, both of his own accord and in response to specific analyst questions about CagriSema's tolerability in REDEFINE 1, Lange represented a series of times over the Class Period that Novo was not changing its clinical approach to CagriSema. (CC ¶¶ 48 ("We've shown that we can [go to higher doses] without introducing more tolerability issues), 59 ("So we get more bang for the buck, so to speak, without having to compromise on safety and tolerability."), 73 ("And based on what we've seen so far, that will come with a safety and tolerability profile broadly in line with what we see with GLP-1 treatment.").) Plaintiffs have sufficiently pleaded that these statements were misleading: As Defendants later admitted, Novo had actually incorporated a flexible dosing protocol in response to tolerability data from Phases I and II. (*Id.* ¶¶ 79–85.) Novo *had*, allegedly, "compromise[d]" on tolerability in REDEFINE 1, (*id.* ¶ 59), using a "patient-centric and individualized treatment regimen" in an attempt to "potentially enhance [the] efficacy of CagriSema while maintaining a favorable safety profile," (Ex. 20 at 7 (Lange discussing REDEFINE 1 results and approach after the Class Period)). The pharmaceutical prudence of this change notwithstanding, this new protocol was, as pleaded, at odds with Lange's representations.

Defendants argue in their Motion that, in reality, the dosing protocols of REDEFINE 1 were not "materially different" from the dosing protocols of previous trials.[24] (MTD at 17; *see id.* at 13.) Defendants point to the "Dose modification" language in the Phase II trial and argue that it too "permitted delaying the dose escalation or reducing" a participant's dose if there were tolerability issues. (*Id.* at 13 (cleaned up).) As above, the language from the Phase II trial protocols is produced below:

6.6 Dose modification

Consider delaying dose escalation or reducing the dose during dose escalation if:

- The current dose is not tolerated by the subject. This should only be allowed if the subject would otherwise

discontinue trial products completely and only if considered safe to continue on any trial products dose, as per investigator's discretion

Consider reducing the maintenance dose if:

- The maintenance dose is not tolerated by the subject. The subject may stay at a lower dose level but only if the subject would otherwise discontinue trial products completely and only if considered safe to continue on any trial products dose, as per investigator's discretion.

- The subject achieves a BMI of <22.5 kg/m^2 and continues losing weight, per investigator's discretion

Dose modifications must be applied to both trial products. In case of deviations from the planned dose escalation regimen, it is recommended that the subject makes at least one attempt to re-escalate to the maintenance dose, as per the investigator's discretion. It is recommended that the investigator consults Novo Nordisk in case of persistent deviations from the planned escalation regimen.

(Ex. 17 at 32.) Defendants argue that this language—available to investors *before* the Class Period—is "*substantively identical*," (Reply at 3), to the dosing modification language in REDEFINE 1:

Dose modifications

Consider delaying the dose escalation or reducing the dose if the current dose is not tolerated. It is recommended that the participant makes at least one attempt to re-escalate to the maintenance dose during the study, as per the investigator's discretion. Participants who are unable to reach the target maintenance dose of 2.4 mg/2.4 mg due to intolerability will be permitted to continue at the maximum tolerated dose.

During dose escalation and – dose maintenance, efforts should be made by the investigator to support participants in escalating and maintaining the corresponding IMP dose. To mitigate and manage GI symptoms the investigator can advise participants to eat more slowly, eat smaller meals, and stop eating when feeling full. In cases of intolerable GI AEs, the investigator may consider use of symptomatic medication (e.g. antiemetic or antidiarrheal).

(Ex. 19 at 51.) Defendants argue that because previous, publicly available CagriSema clinical trials had allowed dose modifications for tolerability, Lange was not withholding any information about the flexible dosing protocol—Novo's previous trials had *already* used a flexible protocol. (MTD at 17.)

[24] Defendants also argue that Lange's statements about tolerability were inactionable opinions or forward-looking statements protected by the PSLRA's safe harbor provision. (MTD at 17–19). However, as discussed above, Lange's withholding of information about the flexible dosing protocol independently undermines each of these arguments at this stage. *See In re Maiden Holdings, Ltd. Sec. Litig.*, 153 F.4th at 358; *Carmignac Gestion, S.A. v. Perrigo Co. PLC*, Nos. 17-10467 et al., 2019 WL 3451523, at *11 (D.N.J. July 31, 2019) ("[T]he PSLRA's safe harbor provision does not apply to the extent Plaintiffs sufficiently allege that Defendants omitted present facts from the challenged statements."). Furthermore, these statements, some of which came in direct response to analyst questions about tolerability, are also not "so obviously unimportant" to a reasonable investor to constitute puffery. *In re Enzymotec Sec. Litig.*, No. 14-5556, 2015 WL 8784065, at *14 (D.N.J. Dec. 15, 2015) (quoting *Shapiro*, 964 F.2d at 280 n.11) (declining at motion to dismiss to conclude certain statements were puffery); (*see* MTD at 19–20 (arguing that certain statements were puffery). Moreover, to the extent that Defendants offer alternative bases for dismissal of these alleged statements in their Reply brief, such arguments are forfeited. (Reply at 5–6); *Cherry v. City of Philadelphia*, 216 F. App'x 205, 209 (3d Cir. 2007).

***20** Although the language has similarities, in that, in the end, both allowed for de-escalation, the Court declines to determine, as a matter of law, that these provisions are "substantively identical" at this stage.[25] (Reply at 3.) The Court notes a number of contrasts and/or inconsistencies in the two protocols. The REDEFINE 1 modification language eliminated the Phase II requirement that trial participants could only modify "if the subject would otherwise discontinue trial products completely." (Ex. 17 at 32.) This omission facially implies that Novo made it easier for trial participants to modify their trial dosage, as the previous dosing protocol was far less "flexible." *Cf.*

Crawford v. Burke, 195 U.S. 176, 190 (1904) ("[A] change in phraseology creates a presumption of a change in intent.").

25 To the extent Defendants make a "truth on the market" defense—i.e., that the market was already aware of the facts to the point that Lange's statement could not be materially misleading—such an argument is highly fact specific and "rarely an appropriate basis" for dismissal at the motion to dismiss stage "[g]iven the strong inferences in favor of" Plaintiffs in the CC. *In re: Enzymotec*, 2015 WL 8784065, at *16 (quoting *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000)); (*see also* Reply at 4 (suggesting that Defendants are not pursuing a truth-on-the-market defense in their Motion).)

The REDEFINE 1 protocol also outlines a more involved role for the trial "investigator" than in Phase II, in particular: (1) recommending the investigator to, in their discretion, "attempt to re-escalate to the maintenance dose" after modification at least once, (2) insisting that the investigator make "efforts ... to support participants in escalating and maintaining the corresponding [dose]," including when presented with gastrointestinal issues, actively advising participants to "eat more slowly, eat smaller meals, and stop eating when feeling full," and (3) suggesting that an investigator may even consider using "symptomatic medication (e.g. antiemetic or antidiarrheal)." (Ex. 19 at 51.) These changes make clear that Novo's clinical investigators were expected to take a more empowered and active role in REDEFINE 1 than in the Phase II trial, particularly in ways that would keep a patient struggling with tolerability *as a participant in the trial*.[26]

26 The Court relies on the key protocol sections discussed by the parties. To the extent there are other sections in the more than 210 pages of Phase II or REDEFINE 1 protocols that suggest further differences or similarities, the Court need not scour the record to find them. *See Doeblers' Pa. Hybrids, Inc.*, 442 F.3d at 820 n.8 ("Judges are not like pigs, hunting for truffles buried in the record." (cleaned up)).

Defendants' assertion that the protocols are "substantially identical" is thus at odds with the plain language of those protocols. (Reply at 3.) Defendants' argument is also inconsistent with Novo and Lange's own statements after the Class Period, indicating that Novo had, in fact, made such a change. (*See* Ex. 20 at 5 ("Based on the CagriSema weight loss data observed in Phase 1 and 2 trials, we *incorporated* a flexible protocol in REDEFINE 1." (emphasis added))[27]; *id.* at 7 (describing REDEFINE 1 as "a patient-centric and individualized treatment regimen"); *id.* at 15 (stating that REDEFINE 1 allowed participants to do "individual dose titration"); *see also* CC ¶¶ 81–82 (alleging extensive reporting and securities analysis "expressing surprise" about "flexible dosing protocol and related tolerability implications"), 93 (alleging that Novo had explicitly disclosed "Flexible Dose Adjustment" in previous semaglutide trial announcement for a different medication).) Accordingly, these alleged misstatements—to the extent they misrepresent and omit information about the changed dosing protocol—are actionable under Section 10(b) insofar as they discuss or predict the tolerability of CagriSema in REDEFINE 1. (CC ¶¶ 48, 59, 73.)

27 Curiously, this statement from Lange after the Class Period attributes the change to the flexible protocol to CagriSema's observed "weight loss" data. (Ex. 20 at 5.) The Court does not see an obvious connection between "weight loss"—as opposed to say, tolerability or safety issues—and a protocol change that allowed for flexible dosing. Such characterization suggests that Novo and Lange's misleading characterization surrounding the flexible dosing protocol continued even after the corrective disclosure.

***21** By contrast, to the extent Lange's various statements project the weight loss of CagriSema in REDEFINE 1, such statements are protected by the PSLRA's safe harbor.[28] Lange's predictions of the "great potential" and "[a]t least 25% weight loss" expected of CagriSema in REDEFINE 1 are sufficiently "forward-looking" and "accompanied by meaningful cautionary statements" so as to warrant safe harbor protection. (*Id.* ¶¶ 59, 73 (stating that "[b]ased on what we know and based on how we understand the biology, as you said yourself, we expect to see really unsurpassed weight loss," but that it was "still early days" in the trial)); *In re Aetna, Inc.*, 617 F.3d at 278. These predictive statements contain careful, aspirational, and hedged language, which is protected by the PSLRA safe harbor. Moreover, although Plaintiffs allege Lange's knowledge of the change to flexible dosing to address *tolerability* (as explained in the scienter Section below), they do not allege Lange's knowledge that Novo's *weight loss* prediction "model" was falsely predicting 25% weight loss.[29] (*Id.* ¶¶ 59, 73, 77); *In re Aetna, Inc.*, 617

F.3d at 278–79 (explaining that forward-looking statements are inactionable if "made without actual knowledge that the statement was false or misleading").

28 Such statements about the weight loss "potential," or "unsurpassed weight loss" of CagriSema are also likely inactionable insofar as they are inactionable opinions or "puffery." (CC ¶¶ 59, 73, 77); *see Spar v. Celsion Corp.*, No. 20-15228, 2023 WL 2069725, at *7 (D.N.J. Feb. 6, 2023) (holding opinion about "prespecified target for [clinical trial success]" was inactionable under Section 10(b) (internal quotation marks omitted)); *Galati v. Com. Bancorp, Inc.*, 220 F. App'x 97, 102 (3d Cir. 2007) (puffery includes statements regarding "dramatic deposit growth," "strong performance," and "unique business model").

29 Similarly, Plaintiffs do not allege that Lange's statement that CagriSema's "safety and tolerability profile ... in Phase I/II was similar to that [of Wegovy,]" was false. (CC ¶ 59 (brackets in original).) Plaintiffs only allege that Lange's stated "expectations" for REDEFINE 1 were based on "fundamentally different dosing protocols." (*Id.* ¶ 60(b).) Accordingly, the entire statement is inactionable.

In summary, Plaintiffs have sufficiently pleaded that Lange's statements about tolerability were misleading for implying—both facially and by omission—that the REDEFINE 1 dosing protocols were the same as previous clinical trials, when it appears that they were not. His statements, however, about the projected weight loss of REDEFINE 1 are not actionable under the PSLRA safe harbor. Accordingly, although Lange's various alleged misstatements about CagriSema's *tolerability* survive the instant Motion, his statements about CagriSema's predicted *weight loss* do not. For the convenience of the parties, the Court delineates these statements below.

Actionable:

- "Specifically on going to higher doses, we're actually following our normal step of more or less doubling the dose. We've shown that we can do that without introducing more tolerability issues. And based on what we know already now, we feel confident that these call them step increases will not introduce more tolerability issues than what we've seen." (CC ¶ 48)
- "So we get more bang for the buck, so to speak, without having to compromise on safety and tolerability." (CC ¶ 59.)
- "And based on what we've seen so far, that will come with a safety and tolerability profile broadly in line with what we see with GLP-1 treatment." (CC ¶ 73.)

Not actionable:

- "At least 25% weight loss with a safety and tolerability profile that in Phase I/II was similar to that [of Wegovy.]" (CC ¶ 59.)
- "We are still basing all of our assumptions on data derived from Phases I and II. Based on what we know and based on how we understand the biology, as you said yourself, we expect to see really unsurpassed weight loss." (CC ¶ 73.)
- "That also means then when we look at our model, that has actually been factored in, because the model is based on the clinical response in Phases 1 and 2, and that lands us nicely at the 25% mark." (CC ¶ 77.)

c. Statements Regarding Future Obesity Trials

***22** The final category of alleged misstatements is based on a Novo slide first presented on March 7, 2024, at Novo's Capital Markets Day without attribution to a specific speaker. (CC ¶ 68.) As discussed above, the slide stated that Novo's "[p]otential future trials" in obesity might "[e]valuate lower doses for personalized treatment." (*Id.*) The title itself, "Potential," bespeaks safe harbor protection:

Tabular or graphical material not displayable at this time.

(*Id.*; Ex. 30 at 7.) Plaintiffs allege that this slide—re-used on three other occasions during the Class Period, (CC ¶¶ 69–70, 75)—was materially misleading because "Novo was already investigating 'lower doses for personali[z]ed treatment' " in the REDEFINE 1 trial through the flexible dosing protocol, (*Id.* ¶¶ 71(b) (alteration in original); 76(b) (same).)

Like the first category of statements about REDEFINE 1's structure and dosing protocol, these statements are not actionable under Section 10(b). Again, Plaintiffs do not allege that these statements are literally false—Novo very well could

have planned, as part of their next wave of clinical trials, to "[e]valuate lower doses for personali[z]ed treatment." (*Id.* ¶¶ 69–70, 75.) Additionally, in the portion of the slide discussing REDEFINE 1, Novo makes no representations whatsoever about the dosing protocol or CagriSema's tolerability. (*Id.*) It also is quite a stretch, in terms of materiality, that any reasonable investor would be moved, one way or the other, based on Novo's general, noncommittal prospect of possible future trials designed to evaluate lower doses.

As with other slides the Court previously determined were inactionable, the benign, single-bullet-point descriptions of "[p]otential future trials" are insufficient to allege falsity by omission. (*Id.*) Unlike the previous category of statements, the slide's references to "lower doses" and "personali[z]ed" treatment do not put Novo's approach to tolerability "in play" such that a complete statement was legally required. (*Id.*); *In re Merck*, 2011 WL 3444199, at *9. The passing, throw-away mentioning of a generalized possibility of a future trial —with personalized, lower doses—was not specific enough to cast any doubt on the details of REDEFINE 1's dosing protocol. *See Winer Fam. Tr.*, 503 F.3d at 330 ("The duty to disclose rule does not mean that by revealing one fact about a product, one must reveal all others ... [only those that] are needed so that what was revealed would not be so incomplete as to mislead.").

Furthermore, Novo's use of the flexible dosing protocol—although certainly a material part of the REDEFINE 1 trial —cannot fairly be characterized as the fundamental *design* of that trial, such that Novo was "already investigating personal titration." (Opp. at 17 (cleaned up).) As discussed, the flexible dosing protocol was allegedly Novo's means of keeping participants in the trial despite the rate of CagriSema's intolerability. It was not the central basis of investigation; CagriSema at a 2.4 mg fixed dose was. The only thing that the slide arguable put "in play" for fuller disclosure was what Novo was then currently studying in REDEFINE 1. *In re Merck*, 2011 WL 3444199, at *9. That was not the flexible protocol. Indeed, because "[t]here is a fundamental mismatch between the challenged statements and the topic they allegedly put in play," this final category of alleged statements is inactionable. [30] *Underland v. Alter*, No. 10-3621, 2011 WL 4017908, at *7 (E.D. Pa. Sept. 9, 2011). Accordingly, all statements in this category are dismissed. (CC ¶¶ 69–70, 75.)

30 In addition, even if the statements were misleading omissions, they would not be actionable. Because Plaintiffs do not allege the identity of the speaker for any of the instances this slide was presented, they have failed to allege that the speaker was "aware, or at least should have been aware" that the statement was false when made. (CC ¶¶ 69–70, 75 (not alleging a speaker tied to the slides)); *Tanaskovic v. Realogy Holdings Corp.*, No. 19-15053, 2021 WL 211049, at *6 (D.N.J. Jan. 21, 2021) (citing *In re NAHC*, 306 F.3d at 1330). "[W]ith no indication that the speaker was aware" of the statement's falsity, this "fraud by hindsight" is inactionable. *Tanaskovic*, 2021 WL 211049, at *6 (quoting *Chubb*, 394 F.3d at 158).

2. Scienter

***23** To survive dismissal, Plaintiffs must also adequately plead scienter, which is "the defendant's intention to deceive, manipulate, or defraud," *Tellabs, Inc.*, 551 U.S. at 313 (internal quotation marks omitted), requiring "a knowing or reckless state of mind," *Avaya*, 564 F.3d at 252 (citing *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534–35 (3d Cir. 1999)). "Under the PSLRA's [scienter] pleading requirement, a plaintiff must 'state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind.' " *Id.* at 267 (emphasis added) (quoting 15 U.S.C. § 78u–4(b)(2)). This standard is met "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc.*, 551 U.S. at 324. The Court conducts this analysis "holistically to determine whether [the complaint's] allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.' " *In re Hertz Glob. Holdings Inc*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Tellabs, Inc.*, 551 U.S. at 323). "[O]missions and ambiguities count against inferring scienter." *Tellabs, Inc.*, 551 U.S. at 323.

Consistent with other courts, the Court assesses scienter with respect to each Defendant. *See, e.g.*, *Allegheny Cnty. Emps.' Ret. Sys. v. Energy Transfer LP*, 532 F. Supp. 3d 189, 227–39 (E.D. Pa. 2021).

a. Lange

Based on a holistic assessment of the CC's allegations, the Court concludes that Plaintiffs have adequately alleged a

strong inference of Defendant Lange's scienter. Lange, Novo's Executive Vice President of Development and a member of its Management Board during the Class Period, was the actual speaker of the various alleged misstatements about CagriSema's tolerability. (CC ¶¶ 19, 48, 59, 73); *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011) ("For purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it.").

Lange and the other Novo executives consistently held Lange out as the "key person" to speak "on Novo's behalf to answer important questions regarding the Company's clinical trial designs and outcomes." (CC ¶ 94.) The CC is replete with allegations showing that, even aside from the alleged misstatements, Defendant Jørgensen and other senior officials at Novo deferred clinical trial-related questions to Lange. (*Id.* ¶¶ 95–101 (discussing multiple instances in which Jørgensen, Novo's CFO, and two of Novo's Heads of Investor Relations deferred questions about REDEFINE 1 and CagriSema's tolerability).) Lange himself spoke with intimate familiarity about his "next [love]" CagriSema and the REDEFINE 1 clinical trial, holding himself out as the expert in details about the study's dosing, recruitment, and structure throughout the Class Period. (*Id.* ¶¶ 102–06 (alteration in original).) This included Lange's direct responses to analyst questions about CagriSema's expected tolerability in REDEFINE 1, which "implied that [he] had first-hand knowledge" of Novo's inevitable approach to that key issue—the flexible dosing protocol. *In re PTC*, 2017 WL 3705801, at *17; (CC ¶¶ 48, 73); *see also Levon v. CorMedix Inc.*, 797 F. Supp. 3d 381, 421 (D.N.J. 2025) (holding that because defendants "provided responses to specific questions" about subject at issue, they "implied firsthand knowledge to investors"). Thus, at this preliminary stage, Plaintiffs have adequately pleaded that Lange "knew at the time that his statements were false or was reckless in disregarding the obvious risk of misleading the public." *Avaya*, 564 F.3d at 272; *Allegheny Cnty. Emps.' Ret. Sys.*, 532 F. Supp. 3d at 228 (finding defendant's scienter based on defendant's "professed knowledge" of project); *Levon*, 797 F. Supp. 3d at 420 (concluding that "[c]ourts have consistently found scienter where defendants represent knowledge about the misrepresented topics" and collecting cases).

***24** Moreover, given the importance of CagriSema and the success of REDEFINE 1 to Novo's "core operations"—in particular, the drug's tolerability—Lange's various misstatements and omissions "give[ ] rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." *In re Toronto-Dominion Bank Sec. Litig.*, No. 17-1665, 2018 WL 6381882, at *17 (D.N.J. Dec. 6, 2018) (internal quotation marks omitted omitted). Plaintiffs adequately allege that, as part of its billion-dollar GLP-1 arms race with Eli Lilly, Novo needed to produce a weight loss and obesity drug that was effective, safe, and tolerable. (CC ¶¶ 29–35, 48 (investor question about how Novo could get better tolerability given Eli Lilly's success), 107.) Lange himself acknowledged the importance of CagriSema and REDEFINE 1, calling the drug "a very important product in our pipeline" and the trial a "pivotal study." (*Id.* ¶ 108.) Because GLP-1 drugs, and CagriSema in particular, "concerned Novo's core business" during the Class Period, this evidence further supports an inference of scienter. *In re Novo Nordisk Sec. Litig.*, No. 17-209, 2018 WL 3913912, at *8 (D.N.J. Aug. 16, 2018) (concluding the same with Novo's production of insulin pre-GLP-1s).

In sum, when assessing the collective evidence of scienter, [31] the Court finds that Plaintiffs' allegations of Lange's scienter at this stage are "cogent and compelling" and "strong in light of other explanations." *Tellabs, Inc.*, 551 U.S. at 324. Specifically, the inference that Lange spoke with the requisite scienter is "at least as compelling" as Defendants' proffered inferences of nonfraudulent intent. *Id.* at 314. A "cogent and compelling inference" from the facts as pleaded is that Lange, hoping to avoid investor alarm about CagriSema's tolerability, withheld the change to the flexible dosing protocol in the hopes that REDEFINE 1's trial outcomes would ultimately prove successful. *Id.* at 324. This "gamble ... in the hope that [bad news] will be overtaken by good news" is an adequate inference for scienter. *See Tellabs, Inc.*, 513 F.3d at 710 ("It is like embezzling in the hope that winning at the track will enable the embezzled funds to be replaced before they are discovered to be missing."). [32]

31 The remaining scienter evidence Plaintiffs include against Lange—while not deleterious to their scienter allegations—is weak evidence at best. In addition to the discussed evidence, Plaintiffs allege that Lange sold 33,000 Class B Novo shares for more than $3.6 million in proceeds during the Class Period. (CC ¶ 121.) When compared to the various misstatements surviving dismissal described above, only *one* of Lange's statements

preceded his sale of shares. (*See id.* ¶¶ 59, 123 (alleging that Lange sold 9,000 shares for just over $1 million a week after his March 7, 2024 Capital Markets Day statement).) As a general matter, Plaintiffs have not alleged how this single sale—or any of the sales alleged through the CC—were otherwise so "unusual in scope or timing" as to support an inference of scienter. *Avaya*, 564 F.3d at 279 (quoting *In re Advanta*, 180 F.3d at 540). Moreover, the 25-month length of the Class Period further "makes it difficult to infer intent from the mere fact of a stock sale, as it is not unusual for insiders to trade at some point during their tenure with a company." *Hertz*, 905 F.3d at 120 (quoting *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 891 (4th Cir. 2014)).

32 Defendants' counter scienter inferences—even if "plausible, nonculpable explanations" for Lange's conduct—are insufficient at this stage to displace Plaintiffs' cogent theory, and, in fact, demonstrate the need for further factual development. (MTD at 29); *Tellabs, Inc.*, 551 U.S. at 324 (holding that plaintiff's scienter theory need not be "the most plausible of competing inferences" (cleaned up)).

b. Jørgensen

In contrast to Lange, Plaintiffs have not adequately alleged Jørgensen's scienter. Plaintiffs do not allege that Jørgensen made or caused any of the alleged misstatements or omissions that the Court determined were materially misleading above. (CC ¶¶ 48, 59, 73.) Moreover, the CC makes no mention of Jørgensen's conduct in any way with respect to *any* of the alleged statements about REDEFINE 1 or CagriSema, only mentioning him in-so-far-as it alleges his stock sales throughout the period. (*See id.* ¶¶ 42–78.) His corporate title alone, without more, does not establish liability under Section 10(b).

***25** Although the person with "ultimate authority" for the making of a statement can be found liable under Section 10(b) as its maker, Plaintiffs' sparse allegations about Jørgensen provide no indication that Jørgensen was the ultimate authority behind any of the remaining misstatements. *Janus*, 564 U.S. at 142–43; (CC ¶¶ 48 (statement made by Lange), 59 (same), 73 (same).) "[A]ny defendant who does not make or affirmatively cause to be made a fraudulent misstatement or omission, or who does not directly engage in manipulative securities trading practices ... cannot be held liable under § 10(b) or any subpart of Rule 10b-5." *In re Charter Commc'n, Inc., Sec. Litig.*, 443 F.3d 987, 992 (8th Cir. 2006) (collecting cases); *see also Allegheny Cnty. Emps.' Ret. Sys.*, 532 F. Supp. 3d at 232 (dismissing defendants who had not made any of the alleged misstatements and lacked sufficient allegations showing they were the ultimate authority on those statements); *see also Janus*, 564 U.S. at 143 ("This rule might best be exemplified by the relationship between a speechwriter and a speaker. Even when a speechwriter drafts a speech, the content is entirely within the control of the person who delivers it. And it is the speaker who takes credit—or blame—for what is ultimately said."). Accordingly, Count I is dismissed against Jørgensen. [33]

33 Plaintiffs insufficient pleading that Jørgensen was a maker of any of the alleged misstatements for Section 10(b) purposes means that the Court need not weigh Plaintiffs' various scienter related evidence against him at this stage. *Cf. Allegheny Cnty. Emps.' Ret. Sys.*, 532 F. Supp. 3d at 231–32 (dismissing defendants who were not alleged to have made any misstatements); *Winer*, 503 F.3d at 337 (holding that group pleading is not viable under the PSLRA).

c. Novo

Because the Court determined that Lange acted with the requisite scienter in making his alleged misstatements about tolerability, such scienter is also attributable to Novo, his principal. "An inference of scienter based upon statements made by Individual Defendants can be imputed to [a corporate defendant] because a corporation is liable for statements by employees who have apparent authority to make them." *Allegheny Cnty. Emps' Ret. Sys.*, 532 F. Supp. 3d at 234 (cleaned up) (quoting *Avaya*, 564 F.3d at 252). This question of imputation of apparent authority is governed by state law. *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 494 (3d Cir. 2013). Under New Jersey law, the question of an agent's apparent authority is a factual question of whether "a person of ordinary prudence" within an industry would reasonably believe that the agent has authority to act. *PXRE Corp. v. Terra Nova Ins. Co. Ltd.*, 76 F. App'x 485, 490 (3d Cir. 2003) (quoting *U.S. Plywood Corp. v. Neidlinger*, 194 A.2d 730, 734 (N.J. 1963)). At this stage, Plaintiffs have plausibly alleged that Lange, acting as a Novo Executive Vice President and a member of its Management Board at

official Novo earnings calls and events, spoke with apparent authority that can be attributed to Novo, and Defendants do not argue otherwise. (CC ¶¶ 19, 21, 48, 59, 73; *see generally* MTD.) Accordingly, the Court imputes Lange's scienter onto Novo through basic agency principles for Lange's various statements. *See Allegheny Cnty. Emps' Ret. Sys.*, 532 F. Supp. 3d at 234 (attributing scienter on corporate defendant based on speaker's apparent authority as agent of corporation).

3. Loss Causation

The final element of Plaintiffs' first Count is loss causation. In the context of Rule 10b-5 claims, the Court must determine "whether the misrepresentation or omission proximately caused the economic loss." *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 426 (3d Cir. 2007). This requires the plaintiff to show that the defendants "misrepresented or omitted the very facts that were a substantial factor in causing the plaintiff's economic loss," *id.* at 425, and that the "share price fell significantly after the truth became known," *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). "Courts in this district have held loss causation is adequately pled when a company's stock price declines after media reports and disclosures presented new information about the alleged fraud to the public." *Levon*, 797 F. Supp. 3d at 430 (quoting *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *15 (D.N.J. June 28, 2024)).

***26** The Court concludes—and Defendants do not contest—that Plaintiffs have adequately alleged loss causation. Plaintiffs allege that, prior to the market opening on December 20, 2024, Novo reported the results of its REDEFINE 1 trial and announced, for the first time, its use of the flexible dosing protocol. (CC ¶ 126.) The alleged 17.83% drop in Novo ADR shares that same day indicates a sufficient causal link with the "disclosure [that] presented new information" about CagriSema's tolerability. *Levon*, 797 F. Supp. 3d at 430 (internal quotation marks omitted); (CC ¶ 127; *see also* CC ¶¶ 128–32 (alleging that media and securities analysts were surprised by the "puzzling" clinical trial data and flexible dosing protocol)).

In summary, Plaintiffs' Count I survives (1) with respect to Lange's three statements about CagriSema's "tolerability," first made on November 3, 2022,[34] (CC ¶¶ 48, 59, 73), and (2) against Defendants Novo and Lange. All other alleged misstatements and Defendant Jørgensen are dismissed.

34 This is one day after the CC's alleged beginning of the Class Period, November 2, 2022. (CC ¶ 43.) Thus, Plaintiffs have adequately stated a claim under Section 10(b) and Rule 10b-5 for a Class Period beginning on November 3, 2022 and ending December 20, 2024.

C. SECTION 20(A) CLAIM

In Count Two, Plaintiffs assert a claim for control person liability against all Defendants under Section 20(a) of the Exchange Act. (*Id.* ¶¶ 155–59.) To allege a violation of Section 20(a), a plaintiff must show "(1) the defendant controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud." *In re Newell Brands*, 2019 WL 6715055, at *14 (internal quotation marks omitted). As such, "liability under Section 20(a) is contingent upon sufficiently pleading an underlying violation of Section 10(b) by the controlled person." *Id.* (internal quotation marks omitted).

Because the Court has determined that at least a portion of Plaintiffs' underlying Section 10(b) claim survives, so, too, does Plaintiffs' Section 20(a) claim. Defendants' argument that Plaintiffs "fail to plead that either Individual Defendant was a culpable participant in the alleged fraud" is undermined by the Court's determination above that Plaintiffs adequately pleaded Lange's Section 10(b) liability. (MTD at 30); *see also Strougo v. Mallinckrodt Public Ltd.*, No. 20-10100, 2022 WL 17740482, at *11 (D.N.J. Dec. 16, 2022) ("[T]he overwhelming trend in the Third Circuit is that culpable participation need not be pled to survive a motion to dismiss." (cleaned up)). Further, despite the Court's above conclusion that Plaintiffs did not adequately allege Jørgensen's scienter with respect to Count I, Plaintiffs have adequately alleged that Jørgensen, as a "high level officer[ ] of the Company during the Class Period," was a control person at Novo, a status that "easily places [him] within the definition of 'control persons' for Section 20(a) liability." *Zhengyu He v. China Zenix Auto Int'l Ltd.*, No. 18-15530, 2020 WL 3169506, at *13 (D.N.J. June 12, 2020) (allowing Section 20(a) claim to proceed against a defendant where the underling Section 10(b) claim against him was dismissed) (citing *Dudley v. Haub*, No. 11-5196, 2013 WL 1845519, at *20 (D.N.J. Apr. 30, 2013)). Accordingly, Defendants' Motion is denied with respect to Count II—Novo, Jørgensen, and Lange each remain Defendants under the Section 20(a) claim.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is **GRANTED IN PART** and **DENIED IN PART**. An appropriate Order will accompany this Opinion.

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