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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHANGYEON MOON, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. NOVO NORDISK A/S, LARS FRUERGAARD JØRGENSEN, and MARTIN HOLST LANGE, Defendants.	Case No. 2:25-cv-00713 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff Changyeon Moon ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Novo Nordisk A/S ("Novo" or the "Company")

with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Novo's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Novo securities between November 2, 2022 to December 19, 2024, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning the details of, and expectations for, Novo's phase 3 CagriSema study on obesity, named "REDEFINE-1." Defendants' statements failed to disclose or otherwise misled investors as to the nature of the dosages provided to patients in the study. Defendants' statements further included, among other things, significant confidence in Novo's expectations for the study, in particular a minimum expected 25% average weight loss for obesity patients treated with CagriSema in the REDEFINE-1 study.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Novo's REDEFINE-1 trial protocol; notably, that it was a "flexible protocol" which gave patients the ability "to modify their dosing throughout the trial." Such statements absent these material facts misled Plaintiff and other shareholders about the study's risks and prospects for success and, in turn, caused them to purchase Novo's securities at artificially inflated prices.

4. On December 20, 2024, during pre-market hours, Novo announced headline results for its REDEFINE-1 trial, which determined CagriSema had achieved a weight loss average of only 22.7% after 68 weeks. The Company attributed this diminished result, in part, on the previously undisclosed "flexible" nature of the protocol. This flexibility resulted in less than 60% of patients apparently completing the dose escalation period and thus being treated with "2.4 mg cagrilintide and 2.4 mg semaglutide once-weekly," the maximum dosage of CagriSema contemplated by the trial, during the 52-week maintenance period in the manner outlined by the published protocol for the REDEFINE-1 study.

5. Investors and analysts reacted immediately to Novo's revelation. The price of Novo's common stock declined dramatically. From a closing market price of $103.44 per share on December 19, 2024, Novo's stock price fell to $85.00 per

share on December 20, 2024, a decline of about 17.83% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Novo's US headquarters are located in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Novo common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Novo is attached hereto.

12. Novo Nordisk A/S is a Danish corporation with its United States principal executive offices located at 800 Scudders Mill Road. Plainsboro, NJ 08536. During the Class Period, the Company's common stock traded on the New York Stock Exchange (the "NYSE") under the symbol "NVO."

13. Defendant Lars Fruergaard Jørgensen ("Jørgensen") was, at all relevant times, the President, Chief Executive Officer, and a Member of the Management Board of Novo.

14. Martin Holst Lange ("Lange") was, at all relevant times, the Executive Vice President of Development and a Member of the Management Board of Novo.

15. Defendants Jørgensen and Lange are sometimes referred to herein as the "Individual Defendants." Novo together with the Individual Defendants are referred to herein as the "Defendants."

16. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Novo's reports to the SEC, press releases, and presentations to securities analysts, money

and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

17. Novo is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

18. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Novo under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

19. Novo is a healthcare company, focused on the research, development, manufacturing, and distribution of pharmaceutical productions globally. The Company operates in two segments, diabetes and obesity on one arm, and rare diseases on the other.

20. Novo is internationally headquartered outside of Copenhagen, Denmark, while its United States headquarters are located in Plainsboro New Jersey.

The Defendants Materially Misled Investors Concerning the REDEFINE-1 Trial Protocol and its Anticipated Results

November 2, 2022

21. On November 2, 2022, Defendants published their third quarter fiscal 2022 earnings and conducted a corresponding earnings call. During the earnings call, Defendants announced the commencement of REDEFINE-1 and pertinently provided the following details:

> Finally, with [indiscernible], we are very excited to have initiated the first trial called Redefine 1 for CagriSema. REDEFINE-1 is a 68-week trial, comparing the efficacy and safety of once-weekly CagriSema with semaglutide 2.4 milligram, cagrilintide 2.4 milligram and placebo. The trial is expected to enroll approximately 3,400 people with obesity or overweight and commodities and is the first pivotal trial in the redefined person.

22. This information was reiterated to investors in a 6-K published by the Company that same day, reflecting Novo's "[f]inancial report for the period 1 January 2022 to 30 September 2022." The 6-K stated, in pertinent part:

> Obesity care
>
> Phase 3a development programme initiated with CagriSema in obesity
>
> In November 2022, Novo Nordisk initiated the first phase 3a trial, REDEFINE 1, for CagriSema. 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 approximately 3,400 people with overweight or obesity. REDEFINE 1 is the first pivotal trial in the REDEFINE programme.

23. Additionally, on November 2, 2022, Novo published an update to the REDEFINE-1 study's entry on Clinicaltrials.gov, a subsection of the National Library of Medicine. The general methods for the study were outlined in a "brief summary" provided in the "Study Description" section of the publication, in pertinent part:

> This study has 2 parts: First part is the main study and second part is the extension study. During the main study participants will receive 1 of 4 study medicines. If participants continue in the extension study, they will not receive any study medicine during the extension. The main study will look at how well CagriSema helps participants with excess body weight lose weight compared to a "dummy" medicine and 2 other medicines, cagrilintide and semaglutide. Participants will either get CagriSema, cagrilintide,semaglutide or "dummy" medicine. Which treatment participants get is decided by chance. They will take one injection once a week. The study medicine is injected briefly with a thin needle, typically in the stomach, thighs or upper arms.

24. The "Arms and Intervention" section outlined the protocol in more detail, pertinently providing the following details for the experimental arm of the REDEFINE-1 study:

> Experimental: Cagrisema s.c. 2.4 mg/2.4 mg
>
> ***Participants will receive 2.4 mg cagrilintide and 2.4 mg semaglutide once-weekly after a dose escalation period of 16 weeks*** (0.25 mg of cagrilintide and 0.25 mg of semaglutide from weeks 0-4, 0.5 mg of cagrilintide and 0.5 mg of semaglutide from weeks 5-8, 1 mg of cagrilintide and 1 mg of semaglutide from weeks 9-12 and 1.7 mg of cagrilintide and 1.7 mg of semaglutide from weeks 13-16) ***during the maintenance period for 52 weeks in the main phase***. Participants randomised to this arm will be included in the extension phase for 97 weeks.

(Emphasis added).

November 3, 2022

25. The following day, on November 3, 2022, Defendants conducted a second earnings call on the same results, providing significantly more color on their expectations for REDEFINE-1, stating in pertinent part:

> ***We think that we have an asset that will lead to a 25%-plus weight loss in the obesity space.*** That's exciting in and of itself. Hopefully, you also noticed that we initiated Phase III for CagriSema this week, which is going to be super, super exciting. We did not know what to expect from CagriSema in the space of type 2 diabetes and glycemia control. And therefore, we conducted a fairly small Phase II study, 90 patients being equally randomized to either CagriSema, semaglutide in monotherapy or cagrilintide in monotherapy.
>
> Super excited after 32 weeks of treatment to observe that we saw not only a numerically and substantially numerically better reduction in hemoglobin A1C for CagriSema as compared to semaglutide, and that

was maybe not so surprising cagrilintide***. But equally excited about seeing the weight loss. You know most of you that's seeing -- and accruing weight loss in type 2 diabetes is actually more difficult than what we see in non-diabetes, so both with semaglutide, but also whatever else is out there. You see somewhat less weight loss in type 2 diabetes than what you see in non-diabetes patients.***

But combining cagrilintide and semaglutide, that leads to a 15% weight loss in 32 weeks. If we extrapolate that to our usual 68 weeks, it's a 20-plus percent weight loss. And that is better than anything we have seen in the type 2 diabetes space.

. . .

Also because, as we've discussed previously, ***the safety profile of CagriSema appears to be very, very attractive***. So from that perspective, you have to factor in the timing of treatment. And that's why we're fairly confident we'll be able to show superiority of the [indiscernible] components, but potentially also of potential competitors. [though this one is in the diabetes space]

. . .

<Q: Michael Leuchten – UBS Investment Bank, Research Division – Co-Head of Pharmaceuticals Research of Equity Research> Two questions for Martin, please. Just on the ultra-high dose sema in the Phase II [type-2 diabetes trial], that's a step change in dose that's quite different from what you tried before. Just wondering where that came from to go that aggressive on the dose range? And then on CagriSema, the tolerability in the Phase II, I think, at -- it was 60-something percent of tolerability and I think discontinuation is up to 20%. Lilly has managed to get that down in Phase III. Just wondering what you can do in Phase III to get a better tolerability.

<A: Martin Holst Lange> So super questions. First of all, [indiscernible] ***tolerability shows a function of titration in this space***. So that would go to both of your questions. ***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. Obviously, we have to show that. That's why we do the clinical trials. But our assumption is that ***when we get to that level, tolerability has already been built, and you can actually do the next step without introducing more GI side effects***.

The other part of it is actually -- and you see that from us and from our competitors, GI side effects reporting in terms of proportions and rates is more often than not a function of how often do you ask, how many visits do you have. ***And that's why you see higher rates in early development and lower rate as you progress because you have fewer site visits as you progress***. We also become wiser on how to titrate.

And specifically for CagriSema, it -- don't misunderstand me, I don't think we should look at the actual rates because they are a function on how did we -- how many visits do we have in the study, but more looking to the comparison to semaglutide and cagrilintide. And in that specific study, we actually saw a similar rate between semaglutide and CagriSema. ***And therefore, we are fairly confident that when we do titration right, we'll actually have a super attractive GI tolerability profile of CagriSema.***

(Emphasis added).

May 4, 2023

26. On May 4, 2023, during the question-and-answer portion of the Company's earnings call for the first quarter of fiscal year, Defendants reiterated their expectations for CagriSema in as a treatment for obesity during the following pertinent exchange:

<Q: Richard J. Parkes – BNP Paribas Exane – Head of Pharmaceutical and Biotechnology Team> . . . Second question is we've seen extremely strong data from the SURMOUNT-2 study of tirzapatide in obese diabetics recently, which could make it a very attractive option for that patient population. And I think the placebo-adjusted weight loss was 2x what you saw in the Wegovy trial. And maybe that reflects the added

> benefit of improved glycemic control with tirzapatide in that population. But I'm wondering if you had a sense of what you think could be achieved in that population with CagriSema. I know you've guided to where you think the weight loss will fall out in terms of obese population but not maybe obese diabetics.
>
> . . .
>
> <A: Martin Holst Lange> . . . But specifically on CagriSema, this is probably where we see the step-up or the step change. Based on what we've seen so far in type 2 diabetes, we would expect an approximate 20% weight loss in and of itself. So actually, more than what we just described, again, with an attractive safety profile. ***And in obesity, without diabetes, we would expect approximately a 25% weight loss***. So from our perspective, semaglutide, maybe with a higher dose is actually already, in and of itself, an attractive offering and, obviously, with CagriSema. ***And as you know, we are currently testing that in Phase III in both type 2 diabetes and obesity. We expect a substantial and significant step-up.***

(Emphasis added).

June 25, 2023

27. On June 25, 2023, Defendants conducted their annual Analyst/Investor Day call. During the call, Defendants fielded various questions relating to dosages and tolerability for Wegovy (semaglutide) and the correlation between dosage and weight loss, pertinently engaging in the following exchanges:

> <Q: Martin Parkhøi – SEB – Head of Danish Equity Analysis> Martin Parkhøi, SEB. First, a question about nausea rates. We saw at the SURMOUNT-2 symposium, Friday that they made this cross-trial comparison, also looked at nausea rates for tirzepatide versus Wegovy in STEP trials. But as I can understand it, Lilly have motivated people to use nausea reducing medication. ***Are you doing similar tricks in Phase III on CagriSema to artificially pull down nausea rates, also maybe with respect to number of visits?*** That was the first question.

<A: Martin Holst Lange> ***So we never do anything artificial in our trials.*** Jokes aside, I think you also indicated that there's something about the number of visits that could drive -- ***it goes without saying that if you have 20 visits in a trial and you ask the patient 20x, you get 20 responses. If you have 10 visits in the same duration trial, you get 10 responses. And that can actually drive a little bit of rate when -- and also patient proportion when it comes to adverse events.*** And that's actually why I'm ever concerned about doing these cross trial comparisons. If we're to really have an objective assessment of efficacy and safety between drugs, we need to do header comparisons. And that is specifically what we do, for example, with REIMAGINE 4.

. . .

<Q: Michael Thomas Nedelcovych – TD Cowen – Research Associate> Michael Nedelcovych from TD Cowen. Two questions. The first is on Wegovy. ***We've spoken to at least one KOL who indicated that some of her patients would like to titrate down from the maintenance that's 2.4 mgs after achieving target weight loss, but that coverage actually is a barrier to that strategy***. Do you plan to develop any data in that area that might support that kind of strategy?

<A: Martin Holst Lange> I'll actually give you the same answer I just gave Martin. Obviously, ***I've heard the same request and obviously, we'll be evaluating our options there***.

. . .

<Q: Peter James Welford – Jefferies LLC – Senior Equity Analyst & European Pharmaceuticals Analyst> Peter Welford, Jefferies. Two questions, I've seen the trend. First on CagriSema. Should we understand then, is the REDEFINE 3 then, is that the limiting factor to understand to file both diabetes and obesity together when the REDEFINE 3 trial finishes? And similarly, just on the dose, and I guess this comes back to Mark's question, have you -- are you confident that the dosing you're using in the CagriSema trials is as high as you need to go or, I guess, what is the limiting factor that this looking? I mean, is this a manufacturing sort of dosing thing? Or given obviously, again, the competitive environment?

> And then just the second question is just on the SELECT study. And this is not peculiarly related with MACE. What I'm actually wondering on the SELECT studies, can you talk a bit about what do you think -- presumably we're going to have an average of, let's say, 3 years, roughly treatment. And there was comments made about how the body weight loss, how we may -- in prior trials, have seen that vary over time. Are you assuming in the SELECT study, can you just talk about what are you envisaging seeing with sema with regards to the sustained effect potentially during the maintenance phase, but the weight effect in the trial?
>
> <A: Martin Holst Lange> So I'm not looking at Daniel, but I can feel him. And he's counting 3 questions there. Just on this SELECT trial, we're -- we have data from STEP 5, which is a 2-year study. And after 2 years of treatment, we see a very nice and flat and sustainable weight loss at around 15% to 17%. I have no reason to think otherwise around SELECT. But obviously, we're super excited to see the data. But what we've seen so far is a sustainable 15% to 17% weight loss that for now lasts at least 2 years.
>
> ***On CagriSema, as you know, we tested the 2.4 milligram of Wegovy together with up to 4.5 milligram of cagrilintide and did not see sort of a substantial up in terms of efficacy. And therefore, we decided on the 2.4 and the 2.4.*** That being said, I don't think you'll ever hear a categorical statement from me that we're really confident that we hit it right because we're and ***I have to announce that also testing 7.2 milligrams of semaglutide as we speak in Phase III because we do believe we can actually see more weight loss with that higher dose. And that would actually also be informative of the potential for CagriSema***. So when we had those data and as I said, the study is ongoing, then we'll speak again.

(Emphasis added).

November 3, 2023

28. On November 3, 2023, Defendants announced during their third quarter fiscal year 2023 earnings call that Novo had "already finalized with the pivotal

recruitment for the obesity [Phase III] program. So really, really happy days in the CagriSema world." During the question-and-answer portion of the call, Defendants again reiterated their faith in the 25% weight loss figure for CagriSema's REDEFINE-1 trial in response to the following, pertinent inquiry:

> <Q: Peter James Welford – Jefferies LLC – Senior Equity Analyst & European Pharmaceuticals Analsyt> Can I ask a question on CagriSema, please. Just with regards to the Phase III trials in obesity are fully enrolled. Can you just talk a little bit about, firstly, when you can go to regulators with those data or you also require data from, I think, the sort of shared cardiovascular study this part of the type 2 diabetes program, to be able to just a bit for obesity. I guess I'm not sure what the hazard ratio sort of requirements are necessary for obesity versus diabetes drug approvals for FDA. And is there any reason why you think with CagriSema with those data, we should expect a bigger disparity, I guess, between obesity and diabetes versus what we see with semaglutide alone in the 2 different indications as far as how the drug performs relatively for the sort of weight loss HPMC and reductions?
>
> <A Daniel Bohsen> Yes. Martin, that's one for you.
>
> <A: Martin Holst Lange> Yes, absolutely. So first of all, we will acquire data from redefined free, which is the cardiovascular outcomes trial that is covering both diabetes and obesity for regulatory submission. That is actually not on time critical test in the way that we designed the program. So at the end of the day, you should still expect to see when we see readouts of redefine 1 and 2, we'll also be able to do the regulatory submissions thereafter. ***When it comes to differentiation, we've discussed the weight loss. The weight loss potential of CagriSema is big. We're currently assuming at least 25%, which is obviously in a non-diabetes population, really good . . .***

(Emphasis added).

March 7, 2024

29. On March 7, 2024, during the Company's annual Analyst/Investor Day call, Defendants again addressed the ongoing REDEFINE-1 study and their expectations for the future of CagriSema. Pertinently, the defendants stated the following:

> 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, are we going? 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. We also discussed the potential obviously, on the cardiovascular system. We've seen more than additivity on some of the biomarkers for cardiovascular risk, blood pressure, dyslipidemia, but actually also inflammation. And that holds a big, big potential for what CagriSema can do.
>
> ***We'll see the first readout from REDEFINE 1 later this year***. And as you can also see in the slide late this year. ***That's going to be incredibly exciting. That's our pivotal study***. It's a 26 -- sorry, 68 weeks study in 3,400 patients. And if I can use a proxy for future success of a molecule, it's typically -- how easy is it to recruit into a trial? We actually recruited these 3,400 patients several months prior to our schedule.
>
> And then obviously, again, at least in my mind, and it is a proxy as to speaks to the potential of CagriSema patients, and these physicians appear to like CagriSema.
>
> . . .
>
> ***The potential of CagriSema also warrants us to take this maybe even further***. Obviously, we'll investigate obstructive sleep apnea, but we'll also specifically go into heart failure, chronic kidney disease, non-alcoholic but also alcoholic liver disease. We saw additional aspirations

> in the diabetes space. ***Again, we have really, really high aspirations and high confidence in this biology.***

(Emphasis added).

November 6, 2024

30. On November 6, 2024, the Company provided final quarterly report prior to the unveiling of the REDEFINE-1 trial results: "Looking ahead, later in Q4, we anticipate the first Phase III results for CagriSema mainly from the REDEFINE-1 study." During the question-and-answer portion of the call, Defendants again reiterated their expectations for CagriSema to achieve 25% weight loss in obesity and briefly discussed the tolerability of CagriSema, generally, during the following pertinent exchanges:

> <Q: Richard J. Parkes – BNP Paribas Exane – Head of Pharmaceutical and Biotechnology & Analyst> I'm going to ask one on CagriSema. I think in the press, you've been reiterating your confidence in hitting the 25% weight loss by. I get lots of questions from investors of how you bridge between that number and the number that was reported in earlier clinical trials, it's obviously an earlier time point. So I know you've mentioned that's based on internal modeling assumptions. But can you help us understand a little bit more in terms of the details that underpins that modeling, and again, your confidence on hitting that.
>
> <A: Jacob Martin Wilborg Rode> Thanks a lot for that, Richard. That goes to you, Martin, on the high level CagriSema expectations.
>
> <A: Martin Holst Lange> Yes. Thank you very much, Richard. So first of all, it's important to call out we have no new data. And therefore, our confidence remains to be the same.
>
> The way that we think about this is that we have 3 sets of data to look at from a modeling perspective. One is Phases I and II for cagrilintide

in mono therapy; then Phase I/II for obesity and CagriSema; and thirdly, the Phase II trial for CagriSema in type 2 diabetes. ***We can then apply our models, I would say, on this based on our extensive knowledge and experience within the obesity space and we arrive then at the 25% weight loss.***

Nothing has really changed there. I've not seen any new data and basically a couple of hours after I've seen that, you will be in the know. So that's where we are today.

. . .

<Q: Florent Cespedes – Sandford C. Bernstein & Co., LLC – Research Analyst> Two quick ones. First for Martin on CagriSema. I know that everybody is focused on weight loss. But Martin, could you share with us what kind of tolerance profile you're looking for at this product as based on Phase II data from diabetes patients. We see that there is increased efficacy on weight loss, but also increased level of nausea or gastrointestinal adverse events with the combination CagriSema versus the individual component. So could you share with us what kind of level of side effects and GI side effects you are all looking for? Will it be the same vein as sema monotherapy or higher?

And my second question, very quick. Maybe could you share with us when you believe that you could provide a new midterm guidance for group.

<A: Jacob Martin Wilborg Rode> Thank you for those 2 questions. Firstly, on Martin, if you could reiterate your previous tolerability commentary on CagriSema?

<A: Martin Holst Lange> Yes. Thank you very much for that question. As we just discussed, these are still early days. 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.***

At this point in time, we expect to see good glycemic control in type 2 diabetes together with a strong 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***.

(Emphasis added).

November 7, 2024

31. On November 7, 2024, Defendants conducted an additional earnings call regarding the Company's performance over the past 9 months. During that call, Defendants once again reiterated the 25% benchmark expectation they had for weight loss in obesity patients treated with CagriSema.

> <Q: Simon P. Baker – Redburn (Europe) Limited – Partner & Head of Pharmaceutical Research> . . . And then on CagriSema, one of the things that cropped up in the Phase I and didn't seem to be a particular issue was the presence of antidrug antibodies, neutralizing antibodies. Firstly, is that anything to worry about? And secondly, how does that factor into your modeling of the 25% weight loss that you expect for the REDEFINE study?
>
> . . .
>
> <A: Martin Holst Lange> . . . On the antibodies, I'm not aware of many, if any, injectable proteins or peptides that do not induce antibodies. The trigger is to assess whether it has any clinical bearing on either efficacy or safety with CagriSema, with cagrilintide. And we have quite a lot of data at this point in time. Some forget that we have already done Phase II for cagrilintide in monotherapy. And in that, we saw no impact of neither efficacy or safety variables. ***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 I and II, and that lands us nicely at the 25% mark.***

(Emphasis added).

32. The above statements in Paragraphs 21 to 31 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the Company's projected successful outcome of the REDEFINE-1 study while avoiding discussions centered around dosage tolerability as it related to the CagriSema or its components. In truth, Novo's repeated optimistic claims CagriSema would achieve at least 25% weight loss in the REDEFINE-1 study fell short of reality. Rather, the utilization of the "flexible protocol" limited the study's ability to effectively provide weight loss data on the dosage tested, suggesting either that tolerability was significantly worse than anticipated, resulting in patients titrating down their dosages to avoid complications, or that the patient selection process was rushed, leading to the onboarding of patients that did not desire to even achieve the 25% weight loss Novo sought to demonstrate.

The Truth Emerges during Novo's Publication of REDEFINE-1's Headline Results

December 20, 2024

33. On December 20, 2024, before market open, Defendants published headline results from their REDEFINE-1 CagriSema obesity trial. In doing so, Defendants also reiterated the trial conditions as previously stated, but also disclosed the flexible dosage protocol, stating in pertinent part, the following:

> REDEFINE 1 is a 68-week efficacy and safety trial investigating subcutaneous ***CagriSema (a fixed dose combination of cagrilintide 2.4***

> ***mg and semaglutide 2.4 mg)*** compared to the individual components cagrilintide 2.4 mg, semaglutide 2.4 mg and placebo, all administered once-weekly. The trial included 3,417 randomised people with obesity or overweight with one or more comorbidities and a mean baseline body weight of 106.9 kg.
>
> The trial achieved its primary endpoint by demonstrating a statistically significant and superior weight loss at week 68 with CagriSema versus placebo.
>
> ***The REDEFINE 1 trial was based on a flexible protocol, allowing patients to modify their dosing throughout the trial***. After 68 weeks, ***57.3% of patients treated with CagriSema were on the highest dose*** compared to 82.5% with cagrilintide 2.4 mg and 70.2% with semaglutide 2.4 mg.
>
> When evaluating the effects of treatment if all people adhered to treatment1, people treated with ***CagriSema achieved a superior weight loss of 22.7% after 68 weeks*** compared to a reduction of 11.8% with cagrilintide 2.4 mg, 16.1% with semaglutide 2.4 mg and 2.3% with placebo alone. In addition, 40.4% of patients who received CagriSema reached a weight loss of 25% or more after 68 weeks, compared to 6.0% with cagrilintide 2.4 mg, 16.2% with semaglutide 2.4 mg, and 0.9% with placebo.

(Emphasis added).

34. In the press release, Defendant Lange pertinently added: "We are encouraged by the weight loss profile of CagriSema demonstrating superiority over both semaglutide and cagrilintide in monotherapy in the REDEFINE-1 trial. ***This was achieved even though only 57% of patients reached the highest CagriSema dose."***

35. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the

alleged false and/or materially misleading statements identified above. In those statements, Defendants routinely reiterated their faith in a minimum 25% weight loss finding for CagriSema as a treatment for obesity in the REDEFINE-1 trial, while simultaneously concealing the flexible dosing asepct of the REDEFINE-1 protocol for CagriSema or the risks or other potential impacts associated with such a protocol.

36. Investors and analysts reacted immediately to Novo's revelation. The price of Novo's common stock declined dramatically. From a closing market price of $103.44 per share on December 19, 2024, Novo's stock price fell to $85.00 per share on December 20, 2024, a decline of about 17.83% in the span of just a single day.

37. A number of well-known analysts who had been following Novo lowered their price targets in response to Novo's disclosures. For example, Barclays lowered their price target 14% while noting that they believed "a fair degree of the decline in share price was attributable to the company missing the bar it had set on weight loss (i.e., at least 25%)." The analyst also noted the confusion that stemmed from the results:

> Friday's press release on CagriSema's REDEFINE-1 study generated more questions than answers
>
> . . .
>
> But the most important question that we cannot as yet answer is…did patients not get to max CagriSema dose because of tolerability or because they were content with the weight lost. We know that in the

> real world clinical setting, dose of GLP-1 is not often maximized, for a variety of reasons. However, in the clinical trial setting, titration is done on a forced schedule in order to maximize efficacy. Did Novo design the trial this way to avoid potential tolerability issues?"

38. Similarly, ABG Sundal Collier noted they "were underwhelmed by the 22.7% weight loss, which was below the firm communicated target of ~25%. But we were mostly disappointed by the large effect on patient behavior in the trial from the implementation of a flexible study design and Novo's surprise at this effect. We do not yet know why only 57% of patients went for the highest CagriSema dose…"

39. Further, Jefferies, while significantly cutting their price target by 19%, provided the following analysis:

> Headline Phase III CagriSema REDEFINE-1 obesity data disappointed, with 20.4% absolute weight loss and patient adherence likely suggesting tolerability concerns, in our view, hence the need to optimize the treatment regimen. The flexible dosing trial design was not well known prior to the Dec readout. We acknowledge some patients may have elected to remain on lower CagriSema doses if rate/extent of weight loss was sufficient, but would argue this calls into question the real world need for next gen obesity drugs.

40. The fact that these analysts, and others, discussed Novo's shortfall and below-expectation projections suggests the public placed significant weight on the success of the REDEFINE-1 study and the Defendants' comments surrounding it. The frequent, in-depth discussions of Novo's guidance and the study's flexible trial design confirm that Defendants' statements during the Class Period were material.

Loss Causation and Economic Loss

41. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Novo's common stock and operated as a fraud or deceit on Class Period purchasers of Novo's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Novo's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Novo's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

42. Novo's stock price fell in response to the corrective event on December 20, 2024, as alleged *supra*. On December 20, 2024, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Novo's REDEFINE-1 Study. In particular, on December 20, 2024, Novo, while disclosing that the "flexible protocol" for REDEFINE-1, announced that CagriSema failed to achieve the Company's guided 25% figure for weight loss. These statements has the effect of correcting Defendants' prior false and/or misleading statements which, in turn, caused Novo's stock price to decline as investors reassessed the risks and benefits of investing in the Company.

Presumption of Reliance; Fraud-On-The-Market

43. At all relevant times, the market for Novo's common stock was an efficient market for the following reasons, among others:

(a) Novo's common stock met the requirements for listing and was listed and actively traded on the NYSE during the Class Period, a highly efficient and automated market;

(b) Novo communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Novo was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Novo was reflected in and incorporated into the Company's stock price during the Class Period.

44. As a result of the foregoing, the market for Novo's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Novo's stock price. Under these

circumstances, all purchasers of Novo's common stock during the Class Period suffered similar injury through their purchase of Novo's common stock at artificially inflated prices, and a presumption of reliance applies.

45. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

46. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with false and/or materially misleading statements about Novo's operations, specifically the REDEFINE-1 trial and its expected outcomes while at the same time concealing material aspects about the trial protocol.

47. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as

"forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

48. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Novo who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

49. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Novo's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure.

Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

50. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Novo's common stock were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Novo or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As reported by Novo in its financial report for the period January 1, 2024 to September 30, 2024 on Form 6-K as filed on November 6, 2024, the Company had 4.46 billion shares of common stock outstanding as of September 30, 2024. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

51. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

52. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

53. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Novo;

(c) whether the Individual Defendants caused Novo to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Novo's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

54. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

55. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

56. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

57. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Novo common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Novo's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

58. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Novo's securities. Such reports, filings, releases and statements were materially false and

misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

59. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

60. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Novo's internal affairs.

61. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-

held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Novo's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Novo's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Novo's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

62. During the Class Period, Novo's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Novo's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or

acquisitions by Plaintiff and the Class, the true value of Novo's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Novo's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

63. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

64. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

65. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

66. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their

senior positions, they knew the adverse non-public information about Novo's misstatements.

67. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Novo which had become materially false or misleading.

68. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Novo disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Novo to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Novo's common stock.

69. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Novo to engage in the unlawful

acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

70. By reason of the above conduct, the Individual Defendants and/or Novo are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: January 24, 2025

Respectfully submitted,

LEVI & KORSINSKY, LLP

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