S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

FH1 2024 Earnings Call Transcripts

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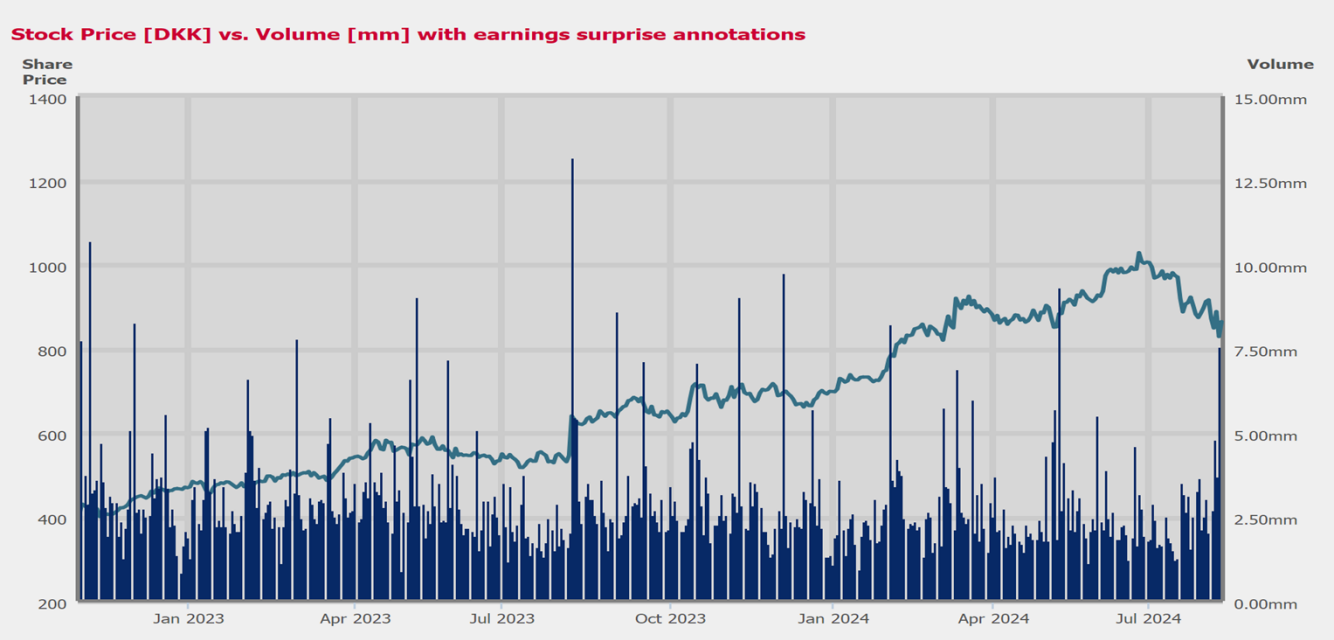
S&P Global Market Intelligence Estimates

	-FY 2024-			-FY 2025-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS
EPS Normalized	23.31	NA	NA	29.01
Revenue (mm)	290621.43	NA	NA	350672.50

Currency: DKK
Consensus as of Aug-08-2024 2:44 PM GMT



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ANALYSTS

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Redburn (Europe) Limited, Research Division

Unknown Analyst

Presentation

James Patrick Quigley
Goldman Sachs Group, Inc., Research Division

So good morning, everybody. I'm James Quigley, European pharma analyst here at Goldman Sachs. And it's a pleasure to welcome you all here to the Novo second quarter management meeting.

So today, we're joined by Lars Jørgensen, CEO; Karsten Knudsen, CFO; Camilla Sylvest, Head of Commercial; and also Martin Lange, Head of Development.

So [with that explained, I'll hand it] over to you guys to kick off. Thank you.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Great. Thank you, James. And thank you, Goldman Sachs, for hosting us today. We're excited to be here.

You have probably seen some of our slides. We'll go through them quickly just to set the stage and then get to the Q&A.

So the first slide is the forward-looking statements. You know we'll be talking about the future. It could turn out to be different than what we preach here, so be aware of that. And there are more notes in our website, et cetera.

So you know our strategic aspirations. We feel we're making good progress serving more patients, strong commercial execution. We're really glad about how we're strengthening our market position in diabetes, how we're growing in obesity. We have a few challenges in rare diseases, but we are encouraged by future growth, not least because of the great data we have received of -- on Mim8 over the past quarter, excited about that. And you can say all of the financial execution -- commercial execution turns into that we have operated our outlook for the year. So you should see that a sign of confidence in the momentum we have in the business and also having a supply of products to fuel that continued growth.

With that, I'll leave the word to Camilla for some comments on the commercial area.

Camilla Sylvest
Executive VP of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. Thank you, Lars.

And here you see our sales growth of 25%, how it's distributed on regions and therapy areas: 36% growth in North America, 11% growth in International Operations, growth driven by all regions. And when it comes to therapy area, it's really our key brands Ozempic, Rybelsus, Wegovy that is driving our growth.

You see a strong growth in GLP-1 diabetes, where we also continue to exceed our leadership in diabetes care, now with a market share in total diabetes above 34%. And if we zoom in on obesity, we have 37% growth. If we take a look at the U.S. on the next slide, you can see that we are continuing to expand the number of starter doses into the market. And also, on total scripts, we now have since the beginning of the year a doubling of the total scripts. So we are progressing very nicely in terms of our ability to provide Wegovy to patients in the U.S. but also in the rest of the world, where we are -- now have launched in 14 countries and are continuing to launch in more and more countries as we speak.

And with that, over to Dr. Lange to give us an update on R&D.

Martin Holst Lange
Executive VP of Development & Member of the Management Board

Thank you very much, Camilla.

If I could have the next slide. As Lars already alluded to, we're very happy with the results that we saw from FRONTIER 2, our Mim8 pivotal trial. It was a complex trial investigating the broad range of hemophilia A, with and without inhibitors across the spectrum of hemophilia A in terms of severity. We had both males and females in the study and we're investigating patients coming from either prophylaxis or on-demand treatment. We're also investigating both once weekly and once monthly, so a quite complex study with a lot of permutations when it comes to the primary end point.

At the end of the day, what you should take away is for the primary end point, regardless of looking at once weekly or once monthly, comparing to prophylaxis treatment or previous on-demand treatment, we see the mean annual bleed rate reduction of somewhere between 60% and 90-plus percent, which is obviously exceedingly gratifying even for patients coming from previous on-demand treatment -- sorry, prophylaxis treatment. If we look at the median annual bleed rate, it was 0 across the board, indicating that, regardless of which analysis we did, more than 50% of patients had 0 bleeds. And if we look at the actual numbers, again it's between 60-plus and 90-plus percent of patients that have 0 bleeds, so very, very strong efficacy data.

Similarly, we saw a strong safety profile with no thromboembolic events; and somewhere between 5% and 12%, again depending on the analysis, of patients reporting injection site reactions, so a very attractive number. Really, really happy with these data and obviously moving towards a submission during the first half of 2025.

If I could have the next slide. We see broad pipeline progress; of course, really, really happy with the almost global access -- sorry, approval for insulin icodec. I have to mention a complete response letter in the U.S. focusing on manufacturing and also obviously type 1 diabetes. We expect to be able to resubmit the icodec file in the U.S. during the course of first half of 2025.

Broadly speaking, we see a lot of progress in our pipeline. I want to call out obviously the data that we will see from monlunabant in this half of the year, first, on obesity; and secondly, on [diabetic care disease], 2 Phase II studies that will read out in Q3 and Q4, respectively. Looking very much forward to see our first CagriSema data, the REDEFINE 1 trial that will read out in December of this year.

I've already talked to Mim8. But maybe also mentioning that we have resubmitted concizumab in the U.S. for both hemophilia with inhibitors but also without inhibitors. And then finally, we've initiated the ARTEMIS study, which is a study in acute myocardial infarction, with ziltivekimab.

I think, with that, over to you, Karsten.

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

Yes. Thank you, Martin.

So when we look at the results in the first 6 months. Then we delivered fantastic 25% sales growth. This is really industry-leading sales growth and a continuation of the sales growth we saw in the first quarter. The 25% has a benefit from rebate adjustments related to the U.S. and also benefits from a reasonably easy comparator from last year linked to phasing of rebates last year. And I'll come back to why that's important.

Our commercial investments are at a low level, in that respect 6%, adjust for something, legal provisions last year around 10%. So really indicating we have the commercial infrastructure in place, perhaps with -- unless we talk about obesity, why we're really investing in obesity market development activities across the board.

R&D really stepping up. 78% is overstating the true R&D step-up P&L-wise due to the fact that we had an impairment on ocedurenone and also another asset in the second quarter. So adjusting for that, R&D is still stepping up more than 30%, which is linked to our intent to really build a competitive pipeline for the company's future growth for the coming decades.

Net-net, that yields a operating profit growth of 19% for the first 6 months. As I said, we have impairment impacts in the quarter, so if you look at it from an EBITDA point of view, then we have an EBITDA growth for the first 6 months of 32%.

Next slide, please. So Lars spoke to that we are upgrading our full year sales outlook. And that's why I said first half is benefiting from gross-to-net adjustments and an easy comparator. On the contrary, the second half has a tough comparator because it was phasing from last year, so the 25% implied in the second half of this year to get to a midpoint of our guidance range actually requires underlying growth closer to a 30% mark if you take the comparator into account. So really talking to an acceleration of underlying growth in the second half driven by our GLP-1 franchise and, of course, enabled by scaling of supply chain.

Operating profit. It's important to note that, since we issued guidance at Q1, we had the impairment of ocedurenone, which had a 6% negative impact. And then the sales upgrade we do this quarter has a 4 percentage point positive impact on our operating profit growth, so we really have a significant flow-through, 2% up on sales growth, 4% on OP, so a really solid gearing in terms of financial performance. And then of course, I was about to say that translates into a step-up in our forecasted free cash flow for the year.

That takes us back to you, Lars.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. So just in summary: We are executing well on progressing towards our strategic aspiration for 2025. We're very encouraged by the growth momentum we have. We have scaled our supply chain to be able to continue that trajectory in the second half of the year, as Karsten just alluded to. And we have really exciting, say, pipeline readout also coming in the second half of the year, so a strong start to the year and even more to come.

With that, I think we should close on the slides and get to the Q&A., so please take a seat.

Jacob Rode

Thank you, Lars. [Thank you, management, for the presentation]. [indiscernible] more than half an hour for the Q&A.
As per usual, please state your name and your institution. And we'll have one question per person, so we'll take multiple rounds. We have some mics going around. And I think we'll start with James, as per tradition, our host.

Question and Answer

James Patrick Quigley
Goldman Sachs Group, Inc., Research Division

James Quigley from Goldman Sachs. So just starting on Wegovy net pricing. So again, I mean, there's a bit of confusion here on the development, following the call, perhaps on the comments on channel mix, rebate adjustments, competition, et cetera, so could you take us through how you expect the Wegovy net prices to develop? And what are the key impacts from the rebate adjustments that we saw in the quarter?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. So if I start. So we'll not get into guiding specifically on net price development for individual products, but I will just say that we don't see any, say, change in the marketplace. What happened in the second quarter was that we had a onetime, one-off true-up for rebates given last year. And of course, if you look at the book of business and, say, the sizable rebate adjustments or rebate accruals we make, when we end up knowing or understanding the real flow of products and true that up, that can lead to, say, changes in the quarter, but these are -- when you look at the total book of business and, say, the yearly flow of business, we're down to a very small adjustment for that business. So I think it's difficult to judge the business based on 1 quarter when you have these, so we have to look at it in totality. And with the guidance upgrade we have given, that's value. So you can take that as a sign that, I think, we have strong value development in our business. And that's what leads to the upgrade we see here.

Jacob Rode

Thank you, Lars. We'll move over here to Jo.

Jo Walton
UBS Investment Bank, Research Division

A question for Martin, please. In the past, you've said that you don't think that there are any scalable small molecules and that the market will largely remain in the injectable space. Since those comments, we've seen a couple of small molecule GLP-type drugs. I wonder if you could update us on your view as to how the market is going to split between injectables and orals. And also, if I can just ask how you're going to choose between your next injectables, should we expect all of them to come to the market? Or should we expect you to just and -- develop one of them your best?

Martin Holst Lange
Executive VP of Development & Member of the Management Board

So first of all, on the small molecules side, actually I've said that I think monlunabant, from a scalability perspective, seems to be an attractive offering. Obviously right now we're working on demonstrating safety and efficacy of monlunabant, but from a scalability perspective, that seems to be, by conventional wisdom, a true small molecule that can be easily scaled. When we look at what else is out there -- and of course, we're looking through the same lens, the certifications. Is it safe? And can it be scaled? And most of what we see out there is, from a chemistry perspective, slightly more complex than conventional small molecules. And that basically means that they are more difficult and more expensive to scale. Of course, if you do the investment, you can scale. And then the question comes to what number of patients. The way we think about this and the way that we scale, as you've seen our investments in the subcutaneous space, you would have to invest quite substantially to be able to scale those small molecules to an impactful degree. I think Karsten and Lars can talk more to that, but from a pure chemistry perspective, they are not trivial. Of course, they can be produced, but they will not be sort of conventional small molecules that you can just produce to, let's say, double, triple million patients [indiscernible] million patients.

Specifically for our own pipeline, we see obesity as a complex disease. And for us, obviously, to have the leading molecules in the incretin space but also working on new modalities based on amylin biology, based on CB1 biology, that allows us to cater to different patient needs. And the way that we look at this, and this is maybe more, Camilla, that you speak to that, if we see clinical, medical differentiation between our molecules, we expect them to be able to coexist to cater for different patient needs. And that's the way that we build our pipeline both in the oral and in the subcutaneous space.

Jacob Rode

We move over here to Pete.

Peter Verdult
Citigroup Inc., Research Division

Pete Verdult. Can we move to actually insulins just for a second and give Wegovy a rest for a bit? Just can you help us understand why there was such a positive rebate adjustment given what we've seen in terms of the interesting price cap and changes there? And when you think about IRA next year, is it really going to matter? Are insulin prices really already at rock bottom? Or is there going to be another downdraft when IRA hits on some of your insulin portfolio?

Jacob Rode

Thanks, Pete. Karsten, will you give that a go, on insulin technicalities and underlying movements?

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

Yes. So for insulins [backlash] coming from before. When we estimate the gross net in the U.S.A. -- and we sell to wholesalers and charge list price. And then it takes like 3, 4 months before we receive rebates; and then the rebates can go to different channels at different rates. So that's the estimates going into it. And that's also what happens for insulins. We had a bigger adjustment in the first quarter but also an adjustment in the second quarter based on these estimates. I don't think it benefits anyone in here to go into the gory details about what channels and what rates and what channel mix, but it is true that the insulin growth in the U.S. was very significant in the second quarter. And it was all driven by price adjustments or rebate adjustments in the second quarter of this year. Underlying, when we look at it, yes, insulin in the U.S. is a declining market in terms of market growth. And our market share is also declining, linked, amongst other items, to the Levemir product discontinuation.

Jacob Rode

Thank you, Karsten. We'll move to Emily.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. It seems that there's been growing concern also coming from the FDA regarding the safety of these compounded formulations of GLP-1, and I was just wondering. With your lowest dose remaining on the drug shortage list and no doses of tirzepatide, at least from what we see on the FDA website, does that mean that compounders can still make your drug and not theirs? How much does the growth of compounding concern you both from a patient safety perspective and then also taking what share could be Novo Nordisk?

Jacob Rode

Thank you, Emily. I'll give that to you, Lars, on drug shortage...

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. So just to align: There's only one sema, and that's produced by Novo Nordisk, so I don't know what compounders -- well, they're compound, but I don't know where they get API from and what the quality of that is. And we've also seen that, I think, some of the safety reportings has -- there's been a high representation from compounded drugs. So we take patient safety very seriously, and so does the U.S. FDA. Specifically on your point, we have, in dialogue with FDA, removed the drug shortage notification on the other doses. We have all along said that we want to dynamically start patients in a way where they can have a good journey on the titration doses. We actually scale capacity significantly, so we could then principally have decided also to remove the shortage notification on the starter dose if we wanted to, but we just think that we've been out consistently saying to physicians and also FDA that we want to have a responsible approach to starting patients. So you can trust, and when you start treatment with Wegovy from Novo Nordisk, we take care of you in the sense that you can titrate up to the doses.

So that led us to keep the notification on the starter dose, but we could in principle have taken it away also because we still manage the doses. So when we look at that, look at it, we have significant step-up in capacity. We allocate that to different doses. And that leads to a significantly higher number of total scripts in the U.S. market, and that's what fuels the growth and that's what turns into this upgraded outlook. Then how we look at individual doses and also, say, classify that from a drug shortage notification, those are minor tactics. And we could have taken them all away if we wanted to, but we just think for consistency because we have said that for some time, that we stick to that. Whether [these end to massive] compounding, I don't know. Because we could just remove it and then there was no compounding. So I don't think compounding is a way forward generally to serve patients.

Jacob Rode

Thank you, Lars. Then we'll move to Sachin.

Sachin Jain
BofA Securities, Research Division

Sachin Jain, Bank of America. Can I just take one clarification on that last point and then ask my CB1 question? I think there was confusion on the lower dose yesterday because it was answered 2 different ways as to whether the 0.25 was going to grow or not grow. Just interpreting from your answer just there, the 0.25 can grow, but you're just not within the boundary of however FDA defines shortage. I just want to clarify that before I ask my CB1.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes, it can grow. So you -- I'm just thinking hypothetically. We could allocate all our capacity to produce the starter dose. And we would have new scripts [explode], but we want to make sure that patients can start and titrate to higher doses because that's good for the patient. But it's also good for our business because we get -- we grow the business by that, so don't put too much emphasis into underlying individual doses because it's totality of the business and how we allocate our capacity to produce that, that matters. I hope that's clear.

Sachin Jain
BofA Securities, Research Division

CB1. There's a lot of focus and predominantly on the CNS safety, so I wonder if you could just frame for us how you're thinking about on 2 metrics: the GLP-1 [C psych] adverse event rates in the high single digits, I think, if that's correct, for Wegovy. So what delta relative to that would give you comfort or not comfort? And then on suicidal ideation, [I compare it] was about 0.5%, so in 600 patients across the 2 studies, we're literally talking about 1, 2, 3 events, so if you see any, is that a problem? And how many patients would you need to see low suicidal ideation before you get really comfortable on the site profile?

Martin Holst Lange
Executive VP of Development & Member of the Management Board

So the way we think about this is that -- and it's a little bit going back to Jo's question. We aim to scale monlunabant to a great number of patients. And that basically means that we need to, the level that we can, exclude concerns about an excess of neuropsychiatric side effects. So to your own point, in any clinical study, there will be patients who report neuropsychiatric events. And just to give you an example: In the SELECT trial, we had 10 events of suicidal ideation on placebo and we have 10 events of suicidal ideation on semaglutide. So [no excess]. We intend to take the same approach for monlunabant. And at the end of the day, for [the 2 onco and] Phase II studies -- reasonably large, more than 600 patients, additional Phase II study continuously derisking the asset; and then obviously our bigger development program to generate, with actually a dedicated focus on this specific issue, enough data to say we don't see an excess risk, as compared to anything else out there. That's sort of our approach, but that is also the bar. And I think that's our bar, but that would also be the bar from regulators.

Jacob Rode

Thank you, Martin. Thank you, Sachin. We'll move to the table at the back; and Mark Purcell, first.

Mark Douglas Purcell
Morgan Stanley, Research Division

Mark Purcell from Morgan Stanley. A question on obesity time lines. A lot of your competitors are trying to accelerate their programs, doing relatively small Phase II studies and taking them to the FDA and looking to go into Phase III or Phase II and parallel Phase III studies together, so in terms of amycretin, can you help us understand the probability you can go from a couple of Phase I studies, one Phase II ongoing in diabetes to a full Phase III program, both for the oral and the injectables side? And then following up on what Sachin was just asking: I mean I don't think you'll learn a lot from an additional 600-patient Phase IIb study with INV 202. So if you see a 15% weight loss in the obesity study, with no excess of grade 1, grade 2 CNS events, what would stop you from moving into Phase III straightaway?

Martin Holst Lange
Executive VP of Development & Member of the Management Board

So maybe I'll take the last question first. I disagree a little bit in the sense that, if you look at the historical data where we have seen neuropsychiatric side effects with other compounds, in one specific example, 30% of patients reported neuropsychiatric events in the development program, 30%. And most of these reported their events quite soon after treatment initiation. And that basically means that, with a sample size of 600 -- 2 additional studies that also amount to almost 600 patients, you have a reasonable volume. And you have a reasonable exposure duration to say, with any likelihood, before you make -- or I convince Karsten to make Phase III investments, we have excluded the safety events. Again there are no guarantees until we have the Phase III data, but given the historical data, I think the sample size and the duration of exposure will take us a long way. So if we see those 3 studies, Phase II studies, come together, with no excess safety concerns and, let's say, 15% weight loss, I'm super happy. And then I will try to convince Karsten to invest in Phase III. On -- could you remind me of the other question?

Mark Douglas Purcell
Morgan Stanley, Research Division

[indiscernible]

Martin Holst Lange
Executive VP of Development & Member of the Management Board

Yes. So at the end of the day, you have to have a reasonable assumption and exposure to secure that safety is reasonable to go into Phase III. That is why we -- the combination of the Phase I studies that we have done in obesity and the type 2 study that we are currently initiating will be able for us to potentially make a decision in -- during the course of 2025 to say maybe we can go directly into Phase III. If we do that, in the Phase I studies, we have to see clear differentiation on efficacy, on safety and on pharmacokinetics so we can pick the right dose. Then it's down to our risk willingness to say do we want to go into Phase III. Have we picked the right dose? Do we believe the efficacy? Do we believe the safety? But we also have to convince the authorities that we have sufficient safety to take that leap of faith. We've in our history done that twice, one with Xultophy and one with CagriSema; and I feel confident that we've sort of gotten that process right. It's not easy. It's not trivial and certain things have to be in place.

Jacob Rode

Thank you, Martin. We'll stay at the same table with Richard Vosser; and a reminder on one question per person, please.

Richard Vosser
JPMorgan Chase & Co, Research Division

Just one question, which would be just you mentioned it's in your behest to remove the starter dose cap and you're managing that. So is that a removal in '25, or is that a removal in '26? How should we think about the step-up into '25 and beyond in terms of the overall doses? But when does that start to dose when you're comfortable enough on supply?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So if you look at what has happened in the first 6 months. We have grown total scripts from 100,000 to 200,000. That's a significant number of doses, so the debate about what is starter dose, what is titration dose is a bit irrelevant, in a way. Because with the guidance we have and with the comparator Karsten spoke about, if you start doing the math in terms of how many doses are going to the market in the second half, that's significantly more doses. So I mentioned before, if there was a priority on starter doses, we could just produce the starter doses. And we would be flooding the market and the new scripts would be skyrocketing, but that's not a sustainable patient journey, so we want to do what creates a good mix titrating up. And that's what fuels the growth and also creates best efficacy of the product. So the whole discussion about starter doses and new scripts is becoming less relevant. It's the total number of scripts across all doses that matters. When you launch a product, it's new scripts. And starter doses later on is actually, say, the total book of business. So it's -- in a way, it's not, say, a '24, '25 decision because we manage this dynamically to create the best possible growth and patient experience.

Jacob Rode

Thank you, Lars. Then we'll move to Simon, same table.

Simon P. Baker
Redburn (Europe) Limited, Research Division

Simon Baker from Redburn Atlantic. First, a quick clarification on Sachin's question on the CB1 development program. Are there any specific exclusion criteria from the studies related to the suicide ideation risk? And then the question I was going to ask, going

back to what I asked yesterday, on the monthly dose form: You're not there yet. I was just trying to get an idea of how far away you are, what the challenges are because others are in this space as well. Is this a question purely of formulation? Is it about the specific pharmacokinetics of the molecules you're trying? So how -- I don't want to pin you down on a date. And I'm sure you won't give me one, but how far away is a monthly for injectable formulation as a viable product?

Martin Holst Lange
Executive VP of Development & Member of the Management Board

So specifically for CB1. We -- for us, it's a journey depending on data, so if we get through the first 2 studies, which are excluding certain patients, and without any new psychiatric side effects in excess, then we will discuss what in an exclusion criteria will we have for the next Phase II study. Will we open a little bit more? If we do that and that also comes out in a good way, then we can maybe -- having no or very few exclusion criteria in Phase III. It has to depend a little bit on the data. And if at the end of the day we had to have an exclusion in our label, I think that is also acceptable, but right now obviously our full aspiration would be that they should [be -- fall]. But it has to depend on the data.

On the once monthly. There are many technologies that you can apply for sort of extended delivery. Our approach is always first to focus on efficacy and safety, and if we can make that more convenient, then we will do that. We have tested once-monthly assets in clinic. It was, honestly, not a viable clinical profile, so we are sort of going back to the bench. In research, we are still pursuing, as far as I can see, at least 3 different ways of protecting administration. It's not our biggest priority. It is a priority because we still see efficacy and safety driving any decision in this space, but obviously it would be good for us to have that offering as well, so therefore, we are looking at it. But I think, for anyone, maybe apart from one player, if you are not in clinic, you are still at least 6 years away from bringing it to patients.

Jacob Rode

Thank you, Martin. We'll move over here.

Unknown Analyst

I just wanted to briefly touch on the Catalent transaction. It's been going on for some time. How do you today feel about the likelihood of reaching a beneficially -- mutually beneficial agreement with, first, Eli Lilly; and then with all the other potential [complainants with] the other parties?

Jacob Rode

Karsten, on Catalent transaction?

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

Yes. So we're still confident that the transaction will close by the end of the year. We had a lot of advice before entering into the transaction, in the first place, in the beginning of this year. And then we've had a lot of interactions with regulators in the U.S. and outside U.S. And we believe that we have a solid case to get to a close of the transaction towards the end of the year, so we look very much forward to that.

Jacob Rode

Thank you, Karsten. We move to [indiscernible].

Unknown Analyst

I had a question on China. You have approval for Wegovy in China. You have a very short patent window there 2 years ago, I think. Can you just comment on whether you still retain a lot of optimism around the China opportunity? The noise being made by the generics is getting louder all the time. There are plenty of people who are going to have a pop at this market. Do you have any indication about how quickly you've gone off with Wegovy in China?

Jacob Rode

I'll give that to you, Camilla, China on [med need] and Wegovy...

Camilla Sylvest
Executive VP of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. Thanks a lot. So in China, there are more than 200 million people living with obesity, and we see great opportunity to make a difference in terms of Wegovy in China. And what is important, of course, is that we have a very strong presence in China in terms of our regional presence, in terms of our ability to launch new products. And we have worked in China also with local competitions before -- in competition with locals before. We at the moment do not see anyone sort of being represented in the short term on Wegovy, so we feel, as long as we continue to bring innovation to China, we will continue to be a step ahead. Our understanding from dialogues with Chinese authorities is also that they very much value the innovation that we actually bring to China. Then of course, over time, there will be most likely, as we've seen before, a system in China that would allow local generics to produce and to compete, but so far, this has been constructed in a way where there's always an incentive to bring innovation to China. And as we are a very innovation-based company, we are quite happy to see now that all of our new products, Wegovy, Rybelsus and so on, have -- including also a weekly or once-weekly insulin, has -- now has approval in China much faster than in the past. So this actually allow us to keep -- to compete even faster in the Chinese market than just 5 years back.

Jacob Rode

Thank you, Camilla. We'll move to Rajesh.

Rajesh Kumar
HSBC, Research Division

Can I just clarify your CB1 comments earlier in terms of -- this is not my question, by the way. I want to ask about rebate.

Jacob Rode

That' fine.

Rajesh Kumar
HSBC, Research Division

On CB1, are you going to do a trial controlled with semaglutide or tirzepatide rather than placebo and compare neuropsychiatric there? Or is it just going to be a placebo control and then you'll see other...

Martin Holst Lange
Executive VP of Development & Member of the Management Board

Without going into details: There will be an active comparator. There will also be a placebo comparator. There will potentially also be combinations [happening] in that study.

Rajesh Kumar
HSBC, Research Division

Understood, very clear. On rebate, you mentioned that you get data back from the wholesalers 2, 3 months, so if my very preliminary understanding of how the accrual accounting and the IT systems work there, you probably are guessing at the moment the level of rebate you have booked in for Wegovy this quarter, right?

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

Correct. And just to be precise: We don't get the data from the wholesalers. We get data from the insurance companies. So we charge the wholesalers at list price. Then the rebate claims comes from the PBMs, who get the claims, of course, through pharmacies. And that's the way we get them.

Rajesh Kumar
HSBC, Research Division

And I would imagine that, given the projection you've made for your full year, you have assumed that there would be a step-up in volumes, therefore a step-up in rebates in the second half. And therefore, you've reflected that in the prices you've assumed for the quarter.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

No.

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

No. So the prices for the quarter, that's an estimate based on the volumes we sold. Then we make an estimate linked to what channels and under what formularies and hence conditions and rebates have they been sold to.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

The upgrade for the second half takes into consideration what pricing will be. And that will be upgraded value.

Jacob Rode

Thank you, Karsten. Thank you, Lars. We'll move over here. And before that, just a reminder on the reminder in terms of one question.

Benjamin Jackson
Jefferies LLC, Research Division

I have 3. [You have] Ben Jackson from Jefferies. Wondering if you have [indiscernible] or data on [indiscernible] discontinuing; [turn around in] 6 months, maybe longer. Are they then rechallenging on a GLP-1? And are you seeing switchers between GLP-1s there? And do you expect over the longer term that people aren't going to take this as a one and done and are willing to go back on after discontinuing?

Jacob Rode

Camilla, will you give it a go?

Camilla Sylvest
Executive VP of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. So thanks a lot. So keep in mind that 6 months is an average stay time. And it's based on experience in the U.S., where we've seen some interruptions to supply in the past, so we continue to be very encouraged about the development of that stay time. And when we look at, we'll say, other countries where we haven't had that interruption of supply, we've seen that, for example, in Denmark, where people started on treatment beginning of 2023, a big part, a very big part close to 90%, were on the treatment also at the end of the year. So we are continuously encouraged about stay time. When we look at different groups of people, we see stay time is significantly longer for people that have been on Saxenda before. Maybe they are more prone to usage of GLP-1. And we also see that stay time is significantly longer with people that are living in, so to say, more affluent areas, so more on the East Coast and in the South of the U.S. And so also, in terms of age, we see stay time being longer for people older than 30 to 40 years compared to younger and so on. So keep in mind 6 months is really impacted by all these things.

Having said that, close to -- or more than 80% of Wegovy scripts are to patients that are naive to therapy, meaning they have not been on therapy before, so of course, there are some switchers between GLP-1s, but I think this is close to -- if we look at competition, they are sourcing probably around 10% to 11% from Wegovy and so on. So there will always be sort of changes of that, but the majority of all patients starting on obesity treatment are new to treatment, just based on the fact that obesity really hasn't been treated to a large extent before, so we are still in the early days of a very low percentage of the total population being treated.

Jacob Rode

Yes, same table.

Unknown Analyst

Another question, if I may, on Catalent. I wanted to ask if you have a sense of how quickly you can ramp up on the fill-finish lines. Because my understanding is that most of them are under a contract that might take a while to expire.

Jacob Rode

Karsten, I'll give it to you.

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board

Yes, we do have a good sense of that because that's the core of the entire acquisition case, to access additional capacity. So do bear in mind that we are already working with Catalent as a CMO. So there are lines working for Novo Nordisk already with Catalent, so what we're getting is additional capacity on the different lines at the different sites. And of course, we honor the contracts that are in place with existing customers, so they have to runoff. And then let's say the deal closes by end of this year. Then we will have to do technology transfer to the new lines also during 2025, so you could say additional capacity beyond what we have already contracted as a CMO will gradually start from '26 and onwards.

Jacob Rode

Thank you, Karsten. And we'll go to Emily -- sorry, over here, same table.

Unknown Analyst

[indiscernible] from Berenberg. Just a question on Wegovy access. So we've heard that certain employers have reversed their initial decisions to provide access to obesity medications just because of the escalating demand and associated costs. Is this a trend that you have seen? And related to that, could you just provide us an update as to your current formulary access and specifically the proportion of covered lives that have employer opt-in?

Jacob Rode

In terms of the employer opt-ins, Camilla, will you give that a go?

Camilla Sylvest
Executive VP of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. So yes, first of all, we have more than 50 million patients being covered in the U.S., so very strong access. And around 80% of them, 80%, pay up to only $25 per script in terms of self-pay. When it comes to opt-ins, there will always be opt-ins and opt-outs, but we continue to have a net opt-in, so to say, of employers. So it just means that we continue to broaden our access.

Jacob Rode

Thank you, Camilla. And then the last question will go to Emily before we round off.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. This is a somewhat similar question but going back to the question of stay time. How much do you think that insurance coverage in the U.S. deflates -- or dampened stay time, just with people switching jobs, aging into Medicare and so they might not have coverage to that degree? I mean, do you see that as also a big dampening effect in addition to supply constraints?

Camilla Sylvest
Executive VP of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. So I think there will always be people that may opt from one [team] to another, where they are not covered or so. And that, of course, happens, but given that 50 million lives are covered, I think we don't need to be preoccupied with the potential in terms of coverage; also keeping in mind, on stay time, it's really in the first sort of 60 days that we really see the drop-offs, probably part of getting used to GLP-1, but then once people continue to stay on, then they stay on longer. So keep in mind that it's 6 months is truly an average. And you have to think about the variation in this. And so of course, that's also why there are significantly higher stay time for people who have been on GLP-1 before, most likely because they have been -- they are either used to being initiated on GLP-1, knowing more what to expect. And therefore, the average stay time is much longer. So think about it much more like that, but we think we're treating 1 million patients now, but 50 million being covered, this is not what is holding anyone back. So to the points from before, we are truly scaling production to be able to supply more doses into -- starter doses so the people can start and continue on the treatment. That's really what we are working on right now.

Jacob Rode

Thank you, Camilla. And before handing it over to you, Lars, for final remarks: Thanks, everybody in the room, for coming; and for everyone online, for dialing in. In case of any follow-ups, please reach out to investor relations.

Lars, [final word]?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

And so thank you. So I hope it comes across that we're very pleased about where we are as a company both in terms of our traction with, say, sema and other products, not least in the U.S. markets. We upgrade because we have more supply coming. And we're upgrading value, so you don't need to worry about the price per script, so to say. A lot of questions, I appreciate that, on pipeline because we have a really exciting second half of the year not only in a growth point of view but also in terms of inflection points for pipeline. And I think Martin had some good points there.
So thank you very much for your interest. We look forward to share more details on all these aspects as they evolve over time. Thank you.