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Novo Nordisk A/S CPSE:NOVO B

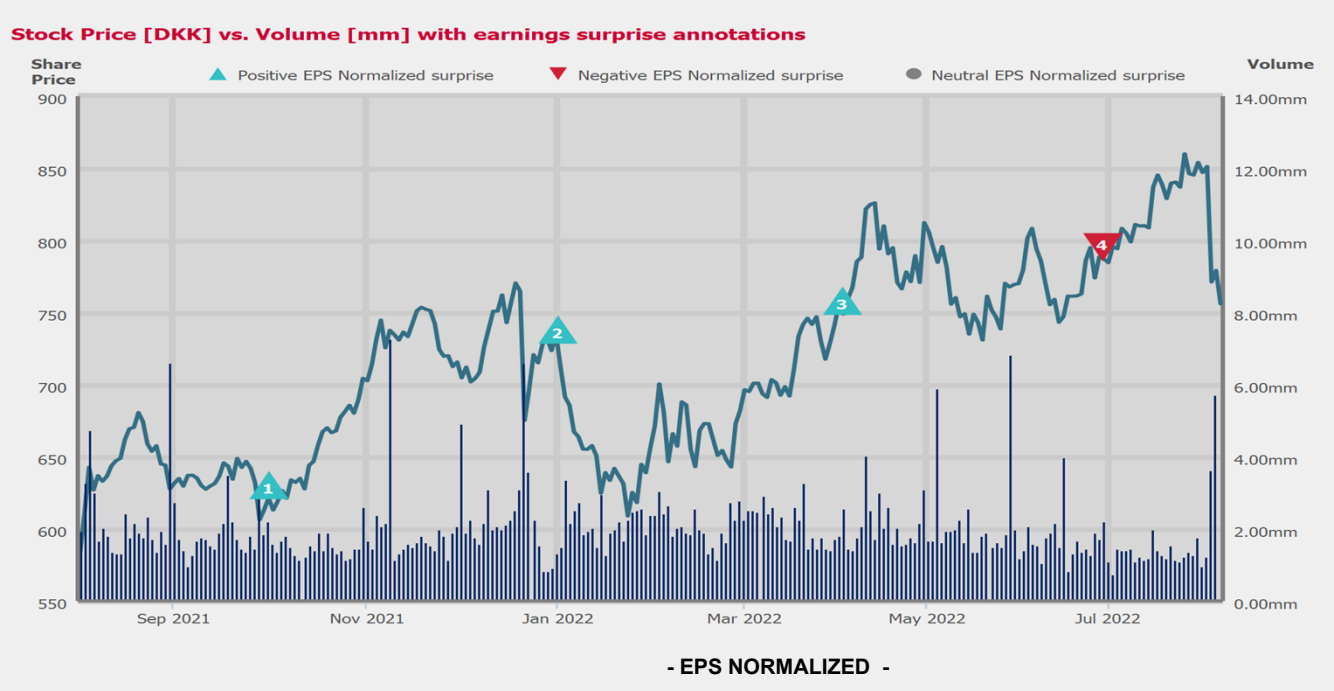
FQ2 2022 Earnings Call Transcripts

Friday, August 05, 2022 12:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ2 2022-			-FQ3 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	6.04	5.86	▼ (2.98 %)	6.27	23.98	NA
Revenue (mm)	41791.83	41265.00	▼ (1.26 %)	43379.61	171101.89	NA

Currency: DKK
Consensus as of Aug-05-2022 2:43 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ3 2021	5.02	5.27	1 4.98 %
FQ4 2021	4.69	4.76	2 1.49 %
FQ1 2022	5.68	6.22	3 9.51 %
FQ2 2022	6.04	5.86	4 (2.98 %)

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EXECUTIVES

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Executive VP, CFO & Member of the Management Board

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Martin Holst Lange
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Presentation

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

I'm Lars Fruergaard Jørgensen. I'm the CEO of Novo Nordisk. And with me, I have Camilla Sylvest from Commercial; Martin from Medical; and Karsten, our CFO. So we'll do a quick introduction and just the theme by making a few presentations here. We will be talking about the future, which is inherently risky. So stay alert on the risk factors and our forward-looking statement here.

On strategic aspirations, we have set these aiming at delivering strong contribution to society, the environment, but of course, also our shareholders. So we see that based on these aspirations, and we believe we're making good progress. We have exciting progress from an innovation point of view. Martin will talk a bit to that, as we really focused on raising the bar in diabetes and obesity and expand into some adjacent disease areas.

You can see our commercial execution is really strong, strong growth in the first half year here, a continuation of an accelerated growth trend we have seen over the past quarters, adding competitive strength in expanded market share in diabetes. And all that translates into very attractive growth numbers, and we have now, for the second quarter in a row, made significant upgrades in our earnings outlook for the year. And I think we also have quite attractive cash conversion and return to our shareholders.

So really strong start to the year, and we are quite confident on the competitive dynamics and commercial execution we see. And we think we have a really interesting and exciting pipeline that can further drive our position in diabetes and obesity and really this innovation bar and stay competitive for the long term.

With that, I'll hand over to Camilla for a few commercial updates.

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

Yes. Thank you, Lars. And as you know, 16% sales growth in the first half of this year, primarily driven by North America, 65% of the sales growth coming from North America, 35% coming from IO, you see 10% growth in IO. You also see each of the regions growing, except for China, where the negative growth is related to the volume-based procurement, VBP, impact that initiated as of May, as we have discussed several times.

On the right-hand side, you see the growth per therapy area. You see strong growth driven by GLP-1, 45% growth, on GLP-1 driven both by North America and also by International Operations. Then you see a decline in the insulin growth primarily driven by price decreases in the U.S., but in IO, the negative growth is related to also Tier 2 China. And then you see obesity growth of 84%, 60% in IO, all driven by Saxenda, and then a 102% growth in North America, of course, driven by a combination of both Saxenda and Wegovy. And then we have flat growth in rare disease.

If we look at the GLP-1 class expansion, you here see a significant increase in the GLP-1 class growth, more than 35% growth. And you also see that Ozempic now has the market leadership in this segment as a brand. And you also see that Novo Nordisk continues to increase our total market share in GLP-1, now up to 56.4%. The market -- underlying market dynamics seen there very strong by a much stronger recognition of the opportunity to treat both HbA1c, weight and cardiovascular risk profile for people living with diabetes.

If we zoom in on obesity care, you see here market growing 84%. We also have an 84% market share in the obesity segment. Much more interesting is, of course, that there is a much stronger desire to treat people with obesity. And this is, of course, a combination of market development, effort, the recognition that obesity needs to be treated because of the risk that it inherently has on other serious chronic conditions.

And in the U.S., we now have formulary access of more than 80% and net access somewhat lower than that. And then we are, as we have discussed, we are looking to make all doses of Wegovy available in the U.S. towards the end of the year. And the commercial production of -- at our CMO has been reinitiated in Q2, and we are progressing towards making all doses available at the end of the year.

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And then finally, we have also outside the U.S., made Wegovy available initially now in France at a clinical experience program. And we're also looking forward to launching Wegovy in a few countries towards the end of the year. And of course, the majority of the launches in International Operations for Wegovy will be in 2023.

And with that, I'd like to hand over to Martin to say a few words about SELECT.

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

Thank you very much. I'm going to start with SELECT. Most of you who have had some attention on that study over the last couple of days, I just want to take a step back and remind us what is SELECT. SELECT is a cardiovascular outcome for 17,500 patients being randomized to either semaglutide or placebo with the primary purpose of looking for cardiovascular outcome.

As with most cardiovascular outcome products, SELECT is -- basically means that we have to accrue a certain number of events in order to do a statistical analysis at end of life. Also, as the most outcome [indiscernible] there is an opportunity to then group and what we call an interim analysis with fewer events in the group. Given that we want to make absolutely certain that we get a good and robust, both from our own perspective, from our patient's, from our investigator's perspective and certainly also from a payer and regulatory perspective.

We set the bar very high. I started on SELECT, this sample size, to be able to show 17% difference between SELECT and placebo. That basically means that we have a 99% power to show [indiscernible].

It also means that we can show statistical difference, so patients with below 17%, but also obviously higher than [10%]. But if we wanted to start at the interim analysis, we needed something that is bigger than that because we have fewer events. That basically means our agreement with the Data Monitoring Committee was to only recommend to start SELECT if the point estimate that they observed on the primary endpoint was substantially above 17%. Some of you are asking what is substantially above 17%. That's a number we don't want to disclose. But we have to mention that, that is 17 percentage points, probably even beyond 20% in terms of what we can disclose.

That also means that when the [indiscernible] or recommend us to continue to [indiscernible], it leads to some minor, we are below that substantial number. That does not mean that the base is -- or sorry, SELECT is the same one. Actually, it means that we basically can go back to our base assumption. There's a potential 17% difference. It could be slightly more, it could be slightly less. But that's our best assumption, and we're going to continue to file until the end towards mid of next year.

I've also been asked a couple of times, does the DMC look at other than the secondary -- sorry, the primary endpoint? As with any [indiscernible] that prerogative to look at the totality of the data that goes for every [indiscernible] that goes [indiscernible]. But we also have to consider, and I'm sorry to become a little technical here, again, this is a function of how many events [we have]. And if you look at the secondary point, we have approximately 1/3 of the events that we have on the primary.

That also means that we don't have a lot of power to take statistical business in those [indiscernible]. And therefore, we specifically recommended and guide that the [indiscernible] primarily focus on the primary. They had the prerogative to look at the totality of the data, but we asked them to primarily look at the primary.

[indiscernible] illustrates 17% was the very [indiscernible] numbers with those 17% will be very [indiscernible]. And we have the statistical power to even detect statistical difference in the [dose]. You have seen smaller outcome trials than this, show statistical difference all the way down to 11%. And therefore, we are very, very confident that SELECT around this next year will come up as planned with variable data..

Turning to something completely different, but also super exciting. We, last week, reported on 2 additional [indiscernible] that basically said we have now reported of 5 of 6 ONWARDS trials. ONWARDS is the development program for [indiscernible]. We're super excited about the results that we've seen so far. They are depicted in this slide. ONWARDS 1 and 2 and 3 are in phase [indiscernible]. We've already heard us talk about ONWARDS 1 and 2. Superiority in terms of glycemic control versus insulin icodec and insulin glargine, with no difference in risk of hypoglycemia in both lines.

ONWARDS 3, this is a similar trial in the sense that we're looking at base load treatment. The difference between ONWARDS 3 and ONWARDS 1 and 2 is that was double blind, double [indiscernible]. So really is very, very high on the

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scientific reason and showing the same superiority over insulin icodec as we've seen in the open label trial, is speaking to the robustness of the data that we've generated, but also to the really exciting profile that we've seen in insulin icodec.

Second reason why ONWARDS 3 is exciting is it caters to approved global regulatory submission of insulin icodec because we have China and Chinese patients in the ONWARDS 3 program. And we have an agreement with the Chinese authorities that integrating China in the global program also allows us to see approved global regulatory submission and finalization of the program.

ONWARDS 4 is important because this is basal-bolus in type 2 diabetes. Has approximately 40% of the volume split between base load and basal-bolus. So from a volume perspective and from a [indiscernible] perspective, [indiscernible]. And we're super happy to see no difference in glycemic control, no difference in [indiscernible].

But then we can conclude that we had an [indiscernible] in type 2 diabetes and a really, really strong candidate in basal-bolus in the good icodec control, good safety and a superior continue profile. And therefore, we are as excited as the -- about the prospects of insulin icodec.

Finally, just taking you through some of the highlights of what is going to come next in the next couple of quarters. Obviously, I think as with some of you, I am super curious and super excited about Phase II CagriSema trial reading out later this year. This is for type 2 diabetes. We can also point out this is [indiscernible] for the combination of semaglutide and [indiscernible] in terms of type 2 diabetes. We know that it has a very, very attractive profile in terms of weight loss. So we need to assess the potential in [controlling] type 2 diabetes. That's going to read out during the course of Q3.

And then obviously, we are excited about the initiation of our combination of semaglutide and it's just [indiscernible]. This is interesting from a clinical, from a medical and also from a commercial perspective, getting the best of two worlds with the GLP-1 and the [indiscernible].

In the space of obesity, obviously, we are looking very much forward to seeing the result of [indiscernible]. That's basically, again [indiscernible] and GLP-1 analogue. And really having the potential that we have seen in [indiscernible] in terms of efficacy, in terms of safety, but the added convenience of an oral [indiscernible].

In the rare disease space, I think you've heard us talk a lot about concizumab. You've heard probably a lot about Mim8. Looking very much forward to initiating Mim8 placebo then. But we're really excited about having started Phase II for NDec, which is our [indiscernible] obviously with a tremendous [indiscernible].

And finally, I just want to point out our initiation of our ATTR asset in ATTR cardiomyopathy. That is an asset that we bought from Prothena last year. As with [indiscernible] also with this very high unmet need. .

So with that, over to you, Karsten.

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

Thank you, Martin. So on to the financials. You've seen the P&L. So I'm not going to go through it in details. You heard 16%, the constant exchange rate sales growth in the first 6 months, in Camilla's presentation. I can do it even better because when I add in currency, then we are accrued 25% reported. So a really, really amazing growth level for the company when you look at both the relative and absolute growth levels.

When you go through our P&L, you see the continued dynamics on our gross margin of benefit from product mix, driven by GLP-1 portfolio, continue to drive efficiencies. And then, of course, we have a negative impact from pricing but net-net and improving gross margin at constant exchange rates of some 60 basis points in the first 6 months.

R&D, look at that growth rate. 26% up on R&D spending that link to basically the investments that Martin and Marcus, our research colleague, are pursuing in terms of expanding and diversifying our pipeline. Around half of the step-up in R&D comes from the acquisition of Dicerna Therapeutics that closed in the fourth quarter of last year. And we're already now starting to see some encouraging signs, not reporting in Martin's slides, but in our early pre-projects with Marcus starting to get additional volumes into our early pipeline. So really encouraging there and the continued investment in R&D going forward.

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Net-net, operating profit up 14%. Then, of course, you see hedging going the other way with net financials of a negative 2.8, which is basically [the opposite]. We account for our hedging in net financials, not in the lines. Taxes, nothing to say and net-net diluted earnings per share of 13% in the first 6 months, very attractive.

This all then plays into an upgrade of our full year outlook is driven by the momentum behind our Tier 1 franchise in diabetes, Rybelsus and Ozempic, as well as market growth in the obesity segment. So you see the step-up, as Camilla showed you, with Saxenda in International Operations and also some Wegovy sales in U.S. So really strong momentum in our obesity franchise, which in combination with type 1 diabetes, enables us to step up our guidance in terms of sales growth and operating profit growth.

And then again, currencies are favorable, especially the U.S. dollar strengthening this year that we're all aware about. So now we are seeing a 9 percentage point benefit on top line and 14 percentage points benefit on our operating profit from currencies, which again will partially be offset by hedging losses. But when you do the net math, we actually do have a favorable impact, net of currencies of -- to the tune of DKK 3 billion to DKK 4 billion this year. So very favorable.

And this then translates into an upgraded cash flow generation of between DKK 57 billion and DKK 62 billion, which plays into our capital allocation strategy that we're sticking to in terms of returning our free cash flow in the form of dividends and share buybacks. So we're maintaining our share buyback program of DKK 24 billion for this year. And then the Board has decided to issue an interim dividend here in August of DKK 4.25 per share, which ties into our strategy of continuing with around 50% payout ratio of net profit in the form of dividends between interim and full year results.

So that was the brief run-up of our financials and off to you, Lars.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. So thank you to my colleagues and now we're ready for the Q&A session and welcome questions from both buy and sell side. And if you could please start by stating your name and affiliation, then we have some microphones working around.
So should we start with our host, out of respect, I think.

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Question and Answer

Wimal Kapadia
Sanford C. Bernstein & Co., LLC., Research Division

Wimal Kapadia from Bernstein. So can I just ask about SELECT, not the interim? So my question is really about how important SELECT is to uptake. So if I think about reimbursement and penetration in the near term, with and without SELECT, how does Novo actually think about it? Because we think it's really important. But given where we are in terms of penetration and how mature this market is, does it actually matter near term to how well Wegovy's actually going to do? That's the first question.

And then my second question is on Rybelsus and pricing. So 2Q looks quite painful again on a net price basis, if I'm just doing the simple math of reported sales and volumes. And so the first half overall looks quite tough. So my question really is, are we now starting to see greater pressure for Rybelsus from payers as they compare to SGLT2 pricing? And so is it fair to assume moving forward that actually Rybelsus' pricing will decline to a greater extent than the injectable GLP-1?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you. So Camilla, first, on SELECT, how important is it to have these days. And then perhaps Karsten on pricing.

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

So it's very clear that Wegovy has already stablished itself as a very important brand in the eyes of people living with obesity, but also with [decisions]. So in the short term, we believe that there's a very, very strong momentum in the obesity market. We even see the market development now, growing the market 84%. And it basically means that there is, both for the short term and the medium term, a clear, important impact from products that can reduce weight loss with -- to the tune of 17% to 18% that we see with Wegovy.

Having said that, of course, over time, a landmark study like SELECT would also describe how this actually transitions into reducing also other serious chronic issues that are related to obesity. And this, of course, then linked to cardiovascular outcomes. But of course, understanding that will be important. Just like 20 years ago, we saw how important it was to understand type 2 diabetes.

So when you ask about whether that has an impact on payers, of course, it's an additional cardiovascular endpoint we will be able to add, but it's also clear that even with Saxenda now, we see reimbursement in many, many more countries because the importance of treating obesity has been much better understood lately and recently. And this, of course, in itself is already very strong. And that's why we see such a strong sales growth even in International Operations.

So short answer, yes, it's very important to get SELECT and we look forward to the readout next year as planned, but it's clear that the demand for Wegovy is there anyhow, and it's very strong.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Camilla. Karsten, on pricing?

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

Yes. So first of all, never look at pricing for just one quarter, right, because there are so many compounding factors there between factories, IQVIA, Scripts inventory, you name it. So never look at it by quarter.

And we price Rybelsus according to the product benefits and which are very closely aligned to the overall benefits of the TF1 category. So I wouldn't tie it to SGLT2 pricing rolling forward or anything like that. This is a TF1-based product with TF1 benefits. And then I would say, depending on how you do your value modeling, then clearly, we have also a nice uptake ex U.S. on Rybelsus.

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So we see Japan moving very nicely, and we also see some European markets pulling up very nicely with Rybelsus. So we see good trajectory and the product doubling and actually being a very nice sales growth driver. But of course, it's a little bit overshadowed by the fantastic Ozempic performance.

Jo Walton
Crédit Suisse AG, Research Division

Jo Walton from Credit Suisse. A couple of questions, please, and I'll be coming back to the first one again. But it seems more than 6 months ago when you were saying 6% to 8% constant currency growth, and now you've delivered 16% in the first half.

Now at the beginning of the year, you said absolutely don't expect any leverage coming through, we'll reinvest everything. Now we've got a much higher top line. I'm just wondering how long you can stick with that line. Absolutely, we can understand more investment in R&D. You invest today, we see the benefit. Well, the shareholders see the benefit in the future.

But in the review that Karsten gave, you didn't highlight just how much the marketing costs have gone up in the first half as well. So I wondered if you could just talk a little bit about the environment, whether this is proactive because Lilly is coming down the road with Mounjaro, and you just want to be sacked in every doctor's seat, so that Lilly can't even get in. Or whether this is massive DTC, which is something about the sustainability and how we should think about that enormous marketing expense going on?

And my second question would be to Camilla on the acceptability of reimbursement. We've all got multibillion dollar numbers out there for the obesity market. And when it's quite small, we can imagine that payers will pay for very obese people to get reimbursed.

But what is it -- can you give us an update on how people are thinking about that reimbursement more broadly? Because you mentioned 80% reimbursement, but you said the net number was less. So perhaps, I don't know whether it's you can only take it for 2 years; or the minute you come down below a certain BMI, you have to stop; or how we should be thinking about that.

And it ties in perhaps to SELECT. If you get SELECT, does that change people like ICER's view, so they come back and say, this is awesome, it's now cost effective at a much lower price and gets you -- is that what really triggers everyone to start reimbursing you?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. Thank you. Allow me to give some initial perspectives on the margin and the leverage, and Karsten can perhaps chip in. You know that there are always year-over-year different things. Like now, we dig in Dicerna. We have impact from volume-based procurement in China, et cetera. But from a strategic point of view, it's really the market shaping of obesity and launching Ozempic, Rybelsus, et cetera, and of course, also Wegovy, that's what's driving our investments. So the opportunity we have over the coming, say, cycle based on the [similar-based] products is a tremendous opportunity.

So it's not something where we say that now competition is coming, so we upped our game. It's really a deep build of both the obesity market, but also the awareness of what a product like Ozempic can deliver. And of course, when you have Rybelsus, you also need to have a bit more of a GP type approach.

And we can see, as you also look for yourself, we can see that when we do those investments, we actually get a return on it. So when you sit with really, really strong products, making sure they are off to a good track and get the right perception in the market is a very important investment to make upfront. And then you can say, longer term, we have also guided that we believe that we'll have some leverage after we have produced those perceptions. And we also have the intention to build further brands that we can invest in down the road. But it's now have to do those massive investments.

And then we look at our options down the road in R&D and commercial. And I think the only thing we can promise is we'll keep investing in the opportunities we have. And then the success of that will then generate the leverage over time.

Camilla, on obesity reimbursement.

Camilla Sylvest

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Executive VP, Head of Commercial Strategy & Corporate Affairs and Member of the Management Board

Yes. Obesity reimbursement, very exciting. And I'll just give you a perspective for the U.S. and then for countries outside the U.S. .

So in U.S., we talk about 80% gross access in the Commercial segment and approximately 40% access, net access, in the Commercial segment, driven by employers' opt-in. So this is the technicalities of the U.S. market. But in summary, it basically means that 20 million people have access to obesity treatments. And when you compare that to how many are being treated today, there is, of course, already a good opportunity for people to get treatment at low copay [indiscernible].

Then outside the U.S., we've seen a very interesting development the last few years, where more and more countries are starting to reimburse Saxenda, our first-generation D2C product. And typically, in most countries are now just treating roughly, but in the 10 countries that have a sort of government reimbursement, we are more looking at people that have a BMI above 30 or all above 35. And in some cases, also with comorbidities. So of course, when Saxenda is already reimbursed at this level, it seems like there are good perspective also for a product like Wegovy with even higher weight loss to also get to that same stage.

And I wanted just to let you know that we also see significant higher uptake in those countries, government-funded where we, of course, have reimbursement. And the dialogue with the government about this is also, of course, where, as we talked about before, SELECT will pay in because when we can model what the long-term impact of this might be, knowing that obesity is related to many, many serious, other health conditions, then, of course, the health economics of this is very positive. And this is also what NICE has endorsed here in the U.K. already for Wegovy.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So there is an interesting dynamic effect here. If you go a few years back and look at the obesity market and the discussion we had about what does it take to unlock it, that is different compared to today. So something has changed in the awareness of obesity as a disease.

And you can speculate whether it's the experiences of health care systems during a pandemic, you can speculate whether it's now that we feel that now there's a real solution to the problem. And often, you can find that problems are not being acknowledged until there is a solution.

So something is changing. And it also brings to the first question that the SELECT data are important, but it's not the only key to unlock the market. So a dynamic effect -- and also when you think ahead, say, the more consumer type nature of the obesity market that we're starting to see is also different compared to what we have seen on, say, classic pharmaceutical interventions.

[Mark], you control the...

Simon Mather
BNP Paribas Exane, Research Division

Simon Mather, BNP Exane. Going back to SELECT. Martin, just wondering, obviously, you talked about this high barrier above the delta above the 17%. For argument's sake, let's say it's 5% to 22%. Could you comment, if -- if the trial was stopped for futility, is that margin the same on the downside as it is on the upside? And so therefore, we could assume the number could be 12 to 21 that the Data Monitoring Board come back to you with, is my first question.

And second one is just again on Wegovy. Hearing talks of payers pushing for prior auths now increase -- increases prior auths. I'm just wondering if you could essentially comment whether or not that's true or not because they're seeing the huge demand for the product. And so they're obviously a bit worried that their budgets are going to be blown out of the water.

I'm just wondering also could you share potentially the average stay time that you're seeing given the drug to market for 12 months.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So Martin, I don't know to what degree you can put more clarity on SELECT.

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

I think a little bit. This is an important question. And first of all, we specifically, again, primarily directed to keep the focus on the primary endpoint and focus for efficacy and not futility. But should they show futility, they would have been looking at this can never be specifically significant. And there, we are not even close to 17%. We would have to go below 10% to reach that level. So from that perspective, we are very far in our assumptions away from the from futility for the 17%, yes.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Camilla, on reimbursement again for Wegovy and prior...

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

Yes. Prioritization, we are not having any new information on that. That is particularly, on the other hand, prevalent. On the other hand, we are seeing that -- we see more and more employers opt in. It's a long tail of a number of employers, of course. But of course, this becomes [indiscernible] to more and more important for everyone to treat and to offer and to make that treatment available.

So of course, over time, it's likely that there will be -- as we've seen when we move into more and more channels, there will be negotiations of price levels and so on. But this is to say because we are adding [indiscernible], also a product that hasn't been on the market for very long.

Then on the stay time, you also asked about that. We see -- we haven't concluded on new stay time data for Wegovy yet since it's too early and given also that we haven't been fully in the market. But what we can say is that we, of course, expect the stay time on Wegovy to be longer, given that we have shown in clinical trials that people reduce weight up until 60 weeks. And even up towards 102 weeks, we see no increase in the weight again. So from that point of view, we expect that people would like to stay longer on the product than what we see on Saxenda today, where the average is more 5 to 6 months.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Karsten?

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

Yes. Just a small additional comment. So as we put in our announcement, now we have more than 80% unrestricted access in commercial in the U.S. So we actually upgraded our commercial access in the U.S. compared to the last quarter.

And when we look at access at a patient level, then we are -- when you go across channels, we're around 20 million people with obesity who have insurance access in the U.S., and that's a number which is increasing as we speak.

Michael Leuchten
UBS Investment Bank, Research Division

It's Michael Leuchten from UBS. Just going back to Wegovy. In Q2, the value of the volume was relatively low. And I was wondering if you could comment to whether you need to respond to Lilly's fairly aggressive copay program that seems to be running for quite a while. And I think about this in terms of Wegovy but also in terms of Ozempic.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. So I can answer that. No, I don't think we have to do that. I think we had a similar tactics when we launched Wegovy to build early experience as we build access. We have robust access, as Camilla just -- for Wegovy, but also for Ozempic. So it's in that state to state commercial model you have to compete long term. It's not in the initial, say, early access experience we feel we have to compete. So we are quite comfortable with that. And yes, we used similar tactics when we launched Wegovy.

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

And sorry, Lars. Just on a very technical specific comment, Michael, on Q2 for Wegovy. So technically, the reason why you get to the value prescript that you get to is also impacted by the current supply chain situation that we've been discussing on Wegovy and the availability of the different dose strengths. So the fact that some of the dose strengths are not available in the U.S. market leads to the fact that the wholesaler inventory levels are lower. And as a consequence, you get to a lower value prescript than you otherwise would have in a growing concern business.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Keyur Parekh from Goldman Sachs. Two questions, please. First, coming out that we met last time in London, your view was that icodec should have majority share of the basal insulin market, and that was before you saw the entirety of the Phase III data. So now that you have the data kind of, and you've shared it with us, what's your updated view on what would be a good or a bad commercial outcome for insulin icodec, the part of the basal insulin market.

Separately, Lars, apologies for going back to this. This is the third time in about 12 months that you've come and given us updated time lines for Wegovy supply. I'm sure it's more frustrating for you than for all of us combined. But love your thoughts on at what point does it start becoming an issue from a patient or a doctor perspective, that people who have been waiting for this drug for 6, 12 months now are still being told, "You're going to have wait a bit longer." And what's kind of your learning from this as a company for it not to happen ever again?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Camilla, first, on the icodec opportunity.

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

Yes. So I think when we met last time, we already had some readouts from the first 2 trials. And I think the last readouts we've had now from the next 3 trials are confirming what we saw when we discussed last time. So we believe icodec has a great opportunity to transform the basal insulin segment.

Imagine to what Martin said, we have a very, very strong HbA1c profile. We have a once-weekly treatment, should be a lot easier to treat. We have patient satisfaction in some of our trials that also shows that this is truly relevant to them. And then we have a very safe profile.

And topping that, we also have a very strong environmental profile. Because of the once weekly, it also means that we reduce carbon emissions and plastics with 70% to 80%. So there is a lot of good things to like about icodec, and we so much look forward to bringing it to the market.

And last time we talked, we also talked about our opportunity in the basal segment. We now have a market share around 37% in value, 33% in volume. And of course, there is room for us to expand on that. So that's what we are coming from. So I would only say that since last time, we have only sort of underlined that this is a great opportunity.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

And a fair challenge on Wegovy supply. You know the history and the flow wins almost. Thus, you can say from a strategic point of view, we decided to launch in a device and a filling format. We do not have in-house to go in with a contract manufacturer. It's not unusual to launch only on 1 site. So we have had a robust plan on adding segment search site, and that's -- we're progressing on that, and that will happen during '23.

The launch volumes we had expected was adequately handled by that one site. And they would be ahead also if issues happen. Then it turned out the launch volumes were significantly larger than we had planned for. And a worst case event happened, and the factory had to shut down. So when things go wrong, it's often a combination of more than one thing happening. So a significantly higher demand, a quality issue.

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And then you can say many learnings in how to avoid that from happening again. You can say you should have a broad set of, say, capabilities in how you choose devices and fulfill the market based on that. And you have that flexibility in your own setup. You have more options to favor optionality in how you fulfill markets to the degree possible is also good.

But it's not unusual that you launch a new product out of one facility. But luckily -- and normally, you have more capacity than what we ended up having here [indiscernible].

In terms of when it comes to problem for our patients and physicians, at the time where you run out, so to say, you have to communicate a lot to the physicians because they can no longer [start a] prescription. So we decided to take the starter doses out to make sure that to kind of handle that in one go. And those patients who then stayed on treatment, they could titrate up to the high dose, which we can provide.

So say, right now, I think it's a relative stable situation from a subscriber patient point of view because those on treatment, they can stay on treatment and physicians do not need to worry too much about can we go, can we not because we have taken the [high] doses out.

Then it's fair to say that we have moved the time line somewhat. When this happened in December, relatively quick, we had to make an assessment and guide what we do believed in. And we guided that there would be limited supply during the first half. And if you look at what our contract manufacturer has done, they have actually, quite competently, delivered on the plan. Now we have a situation where volumes coming out is a bit below that plan that was made back then. But baking in the different remediations we need to do and the oversight you put in to make sure that now it's robust, that is a fine art, [to fail].

So I'm actually online pleased with what they're doing. But it's really important for us that we do not go out in the market, again, until we believe we had the inventory needed not to create that issue with patients and physicians. And we are in this for the long term, so you can tell you the guidance was during second half and now we are towards the end of the year, that's a few months later.

And for me, a few months of delay is the right thing to do if you can get back in a reliable manner and drive that business for the long term because we think the opportunity is intact. We are very confident in what Wegovy can do. And we're also confident in our ability to get the volumes up and have, say, redundancy, more sites, more contract manufacturers doing this part of the workforce.

So we'll come back really, really strong. But I respect the critical point that we didn't get this perfectly right, and we're not happy about that. But certain things happen, and when it happens at the same time, it can end up in this type of challenge.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

The word you described was to transform the basal insulin market. Is that transforming from a volume perspective or a value perspective as well?

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

Yes. It's too early to comment on that, Keyur. So at least I would promise you from a volume perspective and data, we can talk about pricing, right? So I think that's premature for now. When we get [indiscernible] through the launch, around the launch time, that, that is the right time to talk about this.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. A question on the Treat and Reduce Obesity Act in the United States. What needs to happen for that to move forward? Do you need any more data? And could that be impacted if there was a change in legislative control at the midterm? Kind of just any incremental color there.

And maybe a question for Martin. Pfizer looks like they might be advancing a once-daily oral GLP-1. So just any updated thoughts on the competitive landscape from potential novel competition.

Martin Holst Lange

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Executive VP, Head of Development & Member of the Management Board

Camilla [indiscernible] and then Martin.

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

Yes. So what needs to happen in the U.S. is there needs to be a bipartisan vote for the Treat and Reduce Obesity Act to basically allow for obesity prescriptions in Medicare Part D. And of course, it's difficult for -- as with all political processes, to say exactly when will that happen. But there's a lot of just traction around this, as we've talked about a couple of times today. .

Also, in the U.S. about the importance of treating this. And just a -- and a comment to that. We also do know that there is a great underlying need also in this segment, of course. So that's why we continue to work on this. And this may be more a matter of when exactly it happens and if it happens, in my view.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

And while Martin works for Novo Nordisk, not Pfizer, a perspective.

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

Yes. So obviously, Pfizer are not the only ones looking at new or versions of GLP-1. I think small molecules are interesting in the sense that the data we have seen so far is a reasonable efficacy. I think the safety assessment is still out with small molecules, that's always a little bit of an unknown until you've seen the data.

From a timing perspective, they are sort of way into the future. And that means from a true differential perspective, maybe they perceive that, that could be different. And based on our own efforts also and potentially improving not only by availability, but also our manufacturing, as far as we can see, we have also there a competitive profile with Rybelsus in next-generation.

Peter Verdult
Citigroup Inc., Research Division

Pete Verdult. Two questions for Martin, just on GLP/GIP and CMD. Can you just remind us how Novo is trying to differentiate in the GLP/GIP space and the preferential ratio and binding you have between GOP and GLP with your offering?

And then just wondering as we go back to CMD. What was the thinking to stand up and mention this interim analysis at that point? I mean, I'm just wondering, did you do that because you were confident that it's going to hit the endpoint? But if not, I just want to understand why you decided to mention it because judging by the events of the last three days, it could have saved you a lot of hassle, a lot of share price pain if you just let the data speak for itself.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

I guess I can start answering that because Martin has not been responsible for this all along. So sometime back, somebody in the company mentioned a potentially interim analysis. And that was maybe a mistake because it's a difficult topic to actually communicate on because we don't sit with the insights.

So before the CMD, there was increasing talk about it. So we just felt we had to kind of level the playing field by telling what's the setup and what we believe about it. And I think also at the ADA Investor Meeting, there was also a quite clear message coming out according -- along with Martin just mentioned.

So there was a historical mentioning of it. And that meant that we had to kind of clarify at the CMD. Going forward, you should not expect us to talk to interim analysis [indiscernible].

Martin, GLP/GIP.

Martin Holst Lange

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Executive VP, Head of Development & Member of the Management Board

That was a good answer and guidance also. So on GLP-1/GIP, obviously, you've already seen that that's a good combination. From our perspective, when looking at a combination of mechanisms, what we are trying to assess is optimizing efficacy while minimizing potential safety [indiscernible].

As you all know, we both had a [indiscernible] actually in our pipeline. We also obviously had the dual agonist, and we still have that in our pipeline. Always our assessment still depends on efficacy versus risk safety. And when looking at our pipeline, we do see efficacy with GLP-1/GIP. We do see efficacy with the [agonist].

But we also specifically with glucagon saw a potential safety issue. Having then, what we believe, is the potential purchase combination of [indiscernible] in our pipeline, where we saw potential for far superior weight loss, as we just disclosed, it could potentially also work in type 2 diabetes without having to compromise on safety and tolerability, basically the same profile as we have with the [indiscernible].

No reason to progress on the file specifically because of the glucagon. We keep until we are absolutely certain that, that type of [indiscernible] is going to make it. I mean, with any development programs, there are potential risk. And we've seen fewer and fewer risk ahead of us as we speak. They're still there. But to hedge all of our bets, we keep our own GLP-1/GIP in our pipeline. We believe that we still haven't seen the data on efficacy to be a good and safe compound.

But again, based on what we've seen so far, CagriSema is probably the better combination because you get even more efficacy, and you get that without having to compromise on safety, tolerability. So I think I don't want to belittle that combination. I think it's good. I think it's strong. I think we also have something better in our pipeline.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Because we're committed to raising the innovation height in both diabetes and obesity. And with the assets that's on the way market, you need to really be sharp on that step change in innovation heights. And we believe we have some good shots on that, that you know about. But we also believe that we have early stuff that's preclinical that is aimed at redefining what does good look like in a market where there's a lot of good choice today, but still a lot of patients with significant unmet medical need. So it's about understanding what does -- decades from now, what does innovation look like, and then have a state and a pipeline with different horizons doing that.

Richard Vosser
JPMorgan Chase & Co, Research Division

Richard Vosser from JPMorgan. Could I come back to the comment on the volumes not coming out of the manufacturing process, of being a bit below? Is that because there's lots of product wastage that the manufacturing process is not as efficient as you'd like?

Is that because you can't get enough plastic or something from the suppliers? Or are there not enough filters for the manufacturer? Just some color on what's going on there so that we can have comfort that it could be fixed.

And then secondly, just thinking about the oral peptides and future peptides like CagriSema. Is there a way you can file those as a BLA? Or do peptides always have to be NDAs in the U.S.?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Richard. Two rather detailed questions, I would say. So if we look at -- I cannot go into all the details about exactly what's happening on the line. I hope you respect that. But if you look at our own manufacturing setups, we have different performance levels on different filling sites, and that contains a bit over time for different reasons.

So what we're looking at here is not, say, a variance that's much different from what we would see in our own [indiscernible]. And of course, when you have taken a site down and done remediation, there's retraining and oversight that needs to be put in place. And that can sometimes mean that, say, release processes, so volume is lower in a period of time. We have also experienced that ourselves. So there's not a, say, a particular problem that's blocking it.

But of course, when you're running at a demand that's higher than supply, that becomes a problem. And we are aiming at already next year to have enough lines running, enough sites running that we can get ahead of the game. So we don't

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need to have a discussion with you if there's a line running a bit slower than normal because that's actually part of doing manufacturing. So it's a scaling game to make sure that you have, say, robustness against that.

And then, Martin, on all peptides and regulation approach.

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

BLA versus NDA, I'm not at liberty to go into our regulatory strategy, as we speak. As you know, it's an evolving environment, and we will sort of follow the opportunity [indiscernible].

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

Simon Baker from Redburn. I've got two very quick questions and then one for Martin. Just on SELECT. Given there's clearly a surprisingly high focus on the magnitude of the benefit, can you say whether any of the existing access that Wegovy has is conditional on the magnitude of the benefit in a positive SELECT study?

And then a quick question for Karsten on the financials. You gave some commentary in the statement on the net financials for the quarter. I don't think I saw it broken down into financial income and expenses. Just wondering if you could give some color on what was in the financial income line.

And then for Martin, on icodec. We saw across the ONWARDs study, say, for ONWARDS 6, that the level of hypos were broadly the same on both arms. Were the only differences in the distribution of hypos over time on any of those studies? Or are they occurring at roughly the same rates on both arms as difference between icodec and control? That's it.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

I don't think we can get into more details on the first question. But Karsten, on the financials.

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

Yes, we can get into a lot of details on the financials. So -- but [indiscernible] tells me, it has to be a short answer. So put very simply, we had to the tune of DKK 2 billion in benefit on EBIT from currency in the second quarter, and we had roughly DKK 1 billion, a little bit more than DKK 1 billion, in hedging losses in the second quarter. So actually very favorable on a net currency.

The spread between the DKK 1 billion are a little bit more the DKK 1.6 billion in net financials. That's interest costs and all kinds -- and some minor value adjustments to some equity positions we have. So a lot of, I would say, minor stuff.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

And Martin?

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

Yes. So the distribution of hypoglycemia is that we've seen, obviously, with very low numbers in ONWARDS once a day, it's difficult to assess. But in ONWARDS 4 and ONWARDS 6, we see unique distribution over time. And maybe also important to call out, we've not seen prolonged sense of hypoglycemia and we've conducted a specific and dedicated hypoglycemia study, where we saw no difference between insulin glargine and insulin icodec. So from a hypoglycemia perspective, specifically in type 2 diabetes, we are very confident.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Final question.

Peter James Welford
Jefferies LLC, Research Division

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Peter Welford, Jefferies. Two questions and then just a quick clarification. Just on turning back to the SELECT interim analysis. Sorry, we're going back there again. Just to understand, though, I think you said at the Capital Markets Day that the secondary endpoints would be considered. You've now said that 1/3 of events roughly happened in the secondary versus the primary.

So just to be super clear here. If we hadn't seen, should we say, 22%, above 20%, the interim would have then said the trial should be unblinded, irrespective of secondary. Just to be super clear on this. There was a limit at which point it will be unblinded, irrespective of the secondary analysis.

And then just coming back to reimbursement, just based on SELECT. In the U.S., could there be a scenario where SELECT could lead to a secondary prevention style reimbursement? And I guess leading on from that, is it possible to conduct a primary prevention trial in obesity? Or is that the sort of study that would need, I guess, like the U.K., for example, a sort of government access type trial, if you like? Is it even viable to conduct primary prevention in this sort of market?

And then sorry, just to clarify. CagriSema, you said, was really important, the type 2 diabetes trial. Does that mean we should get a press release from the time -- on the Phase II? Or typically, this normal Novo, we should wait for November probably for an update in 3Q?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So Martin, I think there was a new variant of this SELECT question. I don't know if you want to repeat the answer.

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

Well, it's a slightly different answer, but you're absolutely right. I mean, focusing on the primary endpoint, there was a set cutoff. And they -- again, it's a guidance, and they had the prerogative to look at the totality of the data. But we highlight they have been looking at the primary endpoint and follow that guidance of following that specific endpoint -- sorry, set-point.

Just to clarify, when we talk about the decrease power on the secondary endpoint, the primary endpoint is a composite of myocardial infarction, stroke and cardiovascular death. It goes without saying, if you look at individual components of that endpoint, then you lose power and therefore, either the differential has to be very, very big or it has to have a lot of events. It also means that, that's why we add some specifics, is to focus on the primary endpoint because the likelihood of seeing anything on secondary endpoint is not [feasible].

Specifically on CagriSema, don't think I said it was very important. I don't want to belittle it. I said it was very exciting. I think it's really, really interesting also because from a scientific perspective, I'm curious, but goes without saying if this turns out to be as strong in diabetes as it is in obesity, we have a really, really effective [indiscernible].

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So to close, we are really pleased with our execution commercially. We are really pleased in how we are building our pipeline. I think icodec is an example of us aiming to raise innovation height to levels where people have said upfront that, that's not possible.

We are also very pleased with the execution of Wegovy. Despite the challenges we've spoken about here, we think there's a tremendous opportunity in obesity market. I think we're really well positioned to grab that. And when we look at our opportunities for driving growth there, also short term, we are very encouraged about that.
And all of that has led to both exciting clinical data and our operate for the second time this year. So we are on a roll, and I'd like to thank again Wimal and Bernstein for hosting us here today and to all of you for showing up with great questions. Thank you very much.

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