S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

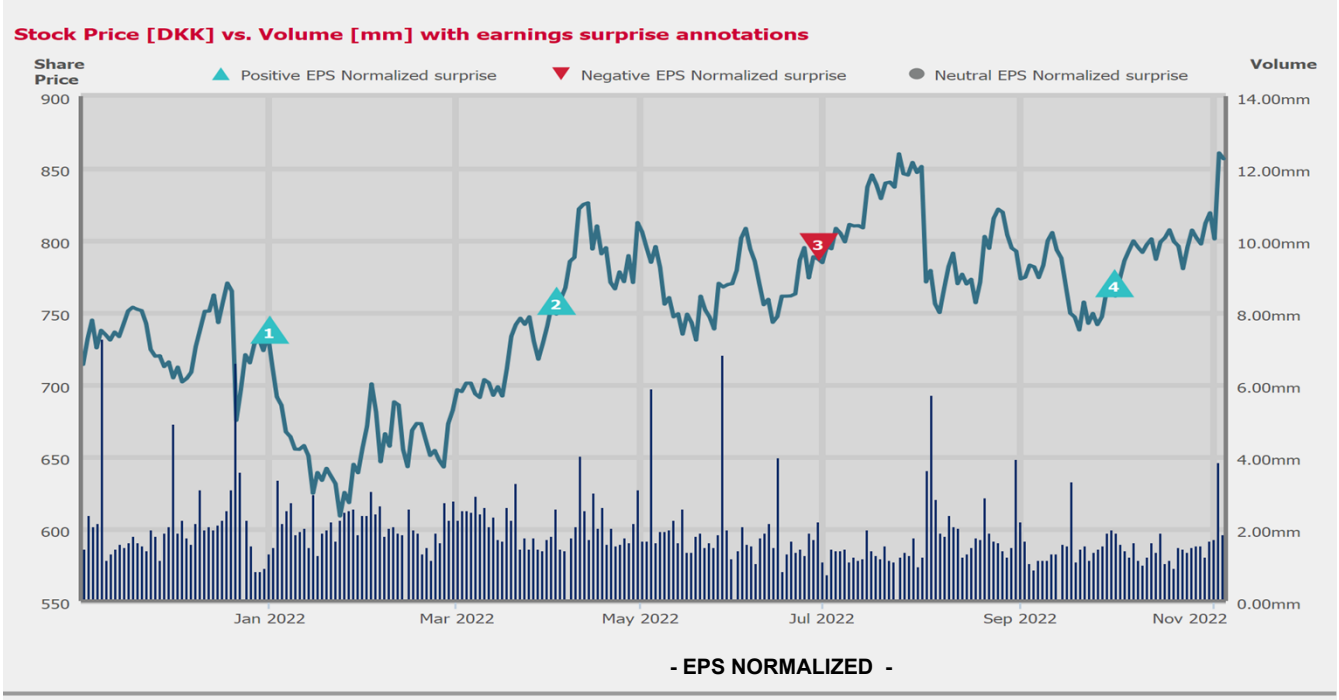
FQ3 2022 Earnings Call Transcripts

Thursday, November 3, 2022 1:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2022-			-FQ4 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	6.19	6.34	2.42	6.23	24.31	NA
Revenue (mm)	44493.00	45566.00	2.41	46976.33	174671.00	NA

Currency: DKK
Consensus as of Nov-03-2022 7:31 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2021	4.69	4.76	1 1.49 %
FQ1 2022	5.68	6.22	2 9.51 %
FQ2 2022	6.04	5.86	3 (2.98 %)
FQ3 2022	6.19	6.34	4 2.42 %

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EXECUTIVES

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Executive VP, Head of Rare Disease & Member of Management Board

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

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Barclays Bank PLC, Research Division

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Keyur Parekh
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Presentation

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Good afternoon all, and thank you for joining us. My name is Keyur Parekh, and I cover Novo for Goldman Sachs. It's a pleasure to have the team in London. It's even a better pleasure to have them the day after they made a new lifetime high from a stock price perspective. Congratulations. With that, I'm going to pass it to you, Karsten, to make some opening comments, and then we'll go to Q&A from there.

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

Great. Thank you, Keyur, and thank you to Goldman Sachs for hosting our quarterly London lunch meeting. And what an opening, right? So it's a tough act to follow. But clearly, with the dream team like this with my good colleagues, Ludovic Helfgott from Rare Disease, Martin Lange from Development and Camilla Sylvest from our Commercial Strategy area. Then I think we're set up for a great session today.

We had kind of an unfortunate situation yesterday with our conference call that -- and some people would say, "Did you plan for that day?" And at least now, we have a sample size of one. Martin will say it's not enough, but that we cut the conference call, and then we get an all-time high on our share price. So I'm not sure if you can do any trending on that. But hopefully, there will be no trend, at least. And knocking on wood, with all kinds of technical support today, that this is being webcasted and out there just for us to be aware about that.

So for today's presentation, and we have brought not too many slides that we'll go through in the beginning. And then in case there should be questions, then we'll have time for that. And if not, then we'll run off. But I would be surprised if there wouldn't be a few questions on 483, so -- whatever the flavor of the day is.

So jumping into our statements, then of course, as usual, our forward-looking statements, that there is a risk that the future doesn't pan out in line with our forward-looking statements. It could be better, it could be worse, but that is the risk that we all live under and enjoy.

And then just one slide on our strategic aspirations, which is basically how we portray the progress in terms of our corporate strategy execution. And without taking too much out of my colleagues' presentations, then briefly on each of the quadrants, purpose, sustainability. This is a core area for us. This is ESG in Novo Nordisk language. We continue to progress on our carbon emissions. So we're down 18% in carbon emissions compared to pre-COVID 2019. And actually, 18% is even not where we'd like to be. We're more ambitious than that. We have some pressures from distribution of our products. So that's why it could have been even better, but it's something that we're really driving performance management on.

In terms of adding value to society, then -- as of today, we are serving more patients than ever before in the history of the company. So of course, the core premise and the core objective of a company like Novo Nordisk is to discover and develop innovative medicine and make it available to patients on a global scale. And therefore, it's not only a pleasure based on the financials and the share price that Keyur alluded to, but even more importantly, we're serving more patients than ever, ever before.

And then we're progressing on our diversity and inclusion efforts and being a sustainable employer. Commercial exclusion, Camilla will go through, but 16% sales growth in an industry like the pharma industry, I don't know what the current run rate is, but at least, the last few years when we've been looking at the value at pharma, run rate for the global industry is to the tune of 4%, 5% or something like that. So having a clock speed at 16% is, of course, clearly competitive and in the top tier of the industry.

And then pipeline, again, as I said before, this is why we're here as a company. This is to discover and develop innovative products for the benefit of patients. And it's just really a pleasure to see the progress we're making both in -- within diabetes care, progress within obesity and rare disease. So as you recall, we are pursuing a corporate strategy where we are expanding and diversifying our R&D pipeline. And I think this is clearly a picture, and Martin will come back to it, that we are stepping up investments in R&D to expand and diversify the pipeline.

And then finally, on financials, 16% turns into 14% operating profit growth. I'll come back to the details. Continued efficiency drive and very competitive cash-to-earnings conversion and more than DKK 40 billion returned to shareholders. So -- and when you look at our balance sheet, then on an MAT basis, we're around 100% return on invested capital. So a fast-growing, high-margin company with

a 100% return on invested capital, I think, these finance folks like myself, that's metrics we truly enjoy. So with that, I'll hand it over to you, Camilla, on Commercial.

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

Yes. Thanks a lot, Karsten, and let's just look at the 16% growth, how that's distributed among North America and international operations. You see 22% growth in North America. It's 62% of our share of growth. And then we have 11% growth in IO. That's driven mainly by growth in EMEA, double-digit. And also in the rest of the world, we have, as you can see, a minus 5% in China. That's related to the volume-based procurement, the VBP, that was implemented as of May this year.

And when we look at how that is distributed across the therapy areas, you see that GLP-1 driving 44% growth, negative growth in insulin both in IO and in North America. And then obesity care growing 75%. Interestingly, 73% in IO without Wegovy, but only from Saxenda. And then in North America, combination of Saxenda and Wegovy, growing 77%. Rare disease, Ludovic will come back to in a minute, growing at 2%.

And if we then look at GLP-1 class, especially in the U.S., you see a significant step-up in terms of the market growth. This is also what we've seen with previous launches into this segment, that the market growth keeps expanding, but now we are at a level where volume growth is above 40%. We can come back to how that is being driven also by guidelines. But what you see is, of course, that Ozempic is still the leading brand in the class. But of course, with the market growing so significantly, volume growth becomes much more significant for sales than actual market share development.

And then on obesity, here again, you see the 75% growth in the first 9 months. You see in the middle also a very strong volume growth of 63%. And I'm sure we'll come back to how our rollout plans are in the rest of the world and also that we are expecting to supply Wegovy, make all doses available towards the end of this year. That's still the plan exactly as we also discussed last time when we met.

And with that, over to Ludovic for update on rare disease.

Ludovic Helfgott
Executive VP, Head of Rare Disease & Member of Management Board

Yes, exactly. Very quickly, just the rare disease franchise grew 2% in this year-to-date with a great growth on the rare blood disorder franchise, RBD, driven by hemophilia A, hemophilia B and NovoSeven, as you can see. Still a growth of 6% on NovoSeven, just to give an example, for a product that had been there for 26 years. It's still a growing franchise. And then the decrease on the endocrine disorder side, mostly driven by pricing essentially.

Because from a volume perspective, the brand is clearly leader across the world, more than 60% of market share in the U.S., around 36% worldwide. So overall, this price declined mostly in the U.S., which explained the 3% slight decline in North America, one is in IO, It's a 4% sales growth. So we are on our sort of long-term trajectory with this 2% growth in year-to-date 2022.

So we move to the rest of the pipeline.

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

So you've heard it for Karsten, we are investing more than ever in R&D, and that is leading to a very nice progress of our pipeline in the early research days, but certainly also in a super nice progress in our clinical pipeline and in the development space. More than ever patients in clinical trials, more than ever active clinical trials in more than ever disease areas. And we're seeing nice progress across the board. So going from the 50,000 patients that we actually have in clinical trials as we speak, I want to talk about [92]. And that's basically because you heard of us talk about CagriSema in the obesity space.

We think that we have an asset that will lead to a 25%-plus weight loss in the obesity space. That's exciting in and of itself. Hopefully, you also noticed that we initiated Phase III for CagriSema this week, which is going to be super, super exciting. We did not know what to expect from CagriSema in the space of type 2 diabetes and glycemia control. And therefore, we conducted a fairly small Phase II study, 90 patients being equally randomized to either CagriSema, semaglutide in monotherapy or cagrilintide in monotherapy.

Super excited after 32 weeks of treatment to observe that we saw not only a numerically and substantially numerically better reduction in hemoglobin A1C for CagriSema as compared to semaglutide, and that was maybe not so surprising cagrilintide. But equally excited about seeing the weight loss. You know most of you that's seeing -- and accruing weight loss in type 2 diabetes is actually more

difficult than what we see in non-diabetes, so both with semaglutide, but also whatever else is out there. You see somewhat less weight loss in type 2 diabetes than what you see in non-diabetes patients.

But combining cagrilintide and semaglutide, that leads to a 15% weight loss in 32 weeks. If we extrapolate that to our usual 68 weeks, it's a 20-plus percent weight loss. And that is better than anything we have seen in the type 2 diabetes space. I'm now looking at a different slide than I was promised. Maybe I should just look at my slide, but that is okay. Now you heard all of my stories about CagriSema. That is super exciting, and I could do it without looking at the slide. It is because -- it's actually some easy number to remember, because this gives me a great opportunity to also talk about what we've seen with in [indiscernible] with ONWARDS 5. It's still 0.4 percentage point difference in A1C, a superior reduction as compared to whatever is out there.

That is also super exciting. We have the vast majority of our patients of -- sorry, of our diabetes patients on insulin treatment still, more than 30 million across the board. And imagine that you can show a 0.4 percentage point different in this space. This is actually -- if I extrapolate UKPDS, I can start talking about reduction in cardiovascular mortality, reduction in all-cost mortality, 20% reduction in risk of amputations. That makes it meaningful for the individual patients, obviously, but actually also for payers. And I think when Camilla has to start to do pricing negotiations for icodec, that will make it super exciting. So obviously, the progress of icodec and a submission during the course of first half of next year is going to be super exciting.

I do want to call out in the obesity space we also will see the readout of high-dose semaglutide in that space, 50 milligrams of semaglutide. We also have a 25 milligram story ongoing. In the rare disease space, Ludovic has already touched on that. But suffice it to say, super exciting to see the progress of [indiscernible]. So we initiated [indiscernible] actually last week. And that basically means that we will -- and I hope you can agree with me that is an impressive record. We will spend approximately 4 years of clinical development. This is to be compared with the normal [AGS] in hemophilia that we spend in clinical development, specifically for [indiscernible] we've progressed it very fast. We are now in Phase III and you should expect a readout from that trial during the course of '24.

And then back to you, Karsten.

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

Thank you, Martin.

Financial outlook. So you've seen our 9-month numbers, 16% sales growth really, amazing push on GLP-1 in diabetes as well as our BC franchise, as Camilla was alluding to. So that has enabled us to raise our outlook for the year from 12% to 16% to now 14% to 17% sales growth at same currencies. And then you layer in currency impacts another 10 percentage points, mostly from the strengthening U.S. dollar. So overall, when you look at the magnitude of growth for the company, then, of course, in absolute terms, this is the biggest absolute sales growth ever, ever in the history of the company at local exchange rates, and then you add in currencies. So the sheer size of step-up in growth is really remarkable in a historic setting.

That, of course, goes through to our operating profit performance where we are raising our numbers correspondingly, then we lose the currency step-up in hedging. That's to be expected. I think when you do our net numbers on hedging, without going into details, then our hedging performance this year, our net currency performance this year is very, very attractive, even after hedging costs. And then finally, our cash flow, to be clear, how can you raise your outlook for the year in terms of sales and OP and then lower free cash flow? And there's a very simple explanation to that because -- the reason is that we lower our free cash flow guidance by DKK 3 billion, the range.

But that is a function of the fact that we closed the [indiscernible] transaction in the fourth quarter at around DKK 5 billion impact to our free cash flow and then underlying benefit of DKK 2 billion. So that's how we get to the net minus DKK 3 million on free cash flow. So excluding BD, a step-up in free cash flow generation, which we, of course, allocate to shareholders according to the classic principles around a 50% dividend payout ratio and then the remainder done through share buyback program, as we covered before. So no changes on capital allocation.
So these are our aspirations for '25. You've seen them before. So I'm not going to reiterate that. I think we're ready to get into Q&A. And I think we have a long tradition of having the host shoot off the first couple of questions. And if we could just restrain, 2 questions each, and then we do the rounds as we move forward.

Question and Answer

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Keyur Parekh, Goldman Sachs. If I could start with 2, please. The first one is, in the unfortunate circumstance that Catalent was to receive a warning letter kind of for the Belgium facility between now and your relaunch date in kind of end of December, early January, how confident are you of maintaining kind of that date? And how is that going to be a function of supply from other parts of the manufacturing network? Or would you reconsider kind of pushing that date out? So that's kind of question #1.

And then separately, Karsten, Lars and you bought kind of yesterday, mentioned a few times about confidence in maintaining current trajectory of growth and having supply kind of from a GLP-1 perspective to kind of continue doing that. How should we think about the timelines associated with that? Was that kind of a fourth quarter comment? Was that a 2023, 2024 outlook? So just kind of any context around that.

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

Thank you, Keyur. On the first question, vis-à-vis Catalent, we do appreciate the sensitivity around the Catalent situation in the capital markets. And as a consequence, it's not a comment that we take lightly and put into our company announcements. So of course, the comment we put in is based on a careful assessment around the current level of inventories, the fact that Catalent is producing for inventory of commercial product as we speak, and then an assessment based on -- from our quality organization in terms of the quality situation at our CMO. So of course, there are no guarantees in this world, but we would not put this statement into our company announcement unless we're confident that we'll be able to resupply the U.S. market in December with Wegovy.

Then to the second point in your question, around our forward-looking commentary. So we put a statement in our outlook section. We're basically saying that we're continuously expanding our supply capacity. And our assessment is that, at a potential -- that we have the supply capacity to supply according to the current growth trajectory of the company. And the reason why we put it in, just to be clear, was that in the beginning of that section we're talking about supply chain limitations, including for Ozempic. So this was just to avoid people becoming overly concerned that we are not able to supply at all or were kept at our current level of supply. So this is a comment intended as a forward looking statement that we are scaling and that we'll be able to cater for the current -- if that materializes based on demand, the current level of growth.

Well, I think we have enough questions. I think, actually, just to make it simple for me, so it's not a speed contest, then we start here -- in front.

Naresh Chouhan

Naresh Chouhan from Intron. Just a couple of questions on the Ozempic 2 mg launch. It looks like it got to almost 10% of total Ozempic scripts, and it looked like a phenomenal launch in 4 months. So 2 things. One, some of the drivers of that, is there a big bolus of patients who need to dose intensify? And therefore should we expect that growth to slow down when you can resupply? And the second thing is, is there any reason to think that this isn't 25%, 30% of total Ozempic scripts in the years to come as patients progress to -- from the 0.5 mg to the 1 mg to the 2 mg and it becomes a big part of the business? Because it's not something that I felt that you guys are focused on massively, but it could feel like it could be a very big opportunity.

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

All right. Camilla, I think that's for you.

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

So you're absolutely right that we've seen a great uptake with 2.0 so far. And of course, this opportunity is in place to make sure the patient can continue on Ozempic treatment over time. We also know from our initial data that not everyone is progressing to the 1.0 from the get-go. So some people are at 0.5 and approximately half are progressing to 1.0. So you can imagine that over time, people will be able to stay on Ozempic, still intensifying the treatment and being very good control both with their blood sugar, their weight and, of course, also with the cardiovascular protection that Ozempic is giving them.

So you are right that over time the individual person is likely to upgrade. But of course, as we see more and more patients coming on to Ozempic with the growth of the market, then it's likely that there'll be a ratio of people on 2.0, but with many more coming in, if not so that this ratio is going to significantly differ from I would assume a 1/4 or a 25% of the total ballpark right. But that, of course, time will show. But it's really an [indiscernible] on the same product. That's the whole purpose of it.

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

Thanks, Camilla. And I think we'll go to Mark Purcell.

Mark Douglas Purcell
Morgan Stanley, Research Division

It's Mark Purcell from Morgan Stanley. So 2 questions. The first one is going back to oral sema and the SNAC technology. So we see it moving once week into clinical development. So could you help us understand where you are with the various generations of SNAC as you try to eliminate food and water interactions, you work on the post component and give us an idea of the advantages and disadvantages versus a capsule peptide where there's competitors entering the market as well as the oral small molecules where we see a lot more data over the next 6 months or so? That's the first question.

And the second question is kind of going back to what [indiscernible] was talking about as well, but the message around sema is becoming increasingly complex. You've got outcome trials such as FLOW and STRIDE focused on 1 milligram injectable. You've got, obviously, 2 milligrams going to 8 milligrams going to 16 milligrams. Then you have Rybelsus ad study, but then you're going to 50 milligrams. And then the obesity dose, I presume, is going to go up as well. So how do you take all this complexity and try to bridge cumulative evidence into the molecule to create a simple message, given that some of your competitors have far more simple messaging when it comes to doses, which they're using consistently for diabetes, for obesity, for sleep apnea, et cetera, et cetera?

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

Thanks, Mark. Martin, if you'll field the first one on oral sema and the SNAC technology and then branding too coming up.

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

Yes. So I think you're exactly right. We are focusing a lot on the SNAC technology because we want to and we need to increase the bioavailability, basically to reduce the amount needed for the efficacious and safe treatment. We are currently in clinical trials in fourth generation and have made some substantial upgrades to the bioavailability that we've seen, without going into too much details. It goes without saying that will give us a good leverage on the [FMC] part.

Our clear aim is actually also going a little bit to your question #2, the efficacy and the safety has to be on par with what we see in subcutaneous. And actually, what we have currently right now with Rybelsus is probably, from an efficacy perspective, somewhere between 0.5 and 1 milligram of subcutaneous Ozempic. Our aspiration is for 25 and 50 milligrams to be able to power with 2.0, 2.4 milligram of Ozempic and Wegovy.

Goes without saying -- if we substantially increase the bioavailability, there will be a little bit of a regulatory complexity in discussing the actual sort of doses because all of a sudden, what was 50 milligram could then in the next generation correspond to something lower. But I think that, for us, at that point in time, will be a luxury problem.

When you talk about other formulations, I think what we've seen so far -- and we are carefully monitoring this SNAC technology is by far the most attractive in terms of securing bioavailability of peptide or protein. Comparing to the small molecules, I think you know my position on this. I think they will be reasonably good when it comes to efficacy. I think they will -- we still have to evaluate the safety. There's always some unknowns with small molecules. My understanding is actually from an FMC perspective, there's not really a big difference. Therefore, I think and Camilla can also talk to this, the small molecules that will have their place, but they will not be sort of super competitive from an efficacy safety or an [FFC] perspective. So we welcome them as vehicles who may be also broadening the field.

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

Thanks, Martin. Camilla?

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

Yes. On the SNAC type molecule, it's clear that we are, of course, optimizing the impact that this molecule can have on different patient populations, And that also caters for the fact that some of these disease areas are very different. For example, diabetes very often driven by the physician in terms of specialist or primary care physicians. Then you have the obesity segment that is to a large extent also driven by demand from patients. It's easy to diagnose, then you have NASH that we are looking into that is very difficult to diagnose at the moment, requires a biopsy.

And then, of course, we are exploring it at Alzheimer's also, that is yet a completely different target group. The reason that I'm mentioning all of this is actually that it can sound complicated when you look at it across. But if you look at each of the disease areas and the target groups both in terms of patients and physicians. We are actually able with different brands as we have it also now to cater for a specific group, a specific key measures that relate to that particular target population. And we are also able, from a rebating structure point of view, to actually work with different segments. So there are some advantages of doing this.

Plus at the very end, we are able to confirm and detail and promote directly on label, which is, of course, very important for us to do so that we make sure that we stay very strongly in our business ethics with regards to what gets promoted to whom, especially the target groups of doctors, and this actually gives us a very flexible approach.

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

Thanks, Camilla. Then we'll move to Richard Vosser.

Richard Vosser
JPMorgan Chase & Co, Research Division

Richard Vosser, JPMorgan. One question on icodec and ONWARDS 5 looked very, very strong, but the type 1 at hypo was not non -- wasn't non-inferior. What needs to happen for that? And does that have any commercial implications when you're talking to payers from a pricing standpoint? And then second question, just on CagriSema and GIP combinations maybe. CagriSema looks pretty good and on weight loss, but the HbA1c was not really at Mounjaro levels. It was better than Ozempic but not Mounjaro. What can you do to further enhance the HbA1c control?

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

Martin?

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

So we've -- if I can take the last question first. CagriSema is investigated in a 32-week study. And specifically on glucose control, part of the effect is seen by the weight loss. And that basically means that, if we extrapolate that weight loss over time into what we would say regulatory grade timelines, 68 weeks, actually up to 2 years, in type 2 diabetes, our extrapolations are indicating that CagriSema on glycemia control will, on a normal day be on par with tirzepatide and on a good day could actually also turn out to be superior. And if you combine sort of be the base case or even the upside with the weight loss that we've seen, this will be the most attractive offering that we would have in type 2 diabetes.

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

On icodec, I think the type 1 diabetes is obviously something where we had to go into a dialogue on the risk of hypoglycemia. As we've also discussed, even though we did see more hypoglycemia with icodec than we did with other basal insulins, it was still at a fairly low level. And therefore, the risk-benefit discussions that we'll have with regulators, I think we are still in a reasonably good place. I don't want to speak to the commercial and the pricing negotiation. That's for Camilla. But overall, the type 1 population is sort of the minority in this space. And my sense is that pricing discussions will be based on phase -- sorry, type 2 diabetes patients, and this is where we see the superiority with -- on par with risk of hypoglycemia.

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

Yes, exactly. You could work in commercial, Martin.

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

Okay. Thank you. That's always good to know.

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

Thank you, Martin. Thank you, Richard. And we're on to Jo.

Jo Walton
Crédit Suisse AG, Research Division

Jo Walton, Credit Suisse. I wonder, Camilla, if you could give us an update on the reimbursement sort of attitude of people and payers given that there's so much publicity about these drugs? Are payers thinking -- good God, if I don't put some restrictions, I'm going to have unaffected demand. And perhaps within that, you could say whether you're seeing any -- the longevity of people on -- will go for your -- sort of 5 months or so on Saxenda? Are people showing their enthusiasm for Wegovy by staying on it for much longer?

And my second question is just a broad one on U.S. pricing. So now that you should only raise your prices in line with CPI, and CPI is so high. Is there an opportunity in 2023 to have your list prices higher than you've materially -- you've had historically because CPI will be 8 or 9 perhaps, which is most unusual?

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

Thanks. So maybe I'll start with the first one, and then I think Karsten would like to speak to next year. Reimbursement attitude towards Ozempic is, of course, generally very strong in markets that traditionally reimburse. When it comes to weight loss products like Saxenda and Wegovy, then we have now 15 markets in international operations that have reimbursed Saxenda. Of course, it comes at a BMI normally around 30 or 35 with comorbidities. In the U.S., we have about 30 million lives covered. So a very good starting point in general to continue prescribing for more patients with reimbursement.

The attitude, of course, with -- towards Wegovy and Ozempic, to make sure that it's not prescribed off-label is increasing. The awareness is increasing, we of course have the advantage that we have 2 different brands. So it's easier to understand and document. And we have been looking back at -- can we see a change in the Ozempic patients that have been prescribed to naive to treatment patients before and after the Wegovy launch. And so we took 1.5 years before the launch up until July last year '21 and then up until now, and there has been an increasing trend of prescribing GLP-1 products in type 2 diabetes earlier.

That trend continues. It has accelerated a bit after the launch of Wegovy, but not significantly. So I just want to say that the trend of prescribing GLP-1 products earlier to type 2 patients has increased a lot coming from guidelines from both ESD and ADA also. And of course, we also learn how well it works, especially with Ozempic, with the 3 benefits it has, including the cardiovascular risk profile. So that's just a great understanding of that.

Then when it comes to stay time on Wegovy, we don't have new numbers to share with you, but we are following up on that. And as soon as we have more to share, we will share that. What we do know from Saxenda in the countries where that has now been reimbursed that the stay time, of course, is significantly extended. Plus, that we have seen in our data from Wegovy that people continue to lose weight beyond 60 weeks. So that also gives us an indication that stay time is likely to be much longer in Wegovy than it has been traditionally on Saxenda. And then to the price.

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

On the inflation turns in the U.S. and the most recent legislation, which where it takes a baseline back to 2021, as you know. And consequently, we will face a minor negative impact already here from the fourth quarter on products where we've taken price increases on and above the inflation since '21. As to our list price increases in '23, there's a multitude of factors that goes into our decision on list price increases.

First of all, the benefits of the products we're providing and the clinical data supporting that for patients, the competitive situation and of course, the overall pricing environment. So this is not the primary factor. But of course, we take all factors into account when we

make that decision. So no further comments around that because there's also a certain level of competitive intel on that front. Then yes, Jeffrey?

Unknown Analyst

Can I just come back to Wegovy. But a different question, which is if the facility were to have to temporarily close for any reason, would that in any way impact your timeline? And have your thoughts on the amount of drug you need for the launch changed at all since the start of the year? Or are you still aiming for the same, if you like, volume of the different doses by the end of the year before you make that decision to launch?

And then can I just ask with next year then when you bring on the other fill finish, should we think about the first half with the second CMO and then the second half with the second Catalent facility? Is this a sort of step function given we're talking about fill finish. We're not talking about sort of ramping up API, if you like. So essentially comes online? Or is this a gradual increase we should think and fill finish capacity coming during the course of 2023?

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

So as to resupply in the U.S. market towards the end of the year, as I said before, this is based on our combined knowledge and the fact that the CMO is producing as of today and the required inventory levels to launch that they're viable. Of course, there are hundred scenarios in the world that can impact any part of the business, but we would not put into our company announcement, the fact that we are resupplying the [market] on this. We believe that's a relevant scenario, speculating in all kinds of hypothetical items.

I don't think that adds any value, then we would have not put this wording in. As to next year and capacity, as you stated, the second CMO will go online in the first half, and online means that they will be supplying to a marketable product. And then the second site will get online in the second half of '23. And consequently, we will have 4 different sites supplying fill finish -- sorry, filling for Wegovy. So that will be step changes in filling capacity and, of course, additional backup capacity in that sense. Sachin.

Sachin Jain
BofA Securities, Research Division

Sachin Jain, Bank of America. I'm going to kick off with a comment you made on Ozempic yesterday with people trying to gauge off-label usage and how much of this switches. You made a comment around 40% of Ozempic being naive to diabetes treatment, I think. Was that NRx or TRx? Could you give a sense of what that number was pre Wegovy? And are you indicating this is a potential switch population to Wegovy? I just want to be super clear what the message was around that, if that's okay.

And then the second question, apologies, going back to Wegovy supply. I just had a really simple question on process. So having had before it and you've been a receipt of it, is there any FDA inspection or process you're aware of that could drive a decision chain between now and launch? Or is it just status quo, i.e., this facilities operation until you hear otherwise? The background of the question is I'm trying to understand if there is a risk, the timeline of when that risk would emerge for you and for the market. And as part of the confidence, you don't know about an [SDN] inspection, therefore, you can bridge the gap to your second facility?

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

Right. So if we start with the -- so my specific comment was related to a question at the conference call around Ozempic source of business. So source of business is basically new starts going on to Ozempic and that was my comment as to the 40% and then the evolution on that metric, Camilla?

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

Yes. So we try to look at the 18 months ahead of Wegovy launch for Ozempic and see what -- how was the evolution in that and that basically moved with a delta that is very close to similar with the 12 months after the Wegovy launch. So it's just to say that we are now at, as Karsten said, close to 40%. It started 1.5 years around 17%. And in the middle around the Wegovy launch, just below 30% or more around 28%, 29%. So it's just to say, if you look at those deltas, this, of course, doesn't give us a full answer, but these are new to treatment patients on Ozempic.

And so there is an increase in the trend, but not a significant increase in that trend. What we're trying to say before was that all along, Ozempic started with having a lot of GLP-1 source of business, and then it moved gradually to less and less of that. So it's natural that moves earlier and earlier in the treatment cascade because the guidelines is now also recommending that.

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

Good. And then a simple answer to a simple question on Catalent. So we would not say that we plan to resupply the U.S. market in December in case there was major uncertainty based on our perception of the ongoing regulatory or quality process. So I don't think it adds any value to get into more speculative around regulatory inspections and so on. This is based on our best assessment of the situation, and I don't think we can give more on that.

Sachin Jain
BofA Securities, Research Division

Can I take one follow-up, Camilla? So that increase in NRx starts of naive from mid-teens when you said 17% to 40%. If I answered that correctly, how much of that has translated into total TRx? So what percentage of TRx do you think is naive to therapy post Wegovy as an increase relative to [indiscernible] that you would say this is a percentage of existing Wegovy business that we're not quite sure why it's there and may switch.

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

So I wouldn't know exactly how that translates. It's quite difficult to get into that. But of course, if you look at the graphics that we showed before, you will see that the number of patients has increased significantly just due to the underlying market growth. Whenever there's a new launch into this segment, we have seen, and you've been following this for many years ever since, Victoza, Trulicity, Ozempic and now tirzepatide launch, keeps growing the underlying market. So of course, this translation from NBRx to TRx is a bit of a -- over time, it's difficult to compare directly. I think We won't speculate on that from here.

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

Thank you Camilla. Then it's Simon.

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

Simon Baker from Redburn. Two questions, looking -- firstly, looking forward. We've obviously had quite a big development issue in Alzheimer's. So I just wanted to get your perspectives on the impact of lecanemab on Alzheimer's, more from the point of view of -- given the reaction to that data, has it changed what you feel you need to do with semaglutide in Alzheimer's? And related to that, is there any preclinical data on combination of anti-amyloid and GLP-1?

And then sticking with the pipeline on CagriSema. We can't -- the data looks really impressive. We can't quite see from the slide because there are no confidence intervals. So is it additive? Or is it genuinely synergistic? And if the latter, what's the reason?

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

Martin.

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

So specifically on Alzheimer's, I think the recent development has made us even more sort of enthusiastic of what we have on our hands. It's increasing the awareness of potential treatment in this space. Obviously, we have to see -- don't misunderstand me, a regulatory approval of what comes next. The data so far looks good. But they also have to be able to stand to regulatory scrutiny. I see this sort of, as we just discussed with obesity, I mean there's no real treatment out as we speak. So being more than one player, building and establishing the market is actually a plus.

We have a complementary mechanism of action to what is in other companies' pipeline. And that allows us to -- if we establish the efficacy part of this, and we would expect to have similar efficacy to what we've seen from other companies coming out, then with a drug that has a well-established safety profile will be a really, really attractive offering. So I think you see us more enthusiastic than ever. And we are obviously full speed ahead in terms of our development. Now you have to remind me of the other 2 questions.

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

So the second part of that was, is there any preclinical data on the combination of anti-amyloid and GLP-1? And the second one was on CagriSema. Is it additive or is it generally synergistic? And the last...

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

I'll just give you 2 fluffy answer to that one. So yes, there are preclinical data, they're not published. We have them in-house, and we have them both on amyloid and on tau. And it seems as if GLP-1 treatment has impact on central inflammation, neuroplasticity, potentially amyloid and tau. And that obviously gives us some confidence in that, there is a reasonable mode of action in addition to what we've seen in the clinical space. And then on CagriSema, as a big, big caveat in trying to doing that kind of interpretation based on 90 patients, 30 in each treatment arm. And if we just take the numbers and also look at what we call the spaghetti plots of the individual patients, it could be a potential for synergy. But right now, we will settle with additivity because that, again, will show superiority versus anything else out there.

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

Thanks Martin. And now just need to -- yes, move over here.

Unknown Analyst

Just a question on Ozempic supply constraints. Is the constraint [filing just in or] finish? Or is it API as well?

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

Yes. So I'll take that one. So on Ozempic supply constraints, as we have seen in a number of markets and we have issued a drug shortage notification, which is something a pharma company has to issue when demand is greater than supply. It's not that we're not supplying it. It's just demand is greater than supply. And we're not going into any details about where our constraints are, but again, coming back to that we're scaling our manufacturing platforms, and we'll be able to cater for the growth trajectory we're currently on when we look forward.

Unknown Analyst

This is the guidance then that those supply shortages would stop at some point in 2022? Or if you continue growing at...

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

So the guidance is, as I said before, the current growth trajectory and then we're doing everything we can. Of course, on our side, it is frustrating that we're not able to meet patient demand and some patients will have to go without product. So -- so we're not holding back. And as you see right now on Ozempic, we are growing year-to-date, we're growing 70% in value, which means almost double up in volume. And so we're already scaling as we speak, and we'll continue to do that into next year. And then whether we meet full demand in all geographies, that's, of course, also a function about how the demand picture will look into next year, but significant scaling also next year. And yes, go here.

Unknown Analyst

[indiscernible] from Morgan Stanley. I just wanted to get your latest thoughts on glucagon agonist, particularly given your competitors here have shown increasingly encouraging data.

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

So we actually also had glucagon agonist in our pipeline. And you may have seen a publication that we should recently talking to potential safety issues, specifically, obviously, on our agonist, but potentially also in sort of a broader class. You think, I can't speculate to that, obviously. But I mean, that at least was our thinking that this could be a potential. And in that space, we were looking at reasonable efficacy.

Yes, we saw good efficacy with our triagonist, but we did also see the safety issues. And then having both the GLP-1 and GLP, but more specifically, CagriSema in our pipeline, the risk to benefit was not really in support of continuing our [indiscernible] approach.

I really have to stress we did see efficacy. It looked good. It did not look as good as CagriSema does. And therefore, our confidence is based on the fact that CagriSema appears to have the superior efficacy profile and probably also the superior safety profile.

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

Thanks Martin. Then we have Michael Leuchten and then [indiscernible] if you can get ready after Michael.

Michael Leuchten
UBS Investment Bank, Research Division

Two questions for Martin, please. Just on the ultra-high dose sema in the Phase II, that's a step change in dose that's quite different from what you tried before. Just wondering where that came from to go that aggressive on the dose range? And then on CagriSema, the tolerability in the Phase II, I think, at -- it was 60-something percent of tolerability and I think discontinuation is up to 20%. Lilly has managed to get that down in Phase III. Just wondering what you can do in Phase III to get a better tolerability.

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

So super questions. First of all, [indiscernible] tolerability shows a function of titration in this space. So that would go to both of your questions. Specifically on going to higher doses, we're actually following our normal step of more or less doubling the dose. We've shown that we can do that without introducing more tolerability issues. And based on what we know already now, we feel confident that these call them step increases will not introduce more tolerability issues than what we've seen. Obviously, we have to show that. That's why we do the clinical trials. But our assumption is that when we get to that level, tolerability has already been built, and you can actually do the next step without introducing more GI side effects.

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

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

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

Thanks Martin. Then [indiscernible] .

Unknown Analyst

[indiscernible] from Bernstein. First, can I just ask on Wegovy price, please. I, know Karsten, you don't like to talk about net price. I'm going to ask anyway. Just first of all, is it fair to assume there was no co-pay volumes in the third quarter? And if the answer is yes, the net price looks at about $28 a day. Is that a fair estimate for the net price of Wegovy? And then maybe if you could just comment on the mix between cash and commercial volumes.

And then my second question, one for Martin, is at obesity week this week, there's been a bit of discussion around the type of weight loss. So there's a competitor drug that has shown quite a nice fat loss, but actually, you saw an increase in lean mass. So I guess my question really is, and if look at step one, I should say, you saw a reduction in also lean mass. So I guess how much of this is considered by physicians today? And as we think about that increase in weight loss with CagriSema, does the quality and the type of weight loss really matter to outcomes?

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

Great. Thanks, [Simone]. So as to net price, I know you like to talk about that more than I do at these meetings. Then in -- when you look at the third quarter, then what I can say is -- as to our early experience program, what we call the bridge program, correct, there's nothing of that in third quarter numbers. But clearly, there would be co-pay support program. So buying down co-pay, that will also be in the third quarter. That's a normal U.S. tactic. So as to your reflection about the net pricing, you can say, it's clean from the bridge

program, but it impacted by co-pay and classic rebate structures in the U.S. And as to the cash share, it's to the tune of 10%. And then Martin?

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

Yes, I think you're exactly right. Healthy weight loss is -- I don't want to call it the next frontier, but it is certainly important. It's also important for me to call out that what we call lean body mass is a function of water and muscle mass. And the way that we assess it, unless we are careful, doesn't really allow you to distinguish. And that also means that when we discuss either increases in lean body mass or losses of the lean body mass, it's not always one-to-one. Fat mass is fat mass, no matter how you look at it. What we saw with semaglutide was actually a modest decrease in lean body mass and a substantially bigger decrease in fat mass. I think that is as good as it gets right now.

But we also have a clear focus on obviously preserving as much lean body mass as we can, while obviously introducing a substantial fat mass loss. It's too early to say what we will see with CagriSema. Obviously, we will look into this. I think it's fair to say in our research effort, we are looking very much into this also. I think it's also important, going actually back to Michael's question in [indiscernible] titrate how fast to introduce the weight loss. There is a risk if you do introduce a very fast and dramatic weight loss, you will lose almost 50-50 lean body mass and fat mass. So the tempered but consistent body weight loss could potentially be healthier than a very dramatic fast weight loss. All of these factors is something that we and I think others are looking very actively in.

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

Thanks Martin. Then we have questions back here.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. You've talked about in the past about the inflation cap component of the IRA as being a limited negative. I was just wondering if you could provide any more color or context on the expected impact of the U.S. business.

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

Yes. So the function is, as I was covering before, it's basically for the products where we've taken list price increases on or above inflation compared to the base of 1st of Jan 2021. Those products, and then you can look at our list price history, you see it's mainly focused on our [GF1-based] products in diabetes. Those products will be exposed to an inflationary currency, so to say, already in the first quarter. Since we have not called it out more specifically, then it's not big enough to justify that. Normally, we're talking about anything beyond 3% on the U.S. business, we'd be calling out. And since we're not specifying -- it means that we're below that threshold.

All right, then I need a time check. One final question. Is there anyone who hasn't asked a question, then we go all the way. Sorry -- this is good exercise -- all the way to the other end.

Richard J. Parkes
BNP Paribas Exane, Research Division

Yes, it's Richard Parkes from BNP Paribas Exane. I just wondered, could you update us on where you think we are now in terms of penetration of GLP-1 in diagnosed diabetics in the U.S.? And then secondly, on -- I know it's been talked about indirectly, but off-label use of Ozempic at the moment in obesity. How much real visibility have you got around how much of that is happening in the U.S.? And if that visibility is low, how do you factor that into your planning assumptions? Obviously, there's a lot less certainty around how long patients will stay on drug for an off-label prescription versus diabetes prescription for Ozempic?

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

I've got -- Camilla.

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

So today, around 10% or GLP-1 treatment is around 10% of U.S. volume. And of course, in diabetes. And when we talk about potential off-label use, I think we talked to it earlier, it's difficult to estimate exactly the size of that, but we have, of course, looked at the trend on the NBRx as we talked about earlier. So that's as close as we can get to giving you an estimate of that. There is no significant change in the trend that was already there before the launch of once-weekly GLP-1 in obesity. But there is an increase in the trend, but not a significant step-up, yes.

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

And then there's the modeling or the switching between Ozempic and Wegovy.

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

Yes. So when we look at international operations, and I know you're asking about the U.S., but when we look at international operations, you see an increase of 73% in Saxenda. And you also see a very steep increase in Ozempic sales. So you have those 2 products in parallel growing significantly. And of course, that's not in -- that's the best sort of one-to-one picture, we can imagine what would also happen we now start to supply Wegovy in the U.S. We are supplying Saxenda now that also -- so the obesity franchise grows also in the 70s in the U.S. as of now, while we also see a continued growth of Ozempic that Karsten mentioned also 70%.

So those 2 franchises are able to actually coexist at very high growth rates because the underlying demand is very, very big, more than 700 million people living with obesity in the world and more than 500 million living with diabetes. And we are all together treating, including insulins, just around 35 million patients, right? So it's fair to say that there's still unexploited potential for better treatment for patients.

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

Thanks, Camilla. I think that was the perfect way to end on a high note, lots of potential for treating patients with [indiscernible] and many years to come. So thank you for attending the Novo Nordisk Q3 lunch meeting in London, and thanks to Keyur Parekh and Goldman Sachs for hosting this fantastic result of fantastic venue, and they are looking forward to see you all, if not before, then the 1st of February when we come with our full year results and 2023 guidance. Thank you.

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

Thank you.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division
Thank you.