S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

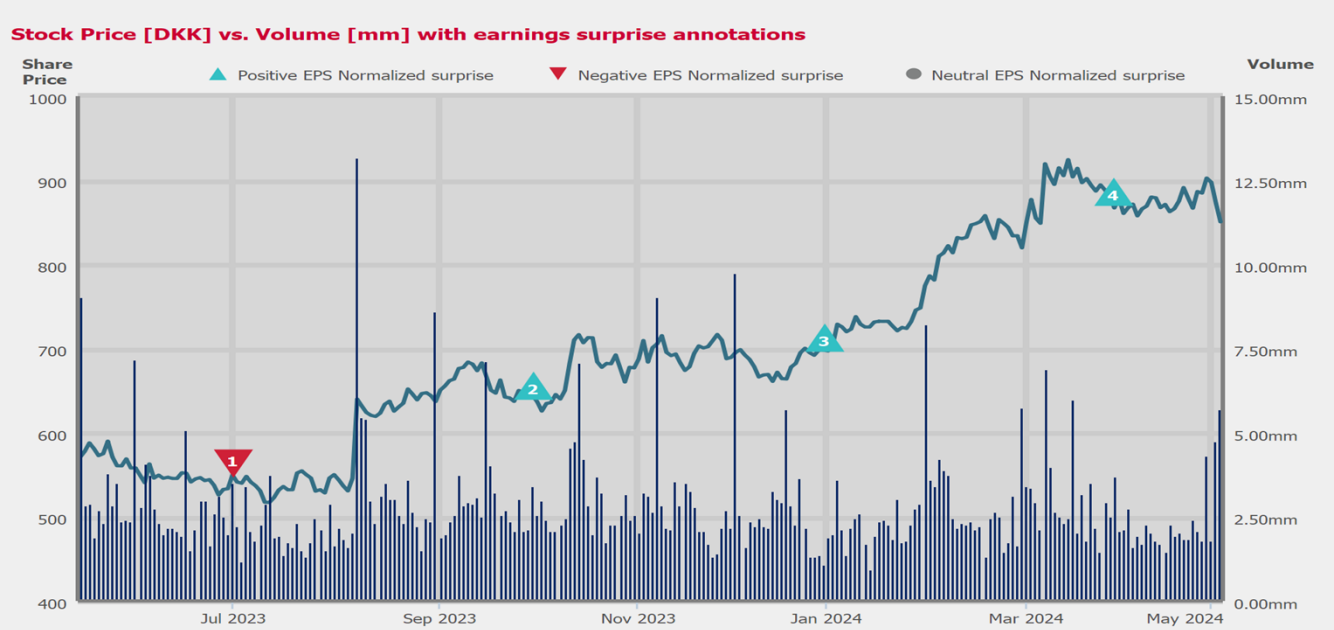
FQ1 2024 Earnings Call Transcripts

Friday, May 3, 2024 12:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ1 2024-			-FQ2 2024-	-FY 2024-	-FY 2025-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	5.22	5.68	8.81	5.49	23.17	NA
Revenue (mm)	63573.45	65349.00	2.79	67756.46	288043.90	NA

Currency: DKK
Consensus as of May-03-2024 4:27 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2023	4.59	4.32	1 (5.88 %)
FQ3 2023	4.53	5.00	2 10.38 %
FQ4 2023	4.58	4.91	3 7.21 %
FQ1 2024	5.22	5.68	4 8.81 %

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

ANALYSTS

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Barclays Bank PLC, Research Division

Evan David Seigerman
BMO Capital Markets Equity Research

Jo Walton
UBS Investment Bank, Research Division

Laura Alexis Hindley
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Peter Verdult
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Richard J. Parkes
BNP Paribas Exane, Research Division

Sachin Jain
BofA Securities, Research Division

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

Unknown Analyst

Presentation

Peter Verdult
Citigroup Inc., Research Division

Good afternoon, everyone. Welcome to the revamped Stirling Square Bank, and good afternoon to everyone in the room. And to those listening on the webcast, good morning, good afternoon, good evening. It's been a very busy week for earnings and in other events, but we are ending the week on a high with the Q1 ratio of Novo Nordisk.

The speakers don't really need introduction, but just out of courtesy, Karsten, Group's CFO; Camilla, Group Commercial Strategy Head; and last but not least, Martin, Head of R&D, joined by us and already of Investor Relations.

Now usually, I'd be saying without further ado, hand it straight over to Karsten to some slides and some Q&A. But I think it is worth just pausing and recognizing that it is Mr. Daniel Bohsen, his last function as the Head of Novo Investor Relations. And I think that needs to be sort of recognized by the audience in the room, not just yet, but when I say. But on that note, I have known Danny, I think, for over 15 years. He was in the [indiscernible] analyst covering Novo Nordisk. And we were discussing instrument back in the days. And then I think with [Martin's flexing], he was sent off to Colombia to go sell some drugs. And then came back in 2020 to be a Head of Investor Relations. And I think we can all agree, being head of IR in 2020 to 2024 for Novo, not a bad place to be.

So Danny, I mean this and hopefully, I'm speaking on behalf of everyone here and on the line, your professionalism, your patience dealing with people like ourselves, your responsiveness, helpfulness and just all around being a good bloke, really appreciate it. And we wish you well on your next venture with Novo Nordisk. But plenty of good times, and I have to say just to call out, I think [meeting] in 2016 was a particular highlight. So thank you for making that special.

So before we say goodbye to Danny and wish him well, I do have a little gift for you. It's within my compliance policy of less than $25, but it's a -- it is to help you immerse yourself in the Taiwanese culture. So Danny, on behalf of everyone here, I do want to say thanks for everything, and good luck going forward. So thank you.

And I will be asking Karsten about Taiwan and the change in performance over the next few quarters under new management. So thank you.

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

Great. Thank you, Pete, for those nice words to Daniel. We are all sad he's leaving, but we're also very much looking forward to following him in Taiwan. And we have a materiality assessment on what we report externally in terms of our segments business on. And every week, we'll be tracking in our weekly sales, if Taiwan sales is becoming big enough to include in the quarterly external announcement. So we're all rooting for you, Daniel, for Taiwan to make one of the coming quarters.

And thank you to Pete and Citi for hosting in your beautiful new premises here, nicely revamped, so we appreciate that. And then we're bringing another strong quarter from team Novo in terms of performance. So continued growth, continued momentum from last year amongst the strongest growth stories in the industry, as you know, and we keep pushing that.

So as you know, the future is uncertain and it might play out differently. And hence, we have a nice deck with the forward-looking statements included. So no further details on that.

Then every quarter, we bring a status on our strategy execution, and I'm not going to go through all the details. You'll hear a lot more about it in the coming hour. Just to say on the environmental side, we keep pushing forward. Now we started reporting on full Scope 1, 2 and 3, and you see that being up 32%. And there's one single key driver for our CO2 emissions being up that much. That is the fact that we're building a lot of new factories, which goes directly into our Scope 3 emissions. So we don't take it lightly, but now we are fully transparent around our environmental footprint.

42 million people now on Novo products, up 4 million compared to a year ago, and then continued strong commercial execution that Camilla will come back to. I think actually, one of the biggest years ever in Novo history in terms of the magnitude and importance of an R&D readout. I'm getting an echo from the new audio. I'll keep talking. And then net-net, 24% sales growth. So really pushing on all fronts. You'll hear much more.

So without further ado, over to Camilla on commercial execution.

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

Thank you, Karsten. And just a recap on our sales growth numbers, this first quarter, we had 24% sales growth, 30% operating profit growth. As you can see from the slide here, 35% growth in North America and 11% growth in International Operations. The growth is really driven by GLP-1. We see a 32% growth in GLP-1 in diabetes, 42% growth in obesity. We are very pleased with the progression of, of course, our GLP-1 business both in diabetes and obesity.

On total diabetes, we continue to gain market share. We have also increased market share this last quarter and now at 33%. And if we now look at the obesity business here, you see a gradual increase of supply continue to expand our obesity business. We very much, of course, understand that at this point in time, the obesity business is a lot driven by the supply into the market. The underlying business is performing very well. There are no major changes to that compared to last year. So we continue to be happy to -- with the progression that we see here.

We have gradually increased our supply of the lower-dose strength since May last year, but again from January this year. And the fourth commercial access on the formularies means that we have approximately 50 million lives covered in the U.S. And we have now also launched Wegovy in 9 countries in International Operations plus Canada. So that means 10 countries now where we have made Wegovy available.

We'll probably talk a little bit more about that later. So now I'll just hand over to Martin to say a few words about R&D.

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

Thank you very much, Camilla. As you all know, we conducted a small study called SELECT that read out last year, and we were very excited about the results. We are equally excited about the update to the U.S. label that we've received during this quarter. Obviously, we get the CV indication indicating that semaglutide is associated with a 20% risk reduction from MACE, major adverse cardiovascular events. That's myocardial infarction, stroke and it's cardiovascular death.

On top of that, this risk reduction is now reflected in the label. It is achieved regardless of baseline gender, age, race, ethnicity, body mass index and baseline renal functions. On top of that, we also saw -- were allowed to indicate the data despite the fact that it was outside of the testing hierarchy, where we see a 15% numerical reduction in cardiovascular death and a 19% significant reduction on all-cause mortality. And that is now reflected in the label, which obviously is something that we are very, very excited about.

In addition, the FDA has indicated that the mechanism of the CV benefit is not fully understood, indicating that, that benefit is associated with more than just the body weight loss. And this is something that we've talked to a couple of times. We see something in semaglutide that goes above and beyond body weight loss when it comes to the CV benefit, potentially also the renal benefits that we have observed with the molecule.

In line with our broader cardiovascular strategy, we are continuing to do acquisitions to bolster our pipeline. As you know, our focus when we talk about cardiovascular disease is not any cardiovascular disease. It's basically in the broader metabolic aspects of cardiovascular disease. Key focus is on [A, phase B] and inflammation and on heart failure with preserved ejection fraction.

We recently acquired a company called Cardior, having a lead asset, which was -- is an ASO, targeting microRNA 132, which is directly involved in heart failure pathophysiology. So this goes directly into our strategy of expanding our cardiovascular presence. We'll focus on heart failure, we'll focus on the [ACBD]. And we're very excited about progressing the cardio assets into further clinical development.

These were just 2 highlights. Obviously, it's quite exciting, as Karsten also alluded, to be in R&D in Novo Nordisk space. We do see progress across all of our study areas, obviously, with chief focus on diabetes, cardiovascular disease, obesity and rare blood disorders. But we do also see progress in our hepatology focus, specifically semaglutide for NASH, where we will see the readout of the ESSENCE Phase III trial later this year.

We also see progress in our readout, obviously, exemplified by FLOW. And that basically means that we continue to press on all cylinders and see very successful readout, very successful initiations throughout the course of the year. This, I think, is almost going to be the quiet quarter because moving into the later stages of this year, we are looking towards 2 advisory committees with the U.S. FDA. One is on icodec. icodec has already received a positive CHMP opinion from the European authorities. It's approved in Canada and Switzerland. And it has an action date in U.S. in July. And the outcome for icodec in U.S. is focused specifically on type 1 diabetes. And the AdComm is also from a timing perspective place so that this is in due time for the action date. So it's going to be a good discussion.

We have been informed that the committee will not discuss the top 2 indications, which we've already discussed is clearly demonstrating a very nice benefit-risk, but also some very nice convenient benefits of icodec in this space.

We have other Advisory Committee hearing is going to be about heart failure with preserved ejection fraction and semaglutide. And this is a huge upside. So as you know, we conducted the STEP HFpEF trials with the purpose of looking at 6-minute walking test and [cancer study] heart questionnaire. But in those 2 studies, we also saw 100 points, heart failure hospitalization and cardiovascular death. When we submitted the data, the FDA actually granted us both priority review, indicating that the data are actually exciting, clinically relevant, but also coming from 2 small studies. So we also got the Advisory Committee here in to discuss the impact of that. And again, a huge upside for semaglutide, specifically with Wegovy.

I can feel Karsten is becoming impatient, so I have to start focusing. Maybe just calling out that in a couple of weeks, we'll see the long-awaited data in our rare blood disorder franchise for Mim8, which obviously also could potentially be something very, very exciting.

So with that, back to you, Karsten.

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

Thank you, Martin, for -- I mean I will walk through the slides, as always. Joking aside, amazing year from R&D in terms of readouts and actions. I cannot remember a year where we've had so much action and so many readouts and decision points. So really, really important to deliver on this.

So results for the first 3 months, you've all seen it in our company announcement that -- coming back to 24% growth, continuing the momentum from last year, the same growth drivers being Ozempic and Wegovy and Rybelsus. Then in the quarter, we had a one-off in terms of an accounting estimate adjustment, which bumped up growth by 5%. So adjust for that, we are in the 19 range. Yes, last year's comparator was easier, but then there were some supply issues. So just to say, the run rate in the first quarter is around 20% apples-to-apples.

Then in terms of our capital and resource allocation, as I called at the Capital Markets Day, of course, we continue to drive productivity for the broadly stable gross margin. Lower growth in commercial investments than sales growth simply due to the fact that we have the infrastructure in place and the demand nature for our products. But then on the other hand, linked to the slide you just saw, a lot of opportunity in R&D, so really pushing to expand and broaden our R&D pipeline, saving up R&D investments by 28%. All in all, operating profit up 30% and our earnings per share up 29% for the quarter.

Outlook for the year. If you adjust for the accounting estimate adjustment in the first quarter, then our guidance is unchanged at constant exchange rates, but bumped by 1% linked to the one-off. So now our full year expectations are between 19% and 27% on top line growth and 22% and 30% on OP. And then given the strengthening dollar, then currencies are a little bit more favorable, which are then in turn offset by our heavy losses on the net financials.
All right. This covers the formal presentations. And then we have Daniel Bohsen facilitating his last Q&A. So we look forward to that. And of course, any specific questions on Taiwan, Daniel is more than open to cover them himself. Should we move to this? Yes?

Question and Answer

Daniel Bohsen
CVP & Head of Investor Relations

Luckily, I know Camilla has been the General Manager for Region China, so she will cover those questions today. But please state your name and institution. Let's go with one question per person, then we can take several rounds. And Emily had her hand up very fast.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. I'm not going to ask directly about the competitor data overnight, but when could we expect to see the Phase I data from your once-monthly GLP-1/GIP? And how important do you think it is to have dosing convenience that goes beyond once-weekly?

Daniel Bohsen
CVP & Head of Investor Relations

Martin, I think this one is for you. A few words on that, our progress there.

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

The study for the once-monthly GLP-1/GIP is currently ongoing. We expect to see the readout around the turn of this year. In terms of the importance, I think the current dynamics, as I see it, and obviously, Camilla can also speak to that, there's a clear drive by efficacy over preference or anything else in this space. And obviously, our question where we have stuff in our pipeline is always -- is the differentiated efficacy. And then obviously, the convenience becomes a secondary factor. And we will continue to pursue that, but efficacy, as I see it, comes first.

Daniel Bohsen
CVP & Head of Investor Relations

So let's go to Simon.

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

Simon Baker from Redburn. I too will refrain from asking you to comment on someone else's data that nobody has seen. But just in terms of how you see the market evolving over time, it seems highly unlikely that it will be the same in 2030 as it is today because of your own products that you have as well as others. It also seems unlikely that everything else outside Novo development will fail. Equally unlikely everything will work. So what's your assumption of how this market evolves both through your own portfolio evolution and the efforts of others?

Daniel Bohsen
CVP & Head of Investor Relations

Camilla, I think -- can you give some perspectives on the obesity market, how we think it will develop?

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

Simon, so of course, if we take a starting point in the number of people living with obesity, we know that there are more than 800 million. We know also today, we are helping treat less than 1 million in terms of full year equivalent patients, if we may call it like that. And that basically means that there's ample opportunity to grow in this space and to help many more patients.

It's likely that there will be different segments in the future where the high-efficacy segment is, of course, where we have our strong focus. From a science point of view, we have a strong label now with SELECT on Wegovy, where we're addressing not just weight loss but also beyond weight loss, cardiovascular risk profile. We know that, that is what people die from. 31% of everyone dies from cardiovascular issues.

Now we have also, of course, our FLOW data. And so to complement Wegovy label with that is, of course, a life cycle management plan for us. In addition to that, we have been bringing on new compounds with also hopefully greater efficacy. But it's not to say that there will not also be a space for high-convenience products maybe with lower efficacy.

So having said that, today, there are 2 companies that are competing in this space. It's still early days. There's probably room for more just given the magnitude of the numbers. So I do expect that we've seen a lot of progress in the last few years on physicians that are willing to prescribe obesity products. Just a few years back, we all remember, it wasn't exactly like that. So there has been a lot of development. And hopefully, this means we can address more of these comorbidities related to obesity. And that, of course, clearly goes beyond just weight loss.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Camilla. So let's move over here, yes?

Evan David Seigerman
BMO Capital Markets Equity Research

Evan Seigerman from BMO Capital Markets. So I'm not going to ask about the FTC's second request because I know that's not you specifically. But I did want to ask about how much more capacity do you think you can get from the 3 facilities from Catalent? And what does that do to the supply of all of your products by 2026?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Evan. And Karsten?

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

Yes. So in terms of FTC, to cover that one first, it's completely normal that when you have a big transaction that there's a process with the FTC to assess any antitrust considerations. So there's nothing unusual there, and we have no changes in our expectations and in terms of deal certainty and confidence in that, just to cover that piece.

As to scalability, we're not out explicitly guiding on the magnitude. But if you look at our current footprint on fill finish, this where we have around a handful or so of filling sites today, then adding 3 filling types of varying sizes, this is a meaningful step-up in capacity on our overall fill finish.

And I would say on the single-dose syringes, we have very, very limited capacity in-house today. So that's mainly a CMO setup. And with this change, then we take a key platform for the company. We use it for currently Wegovy in U.S. as the main product, but then we take a very important production platform in-house under full control. So there's also a risk-control element to what we're doing here. So -- but a significant step-up. And the important part, the reason why we do it just to remind you, this is about speed and scale. So it is to step up capacity as fast as possible compared to other alternatives.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. Thanks for the question. Jo?

Jo Walton
UBS Investment Bank, Research Division

Jo Walton, UBS. It's along the same lines in terms of capacity. So I guess it's for Camilla, this one, though, perhaps. In the market today for obesity, people have moved from Saxenda to Wegovy. They've really moved up and not stayed at the lower efficacy. So let's just assume that CagriSema has good data. Should we be assuming that you would expect pretty much everyone to move from sema to CagriSema? Because that seems to be an even more difficult manufacturing problem given that cagrilintide you're making externally. And I just wonder whether governments, particularly when sema is cheaper if it's in IRA, will say that's good enough and that sema will be your baseload of product. And then in CagriSema would just be reserved for the more difficult patients. So it's more -- perhaps, it's more Simon's question about how the situation evolves and whether we should think of that transition that we've already seen moving to the next one or not.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Jo. Camilla?

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

So thanks, Jo. I think it is -- you are right, it's a completely different situation than what we have with Saxenda and Wegovy, not least just for the bare efficacy of what we have with Wegovy today, including the SELECT trial that Martin has just presented. And so because of the magnitude of the numbers and because of the number of people being treated, just the need and the demand out there, it's more likely to see an expansion of the market with new products coming in and a very strong base, of course, with Wegovy also into many years into the future.

So I would not see this whole additional of a strong pipeline as purely a cannibalization exercise. It wouldn't be the right thing to do because we have so many patients that need to be treated. And some need a higher focus on weight loss, other needs higher focus on comorbidities. So there is a position for also new innovations that are add-ons to the existing base that we are developing for many years into the future with Wegovy also.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Camilla. Let's go to -- yes, James?

Unknown Analyst

It's [James Creedy] from Goldman Sachs. I've got a question for Martin on muscle sparing. So what are you hearing from doctors in terms of if there's like a desirable ratio in terms of fat loss versus muscle loss in terms of -- or is it more of a case of just losing the weight in general? And then as you think about SELECT versus STEP 1 and SUSTAIN 8, where it's 40% loss from lean body mass, have you seen any data from SELECT that suggests that flips over time or get a bit better?

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

So what we hear from training physicians is that, that is currently not a consideration. I think it comes from a lot of these physicians have introduced weight loss with not drug interventions for a period of time. And if you look into sort of the broader literature, when you introduce a weight loss, the proportional weight loss coming from lean body mass is typically between -- somewhere between 25% and 45%. And the driver of that ratio between lean body mass loss and fat mass loss is typically the speed of weight loss.

So when you have a proportional weight loss from lean body mass around 35% to 40%, that's actually within that realm. And that basically means that, that is a normal and healthy weight loss. You could actually argue, and this is obviously also why we are super happy with data from SELECT, we can actually show even in cardiovascular risk, sick patients, so presumably slightly more frail patients, we show that we improved not only cardiovascular morbidity but actually also all-cause mortality. And that basically, again, just plays into this. This appears to be a healthy weight loss.

So based on current treatment, I don't see this as a broader problem. I think it has to be a focus area also with current treatments, in particular, in frail patients. And when we move into the potential for bigger weight loss, it has to continue to be a focus area. This is where we take some comfort from the animal biology because based on animal studies, both from us but also from others, and it appear to be associated with an even bigger improvement of the lean-to-fat mass ratio.

Then to body composition assessment in SELECT, so I don't have any data from there. But again, based on what we see, also based on the actual outcomes for patients, do they live longer, do they live healthier, we are quite comfortable with what we see right now.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thank you, James. Let's go to Sachin Jain on the first row.

Sachin Jain
BofA Securities, Research Division

Sachin Jain, Bank of America. Perhaps at Karsten on S&D phasing through the year alongside supplies. The question is first quarter S&D and the full year guide obviously implies an inflection in spend through the year. So any color on what is gating that inflection in spend? Is it linked to an inflection in supply? And is the supply inflection linked to whatever promotional activity you do around Ozempic, Wegovy, say, for example, SELECT or heart failure towards year-end?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Sachin. Karsten, any comments on S&D phasing?

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

Yes. So S&D in the quarter was 20% of sales. Full year, we're looking at more around 22% or something like that in terms of the S&D ratio. So you are correct that our S&D phasing is slightly backloaded. And of course, that's linked to our commercial strategies, and our commercial strategies are linked to supply availabilities as well as R&D readouts.

So for instance, now we have had SELECT, and now we'll start promoting even more based on the updated label from SELECT. That, of course, entails some promotional spending linked to that in the U.S., as a specific example. So you shouldn't link it directly -- as a direct causality that then, there's more out of manufacturing in a specific quarter. But of course, it's all tied together in a logic. So I think that's as precise as I can get.

Sachin Jain
BofA Securities, Research Division

And on R&D, sorry, is there anything other than SELECT that you'd call out?

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

In terms of readouts?

Sachin Jain
BofA Securities, Research Division

Yes. You said commercial linked to R&D other than SELECT R&D. Apologies. You said commercial linked to R&D, so in SELECT, is there anything else that we should be thinking about this being linked to?

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

Well, you could say in terms of weekly launches, there will, of course, be some launch preparations taking place there. And then Martin's, in pipeline slide there, you saw that whatever we get in terms of feedback from the Advisory Committees also on HFpEF will impact our commercial strategies for the rest of the year.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Sachin. Thank you, Karsten. So we can go to Richard.

Richard J. Parkes
BNP Paribas Exane, Research Division

Richard Parkes from BNP Paribas Exane. So a follow-on for a question I asked yesterday, but it's on the same theme related to potential segmentation of the market. Because obviously, the other companies are making it about if you can develop a scalable oral, then you can unlock a much broader opportunity in maybe that severely obese people with overweight and health issues.

So you've placed your bet on [rimonabant], which -- I suppose my question is what -- how confident are you that the drug isn't getting into the brain, and therefore, won't have psychiatric side effects? Because we see other companies that are developing BTK inhibitors arguing about who's got the best data of the drug's ability to penetrate the brain. So what underpins your confidence that the drug isn't getting into the brain, and therefore, unlikely to cause those side effects?

Daniel Bohsen

CVP & Head of Investor Relations

Martin, this one's for you.

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

Yes. Thank you. So we are quite confident that the brain penetration is substantially less than what has been the case for previous drugs in this class. We've never talked about ruling out some brain penetration. But if you look back at the historical cases, it was actually about exposure. And therefore, with a very low penetration that we expect to potentially see here based on the data, also clinical data that we have seen so far, we are not concerned.

We take it seriously, and that's also why you'll actually see us -- normally, I'll talk about the speed to going into Phase III and further development. In this specific case, we actually specifically want to do a large-scale Phase II study with the purpose of ruling out any new psychiatric risks.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. We can go to Laura. There's a mic behind you.

Laura Alexis Hindley
Joh. Berenberg, Gossler & Co. KG, Research Division

Laura Hindley, Berenberg. Just going back to the once-monthly, what is the latest on applying your once-monthly technology to your other pipeline assets? So could you apply it to amycretin, CagriSema? And if not, what's the limiting factor? And does once-monthly tie into why you progressed the GLP-1/GIP combination, even though it's a once-weekly progression?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you. Martin, that's also for you.

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

So we have actually several different modalities for projected actions. And obviously, the ones that we have in the clinic right now is attracting some attention. That could potentially be applied elsewhere. But we currently have, as I said, several modalities being investigated in the preclinical space.

And what we, at the end of the day, will move forward also into later stages, development depends obviously on the efficacy but also the potential for scalability. So we are not committed to anything yet, and we have to see the current ongoing once-monthly with GLP-1/GIP. As an exposure, we started to investigate the technology.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you. So we can go to Peter.

Peter James Welford
Jefferies LLC, Research Division

Peter Welford for Jefferies. Can I come back to a topic that came up a while ago on Wegovy in terms of the different sort of formulations or types that could be available in the U.S. and sort of, in general, the U.S. strategy. Have you revised at all your current thinking in terms of sticking with the single-use pen in the U.S. market and not launching any other alternatives? And equally, any thoughts on a sort of direct distribution system that I think what your competitor obviously has done as well, where we just cut out the middleman to some extent to supply U.S. patients?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Peter. Camilla, portfolio considerations?

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

Yes. So we continue to, of course, evaluate how can we optimize our portfolio considerations also for the U.S. And right now, we are very focused on the single-dose device. But of course, over time, we are looking at also how can we make efficient dosing of GLP-1s in fixed, you can say, dosing regimen. How can we do that in a smarter way that requires less capacity? It's something that we constantly look at across our value chain. How can we optimize with the presentation format we have across the world? How can we release small products? And with that, also increase our scalability? So constantly, we will be evaluating those things.

Daniel Bohsen
CVP & Head of Investor Relations

Good. Let's go up here to Rajesh.

Rajesh Kumar
HSBC, Research Division

Rajesh Kumar from HSBC. One for Martin. It would be unfair of me to ask you to comment on how others would design their clinical trials. But given the data pack we have seen so far in semaglutide, if you were designing next-generation trials for your next-generation products, would you be -- say, for example, with the like-for-like for SELECT [CAE CKD], would you be using placebo control or would you be using semaglutide? And what does that mean about how do you need to power the trial? What size of trial do you need?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you. Martin, trial design consideration?

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

So a really complex question and a lot of regulatory considerations also. I think you're actually seeing different approaches across industry right now. We are getting closer to, for example, in obesity in the cardiovascular space, if there is a gold standard, you can't compare to placebo. You have to compare to that gold standard, and that could potentially be semaglutide.

That basically means, from our perspective, if we, for example, look at CagriSema, if we want to claim the same benefit as semaglutide, we have to show parity with semaglutide or not a priority to semaglutide, if we did a head-to-head. That would require, I would say, a normal-sized outcomes trial if going for the same endpoint.

If you had to show superiority over semaglutide, obviously, we are talking about a taller order. And there, we would have to be looking at obviously the sample size, but also what are the potential endpoints and what are other aspects of the trial design that would allow us to, within reason, demonstrate superiority on the relevant endpoints. You see others adding to the number of composites in the primary endpoint, and that's obviously a vehicle to increase the number of events that we're looking at and thereby influence the -- allowing it to go with a smaller sample size. So all of that has to play in.

If there is no gold standard, it makes still a lot of sense to compare to placebo. And if we look at other aspects of our product benefits, we would potentially also still be comparing to placebo. CagriSema, for example, is compared to placebo when it comes to cardiovascular outcomes. And that is basically because at the point in time where we initiated the trial, there was no gold standard.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. So let's go to Richard Vosser here in the front row. We have time for a few more questions.

Richard Vosser
JPMorgan Chase & Co, Research Division

Richard Vosser from JPMorgan. Just a thought on the Part D redesign that we're going to see next year, how that could impact the net pricing for Ozempic and Rybelsus into '25?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Richard. Karsten, I think this one is for you.

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

Thank you. So first of all, we are in negotiations -- business negotiation season. So we haven't formularies played out yet. So there's really a lot of uncertainty at this point in time. I would say, 2 pieces to it. There's the redesign and then there are the negotiations dynamics in Part D.

On the redesign, it's important to note that with the redesigned benefit design, then yes, there's a benefit because the donor toll is being eliminated, but then there's a different exposure in terms of catastrophic coverage as well as some other coverage. So net-net, while we initially thought it was directly positive, now we believe it's broadly neutral on the redesign.

And then I'd say on the redesign impact to the plan sponsors, and hence, the insurance companies and how much -- how it impacts them and how much they can pass on to their customers and what that then in turn indirectly impacts us remain to be defined. But I would say that the competitive situation in the marketplace is unchanged between suppliers into the marketplace. So too early to comment on.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. Sachin, you had a question? And we take Emily afterwards and then end.

Sachin Jain
BofA Securities, Research Division

Sachin Jain, Bank of America. For Martin, sema, NASH, increasing flex towards year-end. Just wanted to clarify a comment you made on the call yesterday. I think your wording, and correct me if I was wrong, was if you repeated the Phase II, it would be a good outcome. Just wanted to clarify, the Phase II didn't hit that thing on fibrosis. So is just NASH resolution enough without fibrosis for filing commercial? And if that is incorrect, what's your confidence around hitting fibrosis? Is the effect size you saw in Phase II enough to get you across the hurdles in Phase III?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Sachin. Martin?

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

For regulatory approval, both improvement in steatosis and fibrosis is required, and the study is designed to look at that. Our dialogue with the FDA was that our Phase II trial was never sample-sized to look from a statistical perspective on fibrosis. So we saw a highly significant reduction in steatosis, which actually saw a great numerical reduction in fibrosis as well.

And the statement from the FDA was if we saw a similar numerical reduction in a properly sample-sized study, obviously, that will become statistically significant. And from a regulatory perspective, that would also be acceptable. So instead of asking us to conduct 2 Phase III studies, they said that the Phase II study could serve as one of the 2 regulatory studies, and we now are doing ESSENCE as the other study.

Sachin Jain
BofA Securities, Research Division

Despite the 10% delta? If that's repeated in Phase III, is that going to account for that?

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

Slightly more than 10%. And yes, if that becomes statistically significant, then we are in a good place.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thanks, Sachin. Let's take the last questions from Emily, and then we will have time to talk with management afterwards also before they depart.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. Going back to Wegovy pricing. I know this was asked yesterday but -- and there's an FT article today talking about Novo cuts Wegovy price. So maybe to ask it a little differently, how's the net price evolution for Wegovy in the U.S. than -- within your expectations? And you also mentioned pricing movements in certain channels. I know you'll have more Medicare going forward with SELECT, but could you just give some granularity on what you meant by that?

Daniel Bohsen
CVP & Head of Investor Relations

So Karsten?

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

It's probably me being cold. I better stand up for this. So this is completely as expected, right? So what we're looking at in the market is that this is a volume opportunity, and we are very happy with the market access we have in the U.S. So we have more than 50 million people with obesity covered in the U.S. today. So our market access is very good.

And of course, then we'll work with the payers to ensure that we have the appropriate market access that ensures this level of coverage or even more. And then, of course, the market is also defined through competition and competitive entry. So there are no surprises in pricing in the U.S. And just reminding you, this is a significant volume opportunity. So the 50 million people with obesity that we have covered for today, we are only serving a fraction of that, so less than 1 million now.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. And that concludes the Q&A session. Before giving the word to Karsten for his final remarks, I just want to say thanks, Pete, for the kind words. And thanks to all of you that many of you have met many times over the last 4 years. And I've truly enjoyed the conversations, the challenging questions also in -- also the pushback. So thank you so much, and please remember to keep them on their toes also in the future.

Karsten, over to you. Any final words?

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

Very briefly. Thank you, Citi, again. We feel we're on a roll. So amazing levels of sales growth continuing into this year, 24% for the quarter, turning into attractive profit growth, 30% for the quarter at the current exchange rates. Our innovation machine is really also on a roll in terms of readout and what you just have seen thus far between SELECT, FLOW, and hopefully, to be replicated into the near future on the coming readouts. So a very strong push on innovation for the rest of the year.
So thank you for your attention. And we'll be around for another quarter, so looking forward to discuss in more detail. Thank you.