

Novo Nordisk A/S CPSE:NOVO B

FQ2 2023 Earnings Call Transcripts

Friday, August 11, 2023 12:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ2 2023-			-FQ3 2023-	-FY 2023-	-FY 2024-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	9.18	8.63	▼ (5.99 %)	8.91	35.82	NA
Revenue (mm)	55749.09	54300.00	▼ (2.60 %)	56022.20	222985.35	NA

Currency: DKK

Consensus as of Aug-11-2023 8:23 AM GMT

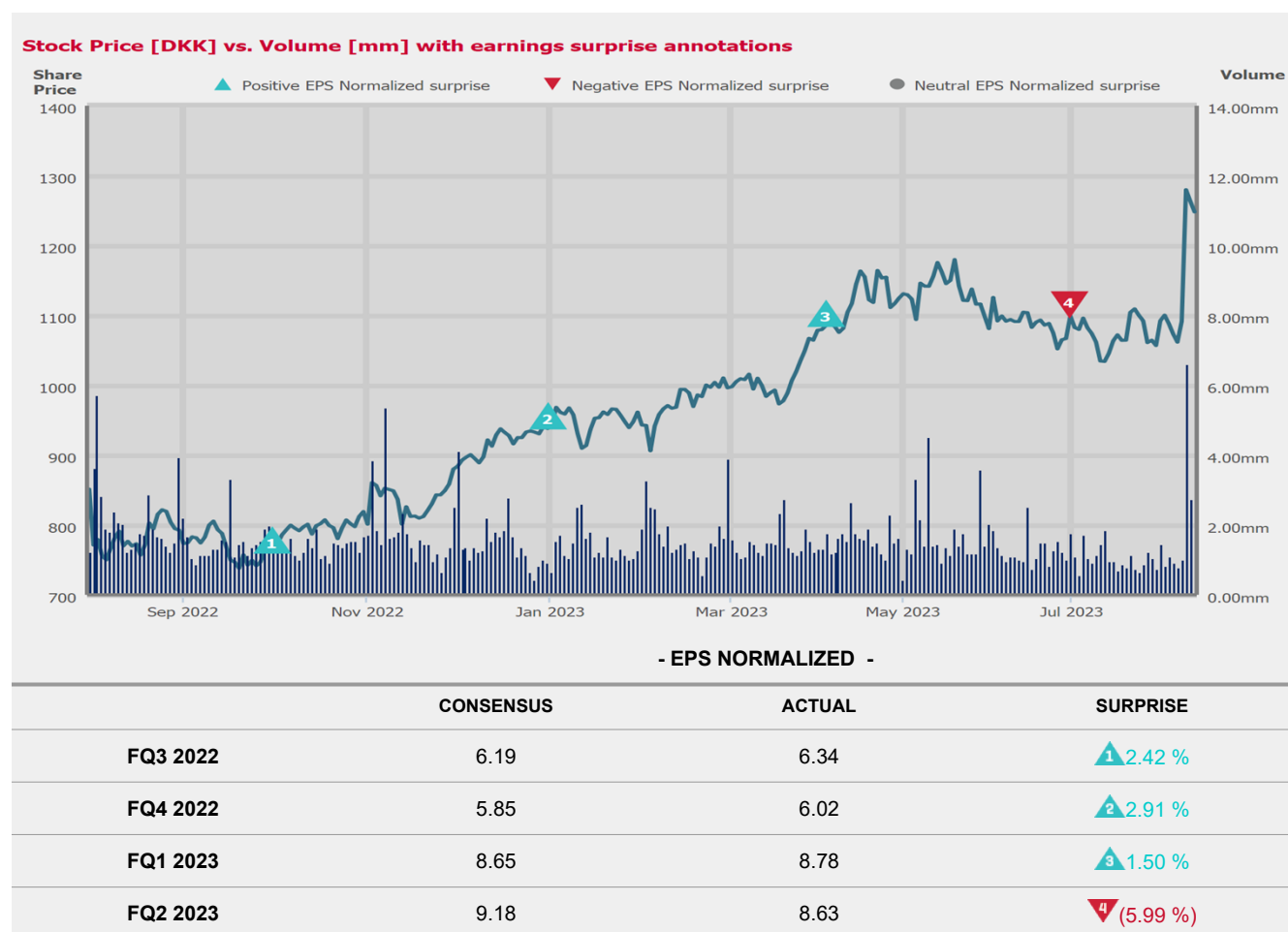


Table of Contents

Call Participants	3
Presentation	4
Question and Answer	7

Call Participants

EXECUTIVES

Camilla Sylvest

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

Daniel Bohsen

CVP & Head of Investor Relations

Karsten Munk Knudsen

*Executive VP, CFO & Member of the
Management Board*

Lars Fruergaard Jorgensen

*President, CEO & Member of
Management Board*

Martin Holst Lange

*Executive VP of Development &
Member of the Management Board*

Peter Verdult

Citigroup Inc., Research Division

Rajesh Kumar

HSBC, Research Division

Richard J. Parkes

BNP Paribas Exane, Research Division

ANALYSTS

Benjamin Yeoh

David Paul Evans

Kepler Cheuvreux, Research Division

Emily Field

Barclays Bank PLC, Research Division

Harry MacKinnon Gillis

*Joh. Berenberg, Gossler & Co. KG,
Research Division*

Jo Walton

Crédit Suisse AG, Research Division

Mark Douglas Purcell

Morgan Stanley, Research Division

Sachin Jain

BofA Securities, Research Division

Simon P. Baker

*Redburn (Europe) Limited, Research
Division*

Presentation

Sachin Jain*BofA Securities, Research Division*

Okay. Everyone, should we get kicked off. Thank you very much. So thanks very much everyone. It's Sachin Jain here from the European Pharma team at BofA. Thank you very much to everyone for coming. It's a real pleasure to be hosting Novo post their results. And obviously, we have a fuller room than anticipated, obviously, Tuesday was a very good day and so demand build. So apologies were tightened here. We have an hour and 15, we have the entire C-suite. I think we have half an hour of presentation and for questions.

So Lars, with that further over to you. Thanks very much.

Lars Fruergaard Jorgensen*President, CEO & Member of Management Board*

Thank you, Sachin. And thank you, Bank of America for hosting us. Indeed, it is a great week for us. We're very excited. It's great to be on the road and talk about where the company is. We will go through the slides relatively quickly, so we can get into the Q&A. I have to advise you that we'll be making some forward-looking statements. And obviously, things can turn out in a different way. So please pay attention to these comments.

So from an overall strategic aspiration point of view, we feel really good about how we're tracking both on our purpose and sustainability. But obviously, really, really strong commercial execution, the 30% growth we had in the first half of this year and the raised guidance underpins both how we are executing commercially but also how we're confident in building capacity to be able to supply to a high and higher degree to this amazing growth opportunity.

We had a major readout this quarter in R&D, not least this week with the SELECT data, very, very comforting for the longer-term prospects of semaglutide in obesity. But it's really a molecule that keeps giving. We have also seen the HFpEF data really leading data in heart failure space and maybe something that goes a bit below the radar. There's been an individual trial for a new molecule, I think, would have attracted even more attention. So really, really encouraging to see how we're broadening out the potential indications for semaglutide and also the all data.

And in the financial quadrant that will also explain a bit more about in the slides, really, really strong growth. We see that we can turn the higher growth momentum into higher operating profit and here also an increased outlook. So really, really strong first half year for Novo Nordisk. We encouraged about our outlook.

And with that, I'll hand over to Camilla for a few more details on the commercial performance.

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

Thank you, Lars. And when we look at our 30% sales growth, you just see here how it is constituted -- I'm just moving in front of the microphone, sorry. Sales growth of 30%, driven by both of our operating units. You see North America 44% growth, IO 17% growth, but also other regions are driving double-digit growth. When we segment the growth into the therapy areas, as you see GLP-1 growth of 50%. You see insulin of minus 7% and then obesity care of 157% and rare D of minus 18%. So basically, more than 100% of our growth is driven by diabetes and obesity.

The growth is driven 71% by North America in terms of share growth and 55% of our sales is now in North America. So that, of course, to a large extent, also is constituted of obesity sales growth. So I'll just dig into that a little bit more on this slide where you see the 150% sales growth in the first half mainly driven by the U.S.

You also know that we have done commercial launches in the U.S., in Denmark, in Norway and most recently in Germany of Wegovy, and we have broad commercial access in the U.S. with more than 80% coverage. And we are, of course, continuing to build supply to cater for this market and these patients. And we are also continuing to make sure that we support continuity of care for patients so that they can keep those who are starting on the product and keep staying on the product. And I'm sure we'll talk much more about the obesity in the Q&A section also.

So I'll hand over now to Martin to talk little bit more about obesity also.

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

Thank you very much, Camilla. So I was also asked by Daniel, to be brief. And I think when it comes to select, that's reasonably easy. You asked us a lot of questions over the last couple of years about SELECT, and that's been interesting. It's really all about 1 number, 20%. You've probably seen the data. We are only disclosing the primary endpoint at this point. And obviously, to see a 20% risk reduction in MACE in the population as we investigated in SELECT. It's no less than stellar from our perspective. It's going to change the way that we see, the way we treat obesity. And obviously, with the safety profile that again confirms the safe approach that we have to the treatment of obesity with semaglutide, we are really, really happy with the data that we've seen.

Next steps, and I've received a lot of questions already about secondary endpoints, about more details about some of the things that all of us both from a clinical, but also from a payer perspective are interested in. You'll have wait a couple of months until the American Heart Association will release more data, both at the actual congress, but also through publications.

And then obviously, we are working hard towards release -- sorry, the regulatory submission of the data in Europe and in U.S. to start. In other R&D news, obviously, we are focusing a lot on oral semaglutide in both diabetes and obesity in the sense that we are planning for U.S. submission in third quarter of this year for both diabetes and obesity 25 and 50-milligram in diabetes, 50-milligram in obesity and then in Europe in Q4, again for both diabetes and -- in CagriSema, we are initiating our Phase III program for Type 2 diabetes. The reason why you don't see CagriSema basically because Phase II has in terms of recruitment being finalized for REDEFINE 2 and 3. And that basically means that we are in the treatment phase, and we are awaiting results.

As a good marker, obviously, you tend to see that it's easier to recruit when patients -- physicians are interested in the drug. And even with 5,000 patients almost being recruited in the CagriSema program, we actually finalized recruitments well ahead of time as compared to our pets. Already talked about SELECT. And I think it's important to also cut as lasted STEP HFpEF trial where we saw Phase III results increasing really, really strong and interesting data on functionality of semaglutide in heart failure with preserved ejection pack.

I think it's also important to call out that these measures of functionality can actually be correlated to outcomes, which is why it's from a regulatory perspective, it's also interesting -- and we can actually expect to see a label update when we combine with the type 2 diabetes results showing the benefits of semaglutide with patients suffering from heart failure.

We terminated a PYY agonist program earlier this year basically based on not sufficient efficacy results, not leading to a differentiated profile. And as you know, we have a very strong opinion on not progressing, not differentiated assets. And then maybe in rare disease, obviously, remind you that somapacitan has been approved in both Europe and Japan for treatment of children with growth hormone deficiency. And as some of you also have noticed, we've announced that we've initiated a Phase III program for ziltivekimab. It's actually an outcomes trial in heart failure with preserved detection.

And with that, over to Karsten.

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

Thank you, Martin, for a brief and selective presentation. So first half results, 30% growth, but of course, looking at the quarters, I would be remittent if not saying 36% growth in the second quarter, probably the strongest growth in the history of the company, for sure, it is in absolute terms. So really a staggering growth level delivered through our portfolio as Camilla presented.

Through that growth, we're investing in the company, first of all, in our supply chain. So we're building our supply chain. We invest in building the obesity market and, of course, invest in building an attractive and competitive pipeline in both the medium and long term. And still, we are able to return operating profit growth of 32% and an earnings per share growth for the first half of 44%.

Outlook for the year, we raised both sales and OP outlook by 3 percentage points that's not even the most impressive part of it because in reality, our outlook for the year mimics the growth rate we saw in the first half. So we deliver 30% in the first half midpoint for the full year is a 30% growth, 3-0 percent growth. So really impressive growth in an industry which is perhaps growing to the tune of low to mid-single digits. Same for operating profit growth even higher in the sense that we get some gearing, of course, linked to our sales growth.

So a guidance now of between 31% and 37% operating profit growth. Currency is unchanged compared to last and a slight downgrade on our free cash flow. And this is purely because our free cash flow definition includes cash flow going to business development activities. As we disclosed, we have done the BIOCORP acquisition on connected devices, and we have the Inversago acquisition. So adjusting for that, then we're actually increasing our free cash flow in line with the strengthening business outlook.

Copyright © 2023 S&P Global Market Intelligence, a division of S&P Global Inc. All Rights reserved.

So much for the outlook and then Lars on strategic aspirations.

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

Yes. I alluded a bit to it in the beginning. We feel comfortable in how we are progressing on our strategic aspirations, an amazing demand for our CB1-based product portfolio. And I think we're executing quite well in taking that opportunity and converting that into sales. And I think you should also rest assured that we're investing what is needed for us to scale capacities to continuously grow and aim to meet that demand. Pipeline progress is equally important for us. I think we have a very long underpinned growth opportunity with semaglutide based on the SELECT data. In parallel, we're building late and early-stage pipeline. And we are quite comfortable that we can add that on top of the growth prospect that semaglutide provides.

So I'll leave with that, and we should then go to the Q&A session, which Daniel will moderate. And maybe we should all come up here and stand so we can easily go to the podium.

Question and Answer

Daniel Bohsen

CVP & Head of Investor Relations

Yes. Thank you, Lars. So I will moderate the Q&A session. Please clearly state your name and institution. And let's go for one question per person, and then we can take different rounds if time allows. And as always, I think we should give the first question to our host, Sachin Jain.

Sachin Jain

BofA Securities, Research Division

Great. Sachin Jain. Going to be challenge for me to have one. So I'm going to have 1 in 2 parts, if that's all right. I'm going to do sema heart failure for me. You've mentioned a couple of times you believe it's underappreciated. So one for Martin, if you can talk about the correlation of this function outcomes to hard outcomes when we see data at ASC in a few weeks, you get hard outcomes data that gets across the 10% to 15% threshold of people. Cardiologists typically think clinically relevant, Camilla, any simple thing if you could just outline the commercial opportunities as an add-on to standard of care.

Martin Holst Lange

Executive VP of Development & Member of the Management Board

So both the KCCQ and the 6 minute walking test can be correlated to outcomes. Obviously, it's always a little bit difficult to quantify that correlation. But it is to a level and it's so well established that from a regulatory perspective, it's actually possible to get both the 6-minute walking test and KCCQ to a label. I think it's important for us to call out that -- and again, we can't disclose the data, but we will obviously be looking at also SELECT where we had at baseline 25% of patients having stable heart failure. And therefore, there's a big opportunity to leak into the SELECT data as a secondary endpoint and evaluate this may have impact on heart failure. That will allow us to potentially not only get the functionality assessment into the label, but also maybe even harder endpoints, depending on, obviously, the data and our interactions with the regulators.

Camilla Sylvest

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

Okay. Thank you, Martin. And in terms of potential, we estimate that approximately 25 million to 30 million people living with HFpEF, of course, a big, big part of them are living with obesity also. So in principle, one could say that Wegovy label almost cover that, if you say a BMI above 27% and obesity-related comorbidities, but it will be very important for us to actually get it in the label so that we're able to promote that. And with that, of course, we are able to establish a differentiator with Wegovy compared to other treatments.

Daniel Bohsen

CVP & Head of Investor Relations

Thank you, Martin. Thanks, Camilla. So we're ready for the next, and I will give it to Emily.

Emily Field

Barclays Bank PLC, Research Division

Emily Field from Barclays. I wanted to follow up on one of Doug Langa's answers yesterday about SELECT maybe having the potential to change the attitude of Medicare? Just how would that work is that you need to have that added to the label first and then Medicare could have those discussions? And then also if there was -- I believe the treatment prevent obesity was reintroduced into the Senate this summer. So any updates on the progression of that legislation?

Daniel Bohsen

CVP & Head of Investor Relations

Thanks Emily. Lars, will you take that?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

Yes. So it's a political process, obviously, and it's hard to predict around that. I feel confident that we'll end up having a courage in Medicare. Exactly when it will happen is hard for us to imagine. You're right that there is now -- it seems like there's bipartisan support of that. But I also know there's a lot of other health care discussions going on. So how this priority is hard to say. You can imagine then when a population has been on obesity treatment in, say, in the workforce and being active taxpayers and eventually retire.

You would also expect to have support for such an intervention there. So I think we'll get there. Short term, it's not something that's rate-limiting for our ability to drive growth because we have maybe 0.5 million patients on treatment, and we have access to 45 million patients. So there's ample of patients for us to source from short term as we build this broad access.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you. We are ready for the next question. I'll give it to Mark Purcell.

Mark Douglas Purcell
Morgan Stanley, Research Division

Thank you, Daniel. It's Mark Purcell from Morgan Stanley. A question for Martin. Martin, when you look back at outcome trials, including SUSTAIN 6, PIONEER 6 you look at the STEP program, you look at the NASH studies. Could you help us understand what percentage of the cardiovascular benefit you believe is weight related? And what percentage is non-weight-related? And maybe then to Camilla, how will you educate and promote the message that the quality of weight loss might be different with sema versus competing incretins?

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

Thanks very much for what I think is a very important question. Obviously, we can see across the board maybe take a step back. When we look at the effect of, for example, semaglutide on cardiovascular benefit, we can look at different variables and their attribution to that effect. And we do that through what we call a mediation analysis. And in that, we can look at various different parameters.

It's relevant, for example, for semaglutide to look at weight loss to look at glycemic control, to look at blood pressure, to look at lipid lowering and potentially also to look at inflammation and other factors. And we know already from diabetes that -- it's not a loss. It's not just a glycemic control. In all of our stories, the anti-inflammatory effects of semaglutide has popped up as being quite important, almost out there with the weight loss and the glycemic control.

I can't disclose the data from SELECT but obviously, we will do mediation analysis here also to explain how -- what is driving the 20% MACE benefit that we see with semaglutide. And my assumption will be that just like we see it in diabetes, it will be in part weight loss, but it will also be the anti-inflammatory effects, but probably also some glycemic control and the other parameters. So I think it's important to take a holistic approach to this. It's not just about the weight loss. It's not just about utilizing control, but it's the bigger picture of benefits that we see with semaglutide.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Martin. And a quick comment from you, Camilla.

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

Yes. So exactly as a follow-up to what Martin is saying, with Wegovy, that is the only product that so far has proven the cardiovascular outcomes reduction in terms of MACE benefit. And when we will disclose a little bit more about the elements of that, then that is, of course, also a clear differentiator for us in terms of how we will promote the products going forward. And you will hear much more about that when we publish more details. But what we can promote always depends on what Martin can deliver. So that's how things are constructed.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Camilla. We'll move down here to Pete.

Peter Verdult*Citigroup Inc., Research Division*

Peter Verdult, Citi. One question, Martin again. Rewind and sustain, if I recall, the event rate was around 9% to 12%, and I realize that's a different population, they were diabetics. But I'm not asking you to disclose the data SELECT, but can you just help us -- I'm assuming that this population, the assumed event rate was much lower. Is that a fair assumption? Or can you at least tell us going into the study? I don't want to know the data but what you were assuming the event rate would be in this population.

Daniel Bohsen*CVP & Head of Investor Relations*

Thanks, Pete. And Martin, Pete doesn't want to know the data, but you still had a question.

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

So you're exactly right. Our assumptions were that typically, we hear on a maybe a little more per year with SELECT we assumed approximately half of that. And I think it's fair to say, without disclosing any data, we were not that far off, slightly above 2.

Daniel Bohsen*CVP & Head of Investor Relations*

Thanks, Martin. We'll move to Simon here.

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

Simon Baker from Redburn. I'll kick this one a bit more general because we've been asked this a lot this week. And a question is on margins and the outlook for margins. There are 2 schools of thought that given your growth, there is inevitably significant operational leverage in the business and margins will rise significantly over time. There are others saying that you have a lot of investment in R&D going forward as you broaden your therapeutic base.

And there are others saying there's only so far you can let margins rise before it becomes an issue with payers. So the question is not such a guidance, but how do we think about that in terms of how far margins could rise and how far margins should rise over time?

Daniel Bohsen*CVP & Head of Investor Relations*

Karsten, I think that's for you.

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

That's well selected, Daniel. So in terms of margin, as we commented on before, our starting point being north of 40% in terms of operating margin is top quartile industry. We're not adjusting for anything, as you know. So a really competitive starting point. So our strategy as a company in terms of resource allocation is not driven by margin leverage. It's driven by top line growth. Top line growth is really our top priority then investing in the business in a rational way. And so at the last Capital Markets Day, we indicated it will be broadly flat given different puts and takes, especially investing in R&D.

And -- but what we didn't fully foresee at the last CMD is quarters like we just passed with 36% growth. And as I said at Q1, when we grow at this pace, then there will be margin leverage. The magnitude of margin leverage is, of course, depending on the investment opportunity. So if I just go through some of the main puts and takes, then for our gross margin, then given the product mix of what's driving top line growth, then that creates a margin -- a gross margin expansion opportunity. Of course, it's partially being offset by some pricing/mix.

And secondly, it's also being impacted by our significant CapEx program because part of our CapEx program even though most goes to the balance sheet, there are certain parts that goes into the P&L. But net-net, slightly improving gross margin. It's already at a high level, as you know, at 85. SG&A, there we'll have leverage since we have the infrastructure more or less in place. There will be investments in driving and delivering on the growth opportunities we have.

But of course, when we are rate limited on certain products, then of course, we don't put more money behind it. That would be a distraction. And then finally, in R&D, this really comes back to the opportunity. So we see -- when you look at our R&D ratio, then

below industry -- and of course, with the growth rate we have, we also need to replenish our pipeline to build our company for the longer term. And that's where we're stepping up both in our anti -- and when you look at this year Inversago, I'm not adjusting for anything linked to BD, right? So that's part of the 3 percentage point guidance upgrade this year. That covers whatever trial running cost related to Inversago as an example, and BIOCORP.

So I expect R&D ratio to go up over time. And net-net, this year, around 30% sales growth that will deliver margin expansion. And then we'll come back to more specifically in the years to come when we come on top line guidance. To what extent that opens up for margin expansion.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Karsten. So we are ready for the next.

Jo Walton
Crédit Suisse AG, Research Division

Jo Walton at Credit Suisse. I'm going to follow on from Simon, I think. And just look at pricing going forward. So it's all very well having a drug that you sold to 0.5 million people. But if you sell it to 45 million people, society isn't going to pay anywhere near the same price. And I would imagine that at the moment because everybody, yourselves and Lilly, both in diabetes and obesity are capacity constrained. You're actually okay on pricing. But if I look going forward, I wonder how competitive that might be and how low the prices might go.

I note, for example, that Kaiser Permanente is removed Ozempic and Trulicity and gone 100% Mounjaro for their Medicare plan, at least that's what it says on the website. So that's just giving you an idea that there are payers out there who could just go 1 way or the other. So I was wondering how you felt we should be looking at pricing because we're very good at assuming that there's massive increase in penetration, and we're not always as good at assuming that the price comes down to match.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Jo. Karsten or Lars, I don't know who want to go.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So in our obesity price point, that is somehow say, historically determined because there was, say, an anchor point in the diabetes indication for Victoza in the market. And then because of linearity, we ended up at the price point we are at now. And then you can say, what is the payer reaction so far, that is actually a willingness to pay that. And that also goes when the payer is an individual person that has tried a lot of different attempts to lose weight.

So I actually think there is an attractive value case. And that value case is just getting better because many of those patients, as alluded to by Camilla and Martin are living with a number of diseases. And now we have a product like Wegovy that's about to be unfold in the number of indications that is actually supporting and many patients would benefit from all of these indications.

We also know that depending on which market we're talking about, that we typically launch at the highest price and then rebate takes it down over time despite the fact that we actually add more and more value to the product. If you look in the single payer territory like what we have in Europe, I think payers are trying to figure out how can we open up for obesity medicine. And we're also trying to look at how can we actually make sure that -- when you get to markets, we actually collaborate with single payers in making sure that those who are structuring the most, that is a psychonomic element to obesity also that those who would not be able to pay out of pocket themselves that we actually work with health care systems to make sure that they are addressed, acknowledging that no health care systems would actually be able to cater for the patients.

And then there will be out-of-pocket segments. So I think we'll see different payer channels or structures, so to say, in different markets where we have an opportunity of getting to actually creating a societal impact that's recognized and that the payers will be willing to pay for, whether that's a health care system or individuals. And I think we'll have an immense impact on health at a population level by this intervention that I think will be recognized and appreciated.

Daniel Bohsen
CVP & Head of Investor Relations

So we'll go here to Richard.

Richard J. Parkes
BNP Paribas Exane, Research Division

Richard Parkes from BNP Paribas Exane. Just on SELECT, so in theory, if you get a secondary prevention label from the FDA, that could allow for Medicare reimbursement. So I'm just wondering how confident you are that might be the case? And what number of patients or individuals that could unlock? I think it feels like it could be 10 million to 15 million lives in the U.S. So just wondering if you could talk about that.

Daniel Bohsen
CVP & Head of Investor Relations

Karsten, will you take that?

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

So thanks for that question. And I think it puts a little bit on what we discussed before. So getting it on label, of course, strengthens our position, vis-a-vis, that is obese medication should be available for all people with obesity in the U.S. When we look at the magnitude, as Lars covered before, if you look at it today, call it, 100 million adults with obesity in the U.S., almost half of those with insurance coverage and 1% of those with insurance coverage on nonalcoholic medication today, 1%.

So the runway on what we have currently is fantastic. But -- and then with the Medicare coming on, it's a political process. So there's no simple causality between clinical trial outcomes even though we would like it and then legislation because it requires a list of change. That's a political process. It will come, we think, but it's politics. Let's see when it comes.

Richard J. Parkes
BNP Paribas Exane, Research Division

I suppose my question was could allow for reimbursement by Medicare with outlets and for the secondary endpoint...

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

So it is a potential, but that's something we're looking into whether -- but it would not being necessarily slammed on to get a broader approach to Medicare Part D through the CV benefit or the heart failure trial. But there could be some opening, vis-a-vis, reimbursement, but it's not something that is fully clarified at this point, what would the process be in terms of, you could say, if not the STEP at it, but the paper work to get to that reimbursement. So that's not clarified at this point. Sorry for not being clear.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Karsten. So we'll move over here.

Rajesh Kumar
HSBC, Research Division

Rajesh Kumar from HSBC. Just -- thank you very much for indicating that you're putting up R&D. You would invest more. When you think of capital allocation over the next 3 to 5 years, which -- would it be more towards organic R&D or acquisitions? And if so, how do you -- what are the thresholds you put internally? So in that context, if you could help us unpack the latest valuation you paid for the acquisition, what was the thinking behind it? What was the logic? And cannabinoid receptor, a lot of get worried when we hear about that. But you found DKK 1 billion-plus valuation for that. So it would really help if you could unpack that.

Daniel Bohsen
CVP & Head of Investor Relations

I don't know, Martin, if you will start by giving the rationale from your perspective and then others can chip in.

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

I wanted to chip in here. But I think when we look at in versus external innovation, it's very, very clear. You will not be successful with external innovation if you don't have very strong internal innovation. So without putting a number, it's very, very clear, we have an ambition in all of our disease areas to have strong internal innovation, but then complement our internal innovation with what we can acquire from the external. We also have a very clear approach where we go externally. We are not going for late-staged assays. We are going to look at assays that are in late clinical, early clinical, so we can deliver the value and build on those opportunities. .

Obviously, there's a little bit of a high risk, but there's also more value creation by taking this approach. Specifically for the Inversago, I don't think you should be worried because you're absolutely right with the CB1 antagonism that there have been historically problems. But these are molecules that have primarily worked in the central part of the body, so in the brain, where they obviously introduced some efficacy in terms of wait loss, but also some quite serious side effects.

With the INV202, we have a CB1 inverse agonist that primarily works in the peripheral tissue. That actually calls for a really good efficacy but also calling for minimization of the historical adverse effects because the impact on the brain is minimized. And that also means that when we look at clinical data, it was very, very clear in the historical trials, it was present in 30% of the patients. So it's pretty easy to spot. And it occurred within 2 to 3 weeks after treatment initiation.

So we can actually allow ourselves to look at the clinical data even if it's Phase I/II data that we're looking at -- and we'll get some confidence that say that they had actually managed to derisk this through a peripheral mode of action and not a central mode of action. So then we take a very deliberate approach to how we do excel innovation and investment. And I don't think you should be too concerned about the CLAVO acquisition.

Daniel Bohsen
CVP & Head of Investor Relations

And for clarification, Karsten on evaluation?

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

Yes. Very briefly, the DKK 1 billion you alluded to, that's a biotech dollars. So we didn't pay DKK 1 billion upfront, just to be clear about that. And the way we think about it is basically, we do an asset valuation like we do on our internal projects, including upfront and whatever subsequent liabilities. And compare that to the risk of the project and the potential future value opportunity in the space.

And I think this one is actually from a -- and then we do deriskings on top of that. So pretty straightforward as any other asset acquisition. And on this one specifically, I think it works out nicely between the upfront and the risk and the market opportunity. And then we front-load, the derisking of the assets. So from a financial point of view, the CFO is having.

Daniel Bohsen
CVP & Head of Investor Relations

That's good to know, Karsten. And David, we'll move to you.

David Paul Evans
Kepler Cheuvreux, Research Division

Dave Evans from Kepler Cheuvreux. So just a question on the SELECT study population. So as I understand this is kind of a subset of ASCVD patients basically, so probably less than 10% of the overall obesity population, if that's fair. I mean, can we extrapolate the results to the broader population and patients who are just CV risk. I mean, especially given what we saw in Leader in SUSTAIN 6 that there was a big difference between efficacy in patients with preexisting CV disease, not really not much of a trend in patients without. So is it actually a different debate around whether you get coverage in ASCVD patients versus the broader population? Or will payers look at this somehow the same population or read across?

Daniel Bohsen
CVP & Head of Investor Relations

I think, Martin, you can start.

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

Maybe also Camilla wants to chip in. But we have to distinguish between secondary prevention and primary prevention. What we've done with SELECT is secondary prevention. So we have investigated in patients with overweight obesity and a combination of either prior myocardial price drop and peripheral artery disease. It's actually a fairly large shop population, if you will, in the obesity space. And to coming to this point, if there's 750 million people out there, even 10% would be a quite sizable. I actually think it's slightly above 10%.

I don't want to speculate whether payers will extrapolate to primary prevention. We have seen actually in the diabetes space that are examples that if you show secondary prevention, you will likely also show primary prevention. We ourselves are looking into primary prevention within diabetes. I think it's fair to say that we will also discuss whether we need to do that with the obesity. At this point in time, I don't think from a commercial perspective, it's required. But I think it would be interesting to know that from a clinical perspective, so we can continue to guide our prescribing physicians.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Martin. Camilla, a quick follow-up.

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

Yes, just very shortly to say that 2 out of 3 people living with obesity die from cardiovascular disease, and we know that they incur 2 to 3x higher cost in the health care system. So of course, with the SELECT data as likely to be a high interest from payers to understand how we can bring down those costs.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Camilla. I'll give the mic to Ben.

Benjamin Yeoh

It's Ben Yeoh at RBC Asset Management. I had a question guys on human capital and organizational resilience. Would you say your execution is average or above average or maybe even below? And you guys are hiring probably at the fastest rate you have ever hired and that obviously causes a lot of friction.

Do you feel that this hiring and the resilience is going well? Do you have enough good people to execute because obviously, a bit supply constrained now, but you're going to need thousands of good people to do this. So I'd be interested on some comments on the human capital side.

Daniel Bohsen
CVP & Head of Investor Relations

I'll give the word to you, Lars.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you. So I think it's a great question. We are a people business. It is people at the end of the day that turns the facilities into products, R&D, et cetera. And the very good point, we have recruited some 8,500 people over a year. So if you talk about, say, whether that's working, you say the HR department is working because they have actually recruited these people the majority of them goes into manufacturing. And when you work in manufacturing, obviously, you need to work in compliance. So there's a significant onboarding task and training task going on.

And when we talk about ramping up capacity and supplies, that's of course, a function of that, that it takes time to train people. I believe, and I have to make the disclaimer that I'm biased because I've been with the company for 32 years. I believe we have a unique culture, what we call the Novo Nordisk way, based on a set of personal values that we actually assess leaders on whether they walk work each and every day and the consequences of not doing that.

So I spent quite some time in understanding from newcomers how they assess joining Novo Nordisk. And the first comment I typically get is one in relation to the culture and the consistency between what we actually say we do and what we do. And apparently, that's a unique feature. And I don't know because I've never tried other places than Novo Nordisk. So it's something we really work

hard on. And we're right now rolling out say, a double down on Novo Nordisk way onboarding and education because among those 8,500 new colleagues are also leaders. So it's really, really important for me, my colleagues and each and everyone work to talk in terms of culture. I think that's the best guarantee for turning that investment in people into assets that helps patients at the end of the day.

Daniel Bohsen

CVP & Head of Investor Relations

Thanks, Lars. We have one here.

Harry MacKinnon Gillis

Joh. Berenberg, Gossler & Co. KG, Research Division

Harry Gillis from Berenberg. So just a quick question on oral Wegovy and whether you can give any indication when you may look to assuming approval when you may launch this product? I'm just trying to understand a sense of how viable a large-scale launch would be given the sort of higher API requirements? And so do you feel confident that maybe in the sort of medium term, you'll be able to meet those requirements? And if I may also ask, just -- I know you may not sort of give any details, but at a high level how you may think about pricing the sort of oral version versus the injectable?

Daniel Bohsen

CVP & Head of Investor Relations

Thanks for that question. Camilla?

Camilla Sylvest

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

Yes. So while I cannot comment on pricing at this point in time, I can comment on the perspective of 50-milligram semaglutide, oral semaglutide. Of course, we are very happy with the result that shows similar efficacy to Wegovy is 2.4 milligram. When we are looking at time to launch, we first need to, of course, this approved. And after approval, we will be considering how we can scale this depending of course, on demand, and capacity.

I'm saying that because, of course, you all know that an oral version requires more APIs than an injectable version. So this rollout, of course, is likely to be depending on how things are developing at that point in time in terms of demand and supply, knowing that we want to make sure we can cater for as many patients as possible. And the demand right now seems to be, of course, very high. And therefore, those are the considerations we have. But much more about that when it's all approved.

Daniel Bohsen

CVP & Head of Investor Relations

Thank you so much, Camilla. So we have time for a few more questions. I think we're back at our host.

Sachin Jain

BofA Securities, Research Division

Sachin Jain, Bank of America, again. One for Martin and then one big picture. Would it really discuss GGG much at ADA, and you had a similar mechanism internally that you sort of preferred category for just any perspectives on how you believe you'll follow on compared to Lilly's follow-on. And I guess if you could just comment on your perspective on safety and then diabetes profile because I don't think they started with Phase III in diabetes.

And then a big picture for Lars. This is a question I get a fair bit, and I'm not sure it's a straightforward answer. GLP-1 consensus at peak cross Novo in Lilly is in the DKK 80 million to DKK 100 million range now. And a question I frequently get even post SELECT is how can the system digest a number much bigger than that. So I wonder if you can touch on that from a couple of aspects in terms of indication breadth, how you think about cash pay of the market? Will the payers digest a much bigger percentage of the pie being a single molecule drug class?

Daniel Bohsen

CVP & Head of Investor Relations

Thanks, Sachin. We'll start with you, Martin, followed by Lars.

Martin Holst Lange

Executive VP of Development & Member of the Management Board

So I'll not do direct comparisons between our pipeline and our competitors. But I think I can do maybe an indirect in the sense that we also had a GGG in our pipeline a couple of years ago. And we obviously also did a clinical assessment of that. In that, we obviously found it works. It gives a good weight loss, and it could potentially also have a good impact in NASH. But it was more difficult in the diabetes space. There is some inherent challenges in that with glucagon. And maybe the combination and the ratios can rectify that a little bit.

But we also saw other safety issues in the cardiovascular space and had some concerns about the broad in metabolism and effects of glucagon as well. Given that we had agreed we had CagriSema and we have a GGG in our pipeline and we actually saw better efficacy with CagriSema and a more clean safety profile. From a pipeline perspective, that was an easy choice.

And therefore, I don't want to speculate what others are doing. I wish them best of luck. I think from an efficacy perspective, we'll see it works. But obviously, again, we are very confident with the efficacy of CagriSema both in diabetes and in obesity. And we're also very confident of the safety profile of CagriSema in diabetes and obesity.

Daniel Bohsen

CVP & Head of Investor Relations

Thanks, Martin. And Lars?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

So I think there's no doubt that the GLP-1 opportunity is a very, very sizable one. And your guess about how large this become is as good as ours. I think it's important to dissect this into a number of health benefits. We started looking at type 2 diabetes. We added CV benefit to that. We're now looking at obesity, adding CV benefit to that. We spoke about the HFpEF data in the SELECT study. We started a number of other outcomes. So I think to really assess how big is this drug class and what does it mean for payers. We actually need to start segmenting the value story from a medical benefit position.

And the population we serve, living with, say, broad cardiometabolic disorders. They would otherwise end up on, say, a handful or 2 handfuls of different individual medicines to deal with these medical conditions. And I think it's really attractive is there's one mechanism that can do it all. And I think it creates flexibility in actually how we can -- you can define the value story for payers because they can chip in different values depending on which population they look at. And I think that's a really, really attractive case for us to be engaged here.

Daniel Bohsen

CVP & Head of Investor Relations

Yes. We'll take one final question before we wrap up, but there will still be time for networking.

Mark Douglas Purcell

Morgan Stanley, Research Division

Mark Purcell from Morgan Stanley. Martin, could you give us your latest thoughts on oral approaches for obesity. So small molecules versus peptides. I guess, covered in this SemaDapa, the decision or to move forward there. Was that a technical reason why you're not moving forward? Can you combine small molecules with the stack technology? Or is there something that you can't do that?

And then it's a question of now having done the Inversago deal, and you've talked about combinations. Are you looking at plus small molecule combinations? Or can you combine peptide and small molecules together.

Daniel Bohsen

CVP & Head of Investor Relations

Thanks, Mark. Martin?

Martin Holst Lange

Executive VP of Development & Member of the Management Board

I think both in the incretin space, but also moving across the incretin space, it's always relevant to look at different modalities that obviously comes also to small molecule versus peptide based. From our perspective, what we've seen with the OASIS program with

the PIONEER PLUS program, I think if we just look at GLP-1, it's going to be from an efficacy and safety perspective, it will be difficult to show even better efficacy or safety as compared to that.

And obviously, that's why we're excited with the PIONEER PLUS and the OASIS data. I think, broadly speaking, if we move them beyond, for example, to Inversago combination, is interesting. I think we see that with our own CagriSema. We see that also from some of our competitors in order to increase efficacy but without having to compromise on safety. We can do that in loose combination combining a subcutaneous and on all, but we could potentially also be looking at combining potential small molecules with small molecules.

Specifically on SemaDapa, you're absolutely right. We terminated that on technical reasons basically because was not really a differentiated profile we saw and showing superiority to the mono components is requiring a really big development program. It was maybe not really warranted in this space.

Daniel Bohsen

CVP & Head of Investor Relations

Thank you, Martin. So that concludes our Q&A session. We'll still have a bit of time for networking and opportunity to talk with management. But before we close, finally, Lars any final words from you?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

I'd just like to take this opportunity to thank Sachin and Bank of America for hosting us for all of you coming and the good questions and also you participating on the live stream. As you can hopefully hear, we're hugely excited about the momentum in Novo Nordisk right now. We're equally excited about both the short and the medium and long-term growth prospects of the portfolio of products we have and what we have in our pipeline. So we look forward to report back to you in the coming quarters on this progress. Thank you.

Copyright © 2023 by S&P Global Market Intelligence, a division of S&P Global Inc. All rights reserved.

These materials have been prepared solely for information purposes based upon information generally available to the public and from sources believed to be reliable. No content (including index data, ratings, credit-related analyses and data, research, model, software or other application or output therefrom) or any part thereof (Content) may be modified, reverse engineered, reproduced or distributed in any form by any means, or stored in a database or retrieval system, without the prior written permission of S&P Global Market Intelligence or its affiliates (collectively, S&P Global). The Content shall not be used for any unlawful or unauthorized purposes. S&P Global and any third-party providers, (collectively S&P Global Parties) do not guarantee the accuracy, completeness, timeliness or availability of the Content. S&P Global Parties are not responsible for any errors or omissions, regardless of the cause, for the results obtained from the use of the Content. THE CONTENT IS PROVIDED ON "AS IS" BASIS. S&P GLOBAL PARTIES DISCLAIM ANY AND ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, FREEDOM FROM BUGS, SOFTWARE ERRORS OR DEFECTS, THAT THE CONTENT'S FUNCTIONING WILL BE UNINTERRUPTED OR THAT THE CONTENT WILL OPERATE WITH ANY SOFTWARE OR HARDWARE CONFIGURATION. In no event shall S&P Global Parties be liable to any party for any direct, indirect, incidental, exemplary, compensatory, punitive, special or consequential damages, costs, expenses, legal fees, or losses (including, without limitation, lost income or lost profits and opportunity costs or losses caused by negligence) in connection with any use of the Content even if advised of the possibility of such damages. S&P Global Market Intelligence's opinions, quotes and credit-related and other analyses are statements of opinion as of the date they are expressed and not statements of fact or recommendations to purchase, hold, or sell any securities or to make any investment decisions, and do not address the suitability of any security. S&P Global Market Intelligence may provide index data. Direct investment in an index is not possible. Exposure to an asset class represented by an index is available through investable instruments based on that index. S&P Global Market Intelligence assumes no obligation to update the Content following publication in any form or format. The Content should not be relied on and is not a substitute for the skill, judgment and experience of the user, its management, employees, advisors and/or clients when making investment and other business decisions. S&P Global Market Intelligence does not act as a fiduciary or an investment advisor except where registered as such. S&P Global keeps certain activities of its divisions separate from each other in order to preserve the independence and objectivity of their respective activities. As a result, certain divisions of S&P Global may have information that is not available to other S&P Global divisions. S&P Global has established policies and procedures to maintain the confidentiality of certain nonpublic information received in connection with each analytical process.

S&P Global may receive compensation for its ratings and certain analyses, normally from issuers or underwriters of securities or from obligors. S&P Global reserves the right to disseminate its opinions and analyses. S&P Global's public ratings and analyses are made available on its Web sites, www.standardandpoors.com (free of charge), and www.ratingsdirect.com and www.globalcreditportal.com (subscription), and may be distributed through other means, including via S&P Global publications and third-party redistributors. Additional information about our ratings fees is available at www.standardandpoors.com/usratingsfees.

© 2023 S&P Global Market Intelligence.