S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

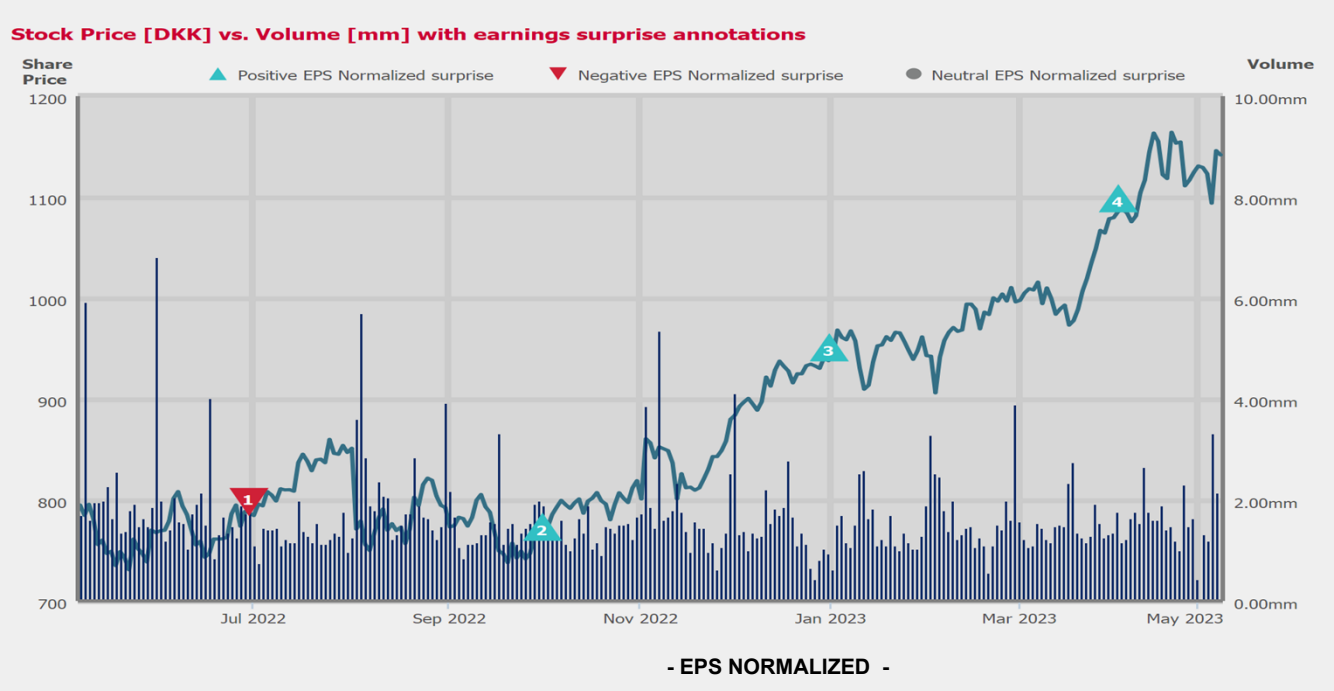
FQ1 2023 Earnings Call Transcripts

Tuesday, May 9, 2023 12:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ1 2023-			-FQ2 2023-	-FY 2023-	-FY 2024-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	8.55	8.78	2.69	9.15	35.32	NA
Revenue (mm)	52191.82	53367.00	2.25	52874.91	222257.95	NA

Currency: DKK
Consensus as of May-10-2023 9:00 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2022	6.04	5.86	(2.98 %)
FQ3 2022	6.19	6.34	2.42 %
FQ4 2022	5.85	6.02	2.91 %
FQ1 2023	8.55	8.78	2.69 %

Table of Contents

Call Participants 3
Presentation 4
Question and Answer 7

Call Participants

EXECUTIVES

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

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

Peter Hugreffe Ankersen
Head of Investor Relations & Corporate VP

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Peter Verdult
Citigroup Inc., Research Division

Peter James Welford
Jefferies LLC, Research Division

Rajan Sharma
Goldman Sachs Group, Inc., Research Division

Richard Vosser
JPMorgan Chase & Co, Research Division

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Redburn (Europe) Limited, Research Division

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ATTENDEES

Unknown Attendee

Presentation

Peter Hugreffe Ankersen
Head of Investor Relations & Corporate VP

Actually, it's Pete Verdult from Citi. So welcome, everyone. On behalf of Citi, delighted to have Karsten Knudsen, Group CFO; and Martin Lange, Head of R&D; plus various members of the Novo [Nordisk] team in London for the Q1 roadshow. You all know the drill, short presentation and then straight into Q&A. A bit of housekeeping. There are microphones on each of the tables, which are on currently. So if you can all have your phones on silent and try and eat quietly and cluster less, that'll be fantastic.

So without further ado, Karsten Knudsen. Thank you.

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

Thanks, Pete, and thanks for the invitation and you're hosting our Novo Nordisk Q1 roadshow in the London lunch meeting in conjunction with Q1. We're bringing fantastic set of numbers. So it's great to be in London and see you all and also for the ones being available online.

So as Pete said, a few slides and then over to Q&A. And I'm sure we'll have some questions about the future and how the things are going to pan out. So -- and as you know, the future has a tendency to play out differently compared to what we expect based on today's knowledge. So that's the usual cautionary statement in terms of forward-looking commentary.

When we look at our strategic aspirations, and you've all seen them before, this is how we hold ourselves accountable, especially you, in terms of our strategy execution as a company. And not going through all the details but just saying when we look at Purpose and Sustainability, ESG, if you will, we are progressing very nicely both in terms of our patient reach, our CO2 emissions as well as being a sustainable employer and the diversity targets we've set out there. [Pipeline margin], we'll get back to but very good progress across these areas. I think this is a very exciting year for Novo Nordisk in terms of readouts on a number of very exciting trials.

And then as to commercial execution, then we continue to be the global leader in diabetes with a global diabetes value market share of 32% now, growing by 1.7% over the last year. We are more than doubling our obesity franchise, of course, driven by the relaunch of Wegovy, mainly in the U.S. And then finally, our rare disease business is down 16%. We, unfortunately, had some very unfortunate production challenges on our rare endocrine side, which pulled down sales growth on rare disease.

And all of that yields a top line growth for the quarter of 25% and operating profit of 28% and corresponding capital allocation to shareholders while we still continue to invest in our business CapEx, et cetera.

Going through our commercial performance for the quarter. I think what is really worth noting is a step-up in sales growth in North America, 41%, really being a key driver of the Novo business growth in the quarter, the 25%. I do note that we had some wholesale inventory fluctuation in the quarter, amplifying the North American and hence group results. However, when we look at the full year, I think we're still operating in the 20s in terms of top line growth.

IO continuing to deliver double-digit growth driven by the different geographies. And one note on China being down 5% in the quarter, the good part about the 5% is, first of all, that this is the last quarter with impact from VBP on the growth rates. So now we'll have annualized it when we get into Q2. And secondly, when you look at our Chinese business results, then of course, we have been moving our resources towards Ozempic and Ryzodeg our growth opportunities in the market and showing very strong growth there. And hence, you should expect us coming back to growth already from the second quarter and almost in China.

As to therapies, the 25% growth is really being driven by GLP-1 in diabetes, now constituting around 50% of group sales, so really delivering strong growth at 50% both IO and North America. [indiscernible] 11%, that's VBP, China and it's U.S. pricing. And I think remarkable to note now GLP-1 in diabetes is profit to double the size of insulins in diabetes. So GLP-1 accounting 50% of group sales where insulins account 25% of sales in the quarter.

[indiscernible], again, that [indiscernible] we'll come back to and rare disease down 16% linked to the Norditropin manufacturing challenges.

Talking about Wegovy, we brought this slide just to show the acceleration in group sales. Only a few years back, we were talking about incremental net sales year-on-year with, call it, DKK 1 billion or DKK 1.5 billion, and then we look at how we're stepping up now. So really a dramatic step-up. We're aiming to the TRx trajectory you see in the middle of the slide. So in round terms, when you

look at added TRx on a year-to-date basis of Wegovy across doses in total, then incremental weekly added TRx [is 6,000]. And as a consequence, we have had to adjust the number of new patients being able to start on Wegovy. So we're reducing the initiation doses, the lower dose strengths, because we're simply scaling a biologic-based platform to a very, very significant level of sales growth.

So you should expect perhaps not imminently but in the coming months, you should expect a step-down in terms of new patient starts as a consequence. And we do this to be responsible and have a sustainable beat business. So we're not creating a bigger pull in demand than what we can sustainably supply and patients type trading through those strings.

And as a consequence, we are also pursuing a gradual rollout ex U.S. We would be very eager to launch in many, many markets. We have accrual, and we know the demand is there. But of course, we need to balance it with the supplies available. Sorry about that.

So let's hand it over to Martin Lange, our Head of Development, to go through the greatest [indiscernible].

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

Thanks very much, Karsten. I think you talk about high doses of alternate both the space of diabetes and business. We talk about the need to show equivalence from an efficacy perspective, from a safety perspective but also from an exposure perspective as compared to [indiscernible] 2.2 milligram in diabetes, but also compared to 2.4 milligram in Wegovy.

We now read out the diabetes results. We're still waiting for the obesity results. Those will come within the next couple of months. But just looking at the diabetes results, we're obviously super happy. Trial was a [3-arm] trial designed to compare 14 milligrams of [indiscernible] basically semaglutide to 25 and 50 milligrams, achieving basically all design outcomes in terms of or when it comes to tons as compared to 14 milligrams for both 25 and 50 milligrams and also a differential between 25 and 50 milligrams and the equivalent data set in [indiscernible].

At the same time, we see both weight loss and [indiscernible] control comparable to that of 2 milligrams of Ozempic. So really achieving the data that we wanted to achieve. This both will obviously go for diabetes, but also data that we put the same one we still have not seen.

I think it's also important to call out that given the supply chain esters -- or rather the high demand that we've seen in other areas of the semaglutide franchises, we have to consider how we roll that out, thinking the broader supply and demand balance. And we will also have [to] when we have the best later to do the same consideration.

Broadly speaking, as Karsten alluded to 2023, first of all, has been but will also be in the next couple of months in terms of. We have Phase II or III poses ongoing in all of our paras, and we are excited to see the fruit of those investments. So maybe in the diabetes space obviously calling out into done a global regulatory space in U.S. and Europe and China. Securing that offset will be made available to patients for diabetes, and hopefully, not-too-distant future in both of them.

Also, I think important to call out, we saw really is from a very strong efficacy in basal only treatment spirit that of both bele and glasses, very good safety profile. And in the basal-bolus treatment clarity on efficacy parity on safety profile. And then obviously, convenience in our case is to have 313 days of injection in the basal only [indiscernible]. So really an attractive offering in type 2 diabetes.

In type 1 diabetes, we did see more hypoglycemia. We still have a full diabetes filing, so both type 1 and type 2 diabetes part of the business profile, but we do expect more dialogue with the regulators on [indiscernible]. And just as a reminder, from a value perspective, type 1 diabetes is 7%, type 2 diabetes is 93%. So obviously, a big potential opt in this space.

I'll talk about the timing cost results, but maybe just calling out something that has caused a good deal of interest. We have reported on 2 studies and Phase II studies with fixed-dose combination with semaglutide and GLP analog and then a mono component co-agonist GLP-1/GLP co-agonist.

For the first one, we compared to semaglutide and the GLPs analog. And with some interest, we saw no impact of adding CIP through semaglutide on weight loss and most effect when adding GLP-1 analog semaglutide on plasma. Several different sort of interpretation of that, and you can maybe go into detail if you're interested [indiscernible]. But we did see a good and strong effective profile of the co-agonist in Phase I. We probably imagine that since we have also announced that so, we also saw some efficacy that financial. And therefore, we will progress the most promising of the 2 in the states of, obviously, diabetes, but potentially also it.

[indiscernible] I have to call out SELECT that's going to be incredibly exciting. We are in the process of closing down the SELECT [indiscernible]. You heard us talk to them. We will have the regard around the mid of this year. We are now more mature in terms of

how we assess that. So we're not looking towards July, August, maybe closer to August. So June sort of not so much in gain anymore. And as you will recall, all of this degraded in nature of the fund. So we now get number we get to announce to start closing down and still conducting the remaining events during the first half.

Then maybe also talk about all and [indiscernible] just very briefly, it's going to be incredibly exciting to see that with a very strong follow-on to Cagrisema. Similar profile basically times to both the amylin and GLP-1 receptors but in a unimolecular format to a core. We've obviously announced some flexibility, and we can have that either as an oral offering or is on, which is obviously [indiscernible].

In the rare disease space, you probably noticed the approval of concizumab in Canada and that almost at the same time, a complete response letter in the U.S. for concizumab, not related to the drug but most with the companion diagnostics that has to follow the drug so we can monitor consistently every patient. They requested more data, and we are working with them to drive these.

Sogroya was approved for both [indiscernible], which is obviously press declining in once-daily -- sorry, once-weekly setting. And then maybe other sales chronic disease is just calling out through first human doses in heart failure and in Parkinson's disease for our cell-based therapies.

And with that, back to you, Karsten.

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

Thank you, Martin. And now we are on the final stretch in terms of slide before Q&A, so you better warm up. So we released our guidance for the year linked to the second CMO coming online here almost 4 weeks ago. So now we're guiding a top line growth of between 24% and 30%, I'm just repeating, between 24% and 30% constant exchange rate sales growth. Really, really amazing growth, if you ask me. That translates into 28% to 34% operating profit growth, so getting a levels given the attitude of the sales growth.

And then, yes, we have currencies going against us this year linked to the weakening U.S. dollar to euro and some of the tight currencies or emerging market currencies. No changes to tax rate and free cash flow outcome linked to the growth of the business, so between DKK 66 billion and DKK 74 billion despite the fact that we're investing DKK 25 billion in CapEx this year to expand manufacturing capacity. And with this cash flow, we have been able to increase our share buyback program this year from DKK 28 billion to DKK 30 billion.
So that covers the outlook, and these are our strategic aspirations. And now we're ready to move into Q&A. And the host was the fastest. So we will start with Peter Verdult even though [indiscernible] to get going. So Pete, first question for you.

Question and Answer

Peter Verdult
Citigroup Inc., Research Division

Look, I'm sure we're going to discuss supply and SELECT and revenue seen late stream the meeting. So maybe we can start off on regulation, and I'll repeat the question I asked last week on pricing. So just on regulation, not in front of the Congress tomorrow. Any thoughts there? And also on the [indiscernible], I mean you've talked about it over the years. Are you hearing anything in Washington about move towards getting Medicare reimbursement in obesity? So that's the regulation question.

And on pricing, I mean, [indiscernible] Wegovy, different brands, different doses, different price points to get it. Mounjaro, same brand, same doses. Are we really going to see this separate price point between diabetes and obesity? Or are we -- are you expecting a rapid -- or should we say, narrowing or price erosion on GLP-1 obesity pricing?

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

Yes. Thanks, Pete, and thank you for restraining shop to 2 questions. I think after last week's conference call, perhaps we get a better process of fair limiting all of us to 2 questions. And then we do move full rounds, if possible.

So on regulations, yes, Lars will attempt the centering the Senate hearing tomorrow, together with the Lilly and Sanofi's CEOs, it's around insulin pricing. And I think rarely you see a lot of regulation coming out of Senate hearings directly, right? So I think it will be a hearing on insulin pricing, and it's something that I know Lars is looking very much forward to discussing.

And we provided a lot of transparency on our U.S. insulin pricing in our annual report, and you've seen our insulin price going down consistently for now [most full] years in terms of -- especially our net pricing. So that's that part on regulation.

Tria, still TBD, so really no news there. Of course, we are encouraging as much as we can that it should be needed to reimburse the treatment for seniors in the U.S. And at the same time, we do know that more and more states have decided to cover the COVID for the Medicaid population in the States, so making it even more confounding why -- who should be covered for seniors. But that's a political decision that then, of course, we'll have to accept and live with them. The opportunity is decisive enough on its own merits.

As to the single-brand versus dual-brand-type strategy, I think it -- ultimately, it's more to Lily to answer about that commercial strategy is -- we've noted the EU approval of -- on tirzepatide, whereas in the U.S., it is still TBD in terms of the leading commercial approach, whether it's a single- or dual-brand approach.

I would say, from our perspective, of course, the synergies running with one brand, but there are also benefits in terms of dual brand in terms of how to manage and navigate the market. I think most recently evidenced in terms of the COVID starter doses and so on. So I think, actually, given the nature of the [indiscernible] market, I think there are clear benefits of running with a dual-brand strategy seen from a normal perspective. But of course, our competitors are free to make up their minds and decisions accordingly.

Thanks, Pete. And we go to Michael.

Michael Leuchten
UBS Investment Bank, Research Division

Michael Leuchten from UBS. Two questions, Karsten. One, despite the inventory in Q1, the value of the volume both for Ozempic and Wegovy sort of very different factory compared to Q4 and Q3. Just wondering how you -- what it could speak to channel mix. Is there anything in there that would be normal?

And then just going back to supply. As we think about the MTS being restricted, the way that ramps through the year, the moment that becomes really relevant is when your new plan should come online and you now have the new CDMO online already. So why restrict the new starter doses now as you go into that incremental supply come?

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

Yes. Thanks for those questions, Mike. And I'd say, as to value volume in the U.S. on Ozempic and Wegovy then I'd say, Wegovy is rather clean. So nothing is very special there. I think one note worth making is linked to my prior comment on increasing Medicaid access, so having some channel mix impact on pricing.

But on a very positive background because it's more than [5 million] incrementalize we have from the Medicaid segment of [indiscernible]. So that's conscious decisions where we have been out negotiating with the state Medicaid agencies for this access. So that's Wegovy and for Ozempic volume value, let's say always be careful about overinterpreting on quarterly volume value because it doesn't take that big swing factors in terms of wholesaler inventory movements and so on, so throw the calculation off.

So to boil it down in all simplicity, what we're seeing this year is similar to what we've seen in the past few years, so call it 10%, 15% net price decline linked to rebate enhancements and channel mix movements. So apart from that, there are some plus/minuses on inventory, and ROA is going the opposite way. But if you peel that away, no change compared to prior years.

Then to the question about limiting the starter doses, this is really about safeguarding continuity of care for patients and allowing patients to step up through the doses and be able to deliver the right treatment experience for patients. We had assessed multiple options on how to manage the market linked to the very significant uptake in demand. So this is something we do while we scale at full speed supply chain-wise.

So this is -- there are no real triggers linked to supply chain. This is just full speed on scaling, and then we adjust how can we put it in market uptake cost so we have a sustainable business gain, so to say.

Yes. Then I'm a little bit down if I take this table first, because here, we have mics and then we can move around for the mic. So if I go this way, Richard, for you first. Richard Vosser?

Richard Vosser
JPMorgan Chase & Co, Research Division

Perfect. Just on -- you've clearly got 3 plants this year, and we know that they're being scheduled and you've got 2 online. So how should we think about that next year in terms of additional lines coming on? Is it the same magnitude as this year in terms of 0 to 3? Or what should we think about that?

And on the existing lines, how should we think about -- over the years, you've been able to scale capacity. And I think there's a chart from a Capital Markets Day where you -- the unit cost goes through the floor. How can you increase capacity at the existing lines as well? And then second question just on icodec. When the follow-up came through, the data seems to lose statistical significance. So how do the regulators view that?

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

Yes. Thank you, Richard. Yes, you're correct. And just [indiscernible] the Wegovy single dose device supply chain in terms of filling: one, a smaller internal line; one CMO line up and running already from the beginning of the year; one CMO line up and running as per April this year, that was linked to our pre-release of full year outlook; and then the third CMO line coming online at the end of this year. So -- and then we have additional lines that we're contracting for in the years to come.

And in magnitude, I would say the lines are broadly of the same size, so just for you to size how much we're stepping up. So when we exit this year, our capacity will be almost around [factor 3] compared to when we exited 2 in terms of building capacity. So a very significant ramp up, and we'll continue to lay on additional lines in the years to come.

I don't want to continue this about when is the next line, when is the next line. Just to say, expect the continued runway in terms of adding line capacity. And then a reminder that for Wegovy ex U.S., we also have our existing manufacturing platforms with [indiscernible] and FlexTouch to utilize for ex U.S. Wegovy rollout. So we have a 2-string approach to supply chain-wise.

Then Martin, on icodec?

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

Absolutely. So I think it or to the call talk about almost close ONWARD 1, which obviously was one of our pivotal studies in the space. We did a 26-week extension. That's for regulatory reasons. We do that to secure top exposure and taste on this. So the primary focus of the extension part. And when you do that in open-label studies, you lose a little bit of [indiscernible].

We know that regulators know that our assumption is that from an efficacy perspective, also given that we now see the same results in ONWARDS 1, 2, 4 and 5, we would expect [of 3] but we would expect that, that sort of superiority that we've demonstrated in 4 studies will be reflected. But I also think that the extension data will be affected by the statement that this was a safe focus expansion for.

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

Thank you, Martin. And I think we'll move to Simon and then back to you.

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

Simon Baker from Redburn. Two, please. Firstly, on capacity, but not the capacity of what else talking about. Understandably, we're focused on fill and finish for Wegovy. But can you share with us where you are in terms of oral capacity given the data you've seen with 50 mg, assuming some point that could be? And then the second one, Slide 5, you talk about broad commercial coverage. I just wonder if you could give us a little bit more detail about how things have changed for 2023.

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

So oral supply, as you know, some 5 years back or so, we initiated a major expansion project in place on North Carolina, where we're producing semaglutide API. That factory is ramping up as we speak. So that's a significant step up in terms of sema API for -- especially for on the oral side.

And then on top of that, we're currently in the process of constructing additional API facility in [Kalundborg]. And that will come online a few years down the road. So that's kind of the capacity scaling. And that's also why, given the viability of all, then we -- apart from CapEx, we're also looking at upgraded formulation solutions for the oil products because that will reduce the capacity stream supply chain-wise.

And then we have the portfolio playing so exactly to what patient populations and in what disease areas and in what dose strengths are we deploying our all products. And before we finally conclude on that, we would like to wait and see both ways as 1, but also as 4. And then we'll make portfolio decisions where we take the right choices between the capacity available and the clinical benefits and commercial attractiveness of the products.

And so that's your first question, Simon. And the second one, in terms of broad access for Wegovy. So I assume that -- farmer Slide 5, but I assume it's under the Wegovy side. So that means that for formulary actions, we are around the 8% mark, but it's employed out in. So we have more than 40 million lives covered in the U.S., 40 million people with obesity covered. So in terms of runway and opportunity with 40 million covered and currently, the run rate for Wegovy is, call it, 200,000 per week or a little bit more than that. So 0.5 million patients on Wegovy, plus/minus, as we speak. So still a very, very significant runway. And do note we are continuing to build access as we speak.

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

Just to be clear, you said 40 million, that's commercial or commercial plus federal?

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

Commercial plus Medicaid.

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

So in total, more than 40 million.

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

I'm not sure I go here and then -- yes?

Unknown Analyst

[Tony Male] from Morgan Stanley. So again to hear your thoughts on the positioning of high-dose injectable sema. So the step-up trial of the 7.2 mg, is that complete around the same time as REDEFINE one, which is obviously expected to produce a superior result? So is it before a future high-dose sema combination as sort of an insurance policy in case CagriSema doesn't work or as a backup in case of manufacturing issues for the more complicated products?

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

I think it's obviously a very natural sort of potential lifetime extension also of CagriSema and the expansion of that opportunity. But it's also to -- while we still have a decade expire an opportunity to maximize value of semaglutide.

And as we're having those data, should they be successful, we will have a step-up as compared to current doses of semaglutide probably be on a everything is that's currently out there. And then we'll have CagriSema, that would be a further step up to that.

So our model is to bring 7.2 milligram in [indiscernible] around the [10%] weight loss in CagriSema [indiscernible]. And having those opportunities also kicking into what Karsten was saying, not only having sort of resin, but also maybe from country-to-country opportunities to work with our portfolio is a really good place. So it's not to be considered as backup but actually maximizing semaglutide. That goes without saying that we see a new and that does [increase], we would also take that into semaglutide.

Unknown Analyst

Yes. On a maximum level of weight loss, I mean, do you think there will be a maximum level that's safe and delight in the market eventually and that the debate will then shift to sort of consistency and quality? And sort of what level do you see that maximum at, I guess?

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

I don't want to speculate into maximum level. Right now, we are at semaglutide at around 25%. That's the both sales and benefit. And if you consider a patient with a BMI above 40, 25% weight loss will still lead you in this realm, and that basically means that potentially even higher weight losses.

Maybe we can achieve that oat. Maybe we need to have something else.

I think to your point, already now thinking about the rate of weight loss and maybe also the quality of weight loss becomes important. And this is why we have to accept safe weight loss. 25% or 30% weight loss for patients. But there will be a good proportion of patients, I think around 20% that had above the [indiscernible]. That's a substantial proportion of patients that may be more than 25% or 30%. We just have secured that [indiscernible] weight.

Peter James Welford
Jefferies LLC, Research Division

Peter, Jefferies. Two questions. So first one, just coming back again to the supply, sorry, just to understand this [indiscernible]. So should I might is the original Belgium facility right here, is that still operating sort of churning the same amount it was before? Is copromotes actually dwindling, if you like, not that going on here? Because we've obviously all read about a lot of problems that are going on there at the moment.

And it just sounds a bit -- I guess, is it really at the moment, double what you had only 3 months ago? Or is the problem is we shouldn't be thinking about just double the at the moment, and there's a bit of a lag before it comes in and equally on the ex U.S. So I should understand in terms of given it's a kind pentane existing silicon, given the delayed ex-U.S. launches, is that constraint on sema that we're seeing here the actual APR because put fill finish shouldn't impact the ex U.S. Wegovy rollout? And then just some I mean...

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

That's too many. So I count 2 already.

Peter James Welford
Jefferies LLC, Research Division

At as simple.

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

I hope to get back to you in the next round. So on Wegovy and the limitation of the low-dose strengths, that's purely a reflection of the very aggressive demand uptick. It's not because of problems in manufacturing. So just to put that out. A lot of concerns are out there if this is reflected in about some of the recent clarifications from Catalent, and no, that's not the case. This is simply a question of demand outpacing supply. So our supply plans are intact for the year, just to be very clear about that.

As to ex U.S., Wegovy launches and the gradual approach, the gradual approach is a function of that Wegovy is sharing API with Ozempic, filling with Ozempic, Saxenda insulins, assembly with the same and packing also. So we have Wegovy on the FlexTrust platform is sharing a lot of capacities with other products. And as you've seen, for instance, on Ozempic, then we have drug shortage notifications in many markets ex U.S.

So adding more pressure on to that entire supply platform is, of course, something that we do not do like, unless we have smart ways to do so. So I wouldn't want to get into individual bottlenecks and so on because we have a supply chain, which fits together and it's the whole supply chain we're lifting. So we are increasing our capacity across the supply chain from API to paving.

Yes. Then we move to -- I think we'll move to the tech for microphones. But you've been very patient in her back. You can move to that microphone then.

Emily Field
Barclays Bank PLC, Research Division

Emily Field from Barclays. One, how interlinked is a successful outcome with SELECT and movement forward of the Treat and Prevent Obesity Act? We get asked that a lot. Like is that something that could help move things through Congress?

And then secondly, while you're limiting supply of the starting dose that will go in the U.S., will you be scaling back promotional efforts as well? And then just any commentary you could provide on the compounding pharmacies out in the market. We get asked a lot, given the lack of FDA oversight on the production there, how -- if that could be a risk to the story overall.

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

I'm sorry, Emily. I count 3 again. But I'm getting really good at the supply moment. So you supplied -- or demanded 3 questions and I'll supply 2. So we're practicing supply demand in this context also. So SELECT versus trial, unfortunately, science meeting politics, I think -- I would love to say yes, there is a [indiscernible]. In reality, no, it's not. So it would be another piece to the body of evidence why it's a good idea. I think it's already a good idea right now.

And of course, we'll -- upon, knock on wood, a successful SELECT, we'll use that evidence as we use SELECT in other payer negotiations. Because SELECT will, of course, assuming the official play favorably into the quality and health economic assessments and hence, overarching payout discussions and negotiations.

As to commercial tactics on Wegovy in the U.S., there vis-à-vis reducing on the starter doses, then I would say, given the current situation, we're not going all in on all our commercial tactics. But of course, at the same time, we're building a new therapy area or value therapy area. And in the context, it's important that we inform and educate around the appropriate use and the benefits of obesity treatment with Wegovy. So don't expect radio silence, but also do know that we would have another gear in the gearbox at the appropriate point in time.

Then we move to back table here.

Richard J. Parkes
BNP Paribas Exane, Research Division

Richard Parkes from BNP Paribas Exane. So a couple of questions. Firstly, I know this is partly asked on the call, but in terms of commercial plan coverage going into next year is something we're not going to go and notice the success you've had with Wegovy. So what risk is that you start to see plans looking to put in place restrictions to the eligibility criteria or treatment duration? Is there anything you see as being a risk good commercial coverage into next year? And then I'll come back with the second one, if that's all right.

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

Sure. Absolutely. Then I only have to remember one. So first of all, market access in the U.S. on Wegovy is slightly different compared to some other disease categories in the sense that we have brought formulary coverage in commercial in the U.S. for Wegovy. And from there, it's very much an employer opt-in. So it's employers electing that they want to cover antigen medications. So it's a slightly different mechanism.

Could we see influence opting out when they see the cost associated with the obesity coverage? Yes. But at the same time, I think we are not at the end of the road in terms of building access with other employers and state Medicaid, et cetera. So that's something we navigate as we move forward.

And at the same time, with some of the additional clinical data reading out, now we just discussed SELECT, of course, the stronger the evidence we can generate both from our clinical trials but also from just real-world evidence about the benefits of anti-obesity treatment, of course, a stronger position we would be in. So it's something where we will navigate over time. And I'd say right now, with the current supply-demand situation, it's not our primary concern in the near term going into next year. But of course, something we look carefully at.

Richard J. Parkes
BNP Paribas Exane, Research Division

And then second question is on margins are asked on the call. But you're obviously seeing more of a margin improvement this year than you'd originally anticipated. It was ramp up R&D as quickly. And I think you sort of mentioned it might be possibility of business development. There might be some step changes in terms of R&D.

So how -- can you just talk about how you sort of going to think about balancing that and what's the priority be going forward? Would you commit to maintaining margins at current levels? Or would you be willing to absorb some contraction for attractive acquisitions?

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

Yes. So if I talk to Martins and then Martin can talk to a BD products because it's all about the pipeline and is part of the company. Then as to margins, when you look at our Q1 margin, it was 47%, right? So -- and we don't adjust it. So it's a clean operating margin. So at that level of margin, we create more value to shareholders if we invest in our business in terms of growth both the short, medium and long term.

So we don't have a margin strategy. We don't have a catch-up in terms of margin. We have an innovation-based growth strategy and very focused on driving that through investing in scaling supply, building the obesity market in terms of commercial build and infrastructure and then building and expanding our R&D pipeline to the extent rational within our therapy areas. So that's our strategic resource allocation principles.

And as I said at last week's call, then clearly, when growth rates come up as high as they are now, in the high 20s for this year, then naturally, there will be a margin benefit because in an organic type of growth setting -- but of course, if we end up buying something ties for inorganic in our string of growth strategy, then that, of course, can have kind of a negative impact on margins.

And as you saw with Dicerna just a few years back, then we accepted to take a dip on margins to get that technology platform in-house. And we're benefiting from that now. And actually, we've ended up recouping that margin impact. So that's just to say, we start from the innovative-based growth and then we're rational about the margin afterwards. So that's kind of the consulting.

So Martin, BD?

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

Yes. Maybe just building on what Karsten said, I mean, we've never been in a situation where we've had to say no to a business development opportunity because of margin considerations. Clearly, take the approach that working within our strategic focus areas, both in terms of the areas, but also in terms of technology platforms, we do the right acquisitions and we do the collaboration.

I think from a specific -- maybe also a technical perspective, we have a clear approach of, at this point in time, focusing on earlier assets. So same preclinical, early clinical assets where we can generate value rather than doing pickup later-stage acquisitions where, obviously, both margin but also venue generation some from the. Given our current point of time and current situation, we can allow

ourself to do that. But careful of having sort of a dual standpoint in terms of strong internal innovation in all of our therapy areas but equally strong external focus in innovation.

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

Yes?

Matthew Weston
Crédit Suisse AG, Research Division

It's Matthew Weston at Credit Suisse. Two for me as well, please. The first one follows on from Richard's question about costs and cost phasing. So you said yourself that it's normally organic within a pharma company. But obviously, now you have this exceptionally broad revenue guidance. I'd be really interested if there are any large chunks of OpEx that at some point in time you have to commit to or make a decision on and how you're going to go about making those or it's very simply an organic decision and waiting for the cost to catch up with the revenue.

And then the second question to you, Martin, it's a bit bigger picture. We're looking at this market of obesity now, and everybody is debating Mounjaro versus Wegovy. Everyone is asking about stay time. If I look at any other big chronic therapeutic area, no one stays on a single drug, and there is no simple approach if you start with one and carry on going forever. There's always finesse. Whether it's a treatment phase and then a maintenance phase, you look at people moving different modes of action.

I'd be really interested as to your views as you kind of look through your crystal ball in obesity how you see it evolving and how you think you need to start looking at combination strategies or treat-and-maintain strategies to actually make this a 20-, 30-year market.

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

Yes. Thanks for that question, Matthew. And no, we don't have any singular major cost or OpEx step up or down. So this is a classic organic build. It comes down to employees and cost of running the business and, of course, the supply chain. So it's classic scalability. And that's why we have paid for good chunks of the infrastructure. So when growth reaches a certain magnitude, then we cannot scale R&D more in terms of organic scaling, and then we have a good flow through to the bottom line and to margin. So it's kind of a classic discipline in terms of financial management.

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

Yes. And a really good question with probably a little bit of a complex answer because clearly, we are at the very early stages of obesity treatment here. In my analysis is actually going back to the advent of Hasuda, you would recall it when you saw UKPDS [once a] treatment available, not a large sophistication in terms of understanding different patient needs an [indiscernible] just pharmacies. We have several phenotypes. It's a progressive disease. And over the years, we've seen different modalities coming in and changing and optimizing the treatment airbag, but also offering more sophisticated treatment for infect patients.

I think we'll see the same development in -- to your point, I mean, we have one -- in well or 15%-plus weight loss approved drug available right now. That doesn't call for a lot of sophisticated motion because yes, treating less than 1% of the obese population. What you will see, I think, in the coming years is a lot of focus on. I think that will drive a focus on just the action let-off in obese population.

But combination of treatment, to your point, will allow us to take weight loss for those who that may not be all, but also thinking the impact on combatant. That has been a major decision driver. I think that would also be the case in looking at the impact of weight loss on a [indiscernible] on diabetes.

And then to your point, maintenance of treatment. I currently -- and obviously, I'm biased and it's still early days. I'm currently seeing obesity as qualities with need for quality treatment. When people are going off treatment today, they start to increase and/or regain weight. To me, that means chronic treatment. But we have to look at different modalities, either stay on treatment, reduced dose. We maybe do it to maintain the accrued weight loss. All of that provides a lot of knowledge insight and innovation. And we'll see research but also innovations in that space in the years to come. I think at the strongest post clinical, but also preclinical pipeline clears.

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

Thanks, Matthew. We'll stay with this table before we move forward. Any answer questions? Rajan?

Rajan Sharma
Goldman Sachs Group, Inc., Research Division

A quick one. Have you done any modeling on the higher dose of summer with category on where you can get that 25% higher? Have you got numbers on that?

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

So yes and no in the sense that we've done the modeling. And if 7.2 pans out in sort of real life, I would be confident to taste right now. I want to clinical data substitute support model. I think it's reasonable to assume that a 7.2 milligrams of semaglutide is providing additional benefit. That will also be an interesting consideration in U.K. since.

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

Then move back to Michael Leuchten.

Michael Leuchten
UBS Investment Bank, Research Division

Just going back to CagriSema manufacturing and the oral alternative in Phase I. Given your capacity on CagriSema is hardly limited, will you wait to see some of that clinical data or the alternative to decide how much CapEx is behind it? Or are those 2 independent from each other?

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

Which one, sorry?

Michael Leuchten
UBS Investment Bank, Research Division

The semaglutide, the...

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

Oh, the oral and CagriSema?

Michael Leuchten
UBS Investment Bank, Research Division

Yes.

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

That's an easy answer because no, we are -- we're scaling and catering to both. So part of the step-up in our CapEx that we announced beginning of this year, DKK 25 billion this year and, say, being in the 10% to 15% CapEx to sales ratio in the coming years, that is catering to both scaling API capacities as well as fill finish.

So the currently ongoing API facility that we're currently building in Calamba in Denmark is what you would call a multipurpose facility for peptides. So as a consequence, we'll be able to deploy that across a number of different assets on the API side.

Simon and then Pete.

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

Just going back to the question of target weight loss. If I pass on back a long time, I remember on some of the early bid studies, the weight loss is plus 5% to minus [40%]. I'm on a set, obviously, quite extreme. But it goes to the point that the point estimates that we

see here are the average is quite a distribution. And I just wondered if you give the current doses, what is the range response which would go? If you push it to 25%, when would you see that range go? Because if that gun example is relevant for the class, then you could have some fairly extreme weight loss you're targeting 25%.

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

So just listening to the numbers that you say. I mean, the range for semaglutide current dose is more than [indiscernible]. So we have also paid to up to 40% of their body weight. I'd say the vast majority, 95%-plus, lose weight and more than [5%] of their body weight. So I don't think we have any gain weight, but it's more or less the same wins. And that to me, without actually having the full inline, suggests that there is maybe a natural limit to the range. I think we'll see what CagriSema way, weight loss being driven towards 25% but still within a range that doesn't exceed something that will be. Obviously, an, but that would be my comment.

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

Pete?

Peter Verdult
Citigroup Inc., Research Division

It's for Martin. On SELECT, we will know the parasumption just to repeat what everyone's already dead about the ranges. But 2 questions. In terms of what we see on the press release, will it be solely related to the primary endpoint? Or can you discuss about what you would reveal or not? Would there be any potential not the secondary endpoint, but we see that headline press release. And that's part one.

And part two of the question is that sees clearly your doctor, you see us now at the low end of the range is. But in numbers in its treat but [a second] strike there is 100-plus patients. One might say rand. That does come up with discussions with some KOLs can we discuss the.

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

Yes. Absolutely. So on the press release, I think you will see us on the something limited, either positively or otherwise, comes up, we'll stint to a statement on the primary end point and on the spot profit. Then we'll have to sort of await further information expect comes.

I think from a clinical perspective, and you as you also see that from more diabetes rat, we have [indiscernible] reporting on to, I would say, 50% apart from semaglutide, that is at 25%. 11% to 15% risk reduction in mix. That is specific in and obviously have been a statistic and something that both prescribers patients and payers are considering growth.

Clinically speaking, if I see [10%] reduction when it comes to CV deaths, stroke or myocardial infarction, I think that is well. But I'd like to see something more, of course. From a statistical perspective, we guide project to continue to come down around the [10%, 11%]. I think it's important to consider. I mean we still believe in [around 10%]. That's our base assumption. That would be not only clinically relevant but also actually statistic. But it should not be seen in isolation. There will be a number of other kind of baseline points that will be important to look at from the SELECT. But there will also be a number of comorbidities or process peripheral disease in diabetes that will allow us to have a iodine on also the economic case for this net.

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

Yes. When we move to the sale to the left. I think we need to find -- get you close to a microphone so the online audience can hear.

Jo Walton
Crédit Suisse AG, Research Division

I have a -- in the U.K., we pulled up on import and marketing impact. I just wanted to check whether that as of any reassessment of how you approach this.

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

Yes. Yes. Thank you for that question. And it's correct. That's been a case around our business ethics practices in the U.K. and the assessment by the industry association, APPI, in that context. The starting point and the objective on our side was to educate and inform medical doctors and pharmacists around the appropriate use of obesity medications. So that is our go intention, which we believe is important in a new disease area like obesity treatment.

And in that context, some mistakes from it, and we deal with the consequences. We've been transparent about our dialogue and clarifications about what and why, and now we take the consequences and learn from it. So we've put in place a number of additional initiatives to strengthen that we don't face similar issues elsewhere or in the U.K. So very unfortunate. And of course, we adhere to all regulations in this context.

Unknown Attendee

Just insulin, if you look at your chart, you've got a global chart in volumes, look so actually in now almost a majority of markets now, insulin volumes are actually going down. Is that some of the fact is transitory? Or is it -- because it doesn't intuitively seem like an obvious dynamics on what's going on in the world and anything else here.

And does that mean from your planning point of view, are you planning now basically your interest in case of the efficiency going up and up, you price yourself that all time. Is that been investments in instant because actually, you do think you've reached sort of steady state when you move into?

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

Yes. So on insulin, you're right, global volumes are slightly down after looking at the infill market for many, many years now. And it is a really, really sticky, really, really slow-moving markets right? So -- and I'd say our historic learnings in this context has been that every time we thought that whatever bile volumes -- balance risk volumes are going down and the best we end up realizing that, no, they're not. So just speaking to the effects around the thickness of the market.

And again, this is chronic therapy, and we are growing populations. So even if we have better treatments like GLP-1s that might take some of the insulin utilization away, then overall, the macro dynamics will keep the global insulin volumes reasonably flat.

So pricing-wise, what does that mean? That means that, of course, it's not insulin driving the big CapEx volumes. But when we build our facilities, we build platforms that can be utilized also for insulins. So the CapEx I was just alluding to before to Michael Leuchten's question, that API facility will also be fitted to produce into an API. And for some of our fill finish capacities we're building, they will also be more teas and hence, be able to fill insulin products.

So then we have one last question, which comes from the back table here.

Unknown Analyst

Stuart from Citi. Just going on the BD, and you're talking about looking at maintenance strategy, thinking that maintenance long term. And everyone's concerned that some have is around the target adipose tissue and muscle mass. So to what extent is looking at strategies that really shows hating an a tissue ROE going to be needed to have a mental gear?

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

That is clearly a priority and a focus area, in particular when we go into the bigger weight losses. That's not our only focus area but clearly something that we are very focused on because we also hear those concerns. And right now, with the [indiscernible] base, I think it's balanced. But moving beyond this has to be something that we would want.

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

Thank you for that question. And unfortunately, I have to close the call now. So thanks a lot to Peter and Citi for hosting. And we'll continue our rounds with our Q1 results. It's a historic year for Novo Nordisk, delivering between 24% and 30% top line growth, and as a consequence, investing a lot of resources in scaling accordingly. So really, really fantastic growth for Novo Nordisk. So thank you for listening in, and thank you for attending here, [Philippe].

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

Thank you.

Peter Verdult
Citigroup Inc., Research Division
Thank you very much.