S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

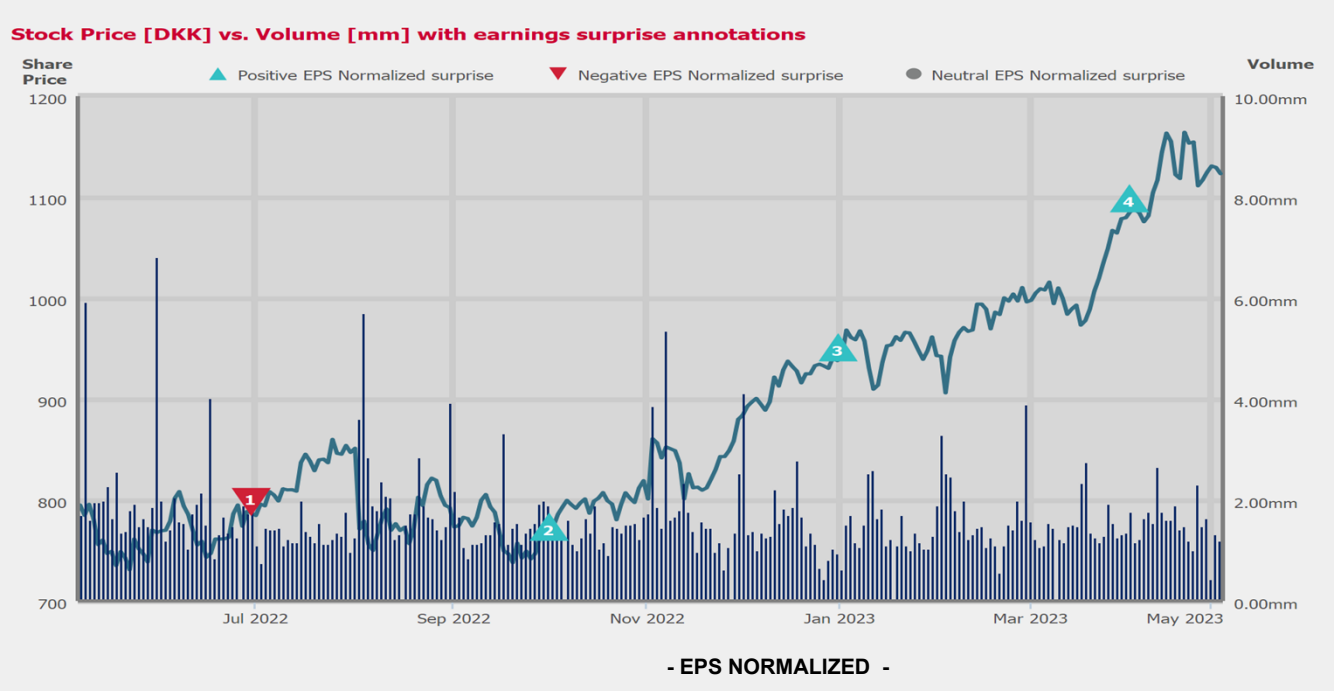
FQ1 2023 Earnings Call Transcripts

Thursday, May 4, 2023 11:00 AM 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	8.32	34.62	NA
Revenue (mm)	52191.82	53367.00	2.25	52672.79	219777.63	NA

Currency: DKK
Consensus as of May-04-2023 2:04 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2022	6.04	5.86	1 (2.98 %)
FQ3 2022	6.19	6.34	2 2.42 %
FQ4 2022	5.85	6.02	3 2.91 %
FQ1 2023	8.55	8.78	4 2.69 %

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EXECUTIVES

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

Lars Fruergaard Jorgensen
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Presentation

Operator

Good day, and thank you for standing by. Welcome to the First Quarter 2023 Novo Nordisk A/S Earnings Conference Call. [Operator Instructions] Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, CEO, Lars Fruergaard Jørgensen. Please go ahead.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, operator. Welcome to this Novo Nordisk earnings call for the first 3 months of 2023. Today's announcement discloses the full set of results following the release of top line results and updated outlook earlier in April. This was shared ahead of time due to Danish securities regulations.

My name Lars Fruergaard Jørgensen, and I'm the CEO of Novo Nordisk. With me today, I have Executive Vice President and Head of Commercial Strategy and Corporate Affairs, Camilla Sylvest; Executive Vice President and Head of North America Operations, Doug Langa; Executive Vice President and Head of Development, Martin Holst Lange; and finally, Chief Financial Officer, Karsten Munk Knudsen. All of us will be available for the Q&A session.

Today's announcement and the slides for this call are available on our website, novonordisk.com. Please note that this call is being webcasted live, and a recording will be made available on our website as well. The call is scheduled to last 1 hour. Please turn to the next slide.

The presentation is structured as outlined on Slide 2. Please note that all sales and operating profit growth statements will be at constant exchange rate unless otherwise specified. As always, I need to advise you that this call will contain forward-looking statements such as subject to risks and uncertainties that could cause actual results to differ materially from expectations. For further information on the risk factors, please see the company announcement for the first 3 months of 2023 and the slides prepared for this presentation. Please turn to the next slide.

In the first 3 months of 2023, we delivered 25% sales growth and 28% operating profit growth. Furthermore, we raised the outlook for the year in the early announcement shared on April 30, 2023 -- 13, 2023. I would like to start this call by going through the performance highlights across our strategic aspirations before handing over the word to my colleagues.

Within purpose and sustainability, we continue to make progress across all dimensions. Our carbon emissions decreased by 21% compared to prepandemic levels in 2019. In line with our strategic aspirations of being a sustainable employer, we continued to expand the number of women in senior leadership positions. This is now 39% compared to 37% end of March 2022.

Within R&D, we are pleased with the successful completion of PIONEER PLUS trial with oral semaglutide 25 and 50 milligrams that is setting the bar for oral incretins in type 2 diabetes. Martin will come back to this and our overall R&D milestones later.

Within rare endocrine disorders, we are happy to announce that once-weekly Sogroya was approved by the U.S. FDA for the treatment of children with growth hormone deficiency. This is an important milestone for patients and for the Rare Disease portfolio.

Quarterly sales growth reflects solid commercial execution across operating units. Both operating units contributed to sales growth driven by demand for our GLP-1 treatments for both diabetes and obesity. In the U.S., the prescription trends for Wegovy highlights the high unmet need for people living with obesity. Camilla and Doug will go through the details per therapy area later. Karsten will go through the financials, but I'm very pleased with the performance so far this year.

With that, I'll give the word to Camilla for an update on execution.

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

Thank you, Lars, and please turn to the next slide. As Lars mentioned, our total sales increased by 25% in the first 3 months of 2023. This sales increase was driven by both operating units, with North American Operations growing by 41% and International Operations growing 10%. Sales growth was positively impacted by U.S. wholesaler inventory movements. Our GLP-1 sales increased 50%, driven by North America growing 50% and International Operations growing 52%.

Insulin sales decreased by 11%, driven by an 8% decline in International Operations and an 18% sales decline in North America Operations. Insulin sales in International Operations were impacted by the implementation of volume-based procurement in China in May 2022.

Obesity care sales grew 124% overall. In International Operations, sales grew 65%, driven by both Saxenda and Wegovy. In North America Operations, Obesity care sales grew 156%.

Total Rare Disease sales decreased by 16%, driven by a 17% decrease in International Operations and by a 14% decrease in North America Operations, where endocrine disorder sales were unfortunately impacted by a temporary reduction in manufacturing output. Please turn to the next slide.

With 21% sales growth in our Diabetes care, we are growing faster than the total diabetes market, leading to an increased market share of 32.2%. With this, we are on track to reach 1/3 of the diabetes value market by 2025. This increase primarily reflects GLP-1 market growth as well as share gains in both operating units. Please turn to the next slide.

In International Operations, total Diabetes care sales increased by 12% in the first 3 months of 2023, driven by GLP-1 sales growing 52%. Novo Nordisk is the market leader in international operations with a GLP-1 value market share of 65%, driven by all geographies. Ozempic continues its GLP-1 market leadership with around 44% market share. We are also pleased to see Rybelsus increasing its market share to just shy of 9%, driven by a strong uptake across geographies.

And with that, I will hand over the word to Doug.

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Thank you for that update, Camilla. Please turn to the next slide. At around 60% volume growth in Q1 of 2023, the U.S. GLP-1 market continued to accelerate. This acceleration is driven by all-time high levels of new patients starting on our portfolio of GLP-1 products. Measured on total prescriptions, Novo Nordisk has expanded its market leadership position, with a current market share of around 53%. Please go to the next slide.

Obesity care sales increased by 124%, with 156% growth in North America Operations and 65% growth in International Operations. The global branded obesity market expansion continues, with a global volume growth of 54%. In International Operations, we are encouraged by the continued performance of Saxenda and that the Wegovy launches in Denmark and Norway are both progressing very well. In the U.S., Obesity care sales grew by 162%, with both Wegovy and Saxenda contributing to the growth.

Since the Wegovy commercial relaunch in January of 2023, the prescription trends have highlighted the high unmet need for safe and efficacious products to help people living with obesity. We continue to scale supply capacity. And the second CMO for Wegovy is now producing to the market providing additional capacity and risk mitigation. However, to safeguard continuity of care, the supply of the lower Wegovy dose strengths in the U.S. will be reduced temporarily. Next slide, please.

Our Rare Disease sales decreased by 16%, driven by a 17% sales decrease in International Operations and by a 14% decrease in North America Operations. Rare blood disorder sales decreased by 3%, driven by NovoSeven and partially offset by the launch of products in hemophilia A and B. Specifically, hemophilia A sales grew by 19%, hemophilia B by 15%, and NovoSeven decreased by 11%. Rare endocrine disorder sales declined by 38%, reflecting a temporary reduction in manufacturing output and lower realized prices in the U.S.

Now over to you, Martin, for an update on R&D.

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

Thank you, Doug. Please turn to Slide 11. In March, we announced the exciting headline results from the PIONEER PLUS Phase IIIb trial with once-daily oral semaglutide 25 and 50 milligram, respectively. PIONEER PLUS was a blinded 68-week trial comparing once daily oral semaglutide 25 at 50 milligram to that of 14 milligram. The objective of the trial was to assess the efficacy and safety of semaglutide 25 and 50 milligram as an add-on to stable doses of 1 to 3 oral antidiabetic medicines in approximately 1,600 people with type 2 diabetes in need of treatment intensification. The trial achieved its primary endpoint by demonstrating a superior reduction in A1c at week 52 with both doses as compared to 14 milligram.

Here, we present the trial product regimen for A1c and weight loss. From a baseline of A1c of 9%, people treated with 25 and 50 milligram achieved statistically significant A1c reductions of 1.9 and 2.2 percentage points, respectively, compared with 1.5 percentage points with 14 milligram.

People in the trial had a mean baseline body weight of 96.4 kilograms. People receiving 25 and 50 milligram of semaglutide experienced a statistically significantly higher weight loss of 7 and 9.2 kilograms, respectively, compared with a reduction of 4.5 kilograms with 14 milligram.

In the trial, all doses of oral semaglutide appeared to have a safe and well-tolerated profile. The most common adverse events were gastrointestinal and were consistent with the GLP-1 receptor agonist class. GI events were most prominent during dose escalation and more frequent with oral semaglutide 25 and 50 milligram than with oral semaglutide 14 milligram.

To sum up, we are very pleased with the results from the PIONEER PLUS trial that will provide people with type 2 diabetes with further dose escalation options if additional glycemic control or weight loss is required. We expect to file for regulatory approval in the U.S. and EU during 2023. Given the impressive growth that we are seeing across semaglutide brands, the global rollout of the 25- and 50-milligram doses is contingent on portfolio prioritizations and manufacturing capacity. Next slide, please.

Turning to broader R&D milestones. I would like to highlight some of the other exciting events, trial readouts and initiations across our therapy areas during the course of 2023. Within diabetes, I'm happy to share that we have submitted once-weekly insulin icodec for regulatory approval in the EU, U.S. and China for the treatment of both type 1 and type 2 diabetes. We have also completed a Phase II trial with a fixed-dose combination of subcutaneous semaglutide and a once-weekly GIP analogue. The fixed-dose combination did not show superior A1c reductions or weight loss compared to semaglutide 2.4 milligram. Following the completion of the trial, we have terminated further development of this program.

In relation to this, we have success completed a Phase I trial with a GLP-1/GIP co-agonist. In the trial, the co-agonist appears safe and well tolerated, and based on the results, we now plan to initiate a Phase II trial with a subcutaneous formulation in pursuit of further innovation within the GLP-1 space.

In April, we initiated the REDEFINE 3 trial, a cardiovascular outcome study, with the objective to confirm cardiovascular safety of CagriSema compared to placebo in addition to standard of care. Furthermore, we plan to initiate REDEFINE 2 in type 2 diabetes patients with obesity in the second half of 2023.

Within obesity, we have many exciting Phase III trials and readouts during 2023, including the cardiovascular outcomes trials, STEP-HFpEF, and SELECT with Wegovy. Both trials are designed to look beyond weight loss and focus on obesity-associated comorbidities. We believe that reducing the risk of obesity-associated comorbidities will not only make a big difference for the individual patients but also add broader value to society.

Later this quarter, we are also looking forward to the readout of the OASIS 1 trial with oral semaglutide 50 milligram. This will be the first GLP-1 in a tablet for the treatment of obesity.

With regard to concizumab for the treatment of hemophilia A and B with inhibitors, we received a complete response letter from the FDA. In the letter, the FDA requested additional information related to the monitoring and dosing of patients to ensure that concizumab is administered as intended. Further information on the manufacturing process was also requested. We will work now closely with the FDA to provide the requested data. And importantly, concizumab was, earlier this quarter, approved in Canada.

In rare endocrine disorders, we are pleased that Sogroya, the long-acting growth hormone somapacitan, was approved by the U.S. FDA for the treatment of children with growth hormone deficiency, aged -- 2.5 years of age and older.

Lastly, within other serious chronic diseases, we are excited to share that we have now initiated 2 cell-based therapy treatments in advanced heart failure and Parkinson's disease, respectively. This reflects our commitment to continuously mature our technology platforms that are essential to drive innovation across the diseases that we target.

With that, over to you, Karsten.

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

Thank you, Martin. Please turn to the next slide. In the first 3 months of 2023, our sales grew by 27% in Danish kroner and 25% at constant exchange rates, driven by both our operating units. The gross margin increased to 84.7% compared to 83.5% in 2022. The increase is driven by a positive product mix, reflecting increased sales of GLP-1-based treatments and a positive currency impact.

This is partially countered by costs related to the ongoing capacity expansions as well as lower realized prices, mainly in the U.S. and China.

Sales and distribution costs increased by 22% in Danish kroner and by 20% at constant exchange rates. The increase is driven by both operating units. In North America Operations, the cost increase is driven by the relaunch of Wegovy and promotional activities for Ozempic. In International Operations, the cost increase is driven by promotional activities for Rybelsus and Ozempic as well as obesity care market development activities.

Research and development costs increased by 29% measured in Danish Kroner and 27 -- 28% at constant exchange rates. The increase is driven by higher late-stage clinical trial activity and increased early research activities compared to the first quarter of 2022. The acquisition of Forma Therapeutics in 2022 also impacted R&D spend.

Administration costs increased by 10% measured in Danish kroner and by 9% at constant exchange rates.

Operating profit increased by 31% measured in Danish kroner and by 28% at constant exchange rates, reflecting the sales growth. Net financial items showed a net loss of DKK 0.3 billion compared to a net loss of around DKK 1.2 billion in 2022. This primarily reflects losses on nonhedged currencies. As per the end of March '23, a positive market value of financial contracts of approximately DKK 2.2 billion has been deferred for recognition in 2023.

The effective tax rate in the first 3 months of 2023 was 19.9% compared to an effective tax rate of 20.7% in 2022.

Net profit increased by 39%, and diluted earnings per share increased by 41% to DKK 8.78. Free cash flow was DKK 24.8 billion compared to DKK 21.6 billion in 2022, supporting the strategic aspiration to deliver attractive capital allocation to shareholders. The cash conversion is positively impacted by timing of payment of rebates in the U.S. This includes provisions related to the revised 340B distribution policy in the U.S. Please note that income under the 340B program has been partially recognized.

Capital expenditure for property, plant and equipment was DKK 4.7 billion compared to DKK 1.5 billion in 2022. This reflects investments in additional capacity for active pharmaceutical ingredient production and fill-finish capacity for both current and future injectable and oral products. Please go to the next slide.

We entered 2023 with a solid growth momentum. And following the acceleration seen in the first quarter, we expect sales growth to be between 24% and 30% at constant exchange rates. This is based on a number of assumptions as described in the company announcement. The guidance reflects expectations for sales growth in both operating units and mainly driven by volume growth of GLP-1-based treatments for Diabetes and Obesity care. This is partially countered by declining sales in Rare Disease due to a temporary reduction in manufacturing output.

The guidance ranges for sales and operating profit reflect the level of volume growth of GLP-1-based diabetes treatments. It also reflects the inherent uncertainty of the pace of Obesity care market expansion following the relaunch of Wegovy in the U.S. and gradual rollout in International Operations.

The outlook includes an expectation of continued periodic supply constraints and the related drug shortage notifications in 2023 across a number of products and geographies. This is driven by higher-than-expected volume growth for GLP-1-based products such as Ozempic and Wegovy and temporary capacity limitations at some manufacturing sites.

We are continuing to increase our supply capacity. We expect that operating profit will grow between 28% and 34% at constant exchange rates. This primarily reflects the sales growth outlook and continued investments in future and current growth drivers within research, development and commercial.

In R&D, we continue to invest to progress the mid- and late-stage pipeline while expanding and progressing our preclinical project portfolio. The step-up in commercial investments are mainly allocated to the relaunch of Wegovy in the U.S., Obesity care market development activities in International Operations as well as promotional activities for Ozempic and Rybelsus.

For 2023, we expect net financial items to amount to a gain of around DKK 3 billion, mainly reflecting gains associated with foreign exchange hedging contracts. Capital expenditure is still expected to be around DKK 25 billion, reflecting investments in additional capacity for active pharmaceutical ingredients and fill-finish capacity for both current and future injectable and oral products.

Our free cash flow is now expected to be between DKK 66 billion and DKK 78 billion (sic) [DKK 66 billion and DKK 74 billion], reflecting the sales growth and investments in capital expenditures. Based on the increased expectations for cash flow generation, the Board of Directors has approved an expansion of the 2023 share repurchase program by DKK 2 billion to DKK 30 billion in total.

That was the outlook for 2023. Now back to you, Lars, for final remarks.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. Please turn to the final slide. We're very pleased with the double-digit sales growth for the first 3 months of 2023. Sales growth was driven by both International Operations as well as North America Operations. While both operating units contribute to sales growth, the Wegovy relaunch has accelerated sales growth in North America. In general, the sales growth was driven by a continued strong demand for our portfolio of GLP-1 treatments for diabetes and obesity care. The commercial relaunch of Wegovy in the U.S. has underlined the high unmet need for efficacious and safe treatments for people living with obesity and value to society.

We're very pleased with the readout of the PIONEER PLUS trial, which has established a new efficacy standard for all diabetes treatments. These results have made us optimistic ahead of the OASIS 1 results, covering oral semaglutide in obesity. Overall, we look forward to sharing results from several exciting trials reading out in 2023.
With that, we're now ready for the Q&A, while I kindly ask all participants to limit her or himself to 1 or maximum 2 questions. Operator, we're now ready to take the first question.

Question and Answer

Operator

[Operator Instructions] And now we are going to take your first question, and the question comes from the line of Peter Verdult from Citi.

Peter Verdult
Citigroup Inc., Research Division

Peter Verdult, Citi. Just 2 quick ones for Karsten. Firstly, just the top end of the updated revenue guidance that you provided last month. Should we, as the market, view that as the best Novo can achieve this year in light of your projected supply capacities? Or is there still potential outside of the table?

And then secondly, Karsten, just what are your latest thoughts on how GLP-1 pricing dynamics between diabetes and obesity changes with the arrival of competition later this year? Does that differential price point you enjoy hold? Or does your guidance assume the GLP-1 pricing quickly coming down? Just any updated thoughts there would be helpful.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So thank you, Pete. So first, Karsten on the top end guidance and then on GLP-1 pricing. I don't know, Camilla, if you have a perspective of that.

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

Yes. Pete, thanks for that set of questions. So as a starting point, delivering and guiding between 24% and 30% sales growth, it's just important to remember as a starting point, this is really historic level of sales growth for Novo Nordisk on a sizable base in the first place.

And then to your question, is 30% the max, of course, in terms of supply capacity, we can supply to the entire guidance range. So that is our starting point. And as I said at the last quarter, the previous ceiling there was not a magic ceiling. What I will say at this point in time is that we're getting closer to a ceiling, but 30% is not a hard ceiling, if I can put it that way. And to put a little bit of color to that comment then I would say, when I look at our current supply-demand balance for our product portfolio, then we do have drug shortage notifications in a number of markets on our GLP-1 portfolio ex U.S. currently. And as we're covering in today's release, then we are reducing the low dose strengths of the Wegovy. So just indicating that we are running closer to max capacity in terms of what we can supply to the market in a sustainable fashion.

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

Thank you. And on the diabetes pricing dynamics, we have previously discussed that, of course, there are, on a yearly basis, adjustment to the pricing also in GLP-1 based on the volume dynamics. But overall, we expect a stable competitive environment, and that basically means that these are the adjustments that we expect. Then worthwhile reminding that the GLP-1 class as such is very underexploited both in North America but also in International Operations. So in North America, it's around 10% of the diabetes market, and in the rest of the world, including the U.S., it's 5%. So there is still potential for more people being supported by GLP-1 treatment.

Operator

And the next question comes from the line of Michael Nedelcovych from TD Cowen.

Michael Thomas Nedelcovych
TD Cowen, Research Division

Although there have been some supply gaps, Wegovy has been on the market now for nearly 2 years in the U.S. Do you have a sense yet of what median treatment duration is starting to look like in real world practice? Should we be thinking along the lines of 1 year, 2 years, maybe longer?

And then on the GIP/GLP, could you provide any detail on this agent? It sounds like it's a single dual-agonist molecule, and it's moving in ahead in the subcutaneous formulation. Is the oral formulation still going to be developed after the subcutaneous? And more broadly on the mechanism, Novo has suggested in the past that it's unclear what contribution GIP may be making to weight loss. Have you become more convinced of this mechanism? Or are you simply being thorough?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Michael. So if I start on duration of Wegovy, then Martin can try to explain about our innovation.

So it's still early -- too early to comment much about duration. If you look at our very, very impressive uptake in terms of number of scripts -- total scripts, if there was a significant dropout, I don't think you would be seeing that trend curve. So we're very encouraged by that. We can also see when we look at the individual dose strengths that there is a close-to-perfect titration of patients who start on the low dose. After some time, you titrate up, and patients are still titrating up on the high dose. So if you had asked me to draw that before launch, I would have brought something that looked like that for a good day. So very, very encouraging, say, response from patients and how they move up the doses and how that drives total scripts. So we still need a longer time to assess what the safe time would be. So I think that's actually a very positive sign.

And Martin, on GIP/GLP?

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

Yes, absolutely. So very briefly, maybe taking a step back. So we had 2 programs run, and 1 was a co-formulation of semaglutide and GIP that we had in Phase II. And that was the one I described where we actually did not see any effect of adding GIP to semaglutide on either glycemic control. Nobody knows that. That would indicate that the role of GIP, at least in effect of dose combination setting, is minimal.

We then had another track, which is a co-agonist or a unimolecular format. This we ran in Phase I, and we saw, as I said, results that would encourage us to progress this into Phase II. When we then discussed the role of GIP, I don't think we've become 100% wiser. Our dose combination -- or fixed-dose combination study would suggest no role of GIP. But we also have to acknowledge that in the unimolecular formats, we see a good efficacy, and this could then be actually a really good activation of the GLP-1 system or maybe a discrete added benefit of also targeting the GIP receptor.

I think the jury is still out. And for now, we're just encouraged by the clinical data that draws us to go into Phase II with this asset.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

And then to add, you should really see it as a leadership aspiration by Novo Nordisk that we want to have a really strong portfolio in this space. So we are turning every stone. And I think we have exciting signs in both the GLP-1 space, [eminent] space, GIP space and potently others, and we're looking at how we can maximize that for the benefit of patients.

Thank you, Martin, and thank you, Michael. So next question, please.

Operator

And we are now taking the question from Harry Sephton from Credit Suisse.

Harry Thomas d'Alton Sephton
Crédit Suisse AG, Research Division

My first question is on Ozempic. Trends in the first quarter were particularly strong. And I wanted to get your thoughts on the contributors to that performance. You talked about increasing penetration in first-line use, but we haven't really seen much drop off in metformin use. So is Ozempic attracting a new cohort of patients to treatment given the high efficacy? Or are you seeing more widespread off-label obesities?

And then my second question. Ahead of OASIS 1 data, can you outline how you view the opportunity for oral sema in obesity and how the opportunity relative to injectable [sema-made data] to the diabetes market given that it competes against many cheaper diabetes alternative?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

Thank you, Harry. So maybe, Doug, if you first give a perspective on the fact that we indeed see very, very strong Ozempic growth. So how do you -- what do you attribute that growth to? And then Martin, any [readout course] on OASIS 1 from the recent data. Thank you.

So first you, Doug.

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Yes. Thanks, Lars, and thanks for the question. What I'd first start by saying is that we did -- it's a good reminder that we did return to full supply with Ozempic and we have had strong momentum. And then importantly, I think we're still seeing well over 80%, almost close to 90% of the prescriptions are coming from new patients and new to GLP-1 class. So we're seeing earlier use in more naive and patients that are new to the category. So I think that's important and continued momentum.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Doug. Martin?

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

Yes. So we haven't seen the OASIS results yet. But based on what we saw with the data from 25 and 50 milligram in diabetes, we would expect to basically see what we plan out to do, namely parity vis-à-vis Wegovy on efficacy, on safety and on semaglutide exposure, which is sort of the regulatory requirement. That basically means that an oral offering in new business space holds a really, really strong potential. First of all, because we get the full efficacy and safety benefit of the semaglutide molecule but also the benefit of a different mode of administration. And we do know that some patients but also some prescribing physicians will prefer the oral offering over a subcutaneous treatment. So having the full palette will obviously release that further potential.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. And also -- I think I'll also just add -- just also add that for IO despite some drug shortage notifications, we still see above 50% growth in IO. So we see really, really strong demand for the type of clinical benefit that Ozempic is giving.

Thank you, Harry. Our next set of questions, please?

Operator

[indiscernible] Societe Generale.

Florent Cespedes
Societe Generale Cross Asset Research

Can you hear me?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Florent, please go ahead. Yes, please do ahead.

Florent Cespedes
Societe Generale Cross Asset Research

Two quick ones. First, for Karsten on margin. Could you elaborate on how you see the trend of your operating profit margin after the strong Q1? So that's on the medium term.

The second question is more early days, but it's regarding the Inflation Reduction Act. Could you please share with us your thoughts on how you see this that could impact your GLP-1 portfolio?

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

Thank you, Florent. So Karsten, first on your expectations for medium-term margin. And then, Doug, you can perhaps cover the Inflation Reduction Act question, how that would potentially impact us.

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

Yes. Thank you, Florent, for that question. So margin is, of course, a function of both our top line momentum and our investments into the business. And then finally, our choices in that respect. And our strategy as company is to drive innovation-based growth. So what we are doing is that we are investing in growth, and that is both short-, medium- and long-term growth, whether it's in our marketed portfolio today or whether it's building a strong pipeline of products in R&D. So that's our intention, and margin -- in itself, as a consequence, is not a target in itself. You see us delivering pretty much 47% operating margin in the first quarter. So top quartile margin compared to that of the industry. So we believe that we generate the most value by driving top line growth and a competitive R&D portfolio.

With that said, clearly, in a scenario, as we are in now with very, very high growth levels in, say, in the 20s, then the organic investments and scaling in the company will most often be below that. And as a consequence, we will have margin leverage for the company in a mainly organic scenario. And then I'd say, then how that entails versus BG, of course, that's more a stochastic function of progress on our BG agenda and the type of assets and companies that will join the company.

So to summarize, not a target in itself. But with a higher top line run rate, then logically, we are disciplined and will be driving margin.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. And Doug -- good, thanks. Doug, on the Inflation Reduction Act, there are different components, some with the short-term impact, some of the longer term. What can you say about that, Doug?

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Yes, exactly, Lars. There's some positives and some negatives. But as a reminder, there are 4 components to the IRA that could impact Novo Nordisk. It's the inflation penalty, Part D redesign, the insulin $35 cap and the direct negotiations. And again, as a reminder, direct negotiations, they're doing 2027. And it does appear that CMS will be implementing a molecule-based negotiation instead of a brand-based. But there's still some uncertainty as it relates to the price and the initial offer of that price and when it will begin. So I would say there's several components, some good guys and bad guys and still some uncertainty around that.

Operator

And the next question comes from the line of Simon Baker from Redburn.

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

Two, if I may. Firstly, on Wegovy capacity. We've obviously talked a lot about fill-and-finish capacity, which is coming on in this year. Firstly, could you remind us where we are into the next coming years of API capacity? And related to that, I've heard a few anecdotal stories in the U.K. of people seeking private payer, Wegovy being told there's no supply and then immediately going on to Saxenda. I just wanted to know if you had any color on that in the U.K. and other markets. Is that a meaningful driver of Saxenda and this Wegovy warehousing?

And then another question on semaglutide. I see 6 weeks ago, you started a Phase I study comparing formulation J with the current semaglutide C. I wonder if you could just give us a flavor for the characteristics of the J formulation versus the current one.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Simon. So on Wegovy, I will start by saying that manufacturing is running well. You have seen that we have now the second contract manufacturer up and running and contributing. And that's what enabled us to lift our forecast, I would say, rather significantly earlier in April. We have also guided that we'll be adding more lines. So later in the year, there will be a third line. And you can imagine that we have -- that's not the end. More will be coming.

We have also guided that we have upgraded our CapEx. So we are investing significantly also in-house, and that includes API. You know we have, a couple of years back, started a project in Denmark with API expansion. You know that we have a facility in U.S. that has just been approved, et cetera. So there's a lot happening. And while we do see some short-term need for holding a bit back on the starter doses in the U.S., we are very, very encouraged about our ability to scale our manufacturing setup and just the fact that we guided as we do now on top of, say, 14%, 16% growth the last few years. And of course, this year, we have the kick-in of Wegovy. And if you, say, normalize for that, it is a very, very sizable and meaningful growth that we believe we can cater to.

So I'm not going to more specifics than that. But these are known technologies for us. We are scaling, and we will be scaling going ahead. I cannot go into a lot of details about what is happening in the U.K. I don't have the knowledge. I don't know anyone here around the table who can give a lot of clarity around that. But I think we have a wise man in Martin, who can talk a bit to the sema formulation?

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

It's going to be a short answer. So I'll just say that the purpose of our formulation upgrades is obviously to, first and foremost, improve bioavailability of semaglutide. And we continue to do further the development of that. To your point, we've had several improvement since our first formulation, but I cannot go into specific details of what the individual upgrades entail.

Operator

And the question comes from the line of Richard Parkes from BNP Paribas Exane.

Richard J. Parkes
BNP Paribas Exane, Research Division

I've got 2 questions as well. Firstly, just to push a little bit more on the bottleneck limiting Wegovy supply. I don't know if you can give any more clarity on whether it's the API or fill-finish. And I suppose, the reason for the question is I'm wondering to what degree you've got...

Operator

Excuse me, Richard, your line is open, please ask your question.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Richard is online, operator. Yes, we can hear you. Please continue.

Richard J. Parkes
BNP Paribas Exane, Research Division

Yes. Okay. So I'll repeat it because I'm not sure what you caught or what you didn't. Just in terms of the bottleneck limiting Wegovy supply, I just wanted to push you a little bit more on that in terms of whether it's API or fill-finish. The reason I'm asking is I wanted to understand what degree you've got headroom with Ozempic capacity to maybe offset that limitation if your demand for Ozempic accelerates as a result of the limitation on Wegovy supply. So that's the first question.

Second question is we've seen extremely strong data from the SURMOUNT-2 study of tirzapatide in obese diabetics recently, which could make it a very attractive option for that patient population. And I think the placebo-adjusted weight loss was 2x what you saw in the Wegovy trial. And maybe that reflects the added benefit of improved glycemic control with tirzapatide in that population. But I'm wondering if you had a sense of what you think could be achieved in that population with CagriSema. I know you've guided to where you think the weight loss will fall out in terms of obese population but not maybe obese diabetics.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Richard. I'll start a bit on the supply side, and then Martin can talk to probably CagriSema more than competition.

So I'm not going to a lot of details, but I'll just say that, obviously, we have the API component. We have different devices. We have different filling setup. And of course, we also have the oral formulation. So first of all, that's a really, really strong setup. And it gives us some flexibility in how we actually build volume that we are not relying on just one presentation. And -- but I'll just say that we are

-- we have a growth strategy, and just looking at our numbers, we are growing tremendously. And we have, long ago, made the choice of expanding that, and we believe we can continuously grow also for the coming period.

But going into very detailed comments about where bottlenecks are, I think that's getting it [through] operational for how we guide. So you have to trust us when we say that we're very confident in our ability to scale and drive growth. And don't play too much into, say, short-term demand management because it's really about building a sustainable experience for the patients, and we are quite confident that we can drive growth that is quite attractive for the coming period also.

Martin, on competitiveness with CagriSema?

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

Yes. So first of all, I just want to call out, with semaglutide in type 2 diabetes into the 2, we see approximately 10% weight loss. I also want to remind you that we are currently running a Phase III trial in both diabetes but also in obesity with 7.2 milligrams of semaglutide, and we do actually, based on our modeling, expect to see in diabetes an approximately 13% to 15% weight loss and in non-diabetes obesity around 20% weight loss. So not too far away from what you just described. And then that comes then with the very attractive safety profile that we know from semaglutide.

But specifically on CagriSema, this is probably where we see the step-up or the step change. Based on what we've seen so far in type 2 diabetes, we would expect an approximate 20% weight loss in and of itself. So actually, more than what we just described, again, with an attractive safety profile. And in obesity, without diabetes, we would expect approximately a 25% weight loss. So from our perspective, semaglutide, maybe with a higher dose is actually already, in and of itself, an attractive offering and, obviously, with CagriSema. And as you know, we are currently testing that in Phase III in both type 2 diabetes and obesity. We expect a substantial and significant step-up.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. I think just underlying what I mentioned before, we believe we can lead in this space, and we have a breadth of a portfolio already visible now but also more coming that we can hopefully keep teasing out superior profiles here.

Next question, please.

Operator

And your next question comes from the line of Kerry Holford from Berenberg.

Kerry Ann Holford
Joh. Berenberg, Gossler & Co. KG, Research Division

Two questions, please. Firstly, just again on Wegovy. Can you detail when we can expect you to return to market with [the formal] doses [compared to the supply of those] lower doses. and then how we should think about quarter-on-quarter growth as you move through the year? And in the context of those constraints, I wonder if you can also talk about your decision to continue to launch Wegovy in ex U.S. markets as opposed to prioritize in the U.S. And can you tell us your position here?

And then secondly, on SELECT, you must be very close to the readout now. And as we head into that catalyst, I wonder if you could remind us, in your minds, what constitutes a hit or constitutes a miss? I think most of us expect a positive result, but I would be interested to hearing your view what you see in the consequence of a SELECT miss would be to Wegovy and the wider obesity market potential?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Kerry. So I'll give a shot on the first question on Wegovy. Then Martin, you can prepare for SELECT. I know it's one of your favorite topics.

So we have mentioned that we are reducing the starter doses in the coming months. So we're not being very explicit on what that means, but it's -- we expect a limited period on this. And I don't think we can get into quarter-by-quarter growth analysis. But of course, when you look at the TRx trend just the past few months here, there is a quite strong growth profile of that, that will drive

growth also in the coming quarters. And you can see our recent upgrade, which is taking this changed, say, availability of starter doses into consideration that we see a very strong opportunity for sustaining growth.

With regards to launches outside of the U.S., we are eagerly interested in doing this gradual rollout also in more countries. We have seen a very strong uptake, both in Denmark and Norway. But of course, just like in the U.S., it's important that we factor in capacity when we do these launches so we can sustainably supply patients. And I'll not go into more specifics about what countries are next and when. There is some, say, competitive nature around that, that we'd like to keep for ourselves.

Martin, on SELECT?

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

Yes. So I'm the R&D guy. So when you ask me for what constitutes a hit for SELECT, I'll only speak to it from a medical and scientific perspective. And in that respect, anything statistically significant makes sense. The primary endpoint is -- [it means] that's MI, that's stroke, that's cardiovascular death, and saving a significant number of patients in that space is obviously a hit. Specifically, for SELECT, we designed the study with the power of detecting 17%. That is still our assumption. We have no new knowledge since we discussed this last. So the 17% would obviously be the perfect hit, but it could be plus, minus a few percent and still be highly statistically significant. So basically nothing new on that.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. And maybe I can add, say, a real-world data point because we have a lot of dialogue with health care systems, payers around the world. And many of them actually approach us with data showing a correlation between high BMI and consumption of medical services. So of course, SELECT is important in establishing the health benefit of obesity intervention, but it's actually already being acknowledged today. Those payers, those, say, integrated health care systems that have data on the population can see that high BMI leads to higher consumption of health care services. So I believe antiobesity medicine has the opportunity of establishing itself as one of the best, say, investment cases for health care systems when it comes to actually addressing this chronic disease.

Thank you, Kerry. And next set question, please?

Operator

Your next question comes from the line of Sachin Jain from Bank of America.

Sachin Jain
BofA Securities, Research Division

Two, if I may. So earlier, you mentioned a stable GLP-1 pricing environment. Payer debates on GLP-1 and diabetes and obesity have come up on a number of payer calls. So I just wonder if you're picking up any pressure in your sort of conversations on attempts to restrict off-label usage and the telehealth phenomenon that's obviously across all of the press. And perhaps can you -- could just update us on what percentage of Wegovy you see as cash usage and the average BMI of Wegovy usage? That would just be helpful, I think, to comfort investors around the off-label.

Secondly, for Karsten, just obviously big upgrading guide. Any color on what fade in GLP-1 market growth or Wegovy trends are assumed in the top end of guide? I just wondered if you could update us on Wegovy bolus discussion from back at full year, which doesn't seem to be correct and it doesn't really feel like that your top end of guidance is assuming a continuation of this 50% market growth rate.

And then if I may, can I just add one clarification to Richard's prior question? If Wegovy flatlined and Ozempic, Saxenda inflect, can you supply that inflection?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you. Sachin, I think we'll go to you first, Doug, on how you're seeing the U.S. payer focus on GLP-1 pricing and if you could also give a perspective on what you see of Wegovy profile cash/on formulary insurance and also BMI profile of those we treat. And then Karsten, there were some questions on what we have assumed in the guidance and also product mix.

We'll go to you first, Doug.

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Yes. Thank you, Sachin. Thank you, Lars. So I think it's, first, important to note that we continue to see very strong access for Wegovy. We have over 40 million lives today that includes all major PBMs. I think it's also normal to see, as you see increasing focus and pressure on products that have volumes going up, and that's in any category, including this one, which continues to add controls to those products. So I think that's just important. As far as the question around cash, we see it about 5% to 10%. But also importantly, we see over 80% of our patients today pay $25 or less. So I think that's important to note.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thanks, Doug. Any -- do you have any data on the BMI for those who are on treatment?

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Yes, I'm sorry. I forgot. Yes, it's about 38 here in the U.S., BMI.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So very, very high BMI. I think that's -- those are encouraging data, both in terms of the type of what payer profile and BMI. And Karsten on some of the assumptions?

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

Yes. So of course, when we build our guidance, then we're looking at the most recent data points in our trending. And the big movers in terms of sales growth for the company this year is clearly Ozempic and Wegovy. I wouldn't go into the details on what exact assumptions we have because, as you know, market growth is a function of competition, payers, prescribers, et cetera, and supplies. And I would say that when we did the Wegovy forecast for our guidance, we did anticipate a slowdown in TRx growth. And we have been out saying that we would not be able to supply to a continuation of the trends we saw in the first month of the year. So guidance-wise, there's no big surprise in a bending curve for Wegovy in terms of the mathematics.

Ozempic, yes, we put an assumption in, which, of course, is linked to the oral trending in the market and supply situation. And as I said in my first commentary around the top end of the guidance, then the key point is that it's not -- 30% is not a hard ceiling, but we are getting closer to our capacity limitations as evidenced by the drug shortage notifications and the reduction in low dose strengths for Wegovy.

Sachin Jain
BofA Securities, Research Division

There was also the Ozempic -- sorry, there was the Ozempic, Saxenda supply inflection question if Wegovy go flatlined. I don't know whether you can address that.

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

I think, Doug, if you could speak to the Wegovy/Ozempic. But if I start out, then I would say, for any spill or consequences from the reduction in low dose strengths of Wegovy, then the key point here is that a big part of the patients getting Wegovy, they actually seek Wegovy when they get to the physicians and get the scripts. And we're not out of the market with the low dose strengths. We're just reducing supply. So I would balance your question by saying that probably a lot of the patients say they will be getting the product. There might just be a delay in terms of when their script is being filled at the pharmacy.

I don't know, Doug, if you have more to add to that.

Douglas J. Langa
Executive VP of North America Operations & Member of Management Board

Karsten, what I would just add is that overall, and Camilla mentioned it earlier, that diabetes has still an overall lower GLP-1 penetration rate. And then secondly, we expect continued strong demand for our GLP-1 products. We have strong demand now, and we continue -- and we expect continued demand.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you. We have time for one quick final round of questions.

Operator

Your next question comes from the line of Mark Purcell from Morgan Stanley.

Mark Douglas Purcell
Morgan Stanley, Research Division

Two questions. On your plans for oral GLP-1, you've obviously solved the clinical challenge, but not the COGS challenge yet. So when should we expect you to achieve small molecule like COGS with your SNAC technology? And can you provide some perspective on whether you would seek to develop a small molecule GLP-1 asset as an insurance policy?

And then secondly, in terms of GLP-1 supply fill and finish, that whole topic, where are you in terms of being able to meet demand for Ozempic in the international markets where penetration rates are so much lower? And can you give us some assurance in terms of how you're building the supply chain behind the CagriSema when it comes to a more complex device than the fill and finish behind that?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Mark. I don't think we can give you a time for when we can produce all SNAC-based GLP-1 to the COGS of a small molecule. And by the way, the COGS of a small molecule might not be that low actually because it's actually a quite complex synthetic process. Whether we would pursue a small molecule, I don't want to be specific on that either. That's part of the strategic considerations. But I would just caution that it's a given that small molecule will actually be as both efficacious and perhaps also as cheap as one might believe.

In terms of the GLP-1 supply chain for Ozempic ex U.S., I think the answer is consistent with what I've been saying so far that we're building capacities. We have a number of lines kicking in. And of course, it's a key priority for us to get the balance right and serve the patients that rely on us. And I would just also underline that International Operations is a key growth opportunity for us. And we have a significant share in that territory, and there are a lot of patients. So it's a very large growth opportunity. So when we scale capacity, it's also to serve those patients.

On CagriSema, you raised a good point that it is indeed a more complex molecule. There are 2 APIs. There is a dual chamber and device component to that. So we have, of course, some scars on our back in terms of scaling supplies from Ozempic and Wegovy. So we're taking this very seriously, but it is a significant task to solve. But I think there's also a significant opportunity what that product can deliver. So it's something that has highest priority in the company.

Thank you, Mark, and thank you all for participating. I trust you can sense that we are very excited about the opportunities we have in Novo Nordisk. And we are investing in our business to drive growth in the coming period. I'd like to thank you for participating. And of course, feel free to reach out to our Investor Relations officers if you have any further questions. Thank you, and have a great day.

Operator
This concludes today's conference call. Thank you for participating. You may now disconnect.