S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

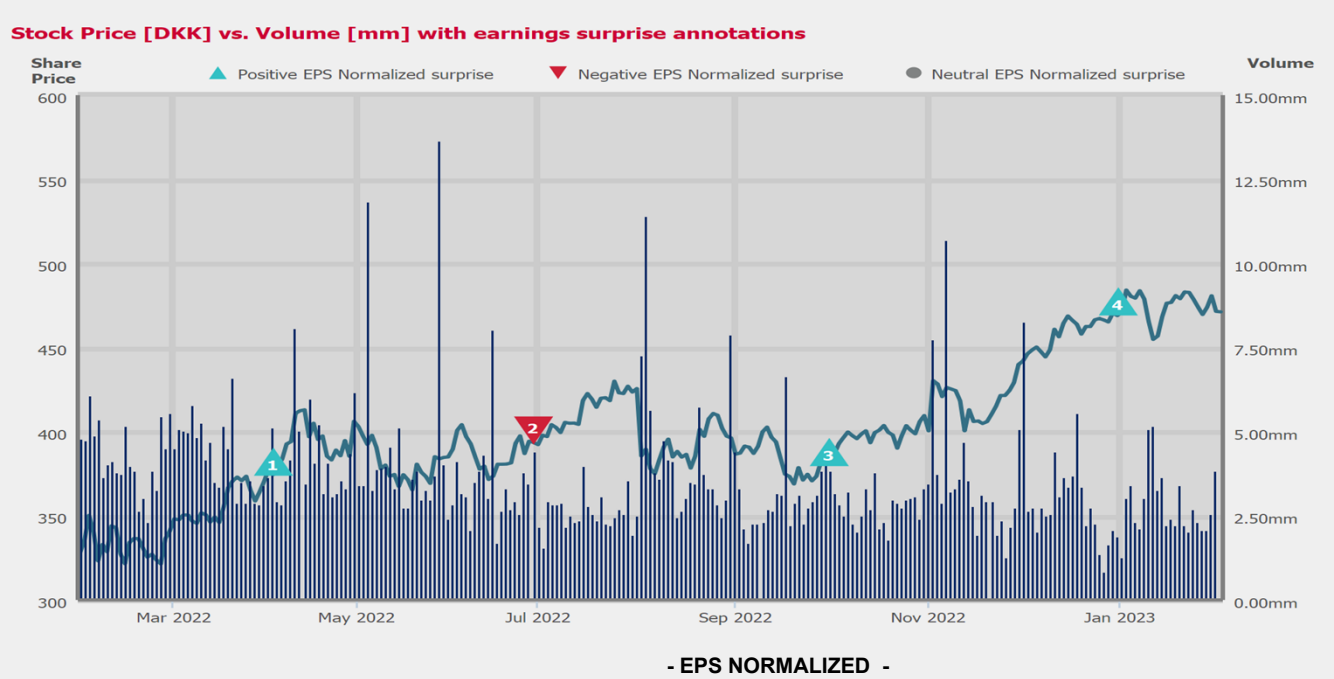
FY 2022 Earnings Call Transcripts

Wednesday, February 1, 2023 12:00 PM GMT

S&P Global Market Intelligence Estimates

	-FQ4 2022-			-FQ1 2023-		-FY 2022-			-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	SURPRISE	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS
EPS Normalized	2.93	3.01	2.73	3.82	1.62	12.11	12.22	0.91	15.11
Revenue (mm)	47116.07	48092.00	2.07	47946.21	2.25	175090.13	176954.00	1.06	199676.30

Currency: DKK
Consensus as of Feb-02-2023 9:57 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FY 2022	12.11	12.22	1 0.91 %

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EXECUTIVES

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

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Martin Holst Lange
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Presentation

Operator

Good day and thank you for standing by. Welcome to the Q4 2022 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, Lars Fruergaard Jorgensen, CEO. Please go ahead.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, operator. Welcome to this Novo Nordisk Earnings call for the full year of 2022 and the outlook for 2023. My name is Lars Fruergaard Jorgensen, 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 would 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 the call is being webcasted live, and a recording will be made available on our website as well. This 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 rates unless otherwise specified.

Please turn to Slide 3. As always, I need to advise you that this call will contain forward-looking statements. These are 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 full year of 2022 and the slides prepared for this presentation.

Please turn to the next slide. In 2022, we delivered double-digit sales growth and operating profit growth, and we continue to make progress on our strategic aspirations. I'd like to go through the highlights before handing over the word to my colleagues. We continue to make progress across all dimensions of purpose and sustainability. Our carbon emissions decreased by 29% compared to pre-pandemic levels in 2019, and we continue to reach even more patients and patients living with diabetes compared to last year.

In line with our aspiration of being a sustainable employer, we expanded the number of women in leadership positions to 39% compared to 36% in 2021. Within R&D, we are pleased that we now have initiated the first 2 Phase I trials based on the Dicerna, in the siRNA technology platform that we acquired in 2021. Looking back at 2022, we have seen exciting trial readouts across all our therapy areas. And in 2023, we look forward to having an equally exciting year. Martin will come back to this and our overall R&D milestones later.

In 2022, we delivered double-digit sales growth, reflecting strong commercial execution in core geographies and our therapy areas. Our both operating units contributed to sales growth, we saw a particular strong sales growth in North America, driven by accelerated demand for our GLP-1 treatments for both diabetes and obesity. Camilla and Doug will go through the details for therapy area later. Karsten will go through the financials, but I'm very pleased with the sales growth of 16% and operating profit growth of 15% in 2022.

Lastly, I have a brief update on our strategic aspirations within financials. We have achieved the U.S. aspiration of converting 70% of sales through products launched since 2015 and IO sales growth has in the last couple of years, surpassed aspiration of 6% to 10% growth. Consequently, we have decided to remove these regional iterations. Going forward, we'll be focused on and committed to delivering solid sales and operating profit growth.

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 16% sales growth for the full year of 2022 was driven by both operating units with North America operations growing by 21% and international operations growing 13%. The strong sales growth has unfortunately resulted in periodic supply constraints and related stock shortage notifications across a number of products and geographies.

Our GLP-1 sales increased by 42%, driven by North America growing 36% and international operations growing 57%. Insulin sales decreased by 11%, driven by a 7% decline in international operations and a 21% sales decline in North America operations. The U.S. insulin sales declined by 22%. This was driven by lower realized prices as well as a decline in volume. Compared to 2021, the U.S. insulin volume market declined by 3%. Furthermore, insulin sales in international operations were impacted by the implementation of volume-based procurement in China, starting in May 2022 and lower sales in EMEA.

Obesity care sales grew by 84% overall. In International Operations, sales grew by 82%. And in North America Operations, Obesity care sales grew 85%. In the U.S., Obesity Care sales grew by 90%.

Rare Disease sales grew 1%, driven by a 5% sales increase in international operations, offset by a 5% decline in North America operations.

Please turn to Slide 6. Our 14% sales growth within Diabetes Care continues to be higher than the overall diabetes market. That means we have improved our market share by 1.8 percentage points to 31.9%. We continue to be 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. International Operations' Diabetes Care sales increased by 10% in 2022, driven by GLP-1 sales growing by 57%. Novo Nordisk remains the market leader in international operations with a GLP-1 value market share of 64%. This is driven by share gains across geographies. Ozempic continues to expand its GLP-1 market share leadership in international operations with around 43% market share. While the GLP-1 class growth is more than 50%, GLP-1 penetration remains low at around 5% of total diabetes patients globally.

Rybelsus sales more than doubled compared to 2021. The growth was mainly driven by new launches and increasing volumes, making Rybelsus the second largest growth contributor in 2022 after Ozempic. The increased momentum in international operation is driven by launches in key markets such as Japan, Italy and Spain.

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. The U.S. GLP-1 market volume grew by around 50%, comparing the fourth quarter of 2022 to the fourth quarter of 2021. The recent competitor launch in GLP-1 has supported the continued acceleration in market growth and from an NBRx perspective, we continue to see all-time high levels of new patients starting on our portfolio of GLP-1 products on the end of 2022. Measured on total prescriptions, Novo Nordisk has maintained its market share leadership with a market share of more than 50%.

Please go to the next slide. Obesity care sales increased by 84%, with 85% growth in North America operations and 82% in international operations. The global branded obesity market expansion continues with a volume growth of more than 50%. We are excited that Wegovy is now launched in Denmark and Norway, the first 2 markets outside of the U.S. But we also remain encouraged by the performance of Saxenda in international operations. Region EMEA is the key growth driver with 96% growth in 2022. In the U.S., Obesity care sales grew 90% with both Wegovy and Saxenda contributing to growth. All dose strengths of Wegovy were made available in the U.S., again in December of 2022. And in only a few weeks, Wegovy prescription trends have accelerated and already reached all-time high levels.

The uptake underlines the significant unmet need for patients with obesity. Many patients have been waiting for all doses of Wegovy to be available again, which has created a pent-up demand. We are now looking forward to continuing the relaunch of Wegovy.

Now back to Camilla for an update on rare disease.

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

Thank you, Doug. And next slide, please. Our rare disease sales increased by 1% in 2022. This was driven by a 5% sales growth in international operations, offset by a 5% decline in North America provisions, where blood disorders grew by 7%, driven by NovoSeven as well as the launch products, Esperoct and Refixia. Specifically, hemophilia A products grew by 6%, hemophilia B sales by 16% and NovoSeven by 6%, rare endocrine disorder sales declined by 6%. The declining sales were driven by international operations decreasing 1% and by North America operations decreasing by 18%. The sales were negatively impacted by lower realized prices in the U.S. as well as the supply constraints in the fourth quarter of 2022.

And 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, Camilla. Please turn to Slide 11. Firstly, I'm very happy to be able to share that we have initiated 2 Phase I trials within NASH. This is particularly exciting because the 2 assets are both based on the small interfering RNA technology that we acquired as part of the Dicerna acquisition back in 2021. Both trials are 52-week trials and target LXR and MARC1, respectively. Both assets are aiming for long-term NASH resolution and fibrosis improvement with monthly or even less frequent dosing.

The objective of both Phase I trials is to investigate the safety, tolerability and PK/PD profile of each asset respectively. The fact that we have now initiated these trials is a testimony to the successful integration and fast progression of the RNA-based research and development in Novo Nordisk. As mentioned at our Capital Markets Day in March of last year, our ambition is to generate an annual average of 3 first human doses across therapy areas based on the RNA technology over the next 10 years.

Please turn to the next slide. We're looking forward to a very exciting 2023 with many important Phase III trial readouts across our therapy areas. I would like to briefly go through a few highlights. We then have 2 diabetes we expect to see results from the Phase III trial PIONEER PLUS with once-daily oral semaglutide 25 milligram and 50 milligram, respectively, during the first half of 2023. The primary endpoint of the 68-week trial is to confirm superiority of oral semaglutide 25 milligram and 50 milligram versus oral semaglutide 14 milligram on A1C reduction. The expectation is to reach an efficacy and safety profile comparable to that of Ozempic.

Also in diabetes, we expect to initiate the Phase III program with CagriSema in the second half of 2023, following the very exciting Phase II results that we shared last year. Furthermore, we have completed the 26-week safety extension phases for the ONWARDS 1 and 6 trials with insulin icodec. The results confirm that insulin icodec has the potential to be the ideal for -- insulin for people with type 2 diabetes, while there are still more assessments to be done in type 1 diabetes. We expect to submit insulin icodec for a regulatory review in the first half of 2023.

In obesity, we look forward to sharing the Phase III results from once daily oral semaglutide type 50 milligram, where our expectation is to reach a level of efficacy and safety comparable to that [OI]. Pending the results, this would add to our portfolio of obesity treatments to address the significant unmet need that remains for many patients with obesity.

Furthermore, we look forward to sharing the results from the ongoing SELECT cardiovascular outcomes trial in the middle of 2023. Within rare disease, we are looking forward to a decision from regulatory authorities on once weekly Sogroya for the treatment of growth hormone deficiency. This will offer a reduced treatment burden compared to daily Norditropin and a device that is easy to use for patients.

Finally, we expect to initiate a Phase IIIb trial with Ziltivekimab for the treatment of heart failure with preserved ejection fraction in the first half of 2023. Altogether, we are looking forward to a very exciting year with clinical trial initiations as well as results across our therapy areas.

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 2022, our sales grew by 26% in Danish kroner and 16% at constant exchange rates, driven by both operating units. The gross margin increased to 83.9% compared to 83.2% in 2021, driven by a positive product mix due to increased GLP-1 sales, a positive currency impact and productivity improvements. Lower realized prices, particularly in the U.S. and China partially offset these effects. Sales and distribution costs increased by 25% in Danish kroner and 16% at constant exchange rates. The increase is driven by launch activities and promotional spend for Rybelsus and Ozempic, as well as market development activities for obesity. The cost increase is reflecting low activity levels in 2021 due to COVID-19 and higher distribution costs.

Research and development costs increased by 35% in Danish kroner and 29% at constant exchange rates. The increase is driven by higher clinical activity levels within other serious chronic diseases and GLP-1, as well as the operating costs and amortizations related to the acquisition of Dicerna Pharmaceuticals. We acquired Dicerna in the fourth quarter of '21.

Administration costs increased by 10% in Danish kroner and 6% at constant exchange rates. Operating profit increased by 28% in Danish kroner and by 15% at constant exchange rates. Net financial items for 2022 showed a loss of around DKK 6 billion compared to a gain of around DKK 0.4 billion in '21. This mainly relates to losses following the appreciation of the U.S. dollar as reflected in the favorable currency impact on operating profit.

As per the end of December '22, a positive market value of financial contracts of approximately DKK 1 billion has been deferred for recognition in 2023. The effective tax rate in '22 was 19.6% compared to 19.2% in '21, mainly reflecting nonrecurring impacts from acquisitions. Net profit increased by 16% and diluted earnings per share increased by 18% to DKK 24 and EUR 44.

Free cash flow was DKK 57.4 billion compared to DKK 29.3 billion in '21, supporting the strategic aspiration to deliver attractive capital allocation to shareholders. The cash conversion in '22 is positively impacted by timing of rebate payments in the U.S., including provisions related to the revised 340B distribution policy in the U.S. Income under the 340B program has been partially recognized.

Please go to the next slide. In 2023, we expect to increase our capital expenditure to around DKK 25 billion. This is a significant step-up compared to 2022 and reflects the innovation-based growth strategy that we are pursuing in Novo Nordisk. The increase in capital expenditure mainly relates to investments in additional capacity for active pharmaceutical ingredient production and fill finish capacity for both current and future injectable and all products across therapy areas.

In the coming years, the capital expenditure to sales ratio is expected to be low double digits. The investments will gradually add capacity, flexibility and resilience in our manufacturing setup while also accommodating for potential upsides to forecast.

Next slide, please. In 2022, we returned more than [DKK 49 billion] to shareholders via dividends and share buybacks. Novo Nordisk has consistently returned its free cash flow to investors through both share buybacks and dividends. At the Annual General Meeting on March 23, 2023, the Board of Directors will propose a final dividend of DKK 8.15 for a total 2022 dividend of DKK 12.40, a 19% increase compared to 2021, making it the 27th consecutive year with increasing dividends.

In addition to the dividends, DKK 24 billion was used for repurchase of shares. For 2023, the Board of Directors has approved a new share repurchase program of up to DKK 28 billion to be executed during the coming 12 months.

Next slide, please. We continue 2023 with solid growth momentum and expect the sales growth to be between 13% and 19% at constant exchange rates. This is based on several assumptions as described in the company announcement. The guidance reflects expectations for sales growth in both International Operations and North America operations, mainly driven by GLP-1 based treatments for diabetes and obesity care. The sales growth within diabetes and obesity care is expected to be partially countered by declining sales in rare disease due to supply constraints. The guidance ranges for sales and operating profit growth reflect the level of volume growth of GLP-1-based diabetes treatments. They also reflect the inherent uncertainty of the pace of obesity care market expansion following the relaunch of Wegovy in the U.S. and expected gradual rollout in international operations.

The outlook includes an expectation of continued periodic supply constraints and 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 temporary capacity limitations at some manufacturing sites. We are gradually increasing our supply capacity.

We expect that operating profit will grow between 13% and 19% on constant exchange rates. This primarily reflects the sales growth outlook and continued investments in current and future growth drivers within research, development and commercial. Commercial investments are mainly related 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. The acquisition of Forma Therapeutics is negatively impacting the operating profit growth due to higher operating costs and amortizations.

Finally, the guidance also reflects inflationary impacts on the cost base. Given the current exchange rates, most notably a weakening of the U.S. dollar, we expect a negative currency impact for 2023. Our reported sales are expected to be 4 percentage points lower at CER and operating profit is expected to be 5 percentage points lower at CER. The negative currency impact on operating profit of 5 percentage points is partially offset by a net gain on financial items. We expect that financial items will amount to a net gain of around DKK 2.4 billion, mainly reflecting gains associated with foreign exchange hedging contracts. Capital expenditure is expected to be around DKK 25 billion in 2023, as I outlined earlier in this presentation. Our free cash flow is now expected to be between DKK 60 billion and DKK 68 billion, reflecting the sales growth and investments in capital expenditure.

That covers the updated outlook for '23. 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 full year of 2022 and that we continue to reach even more patients. 2023 is a truly significant year in history of Novo Nordisk as we celebrate our 100-

year anniversary. In this period, we have grown from a small Danish company into a global one, developing life-saving medicines for millions of patients around the world.

In 2023, we look forward continuing our focus on commercial execution, expanding our pipeline and investing significantly in the expansion of production capacity for current and future products. With that we're now ready for the Q&A, we kindly ask all participants to limit her or himself with 1 or maximum 2 questions.
Operator, we're now ready to take the first question.

Question and Answer

Operator

[Operator Instructions] We will now take our first question. One moment, please. And it comes from the line of Harry Sephton from Credit Suisse.

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

It'll just be the 1 on pricing, please. So our latest pricing data suggests that you've only taken a low single-digit price increase in January across your U.S. portfolio, despite the larger headroom for price increases this year with high CPI. Could you look to increase prices a second time later in the year given the headroom for price increases?

And then just on your international operations as well. There are a number of drug pricing reforms being proposed across European markets. Do you anticipate that these changes could be material near-term headwinds to your growth in international operations?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Harry. So Doug, a perspective on how we look at pricing in the U.S. first.

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

Yes. Thanks, Harry, for the question. We had a commitment back in 2016 around price and we've held to that commitment. And I don't want to give any forward-looking statements on price moving forward.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you. So on Europe, we don't anticipate any single event to be material. We have, over the years, seen various countries operating with different reforms, sometimes in the form of something that looks more like a tax. So we are used to operating in this environment, and you should expect that for now, our guidance incorporates what we anticipate in this. Thank you, Harry.

Operator

We will now take the next question. And it comes from the line of Peter Verdult from Citi.

Peter Verdult
Citigroup Inc., Research Division

Peter Verdult, Citi. Two questions. Doug, you can be the first, just in light of these U.S. GLP-1 trends we're seeing, the intense publicity and media coverage, can you characterize how, if at all, recent payer discussions are evolving? Are you sensing any efforts to step up and restrict access more aggressively? And can you provide an update on the 30 million commercial opt-in number that you provided in Q3?

And then to Lars and Karsten, just if I could try my luck and push you to better understand what is possible and what is not with respect to Wegovy capacities that you have in place for 2023. If I look at the Q1 trends, we're fast approaching 40,000 weekly script rate, which is implying annualized sales around DKK 2 billion. I know you've talked about pent-up demand, but you and Lilly are also going to start promoting proactively to develop the market further. So just with that in mind, do you have the theoretical capacity in place to support Wegovy being a DKK 3 billion to DKK 4 billion drug in 2023? I'm not asking for guidance, but I want to get a handle on what's possible and what is pure fancy with respect to the obesity market potential this year?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Pete. So Doug, first, on U.S. GLP-1 trends, payer discussions and the patient access we have.

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

Yes. Thanks, Pete, for the question. And I would say that certainly, first thing to recognize is that the volume of prescriptions in the GLP-1 category is still only about 10%. So there's a lot of runway there. Secondly, what I would say is that the payers do take notice the categories that are growing. This one is certainly growing at double digit, but they also recognize the need for this product. And again, it's only 10% of the prescription volume. Did I miss something within here?

Peter Verdult
Citigroup Inc., Research Division

30 million.

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

Yes, Pete, I'm sorry. Importantly, we guided on -- in Q3 of 30 million. We're now at approximately 40 million lives. So it's overall 80% access, and that equates to the effective access or number of lives is approximately 40 million. And that's comprised of commercial, Medicaid and some federal business.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Doug. And Karsten, on Wegovy capacity versus what we see in the market now. I know you're not going to tell the whole story. What can you say?

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

Yes. So it's, of course, a key question that we spend a lot of time on also internally to ensure that we're not disappointing our customers when we launch products in different markets. And my starting point to answering the question is, the guidance I just covered before. So it's 13% to 19% top line growth guidance, which in itself is very competitive industry-wise, is, of course, very attractive and a large chunk of that growth comes from Wegovy. So we will not be able to get to this level of guidance without a significant step-up in Wegovy.

And as I'm sure you can appreciate, then it's important for us to say that we can supply to our guidance, to both the top end and the low end of the guidance. So that's what we commit to in terms of our investor communication.

Then in terms of additional scenarios, then what I would say is that the -- that 19% is not a magic ceiling. In terms of our guidance, it's basically a function of products and geographies and timing. And then yes, we continue to scale our manufacturing capacity of Wegovy. As you know, we have 1 line in-house. We have 1 CMO up and running full speed and we have 1 line on track to be online in first half of this year. And then another line on track to be -- get online second half this year. So we have significant step-up in Wegovy production capacity.

And then I'd say, just as a final note, of course, we have -- we do not have unlimited capacity. And so trending on a vertical TRx uptake is impossible. And that's why we've been out saying be careful with the first data points because they are impacted by the pent-up demand that Doug was talking to.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. So to summarize, clearly, a significant addressable market, from an access point of view and also capacity coming in, so we can go after that opportunity. So very encouraging, indeed. Thank you, Pete.

Operator

We will now take the next question. And it comes from the line of Michael Nedelcovych from Cowen.

Michael Thomas Nedelcovych
TD Cowen, Research Division

I have 2. The first is on the SELECT trial. When taking interim looks at SELECT, does Novo consider whether or not a futility analysis has been prespecified and presumably passed the material information to be shared with the market? That's the first question.

And then the second question is on the oral semaglutide readout. So when we see Phase III obesity data for oral semaglutide, some of our consultants are expecting meaningfully diminished weight loss relative to injectables. If that ends up being the case, what percent weight loss would still support commercial success?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Michael. I think Martin those are, both to you.

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

Yes, absolutely. So with regard to SELECT, as we already discussed, we had 1 look before the expected final outcome of the trial. That was done by a DMC. So we are not privy to the data. The DMC is looking at the totality of the data, and there was a prespecification for -- when they could recommend stop use of the -- very convincing superiority for semaglutide, i.e., more than 20% difference between semaglutide and placebo.

They recommended us to continue the trial, which makes us believe that we are probably still in the realm of the 17% that we have sample sized for. But they look at everything and they can recommend to stop the trial should they feel to do so.

With regards to oral semaglutide, both in diabetes and obesity, the trials are assigned and the doses are picked so there we expect to get exposure similar to that of subcutaneous semaglutide, both Ozempic 2.0 milligram, and Rybelsus 2.4 milligram. And we would, therefore, aim to have full efficacy and full safety profile comparable to those 2 formulations.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

So very attractive product profiles from what we can tell from a commercial opportunity perspective. Thank you, Martin, and thank you, Michael.

Operator

We will now take the next question. It comes from the line of Sachin Jain from Bank of America.

Sachin Jain
BofA Securities, Research Division

Sachin Jain, Bank of America. Just 2 very simple questions, trying to get a bit more color on what you can guide. So again, I'll try my luck. So firstly, on obesity, you've noted inherent uncertainty. I think there's been commentary on pent-up demand and careful with those data points. I'm just trying to get a sense of how much of bolus you think this will go over the first couple of weeks and best expectations for a run rate once that bolus comes off?

And then secondly, I know Karsten, we've discussed this a lot before, but GLP-1 growth rate is the biggest delta to guide. Just from your perspective, are you expecting a trend shift through full year '23 from the existing 40% to 50% growth because I don't think a continuation of existing trends as assumed even in the top end of guide.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Sachin. If I try to address the first question on Wegovy pent-up demand and sizing of that, and then Karsten, you can get to the GLP-1. So we know for a fact that patients have been lined up. We have had some 60-plus patients on notice for when products would be available. That's a quite unusual situation to have. So we know for a fact that there is pent-up demand. It's really difficult for us to size it, to be honest. We are obviously encouraged by the trend line we see. But we also do believe that there will be a normalization of that as we have gone through that bolus. But it's really very difficult for us to give any meaningful sizing of it.

We'll be looking at the first, say, a couple of months, say, Q1 to really understand the -- how that looks. So -- but the first data points are really exciting. So we feel we're in a really, really good place. Karsten, on growth rates, I recall we've been saying in prior years that we thought the growth rate was going down. It didn't happen. So any crystal ball now?

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

Yes. Thanks for reminding me on that one. So I'd say for -- first of all, that's 1 of the reasons why we have a forward-looking statement in our announcements. That is when we start to comment on future market growth rates. And I'd say secondly, that's also 1 of the reasons why we are rolling with an unusually broad guidance range this time around.

When we look at the market growth, I can start out with the U.S. MAT-wise for -- based on the latest monthly data points or the latest data points overall. We are around 40%, and that would be the same ex-U.S. also. So a global volume market growth MAT-wise, around 40% being the latest data point. If we take shorter data points in the U.S., we're closer to the 50% mark as a data point.

In terms of what that implies going forward, that's of course, a function of our activities and competitor activities, as well as supply capacity for the players in the markets. So I'd say, we have built our guidance based on continued strong market growth. Of course, I cannot give you our assumptions but more than to say continued strong market growth and GLP-1 in diabetes being a key growth driver for Novo Nordisk also in '23.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Maybe just adding to that. When you have a category where you have efficacious products competing against each other, it typically leads to market growth more than share gain and that's what we see in type 2 diabetes. And I think that's also what we would expect to see in the obesity category that efficacious products drives market growth more than the share play. Thank you, Karsten. Thank you, Sachin.

Operator

We will now take the next question. It comes from the line of Richard Parkes from BNP Paribas.

Richard J. Parkes
BNP Paribas Exane, Research Division

Just got a couple. Firstly, on the CapEx expansion plans. And just wondering whether you can give us any indication of what that increased capacity could allow you to meet in terms of market expansion kind of by the end of the decade, at least some kind of ballpark range in terms of kind of what market -- GLP-1 market expansion, that would allow you to meet supply for would be really helpful.

And then secondly, on the ONWARDS 1 and 2 trials of insulin icodec, I mean, playing devil's advocate looks incrementally worse than previously. I think with the HBA1c advantage no longer significant or significantly worse in both trials showing worse hyperglycemia profile. So I'm just wondering how this impacts your expectations from that product over both approvability and commercial potential.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Richard, so let me just try to give a perspective on CapEx. And then Martin, you can get to the ONWARDS trials. So for us, this is to create, obviously, ability to supply in a market that we believe will have a very, very attractive growth, creates strategic flexibility. And I think in the GLP-1 space, you will have the potential of having one of the biggest, say, drop in categories ever seen. So really being able to build that capacity and serve the markets, I believe, creates a competitive advantage that is very, very attractive.

So we also have a pipeline of products coming that will be using the same type of capacity. So both from an API and fill finish perspective, we have a lot of optionality in the footprint we have. And being able to build this and drive efficiencies is something that's required to play longer term in this category. So you should take it as a sign of confidence and trust in the existing business we have and the pipeline we have coming. Martin, on ONWARDS and the latest there and what is happening for the potential?

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

Yes, absolutely. So first of all, it's important to recall that both ONWARDS 1 and ONWARDS 6 were originally 52- and 26-week studies. This was the regulatory intent. And in the 52-week period of the ONWARDS 1 study, as you know, we showed a superior A1C reduction with a good and flat and stable, sorry, hypoglycemia profile.

We then for regulatory reasons, have to do extensions of those 2 studies in both type 2 and in type 1 diabetes, basically because we need to show safety exposure. So this focus of the extension is safety assessment and establishing the long-term safety profile of insulin icodec in both type 1 and type 2 diabetes.

If I stay with ONWARDS 1, over the additional 26 weeks, we actually saw a completely flat A1C curve, so a maintained glycemic control over time. We lost the statistical significance. But again, in an open label extension, you also lose a little bit of rigor and power, and we sort of have to expect that, but it certainly confirms the efficacy profile of insulin icodec.

With regards to hypoglycemia, first of all, it's important to recall already at 52 weeks, we saw very, very low hypoglycemia rates. There was a numerical difference between the 2 insulins, and that difference actually remained completely stable throughout the trial. So when we then see this is statistically significant, it's a function of more events rather than all of a sudden seeing a difference between the 2 treatment arms. And it's also important if we put that into a clinical context, to recall with the rates that we have seen, a patient on insulin icodec in this setting would have to wait 2 to 3 years to experience an event of not severe hypoglycemia.

And in that context, I also want to call out that the risk of having severe hypoglycemia with insulin icodec in ONWARDS 1 was almost a factor of 10 lower than with insulin degludec. So again, confirming the safety profile of icodec in this setting. So we remain very, very confident from a clinical perspective that icodec is the perfect starter insulin for type 2 diabetes. And obviously, we're looking at ONWARD 6, we have to acknowledge that we have some work to do with type 1 diabetes, and Camilla can maybe talk to the commercial potential of both obviously type 2, type 1 diabetes.

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

Yes. Thanks a lot, Martin. So based on the totality of the data that you just went through and from the total ONWARDS program, we are very confident in the efficacy and the safety profile of once weekly icodec and also the potential to become standard of care and insulin of choice for people with type 2 diabetes. And once-weekly insulin, of course, represents a whole new way of managing insulin that gives a lot of benefits to people, as just described, but also on the convenience part, it by the way, also has a very positive environmental profile.

And to your question about type 1 diabetes, we would estimate that, that is to the tune of potentially 7% of the total potential. So that doesn't change our overall profile of icodec potential.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Camilla. Thank you, Martin. It's a clear sign of our commitment to raising the innovation height also in a classical area. We embarked upon on a journey at Novo Nordisk. We're still investing in insulin and I think we can drive tremendous value for patients and physicians here, still 100 years in. Thank you, Richard.

Operator

We will now take the next question. It comes from the line of Richard Vosser from JPMorgan.

Richard Vosser
JPMorgan Chase & Co, Research Division

First question, just thinking on Ozempic trends and how you see those going forward. I think Q3, you were saying 40% of patients were naive to diabetes treatment of the new patients going on Ozempic. How are you seeing the Wegovy relaunch impact that? And how do you see sort of that Ozempic situation developing throughout this year with Wegovy back into to full supply? Do you see that slowing down significantly because of Wegovy?

And then second question. Just going back to the reimbursement and payers. Obviously, very good getting 40 million patients. How are the payers treating the patients maybe in the second, maybe third year of treatment, if patients get that long? If they reach levels of normal BMI or lose significant amounts of weight, do payers then say, well, that's brilliant, you're back to normal and they come off the drug? Or how are they treating that in your reimbursement discussions?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Richard. First, Camilla, on the Ozempic trends after Wegovy is in the market, then Doug, you can talk a bit to payers with a U.S. perspective.

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

Yes. So on Ozempic, we see a continued increase. We see -- we are back to TRx and NBRx leadership. When it comes to how much of the Wegovy sourcing that is from diabetes, then we can say that the uplift in the Wegovy trends in the U.S. is basically from primarily the 0.25 milligram, the starter dose. And that basically means that these are patients that are new to GLP-1 treatment. Of course, looking forward, that means that we expect that there is a potential for both of these 2 classes to coexist and to continue increasing as we see both unexploited potential for GLP-1 treatment in diabetes as well as in obesity.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Camilla. Doug, on the payer's perspective on multiple years of treatment.

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

Richard, thank you. I think it's important to note that we're pleased with the level of access that we have today. Overall, 80% access is something that we're proud of, and the team has done a nice job. The effective access we've been hard at work at. As you know, this requires opt-ins.

But again, we're pleased with the overall 40 million lives that can have access. And how the payers are treating this. There's no stopping rules in place today. And I think the payers recognize that this is a chronic treatment, and that's important for not only stakeholders, payers, but all the work that we're doing is to realize this as a serious chronic disease, and it's a chronic disease that needs long-term treatment.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Camilla. Thank you, Doug. Thank you, Richard.

Operator

We will now take the next question. It comes from the line of Michael Leuchten from UBS.

Michael Leuchten
UBS Investment Bank, Research Division

2 questions, please. Michael Leuchten from UBS. One, if I look at the value of the volume for Ozempic and Rybelsus in the U.S., there seem to be some trend changes in Q4, maybe Ozempic also in Q3. Is that a fair reflection of the competitive rebating environment? Or should we not overinterpret those trends as we think about the value to volume, looking into 2023?

And then a question for Martin. SELECT isn't really something you talk about actively anymore. It only really comes up in Q&A. Is that because in your mind, the relevance has taken a step back given it didn't stop at the interim? And we're maybe on track for the 17% risk reduction, which may or may not mean as meaningful as maybe a 25% would have been? Or is there another reason why you don't mention it as much more as you have in the past?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Michael. So first, Karsten, on value versus volume dynamics for GLP-1 class.

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

Yes. So Michael, first of all, to your Q4 questions versus '22 overall, then there are no changes vis-a-vis '22. So as you know, normally, then for '24, then we -- give the lag of scripts, then there will be true-ups normally in Q4 that can impact the value to volume equation. So I think the more appropriate way to look at it is for the full year. And then I'd say on top of that, given the supply situation on Ozempic, there might be also some noise in that calculation from changes in inventory levels on Ozempic specifically. From there, moving into 2023, while not guiding for value and volume for '23, then I would say the dynamics remain the same between '22 and '23.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. And Martin, on SELECT, why are you not talking about SELECT?

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

So first of all, we are still very excited and very confident about SELECT. Issue is obviously that we have no results to share. We have no data to share. And therefore, the only thing I can call out, which hopefully you also saw in my part of the presentation is that we are looking very much forward to the data coming out around mid-2023. And that will be incredibly exciting. So we still think SELECT is very important and very exciting.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, that's the reason. Thank you, Michael.

Operator

We will now take the next question. It comes from the line of Keyur Parekh from Goldman Sachs.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Two separate lines of questioning, please. The first one on CapEx. At the 2022 Capital Markets Day, your slides implied CapEx for 2025 to be between kind of DKK 10 billion and DKK 15 billion. What you're guiding today implies CapEx close to DKK 25 billion to DKK 30 billion in 2025. So just wondering, if you can give us a sense for kind of how much of that doubling of CapEx is attributable to your perception of higher demand for the existing products, so B2B kind of Rybelsus or GLP-1 diabetes products versus how much of this is with a view to ensuring supply for the non-diabetes, non-obesity product as that pipeline emerges over the course of the next kind of 2 to 3 years? So that's kind of question #1.

And then separately, kind of coming back to icodec. Camilla, would love your thoughts on how you think ONWARDS 1 and ONWARD 6, the extension data changes, if at all, the commercial positioning kind of for this molecule from your perspective. Does this make it a little bit more of an international product compared to a U.S. product given the convenience at play here? Or do you still think there exists room for you to have differential pricing for this molecule in the U.S. given the extension data?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Keyur. Two very clear questions. So first, Karsten, on CapEx versus what we said at Capital Markets Day and a perspective on existing products, new areas and then Camilla, you can talk to the icodec, say, commercial opportunity?

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

Thank you, Lars. So CapEx, of course, quite a significant step up compared to our Capital Markets Day and again, that's why we have forward-looking statements. So the world has a tendency to change these days more than usual. I would say this step-up in CapEx to me, comes on a very positive background. I can, unfortunately, not to kind of separate how much is what because we have both facing and a different share platform. So it's a little bit trying to separate hot and cold water, unfortunately, Keyur.

But I would say that the main drivers to it is, first of all, a stronger volume uptake than what we had built into our initial CapEx modeling clearly and the stronger volume uptake impacts both on the API side of our currently marketed products as well as the fill finish that we're scaling more so than the initial plans.

And then as to the pipeline, I'd say there are 2 main drivers to step up. And you can say in a historic perspective, where we were like, call it, between 5% and 10% CapEx-to-sales and now we are more in the, call it, between 10% and 15% CapEx-to-sales ratio towards 25%. The delta is, that historically it was injectable peptide-based CapEx investments we're doing. And we continue to do that through the volume scaling I just spoke about. But on top of that, we are building to cater for the oral platform that just requires significantly higher amounts of API, whether it's for Rybelsus or semi obesity or some of the earlier oral compounds.

As you know, we have all oral amycretin in Phase I, and we have an oral GLP-1/GIP also. So clearly, for the oral platform and then for the nonprotein peptide platforms, I would say we're looking at -- and what are we doing to cater for pipeline assets like Mim8 and

ziltivekimab and our ATTR as well which is on an antibody platform. So that's where we're looking at also expanding our capacity on the monoclonal antibody side. So I hope that provides a little bit of color, but not fully able to separate the hot and the cold water.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. Exciting pipeline line leads to need for CapEx. So Camilla, how excited are you on icodec based on the recent data?

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

Thank you, Lars. And as we just discussed before, we remain very confident in the efficacy and safety profile of icodec that's given as a once-weekly insulin has the potential to become standard of care for people with type 2 diabetes.

And to your question, this has not changed our perspectives in terms of a global rollout of icodec. We remain equally confident in the U.S. and in the rest of the world for how this can help people with type 2 diabetes. And keep in mind that the potential of this is that the basal segment approximately includes 30 million patients with a value of around USD 8 billion. So that's a place where we today have a market share in the ballpark of 1/3, so there's ample potential to increase that.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Camilla. Thank you, Keyur.

Operator

We will now take the next question. It comes from the line of Simon Baker from Redburn.

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

Two if I may, please. Firstly, and this relates to some earlier questions. In recent years, the increased spend in the U.S. on GLP-1 was offset by lower spending on insulin, which gave some easy headwind for the category to expand. I just wondering if you could give us an update on whether that is still the case?

And then you talked about the impact of the Dicerna acquisition on 4Q R&D. I am just wondering if you can give us an idea how much of the additional R&D expense incurred was one-off and how much is continuing.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Simon. I don't know if you have those data, Doug from the top of your head.

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

What I would say is this, that insulin, as you saw, as we just reported, continues to be under pressure, pricing pressure, so payers still continue to take value there. And as I mentioned earlier, that's still only approximately 10% of the prescription volumes coming out of GLP-1. So we still think that there's opportunity there.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

You can add that to Q3, Q4. Price decline and soon to come, SGLT2 will also create some space to fund innovation. So yes, Karsten on Dicerna. Any one-off versus continued.

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

Simon, as we've been communicating all along in terms of our overall strategic resource allocation, then we are highly focused on allocating additional resources towards R&D to expand and diversify our pipeline. And that you've seen throughout the year with a significant step-up in R&D spent ending at 29% for the full year.

You're right that in the fourth quarter, we have an extraordinary step-up also when you do the quarterly trending. It's not due to Dicerna because we had Dicerna all along. So it's basically due to 2 factors: 1 being, a, I would say, minor impairment on intangible assets and another piece being costs related to the Forma Therapeutic transaction and restructuring.

And as you recall, then here at Novo, we are reporting clean numbers. So where other companies would have been -- some of the companies have been adjusting this into core earnings or adjusted earnings, then here you get, what you see is what you get. As to a specific number for Q4 in long terms between the 2 impairments and Forma, around DKK 0.5 billion.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Simon. We have time for the final question.

Operator

We will now take the next question. It comes from the line of Mattias HÃ¤ggblom from Handelsbanken.

Mattias Häggblom
Handelsbanken Capital Markets AB, Research Division

Two questions, please. Firstly, with regards to the decision in January to double down and initiate the high dose semaglutide trial. I'm curious to understand what triggered the decision and why now almost 1.5 years after the Wegovy approval and why not earlier?

And then secondly, with top line data from SELECT data due mid-2023, what's a reasonable time frame from top line results and the data can help facilitate reimbursement outside the U.S., 1 year or is it rather 2 years, given the size and complexity of the study?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Mattias. So to you, Martin, high dose in obesity. Why now?

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

So first of all, we see emerging data suggesting that it is possible to max out on GLP-1 biology. And it's very, very clear based on some of our reason studies that we could potentially increase exposure and thereby accruing more weight loss than what we see with the current doses. This obviously, we had to pursue and we had to investigate because there is an opportunity to, without compromising on safety, to accrue even more weight loss, specifically in obesity and potentially also improved glycemic control in diabetes. We aim to conduct these studies very, very fast, and that also means that they will be available to patients if the data supports it in a not-so distant future and still well within the relevant time period for semaglutide.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Then there was a question on time line from SELECT data to reimbursement. So ballpark without going into too much detail.

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

So some of you have heard about -- I was bragging about being able to obviously handle our clinical data in a reasonable way. I would not be looking at a 1- to 2-year time line. Obviously, we will close down the study. We will have the results around mid this year. We'll do a regulatory file, and then we'll have the regulatory interactions. And then it's in U.S. up to Doug and his team to discuss with payers and others on how that will impact the dynamics.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin, thank you, Mattias, and thank you all for participating in our earnings call. Please reach out to our Investor Relations Officer if you have more questions and look forward to meet you and talk to you in the near future. Thank you very much. Bye-bye.

Operator
That does conclude our conference for today. Thank you for participating. You may all disconnect.