S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B

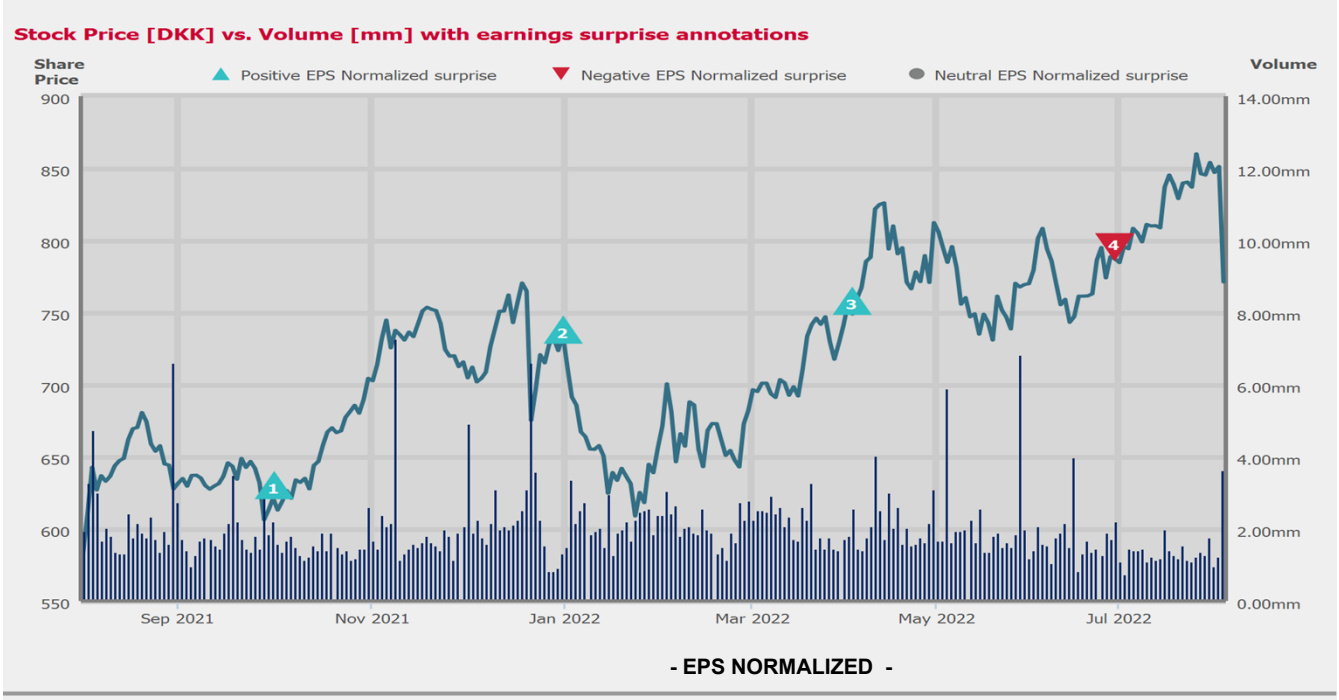
FQ2 2022 Earnings Call Transcripts

Wednesday, August 03, 2022 5:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ2 2022-			-FQ3 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	6.04	5.86	▼(2.98 %)	6.37	23.87	NA
Revenue (mm)	41791.83	41265.00	▼(1.26 %)	43077.42	170653.42	NA

Currency: DKK
Consensus as of Aug-04-2022 12:41 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ3 2021	5.02	5.27	▲1 4.98 %
FQ4 2021	4.69	4.76	▲2 1.49 %
FQ1 2022	5.68	6.22	▲3 9.51 %
FQ2 2022	6.04	5.86	▼4 (2.98 %)

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EXECUTIVES

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

Douglas J. Langa
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Lars Fruergaard Jorgensen
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Presentation

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Welcome to this Novo Nordisk's Earnings Call for the first 6 months of 2022 and the outlook for the year. This call follows the early announcement and raised guidance published today. Due to Danish Securities Regulation, we advanced the release that was recently scheduled for tomorrow morning.

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 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. This call is scheduled to last for 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. The Q&A session will begin in about 25 minutes.

Please turn to Slide 3. As always, I need to advise you that this call will contain forward-looking statements, such 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 first 6 months of 2022 as well as the slides prepared for this presentation.

Please turn to the next slide. In the first 6 months of 2022, we delivered double-digit sales and operating profit growth, which has enabled us to raise our outlook for the full year. I'd like to start this call by going through the performance highlights across our strategic operations before handing over to the word to my colleagues.

Within purpose and sustainability, we continue to make progress across all dimensions. On our Defeat Diabetes strategy, we reached even more diabetes patients compared to the same period last year. In line with our exploration to be a sustainable employer, we expanded the number of women in senior leadership positions to 38% compared to 35% by the end of the second quarter of 2021.

Concerning Russia's invasion of Ukraine, our priorities remains a safeguarding for use and continue the supply of essential medicines. Novo Nordisk medicines are available in more than 90% of Ukraine, and we are collaborating with humanitarian organizations to make products available in the remaining areas. Within R&D, we are encouraged by the completion of 5 of the 6 Phase III trials with once weekly insulin icodec.

The ONWARDS trial have shown that icodec has the potential to improve glycemic control with greater convenience and reduced treatment burden for people needing insulin treatment. The full ONWARDS program is an important step in support of our aspiration for further raising the innovation bar for diabetes treatment and our commitment to insulin innovation.

Martin will come back to this and our overall R&D milestones later in this call. In the first 6 months of 2022, we delivered double-digit sales growth, reflecting solid commercial execution across geographies and our therapy areas. While 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, which has enabled us to increase the outlook for the year. Camilla and Doug will go through the details for therapy area later.

Last, Karsten will go through the financial details, but I'm very pleased with the sales growth of 16% and operating profit growth of 14% in the first 6 months of 2022.

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

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

Thank you, Lars, and please turn to the next slide. In the first 6 months of 2022, our total sales increased by 16%. The sales increase was driven by both operating units with international operations growing 10% and North America operations growing by 24%. Our GLP-1 sales increased 45%, driven by North America growing 41% and international operations growing 53%.

Insulin sales decreased by 8%, driven by a 5% decline in international operations and an 18% sales decline in North America operations. The U.S. insulin sales declined by 19%, driven by lower realized prices and a decline in volume. In line with expectations, insulin sales and international operations were impacted by the implementation of volume-based procurement in China as of May 2022.

Obesity care sales grew 84% overall. In International Operations, Saxenda sales grew 60% and in North America operations obesity care sales grew 102%. In the U.S., obesity care sales grew 110% driven by Wegovy.

Total rare disease sales were flat driven by a 1% sales increase in international operations, offset by a 1% decline in North America operation.

Please turn to Slide 6. Our 15% sales growth within diabetes care is faster than the overall diabetes market. That means we have improved our market share by 1.5 percentage points to now 31% and that we continue to be on track to reach 1/3 of the diabetes value market by 2025. The increase reflects GLP-1 growth of 45% and market share gains in both operating units.

Please turn to the next slide. In international operations, Diabetes Care sales increased by 10% in the first 6 months of 2022, driven by GLP-1 sales that grew by 53% and especially by Ozempic. Novo Nordisk remains the market leader in international operations with a GLP-1 value market share of 61.3%. This is driven by share gains across geographies. And I'm happy to share that Ozempic has become the GLP-1 market leader in international operations with a 39% market share.

In Region China, the 83% sales growth of the GLP-1 products was driven by the uptake of Ozempic, following the launch in June 2021 and the inclusion on the national reimbursements as of January 1, 2022.

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

Douglas J. Langa
Executive VP, Head 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 more than 35%, comparing Q2 of 2022 to Q2 of 2021, with once-weekly injectable GLP-1s and Rybelsus as the main drivers. From an NBRx perspective, we have seen a step up in volume growth in 2021 that has accelerated further since the beginning of 2022. Measured on total prescriptions, Novo Nordisk has expanded its market leadership to 56.4% market share.

In other words, we continue to take share in a fast-growing market. Additionally, we are thrilled that Ozempic has now surpassed dulaglutide, taking the lead in the TRx market with a 40.7% market share. The global rollout of Rybelsus is progressing, having now been launched in 39 countries. It remains 1 of the key contributors to growth in Novo Nordisk.

Please go to the next slide. Obesity care sales increased by 84% with 102% growth in North America operations and 60% growth in international operations. Furthermore, the obesity market expansion continues with the volume growth of the global branded obesity market of more than 60%. We are encouraged by the performance of Saxenda in international operations that was especially driven by the EMEA region that grew 78% in the first half of 2022. The growth was especially strong in countries that had some level of reimbursement, such as the U.K. and Norway.

In the U.S. alone, obesity care sales grew 110%, following the previously announced Wegovy supply issues in the U.S., our focus remains to ensure continuity of care in the patients that have already initiated treatment. In line with expectations, this has negatively impacted Wegovy prescription trends. Positively, Saxenda trends have picked up and are now at all-time high levels.

Regarding Wegovy supply, commercial production at the CMO was reinitiated in the second quarter of 2022 and inventory building is ongoing. We expect to make all doses of Wegovy available in the U.S. towards the end of the year.

Now, Camilla back over to you for an update on rare disease.

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

Thank you, Doug, and our rare disease sales were unchanged in the first 6 months of 2020. This was driven by a 1% sales growth in international operations offset by a 1% decline in North America operations. Rare blood disorders grew by 3%, driven by NovoSeven as well as its launch products Esperoct and Refixia. Specifically hemophilia A products grew by 1%, hemophilia B sales by 6% and NovoSeven by 3%, where endocrine disorder sales declined by 5%. The decline in sales were driven by international operations decreasing by 1% and by North America operations decreasing by 14%. The sales decline was negatively impacted by lower realized prices in the U.S. and timing of shipments.

And now over to you, Martin, for update on R&D.

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

Thank you, Camilla. Please turn to the next slide. For the past month, it has been exciting to share the results from the 5 trials in the ONWARDS program for once weekly insulin icodec. I would like to spend some time just summarizing the results that we've seen so far.

Now ONWARDS 1 and 2 studies that insulin icodec appears to have some of the best insulin data that we've seen the superiority on HbA1c control as compared to both insulin glargine and insulin degludec, respectively. This with no significant risk of hypoglycemia and at the same time, an improved quality of life. We're very excited to see the results from ONWARDS 1 and 2 confront in ONWARDS 3.

ONWARDS 3 was a double-blind, double-dummy 26-week trial comparing once weekly insulin icodec, once-weekly insulin degludec -- sorry, once-daily insulin degludec. The objective of the trial was to assess the efficacy and safety of insulin icodec in 588 insulin naive people with type 2 diabetes. The trial achieved its primary endpoint of demonstrating non-inferiority in reducing A1c at week 26 with insulin icodec as compared with the insulin degludec.

From an overall baseline A1C of 8.5 percentage points once-weekly insulin icodec achieved a superior reduction in estimated A1c of 1.57 percentage point compared to 1.36 percentage points for insulin degludec, thus again demonstrating superiority with an estimated treatment difference of 0.21 percentage points.

Also in this trial, there was no statistically significant difference in estimated rates of severe or clinically significant hypoglycemia. And once-weekly insulin icodec appeared to have a safe and well-tolerated profile. With the ONWARDS program being a fully global program, I'm also excited that ONWARDS 3 will cater for a potential Chinese approval.

As already discussed in ONWARDS 6, we met the primary endpoint of demonstrating non-inferiority in reducing A1c with insulin icodec compared to insulin degludec in people with type 1 diabetes. We do, however, also recognize that managing type 1 diabetes is complex, and that we still have to work -- we still have work to do on the hypoglycemia risk.

Finally, as also shown at this year's ADA, it's important to call out that the risk of hypoglycemia was similar for once weekly into the icodec and daily insulin large impede with type 2 diabetes, as shown in a dedicated hypoglycemia trial, thus underlining the safety profile of insulin icodec.

Now let's take a closer look at ONWARDS 4. Next slide, please. ONWARDS 4 was a 26-week efficacy and safety trial comparing once-weekly insulin icodec to once daily insulin glargine, both in combination with insulin icodec. The trial included 582 people with type 2 diabetes on a basal bolus regimen.

The primary objective of the trial was to demonstrate a non-inferiority of insulin icodec versus insulin glargine in reducing A1c at week 26. This treat-to-target trial achieved its primary endpoint by demonstrating non-inferiority in reducing A1C at week 26 with insulin icodec as compared to insulin glargine.

Thus from an overall baseline A1C of 8.3 percentage points, once weekly insulin icodec achieved a reduction in estimated A1C of 1.16 percentage points compared to 1.18 for insulin glargine with an overall estimated treatment difference of 0.02. In addition, we observed similar rates of severe and clinically significant hypoglycemia. And in the trial, once-weekly insulin icodec appeared to have a safe and well-tolerated profile.

In conclusion, we remain very excited about the attractive profile of once-weekly insulin icodec based on the results from the ONWARDS trials that have read out to date. These have underlined the icodec's potential as an ideal data insulin

for people with type 2 diabetes. Further, also as an attractive option in combination with new trial insulin as shown in ONWARDS 4, thus covering the full spectrum of type 2 diabetes. We look forward to sharing the results from the final trial ONWARDS 5 during the second half of 2022.

Next slide, please. Now turning to the SELECT trial and the interim analysis. As a reminder, SELECT is a double-blinded, randomized placebo-controlled trial in patients with overweight and obesity and established cardiovascular disease. Previously stated, the independent data monitoring committee will be evaluating an interim analysis of the trial during Q3 of this year with the potential for terminating the trial earlier than planned.

The interim analysis has now been conducted. And based on that, the recommendation received from the independent data monitoring committee, we have decided to continue the SELECT trial. It's important to remind you that Novo Nordisk has not seen the data.

As an additional reminder, the SELECT trial is powered for 17%. This is the trial design and given the cardiovascular reduction seen in PIONEER 6 as well as SUSTAIN 6 both trials in type 2 diabetic populations, we remain confident about the semaglutide and what semaglutide can do for people in obesity. The SELECT trial is now expected to complete in the middle of 2023.

Next slide, please. Let's turn to the high-level R&D milestones. We've already touched upon the ONWARDS program and SELECT. So now I would like to highlight some of the other trial readouts and initiations across our therapy areas during the course of 2022. Within diabetes, we expect results from the exploratory Phase II trials with Cagrisema for people with 2 diabetes during the third quarter of 2022.

In addition, we also expect to start a Phase II trial in the same quarter to explore the potential of higher doses of injectable semaglutide for the treatment of type 2 diabetes. Within obesity, we have initiated a Phase I trial with once-daily oral amycretin, a combination of amylin and GLP-1 analogs and expect to start Phase III with Cagrisema during the fourth quarter of 2022.

Within rare disease, we've initiated a Phase II trials with NDec previously known as Eclipse in 84 adults with sickle cell disease. We're also very excited about the recent U.S. approval of once weekly Rebinyn prophylaxis for people with hemophilia B.

Furthermore, the results from the primary analysis of [indiscernible] in London recently, and we expect to submit concizumab for regulatory approval in the inhibitor segment during the third quarter of 2022. Finally, within the other serious chronic diseases, we have initiated a Phase II trial with the anti-amyloid immunotherapy we acquired from Prothena in 2021. The trial includes 99 people with a rare heart disease, transthyretin amyloid cardiomyopathy.

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 6 months of 2022, our sales grew by 25% in Danish kroner and 16% at constant exchange rates, driven by both operating units. The gross margin increased to 84.4% compared to 83% in 2021, driven by a positive product mix due to increased GLP-1 sales, a positive currency impact of 1.4 percentage points and productivity improvements. These effects are countered by lower realized prices in the U.S.

Sales and distribution costs increased by 29% in Danish kroner and 22% 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 also reflecting lower activity levels in 2021 due to COVID-19 as well as higher distribution costs. Research and development costs increased by 31% in Danish kroner and 26% at constant exchange rates. The increase is driven by higher clinical activity models within other serious chronic diseases and GLP-1 as well as the operating costs and amortization related to the acquisition of Dicerna Pharmaceuticals in the fourth quarter of 2021.

Administration costs increased by 7% in Danish kroner and 3% at constant exchange rates. Operating profit increased by 26% in Danish kroner and by 14% at constant exchange rates. Net financial items for 2022 showed a loss of around DKK 2.8 billion compared to a gain of around DKK 1.1 billion in 2021. This mainly relates to losses following the appreciation of the U.S. dollar, which is also reflected in the favorable currency impact on operating profits.

The effective tax rate for the first 6 months of 2022 was 20.7% compared to 19.8% in 2021. Net profit increased by 11% and diluted earnings per share increased by 13% to DKK 12.08.

Free cash flow was DKK 42.7 billion compared to DKK 32.7 billion in 2021. The cash conversion in the first half of 2022 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.

Next slide, please. A key priority for Novo Nordisk is to ensure attractive allocation of capital to shareholders. In line with our strategy, we have returned DKK 28 billion to shareholders through dividends and the ongoing DKK 24 billion share buyback program. For 2022, the Board of Directors has decided to pay out an interim dividend of DKK 4.25 per share, which will be paid out in August this year. This is an increase of 21% compared to the 2021 interim dividend.

Please turn to the next slide. We continue 2022 with a solid growth momentum and now expect sales growth to be between 12% and 16% at constant exchange rates. This is based on a number of assumptions as described in the company announcement. The raised guidance reflects expectations for sales growth in both international operations and North America operations and across therapy areas, but it's mainly driven by diabetes and obesity care.

The guidance update incorporates an accelerated NBRx volume trend within injectable GLP-1 in the U.S. favorable obesity market expansion and the expectation of making all the Wegovy dose strengths available in the U.S. towards the end of the year.

Following a continued higher-than-expected volume growth of GLP-1 based products, including Ozempic, the outlook also reflects expected periodic supply constraints. We now expect that operating profit will grow between 11% and 15% at constant exchange rates. This primarily reflects the sales growth outlook and continued investments in current and future growth drivers. We are also allocating additional resources to both early and late phase R&D pipeline activities.

As mentioned before, our acquisition of Dicerna Pharmaceuticals is negatively impacting operating profit growth by around 3 percentage points due to higher operating costs and amortization of intangible assets. Given the current exchange rates, most notably strengthening of the U.S. dollar, we now expect a positive currency impact for 2022.

Our reported sales are now expected to be 9 percentage points higher than at constant exchange rates and operating profit growth is now expected to be 14 percentage points higher than at constant exchange rates. The positive currency impact on operating profit of 14 percentage points is partly offset by a net loss on financial items.

For 2022, we now expect that financial items will amount to a net loss of around DKK 5.5 billion, mainly reflected losses associated with foreign exchange hedging contracts.

Capital expenditure is still expected to be around DKK 4 billion in 2022, which mainly relate to investments in additional API production capacity at existing manufacturing sites. Our free cash flow is now expected to be between DKK 57 billion and DKK 62 billion. That covers the updated outlook for 2022. 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 are very pleased with the double-digit sales growth in the first half of 2022. In particular, the sales growth was driven by an increasing demand for our portfolio of GLP-1 treatments for diabetes and obesity care, and we continue to reach even more patients.

While both operating units continue to drive growth, we did see a very strong sales growth in North America. The strong financial performance in the first 6 months of 2022 has enabled us to raise our outlook for the full year. From an R&D perspective, we have now successfully completed 5 Phase III trials with once-weekly insulin icodec.

I believe the results underline that we are still committed to further raising the innovation bar in diabetes. We look forward to share results from the final trial in the ONWARDS program in the second half of 2022.
With that, we are now ready for the Q&A. 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

The first question is from Peter Verdult of Citi.

Peter Verdult
Citigroup Inc., Research Division

Two quick questions. Martin, firstly, the market seems to have taken a very binary view that selects not being stopped at the interim as a negative. I thought you'd been at pains to point out since the CMD that you had pre-agreed with the SMB that the trial would be allowed to continue even in the event the primary endpoint will be met if certain key secondary end points were showing curve separation but not quite reaching stat 6. So I realize you're provided to the data. My question is, though, what is the working assumption at Novo? Is it that the primary endpoint was not met at the first interim? Or are you confident the primary endpoint was met and are you excited that potentially you're also hitting on some of the secondaries?

Karsten, second question, much quickly and cleaner. When I look at the litigation section of the report, the appeal of the 340B discount ruling is the only thing you cite as potentially being impactful from a financial perspective. Just in terms of being transparent, can you ballpark quantify what the percentage impact would be if you were to lose that appeal and forced to offer full 340B pharmacy discounts?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Pete. First, Martin, on the SELECT interim.

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

Thanks very much, Pete. I very much agree. We are not disappointed with having to continue the trial because as you also alluded to, designed the outcome trial to add the finalized date having a power of showing 17 percentage point difference between semaglutide and placebo on the primary endpoint of MACE.

If we were to stop at the interim analysis, 17% would actually be statistically significant as thus meeting the primary end point, but as any sponsor, we want to be very, very certain that stopping at an interim analysis is basically a very secured bet.

And therefore, we had agreed with the DMC, obviously, to look at a primary endpoint upon estimate substantially above that of 17%. And obviously, that was an upside. Our base has always been to continue the study through the end. I think it's also important to call out, if we see 17% differential between semaglutide and placebo at the end, thus 17% cardiovascular reduction that would, from a clinical perspective, a medical perspective, also from a commercial perspective, be very, very attractive.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. Very clear. Karsten, the 340B related litigation and potential impact.

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

Yes. So this is kind of a complicated issue. But as you know, we changed our distribution policy under the 340B program beginning in January 2021. And part of that policy change has meant that we are paying less rebates under the 340B program. So we have a positive cash flow impact compared to what we had previously.

On the other hand, the benefit we have in our P&L in '21 as well as in '22, is limited. And recall last year, we said that we have a benefit, which is less than 3% of U.S. sales, and that still holds for this year. So a number of scenarios to play out. But I would say, in terms of revenue recognition, as you also described in our company announcement on Page 14 on the

cash flow, we are recognizing income under the program partially and income according to the accounting rules is that it has to be highly probable.

So I would say in terms of an adverse ruling, I would expect limited impact on our P&L, whereas there would be a one-off impact in terms of financial resources or cash flow linked to the delta between income recognition and cash flow benefits. The exact magnitude I would not want to go into at this point in time.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten, and thank you, Pete. Next question please?

Operator

The next question is from Wimal Kapadia of Bernstein.

Wimal Kapadia
Sanford C. Bernstein & Co., LLC., Research Division

So can I just touching on your comment, Martin, just now. What is your view on the perception of the extent of the MACE benefit with payers and physicians. So what I'm really asking is does it actually matter if the MACE benefit is 17% or 20% or 25%? And is it really the key that the trial succeeds, both with respect to reimbursement and uptake so if just any feedback you could share would be much appreciated.

And then my second question is just on the Phase III Cagrisema obesity start. I appreciate you mentioned 4Q start, but there will be supply time line change actually have any impact on that Phase III study? And what are your confidence in stopping that study on time? Maybe I'm asking because thinking about time lines given with Wegovy relaunches is potentially only coming a few months ahead of tirzepatide in obesity so the Cagrisema time lines are becoming increasingly important.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Wimal. So Martin, first on level of MACE benefits and maybe also talk to the many other benefits of these treatments.

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

So absolutely. And obviously, from a clinical, from a medical perspective goes without saying any reduction in MACE -- MACE being obviously myocardial infraction, stroke and cardiovascular death is a positive, 10% as previously been shown to be okayish, 12%, 15% has been shown to be positive. Anything beyond 12%, 15% and obviously, beyond that, is seen as a positive from a clinical perspective. And I think also from a payer perspective.

That being said, and obviously, Camilla and Doug maybe speak to that. But given the takeoff of Wegovy, I think it's very, very clear that we see a very nice reception even without the cardiovascular data, but goes without saying with the cardiovascular data that will not be it outside to put it like it.

I think it's important to also call out beyond cardiovascular, we look at other comorbidities of obesity in the SELECT trial. Obviously, we look at quality of life. We look at risk of developing dementia so we have a dementia score. We look at arthritis. So a number of other obesity-related comorbidities in the SELECT trial.

I may have misspoken on the dementia score. I actually think that's the SOUL trial so I apologize for that. But overall, we actually also look for dementia in this specific trial as an adverse event.

On the Cagrisema, as we alluded to in first quarter of this year, we took a sort of time hit in terms of initiating Cagrisema because we wanted to prioritize U.S. supply for Wegovy. That has already been accrued, and we are still confident that we'll initiate Cagrisema in Q4 this year.

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

So to kind of wrap up, we see a very, very strong demand for anti-obesity medicine. And the market is opening up now at a time where there's no cardiovascular data. And so we are very bold on the market itself. And we also, I would say, bold on still the prospects of the SELECT trial. And I think as a trial -- the first question you alluded to, and I think we've been quite clear about that all along that a case where we had to continue the trial is still a very good outcome for us.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Wimal. Next question please?

Operator

The next question is from Matthew Weston of Credit Suisse.

Matthew Weston
Crédit Suisse AG, Research Division

Two questions, please. First, Martin, can I just ask for a clarification in your answer to Pete's question, because Pete's question implied that you knew that you had hit the primary endpoint and that you are waiting for secondary endpoints that were close. And I just want to be absolutely clear. Do you have any data? I realize that's a possible reason for continuing, as is it didn't hit the interim stopping criteria. So can you just please clarify what you know and what you don't, while we all acknowledge that there is still a positive reason for SELECT to continue?

And then secondly, it's a question regarding this. You keep caveating guidance with the risk of supply shortages to GLP-1. And I'd be very interested to understand what progress you've made? Because clearly, we can see the prescription data, we can see the sales of GLP-1. And it looks like there is absolutely no handicap at all to your current ability to grow. So can you please tell us whether or not you've managed to improve yield, whether you anticipate in the second half that we will see an impact of these potential supply shortages or whether you're working very hard and hopefully, therefore, able to mitigate it?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Matthew. First on what we know, and I think that's quite easy to answer, Martin.

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

That's the easiest question, but it's also an important question because as we also said in the presentation, basically, we know nothing in terms of the data. I received a phone call saying that DMC recommends that you continue the trial, and that's basically all the interaction and all the data that I have received.

In response to Pete's question, we really wanted to clarify for us, having designed a study to be looking at a 17% differential, it's absolutely a positive thing to continue because if we should have stopped for the interim the data on the primary endpoint should have been substantially be on 17%.

Again, there, we are speaking in hypotheticals because we haven't seen the data.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Matthew. On supply of GLP-1. I will start by saying, if you look at our GLP-1 business, today, Ozempic is the best-selling diabetes medicine in the world. In the first 6 months of '22, it grew by 73%. I think we all know that we're not getting price increase -- price increases. We're actually seeing modest price decreases. So the volume growth is higher.

So I think that speaks, it's clear language that from a high base, we are significantly increasing manufacturing as we go. And we have plans that are on track to further expand volumes produced in our facilities. We have major new facilities coming in line as we speak, state-of-the-art approved facilities. So we are on a journey of driving growth, and we're ramping up manufacturing capacity to cater for that. But it's clear that we are in a situation now where there is a very, very strong demand for our medicines. So we guided after Q1 that we will see periodic supply shortages here and there.

And now we raised our guidance further while also increasing capacity. So that's also what we're facing now. But -- it's not that we don't have supply. We keep growing supply to meet a demand that also keeps growing. So from time to time, we'll have issues in certain markets, but there are products coming in a continuous manner. And we try to manage this the best we can. And we have capacity expansions coming in line. So we will eventually get to a state where we believe we have also excess capacity.

So it's a changing situation, but it's from a very, very positive starting point of a very strong and large platform that's showing tremendous growth. Thank you, Matthew. Next question please?

Operator

The next question is from Sachin Jain of Bank of America.

Sachin Jain
BofA Securities, Research Division

And Martin, apologies, I'm going to try around 3 on SELECT. So I think Pete's question, just to be clear, was not really around the 17% or above or below. So I'm going to rephrase it, is there a scenario where the primary endpoint was substantially above 17%, let's say, '22, '23 at the interim and the study still didn't stop for whatever discussions you've had prior to the date of the DSMB on secondaries. I guess the reason investors are asking this question is to gauge the probability of SELECT hitting at final analysis, i.e., if you're in the 17% to 22% range now interim, people feel differently to if you're well north of 20% and the studies only not stop because of secondaries. So apologies again, but I'm just trying to really clarify the point on secondaries there.

The second question is on Wegovy supply, a couple of months perceived delay. Just if you could provide any color behind that? Is it utilization level of plants? Is it a different level of inventory you've decided to build. I just want to confirm there are no regulatory issues in the background.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Sachin. So interesting number of interpretations of what Pete said, maybe we have to get Pete back on the line. Martin, yes, not a limited number of times you can answer the same but....

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

Yes. So again, first of all, I'm not privy to the data monitoring committees and operations. Obviously, we have a data monitoring charter. And in that, we specifically stated that in order to stop for the interim analysis and without going into numbers, it was important that we had safeguarded ourselves and therefore, specifically on the primary end point, we needed to be substantially beyond 17%.

Based on the fact that we have been recommended to continue the trial, I'm not privy to speculate what the DMC has seen -- what kind of data they have seen -- and that also means that we are as confident as we have ever been in terms of reaching the primary endpoint and the purpose of the SELECT trial because basically, all of our assumptions still hopeful. And our base case has always been to continue the trial until the end.

Doing the interim analysis was an interesting upside, but again, I really don't like to speculate on the data that the DMC has seen because I'm simply not privy to that.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. Let me try to address Wegovy supply. As you recall, during our Q1 release, we communicated our expectation of making all those strengths available in the U.S. during the second half of the year. And also, as Doug also just mentioned that the CMO had reinitiated manufacturing.

And we also mentioned that we had stopped supplying the [too low starter doses] as we experienced really, really strong demand that was hard to control, and we wanted to ensure that patients starting treatment with Wegovy could stay on treatment.

So what is new now is that we have experienced a bit lower ramp-up versus plan and hence volumes coming from the CMO. And that's why we now explained that we expect all those things to be available towards the end of the year, hence the couple of months delay, you're alluded to. And this is really because we want to make sure that we have sufficient inventory levels, not to disappoint patients and physicians, again, you can say.

I'd also like to underline that in parallel with this, we are tracking well on establishing the segment and the third manufacturing site for Wegovy, which will result in a significant step-up in supply availability already in 2023. And as such, we remain really confident in the potential of Wegovy being a game changer in a very significant obesity market currently opening up.

And we have a lot of focus on the U.S., but if you look at the IO data, you can really see that obesity is taking up. So strong confidence in our ability to build capacities and also drive that into patients and fulfilling patient demands in the coming period. Thank you, Sachin. Next question please?

Operator

The next question is from Simon Mather of BNP Paribas Exane.

Simon Mather
BNP Paribas Exane, Research Division

I've got 2. Firstly, over the last few days, there's been increased noise over U.S. pricing reform, Biden, trying to push something through [indiscernible]. I'm just wondering if you could give Novo's perspective on that, obviously, short-term potential upside for you guys. So I'm thinking more when the direct negotiations come in 2027, your thoughts on potential improvement of Ozempic to that partly?

And then secondly, is on SELECT and it might be a crazy question, but I appreciate the double-blind study. But obviously, if you're on placebo, you're not going to lose weight, so there's potential for quite a high dropout rates in the placebo arm. I'm just wondering if over large-scale dropouts within the placebo arm could have actually, in fact, led to reduced power of the trial to be stopped at interim?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Simon. So let me try to talk to the U.S. health care reform. Obviously, we don't have a lot of details around it. We know some of the elements. We support elements that would overall improve, say, affordability for patients. So reforms perhaps like what could be coming out of a Medicare Part D redesign that could help patients. We think are welcomed in terms of, say, what is being labeled as renegotiation or ability to directly negotiate with the industry. We are not worried about that because it sounds more like, say, government pricing mandates. It's too early for us to speculate when it would and how it would impact us.

But I would say that overall, we believe that there would be limited impact short term. So it's more in the medium and longer-term impact that could be expecting, but it's a bit difficult for us to be very precise and quantify what impact. And then Martin, again, again on SELECT, could there be anything about dropout rates that impacts discovery brand?

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

It's actually a super important question and it's something that we'll be focusing on for many years. Patient dropout missing data is scientific and regulatory headaches. So therefore, we've spent the last 10 years refining our approach to doing our constraints. And 1 of the success parameters in doing these trials is actually to secure that we don't have dropout in either treatment arm.

So we predefined a very, very small single-digit percentage number that is allowed to sort of speak dropout from price. And so far, both in SELECT and flow and outflow and other outcomes trials, we are very, very happy with the retention rate, including on the placebo arm.

And just to give you an example that I can actually share -- for example, for the entire icodec program, we are looking at retention rate in excess of 90%, 95%. And that's something similar that you have to imagine for the SELECT trial.

Lars Fruergaard Jorgensen

President, CEO & Member of Management Board

Thank you, Martin. Thank you, Simon. Next question please?

Operator

The next question is from Martin Parkhoi of SEB. .

Martin Parkhøi

Can you hear me?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Now, we hear you.

Martin Parkhøi

Two questions. Firstly, on Wegovy, I know it's only 1 year ago that you made the initial launch, but that has happened a bit since then. I think that the perception in U.S. has really strengthened that Ozempic and Wegovy is the same molecule and maybe you could speculate that many of the patients, which have gone on the drug this year, is maybe for obesity and maybe the same on Wegovy.

Do you think that there's actually some change dynamics already now for the obesity potential compared to 1 year ago, looking at Wegovy since maybe some of the upside are captured by the so-called GLP-1 diabetes market.

And then second question, just on manufacturing, again, our supply, Lars, are you making -- long term -- if you look at the sales this quarter, the growth on an absolute basis from Ozempic from Q1 to Q2 is more than the total sales of Rybelsus this quarter. So firstly, are you making long-term changes where you actually now can use some of the previous planned production capacity for Rybelsus that is now used for the subcutaneous. And maybe Martin can share some light on the trial, which have recently put on clinical [indiscernible], but you're looking at a new production or manufacturing method for Ozempic, is this something that you could elaborate on?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. Camilla, can you maybe talk a bit through what has -- if anything happens over the year [indiscernible] products with the same molecule and how this is looked at.

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

Yes. So there's no doubt that there is -- okay, if you take the big picture, there is a big overlap between the number of living -- in the number of people living with this. And of course, having Wegovy in the market for a year has underlined the importance of the significant to treating people with obesity. It's also clear that many of people living with diabetes, they are also suffering from overweight and obesity, even up to 80% of people living with diabetes are suffering from obesity.

So of course, with the benefit of Ozempic, the proven cardiovascular profile, the A1C profile and also the weight loss profile is clear that this will benefit of course, also people living with obesity. So we've seen that the whole connotation around how important it is to also treat obesity and also treat overweight in people with diabetes has simply just increased.

And this, of course, has been underlined and we see that effectively by the growth, both in the diabetes segment and the strong unmet need in obesity and the demand for Wegovy. Having said that, it's, of course, also important to us to just underline that we promote in each segment, the benefits of the Wegovy and of course Ozempic in the diabetes segment, and hope to cater for each of those 2 groups of patients.

But basically, the understanding and the perception of GLP-1 in general has really taken off and Lars was just talking to significant growth rates that we have seen underlying the profile of semaglutide.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. And maybe picking up on that and trying to address supply, you can say, we see a really, really strong dynamics now with Ozempic. We have the Rybelsus as well. We have Wegovy and we have further combinations and all formulations as well. So it's important for us to build, I'd say, medium, long-term flexible manufacturing setup that can produce all products, so to say, because to be honest, our ability to precisely forecast with presentation and which administration of a molecule like semaglutide is delivering can be hard.

So to your point, it's a priority for us to build flexibility both in our API, but also you can say in our -- say, filling setup, and you're well aware that we have for years been investing in a significant API facility in the U.S., which is now coming in line.

So we have a huge capability there. And obviously, also out of Denmark, where we have an ongoing significant investment in building more API. And then you can say, it's relatively easier and faster to scale up with different times of filling lines, be that for different types of devices. So yes, flexibility across presentations and dosing forms is important. And then finally, Martin on a new trial.

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

Yes, without going into too much detail, we will continuously upgrading our formulations of not only Ozempic but also Rybelsus and other drugs. And obviously, we have to generate clinical data to support that.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. And Martin. Next question please?

Operator

The next question is from Michael Novod of Nordea.

Michael Novod
Nordea Markets, Research Division

Yes. Just 1 question. Sorry about sort of taking down into supply again. I was just wondering is there any risk that supply constraints on the bulk side could also lead to sort of a delayed launch in IO of Wegovy, i.e., will you be significantly ramped up on the production side to also ensure that the Wegovy is broadly launched throughout 2023, as it seems like you're expecting also significant demand there.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. Thank you, Michael. I spoke to our investments in API capacity, some kicking in shorter term, some kicking in medium term. And even within the API capacity, we have now -- we have extra, say, capacity available for next year. So we believe we have capacity to start rolling out Wegovy in the outside of U.S. countries starting significantly next year. We're already active in France, and we expect to have a couple launches later this year.

So '23, we'll see a broader launch planned for Wegovy in international rations. And of course, with the dynamics we see for Saxenda, that is also based on that we believe there will be significant volumes there. We have built flexibility on, say, device platform, which gives some optionality. So back to also the question from before. It is a lot about with the dynamics we see now, which are -- it's massive volumes we are expanding year-over-year.

So the more we build flexibility, the more we can cater for these demands. But that's a pleasure to do when you see the demand we are experiencing now. So we have a lot of heavy colleagues in product supply working really hard and doing a great job. Thank you, Michael. Next question please?

Operator

The next question is from Richard Vosser of JPMorgan.

Richard Vosser
JPMorgan Chase & Co, Research Division

First question -- can you hear me? Sorry.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. Go ahead.

Richard Vosser
JPMorgan Chase & Co, Research Division

Excellent. Awesome. Brilliant. So when I have a look at other obesity trials, 1 of the challenges apart from keeping patients on them has been maintaining weight loss over such a long period of time. So just -- from what you can see, how well have you been able to achieve the maintenance of weight loss in SELECT?

And then just 1 thought on the prevention of diabetes. It was a discussion at ADA. And with the new time lines or full time lines, I should say, on SELECT, at what point do you think you can use it to gain a prevention of diabetes claim for Wegovy?

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Richard. I think those were 2 questions to you, Martin.

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

Yes. I think if I'm maybe -- sorry about not seeing an interim analysis on SELECT, it could be because I'm not allowed to see the data. And obviously, I am as you curious to not only cardiovascular outcomes, but also other aspects of the trial. And specifically on the weight loss, again, I'm not privy to any data, including the weight loss.

What we do know, obviously, is that we have conducted a 2-year trial, where we've seen a sustained weight loss over those 2 years with a similar weight loss, as we've seen in our previous plans. So based on what we know so far, at least at 2 years, semaglutide is able to maintain the weight loss accrued.

On the prevention and diabetes, basically, this doesn't delay anything in the sense that the regulatory requirements and potentially also the payer requirement is to observe patients of treatment for a specific period of time and still see a differential to the comparator treatment in terms of risk of developing diabetes.

Based on what we've seen so far, semaglutide might have that potential. And what we obviously intend to do with the extension of the SELECT trials is after submission of the original trial will continue to follow up, and we'll do that after 1 and 2 years, up to 10 years. As soon as we have the first readout, we will be able to engage in dialogue with not only regulators but also payers on the potential should the data support us in that.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. Thank you, Richard. Next question please?

Operator

The next question is from Kerry Holford of Berenberg.

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

A couple of questions, please. Firstly, on Cagrisema. You're on track for that Phase II diabetes data later this quarter. Can you remind us what you really need to see from that study in order to proceed to Phase III in diabetes? Are you looking for superior HbA1c lowering as well as weight loss -- maybe weight loss [indiscernible] hurdles there in order to proceed. And then just a quick check on SELECT, are there any further interim analysis planned where we're now moving straight towards the client data.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Kerry. Again, Martin, to you.

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

No. So thank you very much for the question on Cagrisema. From a regulatory perspective, in diabetes, we are obviously primarily looking at glycemic control. We are also looking at weight loss, but the primary sort of purpose is to look at glycemic control.

And in that space, we need to be able to show a differential between the combination therapy and the individual mono components. Now the important comparator here is obviously semaglutide, and that basically means that we need to have a statistically significant, but also clinically relevant differential to semaglutide on HbA1c. So that's basically what we're looking at -- and given that we have virtually no data in this space, it's also obviously important to call out that the study is exploratory, and this is specifically why we do it before we potentially initiate Phase III.

On the SELECT, the answer is easy. We are now looking towards the planned finalization of the trial and no more interim analysis will be conducted.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Martin. Thank you, Kerry. We have time for the last question, please.

Operator

The last question is from Mark Purcell of Morgan Stanley.

Mark Douglas Purcell
Morgan Stanley, Research Division

First question going back to the Wegovy resupply -- will there be relaunch in the latter part of this year. I'm thinking about going back to sort of Martin's question, DTC promotion, will we see this kick in, what should we think about the shape of the relaunch? Will it be a hockey stick? Or will it be more gradual? So is it a relaunch or is it resupply effectively?

And then the second question, I was intrigued by the Phase II trial you're starting with a higher dose of injectable sema. I would have thought you had gone in straight into Phase III. So what is the -- about this trial, which means you have to do a proof-of-concept trial versus going straight into Phase III? What's the target product profile? And what does it mean when it comes to fighting back versus the incoming competition? Will you use this higher dose in combination with Cagrisema potentially in combination with the GLP, which could give you a wider therapy window.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Mark. So on resupply, we -- you can rest assured that we are eagerly awaiting driving Wegovy when we can make all those strengths available. I would like to refrain from getting into the specific tactics, I think we are -- we have entered in a situation where we're talking a lot to the details about how we run our business, and it's a very competitive space. So I hope you respect that we would prefer not to get into all the details of that.

Having said that, we are very confident in the product. We know that it does a trick for both physicians and patients, and we expect that we can get back strongly when we have the products in the market. Martin on the high dose sema trial.

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

So in the space of diabetes, again, the purpose has to be showing primarily a differential on glycemic control and subsequently on weight loss. Increasing the doses of semaglutide is something that is interesting for us because based on data that we've seen also from the outside world, it appears that we have not, with semaglutide, reached sort of the maximum effect potentially in glycemic control, potentially also on weight loss. And we have seen other data from the outside where the ceiling appears to have been sort of reached and therefore, it's relevant for us to see if we can achieve more with semaglutide.

Doing a Phase II trial looking at both, obviously, safety and efficacy vis-a-vis the different doses is a prudent approach and can potentially save us time and efforts in the other hand.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board
Thank you, Martin, and thank you, Mark. This concludes our earnings call. Thank you for participating, and please feel free to reach out to our Investor Relations colleagues regarding any follow-up questions you might have. Thank you, and have a great day.