S&P Global
Market Intelligence

Novo Nordisk A/S CPSE:NOVO B
FY Nine Months 2023 Earnings Call Transcripts

Thursday, November 2, 2023 12:00 PM GMT

S&P Global Market Intelligence Estimates

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Presentation

Operator

Good day, and thank you for standing by. Welcome to the Q3 2023 Novo Nordisk AS Earnings Conference Call. At this time, all participants are in a listen-only mode aftersales as a question in the session on your telephone. You will then hear an automated message advising your hand is raised. Please be advised that today's conference is being recorded. I would now like to hand the conference over to your first speaker today, Daniel Bohsen, Head of Investor Relations. Please go ahead, sir.

Daniel Bohsen
CVP & Head of Investor Relations

Welcome to this Novo Nordisk Earnings Call for the first 9 months of 2023. This call follows the early announcement of top line results and the updated outlook for 2023 shared in October. The release was advanced due to Danish securities regulations. My name is Daniel Bohsen, and I'm the Head of Investor Relations at Novo Nordisk. With me today, I have CEO of Novo Nordisk, Lars Jorgensen, 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 Knudsen. All speakers 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 webcast live and the recording will be made available on our website as well. The call is catched 1 hour. Please turn to that. 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 the next slide. As always, we 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 material or further in the risk factors, please see the company announcement for the first 9 months of 2023 and the slides prepared for this presentation. With that, over to you, Lars, for an update on our aspirations.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Daniel. Next slide, please. In the first 9 months of 2023, we delivered 33% sales and 37% operating profit growth at constant exchange rates. I'd like to start this call by going through the performance highlights across our strategic aspirations before handing over the word to my colleagues. Within purpose and sustainability, we continue to make progress. Our carbon emissions decreased by 28% compared to prepandemic levels in 2019 and in line with our aspiration of being a state employer, we continue to expand the number of women in senior leadership positions. This is now 41% compared to 38% last year. In R&D, an important milestone is that we will stop the flow kidney outcomes trial early as semaglutide demonstrated a benefit in people with type 2 diabetes and chronic kidney disease. Further, within R&D, we have recently agreed to acquire osiduriron for the treatment of cardiovascular disease. This supports our expiration of establishing a presence in other serious chronic diseases with a high unmet medical need. Martin will come back to this and our overall R&D milestones later.

The sales growth reflects strong commercial execution with both operating units contributing to continued sales growth, driven by increasing demand for our GLP-1-based diabetes and obesity treatments. Camilla and Doug will go through the details in the therapy area later. Within commercial execution, we are pleased to have reached our obesity aspiration of DKK 25 billion and our expiration for diabetes by reaching a global value market share of 1/3. Naturally, the progress is not holding us back, and we continue to aim for treating more patients with our innovative treatments. Karsten will go through the financial details, but I'm very pleased with our overall performance for the first 9 months of 2023, which has enabled us to raise our outlook for the full year. With that, I'll give the word to Camilla for an update on commercial 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. In the first 9 months of 2023, our total sales increased by 33%. The sales growth was driven by both operating units with North American operations growing 49% and international operations growing 17%. Our GLP-1 sales increased 49% driven by North America, growing 43% and international operations growing 60%. Insulin sales decreased by 7%, driven by a 1% decline in international operations and a 24% sales decline in North America Operations. The sales decrease was driven by a decrease in sales in the U.S. and Region China. Obesity care sales grew 174% overall. In International

Operations, sales grew 52%, driven by both Saxenda and VigoVI. In North America operations, Obesity care sales grew 244%. The Total rare disease sales decreased 18%, which was driven by a 22% decrease in international operations and by a 13% decrease in North America operations. Please turn to the next slide.

With 25% sales growth in our diabetes care, we are now growing faster than the total market, improving our global diabetes value market share to 33.3%. The increase reflects market share gains in both North America Operations and International Operations. In international operations, total diabetes care sales increased by 21% in the first 9 months of 2023. This was driven by GLP-1 sales growing 60%, driven by all geographical areas. Novo Nordisk is the market leader in international operated GLP-1 value market share of 69%. Sampi continues its GLP-1 market leadership with just shy of 46% market share. Rialto has 12% value market share driven by strong uptake across geographies. And with that, I will hand over to Doug.

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

Thank you, Camilla. Please turn to the next slide. The GLP-1 class expansion continues in the U.S. in the first 9 months of 2023. The U.S. GLP-1 market volume grew around 50% comparing Q3 of 2023 to Q3 of 2022. Measured on total prescriptions, Novo Nordisk continues to be the market leader with 53% market share.

Please go to the next slide. Obesity care sales grew by 174% in the first 9 months of 2023. This was mainly driven by the U.S. The global branded anti-obesity market expansion continues with a global volume growth of 94%. In international operations, Obesity care sales are driven by strong Saxenda performance and the Wegovy launches in 5 international operation countries. While eager to launch Wegovy in more I/O countries, our focus remains to do this in a sustainable manner, for example, by capping volumes.

In the U.S. alone, sales of Wegovy grew by 467%. Demand for Wegovy continues to exceed supply and to safeguard continuity of care for patients already on Wegovy, the supply of the lower Wegovy-dose strengths in the U.S. has been reduced since May of 2023. Please go to the next slide. Our rare disease sales decreased by 18%. The sales decrease was driven by a 13% decline in North America operations and a 22% sales decline in international operations. Sales of rare blood disorders increased by 2%, driven by the launch products in hemophilia A and B and partially countered by NovoSeven. Sales of rare endocrine disorder products decreased by 54%, reflecting a temporary reduction in manufacturing output. Now over to you, Martin, for an update on R&D.

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

Thank you, Doug. Please turn to the next slide. Serious chronic noncommunicable diseases affect millions of people globally and have emerged in recent years as a major public health issue. Given our extensive scientific and clinical knowledge within metabolic diseases, we are well positioned to advance our understanding of semaglutide potential benefits and associated health complications.

With the current body of evidence, it is clear that the beneficial effects of semaglutide goes even further than glycemic control and weight loss. Semaglutide has already now demonstrated convincing risk reductions in a number of cardiovascular outcome studies. This includes SUSTAIN 6 and PIONEER 6 in type 2 diabetes as well as TEPP-select in obesity. While we await data from the SELECT trial to be presented, we continue to build evidence for the semaglutide molecule in the cardiovascular space. In 2024, we expect several readouts. This includes type 2 diabetes cardiovascular outcome study sold will or semaglutide 14-milligram, and the functional outcomes trial, STRIDE, which focuses on the high-risk population with peripheral vascular disease.

As previously discussed, we also investigated the potential therapeutic effects of semaglutide on osteoarthritis and metabolic dysfunction associated with daltohepatisis, previously known as nonalcoholic steroid hepatitis. In addition to this, we recently announced early closure of the flow client due to efficacy. Next slide, please. This closure was based on a recommendation from the flow independent data monitoring committee following a preplanned interim analysis. As you know, FLOW is an outcomes trial conducted across 28 countries and more than 400 sites. 3,534 people were enrolled and randomized in a 1:1 ratio to receive either once weekly semaglutide 1.0 milligram or placebo.

The eligibility criteria were designed to include patients with type 2 diabetes and high or very high risk for progression of chronic kidney disease. The primary objective of Flow is to demonstrate delay in progression of chronic kidney disease and to lower the risk of kidney and cardiovascular mortality through the composite primary endpoint. This is on top of standard of care, including the use of SGLT2s. The trial is powered to detect a 20% risk reduction on the primary endpoint.

Key secondary endpoints include annual rate of change in estimated glomerular filtration rate, major adverse cardiovascular events and all cost depth. Today, a few treatment options exist for chronic kidney disease in people living with type 2 diabetes. With a projected global increase in type 2 diabetes, there is a clear need for additional treatment options to help mitigate the residual risk in

people or concomitant chronic kidney disease. The next step for me to close down the trial, start Flow is expected in the first half of 2024. The presentation of detailed data is expected to take place at a medical conference also during 2024.

Next slide, please. In line with our strategic aspiration of establishing a presence in other serious chronic diseases, we are pleased to announce the acquisition of ocedurenone for the treatment of cardiovascular disease from KBP Biosciences. There remains a significant need in treatment of hypertension, which is a leading risk factor for cardiovascular events, heart failure, chronic kidney disease and death. Ocedurenone is a once-daily oral administered small molecule with a long half-life and a higher affinity for the mineralcorticoid receptor. Ocedurenone has an attractive efficacy and safety profile and is currently being examined in the Phase III trial, CLARINKD in patients with uncontrolled hypertension and advanced chronic adidisease. We expect to initiate additional cardiovascular as well as chronic kidney disease outcomes trials during the course of 2024.

Next slide, please. Turning to other R&D milestones. I would like to highlight some of the other trial readouts and initiations across our therapy areas in 2023 and in the first half of 2024. Within diabetes in the third quarter of 2023, we initiated the first pivotal Phase III trial in the reimagined program for CagriSema in people with type 2 diabetes. In the fourth quarter, we have submitted oral semaglutide 25 and 50 milligrams in the EU. We are also anticipating the results from the ongoing pivotal Phase III trial for IcoSema combined free in the first half of 2024. IcoSema has the potential to be a first-in-class once-weekly fixed ratio combination of basal insulin and GLP-1 receptor agonist compared to type 2 diabetes in need of intensification.

Within obesity, we are happy to announce that we in September initiated a 32-week Phase I trial with once weekly subcutaneous amicetin in people with all weight obesity. While we await select data going to be presented at the American Heart Association Congress, we have submitted the trial to the U.S. FDA and the European Medicines Agency. We are pleased that the FDA has granted priority review for the supplemental new drug application. This marks a significant milestone in our ongoing efforts to address unmet needs in patients with overweight and obesity and established cardiovascular disease.

Finally, we also expect the chronic heart failure trial with preserved ejection fraction in obese patients and diabetes to read out in the last quarter of this year. In rare disease, nedosiran was approved by the U.S. FDA for treatment of primary hyperoxaluria type 1. This marks the first approved siRNA treatment for Novo Nordisk. In other serious chronic diseases, we initiated a Phase I trial with our angiopoietin like free protein inhibitor. This is a monoclonal antibody in development for cardiovascular disease, specifically for lowering of cholesterol and triglycerides. 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 9 months of 2023, our sales grew by 29% in Danish kroner and 33% at constant exchange rates, driven by both our operating units. The gross margin increased to 84.5% compared to 84.3% in 2022. The increase in gross margin reflects a positive product mix, driven by increased sales of GLP-1-based treatments. This is partially countered by costs related to ongoing capacity expansions and negative currency impact and lower realized prices, mainly in the U.S. and Region China.

Sales and distribution costs increased by 22% in Danish kroner and by 25% at constant exchange rates. The increase is driven by both operating units. In North America, the cost increase is driven by the relaunch of Wegovy and promotional activities for Ozempic. In international operations, the cost increase is driven by promotional activities for Rybelsus as well as obesity care market development activities. The increase in sales and distribution costs are impacted by adjustments to legal provisions.

Research and development costs increased by 38% measured in Danish kroner and 39% at constant exchange rates. The increase reflects increased late-stage clinical trial activity and increased early research activities compared to the first 9 months of 2022. The excision of former therapeutics in '22 and in Misago Pharma also increased R&D spending. Administration costs increased by 9% measured in Danish kroner and 11% at constant exchange rates. Operating profit increased by 31% measured in Danish kroner and 37% at constant exchange rates, reflecting the sales growth.

Net financials showed a net gain of DKK 1.2 billion compared to a net loss of DKK 5 billion last year. The effective tax rate was 19.9% in the first 9 months of 23 compared to 20.5% in the first 9 months of '22. Net profit increased by 47% and diluted earnings per share increased by 49% to DKK 13.71. Free cash flow was DKK 75.6 billion compared with DKK 62.6 billion in the first 9 months of 22. In line with the strategic aspiration of delivering attractive capital allocation to shareholders, a total of DKK 52 billion has been paid back to shareholders through share buybacks and dividends. The cash conversion is positively impacted by timing of payment of rebates in the U.S. Capital expenditure for property, plant and equipment was DKK 6.4 billion compared to DKK 7.2 billion in 2022. This primarily reflects investments in additional capacity for active pharmaceutical ingredient production and fill/finish capacity for both current and future injectable and oral products.

Please go to the next slide. Nine months into 2023, we are continuing our sales growth momentum, which has enabled us to raise the outlook for the full year. We now expect the sales growth to be between 32% and 38% at constant exchange rates. The increased sales outlook is primarily reflecting higher full year expectations to Ozempic volumes sold in the U.S. and gross to net adjustments for Ozempic and Wegovy in the U.S. The guidance reflects expectations for sales growth in both North America Operations and International Operations.

The guidance is mainly driven by volume growth of GLP-1-based treatments for diabetes and obesity care. This is partially countered by declining sales in rare disease due to a temporary reduction in manufacturing output. The guidance reflects the level of volume growth of GLP-1 based treatments. The inherent uncertainty of the pace of Ozempic obesity care market expansion following the relaunch of govi the U.S. and a limited rollout in international operations are also included in the guidance range. Finally, the sales outlook reflects expected continued periodic supply constraints and related drug shortage notifications across a number of products and geographies. Novo Nordisk is investing in internal and external capacity to increase supply both short and long term.

While supply capacity for Wegovy is gradually being expanded, the lower dose strength in the U.S. will remain restricted to safeguard continuity of care. We now expect operating profit to grow between 40% and 46% at constant exchange rates. This primarily reflects the sales growth outlook and continued investments in future and current growth drivers within research, development and commercial. For 2023, we expect net financial items to amount to a gain of around DKK 1.6 billion, mainly reflecting gains associated with foreign exchange hedging contracts.

Capital expenditure is still expected to be around DKK 25 billion, reflecting the upscaling of the supply chain and the innovation-based growth strategy pursued by Novo Nordisk. In the coming years, the capital expenditure to sales ratio is expected to be low double digits. The free cash flow is now expected to be between DKK 65 million and DKK 73 billion, reflecting the sales growth and favorable impact from rebates in the U.S. and investments in capital expenditure. The updated cash flow expectation is mainly reflecting increased net profit expectations, partially countered by business development activities. That covers the outlook for 2023. Now back to you, Lars, for final remarks.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Thank you, Karsten. Please turn to the final slide. Today's announcement discloses the full set of quarterly results and updated outlook for 2023, which was shared earlier in October. Overall, we are very satisfied with the sales growth in the first 9 months of 2023. The growth is driven by demand for our GLP-1-based theapeutic interventions for diabetes and obesity, which is now reaching more people than ever before. The performance in the first 9 months of the year has enabled us to raise the outlook for the full year. From an R&D perspective, we have reached a significant milestone with the submission of Select and look forward to sharing more data at American Heart Association. In addition, we're excited about the early closure of the FLOW trial and anticipate a read out in the first half of 2024. Finally, the ocedurenone will strengthen volume of cardiovascular disease and underlines the commitment to establish presence with other serious chronic diseases. With that, I'll hand over the final word to Daniel.

Daniel Bohsen
CVP & Head of Investor Relations
Thank you, Lars. Next slide, please. With that, we are now ready for the Q&A session, where I kindly ask all participants to limit her or himself to one or maximum 2 questions, including sub questions. Operator, we are now ready to take the first question.

Question and Answer

Operator

Thank you. We will now go to the first question. And your first question comes from the line of Michael Nedelcovych from TD Cowen.

Michael Thomas Nedelcovych
TD Cowen, Research Division

I have one for Martin. Martin, if you'll allow me to set up something of a straw man, here's a potential set of expectations for the Phase III SELECT data when we see them at AHA. One, clinically meaningful benefit across each of the individual MACE components and regardless of BMI category; two, cardiovascular benefit that clearly emerges within 1 year on Wegovy therapy and does not diminish over time; and three, no noticeable imbalance in any very rare adverse events such as suicide or cancer. My question is, would you urge me to modify these expectations in any way?

Daniel Bohsen
CVP & Head of Investor Relations

Martin a straw man for you?

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

Thank you very much for that question. As you probably imagine, I cannot speculate to anything beyond what we've already disclosed. And that is the 20% risk reduction on the primary endpoint for MACE, which is obviously myocardial infraction stroke and cardiovascular death. We see attribution from all three, but we do not go into more detail. What I will commit to is obviously that we saw a very clear and positive safety profile from Select and with no outliers identified.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin, and thanks, Mike, for the question. Next question please.

Operator

Your next question comes from the line of Richard Parkes from BNP Paribas.

Richard J. Parkes
BNP Paribas Exane, Research Division

I've got a couple. So firstly, when I look at Ozempic and Wegovy U.S. Simphony prescriptions, they're both trending flat to down over the last quarter, assuming due to supply constraints. But your guidance suggests an expected acceleration in top line growth in Q4. So I'm just wondering if you could help me to understand that. Are you expecting to see kind of further improved supply into the end of the year would be, I assume, kind of swing factor there? And then the second question is just your slide outlines the potential benefits of semaglutide beyond IcoSema control and weight loss and maybe we'll see some insight into that from the SELECT study. But your chart suggests there's potential for patients to benefit from the CV aspects that don't have diabetes or obesity. So I'm just wondering how you can capitalize on that given that your trials currently, I think, are just recruiting patients with either obesity and diabetes and comorbidities.

Daniel Bohsen
CVP & Head of Investor Relations

So I'll give the first to you, Karsten, supply going into our guidance.

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

Yes. So thank you for that question, Richard. And clearly, when we put out guidance, that's because we believe that's the most realistic forecast range that we're putting in. And we don't have too many months to roll on. So of course, we see the TRx trends and bake that into our forecast. What I would give of additional flavor on top of that is, of course, the growth rate is also a function of extra factory

sales last year, and we did see a big having a lower base last year in the fourth quarter than what we would normalize into this year. And then, of course, there can be fluctuations in inventories, for instance, with wholesalers. And then finally, I would say this pickup in sales growth in the fourth quarter, this is not to be kind of read into anything, any difference on the supply situation. What we're selling in the fourth quarter has been produced months ago.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. Martin, any comments on the benefits beyond weight loss for the same?

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

So first of all, I think it's exactly right that our starting point is the cardiometabolic space starting out with obesity and diabetes. And these are the patients that we investigate. I think it's important to call out that the best majority of patients offering from ACVD, from heart failure, from chronic kidney disease, but also metabolic liver disease also have an element of metabolic arrangements and there's a clear association and overlap to both diabetes and obesity. So from our perspective, this actually creates some very nice synergies and are certainly not seen as exclusive. But our starting point is patients offering from diabetes and obesity.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thank you, Richard, for the questions, and we are ready for the next question.

Operator

Thank you. Your next question comes from the line of Seamus Fernandez from Guggenheim Securities.

Seamus Christopher Fernandez
Guggenheim Securities, LLC, Research Division

So just very quickly, as we think about the SELECT trial results in the wake, not just in the presentation, but the very rapid filing, there have been a lot of questions around this being actually a cardiovascular medication and perhaps gaining access to CMS in that regard. Can you just talk about the prospects of that actually becoming a reality? And then the second question is just on the oral incretin and the initiation of the subcutaneous incretin. Can you just help us understand, is this more of a supply chain related decision, an IRA-related decision, or a decision related to some challenges with the oral formulation of incretin?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Seamus. Doug, I'll give the first question to you.

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

Yes. Thanks Seamus. We do believe that there's an opportunity, a potential opportunity to use the medical exception process through the CB component, but let's wait to see.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Doug. Martin any thoughts on emicreating.

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

Yes, on incretin in our decision to go also into subcutaneous is actually caused by another of the above of the 3 reasons that you mentioned. It's actually driven by the fact that we are learning that optionality is important for patients and prescribing physicians in both diabetes and obesity. And we've seen a clear potential for incretin to become both an oral, but certainly also a subcutaneous offering. And therefore, in Phase I, it is prudent for us to investigate both.

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Martin, and thanks, Seamus. We are ready for the next question.

Operator

And your next question comes from the line of Peter Verdult from Citigroup Inc.

Peter Verdult
Citigroup Inc., Research Division

Two questions, Karsten, your favorite topics. Supply and pricing. Just on supply, if we take the sort of run rate for GLP-1 volumes, your franchise in the U.S. and just extrapolate into '24, if nothing changes, I mean, there's going to be a big disconnect in terms of people's expectations for growth next year and I think it will be effectively flat. Now I know it's going to improve next year. But can I just push you on when we might see the handbrake being released.

I mean, logical thinking might be that at the time of the Mounjaro launch, you'll want to be in a less capacity constrained position. So I know you can't go into too much detail, but just some incremental color on when we might see the hand break being removed would be helpful. And then on pricing, if we do our value per script calculation, there's a huge jump from Q2 to Q3, you've called out gross to net adjustments. We know that commercial mix has improved. But just making sure, is this a sort of high watermark a one-off in terms of value per prescription? In terms of baselining and thinking going forward, can we use the value per script in Q3 as a baseline? Or is it artificially high?

Daniel Bohsen
CVP & Head of Investor Relations

Thanks, Pete. Karsten supply going into '24 and value per script.

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

Pete, thank you for those my favorite subjects. So I would say, first of all, with the guidance that for the full year this year, that has a midpoint of 35% sales growth at constant exchange rates, at least in the Novo setting, it feels like we have released the hand break and moving at a very high pace in terms of growth rates, at least it's the highest in the history of the company. But that said, and extrapolations into 2024, I would say, first of all, we're clearly suing a growth strategy based on innovation.

We have shown that we have the innovation platforms, especially in Ozempic and Wegovy to drive growth this year and clearly also next year. So not teaching you how to extrapolate, but if you extrapolate our implied Q4 sales growth based on our guidance, then you actually get to a sales growth number next year in the double digits, which is actually not that far away from where consensus is currently. So I do believe that we're scaling very fast. And then specifically on Wegovy and any handbags there. Then what I'd say as to 2024 is that in 2024, we will be delivering significant step-up in volumes through the U.S. market compared to 2023 as we did from '22 to '23.

And then to your pricing questions. As we've said on numerous occasions, the appropriate way of looking at net realized pricing in the U.S. is to look at the year-to-date numbers. So most contracts are contracted on an annual basis. And the trigger part is the lag effect between when a script is written, and then we received the rebate claims from the payers. And there's just a lag effect of several months, and that's on by in reality, Q3 is the first point where we see how the channel payer mix to is falling out for 2023. So I wouldn't use Q3 in isolation for anything forecasting-wise, I would recommend you to use year-to-date Q3 as a starting point.

Daniel Bohsen
CVP & Head of Investor Relations

We're ready for the next question.

Operator

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

Mark Douglas Purcell
Morgan Stanley, Research Division

The first one on GLP-1 on higher doses, at least starting higher dose trials for tirzepatide. You have 8 milligrams coming through at the end by the end of this year. Can you help me understand your expectations there and the importance of increasing your dose where the pivotal trial at 7.2 readout late next year? And then second, in terms of the Penn platform leverage, we estimate about 100 million

GLP-1 pen unit is going to be sold by Novo in 2023 for GLP-1 is. The majority is the FlexTouch platform with a 3ML platform. So will you use those 2 platforms to launch with GOV in the U.S.? And if not, why not?

Daniel Bohsen
CVP & Head of Investor Relations

Martin, the third question for you, GLP-1 higher dose considerations.

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

Yes, absolutely. Thank you for that question. So you're absolutely right. We investigated 8 and 16 milligram in diabetes, but we're also investigating 7.2 milligrams in obesity. The purpose is obviously to assess whether we can achieve an even higher efficacy without compromising on safety. Our model suggests in particular in the new business space, that a high dose could potentially be associated with an even greater weight loss without having to compromise on safety and being diligent, we want to assess this.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. And if I understood your question correct, Mark, then the question was whether we leverage our FlexTop platform also to launch Wegovy in the U.S. in the FlexTouch device. But last, maybe to you, any strategic considerations on our device platforms.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes, Mark, thanks for the question. I'll just say that we have a situation today where we have a number of device platforms outside the company on using outside vendor and technology. So that gives us flexibility. And it's actually part of fueling the growth today that we can flex this. So I'll not go into specific exploration about what we use of device per market, but we see that it's a strength that we can flex between different presentations. And we see today that is really the efficacy of the molecule that drives that. So that gives quite some flexibility in how we go to market country-by-country and strategic flexibility on our side.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Lars. Next question, please.

Operator

Your next question comes from the line of Emily Field from Barclays.

Emily Field
Barclays Bank PLC, Research Division

I'll have 2. One, just on the step 9 osteoarthritis study. I believe that this is not large enough to be added to the Wegovy label. So if this were to be a positive study, what would be your next steps plans? And then just on anti-obese medications and muscle loss. We've seen competitors more explicitly make efforts in R&D for compounds that could preserve lean mass over fat mass and overall weight loss. I was wondering if you could just give an update on where you stand on that within your R&D portfolio.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Emily. Martin, 2 for you?

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

Yes. So specifically on your arthritis trial, you are right. It's not the biggest trial. I think it's too early to speculate whether that will have an impact on the label. It's very, very clear that for us, it's also guiding for future clinical activities, specifically maybe for capacity or GLP-1 GIP combination. So it has actually 2 potentials both to serve for information, specifically for Wegovy, but also to guide us for future activities.

Daniel Bohsen

CVP & Head of Investor Relations

And the second one, Martin, obesity and research and development focus on muscle loss.

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

I think this is a relevant point. It's also a focus of ours with current treatments, specifically with Wegovy and Saxenda, we actually see a reasonable preservation of lean body mass, given the broader weight loss. But it has to be a focus area, and you will probably see also in our pipeline without going into details, maybe even by 2 assets that could lead to a preservation of lean mass.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thank you, Emily. We are ready for the next question.

Operator

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

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

Two, if I may. Firstly, on China, growth looks pretty good over there. But I just wonder if you could give us an update on the impact of which used access to Chinese hospitals and how that is affecting things if indeed at all? And then secondly, on semaglutide, there was an interesting journal preprint on Monday looking at its use in alcohol use disorder, which looked very impressive. It'd be interesting to get your thoughts on the potential of that indication in your opinion.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Simon. So Camilla, the first one to you, do we see reduced access to Chinese hospitals?

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

So in general, we are working across the country, and we also have access to hospitals in general. What we do see in China is an effect of the VPP, of course, that's what we mainly insulin sales results. And that is also when you look at an overall IO business point of view, that is what is actually dragging down the overall IO insulin growth. But in China, Ozempic is going really well. We have a great momentum of Ozempic that we've had since the launch and since the inclusion on the reinvestment list and that can drive growth in China.

Daniel Bohsen
CVP & Head of Investor Relations

No major issues with access. Martin, the second question.

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

Yes. Thank you very much for the question. We have also seen these observational studies and being intrigued by the fact that GLP-1 may have a place in also treating alcohol abuse does actually live within the mode of action of GLP-1. From our perspective, when also considering the timing, the combination of 2 mode of actions that could potentially also help here, namely GLP-1 and amylin so specifically from our perspective, CagriSema is probably the more attractive and efficacious approach. So if you see us going into that space, that would be with CagriSema and not with matte.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. We're ready for the next question.

Operator

Your next question comes from the line of Naresh Chouhan from Intern Health.

Naresh Chouhan
Intrinsic Health Advisors

First one on would go the U.S. market access. We're hearing that a growing number of employers are having to opt out, having already opted in because the demand has been too high. Can you just help us get a sense of how big or small an issue this is? And obviously, next year, that's probably potentially like to increase when supply resumes and demand increases? And secondly, on supply. If I look back at when you seem to be relatively comfortable with the demand, we were around about 30,000 new pet starts a week in the U.S. is that a fair starting point for kind of the ability to supply and growth from there going into 2024?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Naresh. So Doug, any updates on U.S. market access for Wegovy?

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

Yes. Thanks, Naresh. And overall, we're very pleased with the broad market access that we have for Wegovy. Most major PBMs and health plans are covering it, and that derives around 50 million people with obesity now being covered. And importantly, we're seeing about 80% of the patients that are paying less than $25 for Wegovy. Now to your question specifically around employers, we do see some opt outs, but we're seeing overall more opt-in and opt-out. So directionally, we're heading in the right direction. And our focus will be continuing on securing employer coverage as well as stronger access for ARMs overall.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Doug. Karsten any additional comments on the go supply going into next year?

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

Yes. So I think the way to look at the U.S. the good supply is a starting point of currently around 100,000 TRx per week according to IQVIA. And then we have the 5 different growth strengths. And of course, the magic is to get that split right into the link into manufacturing. And then we scale from there. And as we've said in prior quarters, then this is something we do dynamically. So don't look for hockey stick. It's a gradual process where, of course, we'll be starting at the lower doses and then increasing them as we move forward. There are different data sources in terms of new starts. So I'm not really sure what your data source is, but I think my data point is lower than yours in terms of number of new starts per week.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you Karsten. Thank you Naresh. We are ready for the next question please.

Operator

Your next question comes from the line of Florent Cespedes from Societe Generale.

Florent Cespedes
Societe Generale Cross Asset Research

Two, please. First one on Wegovy in Europe. Have you started to talk to the payers in Europe as you have already submitted the data to the European authorities? And do you believe that you will need to show a statistically significant benefit on the cardiovascular base that will be presented at the AHA next week. And my second question is on Ozempic, following the flow results. How would you position the product on this population as we already have products available to treat these patients, notably the SGLT2. And it seems that in the trial of 15% of the patients are under SGLT2 treatment. So some color on this one would be helpful.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Florent. Camilla, maybe the first one for you in terms of Wegovy outside the U.S.

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

Yes. I believe the question was whether we need statistical significance. I would just say, now we await the presentation at the conference. But in general, there is a great interest in Wegovy and, of course, also the benefits in Select. So we will get back to that, but we do see authorities interested in bringing up the discussion again with us already at this point for reimbursement of Wegovy. And just a reminder, we have reimbursement of Saxenda already in close to 15 countries all around the world. And of course, here, we are talking a step-up in treatment.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Camilla. Martin, any medical perspectives on Flow and the population that we potentially could treat.

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

Yes, absolutely. Maybe just also calling out on Select the study was designed to have a power specifically for the primary endpoint. So assuming statistically significant for the secondary endpoints is to be seen as an upside and not as something to be expected. I just want to call that out. But obviously, please tune in on what we can present on November 11 in Philadelphia. Specifically on Flow I think there's a tremendous unmet need in the diabetes space. It's also very, very clear that not all patients today who suffer from diabetes and chronic disease are on SGLT2 and on a GLP-1 and therefore, to have data to suggest that we can actually decrease and again, we haven't seen the data, but we can potentially decrease the kidney disease deterioration by a substantial number on top of standard of care, including SGLT2 is a really, really attractive offering. And it will allow more patients in need to get on a GLP-1.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thanks for the question, and we are ready for the next question.

Operator

Will now take the next question, and the question comes from the line of Richard Vosser from JPMorgan.

Richard Vosser
JPMorgan Chase & Co, Research Division

Question on the European rollout of Wegovy first. Obviously, we know in Denmark in May, there was a substantial demand for Wegovy in about 1% of the population. So I was wondering how that has developed since then, both in terms of volume and how you're seeing patients staying on the drug through Denmark given it's an out-of-pocket market. And then the second question is on your KP Bioscience product. Just wondering how that differentiates from other MR antagonists particularly ocedurenone from buyer, but there are also others in development from AstraZeneca, et cetera. Just your thoughts on how this is different.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Richard. Camilla the first one to you, Wegovy roll out in Denmark.

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

Yes. So in Denmark, we see a continued interest in Wegovy and Wegovy continues to perform very well. And it is more than 1% of the population at this point in time. In terms of how many states on the product, we also have, it's too early to give you exact daytime numbers, but we do have, I could say, anecdotal evidence that there is a very, very high number of the people that stay on the product from the beginning of the year when the product was launched.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Camilla. Martin, reflections on Ocedurenone.

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

Yes, absolutely. So what we've seen with Ocedurenone is a molecule with a very high affinity for the receptor and also a very high half-life. That actually means that we expect to see differentiation not only on efficacy but it also appears to have a potential upside on the safety side, specifically on hyperkalemia. So we do expect to see a differentiated drug in this space.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thank you, Camilla. Thanks, Richard, for the question. We are ready for the next.

Operator

Your next question comes from the line of Peter Welford from Jefferies.

Peter James Welford
Jefferies LLC, Research Division

Hopefully you can hear me. I've got two questions, firstly, if I could come back on the red gross margin. I appreciate the commentary year-to-date. But in the third quarter, it seemed to trend down quite a bit, which is getting somewhat unusual given the quite significant improvements we saw in the gross to net in your most profitable market for both Wegovy and Ozempic. So could you just talk a little bit about in the third quarter, what the incremental costs or whether perhaps any write-downs or something of inventory or something that could potentially depress the gross margin in what would normally be a more profitable quarter.

And then secondly, just coming back to the comment that was made on Stay time thinking about it a different way, which is in the past, you've cited for Saxenda that around 25% or more of patients are on the drug for at least a year, and most of those are treated by obesity experts. I appreciate it's still early for Wegovy to necessarily good comments on the U.S. for state time. But can you sort of talk about whether you're seeing different trends than those of Saxenda, both in terms of the obesity experts versus those arms and also the number of patients perhaps of reaching a year at this point.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Peter. So first of all to Karsten, the gross margin and then later Doug on what we see on state time in the U.S. for Wegovy.

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

Yes, Peter, well supported gross margin Q3 and just a word of caution to begin with, looking at the gross margins at a quarterly basis is always tricky due to fluctuations over the year. But if I am to comment specifically on the quarter, then at constant exchange rates, the gross margin is flat compared to last year. So the decline compared to last year is FX driven. And then you could say, why is it not increasing compared to last year given the gross to net adjustment and the product mix. And there are basically 2 pieces to it. First of all, remember, the starting point, our gross margin is already higher at 84% or so. And then secondly, what is different compared to prior years is that the amount of CapEx we are running these days. And just from an accounting policy standard point of view, we are realizing more costs related to our capital expenditure projects into the P&L. So it doesn't all go to the balance sheet. Some of it also hits the P&L, and that is basically what is offsetting the benefit from product mix.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. And over to you, Doug, any insights on state time on Wegovy in the U.S. so far.

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

Yes. Peter, thank you. Because generally, you're right. We expect to be able to say more about state time in 2024. Obviously, it's been difficult given the few time periods with unrestricted supply. But what I can say is based on early data from multiple sources, persistency on Wegovy, it looks better than Saxenda with fewer patients dropping off in the first 12 months, but we'll have more to say in 2024.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Doug. Thank you, Peter, and we are ready for the next question.

Operator

Your next question comes from the line of Mattias Häggblom from Handelsbanken.

Mattias Häggblom
Handelsbanken Capital Markets AB, Research Division

R&D question. In the scenario that both high dose at 7.2 milligrams as well as CagriSema works in Phase III. Can you help us think about the regulatory pathway for a fixed dose combination with CagriSema the high-dose Sema and whether that would require a new Phase III or if a small bitching study would be enough.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Mattias. Martin?

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

Yes absolutely. Thank you for that question, Mattias. That would most likely require a reasonably -- I think we can bridge some safety data, but we will still have to establish both safety and efficacy. So we actually see that as a potential opportunity, but we see that as a life cycle management activity.

Daniel Bohsen
CVP & Head of Investor Relations

hank you, Martin. And we have time for 2 more set of questions. So we're ready for the next one.

Operator

The next question comes from the line of Emmanuel Papadakis from DB.

Emmanuel Douglas Papadakis
Deutsche Bank AG, Research Division

Okay. Maybe a follow-on for Karsten on supply. Karsten you said you're going to significantly increase supply in 24% versus 23% as you did in '23 versus '22. Eyeball data, it looks like there was approximately a fivefold increase, 23% over '22. So you're telling us you're going to have another 5 fold increase in 2024. And if not, can you help us with the approximate quantum? And then a follow-on also on flow. Martin, you're helpful enough on Select to give us an indication that the contribution of components have been approximately equal, well balanced in Select? Is that also the case at Flow? Or how should we think about the contribution of the composite endpoint components? And what should we expect in terms of labeling?

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Emmanuel. First, Karsten, any additional supply?

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

Yes. And thanks for triangulating that way around Emmanuel. I'd love to give you a further flavor. But as you know, we are guiding for next year come our full year results late January. So that's where we'll be doing our financial guidance for '24 and giving too much granularity in scaling of Wegovy as we get too close to guiding for next year. So I'm sorry, but I'll have to provide that at a later point in time.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. Martin, can you share more on FLOW?

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

I think it's a great question. And I maybe just want to clarify, I don't think we've seen equal contribution from the 3 mono components. We just say that they all contributed and obviously, again, we have to await November 11 until we see the full data set. Specifically for FLOW, I would really love to be able to answer you, but due to the nature of an interim analysis, we've not seen the data. So for better or worse, I know absolutely no more than you do at this point. So I can't speculate.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Martin. Thank you, Emmanuel. Then we'll take the last set of questions.

Operator

Your last question for today comes from the line of Michael Novod from Nordea.

Michael Novod
Nordea Markets, Research Division

Just on the cost side, can you please go through some of the dynamics here in Q4 in order to sort of make the cost go up. As I see it, it needs to go up in an extreme pace for Q4. Are there any specific investments that you're able to take early or anything like that prior going into 2024, just to understand your EBIT guidance.

Daniel Bohsen
CVP & Head of Investor Relations

That's over to you, Karsten.

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

Yes, Michael, thanks for that question. When I look at our total operating cost growth in the fourth quarter, then it's actually not markedly different compared to year-to-date. So what you should be expecting is a continued, what I'll call high level of growth in R&D expenditure around the 40% mark and some 20% plus on S&D expenditure and the competitive gross margin also in the fourth quarter. So in reality, no big swings in the fourth quarter at constant exchange rates.

Daniel Bohsen
CVP & Head of Investor Relations

Thank you, Karsten. Thanks for the question, Michael. And this concludes the Q&A session. Thank you for participating, and please feel free to contact Investor Relations in case you have any follow-up questions. Before we close the call, I would like to hand over to you, Lars, for any final remarks.

Lars Fruergaard Jorgensen
President, CEO & Member of Management Board

Yes. Thank you, Daniel. I also like to thank you all for participating today. I hope it's clear from our comments that we're very pleased with the strong momentum we have in our business also underlined with the base guidance for '23. And many questions on the coming years, not least the coming year. But we are really focused on pursuing innovation-based growth strategy, and I feel confident in our ability to scale supply to support that.

We're really excited about FLOW, underlining the attractioness of semaglutide, and we are equally excited that we soon can disclose what Select has to show at the upcoming conference at AHA in a matter of a few days. So thank you all. We appreciate your time today. And with that, we'll close the call. Thank you.

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