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Novo Nordisk A/S CPSE:NOVO B

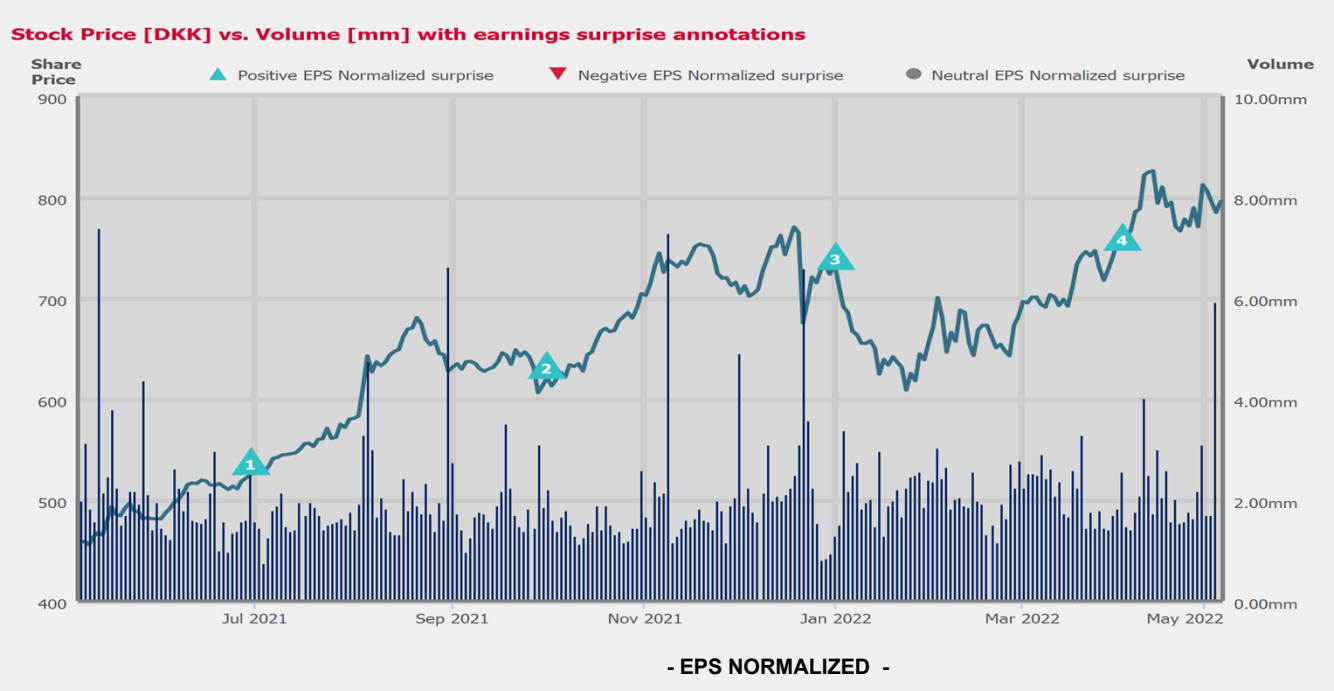
FQ1 2022 Earnings Call Transcripts

Thursday, May 05, 2022 12:15 PM GMT

S&P Global Market Intelligence Estimates

	-FQ1 2022-			-FQ2 2022-	-FY 2022-	-FY 2023-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	5.68	6.22	9.51	5.74	23.25	NA
Revenue (mm)	39192.76	42301.00	7.93	39849.06	164229.37	NA

Currency: DKK
Consensus as of May-05-2022 8:17 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2021	4.88	5.26	1 7.79 %
FQ3 2021	5.02	5.27	2 4.98 %
FQ4 2021	4.69	4.76	3 1.49 %
FQ1 2022	5.68	6.22	4 9.51 %

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EXECUTIVES

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

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

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

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Wimal Kapadia
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Presentation

Richard Vosser
JPMorgan Chase & Co, Research Division

All right. Welcome, everyone, to Novo's Q1 roadshow. I'm Richard Vosser at JPMorgan. It's a great pleasure to have the Novo management team here in this roadshow. Munk Karsten, the CFO; Camilla Sylvest, Head of...

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

Strategy.

Richard Vosser
JPMorgan Chase & Co, Research Division

Exactly, and Martin Lange is Head of Development. So I'll hand over to Karsten for a few introductory remarks in the presentation. Thanks, Karsten.

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

Great. Thank you, Richard, and thank you to JPMorgan for hosting this, launch presentation, and thanks to all of you participating in person. It's always good to interact in person.

And I'd like to remind you that this launch session is being recorded. So just for general use. So we have a great team here in London, and we released our results last week. So you could say it's not as stressed as we had anticipated, but the reason why we released our numbers as I'm sure you're aware. But basically, we have to follow the Danish regulations for listed companies in Denmark. And when you have identified material information, then you have to go really without any undue notice and report as fast as possible.

So that entails a lot of hard work from everybody in the organization and the Board meeting, et cetera. So it's not something we take lightly. But the benefit for you is that then you had the weekend also to prepare for this launch session.

So the session for today is, I'd say, reasonably snappy on the presentation, and then we have a good time for Q&A and perhaps also a bit of time afterwards in the breakout if you didn't manage to ask your question at the launch session.

So I have to remind you about forward-looking statements. And we just saw this again that predicting about the future can be hard, and real events might fall out differently. So that's how the world operates.

And in terms of our strategic aspirations as a company, we launched a concept back in '19, and we updated a couple of them at our latest Capital Markets Day. So this is how we report to the market on an ongoing basis.

And just to cover some of the key components, in terms of our purpose and sustainability, our ESG performance, we continue to drive performance both on CO2, which is, of course, not getting easier this year because people have started to travel, and product distribution is moving a lot more towards air distribution linked to the kind of our supply chain situation. So still down compared to '19, but not as much down as last year.

And on our social responsibility piece, I think it's a great achievement by Martin and the development team that now we have a positive scientific opinion around our thermal insulin solution that basically enables our human insulin to be stored at below 30 degrees for a month, which is really a key feature in developing markets. So really something that can make a difference.

The reason for the European registration is that then we can reference that in all these countries where it would be more relevant where perhaps less access to electricity and so on. And then finally, diversity and inclusion, also a key priority for the company to continue to progress on that.

On our pipeline, which Martin will come back to later, after last year where it's more of an investment year and trial execution year, now we're starting to see some really good trial readouts. You saw some at the Capital Markets Day between Mim8 concizumab. And now you've seen ONWARDS 2, the first Phase III results, favorable Phase III results with

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the once-weekly insulin. So we're really happy about that as you'll hear later on and of course, the high-dose Ozempic in the U.S. marketplace.

Commercial, we keep performing against our aspirations or even ahead of those aspirations. Some of you will remember our initial obesity aspiration about doubling obesity. That's actually exactly what we did in the first quarter compared to the first quarter last year. So really fantastic traction on our obesity franchise these days.

And then all of it turning into a great sales growth of 18%. Actually, the strongest sales growth in relative terms in 2 decades of Novo Nordisk and the biggest absolute sales growth quarter-over-quarter ever in the history of Novo Nordisk. So really amazing performance in terms of commercial execution and turning it into financial results also at 18% operating profit growth. I'll come back to that in more detail.

And then in terms of capital allocation, we had a very strong cash conversion in the first quarter and also allocation to shareholders at DKK 20 billion, a lot of value allocated to shareholders in terms of both dividends and share buybacks.

So with that, I'll hand it over to Camilla to cover our status on commercial execution.

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

Yes. Thanks a lot, Karsten. Good morning, good afternoon, everyone, I should say, here in London. Our sales growth, 18% sales growth driven by a combination of a strong growth in International Operations of 13% and North America Operations growing 24%. We also see nice growth in each of the regions here, EMEA, China and Rest of World, so all units contributing to growth.

When we look at therapy area distribution, you see the 18% is clearly driven by a growth in GLP-1, where we see continued growth in North America of 38% in our GLP-1 franchise, up 60% in International Operations. We see an insulin growth rate of minus 4% driven by minus 15% in the U.S., but a slight increase of 1% in International Operations.

And then as Karsten was alluding to, 107% growth in our obesity franchise driven by 146% increase in North America Operations and 63 in IO. And then we have a continued single-digit growth in our rare disease franchise.

And if we then zoom in on 2 of the biggest growth areas, if we start with GLP-1, especially our Ozempic franchise, you see here the 4 weeks rolling estimates of how prescriptions have really picked up in the beginning of this year on an NBRx level. On the right-hand side, you see the TRx level and a very steady performance, increasing the Ozempic share of the total GLP-1 segment.

The short-term increase is driven by additional focus from our side on DTC, but of course, also on more doctors prescribing Ozempic. We see better pickup now in lower-tier segments also. And of course, there might potentially also be a halo effect to the semaglutide molecule in general.

When we then look at Wegovy here, you see the uptake on the total scripts, so TRx. And of course, we have not been promoting Wegovy the last quarter in the -- last quarter in the U.S. Despite that, we now still see a continued uptake, but we have also 80% coverage now in the commercial segment. We are currently not promoting 3 lowest doses. We don't want patients to be initiated if they cannot continue on the treatment. But we have now seen that our contract manufacturer is initiating the commercial production. So we expect to be back in the market with supply in the second half of this year and making our product available again. So that's the plan for Wegovy in the U.S. and how we expect this to continue.

And with that, I'll just hand it over to Martin to talk a little bit more about R&D.

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

Yes. Thanks very much, Camilla. [indiscernible] This is going to be an exciting year in the R&D space. We'll have a lot of interesting readouts, obviously, starting with the icodec, but certainly also potentially with SELECT later on in the year if we get to do an interim analysis. But also we see very nice progress across all our programs.

We have, as you know, Phase III programs ongoing in all of our therapy areas, which is an interesting place to be especially when we see those reading out in the years to come.

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I just want to call out 2 things in the diabetes space. First of all, obviously, as you know, we've got the 2.0 milligrams semaglutide approved in the U.S. for the treatment of type 2 diabetes. That is very, very exciting. Also because you've seen the data, you've seen the results based on the publication.

Now we have it into the label very nicely describing the benefits of 2.0 milligram versus 1.0 milligram, namely more glycemic control, more weight loss, but no difference in the safety tolerability profile between the 2 doses of semaglutide and also a very nice description of the cardiovascular benefits of semaglutide, not sort of distinguishing between 1 and 2 milligram. So a broad label calling out good efficacy, good cardiovascular safety and good safety and tolerability. And Doug and his team are launching as we speak.

We talked about the ONWARDS 2 program. This is truly, truly exciting. From our perspective, I think you've seen the program, the ONWARDS program is 6 trials. It spans type 1, it spans type 2 diabetes. It's a global program. It even has one study, ONWARDS 5 that caters to payers, potential payer discussions. It's a real-world evidence study with the potential of demonstrating A1c superiority, exactly what payers are looking for. That would be a first insulin treatment having real-world evidence available at the time of launch to cater to that discussion. And obviously, we are a bit excited about that.

ONWARDS 2 was the first study to read out. We're still waiting for the next 5 studies to read out. And it was, in some aspects, the most difficult and therefore, also the most interesting study that we had to look at because the comparison was insulin Tresiba or insulin degludec.

And degludec, as you know, really efficacious drug, but also probably the most hyper safe insulin, basal insulin that we have out there. So going up against Tresiba in our first readout was obviously interesting. Patients were your garden variety type 2 diabetes patients, A1c at baseline between 7 and 10. All patients being treated with basal insulin at time of randomization, any basal insulin.

Approximately 30% of patients came from Tresiba. The rest came from various others, other basal insulins, primarily insulin [launching]. Patients were randomized to either into the icodec or insulin degludec. Really, really interesting.

And obviously, you've seen the headline results, which were truly exciting. This is a treat-to-target study. That's the regulatory requirement from the FDA perspective. That means that for 100 years, what we've seen when it comes to insulin development is noninferiority on primary endpoint.

You guys have commented and asked about that in recent years. Why don't you see superiority if you think this is a better insulin? Basically because we had to do this treated time. And probably also to an extent because there was maybe not that much to differentiate on other than the risk of hypoglycemia. Now we have a once-weekly insulin with a super, super flat and stable profile.

I just remind you, insulin icodec has a peak to trough over a week of 14% difference. So really, really stable to be compared with 80%, 8-0 percent in for [indiscernible] and Levemir and 40% for Tresiba. So really, really a flat and stable profile.

And that actually pans out even in a treat-to-time setting into superiority on A1c. That's the first -- in 100 years, we've never seen that in this kind of story. And that is in and of itself quite encouraging, obviously, making us quite optimistic of what comes next in the next 5 studies.

But what is really also important is no difference in hypoglycemia. I've heard some of you talk about as a numerical difference in hypoglycemia, which is obviously true. You've seen the numbers here was 0.25 and 0.73. Just to remind you again that in previous studies with basal insulin, hypo rates have been in the vicinity of 1.4 to 4 events per patient per year.

Here, we are talking about less than 1 in both treatment arms. Basically means that the patients on insulin icodec has to wait 1.5 years before he or she gets a non-severe event of hypoglycemia. And when we talk about not severe, we saw no severe events of hypoglycemia on insulin icodec. We actually did see severe hypoglycemia with Tresiba in this trial, and therefore, again, speaking to the safety of this company.

Another front is actually a significant improvement in quality of life, significant not only from a statistical perspective but also from a clinical perspective, again speaking to the benefits of this molecule. So Camilla asked me, will we get the trial of efficacy, safety and convenience? I think the answer is yes.

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There's even another upside with insulin icodec, and that's on the environment, going from 7 to 1 injection per week. It obviously also have an impact on how much plastic, how much glass do we have put into landfills. I think in 2022, that's not a trivial thing to have as an added benefit. So not in the bag yet, still waiting for the last 5 trials, but a very, very strong start for icodec.

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

Thank you, Martin. I'm here as Head of Development, really happy with the insulin icodec. So we'll get back much more on that in the quarters to come with the 5 additional trials.

So looking at financials, you've all been through this as part of our release. But just recapping, 18% sales growth at constant exchange rates. Take it into reported 24% sales growth, given the tailwind from especially the U.S. dollar. So really significant sales growth on a big base.

Gross margin adjusted for currency is reasonably flat. And -- but of course, one thing worth noting is when you look at our employee count as we also have in our company release of -- which is up 9% over the last year. The biggest single driver of that is actually an increase in manufacturing. So as we've talked about, scaling manufacturing. Part of that is also scaling employees to all the classic of 7 shifts -- or 3 shifts, 7 days a week.

In terms of sales and distribution cost, 18%, it's a classic. It's investments in GLP-1 diabetes as well as obesity market development, no news there. And then R&D, up 29% being, of course, impacted by our Dicerna acquisition and the run rate of Dicerna, which is actually also what you see in terms of the step-up in other operating income compared to the first quarter last year. So net-net, Dicerna in the first quarter has a negative impact on our P&L to the tune of 2%. So adjust for that, as potentially some companies would do, then actually our operating profit growth would have been 20%, excluding Dicerna.

Apart from that, our R&D costs are really being driven by our focus to expand our pipeline and diversify and a lot of investments going into both research and development and from a therapeutic point of view, investing significantly in what we call other serious chronic diseases so our cardiovascular franchise as well as SNACs and trials in that area, Alzheimer's.

All in all, 18% operating profit, 28% reported in reported terms, then we have the hedging going the other way. That's how it is when you hedge the U.S. dollar for 12 months. So very good hedging efficacy here in the beginning of the year and a net profit growth of 13%.

That start compared with the NBRx trajectory you saw with Camilla, led us to step up our outlook and raise our outlook significantly, I would say, from before 6 to 10 and now 10 to 14. And you see how it drills down throughout all our financial ratios. So pretty much no surprises there from top line all the way through to cash generation and increased share buyback to now DKK 24 billion.
So that covers kind of the warm-up commentary, and now we move into Q&A. And I think we're a small audience. [Operator Instructions] So I'll just sit down, and then I'll give it to Richard to have the opening question as our host.

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Question and Answer

Richard Vosser
JPMorgan Chase & Co, Research Division

So maybe two then. Firstly, on -- Camilla, you mentioned commercial access 80%. I think before the opt-in was sort of 40%. Can you give us update on the opt-in level from commercial employed?

And then secondly, on Ozempic 2 milligrams, you've highlighted, I think Doug highlighted on the conference call that it will be priced in line with other doses for diabetes. So how do you manage that given the brand is very close in dosing to Wegovy. Does that have any impact on Wegovy in terms of cannibalization or -- yes.

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

Thanks, Richard. So there's 2 for you, Camilla, one on opt-ins and the other one for pricing of 2.0

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

Yes. So Richard, we are approximately in a situation where we have 80% coverage gross, and then we have about half of the employers that opt in. So that means a 40% net coverage, so slightly more than what you recall from before. It continues to improve, but it's a long list of employers that we're, of course, working with, but it does consistently improve.

And on delivery on messaging, it's very, very important for us, of course, to stay completely true to what is the label. And we promote Ozempic in diabetes care. And right now, we don't promote Wegovy in obesity care. We will hopefully get back to that.

But for us, it's extremely important to stay completely in line with that for good reasons, for business ethics reasons. Nevertheless, we do see a pickup in the scripts of Ozempic, as I just talked to, also because we're expanding our prescriber base.

But of course, also because Ozempic is recognized for a triad of benefits, HbA1c lowering, strong weight loss but also the significant cardiovascular risk reduction. So all of that with the increasing awareness, of course, builds more and more momentum for Ozempic.

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

Thanks, Camilla. And just a bonus into on the coverage in obesity, as you would have seen then now we have a contract with the Department of Defense also. So in addition of continuing to enroll more employers under commercial, then of course, we're also working with some of the public employers in terms of getting access to whether it's under certain Medicaid plans or Department of Defense. So think we have good progress all. So very happy with that.

Then I think we'll move to Wimal.

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

Great. Can I just come back to Richard's question actually? So Ozempic high dose is priced at the same level as Ozempic 1 milligram, but as on 0.4 milligrams less than Wegovy. If the net price of Wegovy is similar to Saxenda, that's a [51] -- a 30% premium on Ozempic net price.

So I'm just curious, how do the pay discussions go? Because on 0.4 milligrams, that incremental dollar price is quite a lot. So I'm just curious how you -- you have a different rebate for the 2 milligrams within the 1 milligram. So that's the first question just following up on Richard.

And then the second one, again, probably for Camilla, the GLP-1s are clearly doing really well. But if we think about the diabetes market long term, so the bookings of metformin and insulin, and they're relatively stable at about 40 metformin,

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20% roughly is coming down slowly. So you have 40% of diabetes volume to play for. What is the peak penetration for GLP-1 in the U.S.?

Is it 25? Is it 30? How much do we need to leave for the SGLT2s long term? And then I guess tied to that, what does that mean for the rest of the world? Can Europe and the rest of the world get to that U.S. level?

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

Thanks, Wimal. I counted 2.5 question on that one. So thanks for pushing the limits. I think we'll let it pass this time around then we'll get back at you at another time.

So Ozempic 2.0 pricing, I'll give that a shot and then, Camilla, if you can talk to GLP-1 volume/patient penetration U.S./ Rest of World. So yes, on Ozempic 2.0, it's diabetes pricing. That's what we see also from competition. And I think the way you should look at it is it's a flat pricing between 0.5, 1 and 2.

So from a payer point of view, you buy the portfolio. And actually a lot of patients are still only at 0.5. So it's a flat price across, but the blended volume, so to say, per patient is let's see how it all plays out but will be perhaps less than 1 milligram depending on the time horizon.

So you have that, and then you have a different price point in obesity. So that's one key point to consider.

And then the other key point is, of course, that having formularies in 2 different disease categories, so to say, then, of course, the formularies in terms of managing the formularies and the opt-ins or whatever step at it or whatever to get access to the medicines are different and hence, caters for differentiation from a payer point of view also in terms of how they manage their categories in terms of could even be co-insurance designs could be different between those categories.

And we spoke about the opt-in also from -- on Richard's point of view. So the categories are being managed different by the payers also vis-a-vis their customers.

So Camilla, on GLP-1 penetration?

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

Yes. So GLP-1 penetration, very depending on launches of new products and the efficacy that we see. So we now are in Europe and in the U.S. on a volume base sort of 8% to 12% of the market, but we do see that it is significantly picking up.

Of course, a lot of this is related to the continued benefits that we see, the cardiovascular risk protection, weight loss and HbA1c loss. And just to give you an example from China, where we've seen now reimbursement of Ozempic. Then we have seen the market size of GLP-1 out of the total growth of 1% to now being closer to 7% or 8%, and that in a very few -- a very short time frame.

So basically, you should -- of course, if you look at the volume growth, you see that this segment is growing at approximately 30% in volume, roughly across most regions, Europe and U.S. And then you would see other segments of the market growing a lot less. So I think if you apply that dynamics, assuming that whenever there are new launches into the segment, then of course, it keeps fueling the market growth rather than cannibalizing itself.

Then I guess you can try to understand how to do the math of what this could be. It's clear that the benefits of GLP-1 are very, very strong and when we just compare HbA1c and weight and also cardiovascular risk profile versus some of the other compounds in the market.

So I think that's the best way to look at it to try to understand what could this become. But there is also in guidelines now an increased focus on treating with GLP-1s right after metformin. So that's another support to this class.

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

Great. Thanks, Camilla. We'll move to Pete -- Pete Verdult.

Peter Verdult
Citigroup Inc., Research Division

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Pete Verdult, Citi. Two questions. I'm going to -- sorry to harp on about this and expand on the questions from Rich and Wimal. In a couple of years, you're going to have a quite formidable competitor turning up where that whole GLP-1 pricing offset between obesity and diabetes is going to be gone. And that's obviously -- how should you or will be thinking about how you navigate that? Because all the responses you've made so far are all fair, but that dynamic is going to change quite considerably in 2 years. So I'd like you to discuss that.

And then secondly, I asked this morning at the breakfast meeting, I mean, most of the industry have talked about responsible price increases, no more than inflation, but obviously now inflation is 7%, 8%. Is Novo going to eat it? Or do you think you've got the ability to put out your list price increases to protect yourself from inflation?

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

Yes. So Camilla, if you cover the first one vis-a-vis -- I think we explained clearly where we are today. So what could be the scenario vis-a-vis Lilly and what approach could they be pursuing? And how would we think about the market dynamics on GLP-1 pricing. And then I'll cover inflation and how we try to mitigate that.

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

Yes. So what we see now increasingly is that obesity is being reimbursed for Saxenda outside of the U.S. in an increasing number of markets. And of course, when the investment happens, then prices are, of course, not the same as before reimbursement in out of pocket.

And of course, in the same to Karsten's point from before about the different channels in the U.S. by the time that you would expand into other channels, it could be Medicare, for example, over time, if we get the [indiscernible] resolutions in place, then, of course, it's likely that prices will converge towards each other.

So I think that's the dynamic that we are working towards to make sure that more and more patients can get access to obesity treatment. You know the numbers that just very few percentages are being treated despite a huge unmet need. So I think that's what we are pursuing.

And I think that's what I should comment on and actually not what Lilly is more likely to do. And you should check with them on that. But I do think that over time, prices are likely to converge, but of course, this is offset by the volumes. And there is a very, very big demand, as we have noticed, of course, also in the recent year.

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

Yes. Thanks, Camilla. And of course, let's see what Lilly does. That's completely on their prerogative. And I think they've been out counting different scenarios also in terms of how they could go to market. So we'll have to wait and see.

On inflation and how to mitigate inflation, so the classic premise of inflation, we all see it and the numbers whether it's 7% or 8% in the U.S., et cetera. So running a company, then the starting point for mitigating inflation is one, pass on the increased cost to our customers that you see that across many, many industries. Secondly, how do we fend off inflationary pressures from your suppliers?

And if I take the last one first then in terms of suppliers then, of course, we are -- we get the pressures from our suppliers. We have a rather mature procurement setup. So in terms of being clear about the contractual settings we have in our contracts with our suppliers, some of these contracts just doesn't open for suppliers to increase prices, some that lag effect and some they can break the contracts or whatever.

So I think we have a very mature setup there to minimize the immediate inflationary pressures. But clearly, this is something that will happen.

On the cost side, we mitigate that through efficiencies and resource allocation. And then we're in the fortunate setting that as a rapidly growing business, we also have some margin leverage to work with.

So we actually do have a number of levers to alleviate fully or partially the inflationary pressures we face as a company. And then reminding you just -- and I don't think I have to remind you, but mathematically, of course, we are in a better

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setting than low-margin industry. So being a high-margin industry then, of course, just in relative terms, it hits us at 40-plus percent operating margin less than other players or other industries.

On the sales side, I think it's fair to say that in a number of markets, it's hard to kind of reopen contracts, especially in some like European markets that we have negotiated a price point of our products. And hence, it will be a very cumbersome, lengthy process, if at all possible, to open up.

In some emerging market countries or IO markets, especially in hyperinflationary markets, there are already existing mechanisms for basically changing our prices. That could be in markets like Argentina and Turkey.

And so if you -- actually, if you go to the appendix of our company announcement, you can see how we adjust for hyperinflation in terms of our reporting in order not to overstate our constant exchange rate growth. So we are actually backing out some of the hyperinflationary price increases in these markets. So there, we do have mechanisms in place.

In the U.S. and we are negotiating contracts for next year as we speak, not concluded. That's one out of many elements going into these negotiations between formulary positioning, competitive pressures, et cetera. And of course, inflation is one of the [documents] there as are many other aspects. So I think that's as clear as I can be on that one.

Unknown Analyst

The volumes are very strong. So given the inflationary environment, does that slow down any pricing pressure that you might see? Can you start as an argument? You obviously got the volumes to your advantage.

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

Yes. Yes. So you would say the best way to fend off price decreases if you're in a U.S. setting is that you are differentiated enough, and you have the highest possible market share because then, of course, the harder it gets for payers and PBMs to throw off formulary.

So clearly, when we -- on one hand side, when we show strong demand for our products like the Ozempic trajectory on volume and share then, of course, the payers would be very cautious to remove from formulary because they will have a lot of their customers that will be unhappy if they cannot get the product that they wish for. So that's on one hand side.

Of course, on the other hand side, when you're effectively a procurement organization and you see value bucket increasing rapidly then, of course, you have to consider how to deal with that cost increase. So that's kind of the balancing factors.

And that's, of course, their PBM job. And as we've said all along, our strategy is to grow the volumes and to maintain choice for patients to ensure basically co-preferred formulary in the [indiscernible] market in the U.S.

Unknown Analyst

I should know that. I'm sure you said for the upgrade of the sales guidance for growth, is that all -- how much of that is volume and before volume, right, versus price?

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

I'd say for all material purposes, the upgrade in guidance is driven by increased Ozempic volumes. Mark?

Mark Douglas Purcell
Morgan Stanley, Research Division

Two R&D questions. Very busy today. First one, I think most KOLs believe that the SELECT trial is going to be successful and described as being a sort of typical file for the future of obesity medicines. So it's really important you get this right.

So we're also focused on Q3 and this potential interim. We've had CVOT studies reading out early before, and it sort of damages that potential when it comes to discussing with payers and governments and guideline policymakers and things like that.

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So I'm thinking number needed to treat as opposed to percentages there, particularly when it comes to CV [DAF] and all course mortality. So I guess if we say roughly 26 months into the trial, 4.5% event rate at that point, 17% benefit. That's not a massive number they needed to treat if you stop early.

Can you help us understand what the stopping criteria are that ensures that you do not lose the power of this potential study? I mean, a lot of KOLs, I think you should do a primary prevention study and just wait and see what happens. But it's really important you get this one right. That's the first question.

And the second one is really quite simple. For icodec, in the real world, if we see severe hypos, which I think most people feel there will be some, how do you treat a severe hypo with icodec relative to, obviously, a normal insulin given that you're going to have, as you said, I mean, incident levels will be pretty stable to the tune of 14% over a week. So presumably, you have to stay in hospital, you have to stay under some medical care for longer. So I'm just interested in that point, too.

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

Thanks, Mark. That's true for you, Martin, SELECT staffing rules and the pros and cons of doing an interim vis-a-vis stakeholders. And secondly, on icodec, how do we treat severe hypos in the real-world setting?

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

Yes. So actually, I like that. We call it a simple question. The answer is going to be a little bit nerdy and a little bit complex. I think it's a super good question. It's obviously something that we've been looking at.

And in all practical purposes, when you do an RCT for 26 or 52 weeks or however long you do it, that's real world because you send the patient home. And they are basically stopped with that potential problem.

Issues, we haven't seen it. And we have exposed at this point in time 5,000 patients in the ONWARDS program. We've not seen this issue. We look obviously at prolonged hypoglycemia. We haven't seen it.

We also look at what some called repeat hypoglycemia. So there would be several events of hypoglycemia within a day where the patient may be able to eat basically their way out of hypoglycemia. But then when the food is gone, they go back, we haven't seen it.

There's -- I mean, the flat and stable profile in and of itself protects a little bit from that. But the other thing is, and that's the nerdy part, and I apologize to my colleagues for that one.

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

Not to the audience.

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

Not to the rest of you. You have to hear it. You have to learn it. Camilla already knows it. So she can also say it. But the way that icodecs protection works is that it binds to albumin. And that basically means that, that level of albumin, all others being equal, the albumin and the insulin receptor complete all icodec.

And as you also know, if the insulin receptor is being occupied by insulin, it's being internalized into the cell. So therefore, it cannot bind anymore. That basically means that if you have not sufficient insulin receptors, icodec will simply be stuck on the albumin. And that actually in and of itself create, at least in theory, a very nice buffer to prevent hypoglycemia.

The other thing, I actually -- and I probably shouldn't, but I've taken a little bit comfort is that in the ONWARDS 2 program, since it was a switch study, we had to load the patients with icodec to secure that they got up to a sufficient plasma concentration. And that basically meant that they had to start the first treatment, the first week with 150% of expected insulin dose rather than 100%. And we had 8 patients who inadvertently stayed on 150% for longer than 1 week.

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And that basically means that they were, in fact, overdosed, and they did not experience to be hypoglycemic. I think even though that was obviously a mistake, and we need to really optimize in the marketplace and our communication around how to do that switch. It actually speaks to the safety and the robustness of the icodec molecule that, I mean, even in that space, you don't introduce hypoglycemia.

So I mean, I should never say never. But what we've seen so far, it looks really, really good. And it looks really safe. That was a long question to a simple answer.

On the other one, I'm not really prepared to go into numbers and detail. But you all know that we emphasized the main part of the SELECT trial for 17% differential on efficacy on -- based on the primary endpoint. If we do an interim analysis, our instructions to the [indiscernible], the independent body that looks at the data is that whatever sort of happens while closing down the trial has to be a sufficient differential to secure that the approximately 100% -- sorry, 100 events that will be accrued while we closed down the trial cannot change the dynamics and the conclusion of the trial.

And that basically also mean that if you do an interim, the differential that will be, will be in excess of 17%. And not in a triple amount. It will be sort of in excess of 17%. I don't want to give the number.

But that also means that, that would be highly statistically significant. It will obviously be clinically relevant. And I think, Camilla, if we just see on the good side of 17%, she will be happy from a commercial perspective.

And that also means that for some of the secondary endpoints that are also of clinical relevance and probably also both regulatory and payer interest, they would with some likelihood also be statistically significant or at the very least be going in the right direction.

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

Thank you, Martin. Let me move down the line to Keyur.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Quite lots of questions. I'll keep it to two and then come back possibly. But Camilla, given what we know of ONWARDS 2, and Martin noted your point is not yet in the bag. You have still got 5 studies to come. But what would be a good or a bad outcome relative to market shares of the basal insulin market for icodec in 3, 4, 5 years' time?

Secondly, you kind of gave us a long list of reasons why Ozempic has been really strong. And I think all of those make perfectly logical sense. But the one you did not mention was potential rules of Ozempic while that is Wegovy supply constrained.

So I'm wondering if that -- are you saying that's not what you are believing? And consequently, when Wegovy does come back to the market in the second half of the year, you're not expecting to see any sequential decline in Ozempic U.S. volume over the first quarter? Or should we be assuming that you will have some flow-through into Wegovy and therefore, there's a sequential decline on Ozempic?

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

Thanks, Keyur, for those two questions. I'm actually looking forward to hearing the answers on both. So what icodec market share will make us satisfied, Camilla, in the basal segment. And if you can predict Ozempic in direct levels for the next couple of years, I would also be really happy on that one.

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

Thanks a lot, Keyur. Just turned this into my budget meeting. I really appreciate your question. So I have a guy here next to me taking notes and follow-up forever on the answers.

Market share on icodec. We talked about earlier, we have a 37% share in value and 33% in volume in the basal segment. And of course, this is significantly lower than what we've seen in other segments. The premix segment, for example, or even the fast-acting segment.

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So having a superior offering on HbA1c, that gives you no more hypos but equivalent on hypos is a very, very low way. And you really have to wait for a long time to see any hypos based on what Martin explained and also a quality of life that is significantly better.

This is, of course, very, very important. And taking all of that together has a potential to, of course, transform the way we look at basal insulin. So I would hope that we can make a significant inroad into the basal segment.

And probably we should just see the rest of the ONWARDS trials before we get closer to what could a good aspiration level be. And -- but I do think that we need to be able to make something really good out of this for the sake of the many people that are truly concerned about hypos but are also struggling with trying to understand how they should remember their doses on an everyday basis.

We know more than forget to take their daily insulin injections. So I also personally look forward to the more real life -- the results of the trial where we leave patients more alone for a year's time to see what that looks like. Because, of course, compliance with a once weekly is likely to be higher, everything else equal.

So I know I don't give you the market share answer, but at least what potential.

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Majority market share...

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

Sorry?

Keyur Parekh
Goldman Sachs Group, Inc., Research Division

Majority market share.

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

Majority market share, we can always discuss or we discuss the absolute or relative, but that we can come back to. So I think that's enough for now until we've seen the rest of the ONWARDS trials. I appreciate the support from the room.

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

I'm taking notes.

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

Then on Ozempic, actually, I did -- we did discuss. We have seen more prescribers from lower-tier segments prescribing, and we also understand the relevance of GLP-1, the very strong Ozempic performance in terms of approximately 80% getting in good control we know from our clinical trials.

So a really, really great number of benefits. And that, of course, drives our continuous performance with Ozempic.

I also spoke a little bit to the halo effect. There's probably an increased understanding of what this molecule can do, semaglutide. And of course, we cannot rule out that some people have -- are living with diabetes thinking if I can -- that they heard about what can this product do in terms of weight loss and then they are interested in that.

We don't have -- I don't have any evidence to suggest that it's all off-label use or that it is. But I think it's very, very important for us to promote Ozempic for diabetes care and Wegovy for obesity care.

So I think I would leave it with that part. And then would we then later on see a decline in Ozempic? That's, of course, part of what one has to consider would there be -- whenever we are fully supported on Wegovy, would there be some people

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who have even living with diabetes that have easier access to Wegovy this way than Ozempic? That's still to be seen. But these scenarios, of course, we try to cater for in the guidance that we have given you.

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

Yes. And just adding to this one. Forecasting NBRx is pretty much really, really complicated. And it's even more complicated to forecast the conversion from NBRx to TRx just to make it even worse.

But what we saw last year was kind of interesting. When you looked at NBRx -- and then mid last year, there was also -- you remember the step-up in NBRx linked to potential halo effects, et cetera. But we saw a step-up, and then we saw the curve continuing from the step-up.

So I'm not saying we'll see the same now, but it's -- you don't find these very simple direct correlations at least based on historical data.

I think it's Sachin, and then we move the other way.

Sachin Jain
BofA Securities, Research Division

I just like a follow-up on icodec hypos, Mark's question. So if I remember the time of Tresiba, there was a lot of debate around various hypo definitions. My question is fairly straightforward. In an answer to the question, you talked about no severe, no repeat, no prolonged, but you've clearly had an excess of clinically relevant that was less than 3 [minimal]. Just to understand why that is so you've got 3 metrics that you're [indiscernible] on and then one you're not, so what's the driver there?

And the second question is if you could spend a little bit more time on ONWARDS 5 as to what conversations you've had with payers? And now that you know a lot more about the molecule in the first study, what are your expectations in a realized setting or what level of A1c and can you get hypo superiority? [indiscernible] and one very good one on [Sema Cagri]. Having seen Tirzepatide, would you consider a [Sema Cagri] Tirzepatide head-to-head opportunities?

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

Thanks, Sachin. Three questions. So you beat Wimal. So one, Martin, I think you call the hypo nerdiness kind of a second effect question. Then ONWARDS 5, how -- why did we design that based on the payer dialogue and then [Sema Cagri] versus Tirzepatide?

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

Yes. So we'll start from the beginning. So on the hypoglycemia, again, I think it's important to call out when we see a numerical difference at a very low level, I don't want to belittle the difference, but it's sort of comparing 1 to 2 and then say you have a doubling in risk.

This is also why there is no statistically significant difference. It's basically a function of really, really few events. And another way of looking at this is you may have seen the number of -- or the proportion of patients reaching an A1c below 7. If you do that proportion, I think it's around 40-something versus 20-something.

And the interesting thing is if you then make analysis reaching A1c below 7 without hypoglycemia, it's the same numbers more or less, again speaking to the very low rate of hypoglycemia. So absolutely a difference, but at a level where it's difficult to say, is this clinically relevant? I don't think it is.

You'll also see when we don't compare to Tresiba, I mean, next study reading out will be ONWARDS 1 versus [indiscernible]. And we know that there is a different hypo risk associated with that comparison. I think you'll see some maybe slightly different results. And if we can repeat what we do so far, I think both not only we, but also our future customers will say this is the same molecule.

ONWARDS 5, we basically -- I think at the very least, I probably also can share the frustration that we -- from a regulatory perspective, we were forced to increase the target. And that means going for A1c parity.

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From a payer perspective, they don't really care. We saw that with Tresiba. We came with what we think was very nice hypoglycemia data and payers said, "Well, we can't pay for that. We would like to see A1c difference."

We wanted to change that outlook for icodec. So we had a dialogue with some U.S. payers, some European authorities, the Chinese authorities. We asked them, "What are you looking for?" And very clearly, you had to demonstrate A1c superiority.

We know now also based on ONWARDS 2 that is the potential also on ONWARDS 5. And they very clearly stated we want to see real-world data. The problem in doing treat-to-target is that in our [assets], we can get more than 50% of the patients to a certain target. And in real life, that doesn't hold true. And therefore, they wanted to see what happens with real life.

We've never been able to do that. But with the advent of digital tool monitoring, collecting data on remote advising on insulin titration through an app and an algorithm, that basically allowed us to virtually get the patient the app on an iPhone, the insulin and monitoring device for glycemic control and then saying goodbye, we will see you in a year. Obviously, we do have some visits, but I think it's 4 visits in a year.

Sachin Jain
BofA Securities, Research Division

Okay. 4. [indiscernible].

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

They haven't. Historically, we have been looking somewhere between 0.2 and 0.4 depending on who you're talking to. I think, again, in a 26-week study versus Tresiba to see statistically significant points or 2, that's a very nice place to start because it could give us the aspiration of going maybe beyond that in ONWARDS 1 and 5.

And the final question was Cagrisema head-to-head with Tirzepatide. Sitting next to Camilla, I feel very confident that if the data that we see so far with Cagrisema holds true all the way through Phase III, I don't think I would mind doing a head-to-head because as you've also heard me say before, I do think that Cagrisema will hold its own on efficacy.

We have very high aspirations for that. And on the safety and tolerability side, so far, we've seen something that is not additive but actually just the sum of what is semaglutide. And that means that Cagrisema holds the potential for being competitive on both efficacy and safety. Obviously, I would like to see the data before I commit. But if it holds true, then we are all in.

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

Great. Thank you, Martin. Thank you, Sachin. We've time for two more questions. So I'll say it's two persons and one start each. And Jo, you are the first one.

Jo Walton
Crédit Suisse AG, Research Division

Okay. Can I ask a more thought experiment? If sales growth continues closer to the level that you've seen in 1Q then you expect it to go back to because all sorts of fantastic things happen and all [indiscernible] the rest of it. At what level of sales growth do you think we should actually see margin leverage come through? Because at the moment, you have the luxury of stronger sales, and you've got lots of ideas. And you can easily reinvest, and everybody still is very happy with that.

There must be some point at which is diminishing return, you haven't got all the ideas that you need to spend that much money in R&D. And Camilla, all of the [indiscernible].

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

Might just have to interject here. Of course, we will have lots of ideas and R&D on how to spend money.

Jo Walton

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Crédit Suisse AG, Research Division

Well, the huge amount of money that you get if you continue to have sort of 15% top line growth for any extended period of time. So can you just help us think about that level and where we should think about leverage coming through versus that reinvestment?

And I am going to sneak in just a very quick second one. Just wondering whether you've highlighted in the past that stay time is significantly less on obesity than it is on diabetes. Have you seen any evidence of people not staying on Ozempic, which would speak to perhaps some of them being the [B2C]? Or are we seeing much longer straight lines in obesity?

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

Thanks, Jo. Two relevant questions. As you know also from our strategic aspirations, then we have clearly communicated even though that it's not necessarily translating into all spreadsheets in London and other good cities that we are -- we're working with a stable margin outlook in the medium term for the company.

So our clear base plan is also at higher growth rates is really to be investing mainly in R&D. Right now, you should also bear in mind that as we spoke about the inflationary pressures, we also have to have some work to do there. We believe we can do it, but that's also a reality.

So clearly, I don't want to invest in R&D unless I believe it has an attractive return, but that will be the key premise. And I think we've shown our financial discipline over and over again. So you shouldn't be modeling with upside on operating margin than you should be working on also investing in the long term. And stay time, we don't have any data, Camilla?

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

Yes. That's right. We don't have any evidence of any changes in the data.

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

Right. It's too early. So we have a year down the road. Pete, last set of questions?

Peter James Welford
Jefferies LLC, Research Division

Yes. Probably two very quick ones. So just coming back to the Wegovy, Ozempic debate for a minute just in terms of high dose. Can you just remind us, is it generally true that the higher dose GLP-1 to 2 mg is that more commonly needed for larger obese type 2 diabetic figures? Is there any correlation between dose of GLP-1 needed versus -- and equally, what proportion of obesity Wegovy patients on your initial data did have type 2 diabetes? If you have to set the size of that, if you can give us that.

And then can I just ask a quick one just on the Wegovy production? You say you want to make sure you've got enough stocks before you open the gate, if you like, given what's happened. Can you give us some sort of idea what sort of TRx or what the patient -- we have no idea of the range of production from capital.

But what are you assuming in terms of that before you do? Can you give us any idea of what you're assuming in terms of the demand before you do then say this is enough inventory we're opening up to at least give us some sort of idea of the time frame we're thinking about?

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

Yes. So if I just take the inventory build first. And the way we do it in terms of sizing inventories, Pete, is we work with a number of scenarios because it is clearly super volatile what we're looking into based on our historic experiences.

So we based the sizing of inventories as a combination of different scenarios, and then we furthermore combine it with our launch tactics, which you should expect to be probably more gradual than a big bang out of the gate. So it's impossible to give you 1 point estimate without for sure be completely wrong.

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But you have the historic trends, both on TRx [indiscernible] uptake as well as NBRx. So it's also how many new starts should we expect and a little bit longer. But the big question is, of course, to what extent do physicians have patient inventory, so to say, patients waiting for the product.

So that's a big uncertainty, and that's what we are careful how to manage. So in reality, it's not only a TRx matter, it's also a patient-stocking type assessment that we're making. And we just want to make sure that it turns into a more controlled approach this time around.

Then, Martin, on same 2.4 patient profiles and in terms of need of the doses?

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

So the dose part, I think you've seen a differential in terms of the -- those requirements for glycemic control versus weight. So you read the plateau for glycemic control. For example, on semaglutide, when you reach those 2.0 milligram approximately that we just got approved, you can't get much out on glycemic control moving beyond 2.0 milligram.

On body weight loss, we haven't seen any plateau yet. And that also means that, I mean, first of all, you see a difference between 1.0 and 1.2 in terms of body weight loss, but you also see moving beyond 2.0, for example, to 2.4 milligram a further body weight loss. And this is a little bit of an opposition to maybe what also we saw last week, where there was actually a plateau looking at the Tirzepatide data that appears to have sort of reached something between the 10 and 15-milligram in terms of body weight [growing].

We haven't seen that for semaglutide yet. So we actually haven't established a full [indiscernible] for the weight loss part of semaglutide.

On the clinical side, all patients that we've investigated with semaglutide 2.4 milligram have been not diabetics. I think in the real world, I don't know if we have data yet on patients on Wegovy being how many also had diabetes. I haven't seen the data, but so far, I mean, the vast majority of what we have on Wegovy at 2.4 milligrams [indiscernible] not diabetics.

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

Great. Thank you, Martin, and thanks for joining this Novo Nordisk Q1 launch meeting. And thanks to Richard and JPMorgan for hosting it.

I'd just like by closing out with a comment that we'll be at ADA, and we'll be hosting a sell-side event at ADA in the U.S. in early June. So I hope to see you all. We'll probably do both some type of a sell-side, nice sell-side dinner. And then we'll have an investor event with Martin and a couple of his colleagues from R&D. So we hope to see you there, hopefully, with more data also out of R&D, but...

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

Who knows?

Karsten Munk Knudsen
Executive VP, CFO & Member of the Management Board
So thank you, and have a great rest of the day.

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