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3Q23 Earnings Obesity Quotes – Lilly versus Novo

Earnings Review

With Lilly and Novo (covered by Jain/ Parry) 3Q23 earnings behind us, we have compiled what we'd highlight as key thematic quotes from both earnings calls on potentially the most important topic in the Biopharma space, obesity. Areas that particularly stood out, in our view, include **1)** access/ reimbursement, **2)** manufacturing constraints, **3)** on the potential impact of SELECT, and **4)** on persistency rates.

On access/ reimbursement

Lilly on access: *"We're trying to be disciplined, and we're trying to make sure that we bring on access as quickly as is prudent. And so just like we did with Mounjaro"*

Novo on access: *"Overall, we're very pleased with the broad market access that we have for Wegovy. Most major PBMs and health plans are covering it that derives around 50 million people with obesity now covered. And importantly, we're seeing about 80% of the patients that are paying less than $25 for Wegovy."*

On manufacturing constraints

Lilly on manufacturing: *"Of course, we are aggressively planning that and not banking on orforglipron to rescue us from this. We think that there is a need to take up parenteral incretin supply pretty dramatically from the current levels, and we plan to do that."*

Novo on manufacturing: *"And then you could say, when are you out of supply constraints? And then I'll say, given the global magnitude of the opportunity, without knowing competitor supply capacities, then I do believe it will be a number of years, several years, before this market is unconstrained on a global basis."*

On the impact of SELECT

Lilly on SELECT: *"Probably the key question I'm looking at is like how much of the effect was driven by drug effect versus weight losses, probably the key question we're looking at."*

Novo on SELECT: *"On the commercial perspective, we already see now just with the top line results out that there is keen interest from payers and policy makers to understand what does this mean, and to enter into discussions on reimbursement of Wegovy."*

On persistency rates

Lilly on persistency: *"So, what we've seen in the SURMOUNT clinical trials with tirzepatide is that some consumers will feel their appetite increase and experience weight regain when they stop tirzepatide. And so, this should help reinforce treatment adherence."*

Novo on persistency: *"So, the real exact number of stay time, we will only know in a while from now, but we will continue to describe that as good as we can from our real-world evidence data to you. But no doubt that we expect a much longer stay time on Wegovy than what we've seen on Saxenda in the past."*

See pages 2-7 of this note for additional key thematic quotes from the 3Q23 calls

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Abbreviation:
PBM: Pharmacy benefit managers

On access/ reimbursement

Lilly on access: *"We will have a whole suite of real-world evidence and pragmatic trials so that we can answer this question clearly for payers and other stakeholders. In our conversations with payers, while they're concerned about the short-term budget impact, they do understand that losing weight will have benefits. It's not that hard of a sale because they do understand the benefits are intuitive.*

If you look at the total number of like obesity rate of complications, there's over 200. And you look at some of these are just really devasting and very costly, like type 2 diabetes, coronary heart disease, hypertension, dyslipidemia. And then when you look at the cost of these on the U.S. alone, there's $370 billion in direct medical costs associated with obesity comorbidities and over $1 trillion in indirect annual cost. When payers see that people living with obesity and overweight drive 2.7x greater health care costs than normal individuals, that data does get their attention.

And so I think over time, we'll continue to provide health economic data. But also, I think the voice of those living with obesity will be very important in this. This is a disease that really materially impacts someone's both health and mental functioning, and is really important for people who live with obesity. Their goal is to lose weight and maintain that so they can help their long-term health benefits. And they're going to have a lot of voice in this. And I think both in commercial insurance as well as in states and in the federal government. And so I do -- I am confident over time that we will see increase in access. I think the most recent report shows that there's 50 million people in the U.S. that has access to obesity medication. So it will take time, but I think I do think more and more payers are appreciating the value that anti-obesity medications, especially when we get approval for tirzepatide will offer them."

"We're trying to be disciplined, and we're trying to make sure that we bring on access as quickly as is prudent. And so just like we did with Mounjaro, we'll take -- and make sure that we sometimes access has to materialize at an organic pace where it makes sense, and we'll make sure and use our judgment. So just like with Mounjaro, while we'd love to get out of the gate quickly, most importantly is a setup for long-term success. So, you'll see kind of a natural ramp up that you would with any new product. And I think it's important, as you look in the first quarter of our launch last January, when you saw we go resupply, they were resupplying into a market where they already had capacity. So, I think when you look at our access and you look at our volume as we head into next year, you'll see a ramp-up in volume as you see a ramp-up in our access."

"I think maybe at a macro level, I would say that our gross to net for Mounjaro in Q3, kind of normalized. Before then, we had a number of saving card changes that made our gross in that rate dynamic. Our last and co-pay card change occurred late in Q2, so at the end of June. And so, we -- Q3 was kind of a pure quarter where we didn't have any other co-pay card changes. And I would say that our Mounjaro rate normalized at that point.

Going forward, I think what you'll see is what you see normally out of -- for a product at this point in the life cycle, that as we pursue gaining access, there'll probably be some pricing pressure related to that. But we don't have any other co-pay card changes planned in the near future."

Novo on access: *"Overall, we're very pleased with the broad market access that we have for Wegovy. Most major PBMs and health plans are covering it that derives around 50 million people with obesity now 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 are seeing overall more opt-ins, than opt-out. So directionally we're heading in the right direction. And our focus, what could be continue-- on continuing on securing employer coverage as well as stronger access for overall."

"The question was whether we need statistical significance. I would just say now we await their 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. We have-- 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 a close to 15 countries around the world, and of course, here we are talking a step up in treatment."

"We don't think the Treat and Reduce Obesity Act in the U.S. is dead. It does require a bi-partisan change in regulation for it to be enabled. And of course, over time, it will be important to have also that group of patients enrolled on obesity treatment, which is today not allowed in that segment.

Having said that, I want to also reiterate that today we have access to 15 million Americans that have access to the Wegovy in the commercial segment, and we also have and number of states that provide access to the Wegovy on via the Medicaid, so the most poor people, I think around 14 states that keep access this way.

So, we do have compared to the less than 1 million people on the Wegovy today, there is significant access even in the commercial segment and in the segment for the most poor people. So, of course, the Medicare Part D is important and we continue to work towards that, but there is already a very big access that means that -- in the U.S. that means that 80% of people are paying no more than $25 a script."

On manufacturing constraints

Lilly on manufacturing rates: *"Research Triangle Park (RTP) is sort of on track to deliver on its goal as we exit the year and then that kind of in-market volume following that Concorde, which is a few hours away and kind of a replica site, also well on track for coming online in '24. So that's good news in the parenteral presentation, which is the what we call our auto injector that you know from Trulicity and the current presentation for Mounjaro in the U.S.*

We've announced previously that we're introducing now a single-use vial presentation ex U.S. so that we are now basically sitting on approvals and can have patients have access to the medication. That will follow then by a multiuse injector that uses different property, plant and equipment than what we're talking about here. So, a couple of things to point out. You're noting kind of new greenfield site expansions we've rightfully made a big deal out of. We're not done with those. I think you might hear more about that in the future. Of course, we are aggressively planning that and not banking on orforglipron to rescue us from this. We think that there is a need to take up parenteral incretin supply pretty dramatically from the current levels, and we plan to do that.

But that will be in a combination of the current syringe-based auto-injector, the vial capacity we've already talked about; the multiuse injector, which will come online sometime next year, and is a highly efficient play for us because it uses current systems, different ones from the auto-injector. And then there's third-party agreements that have been ongoing in the background. And to point out here, we are not going to only have one, we have a diverse portfolio of third parties, recognizing that the probability of full supply from any one is probably less than one, but buying up as much capacity as available in all those systems.

So, we've got, I think, all hands-on deck, a phrase that as used earlier. I mean this is really all hands-on deck and it's a problem we work every day. So, we're not at all happy with the capacity we've announced already. You'll see more. Some we don't announce. That will just layer in to the volume we ship. And of course, long term, new presentations like a solid oral opens up even more possibilities. But we need to do everything we can now given the huge potential for global obesity treatment for our medicines to play a key role in that and then ultimately impact hundreds of millions of people. So, a lot of work to do here yet ahead."

Novo on manufacturing: *"Specifically on Wegovy and any handbrakes there, then what I would say as to 2024 is that in 2024 we will be delivering significant step up in volumes to the US 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 US is to look at the year-to-date numbers. So most contracts are contracted on an annual basis and the tricky part is a lag effect between when a script is written and then we received the repay claims from the payers. And there's just a lag effect of several months and that's why by in reality Q3 is the first point, where we see how the channel payer tool 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."

"And then on the short-term dynamics, clearly supply. And do bear in mind, when supply is tight, then companies or I'll talk from a novel perspective, then of course we adjust our commercial tactics also. And adjustment to commercial tactics could be items like how much are we sampling in precision practices and how much are we doing in terms of DTC (direct to consumer) activity. And of course, if that pressure is lower than at other periods, that of course has some impact on new starts, that's the logic of promotional tactics.

And then finally, the promotional tactics also spills into social media and we see social media also tapering off over the last few months. And then I would say finally, in a fast growing category, then of course payers are looking at really ensuring that it's the right patients that get reimbursed and stepping stepping up their, what they call, utilization management criteria, really to ensure that they have proper documentation for the patients getting insurance coverage for, say, Ozempic.

And it's not beyond the label, but it is just, stricter requirements in terms of blood glucose based on the right lab test, et cetera, that needs to be documented in the right way, according to new standards in order to get insurance reimbursement. So those are the factors, and I'll say all, we are very-very confident that the runway for GLP-1 and obesity is very attractive for many years to come."

"We had a favorable rebate adjustment to Wegovy in the third quarter, and it's important to note that for launch products or young products, you don't have a lot of experience in terms of exactly what channels and what payers, and hence what rebate rates are being paid on those products. So, there's no magic in the fact that there are rebate adjustments for products like Wegovy.

And -- so that's the starting point. And it turned out different compared to our expectations. Not because of some specific actions in the markets, but just due to the fact that we had provided for more in rebates than what it turned out to be when we got the actual rebate claims in from the PBMs (Pharmacy benefit managers).

In terms of channel mix, et cetera, I'd say one driver was non-rebated business, which is a composite of different factors. So, it's not only pharmacy cash, and the non-rebated was around 10% as we were looking at it."

"And then you could say, when are you out of supply constraints? And then I'll say, given the global magnitude of the opportunity, without knowing competitor supply capacities, then I do believe it will be a number of years, several years, before this market is unconstrained on a global basis."

On the impact of SELECT

Lilly on SELECT: *"Look, I'm excited to see that data, of course, as everyone else is, but the top line looked good. For me, I think we're sort of creating now data points on the line that connect the level of weight loss with the degree of cardiovascular benefit. I think this point fits on that line reasonably well. That in line which shows greater health benefits, including*

better -- fewer MACE (Major adverse cardiovascular events) outcomes, with greater degrees of weight loss, bodes very well for Mounjaro data given the very high degrees of weight loss that we saw in our trials. I'll leave it at that."

"Probably the key question I'm looking at is like how much of the effect was driven by drug effect versus weight losses, probably the key question we're looking at."

Novo on SELECT: *"And that is the 20% risk reduction on the primary endpoint for MACE, which is obviously myocardial infarction, stroke, and cardiovascular death. We see attribution from all there, 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 no outliers identified."*

"We do believe that there is an opportunity, a potential opportunity to use the medical exception process through the CV component, but let's wait to see."

"On SELECT, the study was designed to, have the power, specifically for the primary endpoint. So, assuming statistically significant of-- 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, what we can present on November 11th in Philadelphia."

"We've done the regulatory submission to the U.S. FDA and to the European authorities a couple of weeks ago without going into details. And a couple of days ago, we received a message from the FDA that they have granted priority review for SELECT.

I have gotten a question or two on whether that was based on us using a voucher over the last couple of days. And the answer is no, there was no use of voucher. This is basically based on the FDA criteria for what constitutes a priority review."

"The event rate in obesity for cardiovascular events is low, so it requires bigger trials and it requires potentially longer trials, or it requires that you define events, or composite of events that may not be acceptable from a regulatory perspective. Typically, from a regulatory perspective, you have to look at three-point MACE.

And that basically means that, depending on your purpose, if you have a clear regulatory purpose, you also have to either expect a very-very big differential or you have to figure out a probably large sample size. We don't expect to pursue primary prevention for Wegovy, but we would not rule it out when it comes to CagriSema or amycretin, or some of our other offerings in our pipeline."

"The only thing that we have disclosed is that all of the individual components were contributing to the primary endpoint. And again, the individual components, myocardial infarction, stroke, and cardiovascular death.

We've not said to what extent and we've not said if they are equally distributed. The only thing that we mean by that sentence is they are all on the right side of unity and they are all supporting the assessment of the primary endpoint. So, in opposition to previous outcome studies where you may have seen one of the components going in the other direction, you don't see that here."

"On the commercial perspective, we already see now just with the top line results out that there is keen interest from payers and policy makers to understand what does this mean, and to enter into discussions on reimbursement of Wegovy. So it's clear that this is a landmark trial that provides a lot of evidence and data for us also going forward, understanding much more about obesity. So there are many aspects of this data set that is relevant for payers and policy makers already at this point, before the release."

"Once we have the SELECT data out, we'll be working with the keeping leaders who write the guidelines and who own the guidelines to see if we can see an update of the diabetes guidelines, the obesity guidelines, but certainly also guidelines within the cardiovascular potentially, for example, either based on SELECT, but potentially also on FLOW of kidney

guidelines. So that's the approach that we usually take. You already now see GLP-1s (glucagon like peptide 1) being mentioned in the diabetes and some obesity guidelines. And obviously based on SELECT, we aim to expand that."

On persistency rates

Lilly on persistency rates: *"The best data we have for tirzepatide is in type 2 diabetes patients who started Mounjaro prior to our savings card changes last fall. Mounjaro persistency for those patients is tracking higher than those patients that were started on Trulicity and Ozempic over that same period of time. So, while it's too early to project the average length of therapy or how many out of 100 will still be on therapy after a couple of years. I think this early data is encouraging.*

As for obesity, time is going to tell. I think we've all looked at Wegovy data. But I don't think this is the right benchmark at this point because of Novo supply constraints. And there's been just a very dynamic market. I think as you said, this -- having persistency on a chronic treatment isn't just an issue for anti-obesity medications, it's a goal for all chronic treatments. And I think what's different about obesity is that on many chronic treatments, consumers don't feel differently, are experiencing any acute impacts from stopping treatments. So, what we've seen in the SURMOUNT clinical trials with tirzepatide is that some consumers will feel their appetite increase and experience weight regain when they stop tirzepatide. And so, this should help reinforce treatment adherence.

Seeing in our market research, how important it is for people who live with obesity to lose weight and maintain it, I do think you're going to see just a high motivation. I see people have lost weight that they do want to maintain it. And we do know our SURMOUNT program that chronic use of tirzepatide is a good component, an important component of maintaining weight loss. So, it's too early to project it, but I do think there's things that's rolling in favor of tirzepatide."

Novo on persistency rates: *"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 date and numbers, but we do have, I could say anecdotal evidence that there is a high number, a very, very high number of the people that stay on the product from the beginning of the year when the product was launched."*

"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."

"So, definitely, we've had some disruptions with Wegovy and it's too early days to give you the exact stay time. But of course, anecdotal evidence is very strong in terms of patient's appreciation of being on Wegovy. And we know from Denmark, for example, just to give you some insights, that the majority of the patients actually continues to stay on the product. Also, this was launched in the beginning of the year. At this point, the majority of the patients continue to stay on the product.

So, we also know that stay time often is impacted by the drop-off in the first few weeks. That can be for many different reasons. It can be either not picking up at the pharmacy, access not really working out, or, of course, people dropping out because of other types of issues or nausea or other things. But it's mainly within the first few weeks. And then from there, we know that people are more likely to stay on.

So, the real exact number of stay time, we will only know in a while from now, but we will continue to describe that as good as we can from our real-world evidence data to you. But

no doubt that we expect a much longer stay time on Wegovy than what we've seen on Saxenda in the past."

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