

The Wegovy wait continues



[Madeleine Armstrong](#)



Novo Nordisk delays the full US launch of its obesity drug again, as Lilly breathes down its neck.

Last year Novo Nordisk looked like it was [on the cusp of a strong launch](#) for its new obesity drug Wegovy. Nine months on and, owing to ongoing supply issues, the world is still waiting to see whether this product can really take off.

That wait looks set to continue: the group disclosed yesterday that it would not be able to fully launch Wegovy until the end of the year – having previously guided to the second half of 2022. This – along with the continuation of the [Select cardiovascular outcomes trial](#) following its interim analysis – seemed to spook investors, who sent Novo's stock down 13% yesterday.

The group's chief executive, Lars Fruergaard Jørgensen, insisted during a second-quarter media call this morning that he was not worried about these setbacks. "Short-term events are not really what determines our ability to build the obesity business," he said. "We're very encouraged about its medium to long-term prospects."

Lilly is coming

Still, Lilly is coming for Novo in obesity, and the Danish company will want to make the most of the head start over its rival's GIP/GLP-1 agonist tirzepatide – particularly as tirzepatide's weight loss data look better on a cross-trial basis ([Lilly takes on Novo in obesity, April 28, 2022](#)).

Lilly is gunning for an early tirzepatide filing in obesity; the drug was in May approved for type 2 diabetes, where it is branded Mounjaro. Novo's Mr Jørgensen seemed to welcome the prospect of competition, saying: "We're encouraged to see that, finally, after 20 years of investment, when we've been pretty much on our own, the world is now opening up to obesity treatment."

But it must be embarrassing for Novo that it has not been able to pull off a smooth launch for Wegovy in a sector in which it already has a presence. Novo had initially been supplying doses of 0.25mg, 0.5mg, 1mg, 1.7mg and 2.4mg, with the lower of these representing "starter" doses, from which patients were titrated up.

But problems began in December, [when the group's contract manufacturer had to stop producing Wegovy](#) after good manufacturing practice issues.

Since then, Novo has only been marketing the two highest doses to patients who had already started on drug. Therefore, the latest quarterly Wegovy sales of DKK1.2bn (\$164m) do not include any new patients.

The contract manufacturer got up and running again in the second quarter, and Novo is now building inventory, but Mr Jørgensen admitted that ramp-up had been “a bit below what we had planned”, which has led to the latest delay.

Sellside consensus, compiled by *Evaluate Pharma*, puts Wegovy revenues at \$977m in 2022, a target that now looks out of reach.

Select jitters

Meanwhile, investor jitters were not helped by the continuation of the Select study – which could give Wegovy an important cardiovascular benefit claim – despite Mr Jørgensen stressing that this scenario had always been Novo’s “base case”.

Select is powered to detect a 17% benefit with Wegovy versus placebo on a composite endpoint evaluating cardiovascular death, and non-fatal myocardial infarction or stroke. “One can assume that the trial would only have been stopped if there had been a substantially higher benefit than 17%, which was not the case,” the chief exec said.

Novo still expects a win when the trial reads out in mid-2023, but the fact that it was not stopped early for efficacy has clearly raised questions about the strength of the result.

Lilly touted “early signs of strong demand” for Mounjaro in diabetes today, with second-quarter sales of \$16m beating SVB’s \$10m forecast. The group also appeared to take a swipe at its rival by saying it anticipates “fully supplying” its US launch.

With such a fierce competitor, Novo cannot afford any more slip-ups.

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Evaluate HQ
[44-\(0\)20-7377-0800](#)

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