

Article Title: Eli Lilly 'aggressively planning' manufacturing expansions, CEO says, as Mounjaro soars

Publisher: Fierce Pharma

Author: Angus Liu

Date of Publication: Nov 2, 2023

Source: editors@go.fiercebiotech.com

Article Link: [https://www.fiercepharma.com/pharma/eli-lilly-aggressively-planning-manufacturing-expansions-ceo-says-mounjaro-soars?utm\\_medium=email&utm\\_source=nl&utm\\_campaign=LS-NL-FierceBiotech+Tracker&utm\\_enc\\_id=7797H8224656E1R](https://www.fiercepharma.com/pharma/eli-lilly-aggressively-planning-manufacturing-expansions-ceo-says-mounjaro-soars?utm_medium=email&utm_source=nl&utm_campaign=LS-NL-FierceBiotech+Tracker&utm_enc_id=7797H8224656E1R)

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Supply problems for Eli Lilly's diabetes med Mounjaro were no secret. But strong demand continues to push sales of the GLP-1/GIP agonist to new highs ahead of an FDA decision on weight loss.

Global revenue from Mounjaro reached \$1.4 billion in the third quarter, up 44% from the three months that ended in June, Lilly said Thursday. Wall Street analysts knew that Mounjaro has been flying off the shelf, but they still underestimated the drug's quarterly performance by 15%.

Mounjaro's sales would have been even higher, but "intermittent delays" in filling orders dragged down volume, Lilly said.

Supply of different doses of Mounjaro has become somewhat unpredictable as significant demand outstripped Lilly's output from time to time. During a call with investors Thursday, Lilly's CFO Anat Ashkenazi acknowledged that the company experienced "tight supply" of Mounjaro throughout most of the third quarter.

A regular guest on the FDA's drug shortage list, Mounjaro currently has all six dosing forms available, according to the agency's website. But so was the case back in February, until it came to light in July that Lilly was having trouble providing four solutions.

Shipments and inventory at wholesalers in the U.S. have improved, Ashkenazi said, but supply outside the U.S. remains tight "which materially impacted performance in these regions."

Lilly recently invested \$450 million in its Research Triangle Park facility in North Carolina with additional drug filling, device assembly and packaging capacity for the company's incretin products, including Mounjaro.

With that expansion coming online, Lilly is on track to achieve its goal of doubling capacity by the end of this year compared to what it had a year ago, Ashkenazi said.

"We're also continuing to focus on other parts of the supply chain, as demand is expected to remain high and production bottlenecks may shift over time," the CFO added.

Besides the North Carolina project, Lilly in April also unveiled an additional \$1.6 billion investment in new manufacturing sites in its home state Indiana.

"We're not done with those," Lilly CEO David Ricks said of the manufacturing expansions on Thursday's call, adding that Lilly is "aggressively planning" further production build-up.

"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," Ricks said.

The CEO also noted “third-party agreements that have been ongoing in the background.” Lilly has recruited “a diverse portfolio” of contractors, “buying up as much capacity is available” in all those systems, he said.

“This is really all-hands-on-deck,” Ricks said, “and it’s a problem we work every day. So we’re not at all happy with the capacity.”

Lilly's struggle with Mounjaro's supply comes as a potential FDA approval for the drug, a.k.a. tirzepatide, as a treatment for weight loss is expected to open the floodgates for significantly higher demand. Lilly has applied for the weight management indication with the FDA and the European Medicines Agency, although the regulatory timeline was unclear.

Looking across the ring at Novo Nordisk's rival GLP-1 agonist semaglutide, which is sold under the brand name Wegovy for chronic weight management. While Novo is navigating its own supply bottleneck, Wegovy sales totaled 9.65 billion Danish kroner (about \$1.4 billion) in the third quarter, up 28% over the prior quarter.

Tirzepatide showed better weight reduction results than Wegovy did in their separate clinical trials. A confident Lilly has recently launched a head-to-head trial comparing tirzepatide with Wegovy in obese or overweight patients.

Overall, Lilly's third-quarter sales rose 37% year over year to \$9.5 billion. Breast cancer drug Verzenio also contributed to the growth as the CDK4/6 inhibitor saw sales jump 62% over the same period last year, surpassing \$1 billion in the quarter.

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