Subject: CI update
Date: Thursday, November 2, 2023 at 4:24:32 PM Eastern Daylight Time
From: Robert Stoekenbroek
To: Metsera
Attachments: image001.png, image002.png, image003.png, image004.png, image005.png, image006.png, image007.png, oledata.mso, image008.png, PHP_Logo_Primary_210826_01_1200x294_small_edb56208-d78e-4f54-ba89-2644d9621fe6.jpg, Q3 2023 Lilly Presentation.pdf, Q3 2023 Novo presentation.pdf

Metsera Reports

November 2, 2023

Investor Updates

Key insights from Novo's and Lilly's quarterly calls

Summary and Implications

- Lilly and Novo both had their quarterly calls this morning.
- Lilly: Mounjaro ahead of expectations largely due to strong ASP progression; capacity increase in line with expectations, and 4Q2023 obesity approval on track.
- Novo: Wegovy ahead of expectations due to positive rebating impact; supply constraints to persist; priority review for CV outcomes granted; Phase I for **subcutaneous** amycretin for obesity initiated to gain flexibility around supply; results for **oral** amycretin expected 4Q2023.

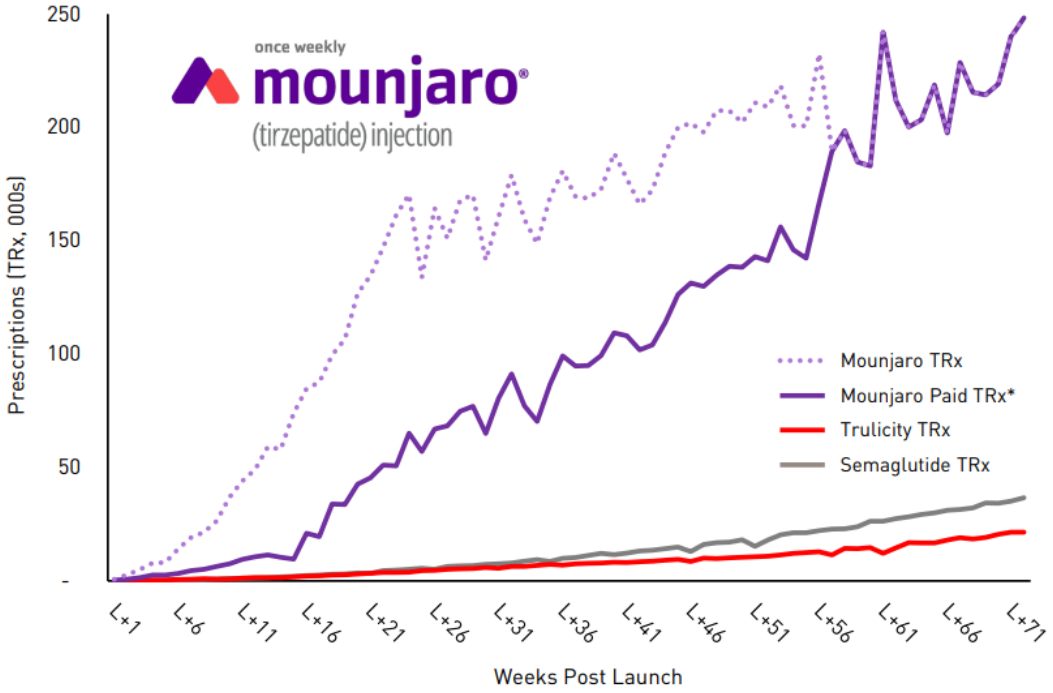
Context

Aside from Mounjaro and Wegovy uptake and sales, areas of interest for the quarterly calls included capacity expansions, the potential label expansion for CV risk reduction for Wegovy (based on SELECT), and pipeline.

Content

Lilly

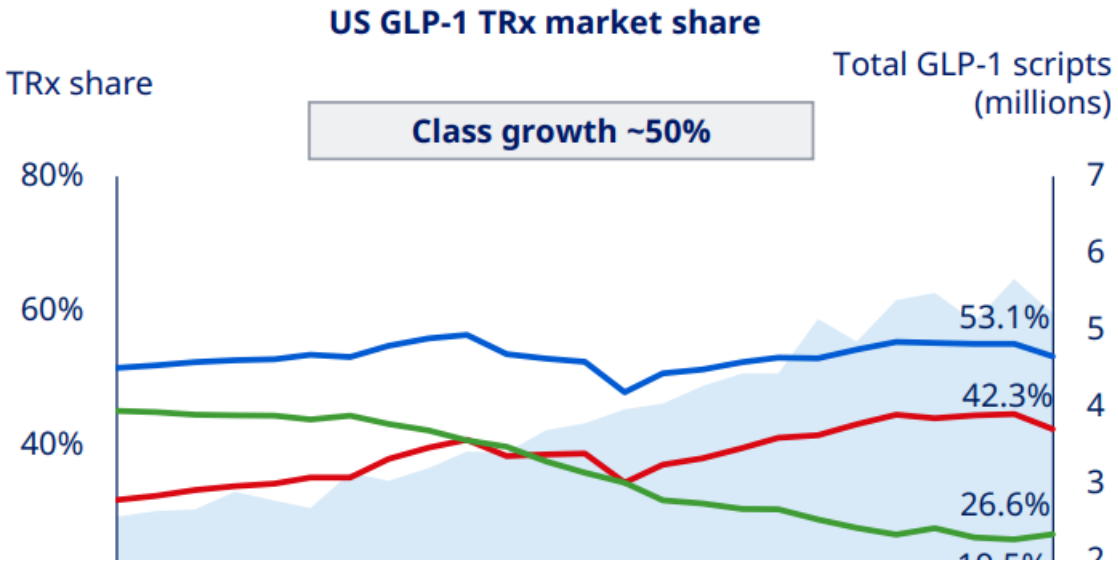
- Mounjaro sales: Mounjaro sales of $1,409M came in above consensus estimate ($1,279M), and LLY noted all prescriptions are now paid due to the copay card program expiring; access as of October 1st is at 78% for patients with T2D across total commercial and Part D lives (up from 72% in Q2). TRx continues to grow approximately linearly (see below).

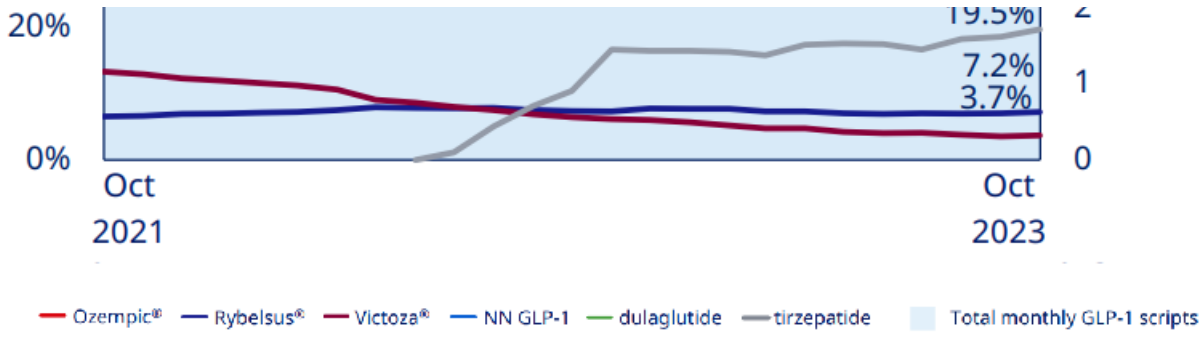


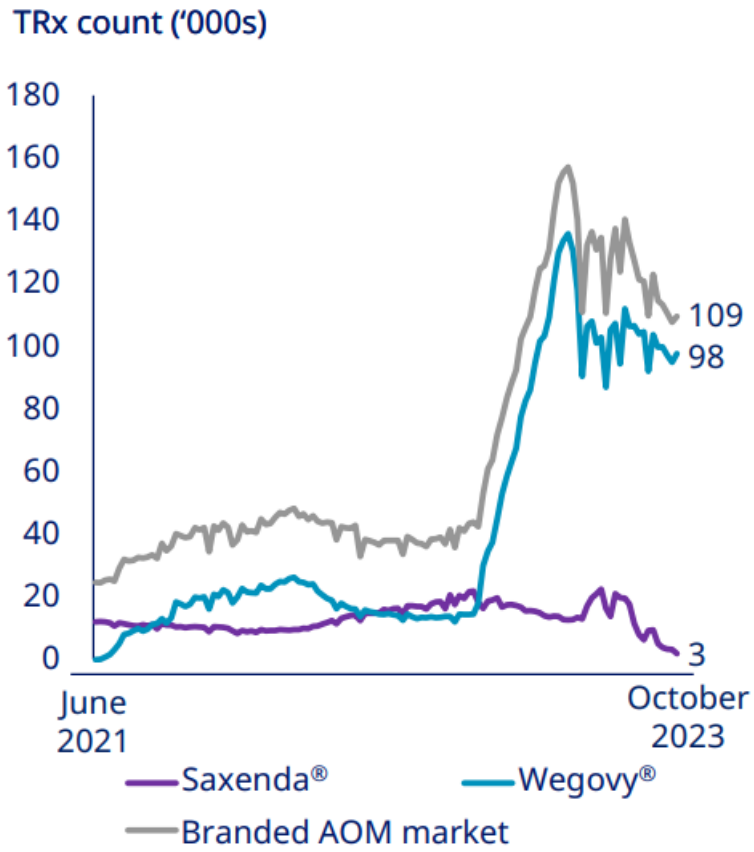
- Capacity: First additional plant is now partially online and ramping (autoinjectors and fill/finish) and this should double the company's capacity once fully online. Second plant on track to come online by late 2024 (this is a similar size to the first one). In addition, ex-US, Lilly will introduce vials and then bridge to multidose pens (4 doses in 1 pen) later in 2024 which should further improve supply.
- Pipeline update: Tirzepatide obesity approval expected in late 2023, NASH data in Feb 2024, and initial outcomes data in sleep apnea/heart failure in March/June 2024.

Novo

- Wegovy sales of DKK 9,648M ahead of consensus (DKK 7,708M); Ozempic sales of DKK 23,912M roughly in line with consensus (DKK 24,288M); Rybelsus sales of DKK 4,496M roughly in line with consensus (DKK4,535M). Obesity care sales grew by 174% in the first nine months of 2023 mainly driven by the US. See graphs below.







- Mid-October, Novo had raised guidance for 2023, reflecting higher full-year expectations for Ozempic volumes sold in the US and gross-to-net sales adjustments for Ozempic and Wegovy in the US.
- Capacity: "Underlying demand will continue to outpace supply in the short to medium term […] Don't look for a hockey stick". While supply capacity is gradually being expanded (through both internal capacity increases and contract manufacturing organizations), the supply of the lower dose strengths will remain restricted to safeguard continuity of care for those patients already on treatment.
- M&A: Novo indicated that the pipeline will be fueled both by internal innovation and by acquisitions, although "It is not on the drawing board to go out and do […] larger transforming deals"

Pipeline updates:

- In September and October 2023, Novo submitted an sNDA to the FDA and a Type II variant application to the EMA for Wegovy for reduction in MACE (cardiovascular death, non-fatal heart attack or non-fatal stroke) in people with an initial BMI of 27 kg/m2 or greater established CVD. The FDA has granted priority review for the sNDA.
- SELECT-LIFE, a long-term follow-up study to SELECT, was initiated in September. The trial is

expected to complete in 2033.

- Novo also plans to submit regulatory filings for both HFpEF trials (STEP HFpEF and STEP HFpEF DM).
- The regulatory submission of 50 mg oral sema for obesity in the US is waiting the completion of OASIS 4; assuming regulatory approval, the global roll-out of oral semaglutide for the treatment of obesity is contingent on portfolio prioritization and production capacity (~2025?).
- The filing for regulatory approval of 25mg and 50mg oral sema in T2DM was submitted to the EMA in October 2023; The submission to the FDA is now expected to take place in 2024.
- NOVO has initiated a 32-wk Ph1 study with subcutaneous amycretin “to gain flexibility around supply”. Results for oral amycretin are still expected 4Q2023. Potential benefit of the SC version vs. CagriSema is not entirely clear based on the information provided, although it should be kept in mind that amycretin is a new, unimolecular construct.

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