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Big Pharma's Blockbuster Obesity Drug Battle is Just Getting Started, and It's Headed for US$100 Billion

(Source: An article by Bob Woods for CNBC)

As evidenced in their most recent earnings reports, Novo Nordisk and Eli Lilly are certainly at the top of the list in the competition for control of the fast-growing weight-loss medications market. Beyond the staggering sales figures for Novo's *Ozempic* and *Wegovy*, and Lilly's *Mounjaro*, news of a study showing *Wegovy* can reduce the risk of heart disease and the anticipated approval of even more powerful prescripton drugs to treat obesity will only strengthen the position of these established pharma giants.

Even so, their competitors are not ceding the market to the current leaders. Pfizer, Amgen, and other pharma companies are rushing to develop weight-loss drugs, though they may not be available for a year or more.

The U.S. Food and Drug Administration (FDA) approved *Ozempic* in 2017 for diabetes and *Wegovy* in 2021 for the treatment of obesity. Over time, both reduce body weight by approximately 15%. *Mounjaro*, introduced in 2022 to treat diabetes, contains GLP-1 plus GIP, a similar appetite suppressor that can lead to weight loss. All three drugs are currently prescribed as injectable pens that patients self-administer weekly.

On August 8, Lilly reported that its Q2 income jumped 85% from the same period the prior year, driven in large part by *Mounjaro*, which generated US$979.7 million in sales for the quarter compared to US$16 million in the prior year, and US$569 million in the first quarter of this year. In December, analysts projected that *Mounjaro* sales could reach US$26.4 billion by 2030.

A month earlier, Lilly released data from a Phase III trial of the drug, showing that it helped patients with obesity, though not diabetes, lose up to 26.6% of their body weight after 84 weeks of treatment. *Mounjaro* is currently only approved by the FDA to treat diabetes, but the company has filed for FDA approval of *Mounjaro* specifically to treat obesity, which could come later this year or in early 2024.

Novo also reported a 344% jump in sales of *Wegovy* (to nearly US$1.7 billion) in the U.S. for the first six months of 2023. *Ozempic* sales jumped 50% to more than US$3.7 billion. According to financial analyst FactSet, sales of both *Ozempic* and *Wegovy*, along with Novo's other injectable *Saxenda*, could reach US$6.1 billion for the year of 2023 and US$15 billion annually by 2030.

Novo also released headline results of a multi-year clinical trial of *Wegovy*, showing that it reduced the risk of major cardiovascular events such as heard attacks or strokes by 20%, compared with a placebo. The company expects to file for regulatory approvals of a label indication expansion for *Wegovy* in the U.S. and the European Union this year, adding the drug's

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In Brief...

- **Walgreens Boots Alliance (WBA)** announced that *Rosalind Brewer's* tenure as CEO and WBA board member will end August 31, 2023. *Ginger Graham* has been named interim CEO by WBA's board. Brewer will continue to advise while the company conducts a search for a permanent CEO. *Stefano Pessina*, Executive Chairman of WBA, said, "On behalf of the entire board, I would like to thank Roz for her contributions to WBA. Roz navigated the company through the global pandemic, overseeing the critical rollout of vaccines in Walgreens pharmacies and to high-risk populations across the country." Separately, WBA announced a strategic partnership with **Pearl Health**, a provider enablement company, to accelerate the expansion of value-based care in collaboration with community-based primary care physicians. Pearl Health offers technology and insight solutions that empower clinical teams to provide holistic, personalized treatment necessary for value-based quality-focused care.
- **Sigma Healthcare Limited** announced the appointment of *Mark Conway* as Chief Financial Officer beginning November 1, 2023. Conway joins Sigma with more than 20 years of financial and commercial experience, with his most recent role being CFO at Fonterra Australia. *Gary Woodford*, Head of Corporate

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CSRD and the Pharma Industry

(Source: An article by Isaac Hanson of Pharmaceutical Technology)

The EU's Corporate Sustainability Reporting Directive (CSRD) entered into force in January, and the first companies will have to adhere to its rules from January 2024.

The regulation "modernizes and strengthens the rules concerning the social and environmental information that companies have to report," including those in the pharmaceutical industry.

Speaking to Pharmaceutical Technology at the Reuters Impact conference, Mark Chadwick, Managing Director for Sustainability Solutions in EMEA and APAC at sustainability consultancy Engie Impact explained how pharma companies will be impacted.

When asked what CSRD mean for the pharma industry and how close are companies aligning to it, Chadwick commented, "It's super difficult to know how close they are to aligning with it because it's a pretty new set of requirements that massively expands the range of things that companies need to talk about. I guess we'll see when the first CSRD-aligned reports start coming out."

He also observed that it is his belief that many people are underestimating the degree of lift involved in going from previous reporting expectations to the reporting under CSRD - simple things like needing to add in new elements of disclosure. Now you need to talk about water and pollution and water systems and biodiversity, which is not necessarily what pharma companies

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Obesity Drug Battle (cont.)...

cardiovascular benefits. The search for new potential uses of these drugs with difficult health care issues continues with the latest headlines saying obesity drugs are now being investigated as potential treatments for dementia and addiction as well.

Results touting heart benefits, combined with pressure from doctors, may prod government and private insurers to reimburse more patients for the high price tag of weight loss prescriptions. By law, Medicare has not covered them since 2006, though some select Medigap and Medicare Advantage plans for retirees do. Private insurers often do not cover GLP-1 drugs prescribed for weight loss only.

Conversely, Medicare, Medicaid and most private insurers cover *Ozempic* when it is prescribed for type 2 diabetes treatment, but not for weight loss.

On July 20, a bipartisan group of U.S. senators and representatives reintroduced the Treat and Reduce Obesity Act, which would reverse the federal ban on Medicare coverage of obesity drugs. Novo and Lilly have lobbied Congress on behalf of this legislation, originally introduced in 2021, and endorsed its reintroduction. The push by pharma giants for expanded coverage of these new blockbusters comes as the federal government is forcing drug companies to negotiate with Medicare. Some reports speculated that *Ozempic* will be a top target for price negotiations in the future. Court challenges have been introduced regarding the new law's constitutionality.

Given the enormous cost of obesity (approximately US$147 billion in annual health care costs) it is no surprise that Novo and Lilly have had trouble keeping up with demand for their weight loss drugs. Meanwhile, neither company is resting on its laurels, and have both increased their R&D budgets towards oral versions of their diabetes and obesity drugs, targeting patients who would prefer a pill to a jab.

Pfizer was testing two different oral drugs for treatment of type 2 diabetes and obesity, but it now is focusing on one, *danuglipron*, after Phase II trial results. Amgen also reported positive results for its injectable obesity drug, with patients showing a weight loss of 14.5% after 12 weeks of treatment. Phase II trials are ongoing, but a product launch is not expected before 2026.

CSRD (cont.)

would have been talking about before.

Chadwick said, "They'd probably be thinking much more about greenhouse gas emissions and health dimensions, things of that sort, which would normally be the most material sustainability things for a pharma company, but they must now consider a broader mandate of things. There's also a huge number of mandatory key performance indicators (KPIs) that need to be reported. All of the internal wiring to produce that in a way that is able to be externally assured is a big job. So it's hard to know right now exactly how well everybody's equipped for it, but I'm sure there's a lot of work going on behind the scenes to be ready."

Regarding economic resilience (as it relates to green transitioning and ESG reporting) and what it will mean in the health sector, and pharma in particular, Chadwick continued, "For us, it really is about that ability to be able to deliver a transition in a way that is cost-effective, that is going to allow our clients to remain competitive while they make this transition. It's also about being resilient to fluctuations in energy prices and availability of energy. Really, it's about not thinking about energy and energy infrastructure as something that's always been there and always will be at a price that I can afford. The level of planning around this needs to increase, so that's really what we have in mind."

In reference to financial incentives as they relate to pharmaceutical companies as they push towards net zero, Chadwick said that it appeared that no one wants this, to but it is a mandate that needs to be factored into the equation.

But on a positive note, thinking about the major pharmaceutical companies and their commitments and actions in the climate change space versus other companies that are selling products B2B, Chadwick sees that pharma companies are probably ahead of many other industries.

He continued, "I don't think they are below the radar in the same way that a traditional B2B business would be, and therefore I think if we look at their commitments and what they're doing, the industry by and large seems to be responding."

Chadwick did point out that the pharma industry has some challenges though in actually reducing greenhouse gas emissions because they have such a high level of quality requirements from their utilities, due to things such as cleanroom environment which are so precise, so they will have to plan significantly.

Overall, Chadwick believes that the pharma industry is setting commitments that are ambitious, and delivering on them while still managing major complexities, but there is always room for improvement going forward.

In Brief (cont.)

Affairs, will assume the role of Interim CFO from September 1 to November 1, 2023.

- **EBOS Group Limited** reported earnings results for the full year ended June 30, 2023 with sales of AUD12,237.4 million (US$7.39 billion) compared to AUD10,734.12 million (US$6.43 billion) year-over-year. Net income was AUD253.37 million (US$151.7 million) compared to AUD202.61 million (US$121.3 million) the previous year.
- On September 11, 2023, the **U.S. Food and Drug Administration (FDA)** approved the latest COVID-19 vaccines from **Pfizer-BioNTech** and **Moderna**, while also saying goodbye to the companies' bivalent shots in the United States. The new formulations are more closely targeted to current variants of the disease, according to FDA officials. Specifically, each company's shot is approved for people ages 12 and up, and emergency authorized for patients 6 months old to 11 years old. The vaccines have also been updated to include a monovalent component aimed at omicron variant XBB.1.5, according to the companies and the FDA. **Novavax's** revised shot is still pending regulatory approval.
- Most of the 10 drugs chosen for the first round of Medicare price negotiations by the **Centers for Medicare and Medicaid Services (CMS)** are heavily rebated, which raises the question of how much lower prices will go in the negotiation process. The list of Part D drugs was released by CMS in late August and includes products with gross Part D spending that ranged between US$2.57 billion to US$16.5 billion between June 1, 2022 and May 31, 2023. Average out-of-pocket spending for drugs on the list by beneficiaries who do not qualify for the Part D low-income subsidy ranged from a high of nearly US$6,500 for *Imbruvia* to US$261 for *NovoLog* and *Fiasp* insulins.

(Sources: Company Press Releases, Drug Store News, FiercePharma, MarketScreener, Reuters and Scrip Intelligence)