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The Biggest Drug Launches in 2024

(Source: an article by Andrew McConaghie for Scrip Citeline)

A key metric for any year in the life of biopharma is the number of drug launches – but their potential value is even more vital.

This year's top 10 biggest expected launches (as compiled by *Scrip*) use data based on analyst consensus estimates, according to their forecast earnings looking ahead four years to 2028. The list contains some familiar names, as well as some companies set to make their market debuts. While these are projected to be the biggest earners for this year's new approvals, the forecasts are on the low side. Just two are currently expected to exceed US$2 billion in sales by 2028, and half may not reach US$1 billion in that timeframe. Included in the list are some major upgrades and downgrades to analyst sentiment.

Karuna Therapeuticcs' first-in-clase schizophrenia drug *KarXT (xanomeline-trospium)* was ranked first, with anticipated 2028 revenues of US$2.8 billion, but has been adjusted to US$1.95 billion. This can be attributed to AbbVie's acquisition of Cerevel Therapeutics, which is developing a potential rival drug *emraclidine*.

This pushes Eli Lilly's *donanemab* (a subcutaneous formulation antibody treatment for Alzheimer's disease) ahead. Consensus forecasts put its 2028 revenues at US$2.24 billion, but the drug's path to approval was delayed last year after the U.S. Food and Drug Administration rejected a request for an accelerated approval (due to limited Phase II data.) Since then, Lilly has unveiled more robust data from a subsequent study, which should be sufficient for the FDA to grant full approval.

Lilly still must contend with its rivals, Eisai and Biogen, whose *Leqembi (lecanemab*) gained full U.S. approval in January of 2023. Consensus forecasts are for *Leqembi* to reach revenues of US$4.68 billion by 2028, reflecting its head start on the market and fewer safety concerns.

The field of non-alcoholic steatohpatitis (NASH) has seen several companies try and fail to gain approval for the first drug to treat fatty liver condition. Madrigal may be the first to achieve that goal with its thyroid hormone receptor beta agonist candidate, *remetirom*. If approved, it could have two years to establish the therapy before any rivals come onto the market.

Meanwhile, AstraZeneca and Daiichi Sankyo are looking to extend their dominance in the antiobody-drug conjugates with the approval of *datopotamab deruxtecan (Dato-Dxd)*, a TROP2-directed agent. After concerns in mid-2023 about overall survival data in the phase III TROPION-Lung-01 study in non-small cell lung cancer, updates from this and TROPION-Breast01 Phase III study in breast cancer provided reassurance to investors.

A blow to Gilead's competitor *Trodelvy (Sacituzumab govitecan)* have seen consensus 2028 forecasts for *Dato-DXd* revive, and now currently stand at just under US$2 billion.

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In Brief...

- **Walgreens Boots Alliance** sold shares of **Cencora** common stock under Rule 144 for approximately US$942 million and, subject to the completion of the Rule 144 sale, a concurrent share repurchases by Cencora for approximately US$50 million. WBA's ownership of Cencora's common stock has decreaed from approximately 15% to approximately 13%. Proceeds will allow WBA to pay down debt and for general corporate purposes as the company continues to build out a more capital-efficient health services strategy in its retail pharmacy footprint. Additionally, the company has named several appointments to its executive committee, including *Mary Langowski* as Executive VP and President, U.S. Healthcare; *Manmohan Mahajan* as Executive VP and Global Chief Financial Officer; and *Elizabeth Burger* as Executive VP and Chief Human Resources Officer.
- Two pharma giants, **CFAO Healthcare** and **Sanofi Pharmaceutical Industry Company**, have strengthened their partnership by extending what they described as "the exclusive distribution of general medicines in Nigeria." In a statement Friday, CFAO announced the expansion with Sanofi noting that the "move fortifies their strategic partnership." CFAO continued, "Aware of the evolutions and challenges in the Nigerian pharmaceutical landscape, CFAO Healthcare and Sanofi are joining forces, capitalizing on their expertise and historical presence to optimize access to quality healthcare."
- **GSK** sold 300 million shares of **Haleon** (valued at approximately £974 million (US$1.24 billlion). The sale represents approximately 3.2% of Haleon's total ownership, leaving GSK with roughly a 4.2% stake in the company. In a

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Sanofi Issues Warning Against Innovation-Unfriendly EU

(Source: An article by Kevin Grogan for Scrip Citeline)

Sanofi CEO Paul Hudson has again spoken out about plans to overhaul EU pharmaceutical legislation and its negative impact on innovative R&D firms, saying further obstacles to market access will hamper the continent's efforts to compete with the U.S. and China.

In response to questions at the French pharma giant's annual press conference on February 1st, Hudson did not go into specific concerns about the first major overhaul of the bloc's medicines regulations in 20 years, stating that Sanofi and "most of the big EU-led R&D companies have expressed their disappointment of the lack of focus around innovation and the support for it." He said that the European Commission was "working hard on hydrogen, chips and batteries for electric vehicles, where they think there's a strategic imperative to

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Drug Launches (cont.)...

2024 is also set to be a pivotal year for Moderna and its mRNA platform, with two likely launches on the list – one for its flu vaccine candidate *(mRNA-1010)* and the other for its syncytial virus vaccine candidate *(mRNA-1345)*. Its RSV candidate does stand to face significant competition from GSK and Pfizer's RSV vaccines, two of 2023's biggest launches. Moderna has pledged to show superior efficacy to the frontrunners.

Three of the ten most valuable upcoming launches for 2024 are set to come from small companies who have never before brought a drug to market. Alongside previously-mentioned Karuna Therapeutics and Madrigal is Cymabay Therapeutics, which is looking for approval for its PPAR delta agonist *seladelpar*. It was initially tested for NASH, but Cymabay abandoned those plans based on safety concerns. It now has its sights set on an approval for primary biliary cholangitis, a rare chronic inflammatory liver disease, with a possible FDA approval in the second half of 2024, giving CymaBay time to prepare, although a big pharma buyout or a late licensing deal cannot be ruled out.

Last year saw the FDA approve 55 novel therapeutics, the second-highest count in the past 30 years, but there is evidence to suggest that they are proving less profitable for the industry. Whether or not new launches can overcome this trend remains to be seen. If not, the sector will be forced to accelerate its search for new efficiencies in drug discovery and reinvention of R&D models.

Sanofi (cont.)...

compete and well done, [but] healthcare should also be a strategic imperative."

However, the Commission should not only be focused on delivery of healthcare, "but also the innovation associated with it" in order to compete with China in the U.S., Hudson continued. "If your priority in Europe is to have the lowest prices and the lowest impact on budget, you will make a short gain, of course, but you can see now that one or two major markets understand that they need to make it more attractive to the industry to remain."

It is logical that inward investment in the EU from its major pharmaceutical companies declines as access to medicines declines, Hudson argued, claiming that "50% of therapies that are approved by the European Medicines Agency are not available for patients in Europe, one in two, so you have to ask yourself why that is." He added, "If companies do clinical research on a breakthrough drug in a rare disease in a country in Europe, and when the drug is approved, the patient says 'I've done great, can I be on it?' and the systems says 'sorry, no,' that is not an acceptable consequence."

Hudson said that "this is a view shared by all of the European pharmaceutical companies and many outside Europe when making an investment decision. You must reward innovation in Europe or accept that it will slow down. That's not where people should want to be, it is not good enough for patients in Europe. We can debate price and budget impact, but on a human level, it is not acceptable."

Hudson also spoke about the sector in China, stating that around 75% of initial public offerings in China were trading below their list price, and "while you may think that's a lot, 25% trading above is a large number of biotechs. Don't underestimate the speed at which China's trying to evolve and because of the scale of it, there are going to be a big number, perhaps bigger than Europe."

He agreed that dealmaking by the big pharma multinationals in China was becoming more innovation-driven rather than purely commercial, saying that scientific breakthroughs are taking place, while "many incredible scientists are returning to China, well supported by the long-term healthcare strategy Health China 2030 and beyond." Certainly, the Chinese market is becoming more attractive overall.

Hudson said he expected Sanofi and other big pharma companies to become even more interested in the science coming out of China. "A lot of it may not be of the quality you see from academic institutions in Paris, Berlin, London, Cambridge, or Oxford [but] the scale of it means some of the innovation will be staggering so we will have to think about participating," he concluded.

In Brief (cont.)

statement, GSK said the company "will continue to follow a disciplined a pragmatic approach for further sales of our stake, which will be dependent on market conditions."

- U.S. senators questioned three big pharma CEOs about the high price of drugs in the U.S. Health, Education, Labor and Pension Committee. Representatives from **Merck, Bristol Myers Squibb** and **Johnson & Johnson** testified for nearly three hours under questioning from committee members, including *Bernie Sanders* (I-Vermont) and *Rand Paul* (R-Kentucky). A **Kaiser Family Foundation** tracking poll from July of 2023 showed that there is widespread support for greater government control.
- **Cardinal Health** released is *Fiscal 2023 Environmental, Social and Governance Report*, highlighting the company's work toward building a healthier and more equitable future. "At Cardinal Heath, we approach ESG in a way that supports our business, positions us as a partner of choice for customers and suppliers, and ensures compliance with evolving regulatory requirements," said *Jason Hollar*, Cardinal's CEO. "We know that ESG is the right thing for our business. Our new report illustrates how our ESG priorities are helping us create long-term, sustainable value for our stakeholders."
- Germany is planning to oppose a European rule that would require large companies to take action if they find their supply chains either damage the environment or use child labor, based on a letter from two German ministers. The letter by Finance Minister *Christian Lindner* and Justice Minister *Marco Buschmann*, said that the German government would abstain on the issue. German businesses and industry bodies have criticized the proposal, arguing that the law could create significant bureaucratic processes and legal uncertainties.
- **Novo Holdings** (operating under **Novo Nordisk's** owner the **Novo Nordisk Foundation**) is buying CDMO giant **Catalent** in a deal valued at US$16.5 billion. As part of the transaction, Novo Nordisk will acquire three of Catalent's fill finish sites from Novo Holdings. The merger is expected to close later in 2024, and the buyout has gained approval from **Elliott Management**, the activist investor that struck up a cooperation agreement with Catalent in the summer of 2023.

(Sources: Drug Store News, FiercePharma, Reuters, Scrip Citeline and World Pharma News)