SCRIP
CITELINE COMMERCIAL

30 Jan 2024 | **Analysis**

The Biggest Drug Launches Expected In 2024

by Andrew McConaghie

A rundown of the ten most valuable drug launches expected in 2024 from both big pharma and some first-to-market companies.

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

Using Evaluate Pharma data based on analyst consensus estimates, *Scrip* has compiled the top 10 biggest expected launches of 2024, according to their forecast earnings four years down the line, in 2028.

The list contains some familiar big pharma names, as well as some companies set to make their market debuts. However, 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 $2bn in sales by 2028, and half may not have reached $1bn revenues by that time.

This is an updated version of the list in Evaluate Pharma's 2024 Preview published in December, and illustrates some major upgrades and downgrades to analyst sentiment since then.

Key Takeaways

- A newly updated list based on Evaluate Pharma research and consensus estimates
- Alongside the big pharma players are new entrants Madrigal and CymaBay Therapeutics
- The sub $1bn forecasts for half the list revives concerns about declining ROI for biopharma

Notably, in August 2023 when the original list was compiled, *Karuna Therapeutics*' first-in-class

schizophrenia drug KarXT (xanomeline-trospium) was ranked in first place, with anticipated 2028 revenues of $2.8bn. This has now been downgraded to $1.95bn - most likely in response to *AbbVie*'s acquisition of *Cerevel Therapeutics*, which is developing a potential rival drug emraclidine. (Also see "*AbbVie Strikes Again By Teeing Up $8.7bn Offer For Cerevel*" - Scrip, 6 Dec, 2023.)

A Subcutaneous Alzheimer's Drug

Topping the updated list is *Eli Lilly*'s donanemab, a subcutaneous formulation antibody treatment for Alzheimer's disease.

Consensus forecasts put its 2028 revenues at $2.24bn, but the drug's path to approval was delayed las year after the US Food and Drug Administration rejected a request for an accelerated approval as it was based on limited Phase II data.

Since then, the company has unveiled more robust data from TRAILBLAZER-ALZ 2 study, which should be enough for the FDA to grant it a full approval. The fact that the drug is also available as a convenient subcutaneous injection may also influence this decision.

Lilly is expected to provide a regulatory update in the first half of the year, but current revenue forecasts put Lilly some way behind its rivals, *Eisai* and *Biogen*, whose Leqembi (lecanemab) gained full US approval in January 2023.

Consensus forecasts are for Leqembi to reach revenues of $4.68bn by 2028, reflecting its head start on the market and fewer safety concerns.

Click here to explore this interactive content online

A NASH Breakthrough At Last?

The field of non-alcoholic steatohepatitis (NASH) has seen a string of companies try and fail to gain approval for the first drug to treat the fatty liver condition. Madrigal may finally be the one to achieve that goal, with its thyroid hormone receptor beta (THRβ) agonist candidate, resmetirom. If approved, it could have around two years to establish the therapy before any rivals join them on the market. (Also see "*A Look Into The Future Of NASH*" - Scrip, 22 Sep, 2023.)

Meanwhile, *AstraZeneca* and *Daiichi Sankyo Co., Ltd.* are looking to extend their dominance in antibody-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-Lung01 study in non-small cell lung cancer (NSCLC), updates from this and TROPION-Breast01

Phase III study in breast cancer reassured investors. (Also see "*ESMO 2023: TROPION-Breast01 And -Lung01 Studies Breathe Life Into Dato-DXd*" - Scrip, 25 Oct, 2023.)

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 $2bn. (Also see "*Do The Dark Clouds Over Gilead's Trodelvy Have A Silver Lining?*" - Scrip, 22 Jan, 2024.)

2024 is also set to be a pivotal year for *Moderna* and its mRNA platform, with two likely launches on the list. These are for its flu vaccine candidate, mRNA-1010, and respiratory syncytial virus vaccine candidate, mRNA 1345. The latter will face a particularly competitive environment, as *GSK* and *Pfizer*'s RSV vaccines were two of 2023's biggest launches. Moderna has pledged to eventually show superior efficacy to the frontrunners, but could struggle to challenge GSK, which has established a strong early lead.

Small Companies With Blockbusters

Three of the ten most valuable upcoming launches on this year's list are set to come from small companies who have never before brought a drug to market.

These include Karuna Therapeutics' schizophrenia treatment KarXT, which could be a major step forward in a therapy area that has lacked progress for decades. As such, this proved irresistible to big pharma – *Bristol Myers Squibb* moved to acquire Karuna for $14bn in December. That acquisition is expected to close in the first half of this year, with an FDA decision expected by 26 September. Many analysts believe KarXT's potential could be great if it is can expand its licensed uses - Mizuho Securities forecasts potential peak annual revenues of more than $6bn.

Alongside Madrigal, the other small company on the list is *CymaBay Therapeutics*. For CymaBay, an approval would represent a triumph after years of setbacks for its PPAR delta agonist seladelpar. It initially tested the drug in NASH, but abandoned these plans after safety concerns, and now looks set for an approval in a primary biliary cholangitis, a rare chronic inflammatory liver disease.

The omens are promising after the FDA updated its breakthrough therapy designation for seladelpar in October in recognition of Phase III data from its RESPONSE and ENHANCE studies that showed the drug could provide meaningful improvement over existing therapies.

An FDA decision is possible in the second half of the year, giving CymaBay time to prepare for its maiden launch – though a buyout by big pharma or a late licensing deal cannot be ruled out. If it does bring its product to market alone, the company will be aware of investor intolerance of disappointing drug launches given the fate last year of *Apellis.*. Its blockbuster-tipped geographic atrophy drug Syfovre (pegcetacoplan injection) was launched by mid-2023, but concerns about its safety and the company's messaging in June saw the company's share price

plummet, and are still down more than 20% compared with a year ago, at around $64 a share. (Also see "*Apellis Slashes Costs To Focus On Troubled Syfovre Launch*" - Scrip, 30 Aug, 2023.)

Value Remains A Concern

Meanwhile, the limited revenue potential of new launches remain a concern for the sector. 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.

Research by Deloitte in early 2023 found that projected returns on investment (ROI) in pharma R&D in 2022 had fallen to 1.2%, the lowest ROI observed in the 13 years since the research began.

It also found that average forecast peak sales per asset had decreased to $389m in 2022, falling from $500m in 2021 and $422m in 2020.

Whether or not new launches can buck this trend, and exceed what are often conservative early forecasts will have to be seen. If not, the sector will be forced to accelerate its search for new efficiencies in drug discovery and reinvention of its R&D models.

As 2024 Begins, US FDA's Novel Agent Prospects Look A Lot Like 2023

By Bridget Silverman

30 Jan 2024

Immuno-oncology will remain a major force at both FDA's drugs and biologics centers, but watch for psychiatry and antibiotics to make some noise; rare pediatric diseases will remain prominent as the priority review voucher program heads into the sunset.

Read the full article here

For a look at all the products under review at the US FDA, read the sidebar for a story on from our sister publication the *Pink Sheet*.