



FOCUS

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U.S. Approvals of Novel Drugs Set to Hit 10-Year High in 2025

(Source: An article by Elizabeth Cairns for Scrip Citeline)

The U.S. Food and Drug Administration (FDA) is forecasted to approve the highest number of novel drugs in at least ten years, according to new analysis and data released by Evaluate Pharma. The forecasted 2025 total of 74 is higher than the 2023 total of 73, which was the highest since 2016.

However, the expectation is that they will not be as lucrative. A look at the forecast sales for the drugs expected to gain the FDA's imprimatur in 2025 shows that in 2030, after having been on the market for five years, their combined U.S. revenues will be US\$26.3 billion. The five-years-out U.S. sales figure for the novel drugs of 2023 is nearly US\$10 billion higher.

Analysis is based on the historical approvals on the FDA's lists of approved NDAs and BLAs for new molecular entities, with approvals of diagnostic tests and reagents removed. Also of note, the subsequent approvals of the same molecule are not counted, even if they are launched under a different brand name. Thus Eli Lilly's *Mounjaro* (*tirzepatide*) is counted but *tirzepatide's* second approval, *Zepbound*, is not.

Predicted approvals are based on Evaluate Pharma's consensus approval dates, then further filtered using Evaluate's *Omnium* module to assess probability of success. Evaluate's sellside consensus is used for all forecast sales, and because a drug approved by the FDA might not be approved in any other territories, only U.S. sales are used to ensure a fair comparison.

2023 was an extraordinary year, with the approval of no less than 12 drugs that carry U.S. forecasts in excess of US\$1 billion

Biggest Drugs of 2024 and 2025		
Projected 2029 US Drug Sales (USD Billions)		
Drug	Company	
2024 Approvals		
3.8	<i>Winevair</i>	Merck & Co.
2.6	<i>Rezdiffra</i>	Madrigal
2.1	<i>KarXT*</i>	Bristol Myers Squibb
1.9	<i>Casgevvy</i>	Vertex
1.9	<i>Datopotamab Deruxtecán*</i>	AstraZeneca/Daiichi Sankyo
1.1	<i>Acoramidis*</i>	BridgeBio
2025 Approvals		
2.1	<i>Aficamten</i>	Cytokinetics
1.5	<i>mRNA-1010</i>	Moderna
1.3	<i>Amnolake</i>	Syros Pharmaceuticals
*yet to be approved		

by 2028. Included in this list are Sarepta Therapeutics Duchenne muscular dystrophy gene therapy, *Elevidys*, Biogen and Eisai's Alzheimer's therapy *Leqembi*, and GSK's respiratory syncytial virus vaccine, *Arexvy*. These three are each forecast to earn more than U.S. \$2 billion in the U.S. in 2028.

The prior year was the highlight in terms of five-year forecast sales, singularly due to Lilly's *Mounjaro*, which has a
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In Brief...

♦ **Pfizer** announced the launch of *PfizerForAll™*, a direct-to-consumer digital care platform combining education, telehealth, digital pharmacy, and financial support resources to expedite access to Pfizer tests and treatments for patients with migraine, COVID-19, or flu, and will be a resource for medicines and vaccines, including those for COVID-19, RSV or pneumococcal pneumonia. A similar program was recently announced by **Eli Lilly & Co.** under the name *LillyDirect*.

♦ **Salehiya** (Saudi Arabia) announced that the company has been awarded the esteemed *Authorized Economic Operator (AEO) Certification*. This program is a collaboration between **ZATCA Saudi Arabia** and commercial establishments to enhance global supply chain security and facilitate international trade. AEO certification aligns with international standards set by the World Customs Organization and the World Trade Organization's Trade Facilitation Agreement.

♦ **McKesson** has signed an agreement to sell its Canada-based **Rexall** and **Well.ca** businesses to Private Equity firm **Birch Hill Partners**. "This transaction marks an important

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Bausch & Lomb Joins IFPW

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See better. Live better.

IFPW is pleased to announce that Bausch & Lomb has joined IFPW as a manufacturer member

Bausch + Lomb, a leading global eye health company, is dedicated to protecting and enhancing the gift of sight for millions of people around the world – from the moment of birth through every phase of life. For nearly two centuries, Bausch + Lomb has been at the forefront of optical innovation with unique advancements underscoring the quality and craftsmanship of its employees around the globe.

IFPW warmly welcomes Bausch & Lomb as member. **IFPW is also excited to announce Bausch & Lomb CEO Brent Saunders as a Keynote Speaker at this year's General Membership Meeting in Miami.**

U.S. Approvals (cont'd.)...

2027 U.S. sales forecast of an astounding US\$14.2 billion, upping the overall figure for that year to US\$41.3 billion. This is despite the fact that only 44 other products were approved in 2022, the lowest number since 2016.

2024 looks to be a bit of a low, with both U.S. approval number and five-year U.S. sales dropping from the year prior. Thus far, the FDA has waved through 36 new medicinal compounds. Merck's pulmonary arterial hypertension therapy *Winrevair* is the leader with forecast 2029 U.S. sales of US\$3.8 billion. Of the 28 agents forecast to gain U.S. approval by the end of this year, only three are expected to be blockbusters by 2029.

Next year, the FDA is expected to accelerate approvals, with relatively high expectations for Cytokinetics myosin inhibitor *Aficamten*. The forecast for the drug is expected to top US\$2 billion in 2030.

The prediction that next year will realize 74 approvals is, to some extent, a supposition on the part of analysts. Unlike those drugs expected to gain FDA approval in the late half of 2024, almost all of which have solid approval decision dates, most of those predicted to get the green light in 2025 will not yet be filed. The downside is that only three of the 74 are forecast to have U.S. sales higher than US\$1 billion. Those three include Cytokinetic's *Aficamten*, Moderna's *mRNA-1010* flu vaccine, and Syros Pharmaceutical's *Amnolake* used in the treatment of Myelodysplastic syndrome.

Sustainability is Important but Poses Hurdles that Can Slow Efforts

(Source: An article by Kevin Dunleavy for *FiercePharma*)

A survey conducted by Cytiva and FT Longitude shows that sustainability has become increasingly important, but companies are struggling to achieve it, thus putting their business at risk.

The study tabulated the input of executives from organizations in 18 different countries. Of the respondents, 26% hold C-suite positions and 30% represent companies that generate more than US\$1 billion in annual revenue.

Over the past 12 months, more than half of the sustainability leaders who participated in the survey said their organizations have experienced increases in brand reputation (58%), profit (57%), share price (56%), revenue (55%) and their ability to attract talent (54%) through their efforts to achieve sustainability.

Firms in the industry generally recognize these potential benefits, as 62% of the respondents said that their organization has identified sustainability as a top priority. Additionally, 63% of those surveyed see sustainability as an imperative to foster differentiation and business growth, while 64% said that failure to achieve sustainability targets and goals poses a critical threat to their business's success.

Unfortunately, barriers to achieving sustainability are formidable. One of the major challenges is that there is weak collaboration across the value chain on shared sustainability strategies and on setting achievable goals. Measuring sustainability objectives is also problematic for companies. In the survey 76% of the respondents said their organization's approach to quantifying and forecasting the financial impact of sustainability measures is somewhat or not at all accurate.

Sustainability efforts by companies, particularly larger ones, are underway. At least 50% of those surveyed said that their

organization has made efforts to reduce water consumption, switch to renewable energy, reduce single-use plastics, create more sustainable packaging, and switch to greener chemicals.

Adversely, only 41% of companies can track their carbon footprint due to a lack of ability to measure the upstream and downstream environmental impacts of their business, creating a barrier to fully achieving sustainability targets.

While Scope 1 and Scope 2 emissions are relatively easy to gauge, Scope 3 emissions, which are created across every step of the supply chain, encompass everything from the manufacturing process to product disposal. According to the report, only 17% of those surveyed are confident in their ability to accurately measure Scope 3 emissions.

The study concludes that organizations must place sustainability at the top of their agenda and communicate this initiative both internally and externally. They also need to measure emissions by "moving away from spend-based methods by investing in technology and encouraging transparency with suppliers."

In Brief (cont.)

milestone aligned to our enterprise strategy, advancing our strategic priorities, further streamlining our business and prioritizing investment in our growth areas on oncology and biopharma services. We remain fully committed to and confident in the strength of our Canadian distribution and biopharma businesses," said *Brian Tyler*, McKesson's CEO.

- ◆ **Johnson & Johnson (J&J)** is not ruling out being a late entrant into the obesity space. During the recent **Morgan Stanley Healthcare Conference**, CEO *Joaquin Duato* said the company is interested in obesity – but it would have to develop a differentiated product. "If we were able to identify assets in obesity that were sufficiently differentiated, it would be an area of interest to us," Duato said. The company has not invested as heavily in cardiovascular and metabolic disease recently but does have experience in the disease areas, with the blood thinner *Xarelto (rivaroxaban)* and the first-in-class SGLT2 inhibitor *Invokana (canagliflozin)* for diabetes.

- ◆ **Rite-Aid** named *Matt Schroder* as the company's new chief executive officer as the U.S. drug store chain emerges from Chapter 11 bankruptcy protection. Schroder has been with the company since 2000 and most recently served as chief financial officer. He succeeds *Jeffrey Stein*, who has stepped down as CEO and chief restructuring officer.

- ◆ After a regulatory setback earlier this summer, **Novo Nordisk** is working to get heart failure ambitions for its obesity drug *Wegovy (semaglutide)* back on track. The drug was shown to cut the risk of combined cardiovascular death or worsening heart failure risks by 31% based on an incident rate of 5.4% in *semaglutide* patients versus 7.5% of those taking a placebo.

- ◆ In the second quarter of 2024, 21 of the biopharma industry's top 25 companies achieved year-over-year revenue increases. The period saw a consistent surge in sales throughout the sector. Of the top 25 drugmakers, nine had double-digit increases year over year, and nine more companies saw sales increases of between 6% and 9% in the second quarter. Of the four companies that didn't show growth in the second quarter each still had sequential sales increases of at least 4%.

(Sources, Company Press Releases, Drug Store News, *Fierce Pharma*, *Nephron Research*, and *Scrip Citeline*)