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WORLD PREVIEW 2023: Pharma's Age of Uncertainty

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▶▶ The Evaluate World Preview 2023 was written by Melanie Senior

Key assumptions underpinning the pharmaceutical sector are being tested.

In 2023, key assumptions underpinning the pharmaceutical sector, such as the US market's supreme profitability and reliance on big M&A to fuel growth, are being tested. The far-reaching Inflation Reduction Act (IRA) curbs profits on high-spend drugs, limits price rises and dampens incentives to develop small molecules and some orphan products in the world's largest market. The anti-trust FTC is apparently willing to try and block M&A deals that may encourage dubious pricing practices, while regulators are less predictable in the face of new modalities.

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In short, working out what kind of assets to develop or buy has become much more complicated. Multiple legislative, regulatory and commercial unknowns make this pharma's Age of Uncertainty.

For now, the sector's near-term growth trajectory nevertheless looks healthy. Pharma revenues are forecast to grow at a compounded annual rate of 5.9% from 2022 to 2028, reaching almost $1.6 trillion. The top ten biggest drugs in 2028 will still pull in over $160 billion.

Innovation continues: in 2022, FDA for the first time approved more biologics (including new modalities such as conjugates, cellular therapies) than small molecules. This year has already brought a second, potentially more effective Alzheimer's therapy to market, and may deliver another game-changing anti-obesity drug in Eli Lilly's tirzepatide.

Dealmaking has picked up in 2023, with over $80 billion worth of M&A deals announced in the first half of the year.

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The Federal Trade Commission's lawsuit against Amgen's $27.8 billion Horizon deal, announced in late 2022, raised concerns. But the dealmaking engine must continue turning: pharma faces a minimum of $118 billion in lost sales due to patent expiries over the next five years. (This number is based only on lost sales during the first year post expiry, cumulative losses could be much higher). Pharma needs external programs to fill those gaps and drive projected growth: home-grown new molecular entities account for less than half of annual sales at six of the top ten big pharma in 2023.

And biotech needs deals: public markets remain subdued, IPOs are still nigh on impossible and private investors are, as a result, holding back cash. Despite large funds raised in the last 2-3 years, the hurdles for accessing VC capital have risen. Biotechs need more compelling, later stage data and highly differentiated assets. Pharma financing – through acquisitions or partnerships – has become more important for biotech, especially now that over half of biotechs have less than two year's cash, according to EY.

Biotech's struggles don't translate directly into an easier life for pharma, though. The IRA and related pricing pressures, plus tighter VC funding, have made "good" assets even rarer, driving up competition. Meanwhile, uncertainty over how (and when) the new US pricing rules will play out – the first lawsuits have been filed – makes it harder to identify the most promising programmes. Should industry revert to niche biologics at the expense of further progress treating more widespread conditions best addressed with oral molecules?

More efficient R&D would help address many of these challenges. Bringing more products to market, faster, and easing patient access would dampen IRA's downstream impact on profitability – if lawsuits don't neutralise it first.

Perhaps fittingly, pharma's R&D spending growth is projected to fall slightly over the next five years according to Evaluate Pharma data. Whether that's down to anticipated AI-powered efficiencies or a more cautious outlook remains to be seen.

Figure 1: Worldwide Total Prescription Drug Sales (2014-2028)
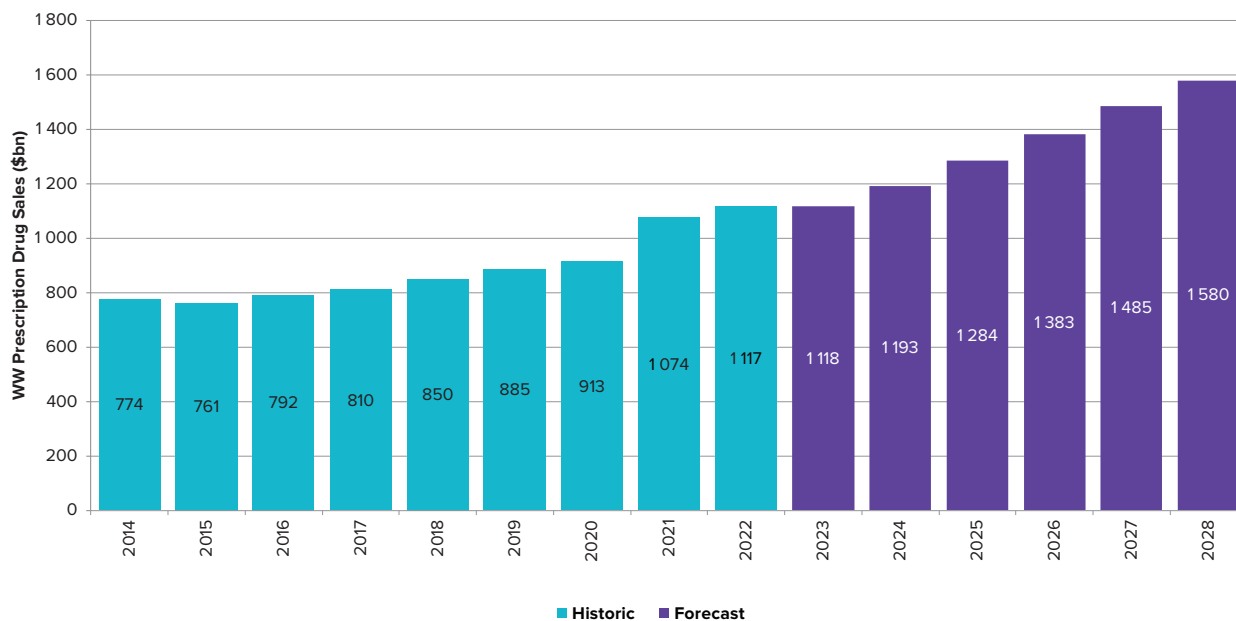
Sales of prescription drugs are expected to grow almost 6% year-on-year out to 2028, according to Evaluate Pharma's consensus forecasts. These numbers are based on sellside analyst estimates and include forecasts for R&D projects as well as products already on the market.

In the shorter term, these data show the pandemic bounce to be over. Zero growth is predicted in 2023 over the previous year. Demand for Covid-19 prevention and treatment is now more knowable than in the pandemic years, and this is a market in decline.

2028: Market Growth & Patent Cliffs
What's the impact of looming patent expires on the overall market?

Figure 2: Worldwide Sales At Risk from Patent Expiration (2014-2028)

CDER & CBER novel approvals – therapeutics only.   Source: Evaluate Pharma

Patent expiry pressures are set to amplify as the decade progresses. From 2026 a swathe of huge blockbusters could start to face lower-cost competition. These include Bristol Myers Squibb/Pfizer's Eliquis; Regeneron and Bayer's Eylea; Johnson & Johnson/AbbVie's Imbruvica; and the checkpoint inhibitor giants Keytruda and Opdivo, from Merck & Co and Bristol respectively.

With intellectual property still being litigated in several of these cases, the exact date of exclusivity loss remains hard to know. As such, while the shape of the chart above could change, these products will fall eventually.

The Top Players in 2028

Figure 3: Worldwide Prescription Drug Sales in 2028: Top 10 Companies
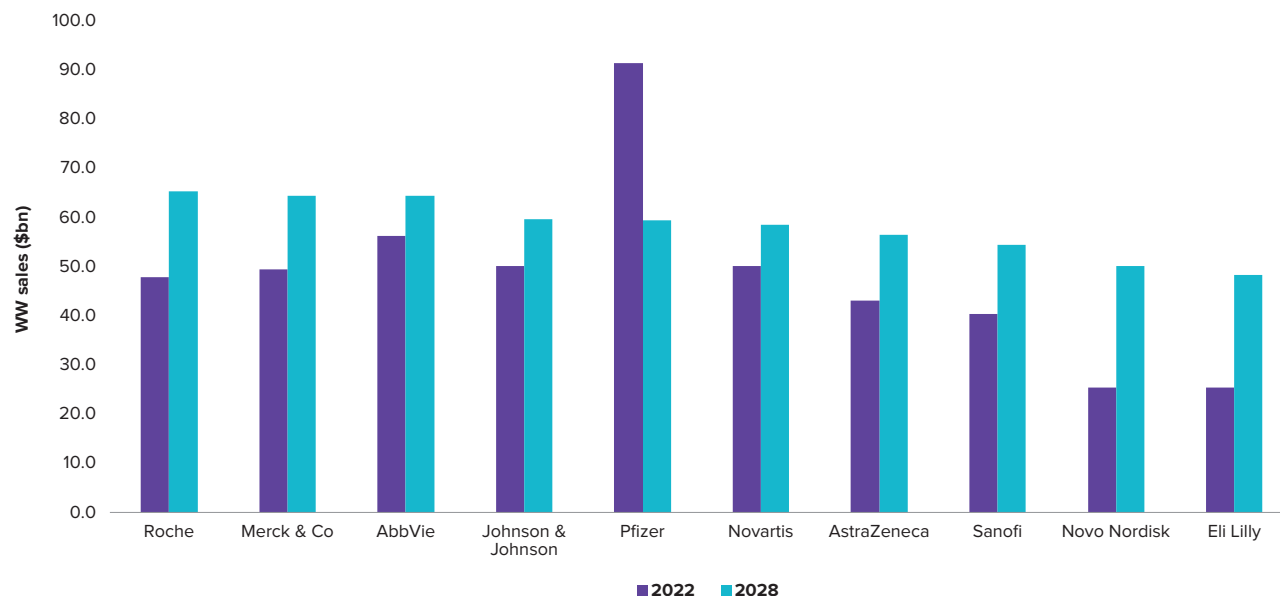
Note: Funding for pure-play drug developers only.   *Source: Evaluate Pharma*

Biotech products' high prices and longevity will keep many of the biggest biological players amongst the world's largest drug makers. Roche comes out on top in 2028 when the sector is ranked on prescription drug sales. The Swiss developer helped trigger the cancer antibody revolution with products like Herceptin and Avastin, and its future growth will be driven by a new suite of monoclonals. Roche also boasts the leading non-oncology bispecific Hemlibra, sold for haemophilia.

This broad estate means that, based on current projections, the Swiss giant will keep Merck & Co from the top spot in 2028. With little between the top three companies' sales forecasts that year, however, the order of names on the podium is far from finalised.

This analysis also finds two new entrants into the top 10: Novo Nordisk and Eli Lilly. The Danish firm is currently enjoying a leading position in the successful incretin class, which includes drugs sold for type 2 diabetes and, increasingly, obesity. But Lilly is catching up.

The GLP-1 agonist semaglutide, which is sold under various brand names, lies behind Novo Nordisk's growth prospects. Lilly's Mounjaro arrived on the market in May 2022,with massive demand creating one of biopharma's most successful drug launches.

The huge sales these agents are seen generating will help Novo and Lilly push Bristol Myers Squibb and GSK out of the top 10 by 2028, Evaluate Pharma predicts.

Merck & Co's Keytruda is projected to become the world's top-selling drug in 2023, a status that the anti-PD-1 antibody is seen retaining until the end of this decade. This forecast does not include numbers being attached to a subcutaneous formulation that Merck has in phase 3 development; 2028 sales forecasts for that project currently sit at $2.4bn.

This class of anti-cancer checkpoint inhibitor, which also includes Bristol Myers Squibb's Opdivo, Roche's Tecentriq and AstraZeneca's Imfinzi, is a big driver of the sector's top line. After topping $40bn last year, sales generated by the anti-PD-(L)1 mechanism are seen hitting $71bn by 2028.

Incretins are also seen contributing billions of new sales in the coming years. Both Ozempic and Mounjaro have consistently beat analysts' revenue expectations, and a lot more data are due in potentially large new settings like the liver disease non-alcoholic steatohepatitis, or NASH.

To read the full World Preview report, scan the QR code. You'll find more data, analysis and commentary on the key issues.

IRA Looms Large

The US Inflation Reduction Act is behind many of the uncertainties tainting pharma's growth prospects. Products without generic competition and which have been on the market for a minimum of 9 years (for small molecules or NDAs) or 13 years (for biologics/BLAs) will be subject to price negotiation.

Price negotiations on older drugs – though attracting the most attention – aren't the only threat to pharma's bottom line; the above inflation price rise limits could do as much, if not more, damage.

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www.evaluate.com | 🐦 **@EvaluatePharma**

Evaluate Headquarters
Evaluate Ltd.
3 More London
London SE1 2RE
United Kingdom

T +44 (0)20 7377 0800

Evaluate Americas
EvaluatePharma USA Inc.
265 Franklin, Suite 1101
Boston, MA 02109
USA

T +1 617 573 9450

Evaluate Asia Pacific
Evaluate Japan KK
Holland Hills Mori Tower 2F
5-11-2 Toranomon, Minato-ku
Tokyo 105-0001, Japan

T +81 (0)80 1164 4754