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The $120bn Biosimilar Opportunity

More than 100 biologics will lose exclusivity in the US over the next six years with combined sales of $120bn in the year before expiry. This represents a tremendous opportunity for a biosimilars market that has until now failed to realise its potential.

The coming years will yield a plethora of case studies. The lessons learned, both from the originator and biosimilar manufacturers, will govern the future direction of the biosimilar market.

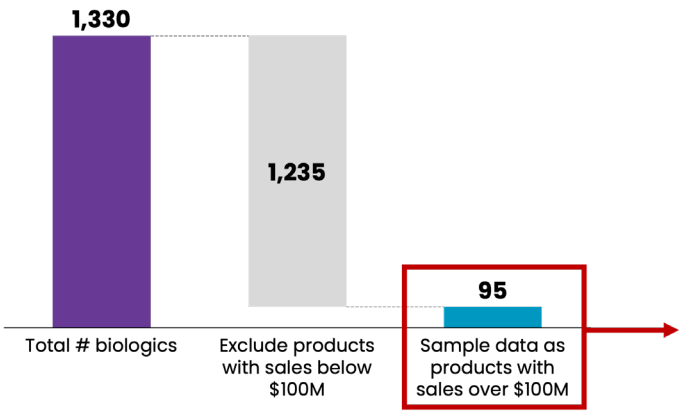
In this article, **Evaluate** dissects the opportunity ahead and theorises around how dynamic market forces such as defensive strategies, biosimilar contracting, and the Inflation Reduction Act will come into play.

More Than 100 Products with Substantial US Sales Will Enter Biosimilar Crosshairs

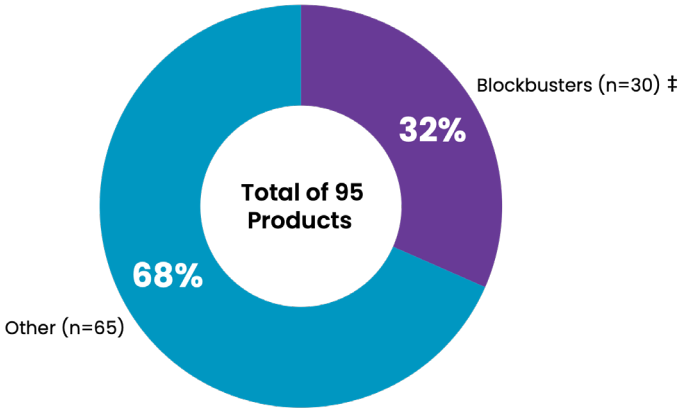
Combing through **Evaluate's comprehensive database** reveals 95 biologics with peak-year US sales of at least $100m and a patent expiry between 2024 and 2030. These are the products that can become meaningful revenue generators and form the biosimilars pipeline. Among these include 30 blockbusters, with Keytruda ($18.3bn), Darzalex ($9.5bn), Opdivo ($6.3bn), Eylea ($6.3bn), and Ocrevus ($6.1bn) the standout candidates.

Dataset Extract Based On Patent Expiry From 2024-2030

In total, **95 products with max sales* data over $100M** were included in this analysis.



Breakdown of Sample Data

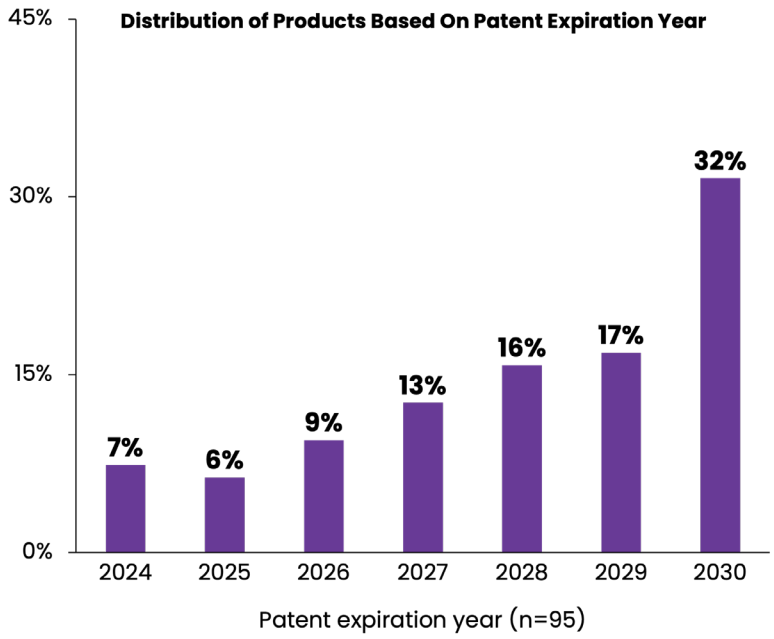


** Defined as peak sales during a product's full lifetime in the US*

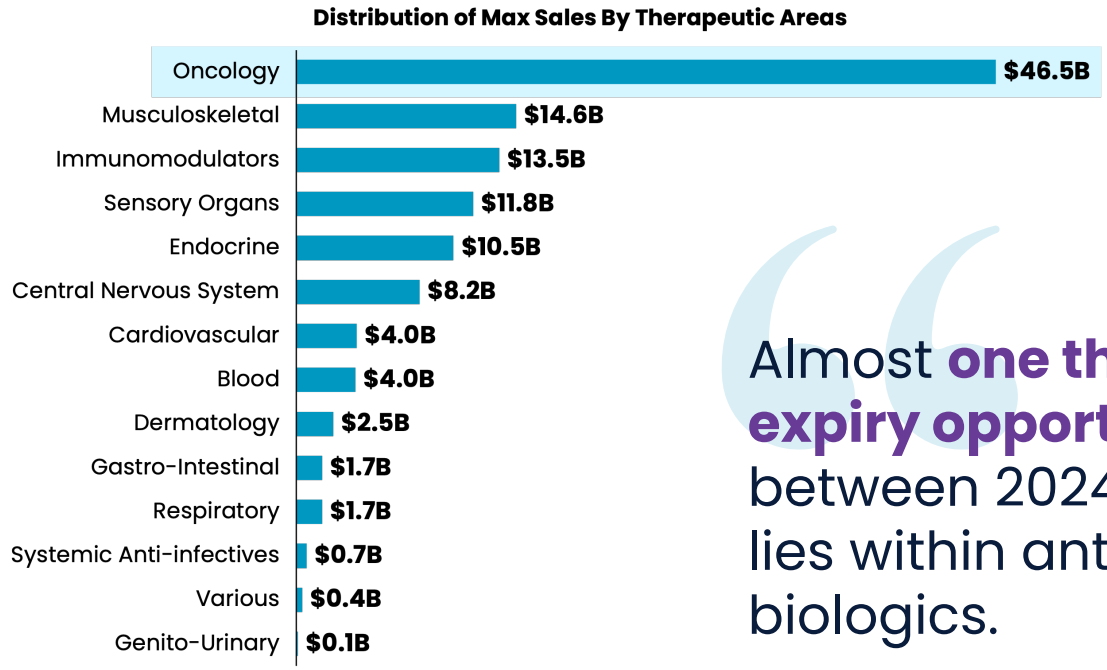
‡ Defined as products with peak sales greater than $1B

Oncology Will Be Fertile Grounds For Biosimilars

As can be expected with three out of the top five expiries, oncology will be a main focus for biosimilar developers. Almost one third of the expiry opportunity between 2024 and 2030 lies within anticancer biologics. It is also within the US oncology market that biosimilars have had the most success to date. In particular, Roche has experienced greater-than-expected erosion of its former flagship brands Avastin, Herceptin, and Rituxan.



A majority of expiry opportunities are backloaded towards the end of this decade. Just seven of the 95 high-value biologics (7%) identified will be eligible for biosimilar competition in 2024, rising to 30 (32%) during 2030. The proliferation in biosimilar opportunities will require the relatively small number of current market players to prioritise and form portfolio strategies. Clearly the scale of Keytruda's market position will allow for multiple biosimilar entrants, although there will be opportunities to be the single biosimilar source for more niche products.



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The Challenges of Hitting a Moving Target

While the total revenue opportunity stands at $120bn, this is not a market that originators will cede without a fight. Humira still remains highly lucrative – and profitable – for AbbVie despite biosimilars launching last year (and being first approved back in 2016).

AbbVie's delaying tactics aside, there are myriad defensive strategies that originators are employing to reduce the addressable biosimilar market. For Keytruda, Merck is betting on a subcutaneous formulation being sufficiently more convenient for physicians and patients in order to retain preference over intravenous copies. Regeneron gained approval for a high-dose version of Eylea that can be dosed at extended intervals, meaning that biosimilars will require more physician visits and injections. As drug design becomes more sophisticated, biologics developers are exploring techniques from fixed-dose combinations through to multi-specific and conjugated antibodies.

All of these mean that biosimilar manufacturers must be mindful of originators' lifecycle management strategies that are designed to protect market share. When prioritising the biologics to compete with, it is imperative to plan for such scenarios and model the effect they will have on the addressable market.

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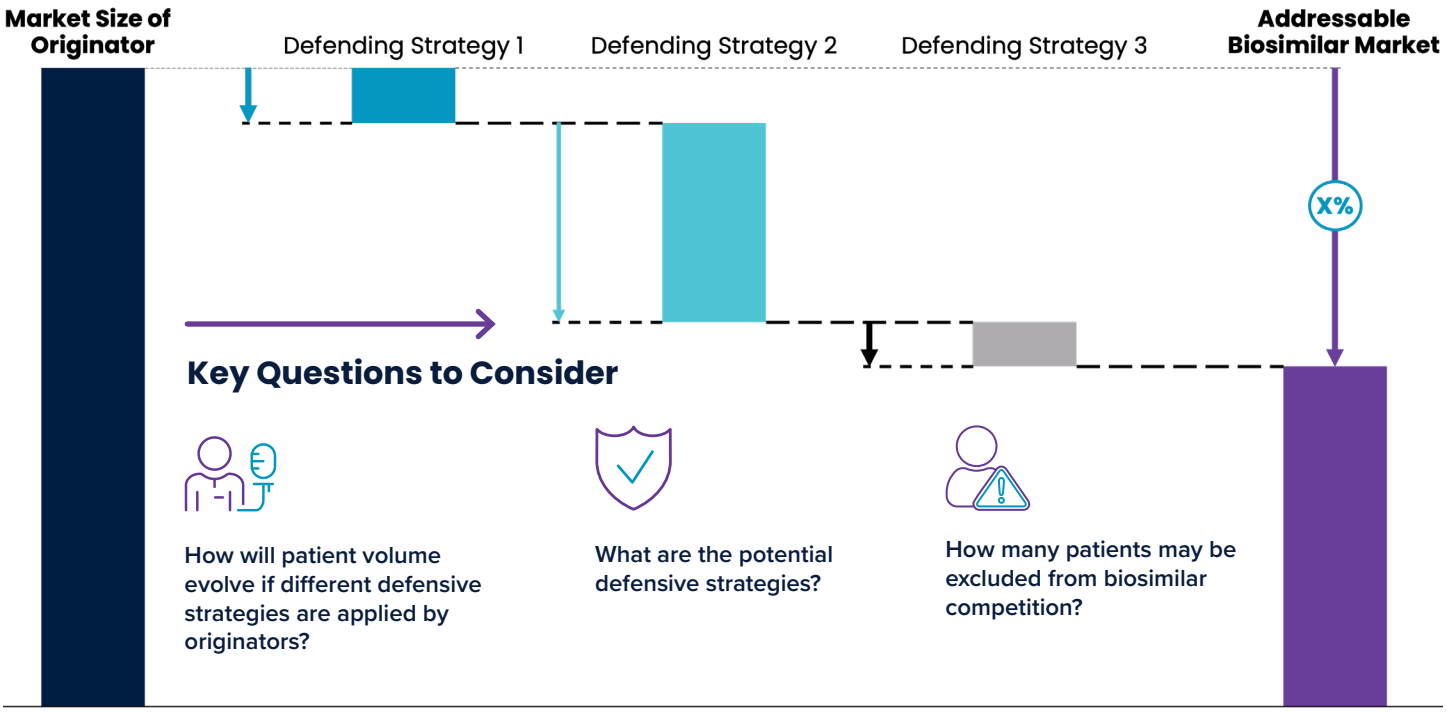


Biosimilars Must Contend With Setting The Right Price

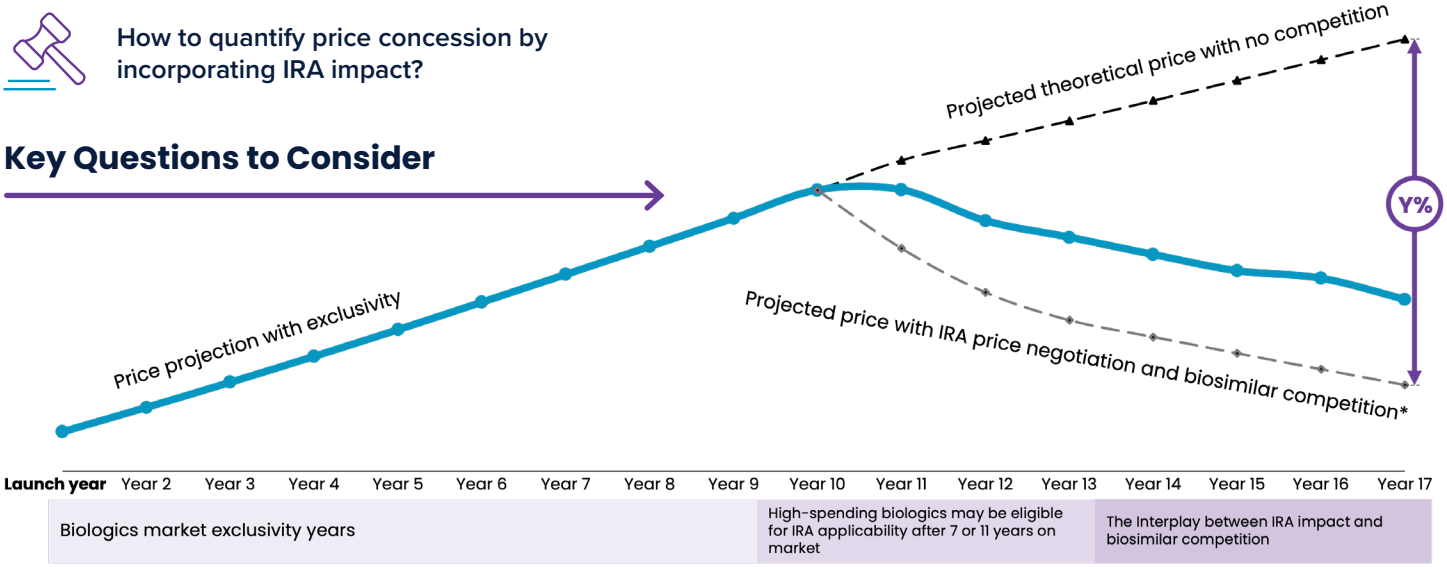
It is a real challenge to set a price point that optimises for market share while being sustainable considering the various incentives within the healthcare system. The lowest list price does not necessarily translate to the highest market share, as the pharmacy benefit managers (PBMs) that set formularies can recoup greater rebates from higher cost drugs. 2024 has witnessed the phenomenon of PBMs contracting directly with biosimilar manufacturers in order to secure preferential formulary positioning of own-brand therapies. CVS Health has successfully grown market share of Hyrimoz (Sandoz) in such a way after dropping Humira from its formularies.

Strategic planners must also factor in the Inflation Reduction Act into the mix as many of the high-value biologics will face Medicare price negotiation prior to biosimilar entry. Drugs in the first Medicare Part D cohort are facing list price reductions of 38–79%, although this drops to 4–30% when factoring in net prices. Regardless, such price erosion limits the ability of biosimilar manufacturers to further undercut the originator brand to win market share while retaining profitability. Timing of loss of exclusivity (LOE) and/or exemption from price negotiation is critical and there will be examples of biologics that become far less attractive for biosimilars as a result.

Key Questions to Consider

How would the originator's price evolve over time?

How to quantify price concession by incorporating IRA impact?



In Summary

The biosimilars market has so far proven a difficult nut to crack, but the landscape is highly dynamic. There are a large number of LOEs in the near future, which provides a large pipeline of new launch opportunities.

Prioritisation will be critical for the biosimilar manufacturers competing for the $120bn of revenues at risk. Decision making will need to factor in strategies to defend originator market share, as well as careful consideration of pricing strategy. Contracting agreements with payers, providers, and PBMs is an important step to win market share, although price erosion must be managed.

Look for lessons in the upcoming spate of biosimilar launches for the key success factors that either enable strong biosimilar uptake, or allow for originator brands to successfully protect revenues. **Evaluate** is actively working with pharmaceutical companies on both side of the equation to secure positive outcomes for their business. If you would like to learn any further about our capabilities and case studies in this space, **please get in touch**.

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www.evaluate.com

Evaluate Headquarters
T +44 (0)20 7377 0800

Evaluate Americas
T +1 617 573 9450

Evaluate Asia Pacific
T +81-80-1164-4754

Authors

Sheila Li, Senior Consultant | Evaluate

James Drew, Senior Manager | Norstella

Daniel Chancellor, VP Thought Leadership | Norstella

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