Growth of the US biosimilars market - Key trends and opportunities

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Advisors

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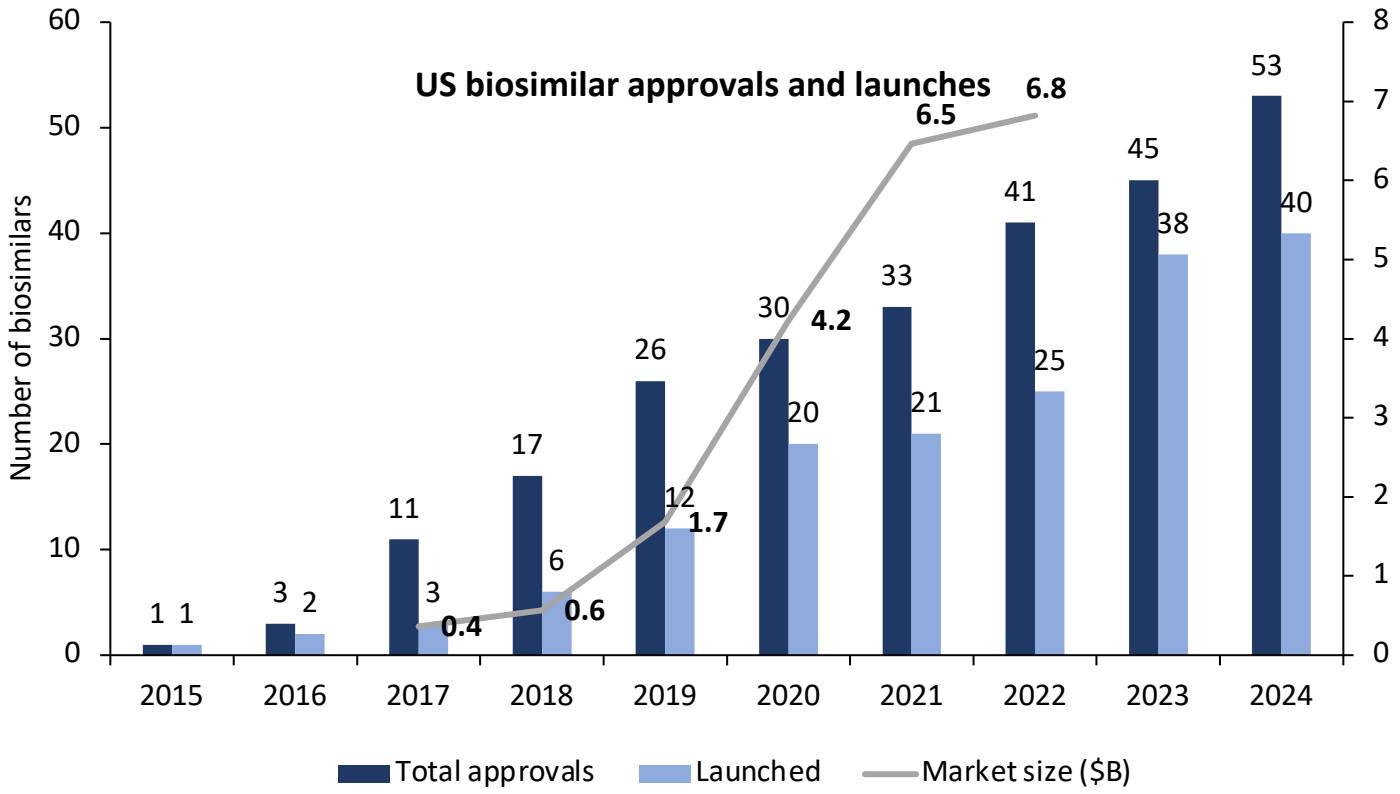
- Biosimilars have yielded a $21B savings in healthcare spending in the US
- With twice the number of biosimilars approvals in the last 5 years as compared to the previous years, US biosimilars sales have reached ~$7B in 2022
- Recent biosimilars have achieved market shares >50% within just 2-3 years of launch
- The originators' attempts to retain market share and compete with the biosimilars are diminishing
- Marketplace is now evolving as the biosimilar success is extending beyond innovators to generic players
- Innovators like Pfizer, Boehringer, and Coherus are shifting their focus to innovation, paving the way for generic and specialty biosimilars companies
- Generic and specialty biosimilars players have opportunity to capitalize on the biosimilars' market potential

Biosimilars have led to ~$21B in healthcare savings in the US alone, over the last 7 years

	Early 2010s	Late 2010s- Present
Development	▪ Clinical development consisted of more than 1 phase 3 trials for a broader approval ▪ Phase 3 trials involved a large and geographically diverse patient population ▪ Developing a single biosimilar could take up to 10 years and $200m+	▪ Biosimilars approved based on only 1 pivotal phase 3 trial ▪ Phase 3 trials are now conducted with a third of the patient population as compared to that required in the last decade ▪ Biosimilar development timelines and cost are now reduced to >50% as compared to the last decade
Regulatory framework	▪ Uncertainty around regulatory requirements caused companies to conduct extensive trials ▪ An abbreviated pathway and guidelines for the development of biosimilars providing clarity were introduced about a decade back, albeit with some ambiguity	▪ Regulatory pathway streamlined ▪ Certain agencies, for instance, MHRA, are further adapting, moving towards approvals based solely on Phase 1 trials; US may follow soon ▪ Geography-specific trials no longer mandated ▪ Biosimilar players now use other biosimilars as comparators, reducing development costs
Market acceptance	▪ Only a few players ventured into biosimilars due to the development uncertainty, and high time and cost commitment ▪ The prescribers were hesitant about the safety of biosimilars	▪ Prescribers are becoming increasingly aware and confident of biosimilars ▪ Biosimilars are now rapidly penetrating the market with 50%+ market shares within 2-3 years of launch ▪ Originators, focused on innovation, show limited resistance to competition from biosimilar players

Source: Amgen report, secondary research, MP Analysis

Increasing number of approvals and launches demonstrating that the US biosimilar market is now opening up



By 2022, ~$20B of the US biologics market already faced competition from biosimilars

25 biosimilars targeting 6 molecules achieved ~$7B in sales driven by the 2019 inflection point of Trastuzumab, Rituximab, and Bevacizumab launches

An **additional $35B biologics market is expected to face biosimilar competition in the next 4-5 years** with launches including Adalimumab, Tocilizumab, Ustekinumab, Aflibercept, Natalizumab, Denosumab, and Eculizumab biosimilars

Source: Secondary research, MP Analysis

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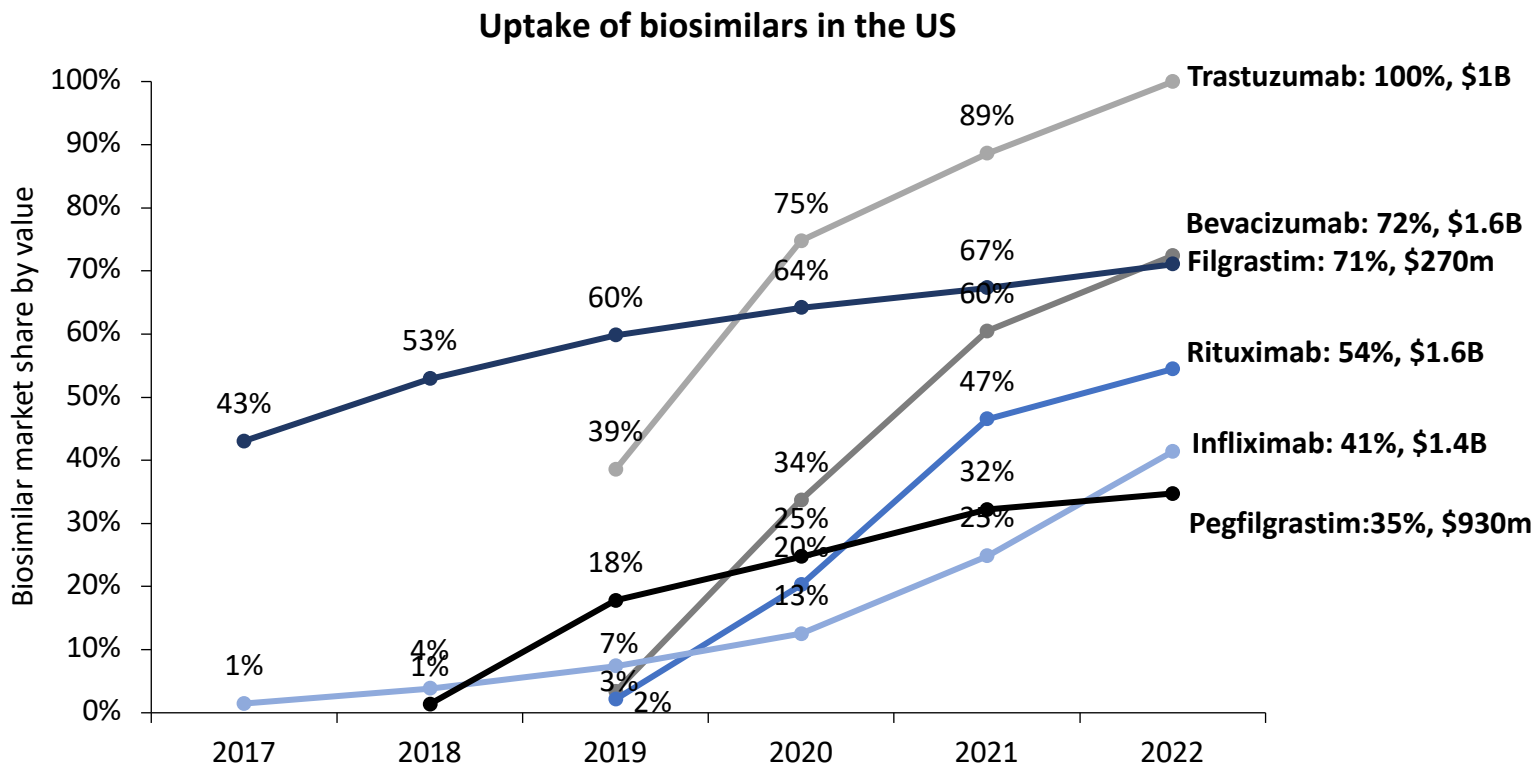
Biosimilars are capturing significant market share in the US

Recent biosimilars have captured 50%+ market share within 2-3 years, unlike early ones like filgrastim, infliximab, or pegfilgrastim



Biosimilars have achieved sales exceeding $1B for most molecules, involving 3-5 players, while originators' efforts to retain market share have diminished over time

There is now visibility on the launch of biosimilars, with exceptions like adalimumab and etanercept experiencing longer delays in IP and litigation settlement

Source: IQVIA Database, secondary research, MP Analysis

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The attempt of originators to retain share is decreasing over time

The market shares of biosimilars over the last 3 years indicate reducing efforts from the originators to retain market share

Product	Originator price decline	Originator share#	Biosimilars launched	Avg Biosimilar discount*	Biosimilar share#
Filgrastim	13%	29%	4	49%	71%
Infliximab	47%	59%	3	10%	41%
Pegfilgrastim	33%	65%	4	28%	35%
Trastuzumab	14%	<1%	5	48%	100%
Rituximab	7%	46%	3	30%	54%
Bevacizumab	10%	28%	3	40%	72%

*Discount to existing innovator price
Share by value

Increased competition has led to higher discounts for biosimilars, typically ranging from 30% to 50% over current originator prices

Recent biosimilars launches have seen limited efforts from the **originators to increase discounts to compete**, resulting in a majority biosimilar market share

However, earlier launched **Infliximab and Pegfilgrastim are exceptions with slower uptake** due to significant price cuts by originators and physician preferences

Source: IQVIA Database, secondary research, MP Analysis

Marketplace is now evolving as the biosimilar success is extending beyond innovators to generic players

Early movers benefit, but late entrants are achieving $150m+ annual revenues within 2-3 years of launch, even with a 5-10% market share

Product	Originator	BS 1	BS 2	BS 3	BS 4	BS 5
Bevacizumab	Roche	Amgen 41%	Pfizer 31%	Amneal <1%		
Rituximab	Roche	Teva 24%	Pfizer 28%	Amgen 3%		
Trastuzumab	Roche	Amgen 55%	Viatris 10%	Pfizer 28%	Teva 2%	Organon 6%
Infliximab	JnJ	Pfizer 30%	Organon 7%	Amgen 5%		
Filgrastim	Amgen	Teva* 14%	Sandoz 44%	Pfizer 13%	Amneal <1%	
Pegfilgrastim	Amgen	Viatris 7%	Coherus 12%	Sandoz 12%	Pfizer 4%	

* Not approved via biosimilar pathway, technically not considered a biosimilar

While historically Amgen and Pfizer dominated the market, generic players are now witnessing success

- Teva has $700m+ in revenues from 2 biosimilars
- Viatris and Organon have $250-300m in revenues from 2 biosimilars (<10% share)

Market is opening up for generic players as key innovators strategically exit biosimilars

- Pfizer, Boehringer, Coherus, etc. are shifting their focus to innovation
- Companies such as Valorum Biologics and Cordavis are founded solely to focus on promoting biosimilars aiming to capitalize in this oligopolistic market

Source: IQVIA Database, secondary research, MP Analysis

The US biosimilars market offers a significant opportunity to create value for the generic and specialized biosimilar players

	Future outlook
Biosimilar development	▪ Phase 1 PK PD data will form the foundation of approvals, offering a potential shift away from extensive phase 3 trials ▪ Development times are expected to reduce significantly to 2-4 years with low to mid-double-digit million-dollars investments
Regulatory framework	▪ Robust product characterization along with Phase 1 data demonstrating clinical similarity may waive Phase III studies ▪ Clinical trials may not be needed for interchangeability designation if analytical characterization supports the demonstration of a highly similar molecule; the recent draft guidance in June 2024 removes switching study requirements for biosimilar interchangeability
Market uptake	▪ Players with vertically integrated capabilities are likely to reap the maximum benefit from the market ▪ A portfolio of biosimilars will offer a better negotiating position with the PBMs, while justifying capital investments ▪ The biosimilar market will not be limited to innovators, MNCs or first movers; generic players and late entrants are already witnessing success ▪ Newer players like Valorum Biologics and Cordavis have entered to promote biosimilars, further validating the market potential ▪ With 5-10 biosimilars competing against high-value biologics and anticipated discounts exceeding 80%, the biosimilar market will enhance patient access and result in billions of dollars in savings ▪ Generic players are positioned to compete on cost and show promising potential in the US biosimilar market

Source: MP Analysis

How can MP Group help?

With over 3 decades of diverse experience and integrated perspective in the global biopharma space, and a deep understanding of the biosimilars space, MP Group can catalyze your biosimilars initiative

MP Team will be happy to be an extension of the management team and support the following:

- Catalyze the growth and expansion strategy of your biosimilars initiative for long-term success
- Market and product portfolio due diligence
- Comprehensive market landscaping and competitive intelligence to identify potential opportunities
- Leverage MP's global network to identify potential below-the-radar opportunities for partnering or investment, unique to the vision of the company
- Deep-dive assessment of specific opportunities
- Technical due diligence of the target of your interest

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>75% Returning client's that engage us frequently

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Thank you

We invite you to write to us -

Viren Mehta
mehta@mpglobal.com

Neel Fofaria
neel@mpadvisor.com

Astha Tanna
astha@mpadvisor.com

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