evotec

DRUG
DISCOVERY
INSIGHTS

DDin

Just – Evotec Biologics launches tech partnership for biosimilars development and commercial manufacturing

Maximizing collective expertise to expand global access

2023/05

Partnership supports our mission to provide global access to important biotherapeutic medicines

Just EVOTEC BIOLOGICS + SANDOZ A Novartis Division

Mission/Rationale

- Long-term tech partnership aspires to disrupt the biosimilars market with affordable and accessible highest-quality medicines
- Just – Evotec Biologic to bring AI-driven, fully integrated tech platform and continuous manufacturing and Sandoz leading biosimilars pipeline and capabilities
- This collaboration is uniquely structured and marks a step-change in the CDMO environment
- Transformative two-pronged agreement secures highest flexibility in aligning the needs of both companies

Agreement with Sandoz

- Multi-year, long-term tech partnership for the immediate development and subsequent manufacturing of multiple biosimilars
- Option for the non-exclusive in-licensing of Just – Evotec Biologics' proprietary J.DESIGN platform process development and continuous manufacturing technology by Sandoz for building its fully-owned S.POD facility (in analogy to Just – Evotec Biologics' state-of-the-art J.POD® facilities).
- The development of the biosimilars will ramp up over the coming 12-18 months in a highly collaborative fashion at Just – Evotec Biologics' J.POD® facilities
- Just – Evotec Biologics to receive double-digit-million upfront, future payments dependent on successful development progress of US$ 640 m, additional undisclosed payments dependent on progress into commercial manufacturing and exercising the S.POD option

Biosimilars – Facts & Figures

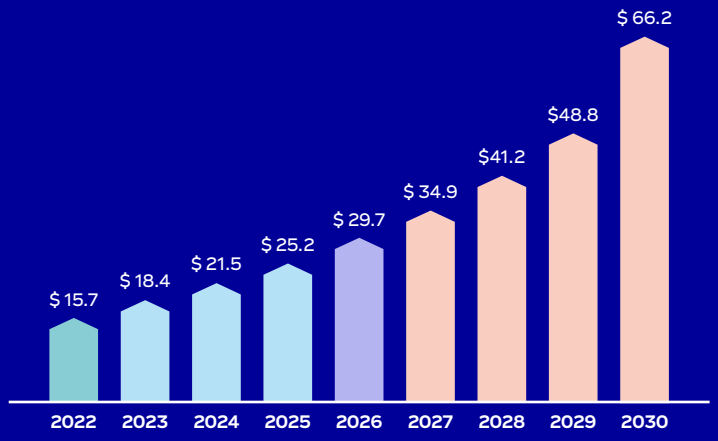
A biosimilar is a biologic medication, it is highly similar to a biologic medication already approved by the FDA and/or EMA.

Biosimilars also have no clinically meaningful differences from the reference product. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product.

For biosimilars to be approved by FDA, studies must show that there are no differences in the safety and effectiveness of biosimilars and the original biologics.

The biosimilar market size was about $ 15 bn in 2022 and is estimated to grow at a registered CAGR of >15% till 2030 to more than $ 60 bn.

Biosimilars Market Size, 2022 to 2030 (US$ billion)



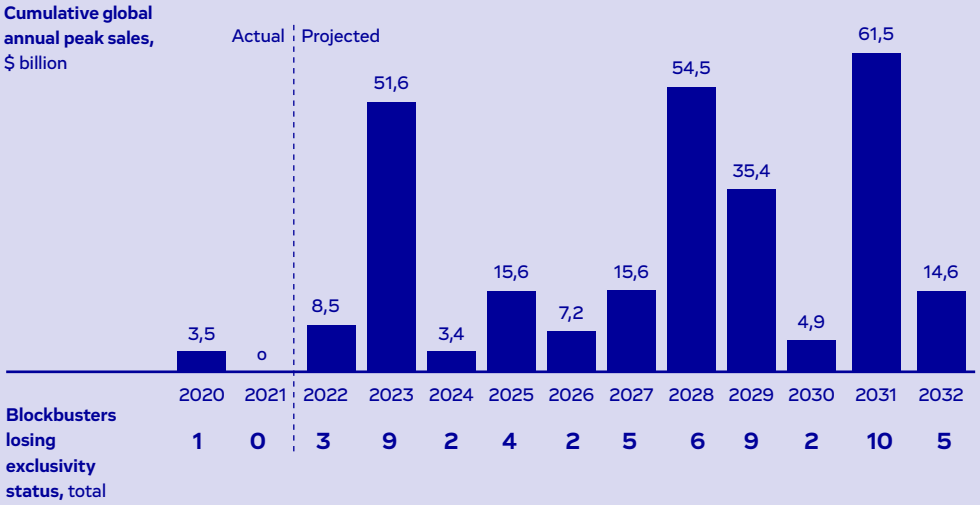
Reference: https://www.precedenceresearch.com/biosimilars-market

Perfect time for this collaboration to step into the biosimilar market

There are currently 40 approved biosimilars by the FDA, with the first approval taken place in 2015. The EMA has approved 86 biosimilar medicines since 2006.

Number of approvals is expected to raise significantly in the next decade but with cost pressure – our tech partnership is focused on that.

>50 blockbuster drugs losing exclusivity till 2032

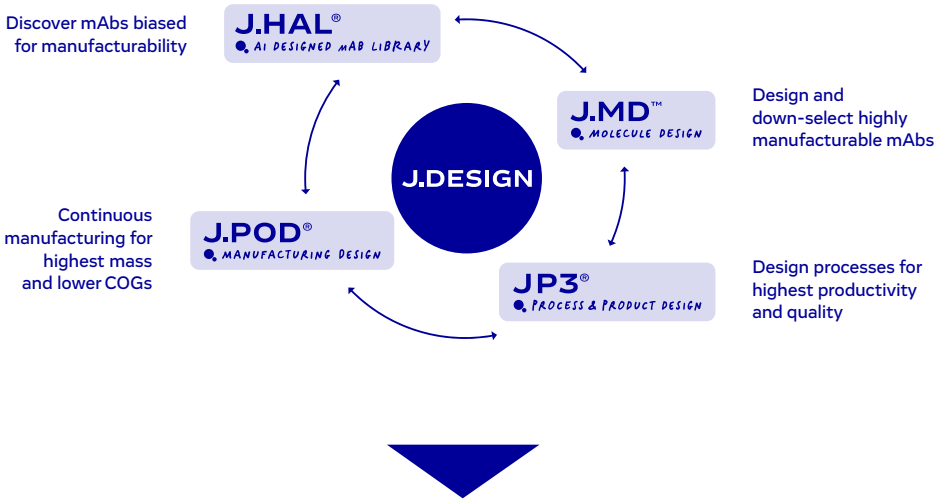


Reference: https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars

40 approved biosimilars by FDA for just 11 reference products
→ absolutely essential to bringing down manufacturing COGS (see page below) to be competitive

Just – Evotec Biologics

A paradigm shift in biologics



Best-in-class facility design

+

Continuous manufacturing

+

High-end process development

+

Latest molecular design & discovery

× **A.I./M.L./ Automation**

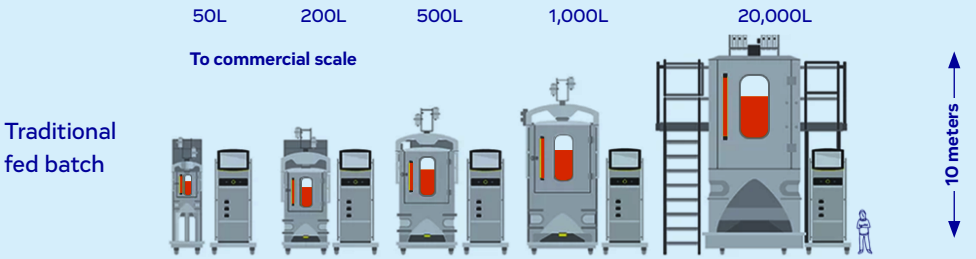
J.POD® – best-in-class biologics facility worldwide

Lowest COGS in terms of US$/g will allow:

- Underserved indications and multiple combination treatments
- Access to underserved populations and stress reduction for healthcare systems
- Access to life saving therapies for underdeveloped regions
- Rapid response in global health & pandemic situations

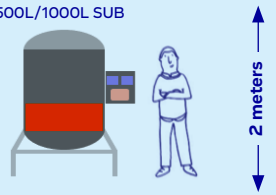
Quality & agility as key factors

1. No need to scale up from clinical to commercial



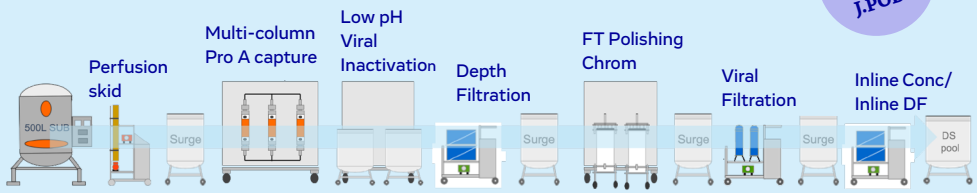
Just EVOTEC BIOLOGICS

No need to scale up to make more mass



3. Add additional trains/capacity in < 12 months

Up to 6 per J.POD®



500L or 1000L bioreactor

Potential for one polishing step

Continuous VF and formulation

Additional trains can be added into an existing facility

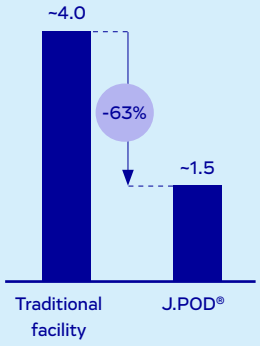
- Maximum flexibility for build out of facilities
- Limited CAPEX at the beginning
- Fully adjustable to clinical and market needs

Less than 12 months

2. Ability to build a new J.POD® facility < 24 months

Time to set up a J.POD® is short

Years



4. Change over time between products < 2 days

Change over (from product A to B) in manufacturing is fast