

Gedeon Richter Biotechnology (BIO) Business

13 March 2024



Richter Biotechnology – Executive summary

- The Biosimilar opportunity: the fastest growing subsegment in pharmaceuticals, as more than 40 biological blockbusters (USD 1bn+) with total global sales volumes of USD 200bn+ are expected to lose exclusivity in the next 10 years
- Richter biosimilar strategy: carefully selected proprietary biosimilar development projects combined with strong biological manufacturing capability and a growing complementary CDMO business
- Richter biosimilars today: a balanced pipeline with two commercial products (teriparatide & FSH); one with successfully completed clinical phase ahead of filing for registration (denosumab); one in phase-3 (tocilizumab) and several pre-clinical candidates
- BIO assets in Hungary: state-of-the-art mammalian cell expression based DS (Drug Substance) R&D and manufacturing capability; fill & finish DP (Drug Product) capability in addition to medical device assembly
- BIO assets in Germany: high quality microbial R&D and manufacturing CDMO capabilities; three sites, one undergoing a major capacity expansion; teriparatide biosimilar DS manufacture
- BIO assets in Germany: HELM transaction allows the exit of the long-time partner and raises Richter's ownership to 100%
- Formycon deal: a new partner with an equity link to jointly explore development, manufacturing and commercial opportunities along the whole biosimilar value chain

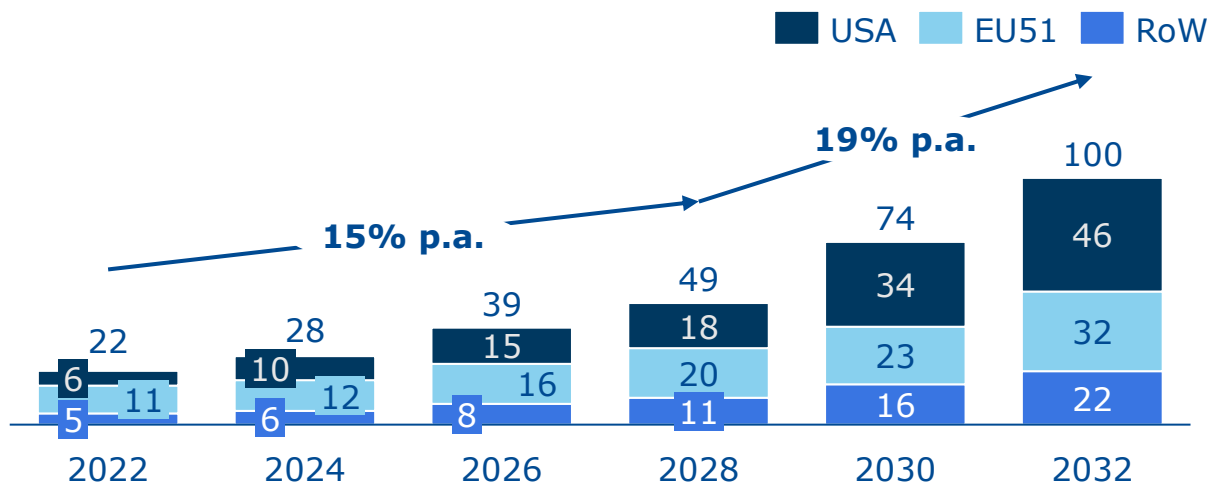


The Biosimilar opportunity

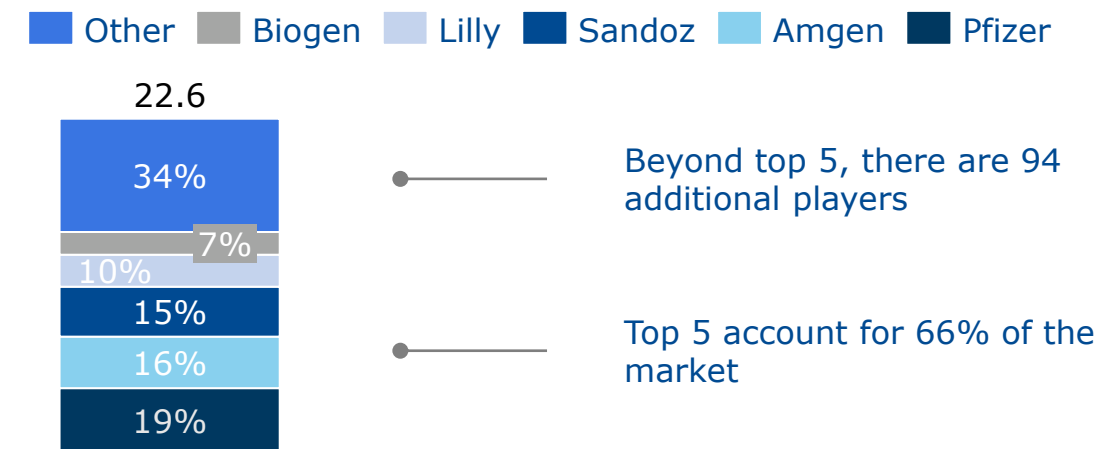


15% CAGR of the biosimilar market mainly driven by 50+ blockbuster LOEs until 2031

Total Biosimilars net sales (in USD bn)



Market concentration (% of total gross sales)



Biologics LOEs 2022-2031

50+

Assets with >1bn LOE sales over next 10 years

\$210+bn

Cumulative peak sales for products going off-patent between 2022-31



Biosimilar strategy and proprietary development assets



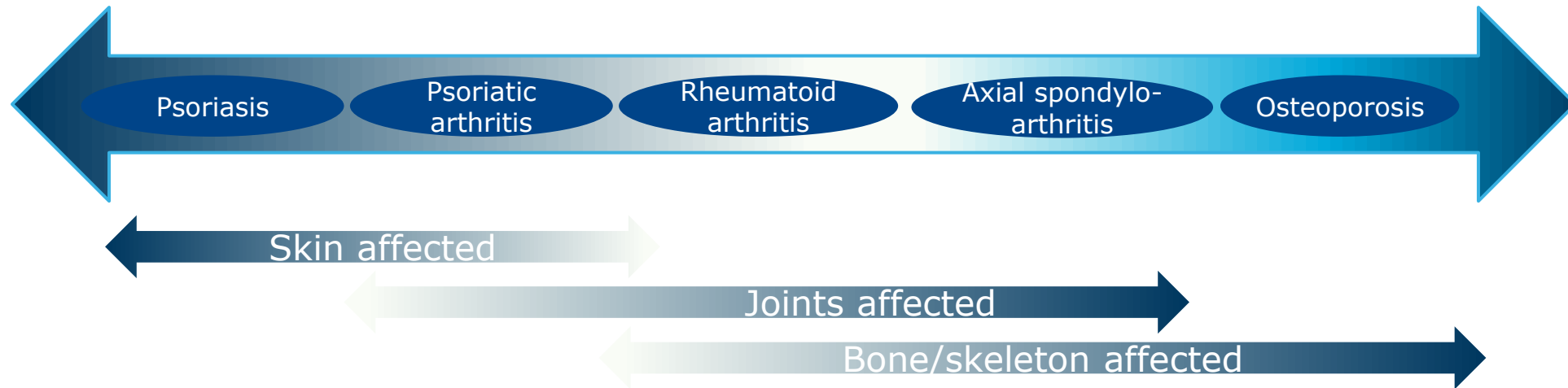
Gedeon Richter Biotechnology business unit focus



Development and manufacturing of Biosimilars / Biologics
















Commercialization of Biosimilars / Specialty products for treatment of Rheumatology, other Auto-immune diseases and Osteoporosis (RIO) in Europe and Australia



Biologics CDMO services (microbial & mammalian)

Gedeon Richter Biosimilar portfolio and product pipeline

Molecule	Indication	Originator	Early CMC dev	Late CMC dev	Clinical dev	Submission	Commercial
BEMFOLA® * r-hFSH	Infertility						
TERROSA® Teriparatide	Osteoporosis						
RGB14 Denosumab	Osteoporosis Oncology	 					
RGB19 Tocilizumab	RA						
RGB17 Romiplostim	Thrombocytopenia						
RGB20	Autoimmune						
RGB24	Autoimmune						

* Bemfola is a biosimilar product manufactured by the BIO business unit, but is marketed by and its sales are reported under the WHC business unit. Bemfola was acquired by Richter in 2016.



Richter BIO assets in Hungary



Biotechnology R&D – Budapest

- **R&D facilities cover process technology and analytical method development laboratories**
- **Full service portfolio to address small-scale and scale-up development requirements**
- Small scale process development/clone selection capabilities (AMBR – 200 L)
- Formulation development capabilities
- Broad range of analytical method development capabilities (including MS & wide array of bioassays)
- Pilot plants for both drug substance and drug product development and scale down activities
- Packaging development services
- Dedicated clinical team
- Strong regulatory affairs capabilities



Established in 2007

**Mammalian cell
expression based
R&D projects**



Mammalian cell expressed Drug Substance (DS) and Drug Product (DP) manufacturing facilities – Debrecen

DS

- 2 x 5000 L stainless steel fermentation capacity
- 4 x 2000 L single use & 2 x 50 L pilot scale bioreactors added in 2019
- Analytical services support
- Scale down development capabilities available

DP

- Syringe, cartridge, vial filling (RABS)
- Automated freeze drying
- Variable batch sizes
- Stainless steel / single use available
- Label / blister technology
- QC & QA services

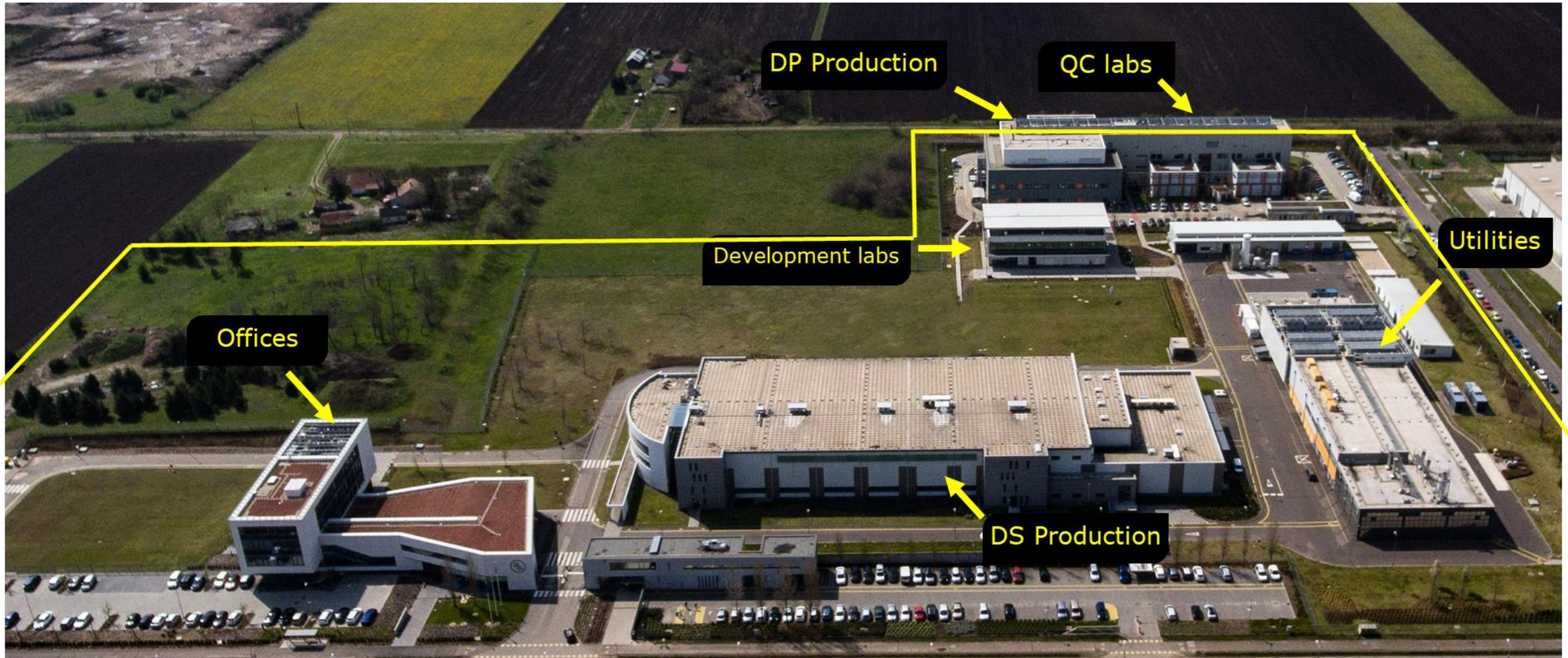


Opened in 2012
Greenfield investment
Expansion finished 2019

Mammalian cell
fermentation &
downstream processing
Fill and Finish capabilities

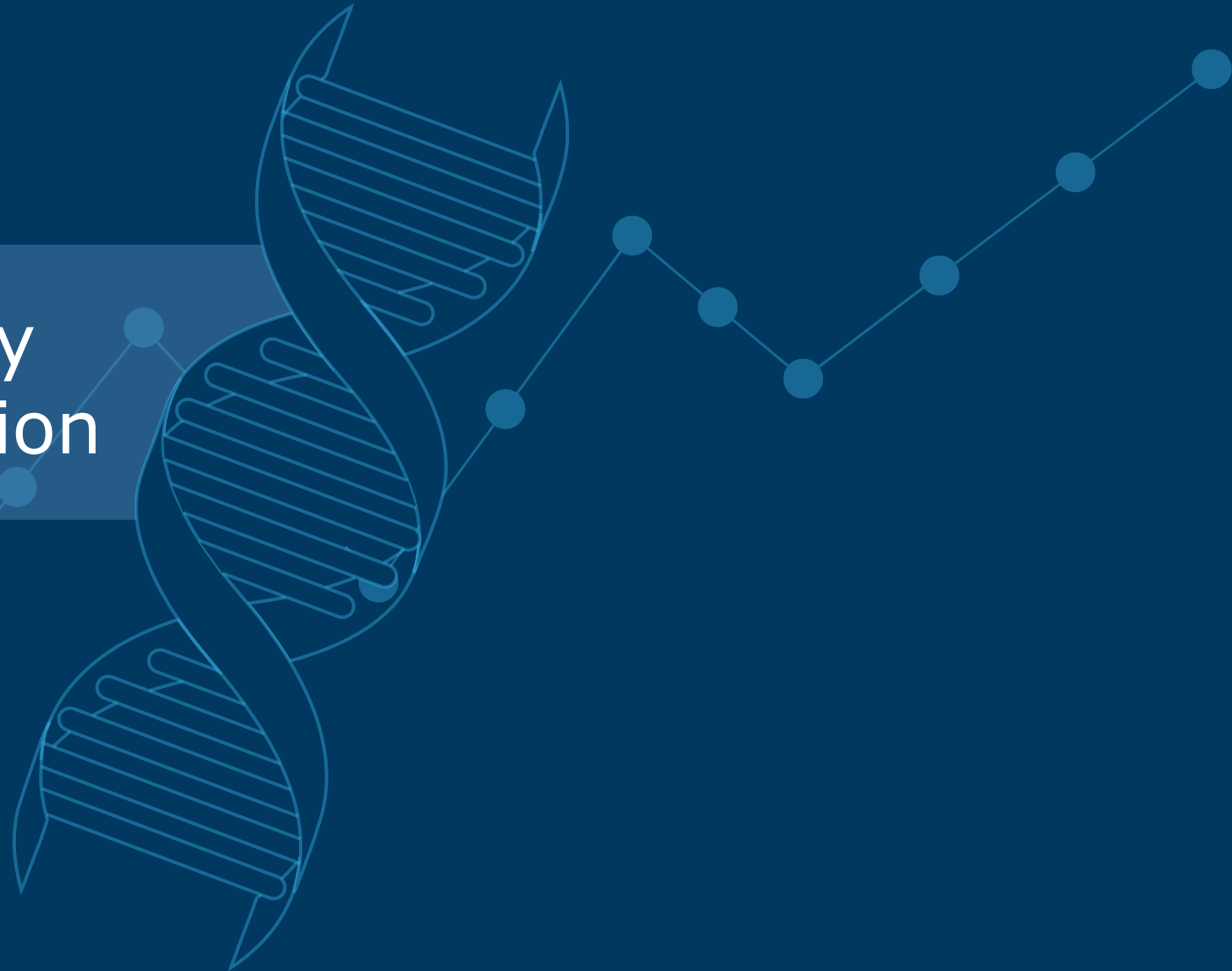


Overview of the Debrecen manufacturing site





BIO assets in Germany Richter-Helm transaction



Transaction overview

Highlights of the deal

- Richter agreed to acquire its partner's, HELM's interest in all of its German biological assets, assuming 100% ownership of both RHB (Richter-Helm BioLogics) and RHT (Richter-Helm BioTec)
- Total transaction value includes a cash payment of EUR 40.6mn for the RHB stake and EUR 71.8mn for the RHT stake, due upon closing, and further earnout payments in 2025-29, contingent on the performance of RHT
- The transaction allows Richter to consolidate its ownership and control over all biological research, development and manufacturing assets in Germany. This is at a time of completing a significant capacity expansion.
- This deal is a further step on the road towards making the Biological business unit sustainably profitable and creating value



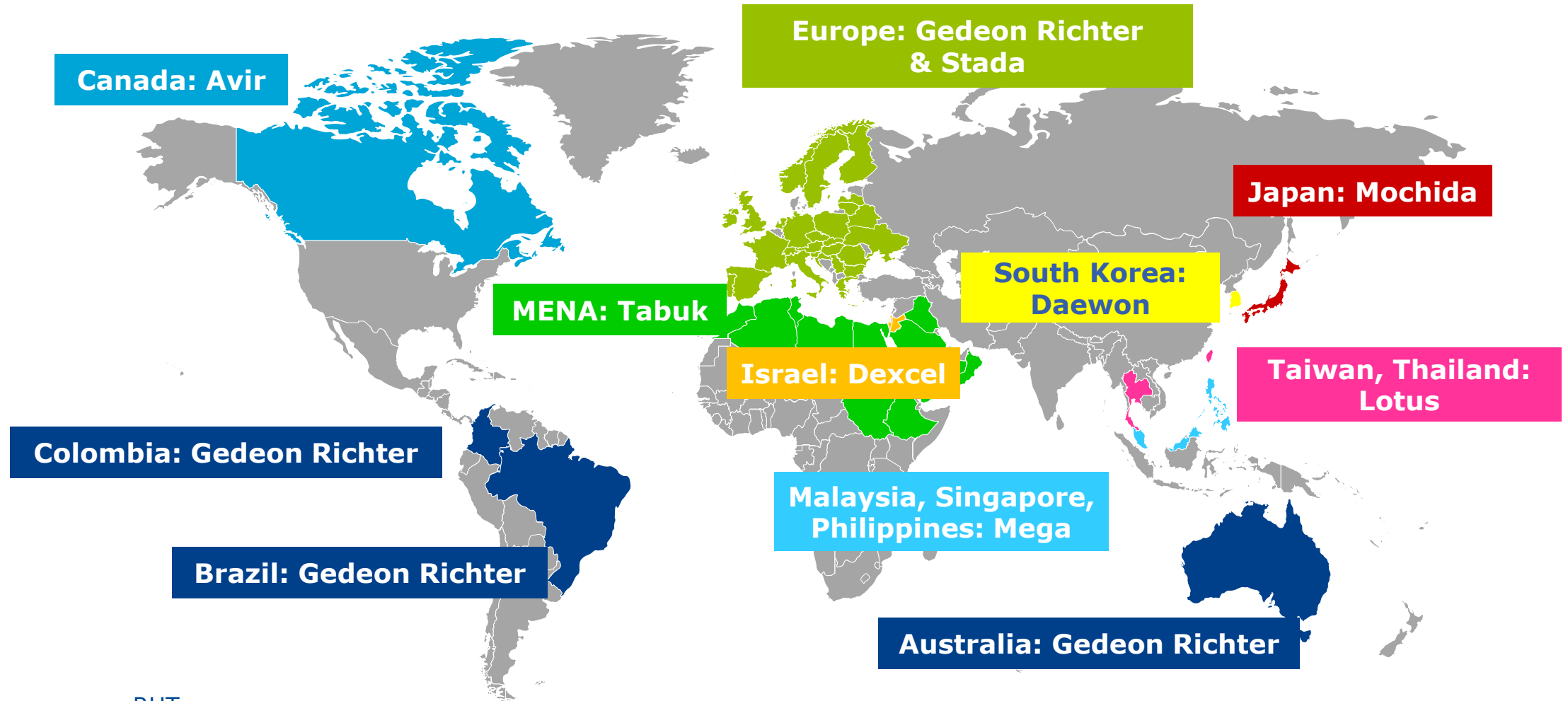
RHB - Richter-Helm BioLogics

- Leading microbial CDMO company with 3 sites in Germany, an experienced management team and 300+ associates
- Ownership structure (pre-deal): 70% Richter, 30% Helm
- Around EUR 60mn annual revenues, mostly third-party business, which is expected to grow materially after the capacity expansion
- ~25% EBIT margin
- RHB is manufacturing teriparatide biosimilar drug substance

RHT - Richter-Helm BioTec

- Legal entity with a single asset: it owns biosimilar teriparatide asset rights
- Ownership structure (pre-deal): 50-50% JV between Richter and Helm
- Once reaching teriparatide peak sales, revenues are expected to decrease over time

RHT - teriparatide biosimilar is partnered globally with overall sales of ~EUR 125mn in 2023



Licence owner: RHT

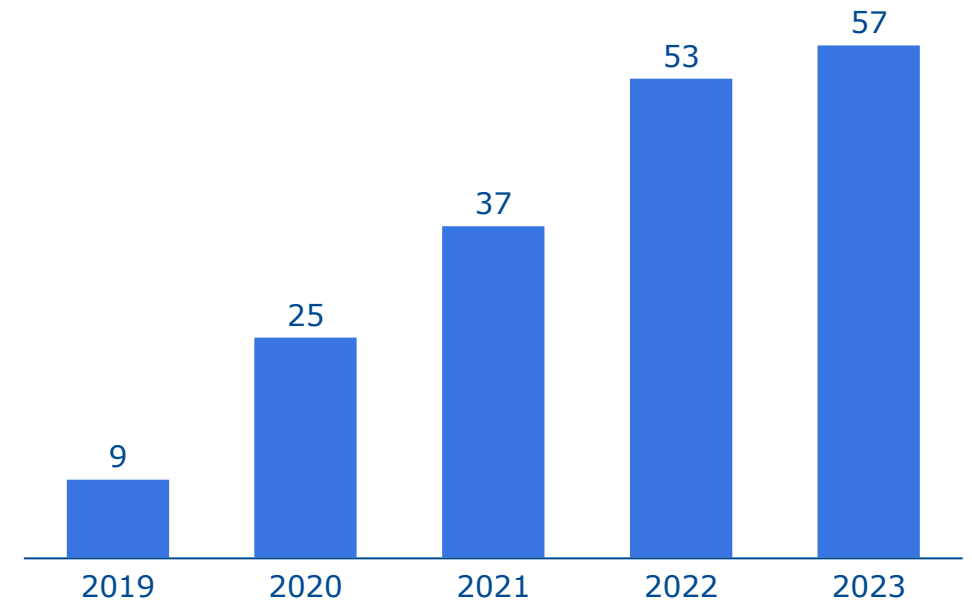
Manufactured by: RHB & Gedeon Richter

First launched in 2019 in Europe and Japan

RHT – teriparatide biosimilar; Gedeon Richter brand - TERROSA®

- PTH fragment for treatment of postmenopausal osteoporosis
- Total turnover of the molecule was close to EUR 125m in 2023...
- ...including EUR 56.8mn sales generated by Gedeon Richter through direct sales (**TERROSA®**) and partner revenues
- Additional (EUR 8.9m) were recorded as income from RHT dividends
- Primary packaging: cartridge
- Route of administration: subcutaneous injection through multiple & single dose pens (Terrosa has both)
- Originator: Eli Lilly; brand name: Forsteo®
- Geographic coverage: Europe, Japan, South Korea, Canada and other smaller markets globally
- Richter and Stada have co-marketing rights in Europe

GR teriparatide sales in 2019-23 (EUR mn)



Richter BIO facilities



RHB facilities in Germany



Bovenau

up to
1500
liter



Hannover

up to
300
liter



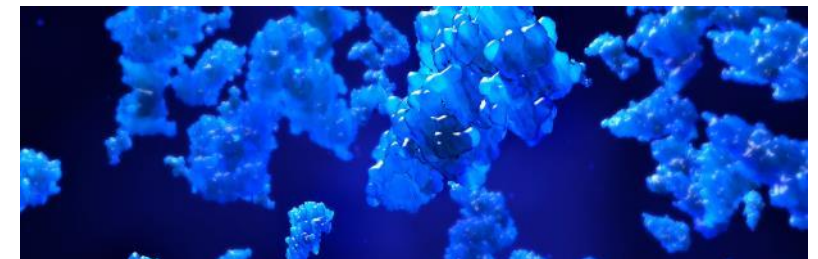
Hamburg

- Headquarters & Administration
- Development Center
- GMP Analytical Laboratories
- Non-GMP production at 10 L scale

Richter Biologics Germany (RHB) – focused on microbially expressed development & manufacture of biopharmaceuticals

Production in Bacteria

- **Recombinant proteins**
e.g. secreted, periplasmic and insoluble proteins
- **Bacterial vaccines**
e.g. attenuated whole cell vaccines
- **Plasmid DNA**
proprietary pDNA process
e.g. gene therapy, vaccines,
starting material for virus and mRNA prod.



Production in Yeast

- **Recombinant proteins**
e.g. enzymes, VHH

Microbially expressed Biopharmaceuticals production value chain

Complete Drug Substance Development & Manufacturing from one Source

Strain Development / Optimization

Process Development / Analytical Development

Process Transfer / Scale-up

Clinical Trial Supply Phase I –III

Commercial production



Development center, Hamburg

- Strain development
- Process development
- Analytical method development incl. bioassay development
- GMP compliant QC labs



GMP production plant, Hannover

- GMP compliant multipurpose facility
- Manufacturing in up to 300 L scale
- 1000 m² production area
- Manufacturing license for proteins, DNA, vaccines and chemical conjug.



GMP production plant, Bovenau

- GMP compliant multipurpose facility
- Manufacturing in up to 1500 L scale
- 4500 m² production area
- Manufacturing license for proteins, DNA and vaccines

Capacity expansion at the Bovenau site – to become operational in 2024

- New production building housing two additional production lines
 - (200L and 1000L working volume), focused on production of rec. proteins, Nanobodies, vaccines and pDNA
 - Space, connections and energies for an additional line prepared
- Increase of capacity from 40 to up to 120 batches per year
- Major increase in the number of employees
- Increase of analytical capacity on site & highest flexibility with respect to scales and products



RHB – audits and accreditations



ANVISA

Health Regulatory Agency - **Brazil**



Pharmaceutical and Medical Devices Agency - **Japan**



Ministry of Health and Welfare - **China**



Ministry of Food and Drug Safety – **Republic of Korea**



Ministry of Health - **Türkiye**



- ✓ Inspections by local German Federal State authorities:
- ✓ Audits by customers:

altogether **27** inspections since 2004
altogether **110** audits since 2004



Formycon AG



Richter became a strategic partner of Formycon AG

Highlights of the deal

- Richter became a strategic investor of Formycon AG via equity investment on 29 January 2024, acquiring 9.08% of Formycon's share capital in a cash capital increase
- The placement price per new share was EUR 51.65, total proceeds to Formycon amounted to EUR 82.84mn

Formycon in brief

- Established in 2012 in Munich, Germany
- MCAP of c. EUR 850mn, listed in Frankfurt
- A pure play biosimilar company
- 230+ employees from 31 countries, 80%+ of them engaged in R&D
- Covers all stages of biopharmaceutical development
- Formycon assets include one biosimilar product approved and launched, two product candidates currently in approval process and three in pre-clinical development
- Business model includes revenue generation through success payments and royalty streams
- Revenue guidance for 2023: EUR 75-85mn (2022: EUR 42.5mn)





GEDEON RICHTER

Health is our mission

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Financial calendar

| 25 April 2024 – AGM
| 14 May 2024 – Q1 2024 results
| 6 August 2024 – H1 2024 results
| 12 November 2024 – Q1-Q3 2024 results



<https://www.gedeonrichter.com/en/>



<https://www.linkedin.com/company/richter-gedeon-hungary/>



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