






Formycon AG

The Biosimilar Experts

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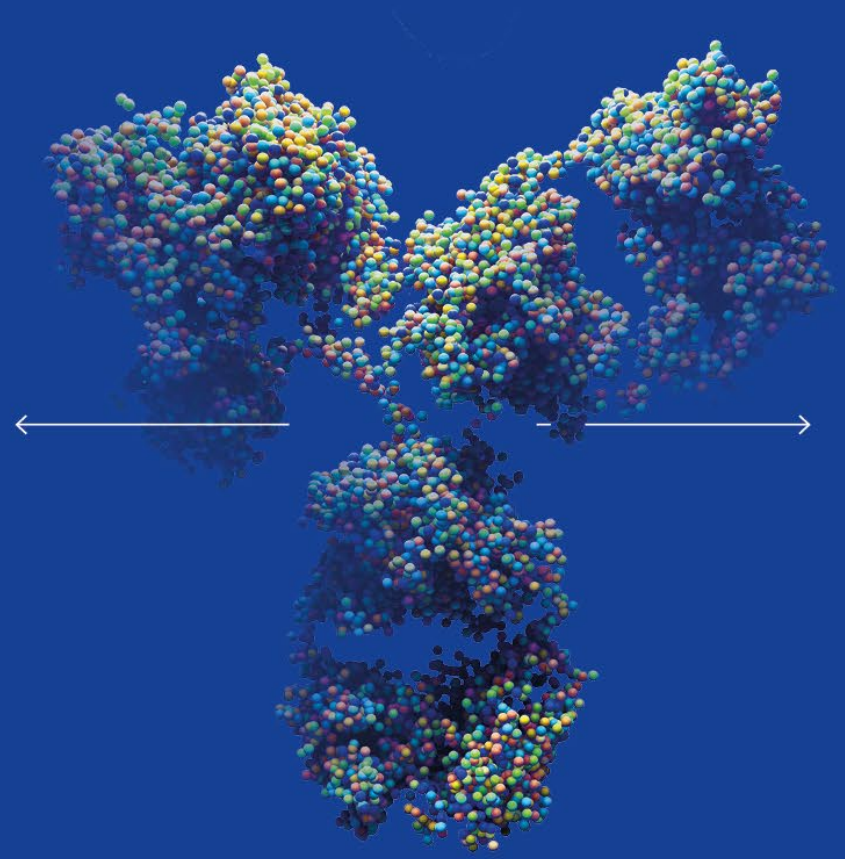
BIOSIMILAR MARKET

VISION & MISSION

Biosimilars open up enormous opportunities

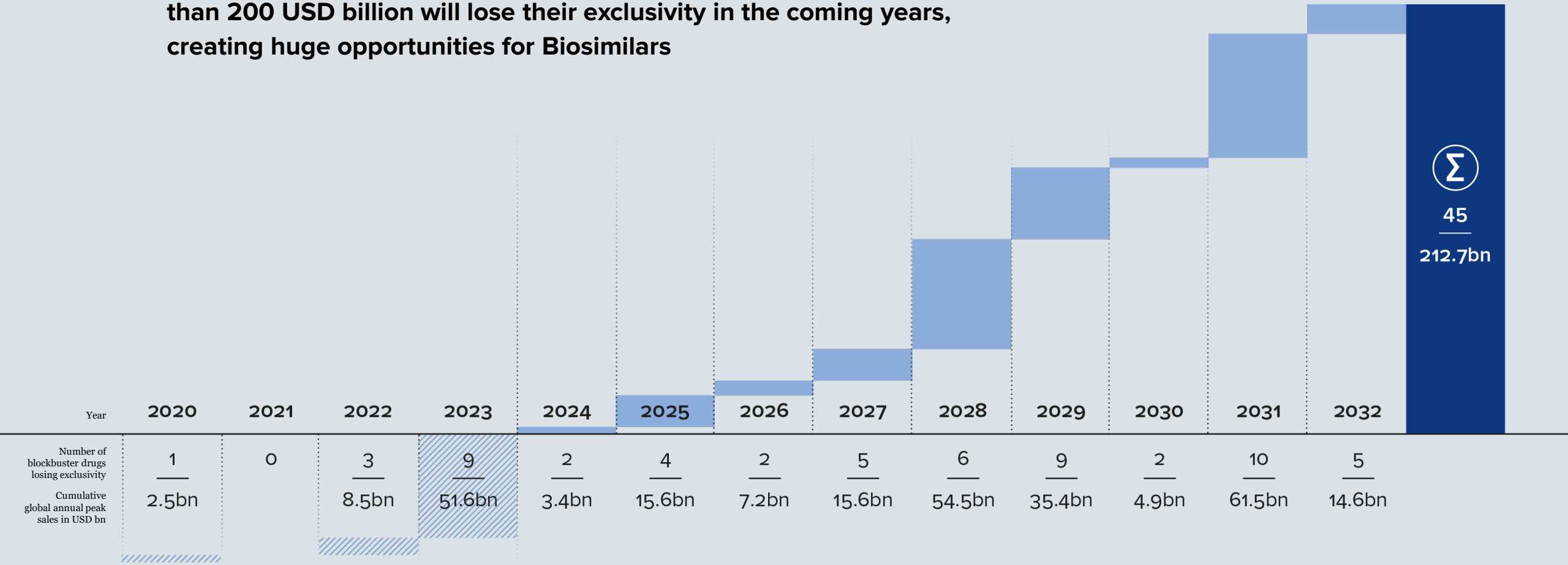
*Contributing to ease the **financial strains** on the world's healthcare systems*



*Improving **patient access** to vital medicines*

BIOSIMILAR OPPORTUNITIES

45 Blockbuster drugs with an expected global sales volume of more than 200 USD billion will lose their exclusivity in the coming years, creating huge opportunities for Biosimilars

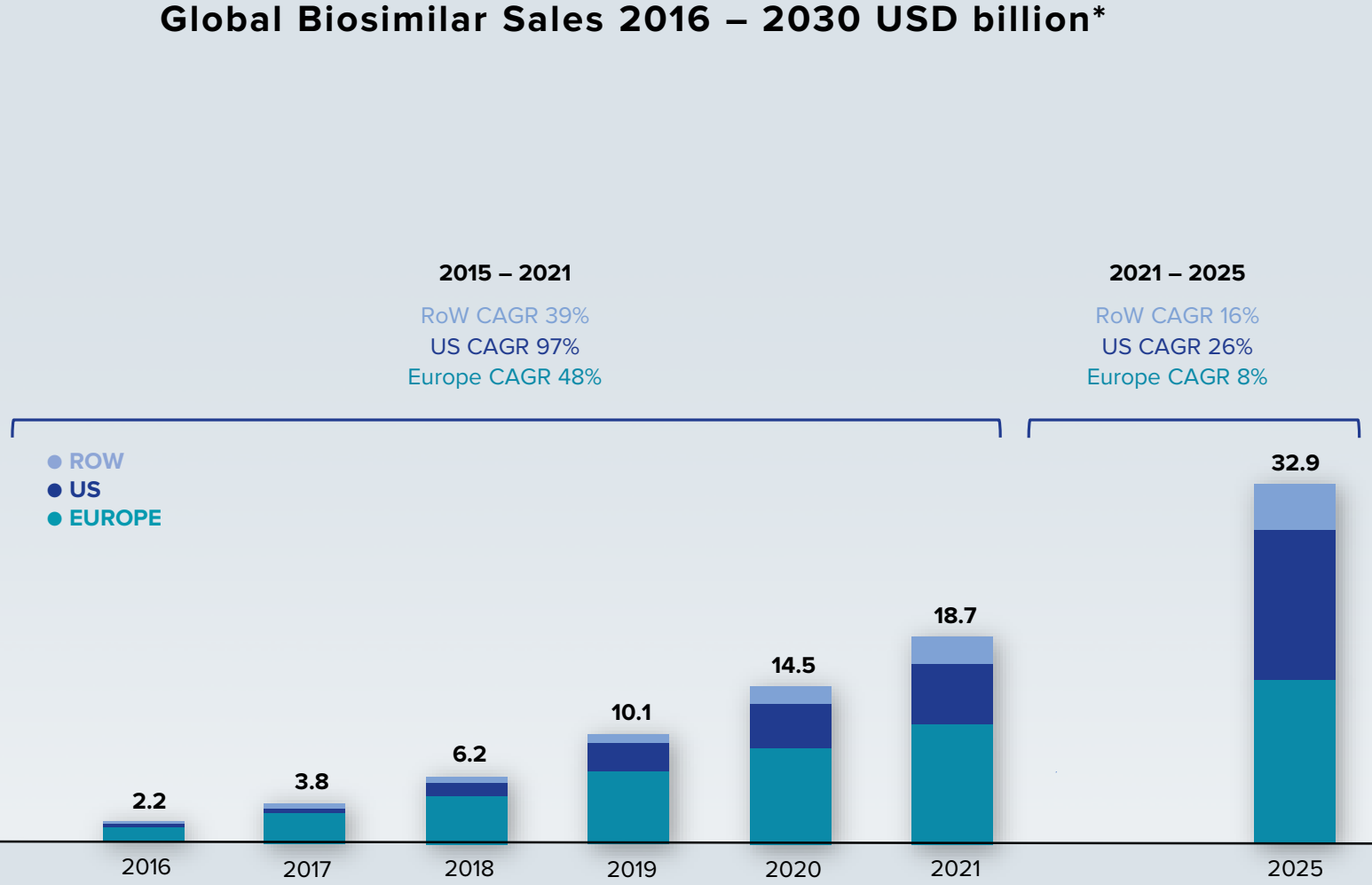


Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Σ
Number of blockbuster drugs losing exclusivity	1	0	3	9	2	4	2	5	6	9	2	10	5	45
Cumulative global annual peak sales in USD bn	2.5bn		8.5bn	51.6bn	3.4bn	15.6bn	7.2bn	15.6bn	54.5bn	35.4bn	4.9bn	61.5bn	14.6bn	212.7bn

Blockbuster is defined here as a drug with annual sales of more than $1 billion in the peak year.
Analysis based on timing of US patent expiry. Source: EvaluatePharma database, Evaluate, Apr 2022; press reports; McKinsey analysis

THE BIOSIMILAR MARKET IS HIGHLY DYNAMIC

Global Biosimilar Sales 2016 – 2030 USD billion*

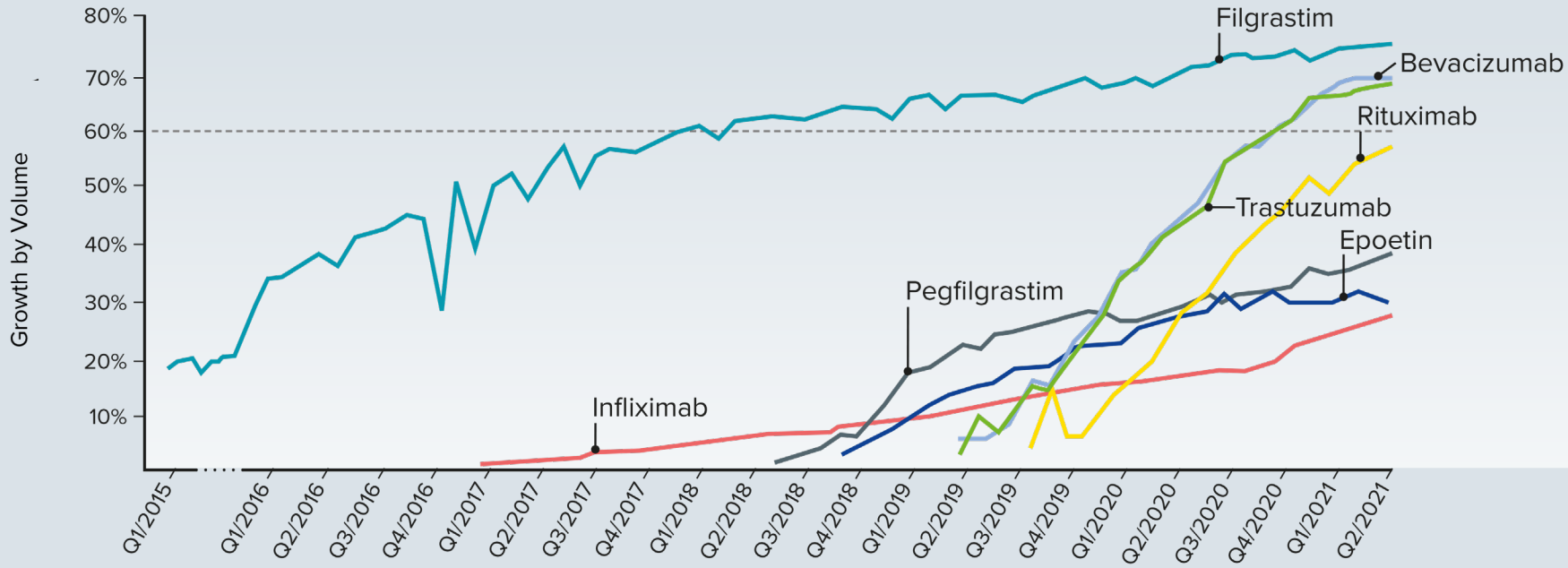


Biosimilars is the fastest growing segment in Pharma. The US market has seen the fastest growth in Biosimilars with a CAGR of 97 % from 2015 – 2021. Although projections to 2025 show a lower rate of growth, the United States is expected to stay in pole position.

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

US BIOSIMILAR LAUNCHES IN THE MEDICAL BENEFIT CHANNEL SHOW ACCELERATED UPTAKE

- For US Biosimilars launched prior to 2019, the average share after two years was **13 %**
- For US Biosimilars launched in the last two years, the average share was **65 %**!

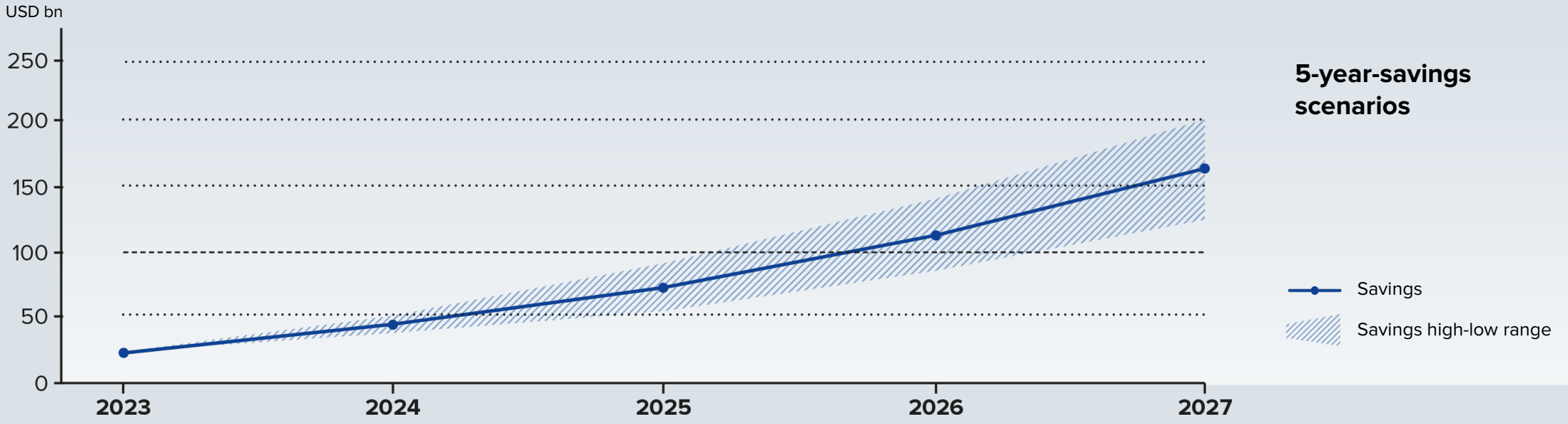


Source: Amgen 2022 Biosimilar Trend Report

BIOSIMILARS GENERATE SIGNIFICANT SAVINGS

Global savings from Biosimilars

- Annual savings could exceed USD 100bn in 2026 and 2027 as some of the largest spending biologic molecules will have well developed biosimilar competition by this time
- This level of savings will also likely mean the opening of access to relevant biologic medicines to more people globally



Source: IQVIA Market Prognosis, Sep 2022

BIOSIMILAR DEVELOPMENT

DIFFERENCES BETWEEN GENERICS AND BIOSIMILARS

New **Chemical** Entity (NCE)

Innovative
Small Molecule Drug
Development: 10–14 years
Budget: $ 1–2bn

Patent protection 20 – 25 years

Generic

Follow on version of
Small Molecule Drug
Development: 2–3 years
Budget: $ 5–10m
Clinical Study: Phase I*

Biological active ingredients are up to 1000 times larger and more complex than conventional small molecules

New **Biological** Entity (NBE)

Innovative
Biopharmaceutical Drug
Development 10–14 years
Budget $ 1–2bn

Patent protection 20 – 25 years

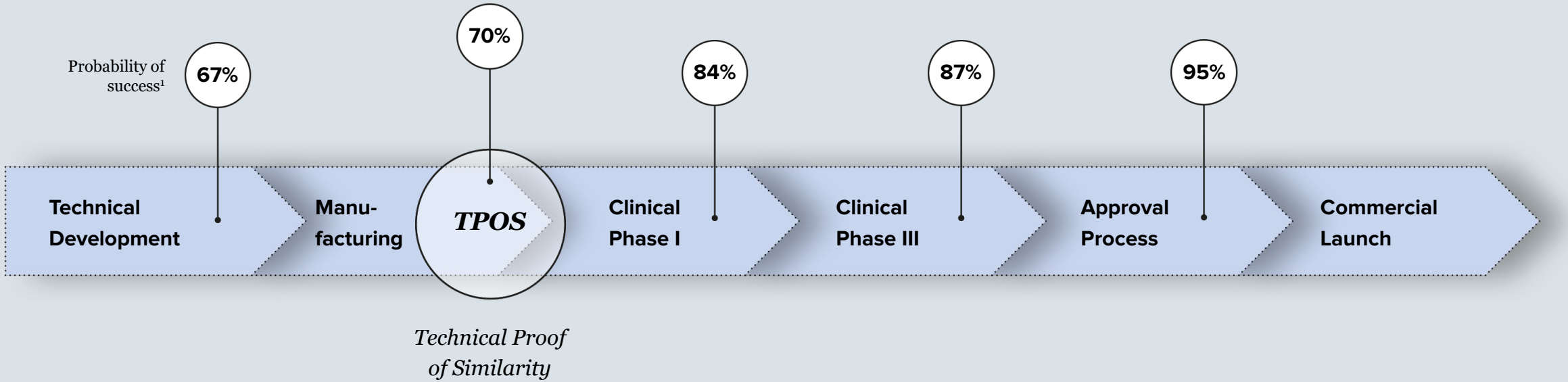
Biosimilar

Follow on version of
Biopharmaceutical Drug
Development: 6–8 years
Budget: $ 150–250m
Clinical Study: Phase I + Phase III

*Only orals, Injectables not even phase I needed

BIOSIMILAR DEVELOPMENT PROBABILITY OF SUCCESS

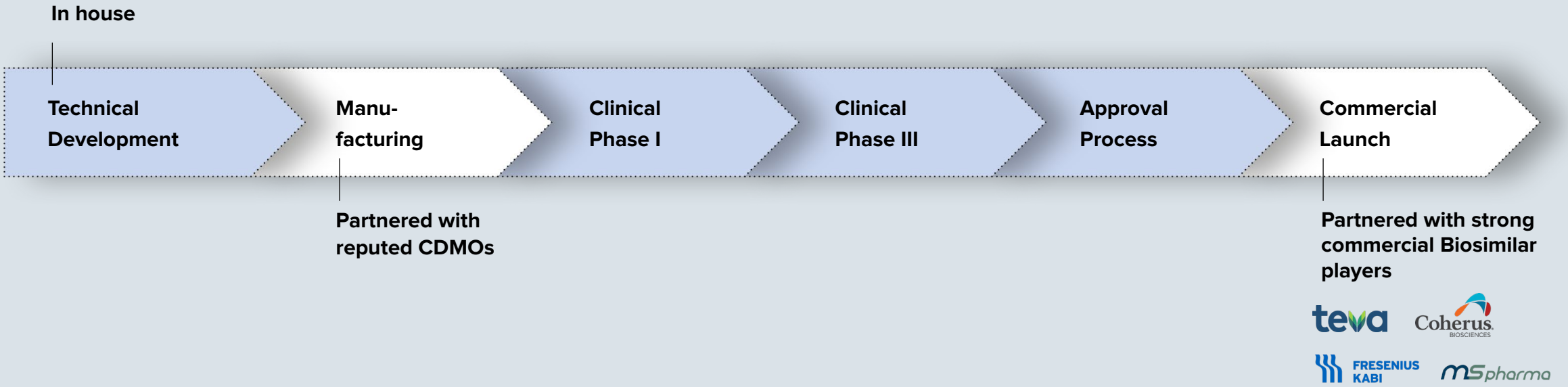
The **probability of success for a Biosimilar is continuously high** over the course of development[1]. This is different **for innovative drug developments**: Here, on average, **only one in twelve innovative drugs makes it from the preclinical stage to approval.**[2]



[1] The path towards a tailored clinical biosimilar development, Schiestl et. al 2020
[2] Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)

FULL VALUE CHAIN COVERED IN SUCCESSFUL HYBRID MODEL

With our team of **highly experienced scientists** and **regulatory affairs experts**, **Formycon covers a large part of the Biosimilar development value chain in-house**. For the areas of manufacturing and commercialization, we rely on well trusted **long-term partners** located in the US and EU.



FORMYCON AG – R&D POWERHOUSE & PIPELINE

ABOUT FORMYCON

Pure Play Biosimilar Company – established 2012 in Munich, Germany.

Business model contains Income from **success payments and royalty streams.**

More than **230 employees** from 31 different countries.

More than **80%** of Formycon's workforce is engaged in **R&D activities.**

Combining high **professional expertise** in biopharmaceutical development **with agile mindset** enables Formycon to develop **multiple Biosimilar projects** in competitive timing and high quality.

Formycon's Pipeline consists of one **approved and launched Biosimilar** product, **two Biosimilars** in current **approval processes** and three **pre-clinical** development projects.

#teamformycon

HIGHLIGHTS 2023

Formycon reached all key milestones in 2023

RESEARCH & DEVELOPMENT

- **FYB202** (Stelara® Biosimilar Candidate) submission to FDA and EMA
- **FYB203** (Eylea® Biosimilar Candidate) submission to FDA and EMA
- **FYB201** (Lucentis® Biosimilar) approval in Canada and other territories
- **FYB206** (Keytruda® Biosimilar Candidate): Clinical design aligned with regulatory authorities and commercial production process established

BUSINESS OPERATIONS

- **FYB201** (Lucentis® Biosimilar) gained strong market share in US, ramping up in EU.
- **Exclusive partnership with Fresenius Kabi** for the commercialization of **FYB202** in key global markets
- **Settlement with J&J** secures **FYB202 market launch** in the US „no later than April 15, 2025“
- **Advanced negotiations** with potential **commercialization partners for FYB203**

FINANCE & IR

- **Successful capital increase** of approx. € 70 Mio.
- **Strong YTD revenue growth** due to significant **success payments** (FYB202) as well as participation in **marketing proceeds** (FYB201)

OUTLOOK FOR 2024

2024 is expected to bring some further important milestone achievements

RESEARCH & DEVELOPMENT

- **FDA approvals for FYB202** (Stelara® Biosimilar Candidate) and **FYB203** (Eylea® Biosimilar Candidate)
- **CHMP** Opinion and **EC decision** for **FYB202**
- **Start** of **clinical program for FYB206** (Keytruda® Biosimilar Candidate)
- **Start** of new Biosimilar project **FYB210**

BUSINESS OPERATIONS

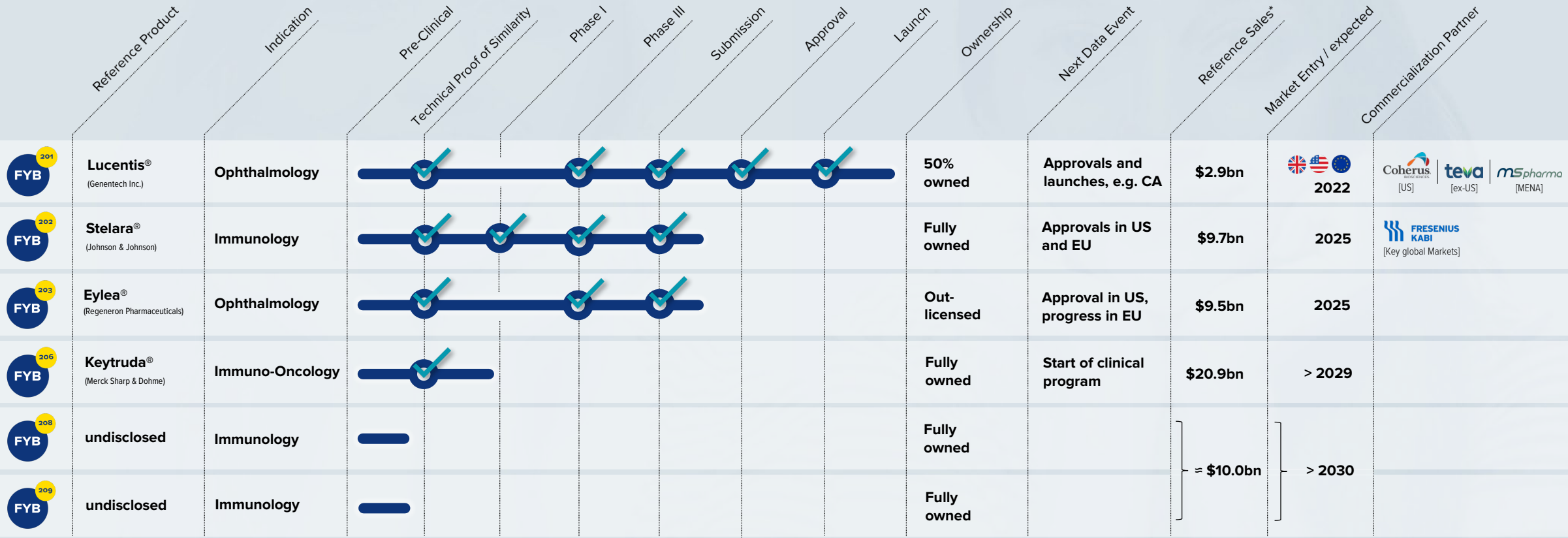
- **Commercialization partnerships** for **FYB203**
- **FYB201** (Lucentis® Biosimilar) approvals and launches in Canada, Latin America and the MENA region
- **FYB201** further sales ramp-up
- **FYB206** commercialization partnership

to be continued ...

Stelara® is a registered trademark of Johnson & Johnson
Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.
Lucentis® is a registered trademark of Genentech, Inc.
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC.

STRONG PIPELINE

Diversified portfolio of commercial, late and mid stage programs with multiple catalysts over the next 12 – 18 months



Submission, approval and launch checkboxes initially refer to the US and Europe
*Global Sales 2022

FYB201 – LUCENTIS® BIOSIMILAR

Approved and launched

Indications

Neovascular Age-Related Macular Degeneration (nAMD), DME[1], CNV[2], PDR[3], RVO[4]

Target Market 2022

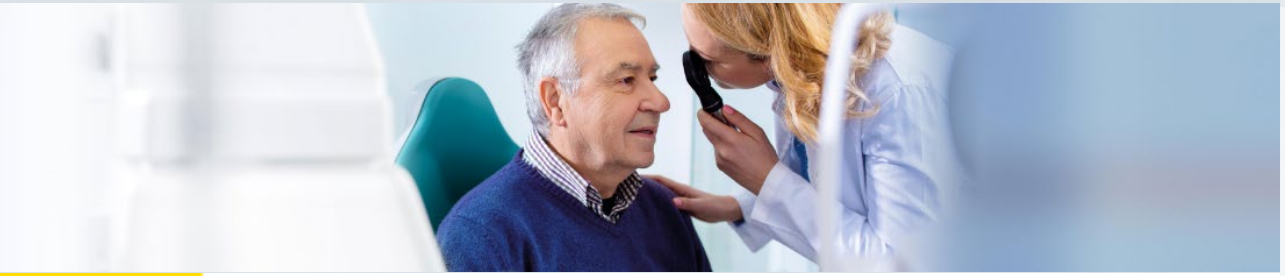
USD 2.9 billion

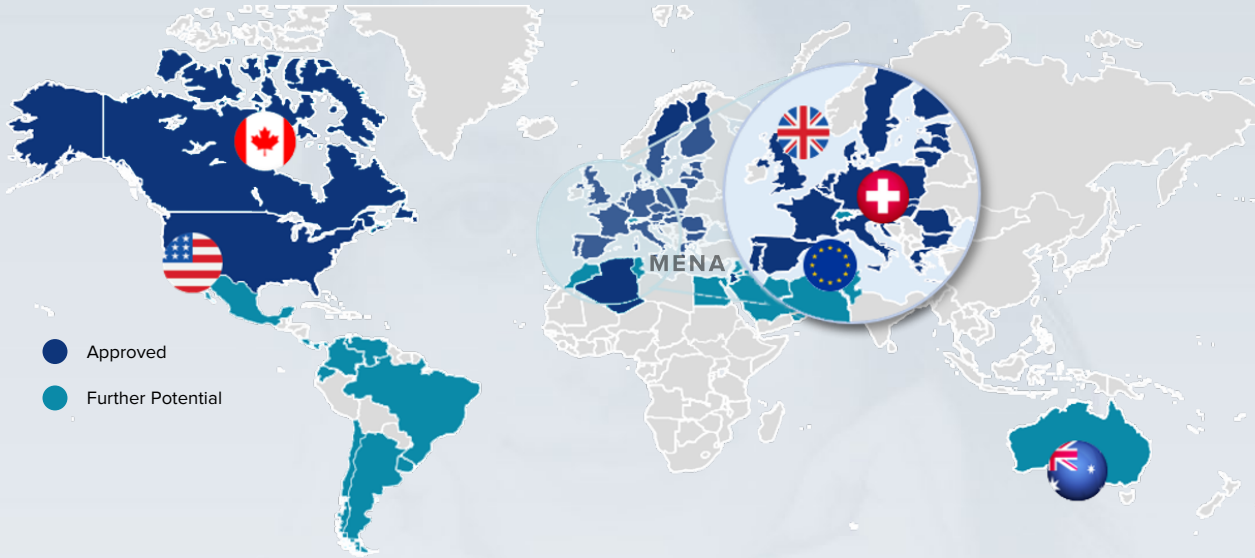
Project Rights

50% ownership in Joint Venture (Bioeq AG) which holds project and commercialization rights

Next important Milestones

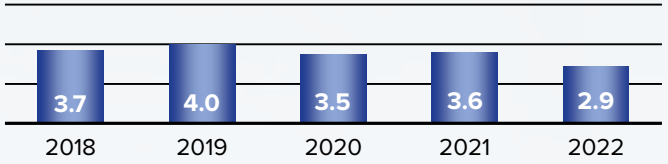
Various regulatory filings, approvals and launches e.g. in Canada, Latin America, Middle East & North Africa (MENA)





Commercial Partnership with Coherus (US) and Teva (ex-US), MS Pharma (MENA)

Lucentis® Sales in USD billion



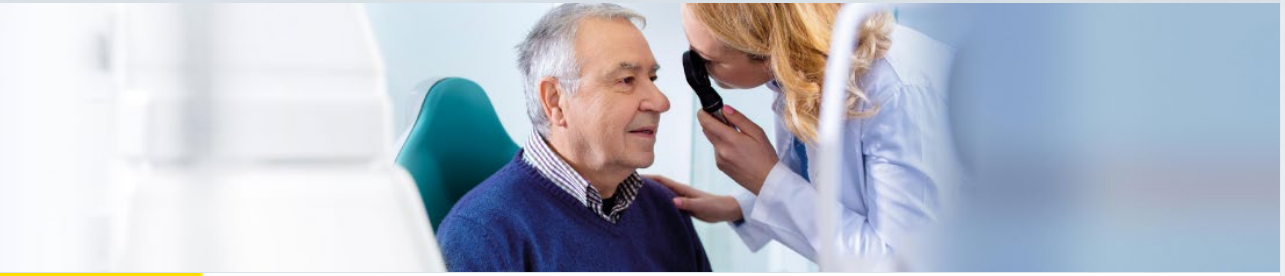
Patent expired:
US 06/2020
EU 07/2022

[1]Diabetic Macular Edema (DME), [2]Choroidal Neovascularization (CNV)
[3]Proliferative Diabetic Retinopathy (PDR), [4]Macular Edema following Retinal Vein Occlusion (RVO)

LUCENTIS® BIOSIMILAR FYB201 (RANIBIZUMAB) WELL POSITIONED

FYB201 / Ranivisio® / Ongavia® / Cimerli™
Competitive Advantage

- Unique position in the US due to availability in both dosages and exclusive "interchangeability" status for 12 months.
- CIMERLI™ ramp-up in the US with more than 100,000 doses in sales within the first year and 29% market share* in the ranibizumab market in Q3/2023
- Pioneering role in the UK and promising positions in key EU markets.



Formycon
Income Position

- Low teens % from Cimerli® (US), Ranivisio® (EU) and Ongavia® (UK) at peak net sales.

*based on weekly sales data https://www.iqvia.com & Coherus BioSciences Reports Third Quarter 2023 Financial Results and Business Highlights | Coherus BioSciences, Inc

FYB202 – STELARA® BIOSIMILAR CANDIDATE

FYB 202

Targeted Reference Indications
Psoriasis (Arthritis), Crohn's Disease, Ulcerative Colitis

Target Market 2022
USD 9.7 billion

Project Rights
100% of project and commercialization rights

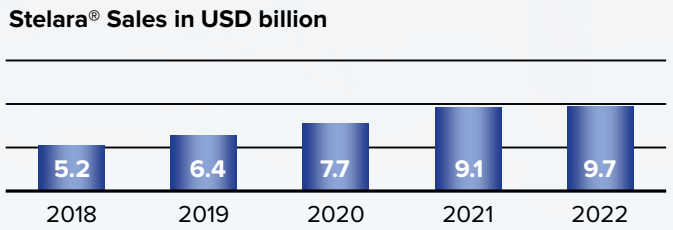
Achievements

- Clinical development successfully completed
- Settlement with J&J for US license date no later than April 15, 2025
- EU and US regulatory submissions

Commercial Partnership

FRESENIUS KABI

- Fresenius Kabi (key global markets)
- Semi-exclusive commercialization rights remain with Formycon (Germany, Parts of MENA, Latin America)



Basic / Key Patent Expiration
US 09/2023
EU 07/2024*

Stelara® is a registered trademark of Johnson & Johnson

*Patent expiry in the key markets depending on SPCs

STELARA® BIOSIMILAR CANDIDATE FYB202 (USTEKINUMAB)

FYB202
Competitive Advantage

- Submission according to initial schedule and settlement with J&J puts FYB202 in good position for US market entry no later than April 15, 2025.
- Fresenius Kabi as strong commercial partner with potential for commercial lead position.
- Working on competitive differentiations.

Formycon
Income Position

- Milestone payments related to the completion of clinical phases of about 25 million in H1 2023. Additional milestone payments upon approval in US and EU expected in late 2024 / early 2025 (estimated to total in the mid double digit million Euro).
- Post-commercialization value shared approximately equally by Formycon and Fresenius Kabi.

FYB203 – EYLEA® BIOSIMILAR CANDIDATE

FYB 203

Targeted reference Indications
Neovascular Age-Related Macular Degeneration (nAMD), DME[1], mCNV[2], DR[3], RVO[4]

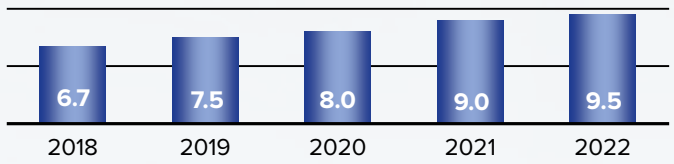
Target Market 2022
USD 9.5 billion

Project Rights
since 2015 License Agreement with Klinge Biopharma GmbH as Royalty Model

Achievements and next important Milestones

- Biologics License Application submitted to the FDA in June 2023. FDA file acceptance on August 28, 2023 set target action date of June 2024
- MAA submitted to EMA in November 2023. EMA MAA acceptance on December 22, 2023
- Contract negotiations with commercialization partners

Eylea® Sales in USD billion



Basic / Key Patent Expiration
US 05/2024
EU 11/2025*

[1]Diabetic Macular Edema (DME), [2]Choroidal Neovascularization (CNV)
[3]Proliferative Diabetic Retinopathy (PDR), [4]Macular Edema following Retinal Vein Occlusion (RVO)

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc
*Patent expiry in the key markets depending on SPCs

EYLEA® BIOSIMILAR CANDIDATE FYB203 (AFLIBERCEPT)

FYB203
Competitive Advantage

- Commercialization experiences and lead position from FYB201 in the ophthalmology/AMD space will be leveraged.

Formycon
Income Position

- Mid-single to low-double-digit-percentage participation in all Klinge income from commercialization partners across all territories.

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc

FYB206 – KEYTRUDA® BIOSIMILAR CANDIDATE

FYB 206

Targeted reference Indications
Immuno-oncology: Melanoma (black skin cancer), non-small cell Lung Cancer, classical Hodgkin's Lymphoma and other Tumor Diseases

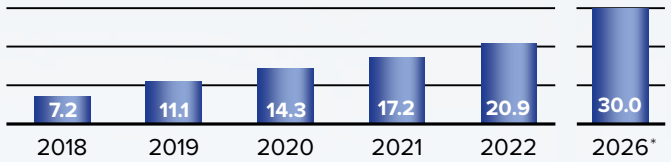
Target Market 2022
USD 20.9 billion

Project Rights
100% of project and commercialization rights

Achievements and next important Milestones

- Process development and development of the manufacturing process at commercial scale in progress
- Important IP has been generated
- Development and clinical strategy aligned with regulatory authorities (Scientific Advice)
- Intense preparation for start of clinical phase in 2024

Keytruda® Sales in USD billion



*Pharma Intelligence UK Ldt: Keytruda Consenus Forecast
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

Basic / Key Patent Expiration
US 05/2029
EU 07/2030**

**Patent expiry in the key markets depending on SPCs

FINANCIALS AND STOCK MARKET

FINANCIAL PERFORMANCE (IFRS)
ACCELERATING BUSINESS

	REVENUE	EBITDA	WORKING CAPITAL	NET INCOME
Fiscal year 2023 current forecast	75 *to* 85 € million	-15 *to* -5 € million	15 *to* 25 € million	50 *to* 60 € million
Financial Performance 9M 2023	60.2 € million	5.2 € million	41.3 € million	74.3 € million
Financial Performance H1 2023	43.8 € million	7.3 € million	55.0 € million	1.8 € million

- **Guidance:**
  + Topline and EBITDA unchanged
  + Significant increase in net income due to one-off and non-cash effect in financial income
- **Revenue increase:**
  + FYB202 success payments
  + Share of FYB201 sales proceeds
  + Development compensation (especially FYB203)
- **EBITDA:**
  + Revenue from FYB201, FYB202 and FYB203
  - Investments in FYB208 and FYB209
- **Working Capital:**
  + Proceeds of capital increase (Q1)
  - Investments in FYB202 and FYB206
  - Repayment of shareholder loan (Q1)

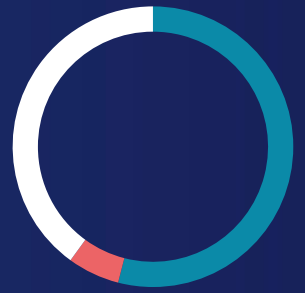
Net income:
+ Fair value decrease of earn out obligation
+ At Equity valuation of Bioeq AG
- Impairment of Goodwill

FORMYCON ON THE STOCK MARKET

- Listed on **Frankfurt Stock Exchange** since June 2012 / SME segment **“Scale”** (Open Market)
- **Registered capital: € 16,053,025**
  Shares outstanding: 16,053,025 (w/o par value)
- **Market price / Market capitalization: ~ € 1.0 billion**
- **Research coverage:** Jefferies, Kepler Cheuvreux, Hauck & Aufhäuser Privatbankiers, B. Metzler seel. Sohn & Co. KGaA, First Berlin Equity Research, Alster Research, M. M. Warburg

Shareholder Structure

- ~54 % Anchor Investors incl. Athos KG, Active Ownership Capital, Wendeln & Cie. KG, DSP
- ~ 6 % Founders & Management
- ~40 % Free Float***



Key Financial Figures / € million

Y/E 31.12.	2015	2016	2017	2018*	2019	2020**	2021**	2022**
Sales	16.9	19.5	29.0	43.0	33.2	34.3	36.6	42.5
EBITDA	1.5	-3.4	-0.8	8.0	-1.4	-5.2	-12.6	-15.9
EBIT	0.5	-4.1	-1.5	7.1	-2.3	-6.5	-14.0	-17.7
Net Income	0.6	-4.1	-1.6	7.1	-2.3	-6.7	-13.3	36.0

Performance Formycon Share

* FYB202 GmbH & Co. KG.: Effect on sales and earnings but not on liquidity
** According to IFRS
*** Free float as defined by Deutsche Börse

MANAGEMENT TEAM & BOARD MEMBERS

Complementary Skills and Experience

Dr. Stefan Glombitza,
CEO of Formycon

- More than 27 years of experience in pharmaceutical industry
- Track record of > 500 developments and launches in > 70 countries at Hexal/Sandoz
- Strong skills in designing and integrating new organizations
- Broad span of leadership from global roles to lead of huge interdisciplinary development center

Nicola Mikulcik
CBO of Formycon

- More than 20 years of experience in pharmaceutical industry
- Track record of > 400 Licensing deals generating multibillion USD sales
- Extensive commercial and strategic experience with outstanding network in pharmaceutical industry
- Entrepreneurial leadership experience as Managing Director of Bioeq GmbH

Dr. Andreas Seidl,
CSO of Formycon

- More than 20 years of extensive experience in development of Biologics
- Track record of 8 biosimilar approvals in US and EU, including approval of first complex biosimilar in 2006
- Local and international management experience with strong focus on science and new technologies
- Senior leadership experience as COO of Leukocare AG

Enno Spillner,
CFO of Formycon

- More than 24 years of experience in Biotech industry
- Track record of successful capital market positioning including MDAX, TecDAX and NASDAQ listing as former CFO at Evotec SE
- Strong expertise in financial and M&A transactions, supporting dynamic international company growth and transformation

HIGHLY EXPERIENCED SUPERVISORY BOARD

Strategic advice with a broad corporate perspective

Dr. Olaf Stiller
Chairman

- CEO of Paedi Protect AG
- PhD in economics for his work on the economic potential of innovations in the area of nano- and biotechnology
- Co-founder of NanoRepro AG and Formycon AG. He actively accompanied both companies from their foundation until their listings on the stock market.

Peter Wendeln
Deputy Chairman

- Managing partner of Wendeln & Cie. Asset Management GmbH
- Studied at the Academy of Business in Hanover, Germany
- Headed the sales and marketing activities at Wendeln GmbH & Co. KG and later became managing partner of Wback GmbH

Klaus Röhrig
Member

- Founding partner of Active Ownership Group (AOC)
- Holds a Master of Economics and Business Administration from Vienna University of Economics and Business Administration
- Was responsible for the funds' investments in the German speaking countries at Elliott Associates

Wolfgang Essler
Member

- Chief representative of ATHOS KG
- Holds a degree of Diplom-Kaufmann / University of Augsburg
- Strong expertise in corporate finance and transactions
- Held various management positions responsible for investments and portfolio management

FORMYCON IS A FULLY FOCUSED PURE-PLAY BIOSIMILAR COMPANY

Proof of capabilities with recent Lucentis® biosimilar approvals and successful launches

Efficient hybrid business model taking advantage of in-house expertise and selected external partnerships

Remarkable pipeline including late-stage opportunities in multibillion target markets

Driven and experienced management and operational team, supported by strong supervisory board

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Formycon AG
The Biosimilar Experts

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