

# Formycon AG

## The Biosimilar Experts

April/May 2024

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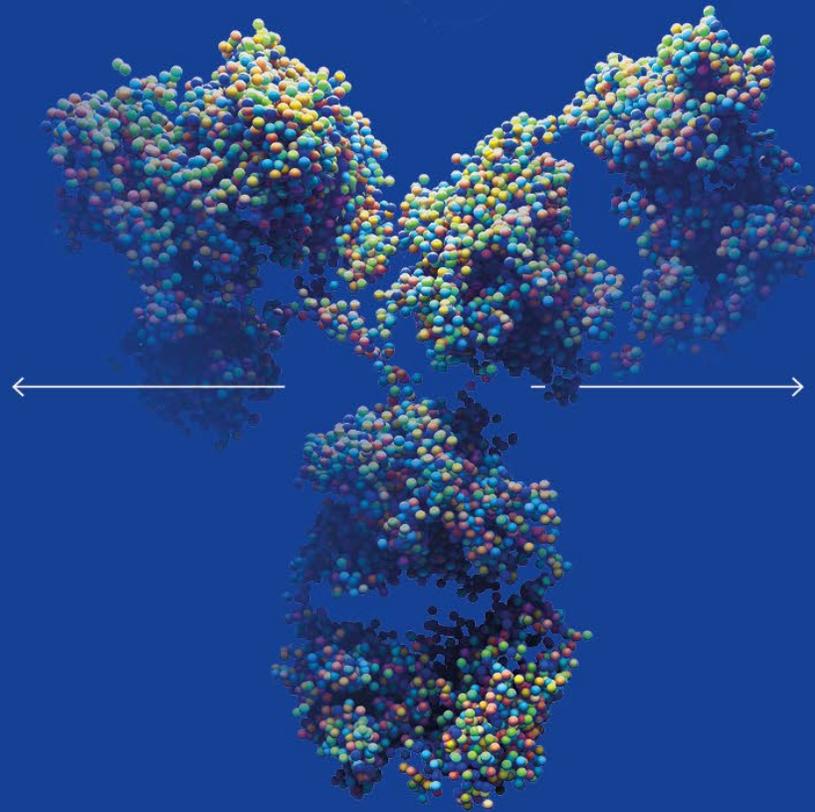
# BIOSIMILAR MARKET

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## VISION & MISSION

Biosimilars open up enormous opportunities

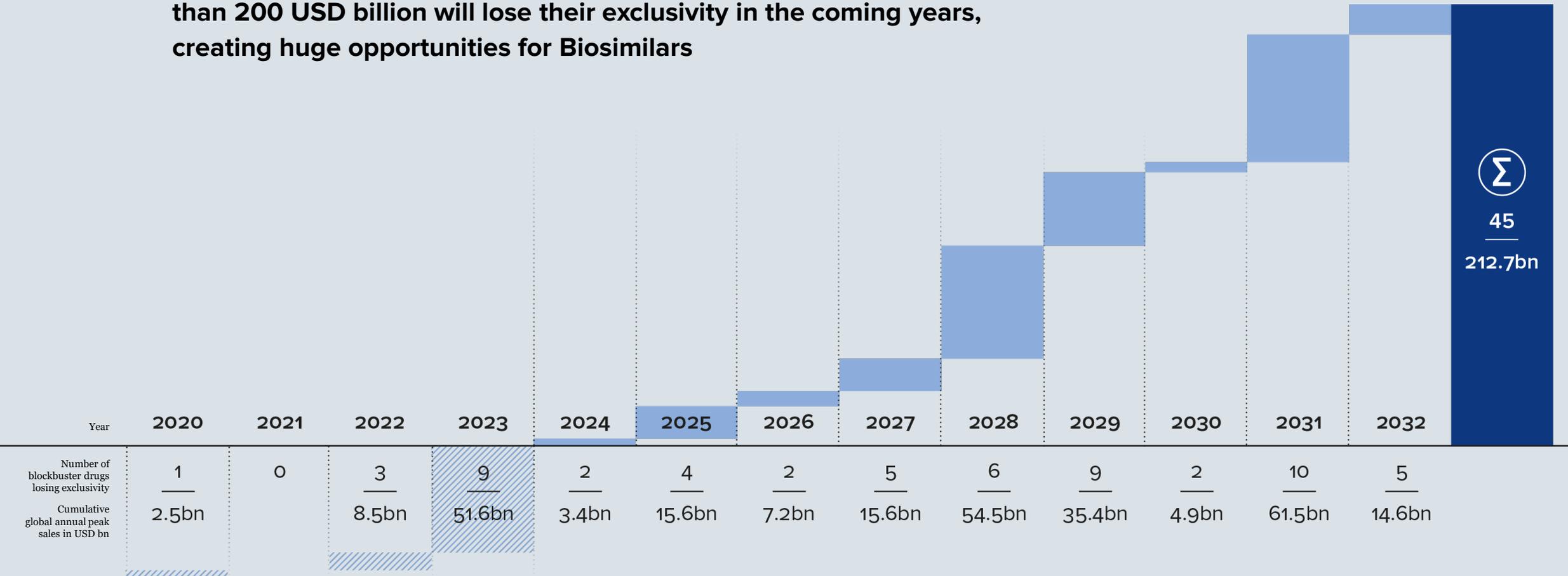
*Contributing to ease  
the **financial strains** on the  
world's healthcare systems*



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

## BIOSIMILAR OPPORTUNITIES

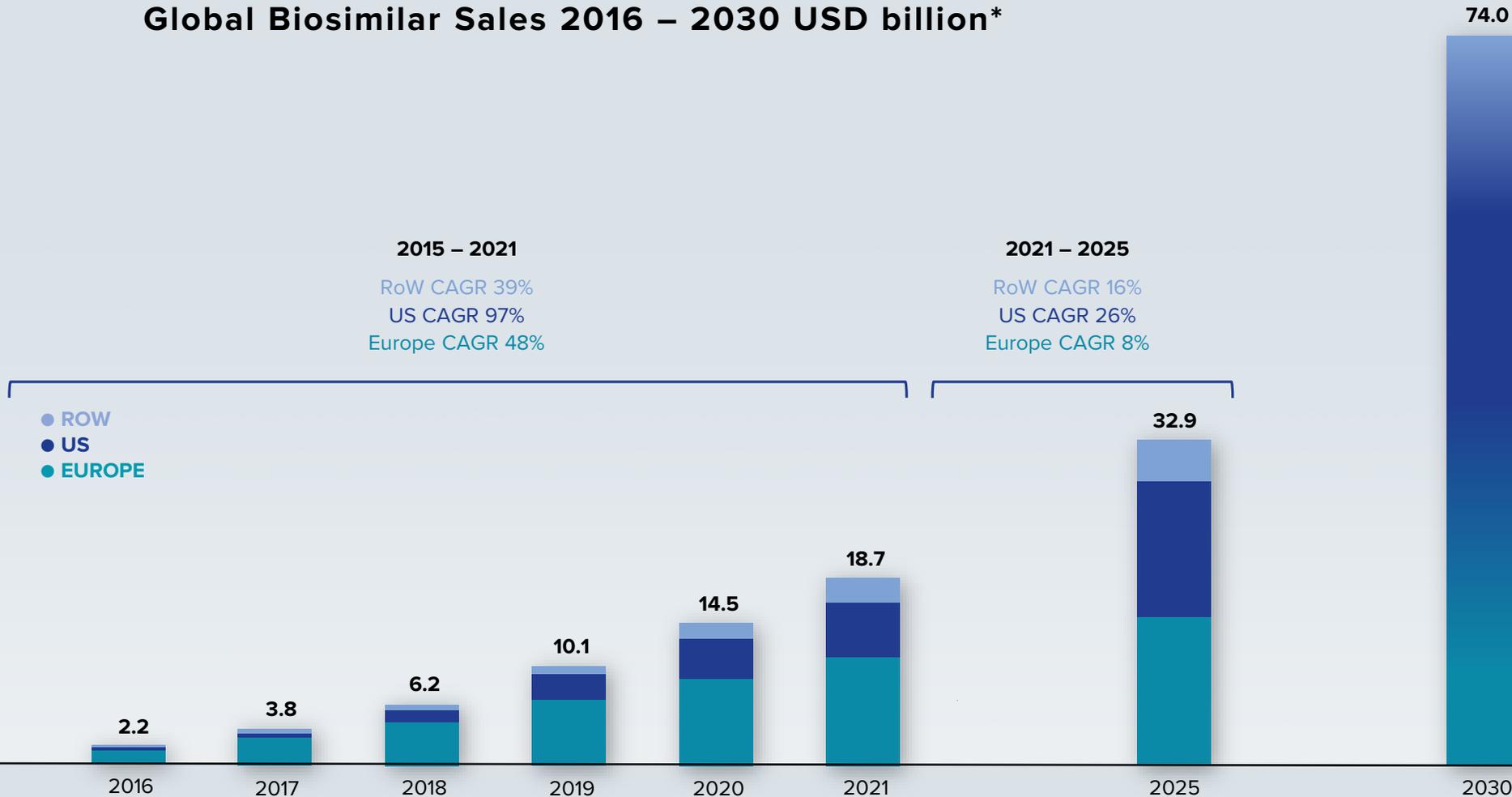
**45 Blockbuster drugs with an expected global sales volume of more than 200 USD billion will lose their exclusivity in the coming years, creating huge opportunities for Biosimilars**



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

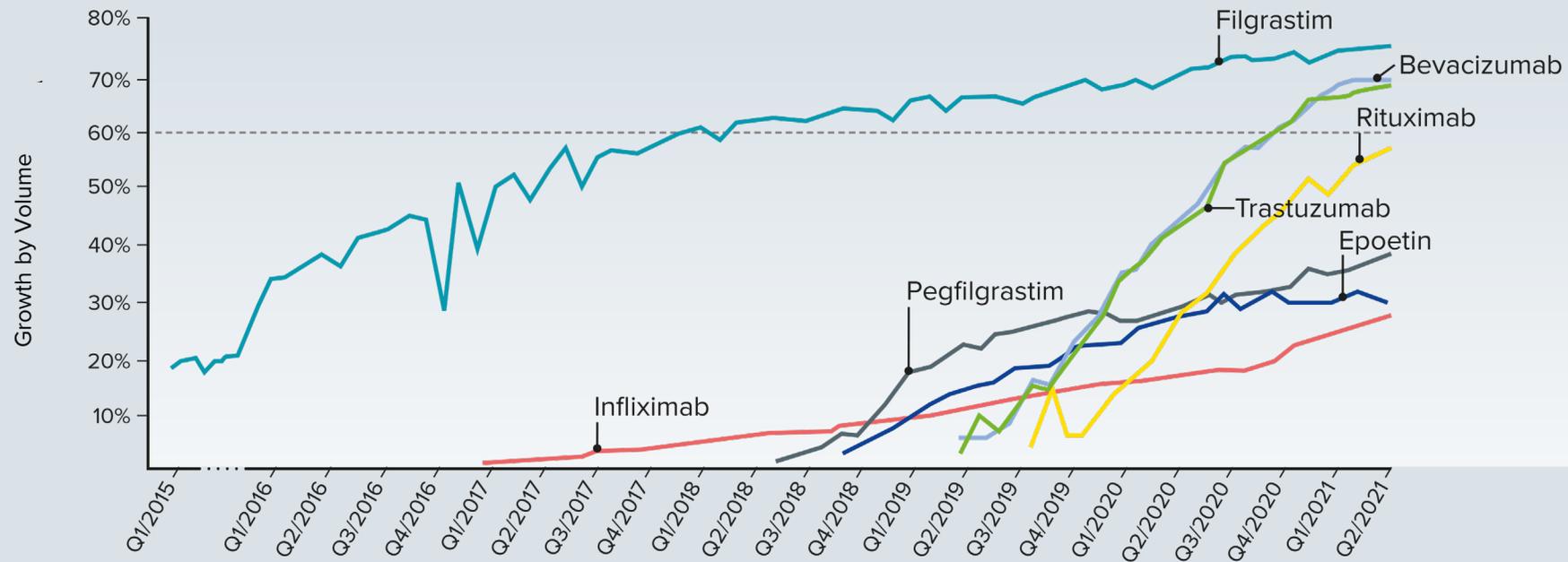
Global Biosimilar Sales 2016 – 2030 USD billion\*



*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.*

## US BIOSIMILAR LAUNCHES IN THE MEDICAL BENEFIT CHANNEL SHOW ACCELERATED UPTAKE

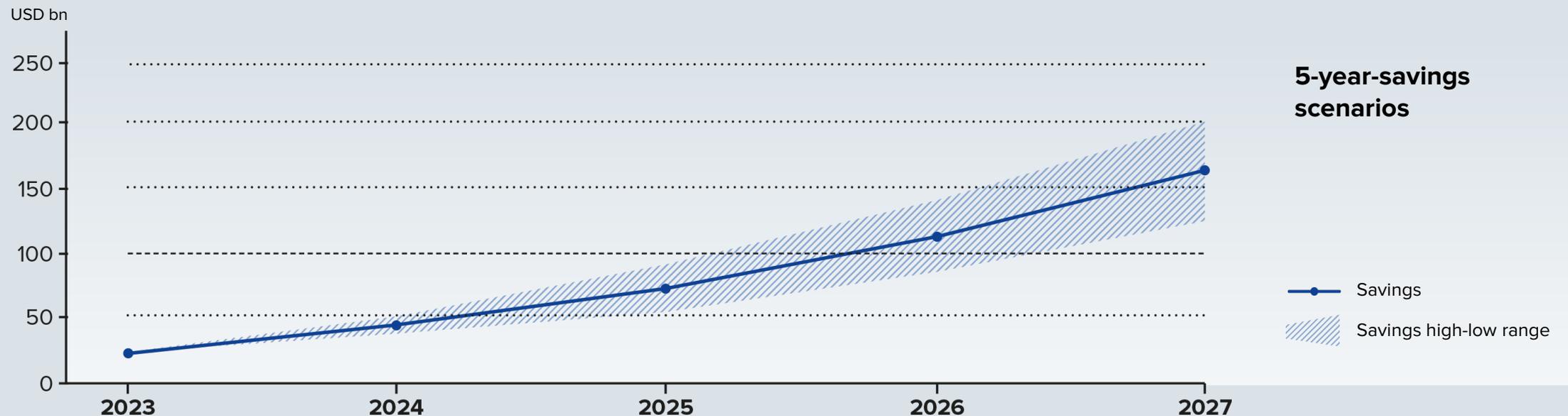
- For US Biosimilars launched prior to 2019, the average share after two years was **13 %**
- For US Biosimilars launched in the last two years, the average share was **65 %!**



## 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



A background image of a scientist in a white lab coat, wearing a white hairnet, safety glasses, and a white face mask. The scientist is holding a pipette and appears to be working in a laboratory setting. The image is overlaid with a semi-transparent teal color.

# BIOSIMILAR DEVELOPMENT

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## 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\*

New **Biological**  
Entity (NBE)

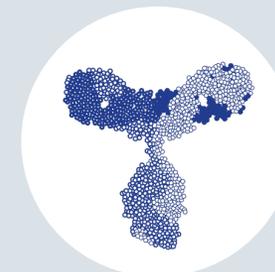


**Innovative  
Biopharmaceutical Drug**  
Development 10–14 years  
Budget \$ 1–2bn

Patent protection 20 – 25 years



**Biosimilar**

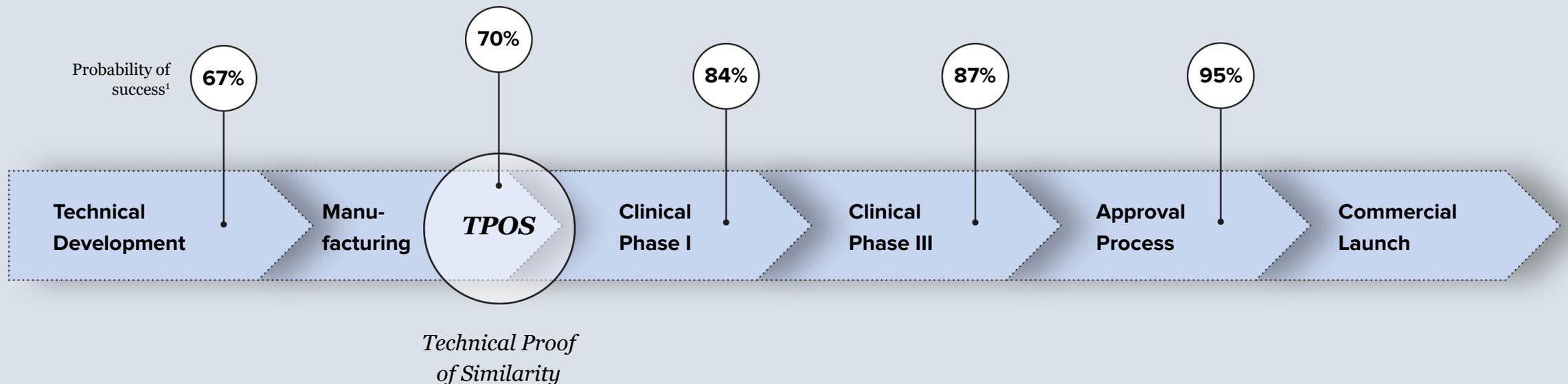


**Follow on version of  
Biopharmaceutical Drug**  
Development: 7–10 years  
Budget: \$ 150–300m  
Clinical Study: Phase I +  
Phase III

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

## BIOSIMILAR DEVELOPMENT PROBABILITY OF SUCCESS

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



## 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.



GEARED TOWARDS GROWTH

# FORMYCON AG – R&D POWERHOUSE & PIPELINE

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## 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

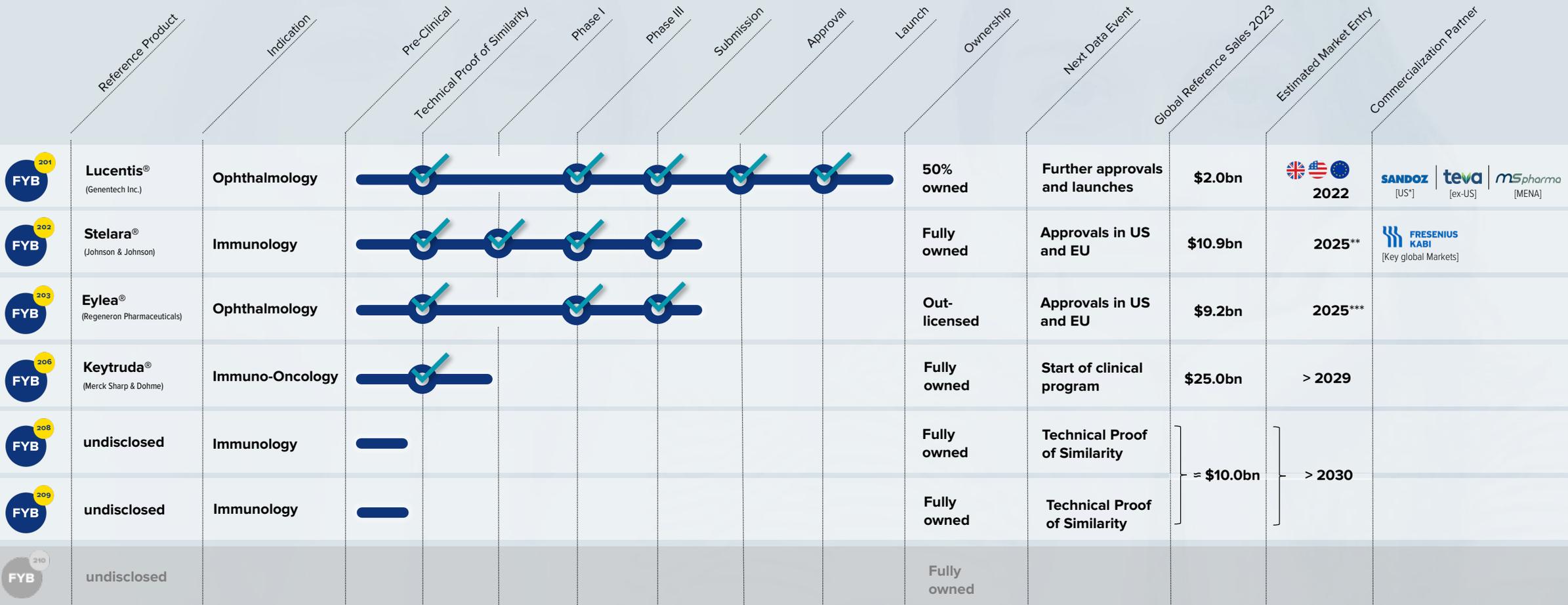


### FINANCE & IR

- ✓ **Successful cash capital increase**  
Gedeon Richter became strategic investor via cash capital increase of EUR 82.84 million

## STRONG MATURING AND GROWING PIPELINE

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



\*FYB201 US business was transferred from Coherus to Sandoz in March 2024

\*\*US launch date "no later than April 15, 2025" based on settlement agreed with J&J and subject to regulatory approval

\*\*\*Depending on litigation progress

# FYB201 – LUCENTIS® BIOSIMILAR



Approved and launched   

### Indications

Neovascular Age-Related Macular Degeneration (nAMD), DME<sup>1</sup>, CNV<sup>2</sup>, PDR<sup>3</sup>, RVO<sup>4</sup>

### Target Market 2023

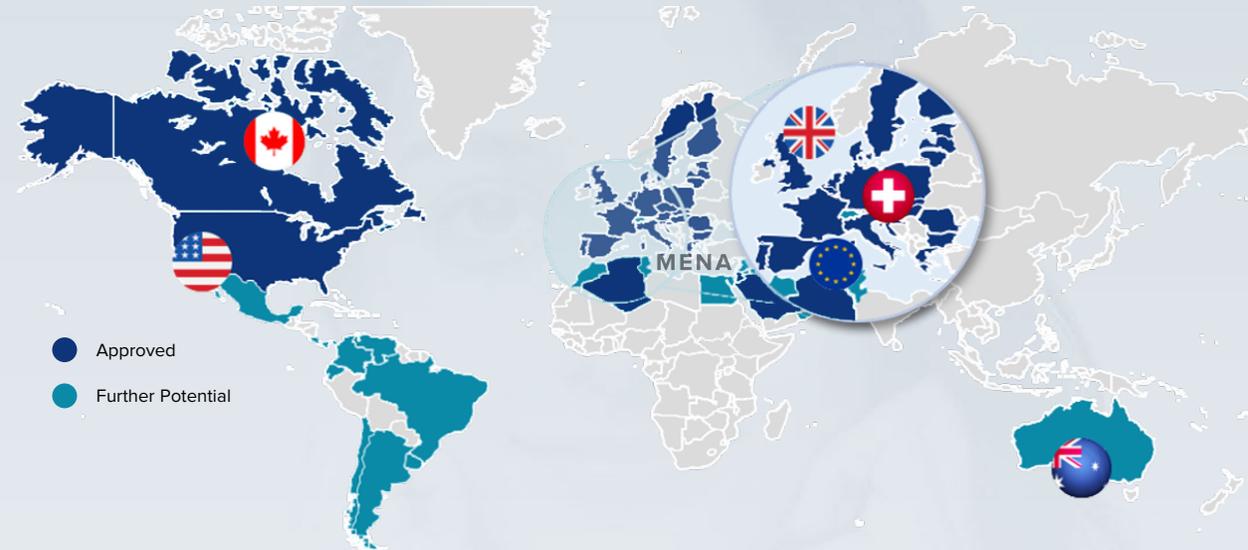
USD 2.0 billion

### 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 Latin America, Middle East & North Africa (MENA)



Commercial Partnership with Sandoz\* (US) and Teva (ex-US), MS Pharma (MENA)



Lucentis® Sales in USD billion



<sup>1</sup>Diabetic Macular Edema (DME), <sup>2</sup>Choroidal Neovascularization (CNV)  
<sup>3</sup>Proliferative Diabetic Retinopathy (PDR), <sup>4</sup>Macular Edema following Retinal Vein Occlusion (RVO)

\* US business was transferred from Coherus to Sandoz in March 2024  
 Lucentis® is a registered trademark of Genentech, Inc



# LUCENTIS® BIOSIMILAR FYB201 (RANIBIZUMAB) WELL POSITIONED

## Ranibizumab Competitive Landscape

Development Company	Commercialization Partner	Status Phase III	Submission / Approval
Samsung Biologics	Biogen	Completed (End of 2019)	Approved in US, EU, UK, CA
Xbrane	STADA (EU) / Commercialization in the US to be settled	Completed (06/2021)	Approved in EU, UK, US-Filing (04/2023)
Qilu		Completed (EU-reference)	Approved in EU (01/2024)

### 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 190,000 doses in sales within the first 15 months and 38% market share in the ranibizumab market in December 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.



## FYB202 – STELARA® BIOSIMILAR CANDIDATE



### Targeted Reference Indications

Psoriasis (Arthritis), Crohn's Disease,  
Ulcerative Colitis

### Target Market 2023

USD 10.9 billion

### Project Rights

100% of project and commercialization rights

### Achievements

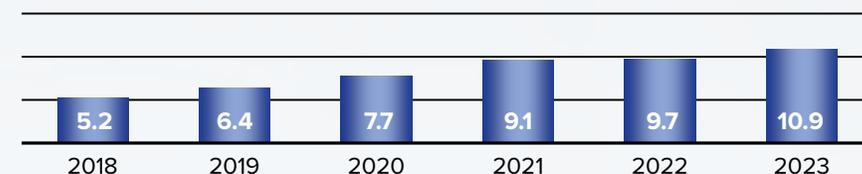
- Clinical development successfully completed
- Settlement with J&J for US license date no later than April 15, 2025
- EU and US regulatory submissions

### Commercial Partnership

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



Stelara® Sales in USD billion



## STELARA® BIOSIMILAR CANDIDATE FYB202 (USTEKINUMAB)

### Ustekinumab Competitive Landscape

Development Company	Commercialization Partner	Status Phase III	Submission / Approval
Alvotech	Teva (US) / Stada (EU)	Primary endpoint met	US-/EU-Filing (Q1/2023), CRL (10/2023), Approved in EU (01/2024)
Amgen		Primary endpoint met	US-Filing (11/2022)
Celltrion	Hikma (MENA)	Completed	EU-Filing (05/2023), US-Filing (07/2023)
Meiji Selka Pharma & Dong A	Intas (Accord)	Primary endpoint met (01/2023)	EU-Filing (06/2023)
Samsung Bioepis	Sandoz	Completed (11/2022)	Not yet communicated
Bio-Thera		Last patient out (04/2023)	n/a
Biocon		Last patient out (expected Q2/2024)	n/a

### 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



### Targeted reference Indications

Neovascular Age-Related Macular Degeneration (nAMD),  
DME<sup>1</sup>, mCNV<sup>2</sup>, DR<sup>3</sup>, RVO<sup>4</sup>

### Target Market 2023

USD 9.2 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



## EYLEA® BIOSIMILAR CANDIDATE FYB203 (AFLIBERCEPT)

### Aflibercept Competitive Landscape

Development Company	Status Phase III	Submission / Approval
Alvotech	Start (07/2022)	—
Amgen	Primary endpoint met (Q3/2022)	US File Acceptance (11/2023)
Biocon (Mylan / Momenta)	Completed	US-Filing (10/2021), EU-Approval (07/2023)
Celltrion	Positive 24-week results (04/2023)	US-Filing (07/2023), EU-Filing (11/2023)
Samsung Bioepis	Last patient in (02/2022)	n/a
SamChun Dang	Recruitment completed	n/a
Sandoz	First patient out (05/2023)	n/a

#### 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.

## FYB206 – KEYTRUDA® BIOSIMILAR CANDIDATE



### Targeted reference Indications

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

### Target Market 2023

USD 25.0 billion

### Project Rights

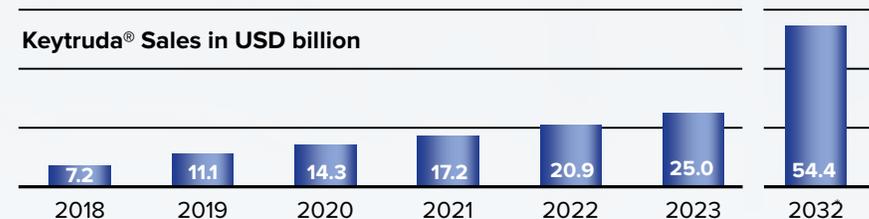
100% of project and commercialization rights

### 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



\*<https://www.custommarketinsights.com/report/keytruda-market/>  
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

## KEYTRUDA® BIOSIMILAR CANDIDATE FYB206 (PEMBROLIZUMAB)

### Pembrolizumab Competitive Landscape

Development Company	Status	Submission / Approval
Alvotech	Pre-Clinical	
NeuClone	Pre-Clinical	
PlantForm	Pre-Clinical	
Sandoz	Pre-Clinical	
Samsung Bioepis	Pre-Clinical	

*more competitors to be expected  
but not officially confirmed*



# FINANCIAL PERFORMANCE – STRONG 2023

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## 2023 RESULTS – STRONG OVERALL PERFORMANCE

### 2024 OUTLOOK – INVESTING FOR SUSTAINABLE INCOME

Fiscal  
year 2023  
forecast

Revenue	EBITDA	Adjusted EBITDA*	Working Capital	Net income
75 to 85	-15 to -5	/	15 to 25	50 to 60
€ million	€ million	€ million	€ million	€ million

Key financial  
Figures 2023

Revenue	EBITDA	Adjusted EBITDA*	Working Capital	Net income
77.7	1.5	13.3	38.9	75.8
€ million	€ million	€ million	€ million	€ million

Fiscal  
year 2024  
forecast

Revenue	EBITDA	Adjusted EBITDA*	Working Capital
55 to 65	-15 to -25	-5 to -15	10 to 20
€ million	€ million	€ million	€ million

#### Guidance 2024:

- **Revenue:** Reduced development recharges FYB201 and FYB203 and reduced success payments FYB202
- **EBITDA:** Lower revenue (10m upfront FYB202 in 2023) and increasing R&D expense on FYB208, FYB209 and new FYB210
- **Adjusted EBITDA – new!** Expected At-Equity Result of 10m from Bioeq AG adding to EBITDA
- **Working Capital:** Decrease due to development investments R&D and CAPEX (FYB206), capital increase and repayment of shareholder loan (1Q 2024) already factored in

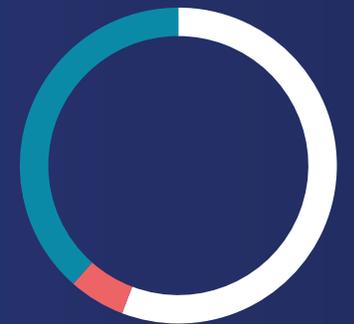
*\*EBITDA is derived and calculated from reported operating income (EBIT). Adjusted EBITDA additionally includes the contribution from Formycon's jointly controlled investment accounted for using the equity method Bioeq AG.*

## Formycon on the Stock Market

- Listed on **Frankfurt Stock Exchange** since June 2012 / SME segment “**Scale**” (Open Market)
- **Registered capital: € 17,656,902**  
Shares outstanding: 17,656,902 (w/o par value)
- **Market price / Market capitalization: ~ € 700 million**
- **Designated Sponsors:**  
Oddo BHF Corporates & Markets AG  
M.M. Warburg & Co.
- **Research coverage:** Jefferies,  
Kepler Cheuvreux, Hauck & Aufhäuser Privatbankiers,  
B. Metzler seel. Sohn & Co. KGaA, First Berlin Equity Research,  
mwb Research, M. M. Warburg, Berenberg

### Shareholder Structure

- ~58 % Anchor Investors incl. Athos KG, Active Ownership Capital, Wendeln & Cie. KG, Gedeon Richter, DSP
- ~ 6 % Founders & Management
- ~36 % Free Float\*



\* Free float as defined by Deutsche Börse

# MANAGEMENT TEAM & BOARD MEMBERS

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## MANAGEMENT TEAM

### 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

## FULLY FOCUSED PURE-PLAY BIOSIMILAR COMPANY



**WE HAVE** all ingredients to successfully develop and commercialize a growing pipeline



**WE ACT** in a highly attractive market



**WE CREATED** a strong Platform with track record



**WE ARE** entering the next stage of the Formycon Growth Story

## FORMYCON AG

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