



# Formycon AG

## The Biosimilar Experts

November 2024

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## Skillset and mindset are our key ingredients



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

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



More than **240 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.

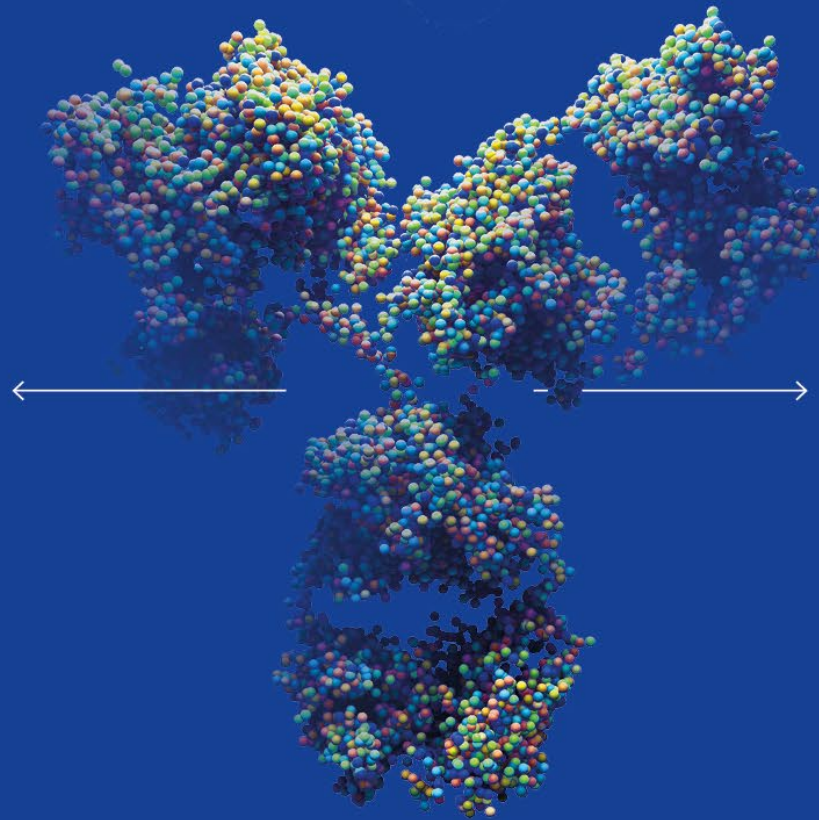


**Formycon's pipeline** includes **three approved biosimilars**, one of which is already launched **in 20 countries worldwide**, as well as three biosimilar candidates in development.

**We are acting along a clear mission**

**Biosimilars open up enormous opportunities**

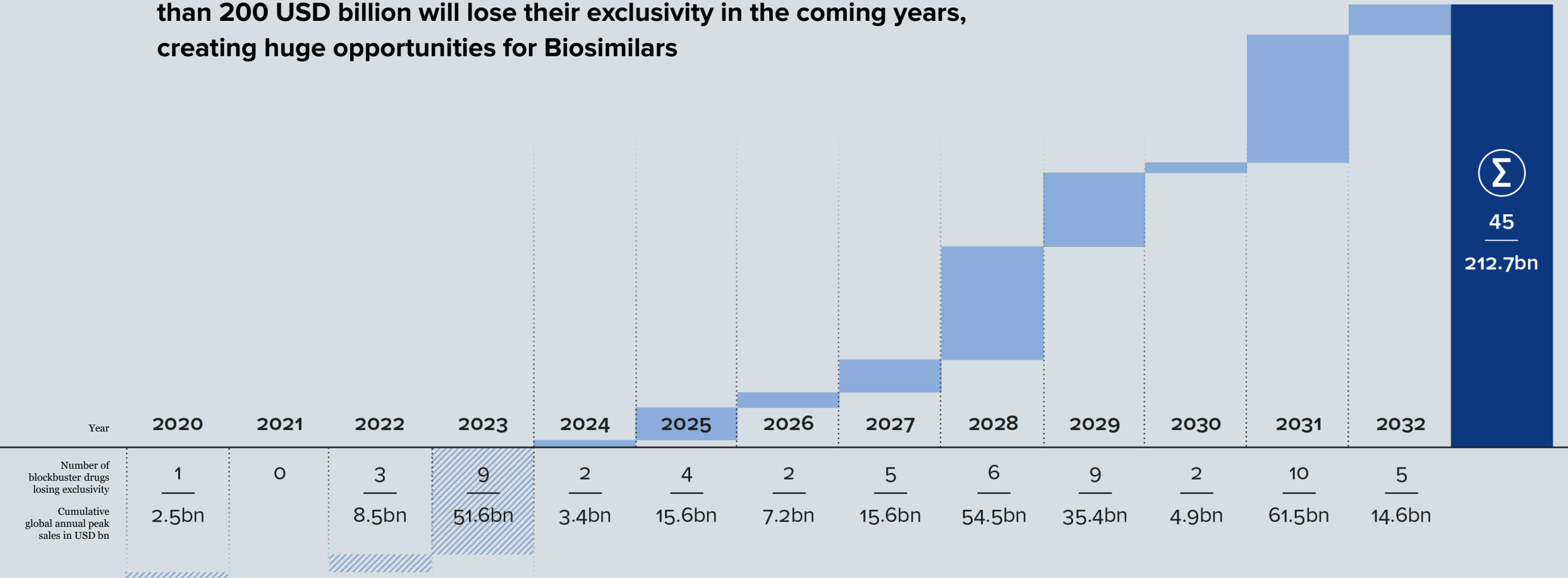
*Contributing to ease  
the **financial strains** on the  
world's healthcare systems*



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

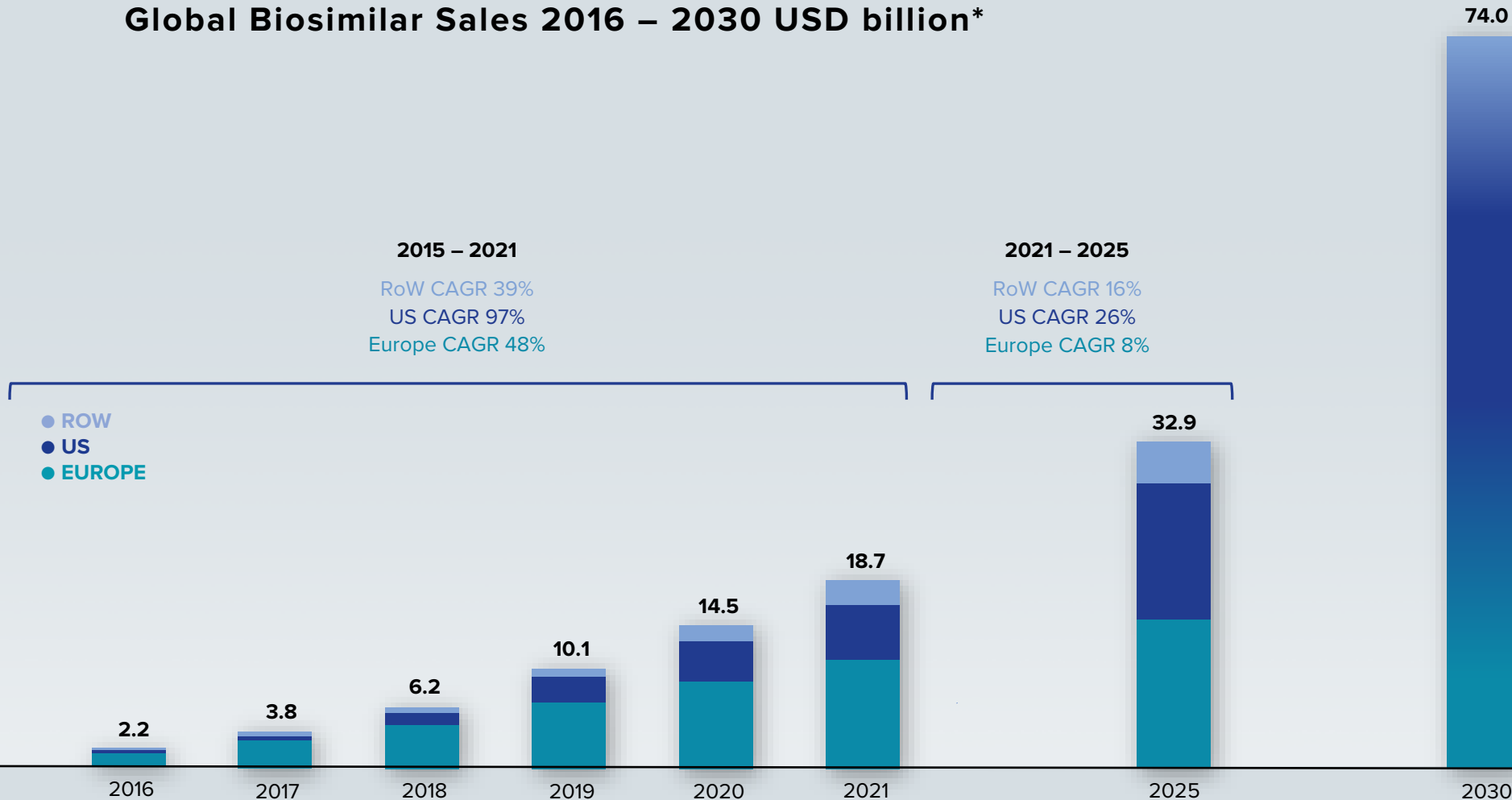
## Huge Biosimilar target opportunities

**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**



## The Biosimilar market develops very dynamically

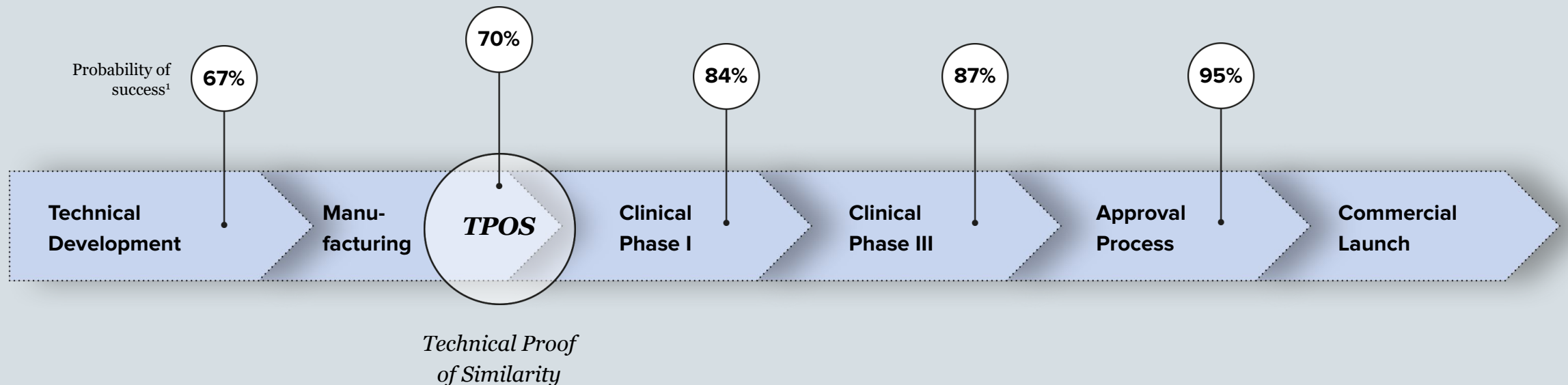
Global Biosimilar Sales 2016 – 2030 USD billion\*



*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.*

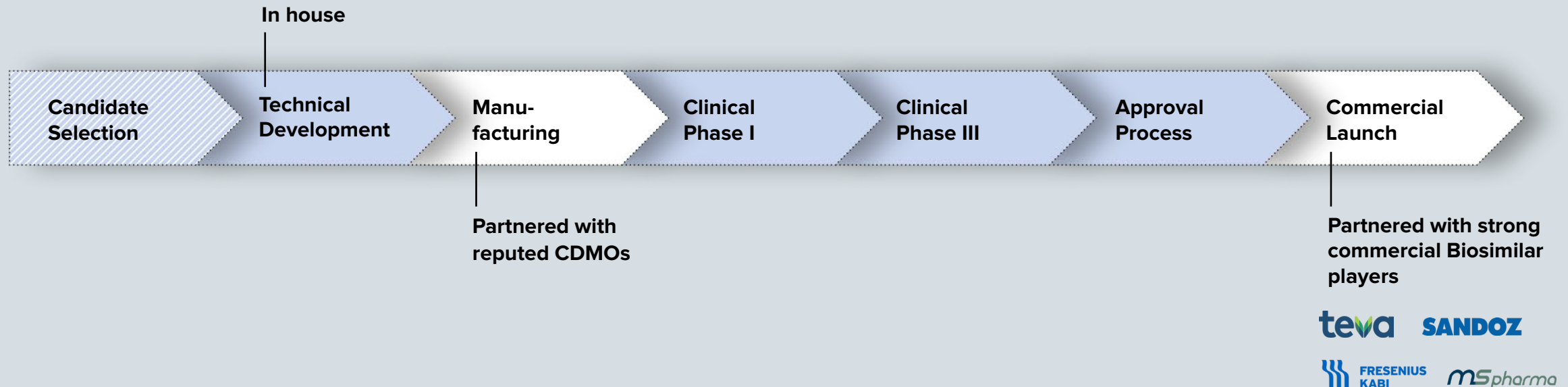
# Biosimilar development – high probability of success

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.





# Laser focus on pipeline execution and expansion



## Maximizing our assets along a clear pathway



**2023**

Strong financial and operational performance

**2024**

Important year to prepare the ground for the next ignition stage

Sustainable profitability with continuous pipeline growth

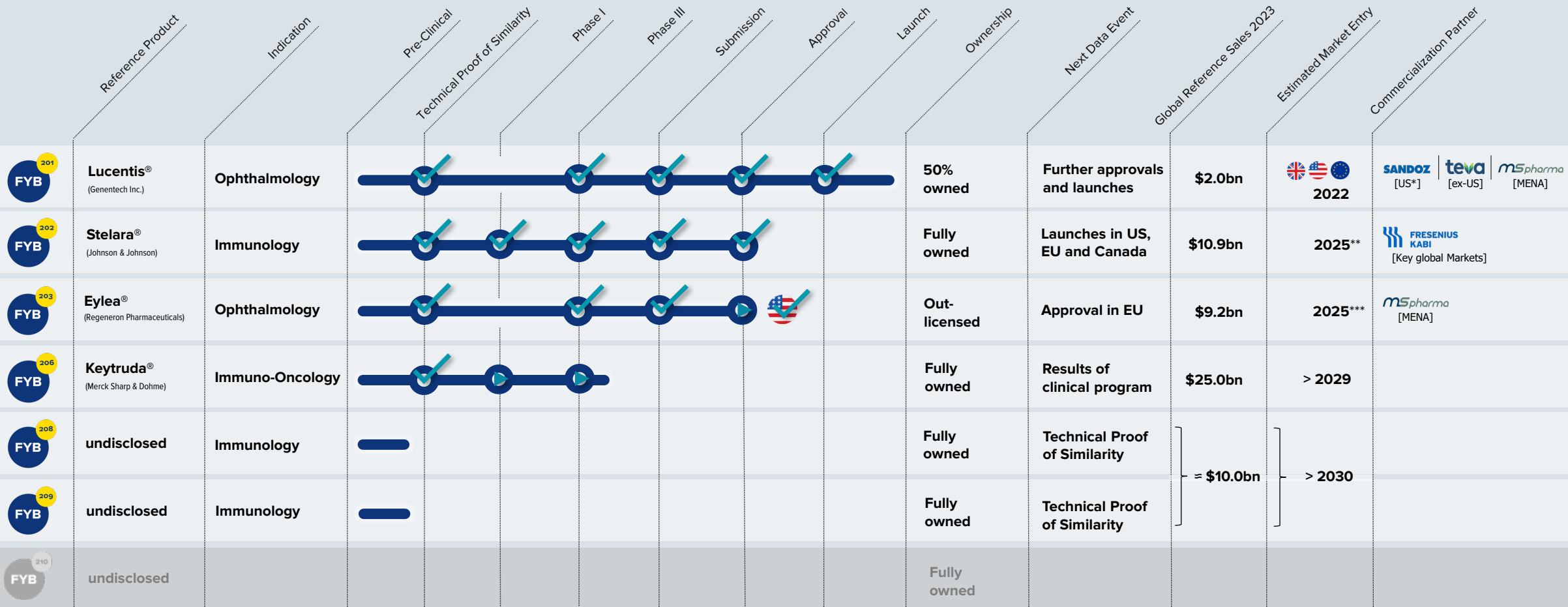
#TeamFormycon

Formycon

Biosimilar Experts

# Strong maturing and growing pipeline

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



▶ ongoing ✓ completed

# Launched & late-stage Projects well on track – Strong Newsflow ahead

**FYB<sup>201</sup>** **Lucentis® Biosimilar**  
[Ranibizumab]

- **Launch in Canada and Switzerland** by Teva.
- **Approval and Nupco tender in Saudi Arabia. Launch of Ravegza®** in May 2024 by MS Pharma.
- **Approval in Kuwait.**
- FYB201 is so far **launched in 19 countries worldwide.**
- **Successful commercialization transfer** from Coherus to Sandoz.
- **Strong performance** across the world exceeded expectations in terms of volume and pricing. 

● Further **approvals and launches** expected until 2026. 

**FYB<sup>202</sup>** **Stelara® Biosimilar Candidate**  
[Ustekinumab]

- **Settlement for Launch in Europe and Canada** with Johnson & Johnson.
- **Settlement with J&J** sets US market entry date to no later than February 22, 2025 within the first launch group of biosimilars.
- **FDA Approval for FYB202/Otulfli™** on Sept. 27, 2024.
- **EC Approval for FYB202/Otulfli®** on Sept. 26, 2024.

● **MHRA approval** expected in Q4/2024 



**FYB<sup>203</sup>** **Eylea® Biosimilar Candidate**  
[Aflibercept]

- **FDA Approval** for FYB203/AHZANTIVE® on June 28, 2024.
- Regulatory procedure at **EMA** progressing.
- **MS Pharma** becomes commercialization partner for FYB203 in **MENA region.** 


● **CHMP Opinion** expected in Q4/2024. EC approval targeted early 2025.

● **Partnering for commercialization** across further regions expected. 

Lucentis® is a registered trademark of Genentech, Inc · Ravegza® is a registered trademark of MS Pharma Saudi  
Stelara® is a registered trademark of Johnson & Johnson · Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc  
Otulfli® is a registered trademark of Fresenius Kabi · Fymiskina® is a registered trademark of Formycon AG  
AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH


## 2nd wave of Projects progressing well

**FYB** <sup>206</sup> **Keytruda® Biosimilar Candidate**  
[Pembrolizumab]

- **First patient entered Phase I clinical trial “Dahlia”** to compare the pharmacokinetics (PK), safety and tolerability of FYB206 with the reference product Keytruda®.
- **First patient entered Phase III “Lotus” trial** to compare safety and efficacy of FYB206 with reference drug Keytruda®.
- Start of clinical trial strengthens FYB206 **excellent position in the leading group** of pembrolizumab biosimilar developers. 


- Further **enrollment and progress** in clinical development. 


**FYB** <sup>208</sup> **FYB** <sup>209</sup> **Undisclosed Biosimilar Candidates**

- **Clones** with superior stability, productivity and quality have been **identified**.
- **Lead Clones have been transferred to CDMOs** (contract development and manufacturing organizations) for further **process development and scale-up**. 

- **Further technical development** towards technical proof of similarity. 

**FYB** <sup>210</sup> **New biosimilar candidate in selection process**

- Selection process initiated along comprehensive set of selection criteria.
- The final phase of the selection process has already been entered. 

- **Selection decision and development kick off** targeted in H2/2024. 

# FYB201 – Lucentis® Biosimilar



## 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

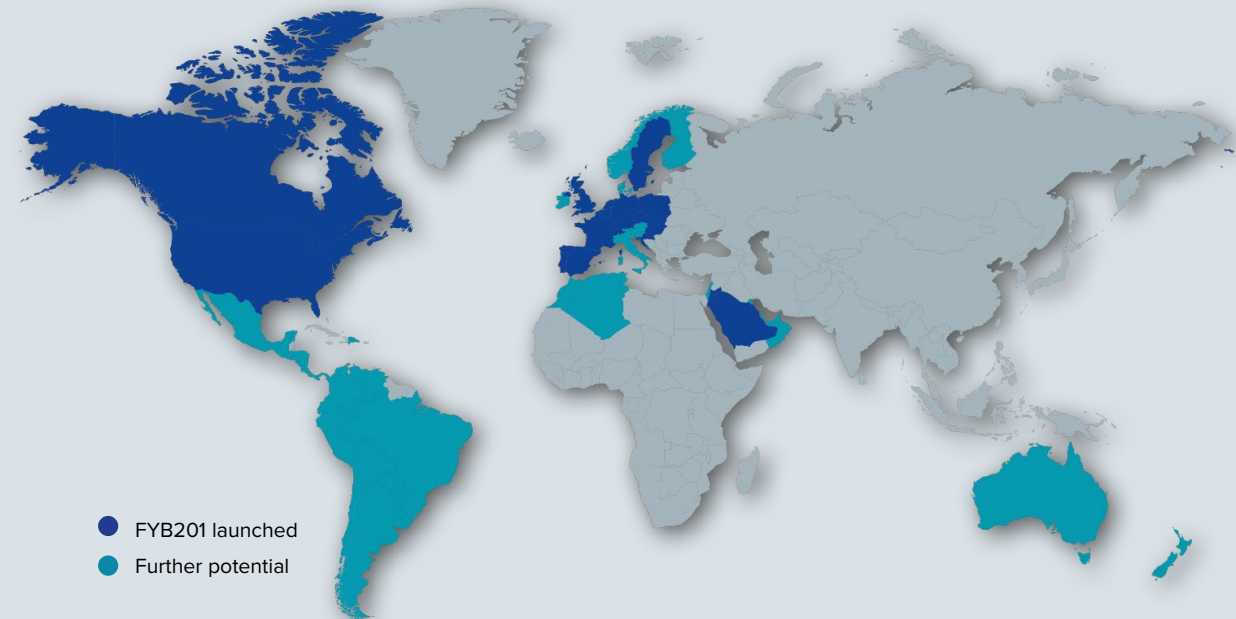
USD 2.0 billion

## Project Rights

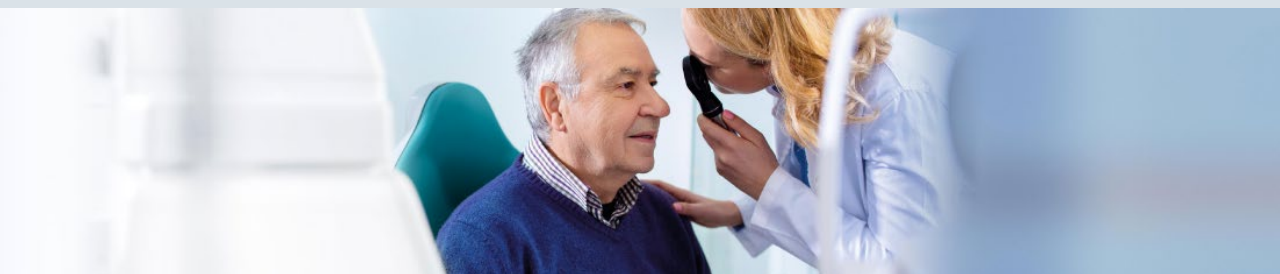
50% ownership in Joint Venture (Bioeq AG) which holds project and commercialization rights

## Next important Milestones

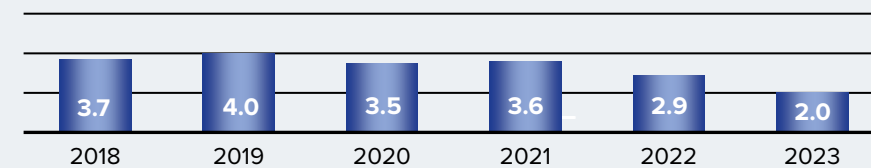
Further approvals and launches expected until 2026.



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) / US to be settled	Completed (06/2021)	Approved in EU, UK, US-Filing (pending due to CRL)
Qilu Pharma	Own commercialization	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
- CIMERLI® ramp-up in the US with 45% market share in the ranibizumab market in April 2024\*.
- Pioneering role with 79% market share in the UK Ranibizumab market in April 2024\* and promising positions in key EU markets.

\*Volume-based - Source: IQVIA Monthly Data R3M (rolling 3-month)

### Formycon Income Position

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



Cimerli® is a registered trademark of Coherus Biosciences Inc. - Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd. Ranivisio® is a registered trademark of Bioeq AG - Ranopto™ is a registered trademark of Teva Canada Ltd. Ravegza® is a registered trademark of MS Pharma Saudi - Uptera® is a registered trademark of MS Pharma Jordan.

# FYB202 – Stelara® Biosimilar Candidate



## Targeted Reference Indications

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

## Target Market 2023

USD 10.9 billion

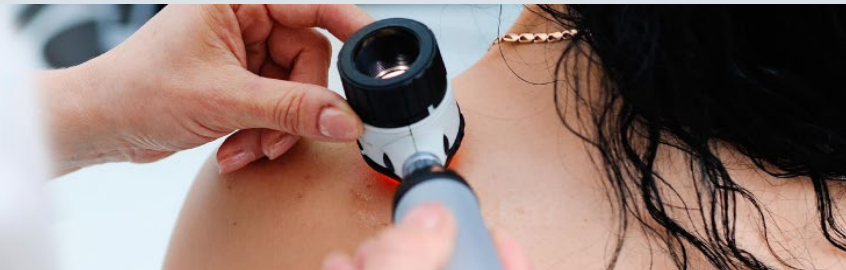
## Project Rights

100% of project and commercialization rights

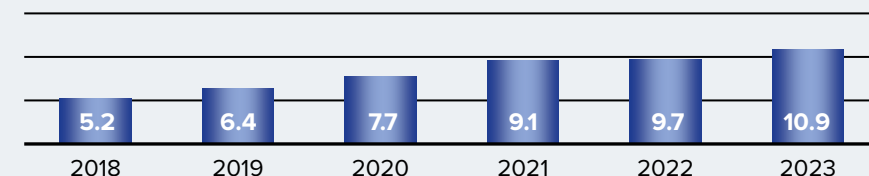
## Achievements

- Settlement with J&J for US license date no later than April 15, 2025
- Settlement for launch in Europe and Canada with J&J
- FDA Approval for FYB202/Otulfi™ on Sept. 27, 2024.
- EC Approval for FYB202/Otulfi® on Sept. 26, 2024.

Commercial Partnership with Fresenius Kabi (Key Global Markets), semi-exclusive rights remain with Formycon (Germany, Parts of MENA/LATAM)



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)	Completed	Approved and Launched in EU / Approved in US Expected Launch in US: 21. Feb.2025
Amgen	Own Commercialization	Completed	Approved in EU / Approved in US – Expected Launch in US: Jan. 2025
Celltrion	Hikma (MENA)	Completed	Approved in EU (08/2024), US-Filing (07/2023) Expected Launch in US: March 2025
Meiji Selka Pharma & Dong A	Intas (Accord)	Completed	EU-Filing (06/2023), US Filing (01/2024) Expected Launch in US: May 2025
Samsung Bioepis	Sandoz	Completed	Approved and Launched in EU Filed in US – Expected Launch in US: 22. Feb. 2025
Bio-Thera	Hikma (US)	Completed	n/a
Biocon	Own Commercialization	Last patient out (expected Q2/2024)	n/a – Expected Launch in US: Feb. 2025



### FYB202 Competitive Advantage

- Submission according to initial schedule and settlement with J&J puts FYB202 in position for market entries in US, EU and Canada
- 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

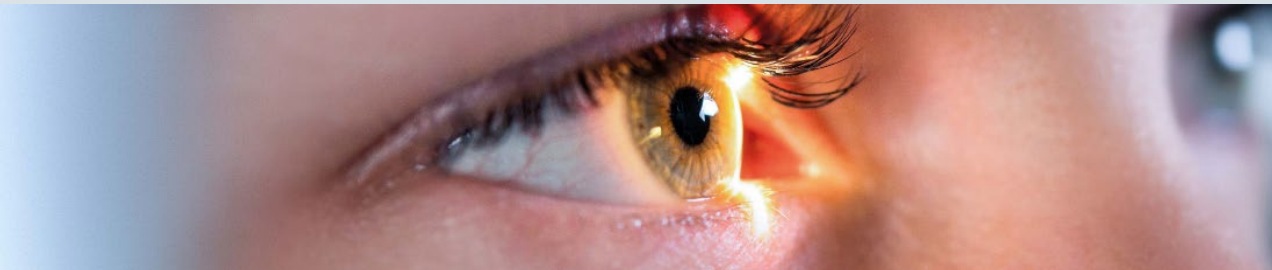
## Project Rights

since 2015 License Agreement with Klinge Biopharma GmbH as Royalty Model

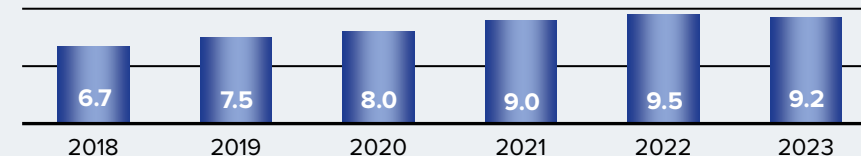
## Achievements and next important Milestones

- On June 28, 2024, the FDA granted approval for FYB203 / AHZANTIVE®
- Approval by the European Commission is expected in early 2025.

Commercial Partnership with MS Pharma (MENA Region), Negotiations with potential commercialization partners for the US and Europe well advanced.



Eylea® 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)

Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.  
 AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH

# Eylea® Biosimilar Candidate FYB203 (Aflibercept)



## Aflibercept Competitive Landscape

Development Company	Status Phase III	Submission / Approval
Alvotech	Completed	n/a
Amgen	Completed	Approved in US & EU
Biocon (Mylan / Momenta)	Completed	Approved in US & EU
Celltrion	Completed	US-Filing (07/2023), EU-Filing (11/2023)
Samsung Bioepis	Completed	Approved in US / EU pending
SamChun Dang	Recruitment completed	EU Filing / ND in the US
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

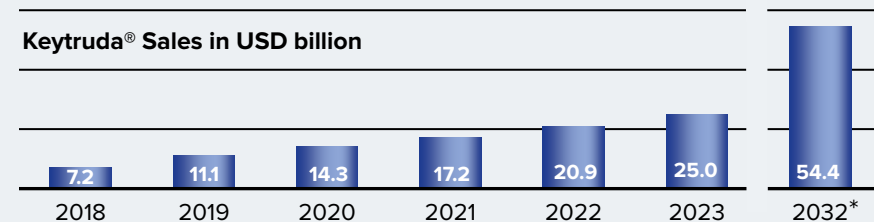
100% of project and commercialization rights

### Achievements and next important Milestones

- Important IP has been generated
- Clinical Phase I trial “Dahlia” started in June 2024 investigating the PK equivalence as part of a preventive therapy for patients who have had a malignant melanoma (black skin cancer) completely surgically removed
- Clinical Phase III trail “Lotus” started in July 2024 comparing safety and efficacy of FYB206 with Keytruda®. Treatment of around 500 randomized NSCLC2 patients in various countries in Eastern Europe and Southeast Asia.



Keytruda® Sales in USD billion



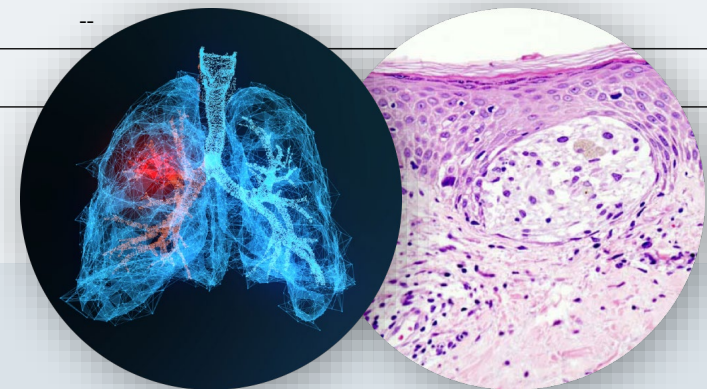
\*<https://www.custommarketinsights.com/report/keytruda-market/>  
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

# Keytruda® Biosimilar Candidate FYB206 (Pembrolizumab)



## Pembrolizumab Competitive Landscape

Development Company	Status	Submission / Approval
Alvotech	Pre-Clinical	--
Amgen	Phase I / III to be launched	--
Bio-Thera	Phase I / III to be launched	--
Henlius	Pre-Clinical	--
mABxience	Phase III launched	--
NeuClone	Pre-Clinical	--
PlantForm	Pre-Clinical	--
Sandoz	Phase I / III launched	--
Samsung Bioepis	Phase I & III launched	--



## 2024 Guidance raised for adjusted EBITDA & Working Capital

Fiscal year 2024 updated forecast	Revenue	EBITDA	Adjusted EBITDA*	Working Capital
	55 to 65 € million	-25 to -15 € million	-5 to +5 € million	35 to 45 € million
Key financial Figures 1H 2024	Revenue	EBITDA	Adjusted EBITDA*	Working Capital
	26.9 € million	-16.9 € million	-2.1 € million	63.0 € million
Fiscal year 2024 initial forecast	Revenue	EBITDA	Adjusted EBITDA*	Working Capital
	55 to 65 € million	-25 to -15 € million	-15 to -5 € million	10 to 20 € million

### Guidance 2024:

- Revenue: Unchanged 
- EBITDA: Unchanged 
- Adjusted EBITDA: Raised 
- Working Capital: Raised 

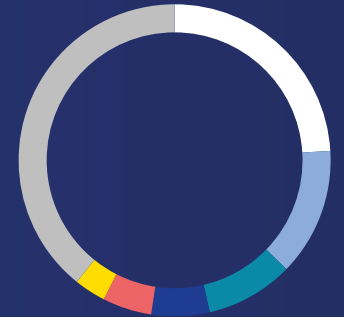
\* EBITDA is derived and calculated from reported operating income (EBIT). Adjusted EBITDA additionally includes the contribution from Formycon's jointly controlled investment accounted for using the equity method Bioeq AG.

## Formycon on the stock market

- **Market Segment:** Frankfurt Stock Exchange Regulated Market (Prime Standard)
- **Registered capital: € 17,656,902**  
Shares outstanding: 17,656,902 (w/o par value)
- **Market price / Market capitalization: ~ € 900 million**
- **Designated Sponsors:**  
Oddo BHF Corporates & Markets AG  
M.M. Warburg & Co.

### Shareholder Structure

- **24.04 %** Santo Holding (Deutschland) GmbH
- **13.25 %** Wpart GmbH, Wen.Co Invest GmbH, Peter Wendeln
- **9.08 %** Gedeon Richter
- **6.04 %** Active Ownership
- **5.10 %** Detlef & Ursula Spruth
- **3.28 %** Stefan Reichensperger
- **39.21 %** Free Float\*\*



\*\*per definition of Deutsche Börse

International Analyst Coverage – **Recommendation: 11 x buy!** / **Ø Price target: € 85**



FIRST BERLIN



Jefferies



METZLER  
B. Metzler seel. Sohn & Co.

M. M. WARBURG & CO



## Exciting newsflow expected in the next 6 months



“First Patient In” Phase I  
clinical trial of Keytruda®  
Biosimilar-Candidate  
FYB206



“First Patient In” Phase III  
clinical trial of Keytruda®  
Biosimilar-Candidate  
FYB206



Approval of  
Eylea® Biosimilar-Candidate  
FYB203 in the US



Positive CHMP Opinion  
for Stelara® Biosimilar-  
Candidate  
FYB202



Approval of  
Stelara® Biosimilar-  
Candidate  
FYB202 in the US



Approval of  
Stelara® Biosimilar-  
Candidate  
FYB202 in the EU



Approval of  
Eylea® Biosimilar-Candidate  
FYB203 in the EU



Commercialization  
partnerships  
(US / EU) for Eylea®  
Biosimilar-Candidate  
FYB203



Development  
start of FYB210  
Biosimilar-  
Project

## 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



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