



# Formycon AG

## The Biosimilar Experts

January 2025

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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**.



**250 employees** from more than 30 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.

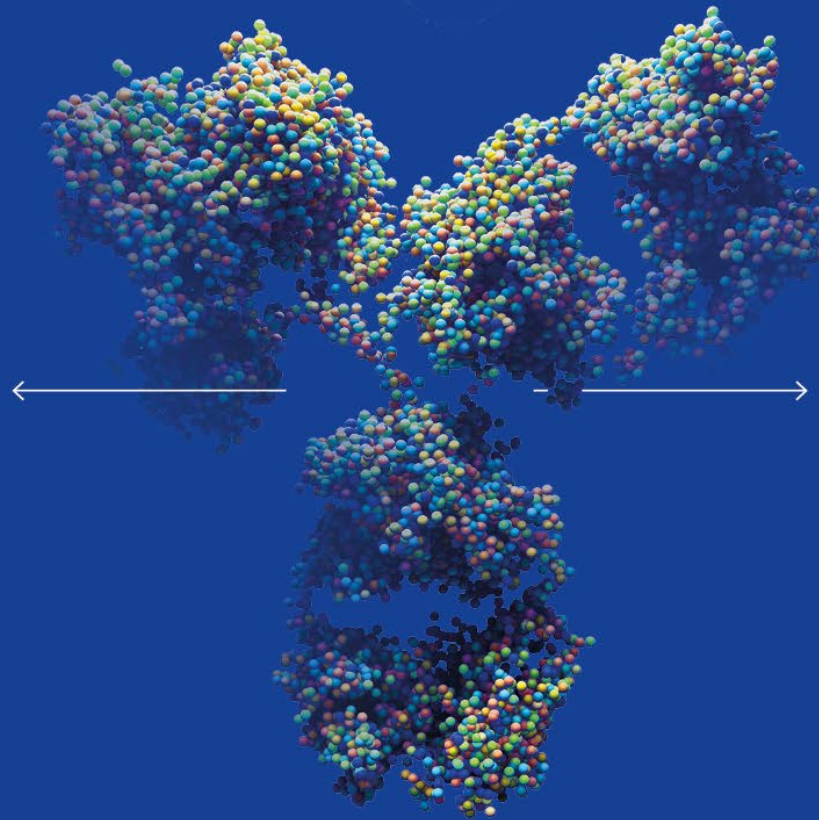


**Formycon's pipeline** includes **three approved biosimilars**, one of which is already launched in **20 countries worldwide**, as well as four biosimilar candidates in development.

We are acting along a clear mission

Biosimilars open up enormous opportunities

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

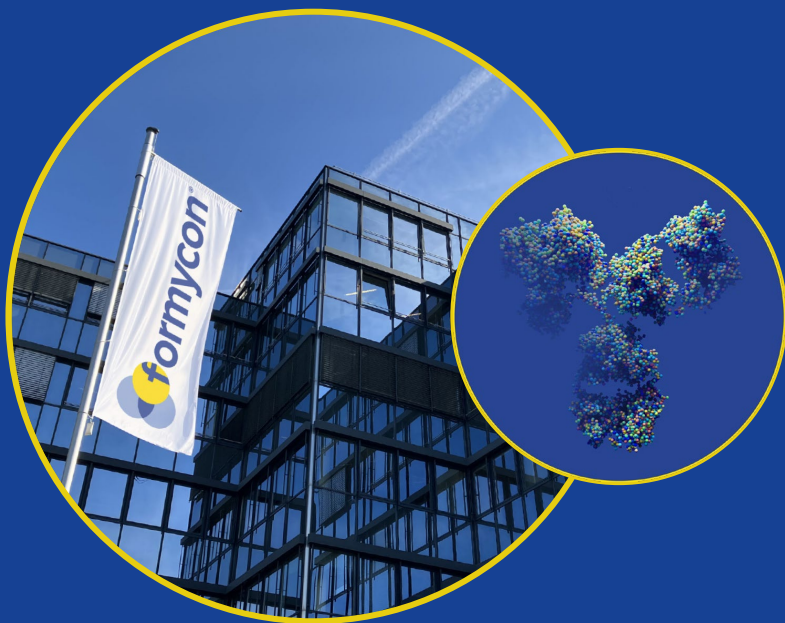


*Improving  
**patient access** to vital  
medicines*

# Laser focus on pipeline execution and expansion



## Maximizing our assets along a clear path



**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

## Many important Milestones achieved in 2024 – further exciting News expected in the upcoming weeks



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 US



Positive CHMP Opinion  
for Eylea® Biosimilar-  
Candidate  
FYB203



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



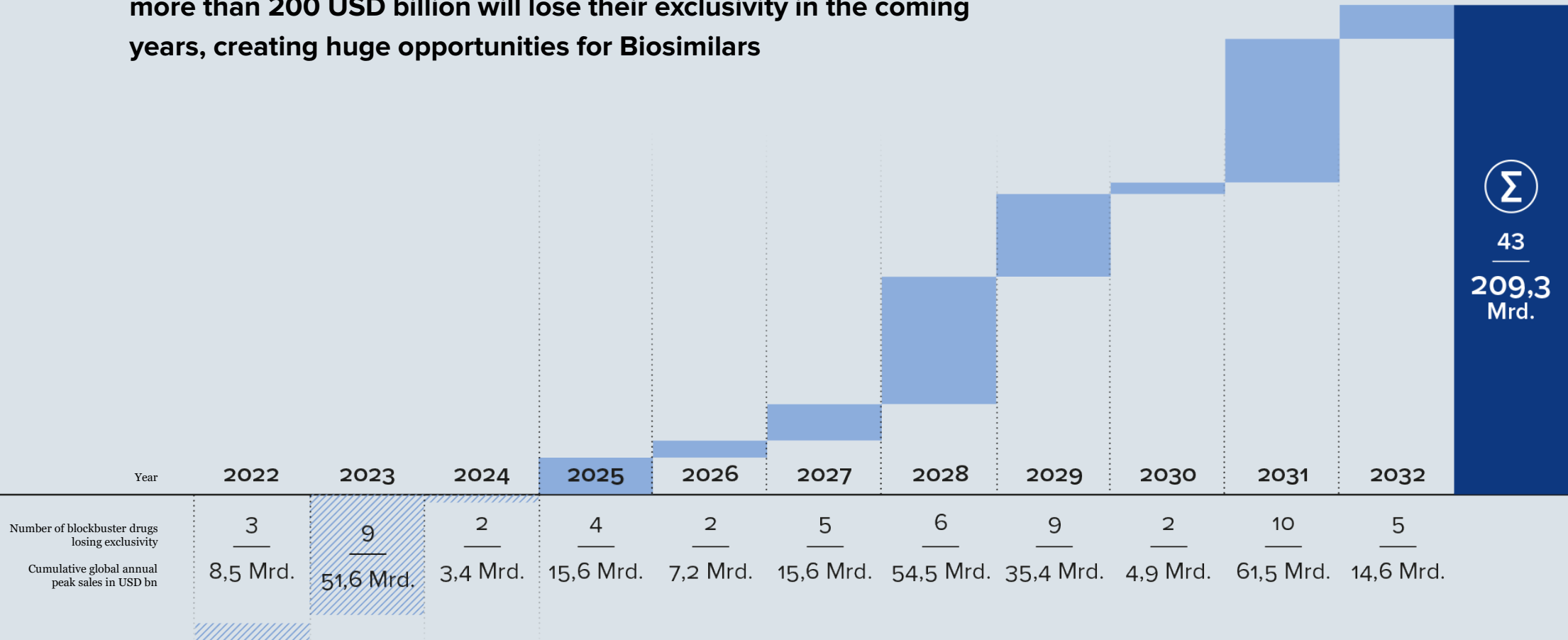
“First Patient In” Phase III  
clinical trial of Keytruda®  
Biosimilar-Candidate  
FYB206



Development  
start of FYB210  
Biosimilar-  
Project

## Huge Biosimilar target opportunities

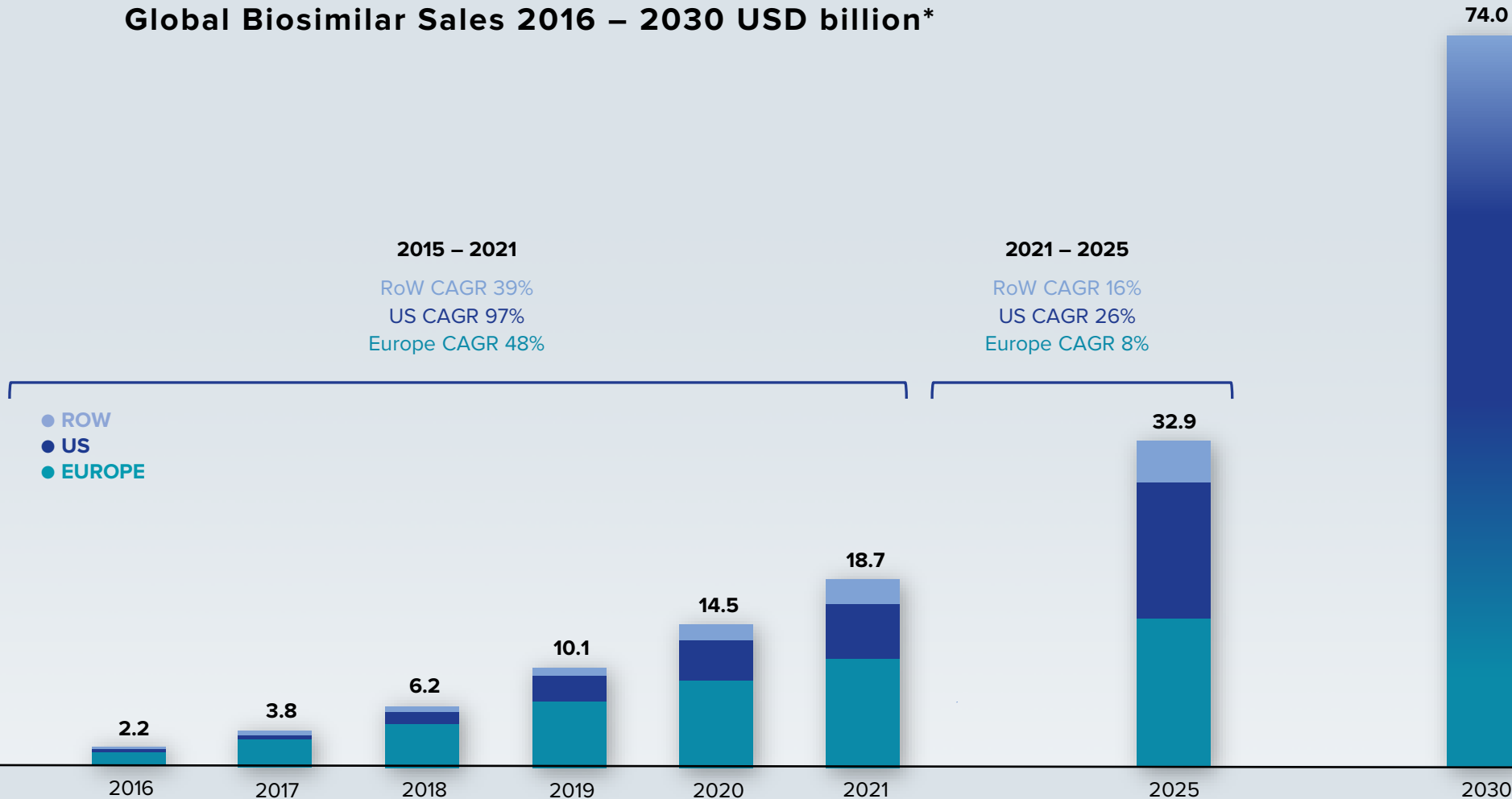
> 40 Blockbuster drugs with an expected global sales volume of more than 200 USD billion will lose their exclusivity in the coming years, creating huge opportunities for Biosimilars



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 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.*



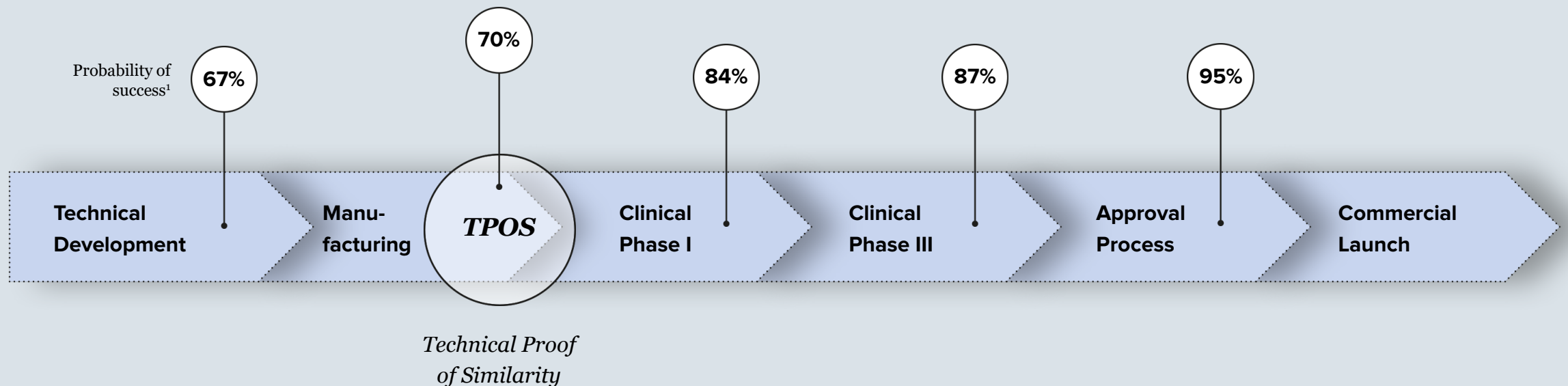
## Full value chain covered in successful hybrid model

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.



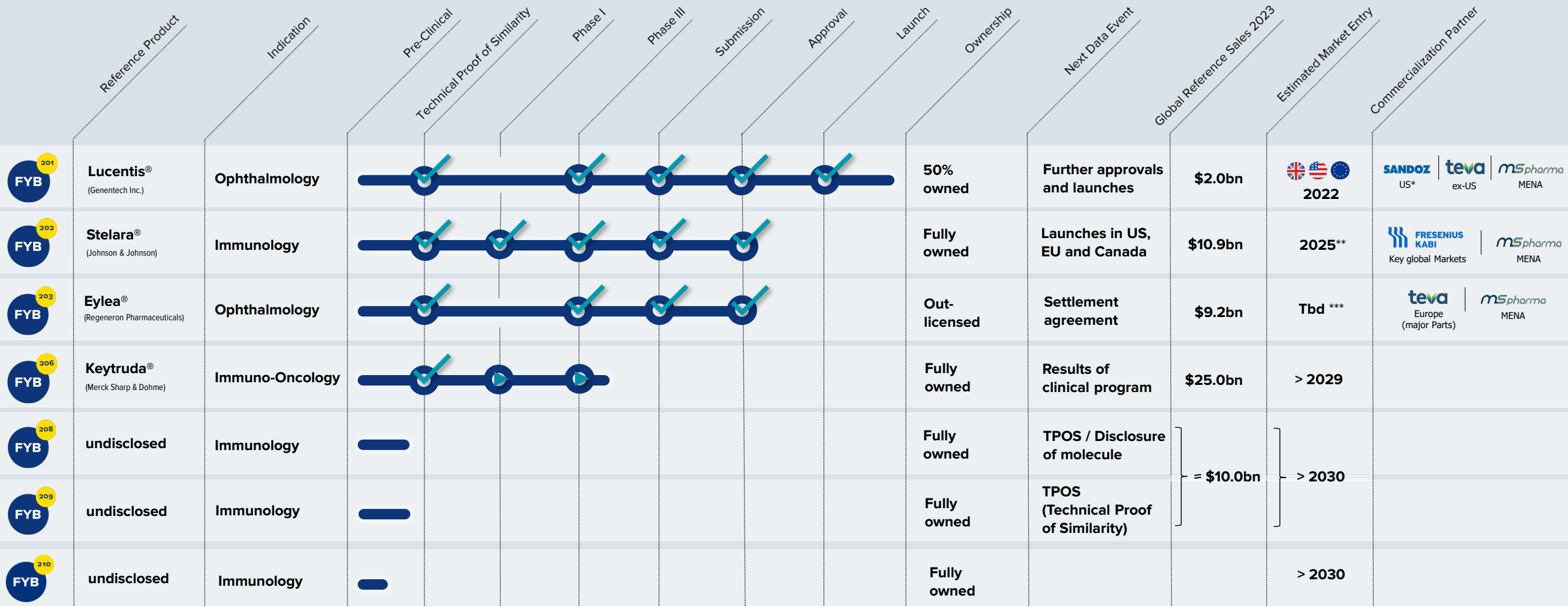
## Biosimilar development – high probability of success

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>



# Strong maturing and growing pipeline

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

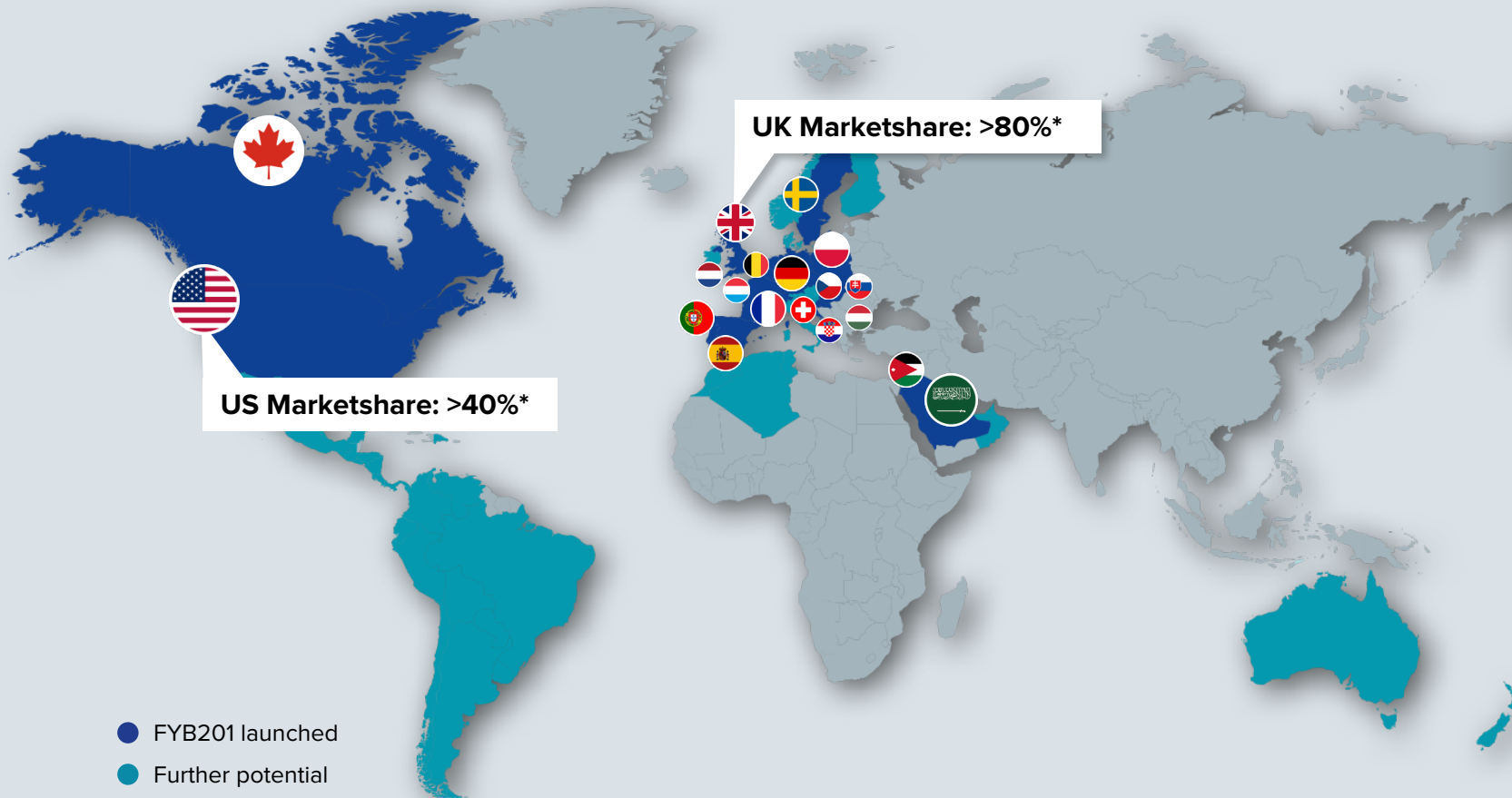


▶ ongoing ✓ completed

# Lucentis® Biosimilar FYB201 – Strong Performance across the World



FYB201/Ranibizumab is so far launched in 20 Countries



- FYB201 launched
- Further potential



SANDOZ

teva

MSpharma

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

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 ready to launch



### 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

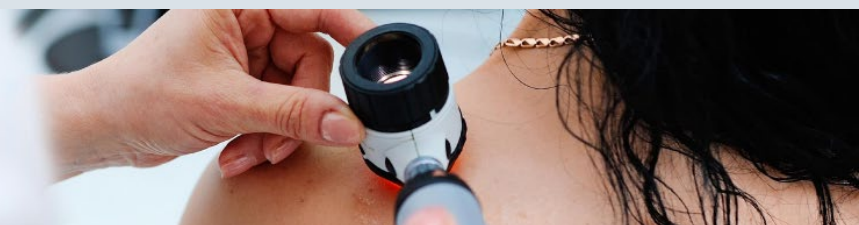
### Achievements:

- Settlement with J&J for US license date no later than February 22, 2025
- Settlement for launch in Europe and Canada with J&J
- FDA- and EC-Approval for FYB202/Otuffi® in Sept. 2024

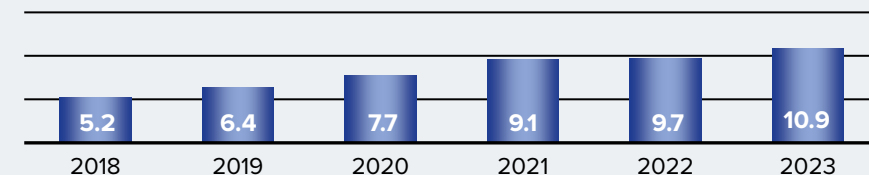
### Formycon Income Position

- 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.

Commercial Partnership with  
**Fresenius Kabi** (Key Global Markets),  
**MS Pharma** (MENA/semi-exclusive)  
 Semi-exclusive rights for Germany and  
 Parts of LATAM remain with Formycon



Stelara® Sales in USD billion



Stelara® is a registered trademark of Johnson & Johnson  
 Otuffi® is a registered trademark of Fresenius Kabi

# FYB203 – Eylea® Biosimilar approved in US and EU



## Targeted Reference Indications

Neovascular AMD<sup>1</sup>, DME<sup>2</sup>, mCNP<sup>3</sup>, RVO<sup>4</sup>

## Target Market 2023

USD 9.2 billion

## Project Rights

License Agreement with Klinge Biopharma GmbH (Royalty Model)

## Achievements and next important Milestones:

- FDA Approval FYB203 / AHZANTIVE® in June 2024
- EC Approval announced January 20, 2025
- Progress on litigation / settlement

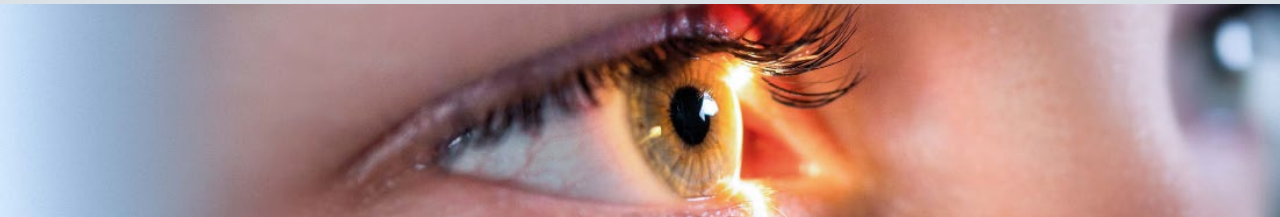
## Formycon Income Position

- Mid-single to low-double-digit-percentage participation in all Klinge income from commercialization partners across all territories.
- Income for managing the entire commercial supply chain of the finished product on behalf of Klinge

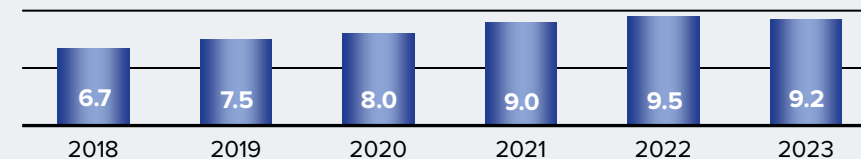
Commercial Partnership with Teva (EU/major parts; ISR) and MS Pharma (MENA Region)



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



Eylea® Sales in USD billion



<sup>1</sup> Neovascular Age related Macular Degeneration Edema (nAMD),  
<sup>2</sup> Diabetic Macular Edema (DME),  
<sup>3</sup> Choroidal Neovascularization (CNV)  
<sup>4</sup> Macular Edema following Retinal Vein Occlusion (RVO)

# FYB206 – Keytruda® Biosimilar Candidate in the leading group



## 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

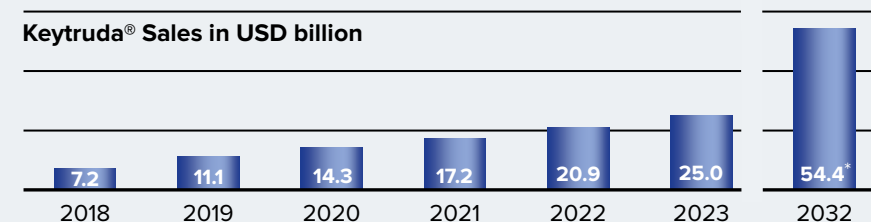
100% of project and commercialization rights

## 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 trial “Lotus” started in July 2024 comparing safety and efficacy of FYB206 with Keytruda®. Treatment of around 500 randomized NSCLC patients in various countries in Eastern Europe and Southeast Asia.



Keytruda® Sales in USD billion



\*[www.custommarketinsights.com/report/keytruda-market/](http://www.custommarketinsights.com/report/keytruda-market/)  
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

## Outlook for 2025 – the next operational and commercial milestones are coming soon



Approval of Stelara® Biosimilar FYB202/Otulf® in Canada



Approval of Stelara® Biosimilar FYB202/Otulf® in UK



Approval of Eylea® Biosimilar Candidate FYB203 in the EU



Commercial Launch of Stelara® Biosimilar FYB202/Otulf®



Approval of Lucentis® Biosimilar FYB201/Ranivisio® in LATAM



Commercialization Partnerships for Eylea® Biosimilar FYB203/Ahzantive® in further regions



Disclosure of Biosimilar Candidate FYB208



Launch of prefilled Syringe for Lucentis® Biosimilar FYB201



Commercialization Partnerships for Keytruda® Biosimilar Candidate FYB206



... and many more important milestones in the course of 2025



## Solid financial Performance as expected

Guidance  
2024

Revenue	EBITDA	Adjusted EBITDA*	Working Capital
55 to 65	-25 to -15	-5 to +5	35 to 45
€ million	€ million	€ million	€ million

9M 2024

Revenue	EBITDA	Adjusted EBITDA*	Working Capital
41.1	-17.7	2.9	65.8
€ million	€ million	€ million	€ million

YE 2023

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

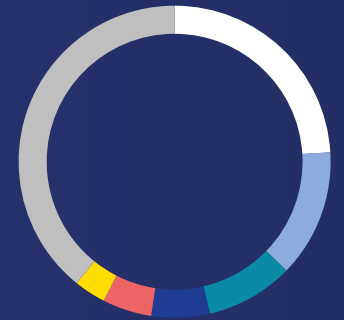
- **Revenue:**  
4Q 2024 expected in the range of € 20m
- **EBITDA:**  
4Q EBITDA expected to be “black zero”
- **Adjusted EBITDA**  
At equity result 4Q also expected to be zero as reduced profit shares expected
- **Working Capital:**  
Expected to decrease in 4Q 2024 due to projected invest in FYB206 of € 19.4m
- **Updated Guidance 2024**  
Resulting from H1 2024: No need to adjust in context of Q3 reporting but to be confirmed

# Formycon – uplisted to Prime Standard and Part of the SDAX and the TecDAX

- **Market Segment:** Frankfurt Stock Exchange Regulated Market (Prime Standard)
- **Uplisted to Prime Standard on Nov. 12, 2024, part of the SDAX since Dec. 23, 2024, joined the TecDAX on Jan. 13, 2025, gaining further momentum with:**
  - more **international Investors**
  - higher **Liquidity**
  - better **Transparency**
- **Registered capital: € 17,664,427**  
Shares outstanding: 17,664,427 (w/o par value)
- **Market price / Market capitalization: ~ € 1 billion**
- **Member of Indices:** SDAX, TecDax, MSCI Europe Small Cap, MSCI EAFE IMI, MSCI Germany Small Cap

## 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 R.
- **39.21 %** Free Float\*\*



\*\*per definition of Deutsche Börse



## 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



### **Formycon AG**

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