



Formycon AG

The Biosimilar Experts

November / December 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.

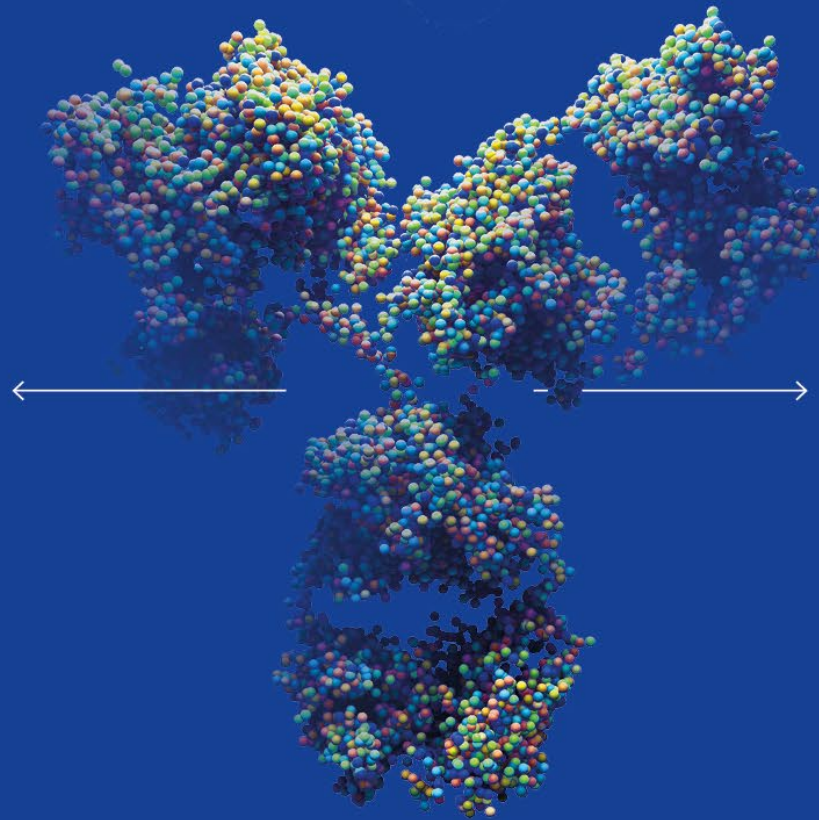


Formycon's pipeline includes **three approved biosimilars**, one of which is already launched in **20 countries worldwide**, as well as four biosimilar candidates in development.

We are acting along a clear mission

Biosimilars open up enormous opportunities

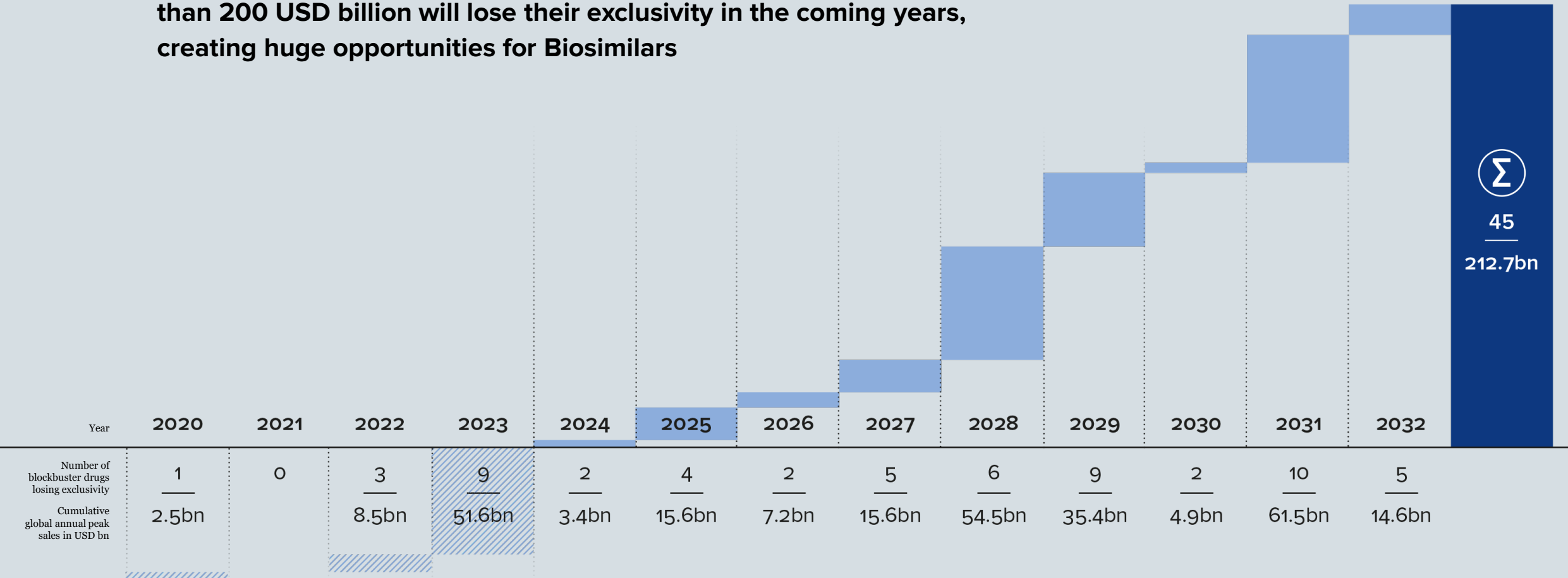
*Contributing to ease
the **financial strains** on the
world's healthcare systems*



*Improving
patient access to vital
medicines*

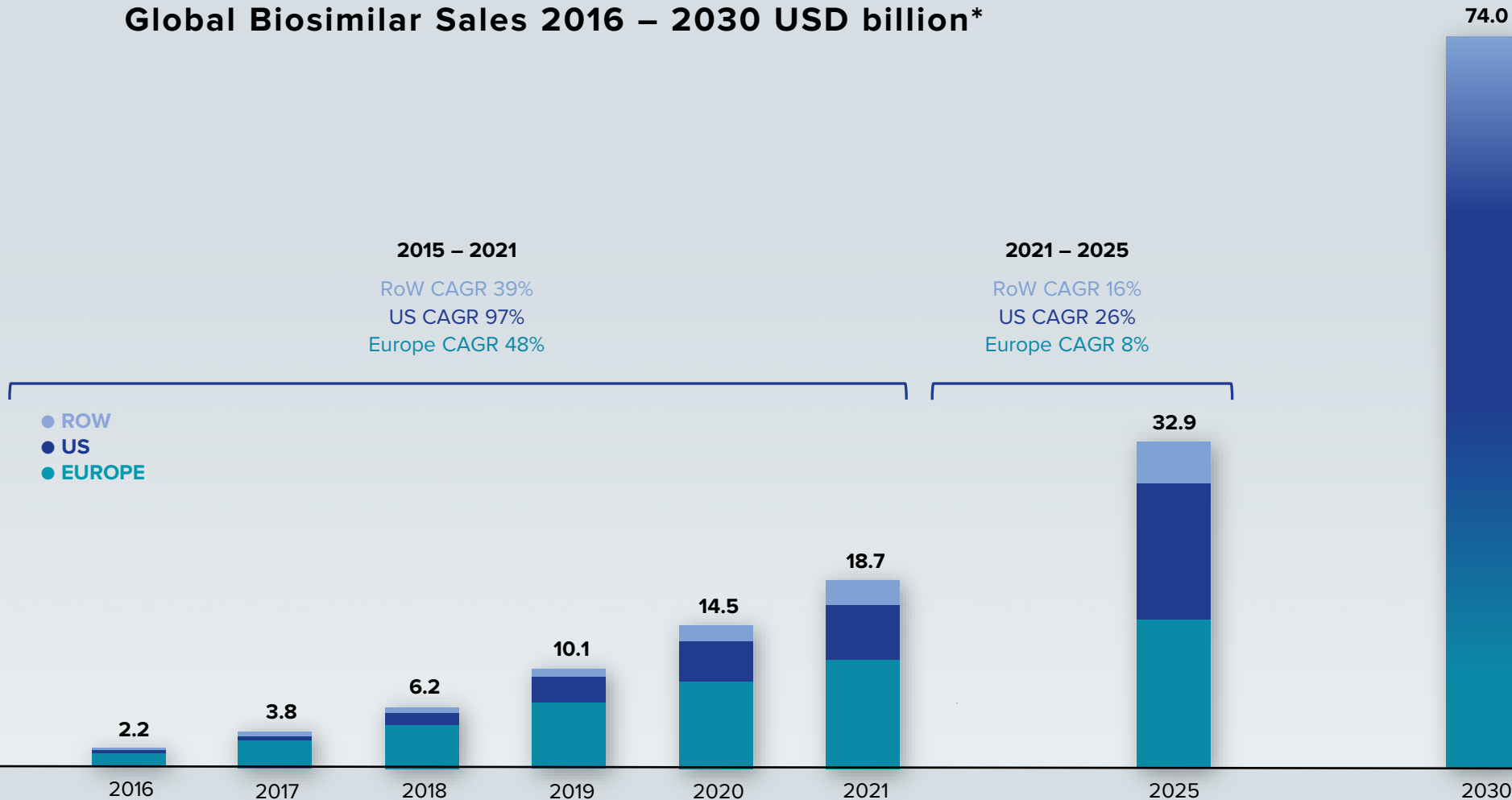
Huge Biosimilar target opportunities

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

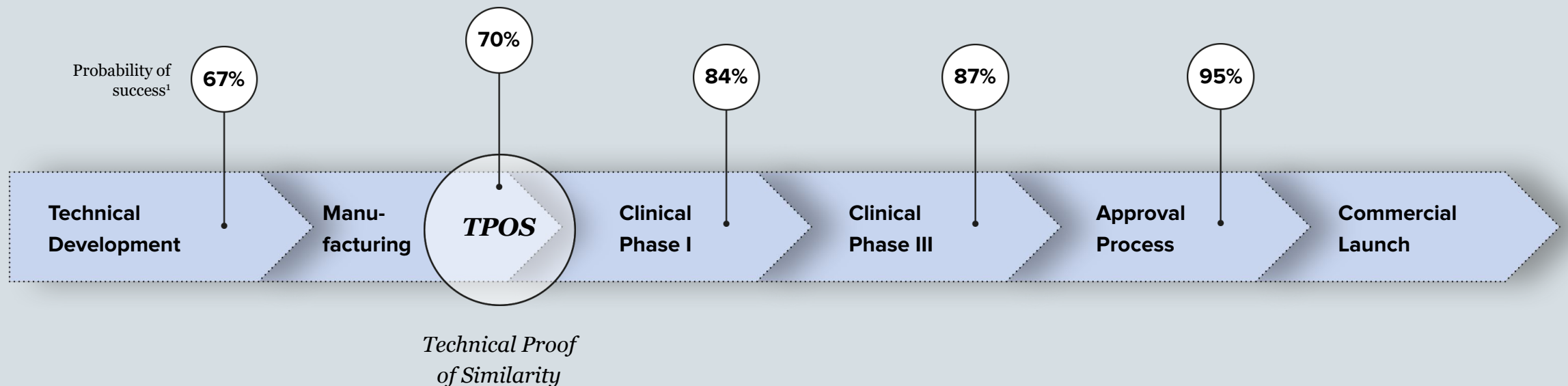
Global Biosimilar Sales 2016 – 2030 USD billion*



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.

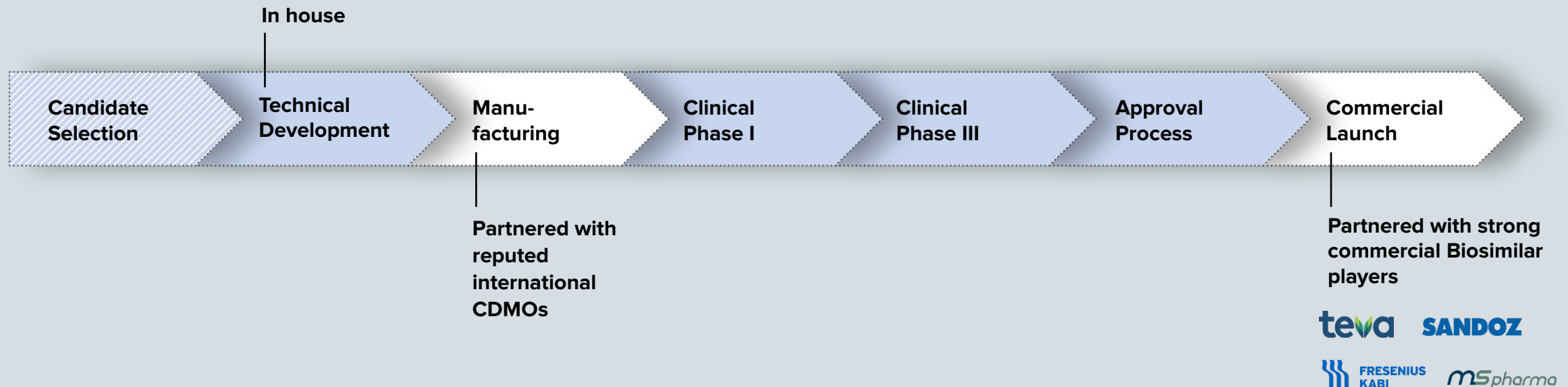
Biosimilar development with different risk profile – high probability of success

The **probability of success for a Biosimilar is continuously high** over the course of development¹. 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



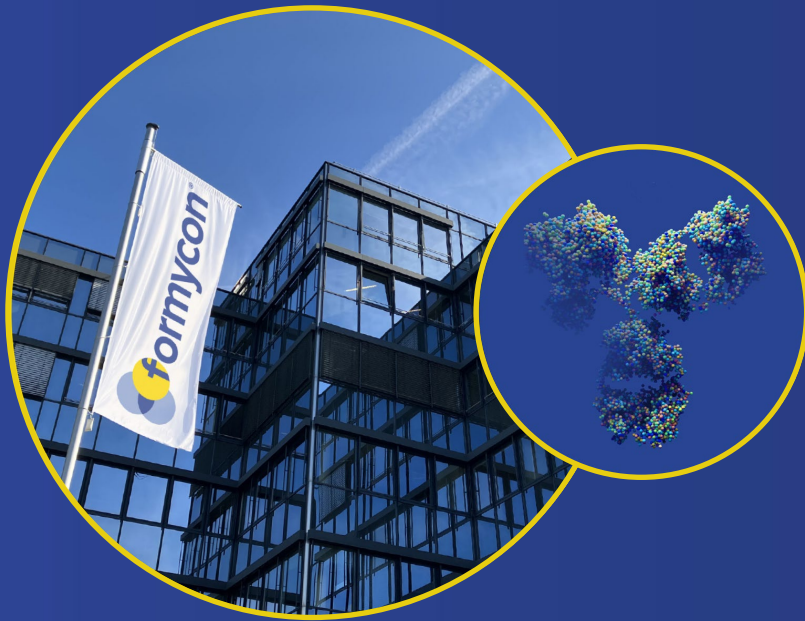
Full value chain covered in successful hybrid model

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

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




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

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


FYB²⁰¹ **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 20 countries worldwide.**
- **Successful commercialization transfer** from Coherus to Sandoz.
- **Strong performance** across the world exceeded expectations in terms of volume and market-share. 


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


FYB²⁰² **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 

FYB²⁰³ **Eylea® Biosimilar Candidate**
[Aflibercept]


- **FDA Approval** for FYB203/AHZANTIVE® on June 28, 2024.
- **MS Pharma** becomes commercialization partner for FYB203 in **MENA region.**
- Regulatory procedure at **EMA** well advanced with **positive CHMP Opinion** on November 15, 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 · Fymaskina® is a registered trademark of Formycon AG
AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH


2nd wave of Projects progressing well


FYB ²⁰⁶ **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 ²⁰⁸ **FYB** ²⁰⁹ **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. 

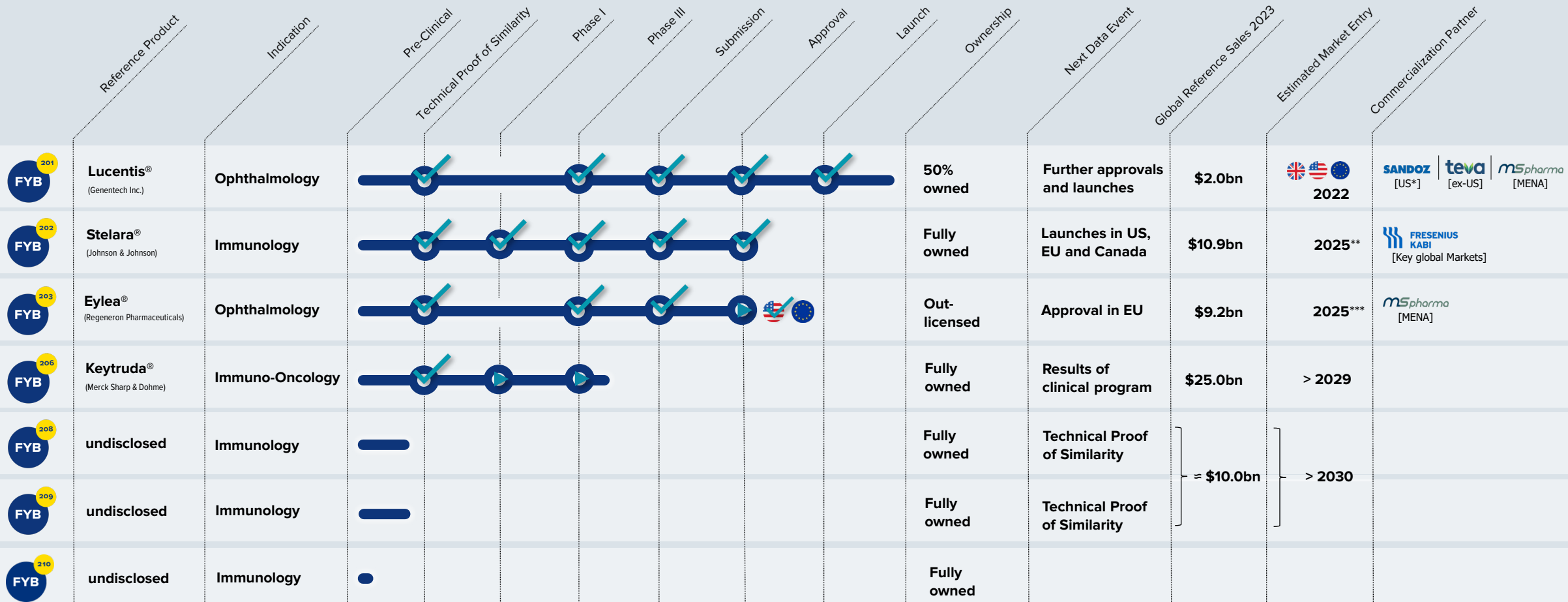
FYB ²¹⁰ **New undisclosed Biosimilar Candidate**

- **New Biosimilar Candidate** in the field of **immunology** selected.
- **Development kick-off**. 

- **Analytical and technical development steps** 

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

FYB201 – Lucentis® Biosimilar well positioned



Approved and launched



Indications

Neovascular age-related Macular Degeneration (nAMD), DME¹, CNV², PDR³, RVO⁴

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.

FYB201 well established

- Launched in 20 countries.
- CIMERLI® ramp-up in the US with > 40% market share in the ranibizumab market as of August 2024*.
- Pioneering role with > 80% market share in the UK Ranibizumab market as of August 2024* and promising positions in key EU markets.

Formycon Income Position

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

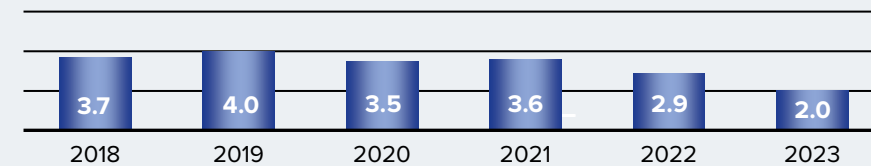


*Volume-based / Source: IQVIA Monthly Data R3M (rolling 3-month)

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



Lucentis® Sales in USD billion



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

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)



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)



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 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

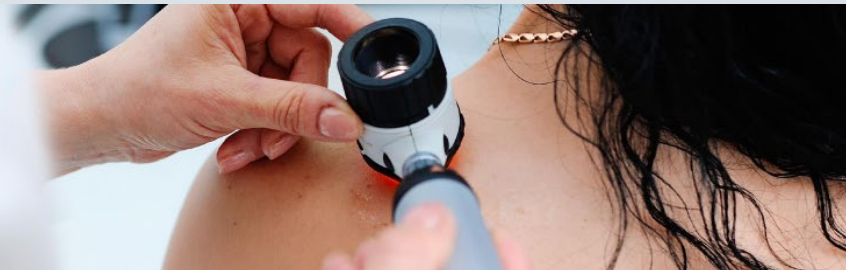
FYB202 Competitive Advantage

- 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 partner with potential for commercial lead position.

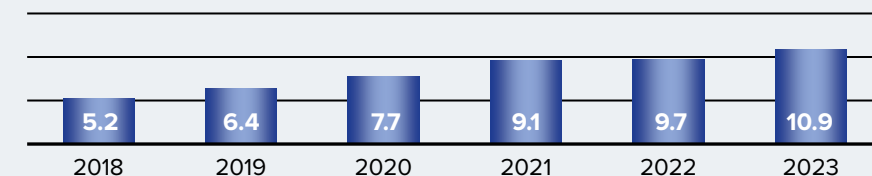
Formycon Income Position

- 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), semi-exclusive rights remain with Formycon (Germany, Parts of MENA/LATAM)



Stelara® Sales in USD billion

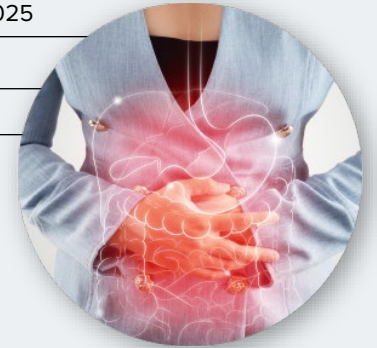


Stelara® Biosimilar Candidate FYB202 (Ustekinumab)



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




Stelara® is a registered trademark of Johnson & Johnson

FYB203 – Eylea® Biosimilar Candidate approved in US & recommended for EU



FYB ²⁰³

Approved 

Targeted reference Indications

Neovascular Age-Related Macular Degeneration (nAMD), DME¹, mCNV², RVO³

Target Market 2023

USD 9.2 billion

Project Rights

since 2015 License Agreement with Klinge Biopharma GmbH as Royalty Model

Formycon Income Position

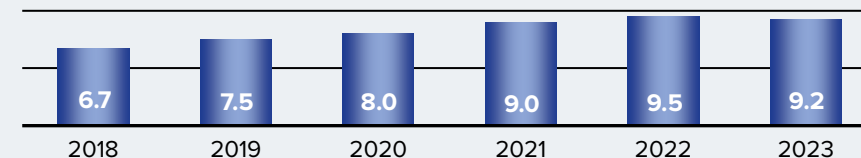
- Mid-single to low-double-digit-percentage participation in all Klinge income from commercialization partners across all territories.



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



Eylea® Sales in USD billion



¹ Diabetic Macular Edema (DME),
² Choroidal Neovascularization (CNV)
³ 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 / Launch in US
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)	Approved in US



Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc

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

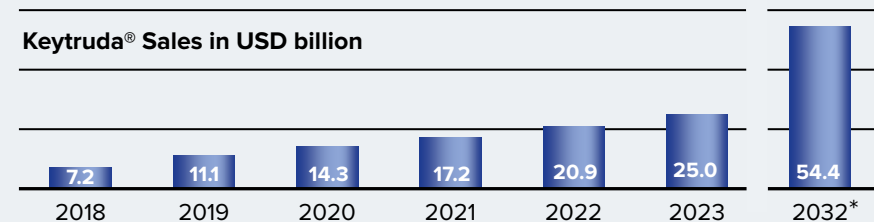
USD 25.0 billion

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 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.



*<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	--



Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

2024 Guidance confirmed

9M 2024

Revenue

41.1

€ million

EBITDA

-17.7

€ million

Adjusted EBITDA*

2.9

€ million

Working Capital

65.8

€ million

Guidance
2024 (last
adjusted @
H1 2024)

Revenue

55 to 65

€ million

EBITDA

-25 to -15

€ million

Adjusted EBITDA*

-5 to 5

€ million

Working Capital

35 to 45

€ million

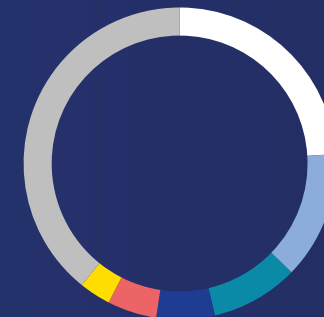
- **Revenue:**
4Q 2024 expected in the range of € 20m
- **EBITDA:**
4Q EBITDA expected to be “black zero”
- **Adjusted EBITDA**
At equity result 4Q also expected to be zero as reduced profit shares expected
- **Working Capital:**
Expected to decrease in 4Q 2024 due to projected invest in FYB206 of €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

Formycon – now uplisted to Prime Standard!

- **Market Segment:** Frankfurt Stock Exchange Regulated Market (Prime Standard)
- **Uplisted to Prime Standard on Nov. 12, 2024** enables **Formycon's share to gain 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: ~ € 830 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 R.
- **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



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

Thank You!

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