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.**

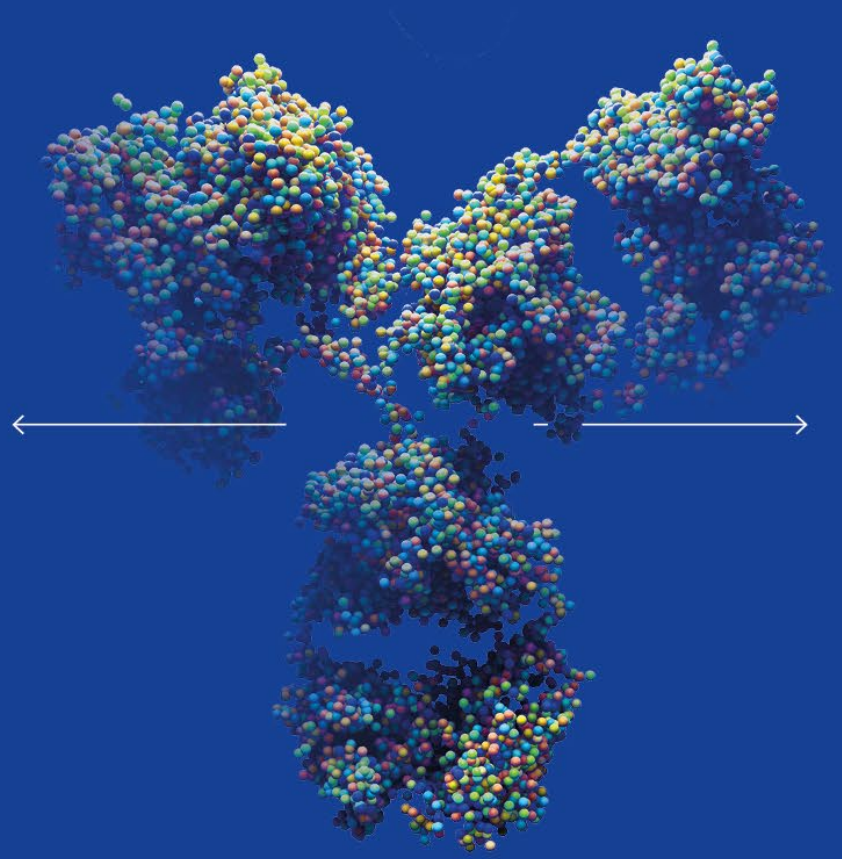
Combining high **professional expertise** in biopharmaceutical development **with agile mindset** enables Formycon to develop **multiple Biosimilar projects** in competitive timing and high quality.

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

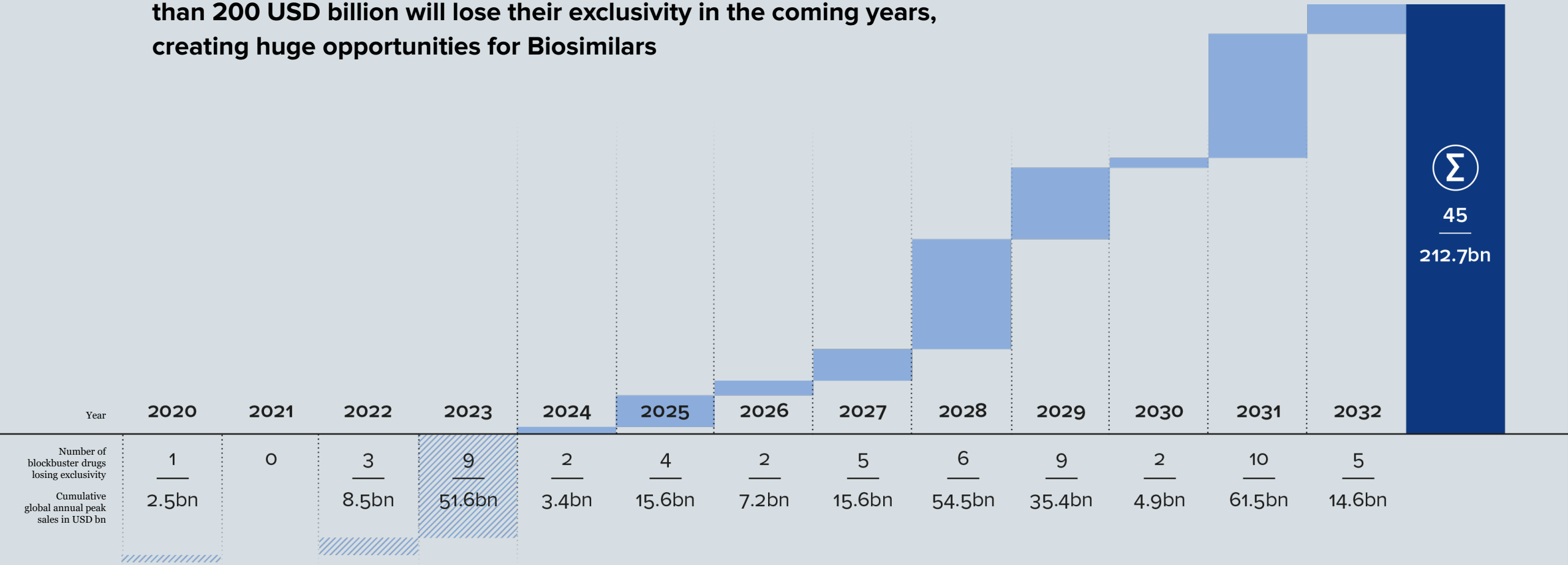
*Contributing to ease the **financial strains** on the world's healthcare systems*



*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

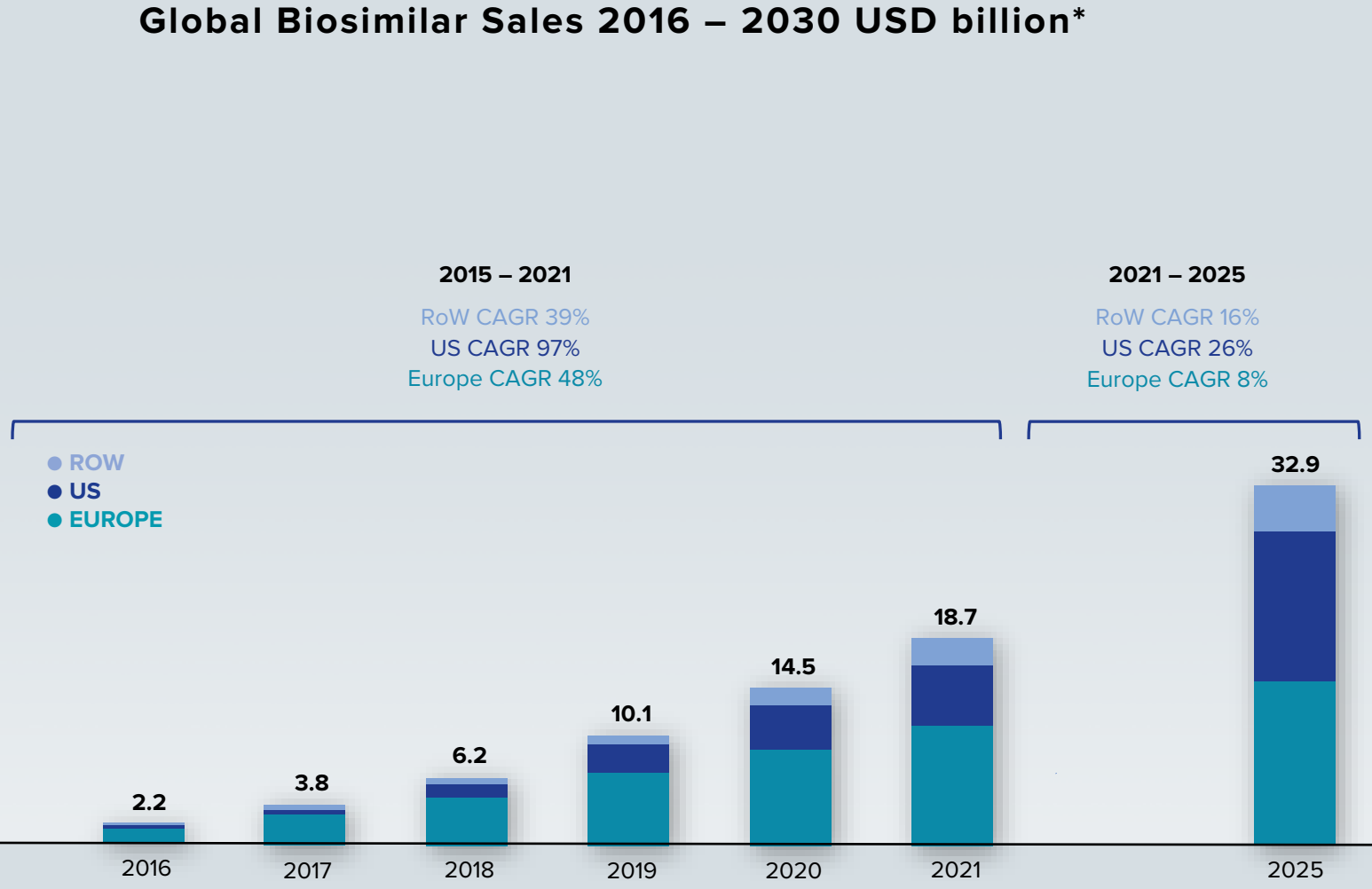


Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Number of blockbuster drugs losing exclusivity	1	0	3	9	2	4	2	5	6	9	2	10	5
Cumulative global annual peak sales in USD bn	2.5bn		8.5bn	51.6bn	3.4bn	15.6bn	7.2bn	15.6bn	54.5bn	35.4bn	4.9bn	61.5bn	14.6bn

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*

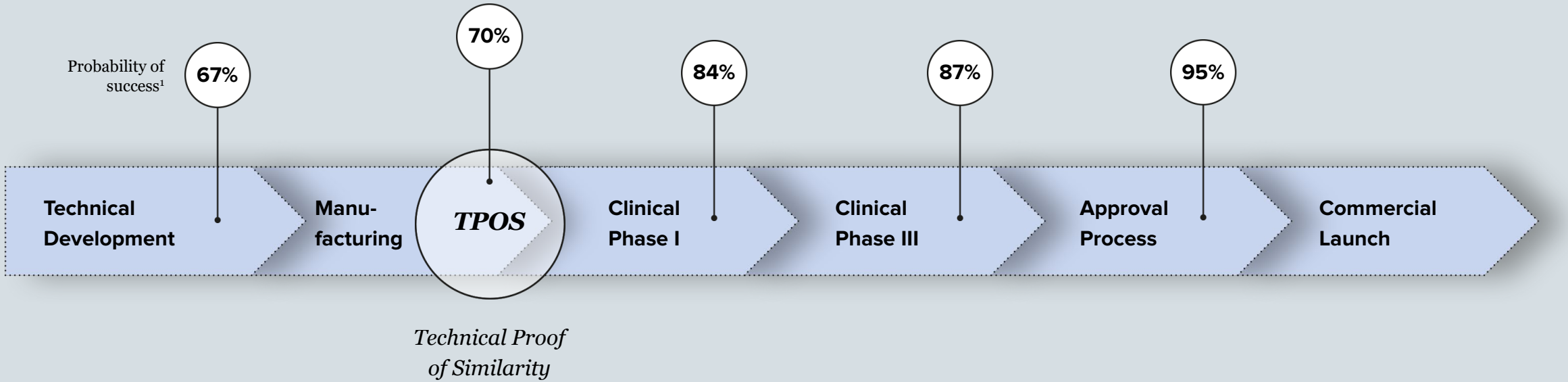


Biosimilars is the fastest growing segment in Pharma. The US market has seen the fastest growth in Biosimilars with a CAGR of 97 % from 2015 – 2021. Although projections to 2025 show a lower rate of growth, the United States is expected to stay in pole position.

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

Biosimilar development – high probability of success

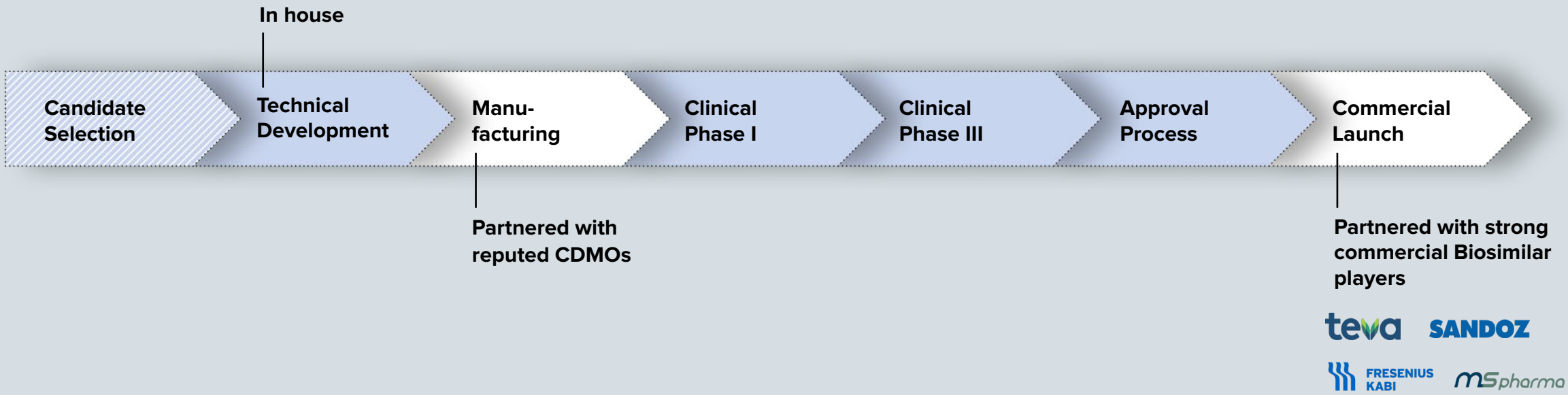
The **probability of success for a Biosimilar is continuously high** over the course of development[1]. This is different **for innovative drug developments**: Here, on average, **only one in twelve innovative drugs makes it from the preclinical stage to approval.**[2]



[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.



Laser focus on pipeline execution and expansion

Maximizing our assets along a clear pathway

2023

Strong financial and operational performance

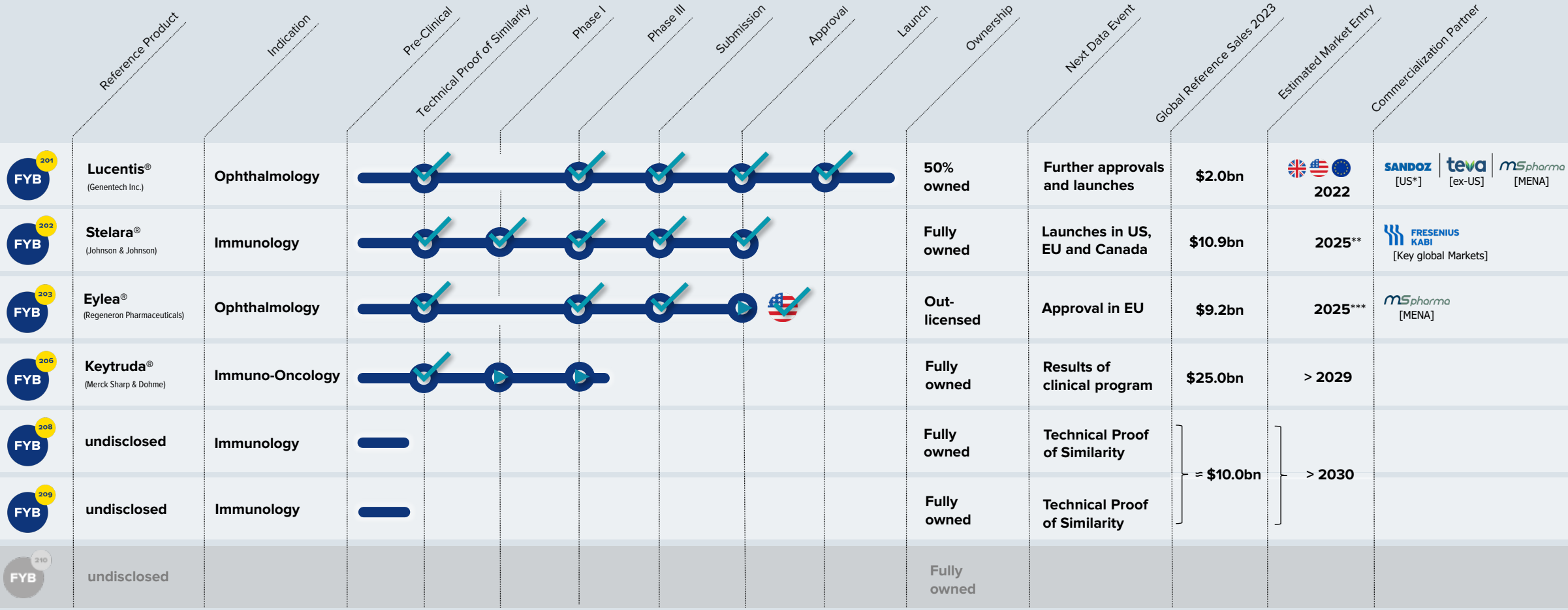
2024

Important year to prepare the ground for the next ignition stage

Sustainable profitability with continuous pipeline growth

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 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

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

FYB 201 – 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 202 – 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/Otulfi™ on Sept. 27, 2024.
- **EC Approval for** FYB202/Otulfi® on Sept. 26, 2024.

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

FYB 203 – 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.

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 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.

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

FYB201 – Lucentis® Biosimilar

FYB 201

Approved and launched

Indications

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

Target Market 2023

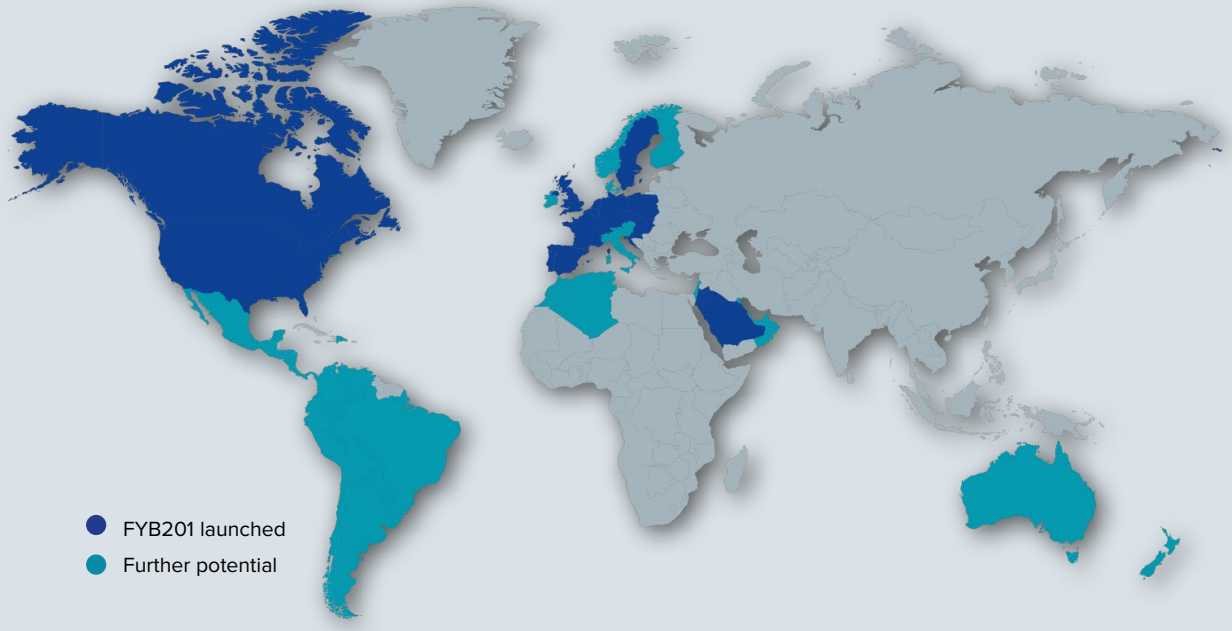
USD 2.0 billion

Project Rights

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

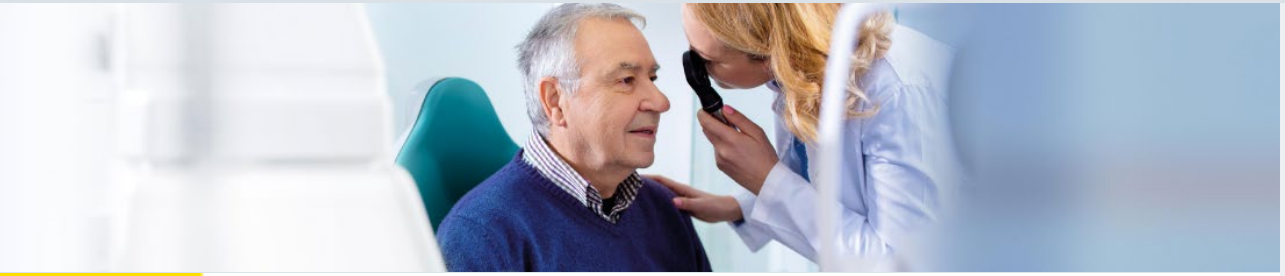
Next important Milestones

Further approvals and launches expected until 2026.

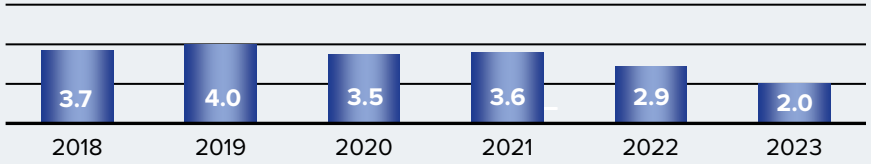


Commercial Partnership with Sandoz* (US) and Teva (ex-US), MS Pharma (MENA)

SANDOZ* | teva | MSpharma



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) 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.

FYB202 – Stelara® Biosimilar Candidate

FYB 202

Approved

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

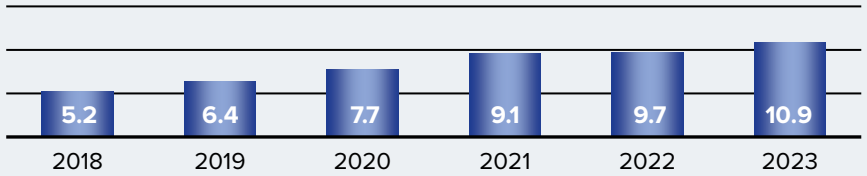
Achievements

- 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)

FRESENIUS KABI

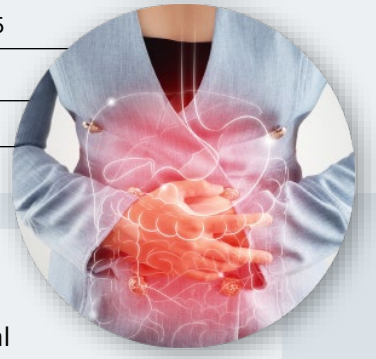
Stelara® Sales in USD billion



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

FYB 203

Approved

Targeted reference Indications

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

Target Market 2023

USD 9.2 billion

Project Rights

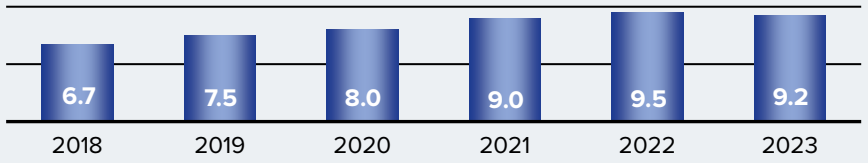
since 2015 License Agreement with Klinge Biopharma GmbH as Royalty Model

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

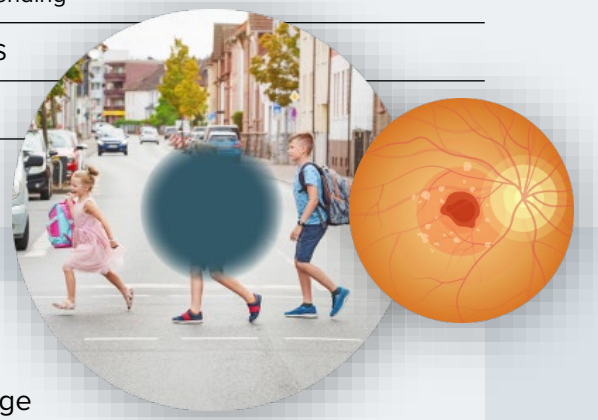


[1] Diabetic Macular Edema (DME),
[2] Choroidal Neovascularization (CNV)
[3] Proliferative Diabetic Retinopathy (PDR),
[4] Macular Edema following Retinal Vein Occlusion (RVO)

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

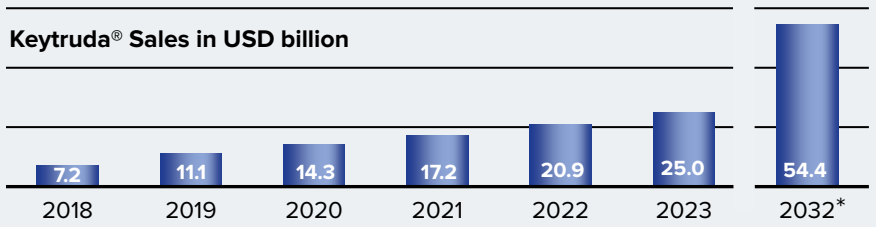
Targeted reference Indications
Immuno-oncology: Melanoma (black skin cancer), non-small cell Lung Cancer, classical Hodgkin's Lymphoma and other Tumor Diseases

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.

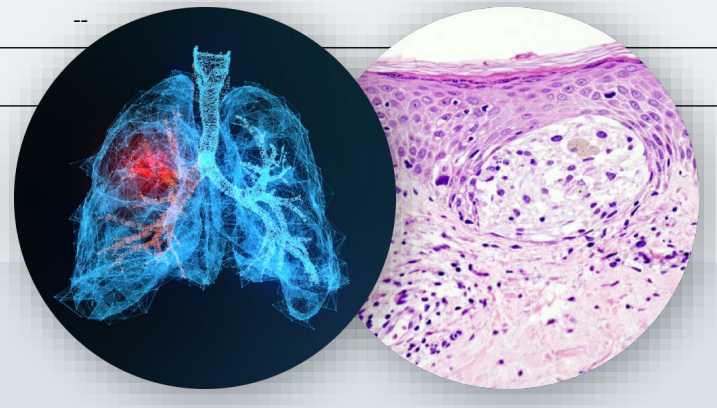


*https://www.custommarketinsights.com/report/keytruda-market/
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

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

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

Guidance 2024:

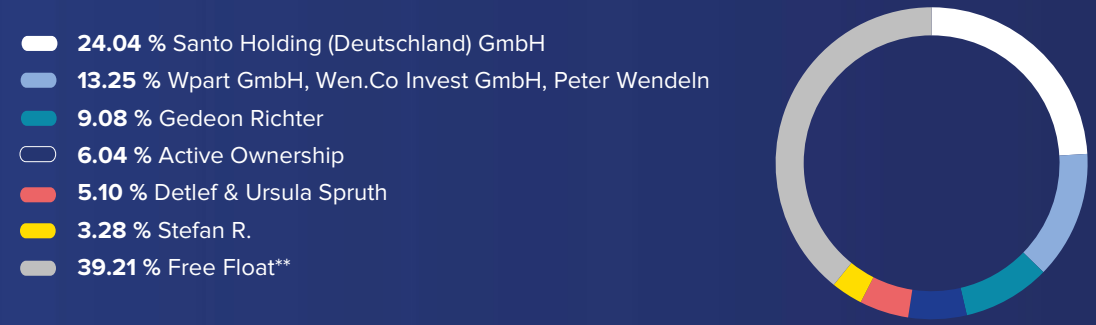
- **Revenue:** Unchanged
- **EBITDA:** Unchanged
- **Adjusted EBITDA:** Raised
- **Working Capital:** Raised

* *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



**per definition of Deutsche Börse

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

NEW! BERENBERG · FIRST BERLIN · HAUCK & AUFHÄUSER · NEW! HCW · Jefferies · Kepler Cheuvreux · METZLER B. Metzler seel. Sohn & Co. · M. M. WARBURG & CO · mwb research · NEW! ODDO BHF · NEW! RBC

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

Formycon AG

Formycon AG
Fraunhoferstraße 15
82152 Martinsried / Planegg
Germany

T + 49 89 864 667 100
F + 49 89 864 667 110

E ir@formycon.com
I www.formycon.com

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Formycon AG
The Biosimilar Experts