



Formycon AG
The Biosimilar Experts



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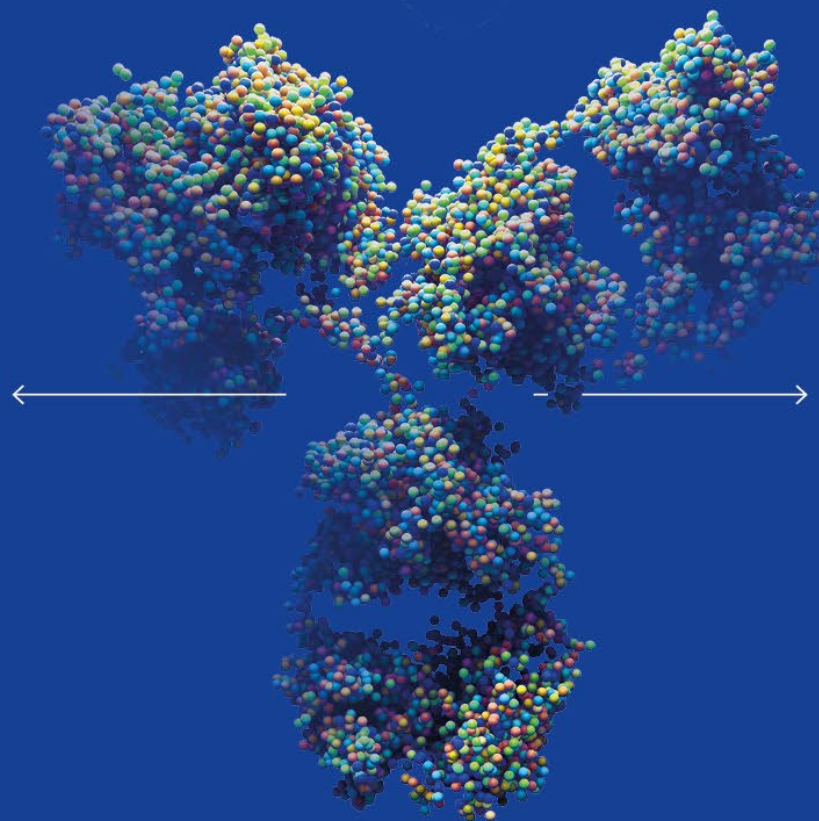
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BIOSIMILAR MARKET

VISION & MISSION

Biosimilars open up enormous opportunities

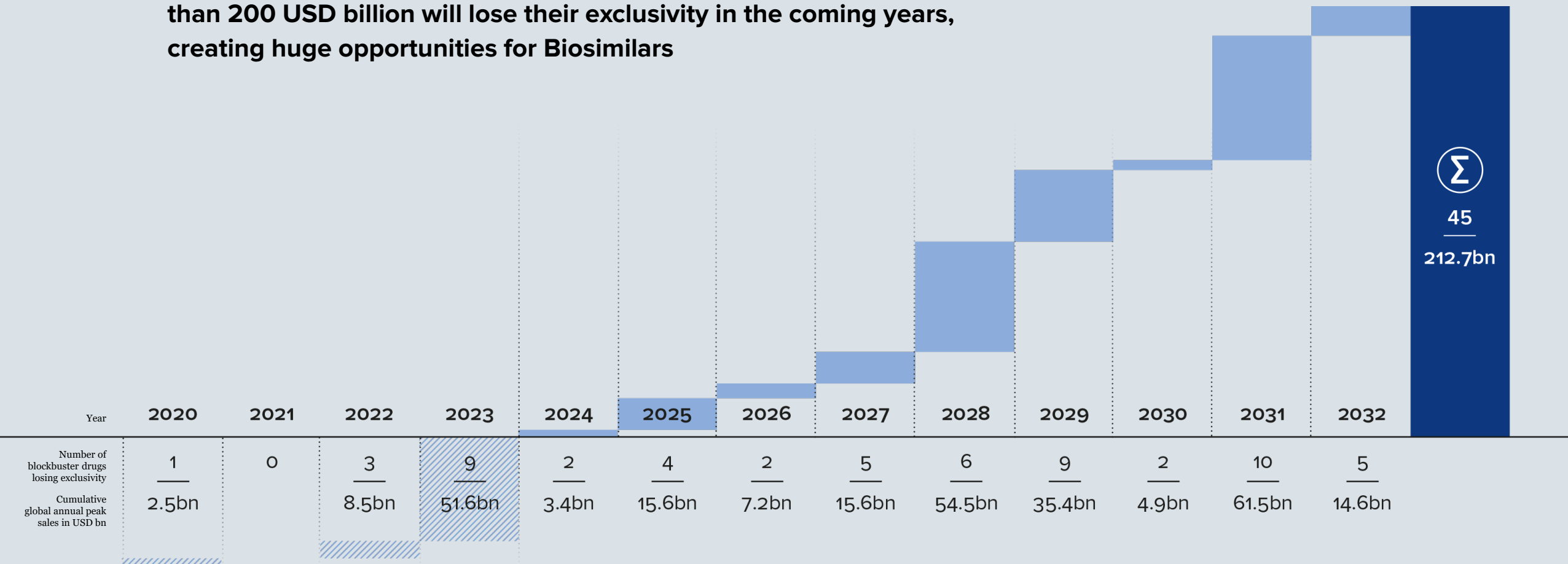
*Contributing to ease
the **financial strains** on the
world's healthcare systems*



*Improving
patient access to vital
medicines*

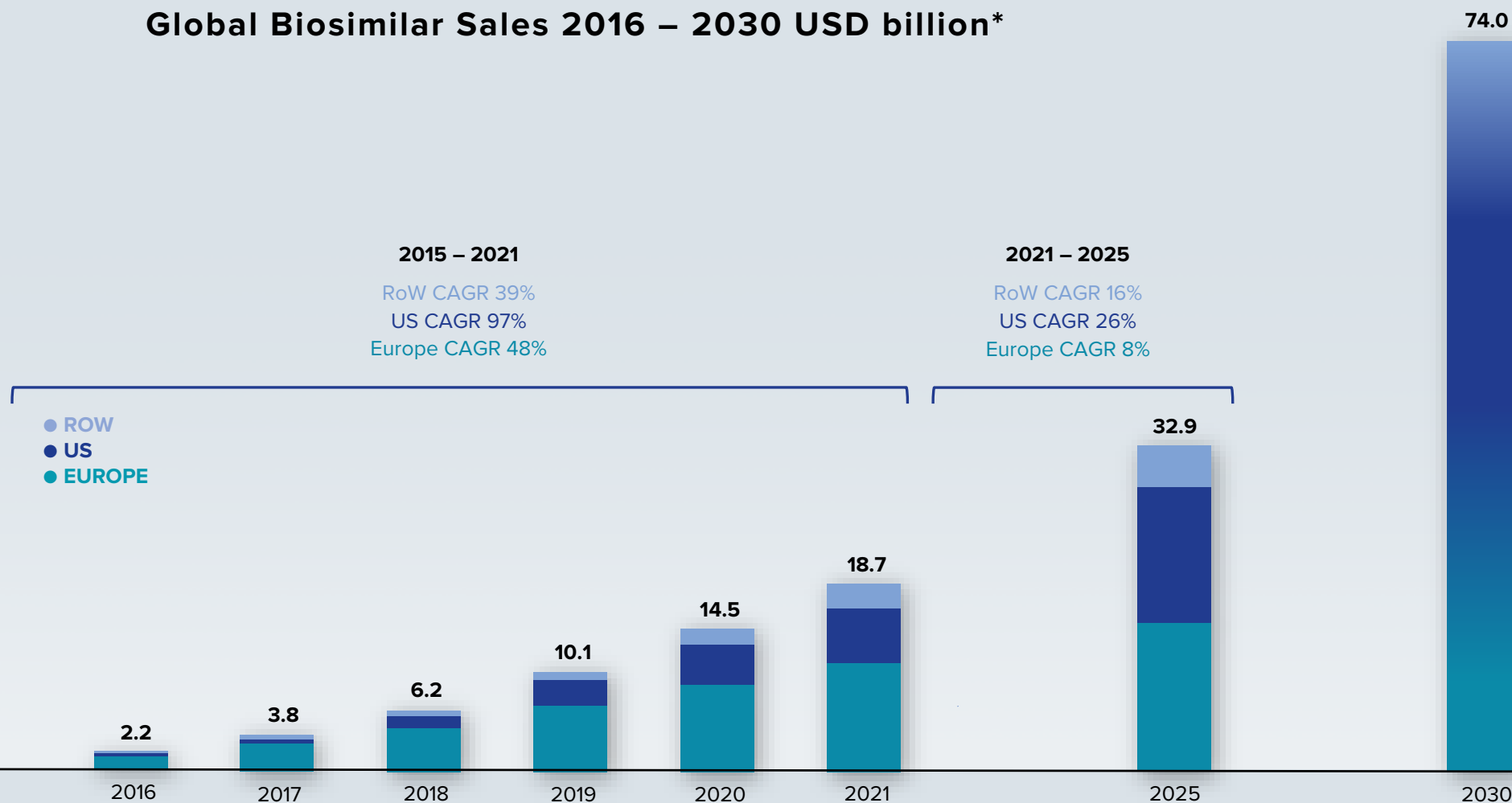
BIOSIMILAR OPPORTUNITIES

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



THE BIOSIMILAR MARKET IS HIGHLY DYNAMIC

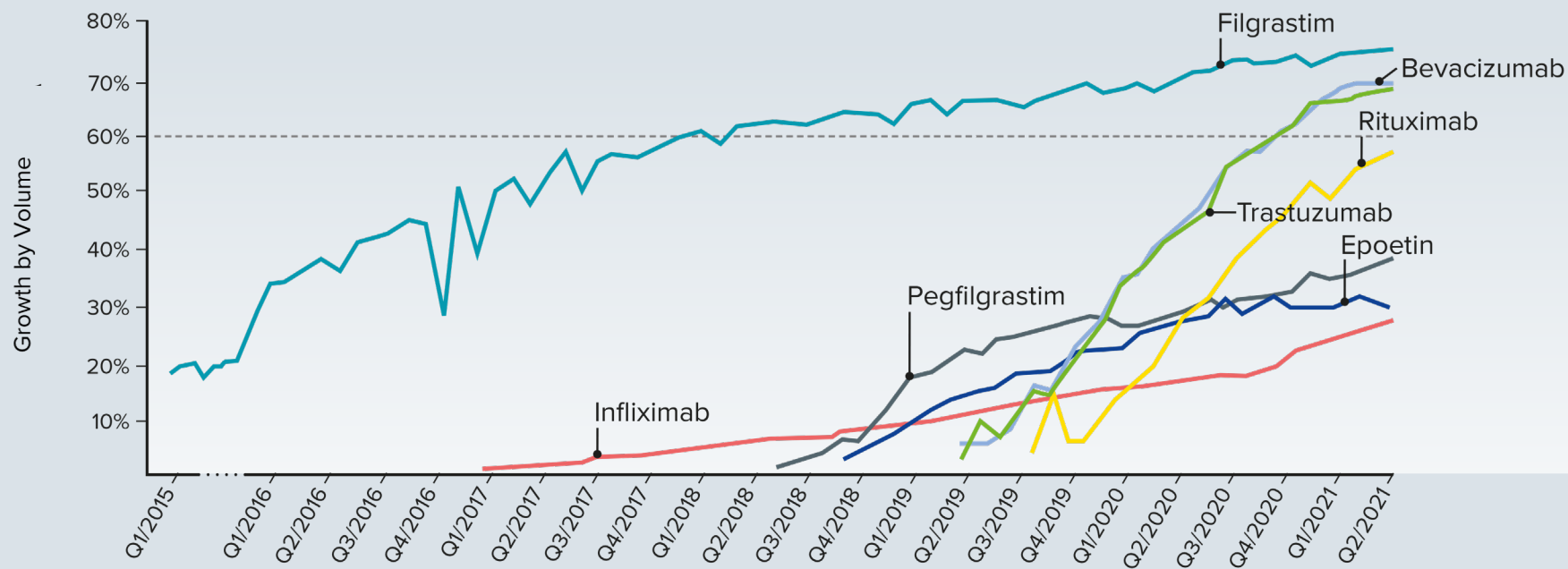
Global Biosimilar Sales 2016 – 2030 USD billion*



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

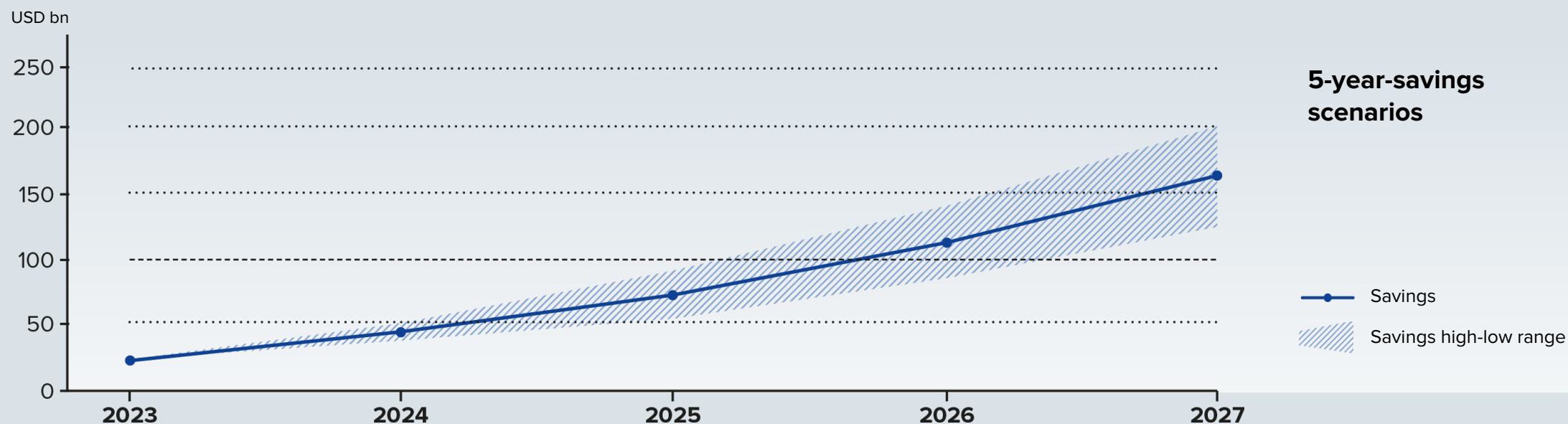
- For US Biosimilars launched prior to 2019, the average share after two years was **13 %**
- For US Biosimilars launched in the last two years, the average share was **65 %!**



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



BIOSIMILAR DEVELOPMENT

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

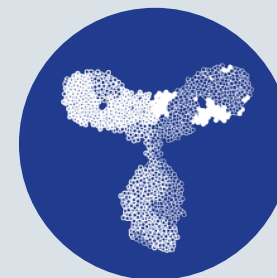


Generic



**Follow on version of
Small Molecule Drug**
Development: 2–3 years
Budget: \$ 5–10m
Clinical Study: Phase I*

New **Biological**
Entity (NBE)

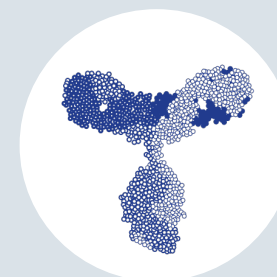


**Innovative
Biopharmaceutical Drug**
Development 10–14 years
Budget \$ 1–2bn

Patent protection 20 – 25 years



Biosimilar

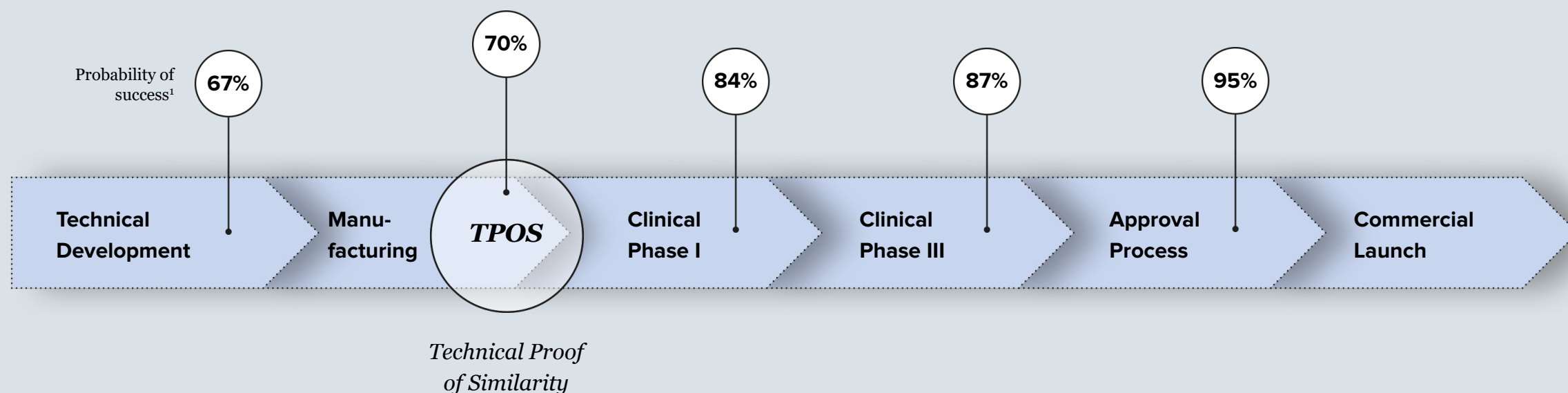


**Follow on version of
Biopharmaceutical Drug**
Development: 6–8 years
Budget: \$ 150–250m
Clinical Study: Phase I +
Phase III

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

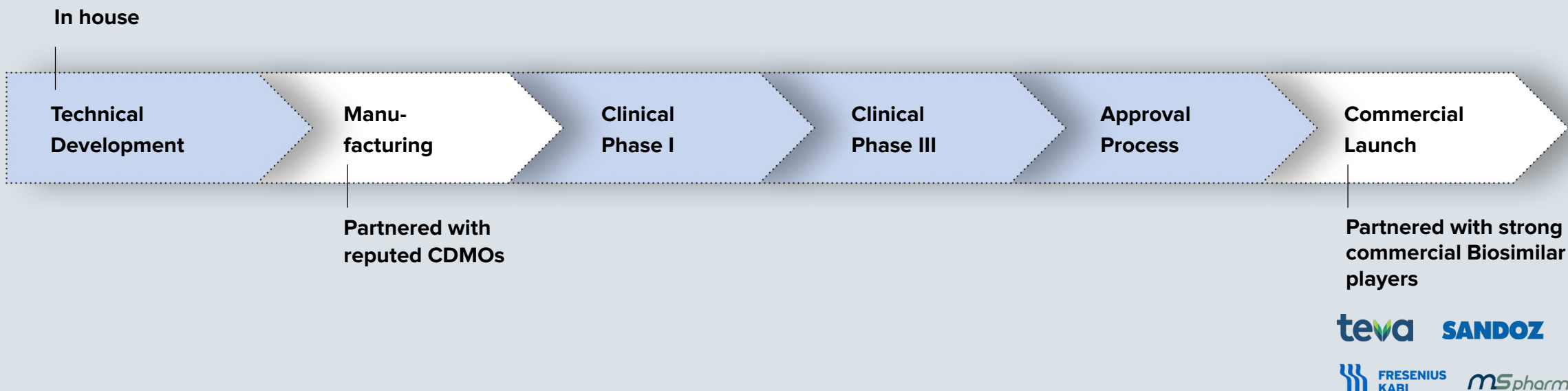
BIOSIMILAR DEVELOPMENT PROBABILITY OF SUCCESS

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



GEARED TOWARDS GROWTH

FORMYCON AG – R&D POWERHOUSE & PIPELINE

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)

Stelara® is a registered trademark of Johnson & Johnson
 Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.
 Lucentis® is a registered trademark of Genentech, Inc.
 Keytruda® is a registered trademark of Merck Sharp & Dohme LLC.

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 PIPELINE

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

	Reference Product	Indication	Pre-Clinical	Technical Proof of Similarity	Phase I	Phase III	Submission	Approval	Launch	Ownership	Next Data Event	Global Reference Sales 2022	Estimated Market Entry	Commercialization Partner
FYB ²⁰¹	Lucentis® (Genentech Inc.)	Ophthalmology	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		50% owned	Approvals and launches, e.g. CA	\$2.9bn	 2022	SANDOZ [US**] teva [ex-US] mspharma [MENA]
FYB ²⁰²	Stelara® (Johnson & Johnson)	Immunology	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				Fully owned	Approvals in US and EU	\$9.7bn	2025***	FRESENIUS KABI [Key global Markets]
FYB ²⁰³	Eylea® (Regeneron Pharmaceuticals)	Ophthalmology	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				Out-licensed	Approvals in US and EU	\$9.5bn	2025	
FYB ²⁰⁶	Keytruda® (Merck Sharp & Dohme)	Immuno-Oncology	<input checked="" type="checkbox"/>							Fully owned	Start of clinical program	\$20.9bn	> 2029	
FYB ²⁰⁸	undisclosed	Immunology	<input type="checkbox"/>							Fully owned		} ≈ \$10.0bn	} > 2030	
FYB ²⁰⁹	undisclosed	Immunology	<input type="checkbox"/>							Fully owned				

Submission, approval and launch checkboxes initially refer to the US and Europe

**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

FYB201 – LUCENTIS® BIOSIMILAR



Approved
and launched



Indications

Neovascular Age-Related Macular Degeneration (nAMD),
DME¹, CNV², PDR³, RVO⁴

Target Market 2022

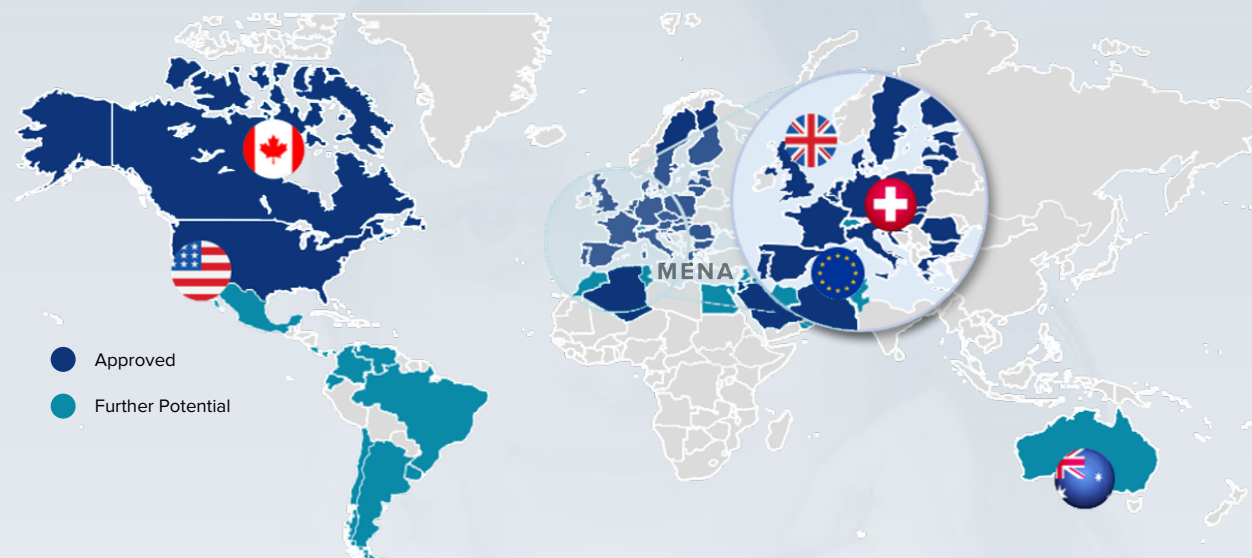
USD 2.9 billion

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)



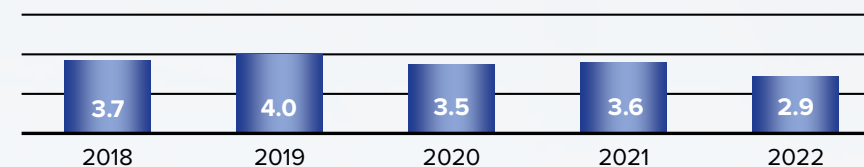
Commercial Partnership with
Sandoz* (US) and Teva (ex-US),
MS Pharma (MENA)

SANDOZ

teva

mspharma

Lucentis® Sales in USD billion



¹Diabetic Macular Edema (DME), ²Choroidal Neovascularization (CNV)
³Proliferative Diabetic Retinopathy (PDR), ⁴Macular 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 2022

USD 9.7 billion

Project Rights

100% of project and commercialization rights

Achievements

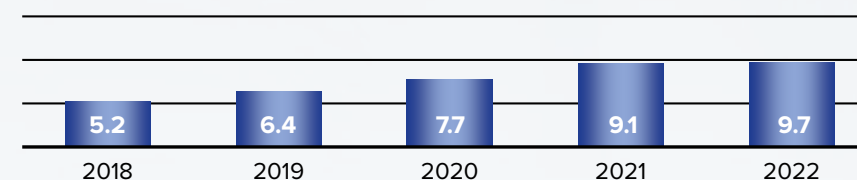
- Clinical development successfully completed
- Settlement with J&J for US license date no later than April 15, 2025
- EU and US regulatory submissions

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® is a registered trademark of Johnson & Johnson

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),
DME¹, mCNV², DR³, RVO⁴

Target Market 2022

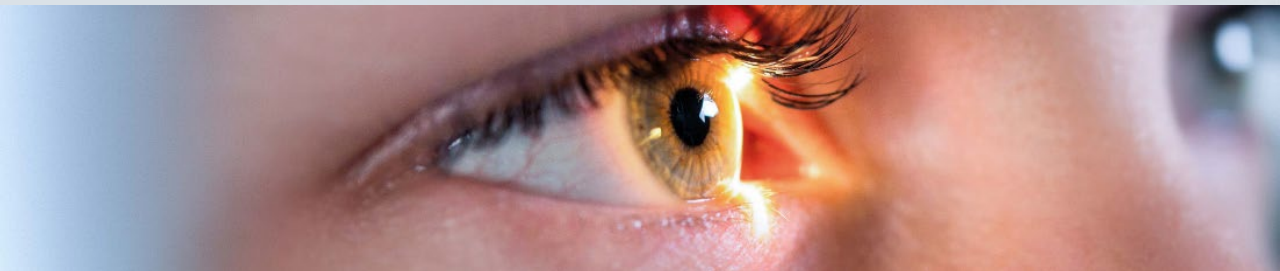
USD 9.5 billion

Project Rights

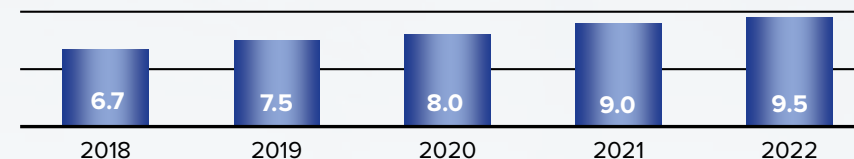
since 2015 License Agreement with Klinge
Biopharma GmbH as Royalty Model

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 2022

USD 20.9 billion

Project Rights

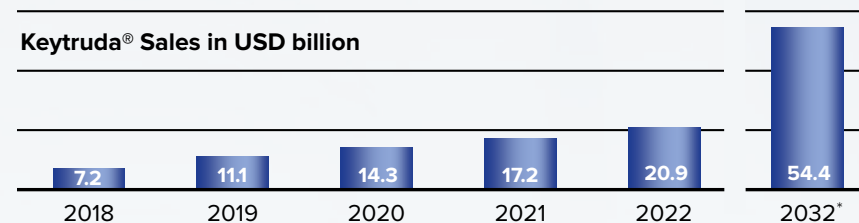
100% of project and commercialization rights

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*



CREATING VALUE WITH BIOSIMILARS

FINANCIALS AND STOCK MARKET

FINANCIAL PERFORMANCE (IFRS) ACCELERATING BUSINESS

Fiscal
year 2023
current
forecast

REVENUE

75 to 85

€ million

EBITDA

-15 to -5

€ million

WORKING
CAPITAL

15 to 25

€ million

NET INCOME

50 to 60

€ million

Financial
Performance
9M 2023

REVENUE

60.2

€ million

EBITDA

5.2

€ million

WORKING
CAPITAL

41.3

€ million

NET INCOME

74.3

€ million

Financial
Performance
H1 2023

REVENUE

43.8

€ million

EBITDA

7.3

€ million

WORKING
CAPITAL

55.0

€ million

NET INCOME

1.8

€ million

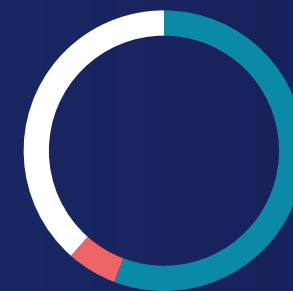
- **Guidance:**
 - + Topline and EBITDA unchanged
 - + Significant increase in net income due to one-off and non-cash effect in financial income
 - **Revenue increase:**
 - + FYB202 success payments
 - + Share of FYB201 sales proceeds
 - + Development compensation (especially FYB203)
 - **EBITDA:**
 - + Revenue from FYB201, FYB202 and FYB203
 - Investments in FYB208 and FYB209
 - **Working Capital:**
 - + Proceeds of capital increase (Q1)
 - Investments in FYB202 and FYB206
 - Repayment of shareholder loan (Q1)
- Net income:**
- + Fair value decrease of earn out obligation
 - + At Equity valuation of Bioeq AG
 - Impairment of Goodwill

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: ~ € 1.0 billion**
- **Research coverage:** Jefferies, Kepler Cheuvreux, Hauck & Aufhäuser Privatbankiers, B. Metzler seel. Sohn & Co. KGaA, First Berlin Equity Research, Alster Research, M. M. Warburg, Berenberg

Shareholder Structure

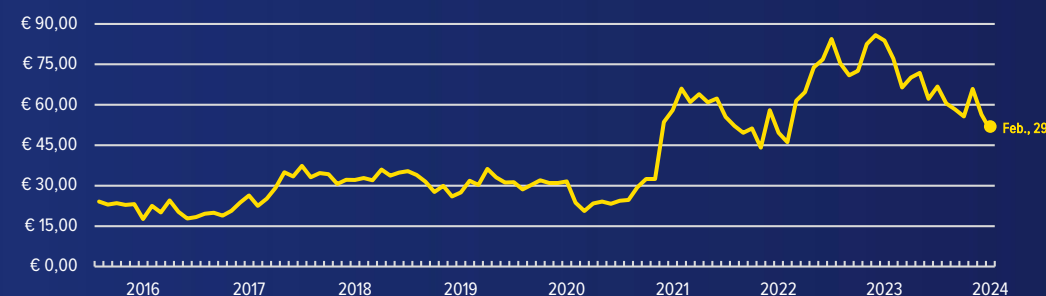
- ~58 % Anchor Investors incl. Athos KG, Active Ownership Capital, Wendeln & Cie. KG, Gedeon Richter, DSP
- ~ 6 % Founders & Management
- ~36 % Free Float***



Key Financial Figures / € million

Y/E 31.12.	2015	2016	2017	2018*	2019	2020**	2021**	2022**
Sales	16.9	19.5	29.0	43.0	33.2	34.3	36.6	42.5
EBITDA	1.5	-3.4	-0.8	8.0	-1.4	-5.2	-12.6	-15.9
EBIT	0.5	-4.1	-1.5	7.1	-2.3	-6.5	-14.0	-17.7
Net Income	0.6	-4.1	-1.6	7.1	-2.3	-6.7	-13.3	36.0

Performance Formycon Share



* FYB202 GmbH & Co. KG.: Effect on sales and earnings but not on liquidity

** According to IFRS

*** Free float as defined by Deutsche Börse

MANAGEMENT TEAM & BOARD MEMBERS

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

FORMYCON IS A FULLY FOCUSED PURE-PLAY BIOSIMILAR COMPANY



**Proof of capabilities with recent Lucentis®
biosimilar approvals and successful
launches**



**Efficient hybrid business model taking
advantage of in-house expertise and selected
external partnerships**



**Remarkable pipeline including late-stage
opportunities in multibillion target
markets**



**Driven and experienced management and
operational team, supported by strong
supervisory board**

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