






Formycon AG

The Biosimilar Experts

Pioneering Work in
Biosimilar Development

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

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Biosimilar Development

Improving Patient Access to Vital Medicines

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ABOUT FORMYCON

Key Data

- Commercial Stage Biosimilar focused Biotechnology Company – established 2012 in Munich, Germany
- > 220 Employees (84% R&D)
- Business Model contains Income from Project Ownership and Royalty Streams

Core Competences

- Exceptional Pool of Biosimilar Experts with extensive Experience in Drug Development
- Successful track record from Selection to Market Approval
- Capable of developing multiple Biopharmaceutical Projects in Parallel

Strong Pipeline

- Three late-stage Biosimilars – one approved and launched, two heading towards filing in 2023
- Three preclinical Biosimilars – one heading towards clinical phase in 2024
- Late-stage Pipeline addresses ≃ 22bn USD Target Market

HIGHLIGHTS H1/2023

JANUARY 2023

- Coherus BioSciences, Inc. becomes comercialization partner for Eylea® Biosimilar Candidate FYB203 in US (binding term sheet)

FEBRUARY 2023

- Fresenius Kabi becomes commercialization partner for Stelara® Biosimilar Candidate FYB202 in key global markets and is eligible for milestone payment upon signature
- Formycon places capital increase of approx. € 70 Mio.
- Eylea® Biosimilar Candidate FYB203 successfully concludes Phase III clinical trial

APRIL 2023

- Stelara® Biosimilar Candidate FYB202 shows positive results of Phase I clinical trial and concludes clinical development
- Q-Code assigned to CIMERLI™ (FYB201) in the US
- Enno Spillner joins Formycon as new CFO

JUNE 2023

- Biologics License Application for Eylea® Biosimilar Candidate FYB203 submitted to the FDA

HIGHLIGHTS H2/2023 – TO BE CONTINUED …

AUGUST 2023

- Formycon and Fresenius Kabi entered into a settlement agreement with J&J and secured US license date for Stelara® Biosimilar Candidate FYB202 no later than April 15, 2025
- FDA accepts BLA for FYB203 and sets target action date of June 2024

SEPTEMBER 2023

- EMA accepts MAA for FYB202

OCTOBER 2023

- Sales of CIMERLI® (FYB201) have exceeded 100,000 doses in the US since commercial Launch on Oct. 3, 2022.
- CIMERLI® with 29% share of the overall ranibizumab market in third quarter 2023.

TO BE CONTINUED …

- EU-regulatory submission for FYB203
- Regulatory submission for FYB202 in the US
- …

ABOUT BIOSIMILARS

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: $ 5–10mn
Clinical Study: Phase I*

New **Biological** Entity (NBE)

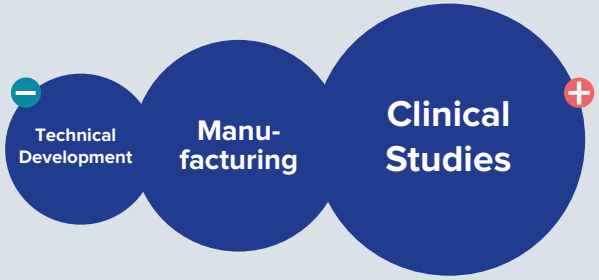
Innovative
Biopharmaceutical Drug
Development 10–14 years
Budget $ 1–2bn

Patent protection 20 – 25 years

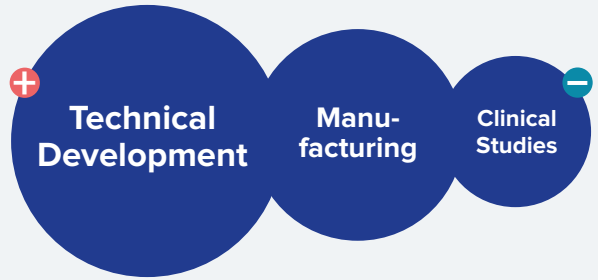
Biosimilar

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

Development and Risk-Profile ⊖ / ⊕



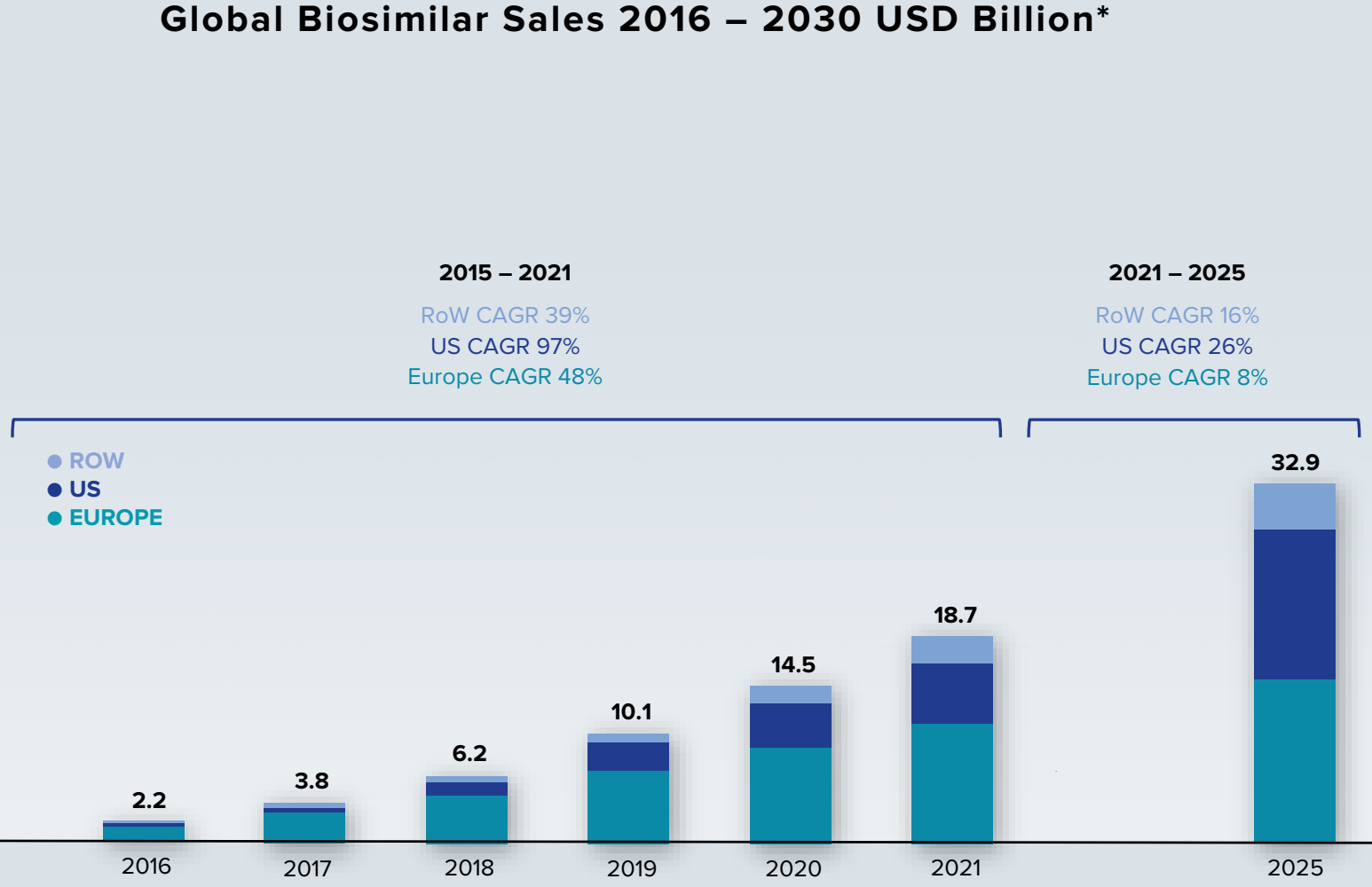
Development and Risk-Profile ⊕ / ⊖



* Only orals, Injectables not even phase I needed

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.

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

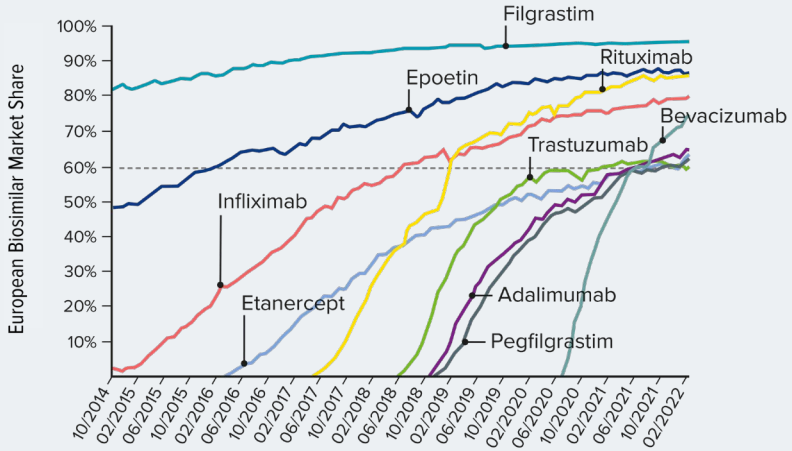
RECENT US BIOSIMILAR LAUNCHES SHOW ACCELERATED UPTAKE

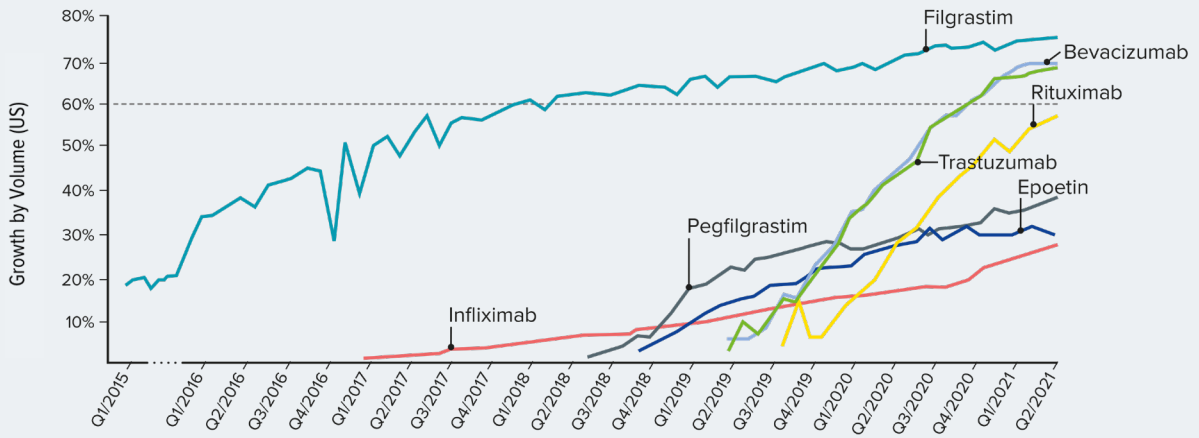
EU

- EU Biosimilars have taken above 60 % of reference market volume
- Timing for market adoption has been significantly reduced

US

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



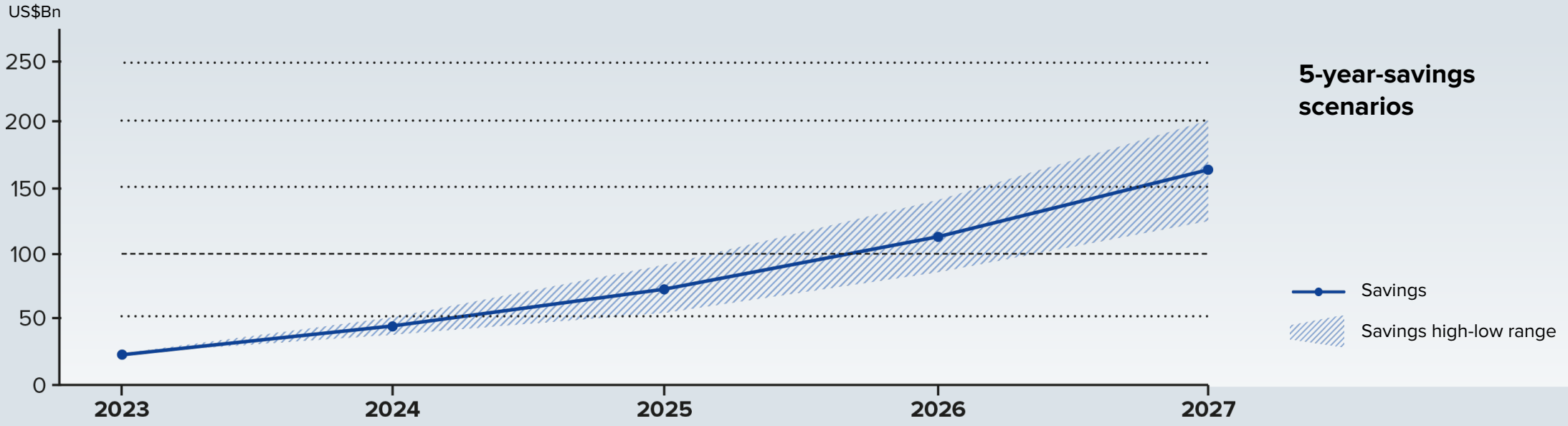


Source: Amgen 2022 Biosimilar Trend Report

BIOSIMILARS GENERATE SIGNIFICANT SAVINGS

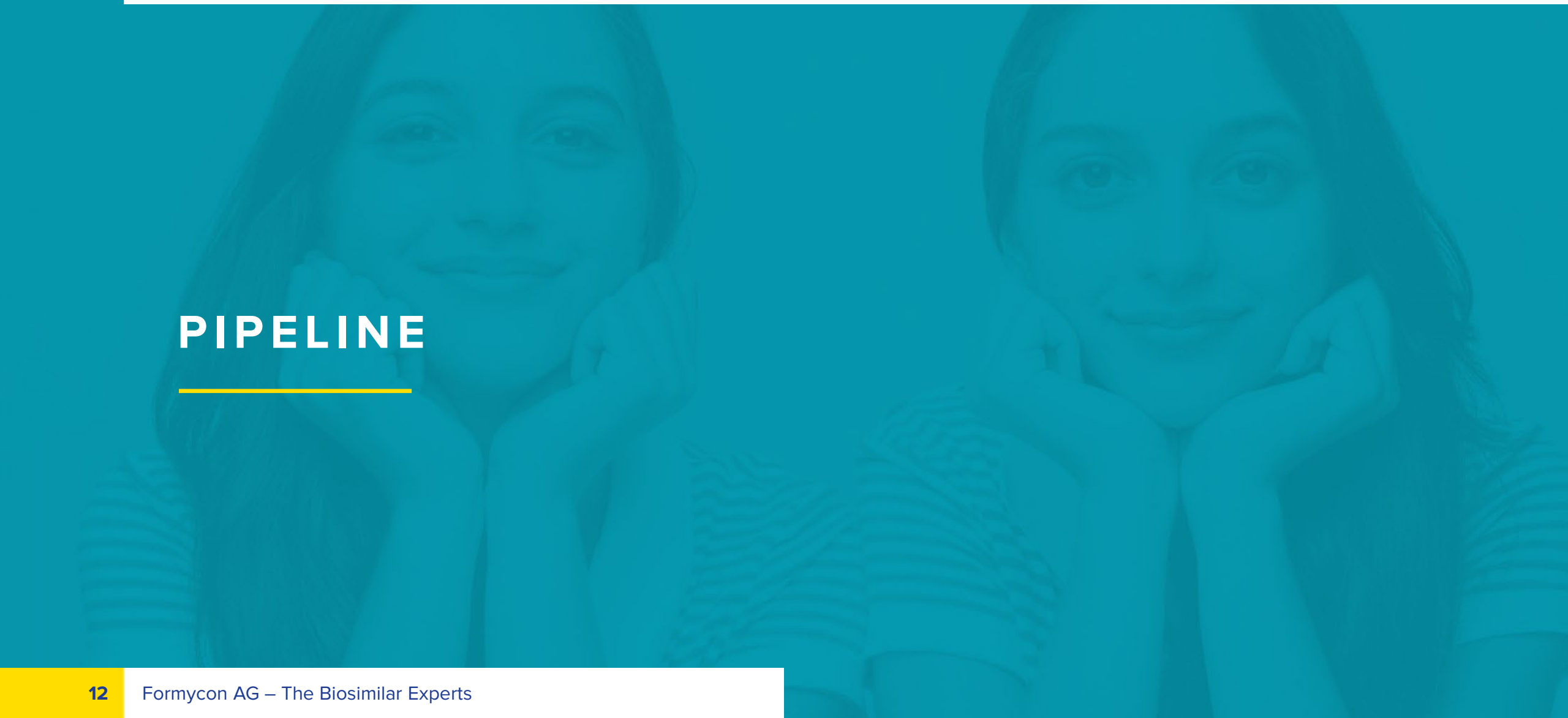
Global savings from Biosimilars

- Annual savings could exceed $ 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



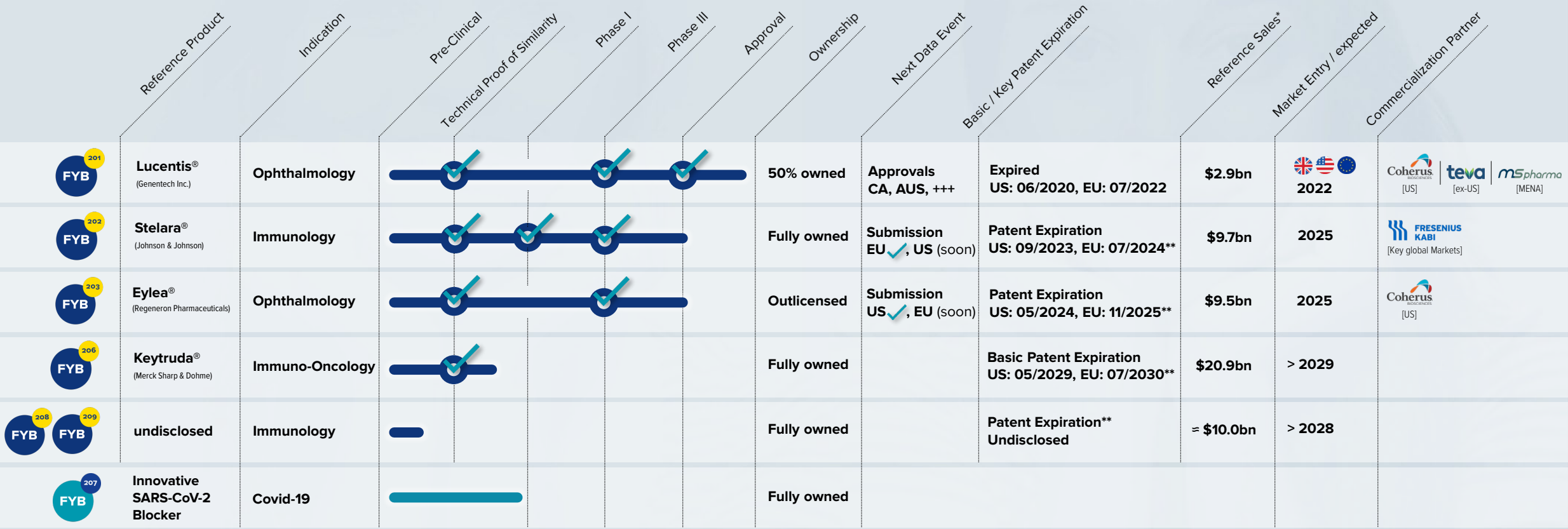
Source: IQVIA Market Prognosis, Sep 2022

PIPELINE



STRONG PIPELINE

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



*Global Sales 2022 **Patent expiry in the key markets depending on SPCs

FYB201 – LUCENTIS® BIOSIMILAR

FYB 201

Approved and launched

Indication

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

Target Market 2022

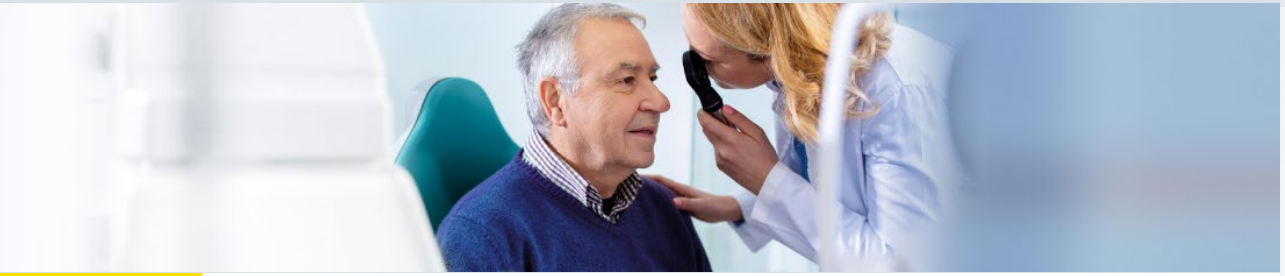
USD 2.9 billion

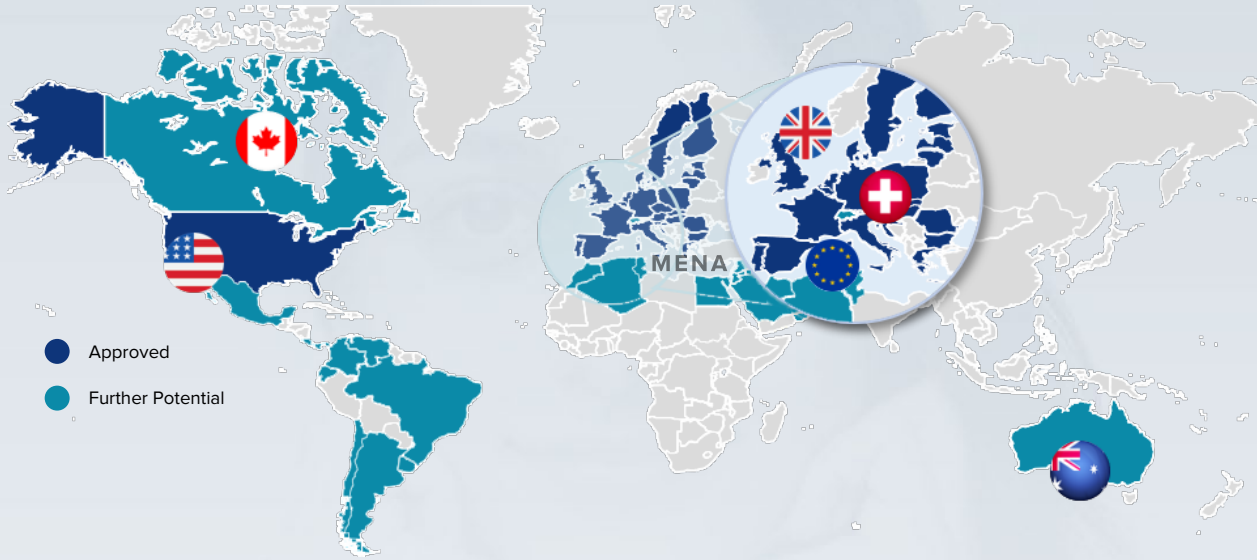
Project Rights

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

Next important Milestones

Various regulatory filings/approvals in further geographies e.g. Canada, Australia, Middle East & North Africa (MENA)

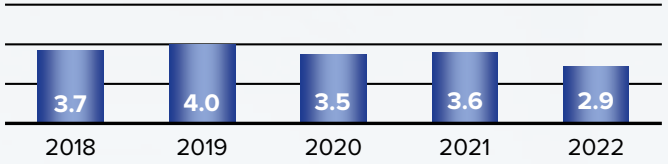




Commercial Partnership with Coherus (US) and Teva (ex-US), MS Pharma (MENA)

Coherus BIOSCIENCES | teva | MSpharma

Lucentis® Sales in USD billion



Patent expired:
US 06/2020
EU 07/2022

[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) / Commercialization in the US to be settled	Completed (06/2021)	Approved in EU, UK, US-Submission (04/2023)

FYB201 / Ranivisio® / Ongavia® / Cimerli™ Competitive Advantage

- Unique position in the U.S. due to availability in both dosages and exclusive "interchangeability" status for 12 months.
- CIMERLI™ ramp-up in the US with more than 100,000 doses in sales within the first year and 29% market share in the ranibizumab market in Q3/2023
- Pioneering role in the UK and promising positions in key EU markets.

Formycon Income Position

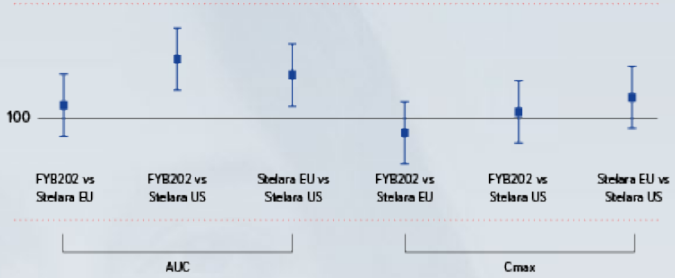
- Around 15% from Cimerli™ (US), Ranivisio® (EU) and Ongavia® (UK) at peak net sales.

FYB202 – STELARA® BIOSIMILAR CANDIDATE

Indication
Psoriasis (Arthritis), Crohn's Disease, Ulcerative Colitis

Target Market 2022
USD 9.7 billion

Project Rights
100% of project and commercialization rights



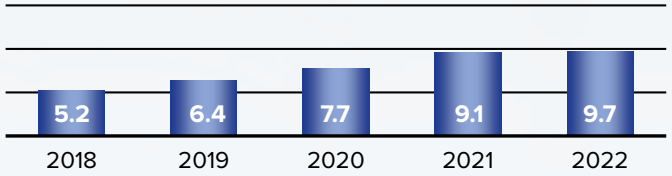
Achievements and next important Milestones

- Clinical development with extended pharmacokinetics study successfully completed
- Settlement with J&J for U.S. license date in April 2025
- EU and US regulatory submissions planned for H2/2023

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



Basic / Key Patent Expiration
US 09/2023
EU 07/2024*

Stelara® is a registered trademark of Johnson & Johnson

*Patent expiry in the key markets depending on SPCs

STELARA® BIOSIMILAR 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)
Amgen		Primary endpoint met	US-Approval (11/2023)
Celltrion	Hikma (MENA)	Completed	US-Filing (07/2023)
Meiji Selka Pharma & Dong A	Intas (Accord)	Primary endpoint met (01/2023)	EU-Filing (06/2023)
Samsung Bioepis		Completed (Nov 11/2022)	—

FYB202 Competitive Advantage

- Submission according to initial schedule and settlement with J&J puts FYB202 in good position for U.S. market entry in April 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 2024 (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

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

Target Market 2022
USD 9.5 billion

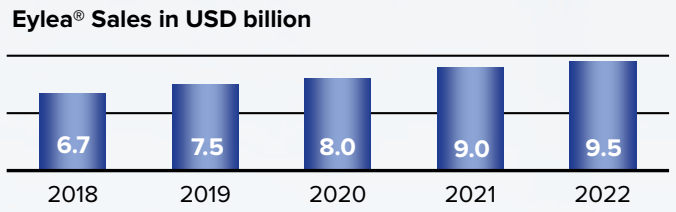
Project Rights
since 2015 License Agreement with Klinge Biopharma GmbH as Royalty Model

Achievements and next important Milestones

- Biologics Licence Application submitted to the FDA in June 2023. FDA file acceptance on August 28, 2023 set target action date of June 2024
- Regulatory submission in the EU coming soon
- Commercialization partner ex-US

Commercial Partnership (Binding Termsheet)

- Coherus BioSciences, Inc. (US)



Basic / Key Patent Expiration
US 05/2024
EU 05/2025*

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc. *Patent expiry in the key markets depending on SPCs.
[1]Diabetic Macular Edema (DME), [2]Choroidal Neovascularization (CNV), [3]Proliferative Diabetic Retinopathy (PDR), [4]Macular Edema following Retinal Vein Occlusion (RVO)

EYLEA® BIOSIMILAR FYB203 (AFLIBERCEPT)

Aflibercept Competitive Landscape

Development Company	Status Phase III	Submission / Approval
Alvotech	Start (07/2022)	—
Amgen	Primary endpoint met (Q3/2022)	—
Biocon (Mylan / Momenta)	Completed	US-Filing (10/2021)
Celltrion	Positive 24-week results (04/2023)	US-Filing (07/2023)
Samsung Bioepis	Last patient in (02/2022)	—
SamChun Dang	Recruitment completed	—
Sandoz	First patient out (05/2023)	—

FYB203 Competitive Advantage

- Commercialization experiences and lead position from FYB201 in the ophthalmology/AMD space will be leveraged.
- Favorable IP position by own patented.

Formycon Income Position

- Mid-single to low-double-digit-percentage participation in all Klinge income under term sheet with Coherus and commercialization partners in other territories.

FYB206 – KEYTRUDA® BIOSIMILAR CANDIDATE

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

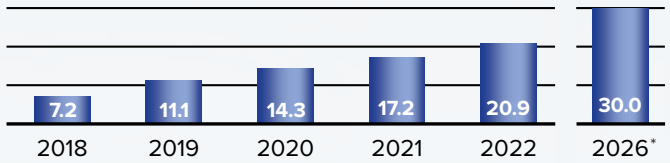
Target Market 2022
USD 20.9 billion

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



*Pharma Intelligence UK Ldt: Keytruda Consensus Forecast
Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

Basic / Key Patent Expiration
US 05/2029
EU 07/2030**

**Patent expiry in the key markets depending on SPCs

FINANCIALS AND STOCK MARKET

FINANCIAL PERFORMANCE (IFRS) – ACCELERATING BUSINESS

	REVENUE	EBITDA	WORKING CAPITAL	NET INCOME
Fiscal year 2023 current forecast	75 *to* 85 € million	-15 *to* -5 € million	15 *to* 25 € million	50 *to* 60 € million
Financial Performance 9M 2023	60.2 € million	5.2 € million	41.3 € million	74.3 € million
Financial Performance H1 2023	43.8 € million	7.3 € million	55.0 € million	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 FYB206, FYB208 and FYB209
- **Working Capital:**
  + Proceeds of capital increase (Q1)
  - Investments in FYB202 and FYB206
  - Repayment of shareholder loan (Q1)

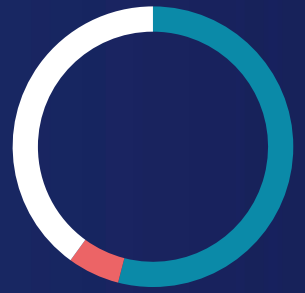
Net income:
+ Fair value decrease of earn out obligation
+ At Equity valuation of Bioeq AG
- Impairment of Goodwill

FORMYCON ON THE STOCK MARKET

- Listed on **Frankfurt Stock Exchange** since June 2012 / SME segment **"Scale"** (Open Market)
- **Registered capital: € 16,053,025**
  Shares outstanding: 16,053,025 (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

Shareholder Structure

- ~54 % Anchor Investors incl. Athos KG, Active Ownership Capital, Wendeln & Cie. KG, DSP
- ~ 6 % Founders & Management
- ~40 % 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

Complementary Skills and Experience

Dr. Stefan Glombitza,
CEO of Formycon

- More than 20 years of experience in pharmaceutical industry (Hexal/Sandoz)
- Track record of > 500 developments and launches in > 70 countries
- 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

- 12 years Global Head of Business Development and Licensing at Hexal and Sandoz
- 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

KEY INVESTMENT HIGHLIGHTS

- Commercial-stage biosimilar-focused biotechnology company
- Potential to address a large and growing market with constantly expanding product pipeline
- Proof of capabilities with recent Lucentis® biosimilar approvals and successful launches
- Remarkable pipeline including late-stage opportunities in multibillion target markets
- Efficient hybrid business model taking advantage of in-house expertise and selected external partnerships
- Driven and experienced management and operational team, supported by strong supervisory board

DISCLAIMER

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