



# Formycon AG

## Half Year 2024 Results

August 13, 2024  
15:00 (CEST)

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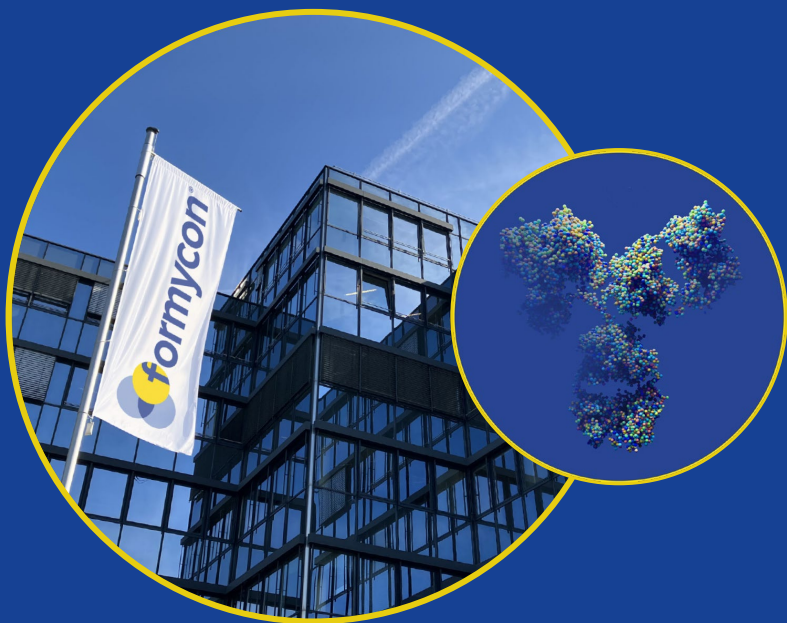
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# Laser focus on pipeline execution and expansion



## 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

# HIGHLIGHTS H1/2024

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

**FYB<sup>201</sup>** **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<sup>202</sup>** **Stelara® Biosimilar Candidate**  
[Ustekinumab]

- **Settlement for Launch in Europe and Canada** with Johnson & Johnson.
- **2023: Settlement with J&J** sets US market entry date to no later than April 15, 2025 within the first launch group of biosimilars.
- **Positive CHMP Opinion** on July 26, 2024.




- **FDA approval** targeted Sept. 2024.
- **EC approval** targeted early Q4/2024.
- **MHRA approval** expected in Q4/2024



**FYB<sup>203</sup>** **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.**

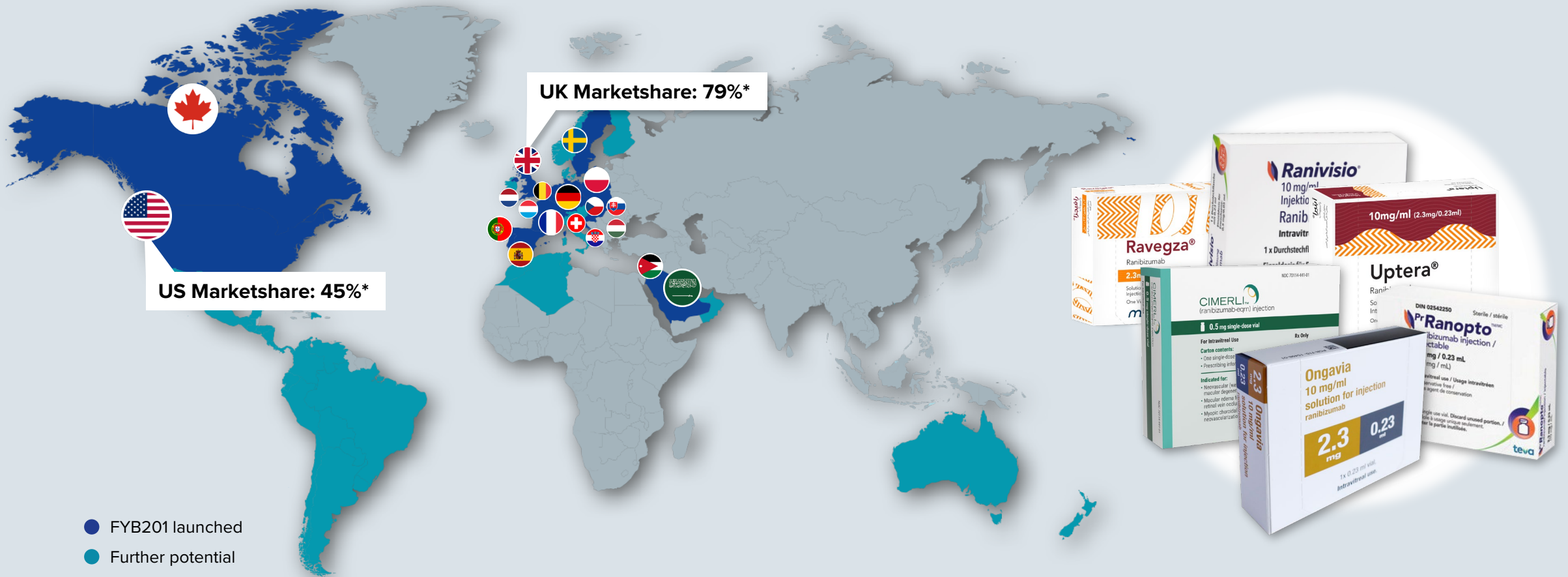


- **CHMP Opinion** expected in Q4/2024. EC approval targeted early 2025.
- **Partnering for commercialization** across further regions expected.



# Strong FYB201 Performance across the world

FYB201 is so far launched in 19 countries





\*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.


## 2nd wave of Projects progressing well


**FYB**<sup>206</sup> **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**<sup>208</sup> **FYB**<sup>209</sup> **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**<sup>210</sup> **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. 

# FINANCIAL PERFORMANCE – H1/2024

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## Profit & Loss fully on track

### 1H 2024 vs. 1H 2023 – Financials in expected range

In € million	1H 2024	1H 2023	Change in %	Comment
<b>Sales</b>	<b>26.9</b>	<b>43.8</b>	<b>-39%</b>	H1/2023 included 10m Upfront Fresenius Kabi Decreasing development services as anticipated H1/2024 Higher royalty income FYB201
<b>Cost of Sales</b>	<b>-25.0</b>	<b>-26.2</b>	<b>-5%</b>	Decreasing development services as anticipated
<b>R&amp;D Expense</b>	<b>-9.7</b>	<b>-5.2</b>	<b>+87%</b>	H1/2023 included FYB207 with 4.5m, H1/2024: FYB208 and FYB209 with (planned) increasing expenses
<b>Other Expense</b>	<b>-10.2</b>	<b>-6.1</b>	<b>+67%</b>	Increase of capacity and personnel over time (+1.1m) and consulting for Exploring strategic & financing opportunities (+2.0m)
<b>EBITDA*</b>	<b>-16.9</b>	<b>7.3</b>	<b>n/a</b>	Increased R&D and SG&A expensens vs. Reduced revenues, one time impoact 10m signing fee FK
<b>Adjusted EBITDA</b>	<b>-2.1</b>	<b>1.1</b>	<b>n/a</b>	H1/ 2023 At Equity result still negative at -6.2m H1/ 2024 At Equity result at +14.8m (higher than expected)
<b>Capitalized development expenditure</b>	<b>16.6</b>	<b>12.3</b>	<b>+35%</b>	H1/ 2023 2m FYB202 and 10m FYB206 H1/ 2024 Clinical costs FYB206 in 2024 only

## Group asset Structure as of Jun. 30, 2024 *vs.* Dec. 31, 2023

### Balance Sheet total

**€ 947.8 million**

+ € 57.4 million

+6%

### Equity

**€ 576.3 million**

+ € 73.6 million

+15%

### Liabilities

**€ 371.5 million**

- € 16.1 million

-4%

### Equity Ratio

**60.8%**

+4%

### Non-current assets *vs.* Total equity and liabilities

**90%**

-2%

### Cash & Cash Equivalents

**€ 40.6 million**

+ € 13.6 million

+50%

## Cash-Flows and Working Capital

### 1H 2024

In € million	1H 2024	Remarks	Working Capital	June 30, 2024
<b>Net cash from operating activities</b>	<b>-31.2</b>	<ul style="list-style-type: none"> <li>-16.9m EBITDA</li> <li>-12.2m contract assets FYB202</li> <li>Remainder other WC</li> </ul>	<b>Cash and cash equivalents</b>	<b>40.6</b>
<b>Net cash from investing activities</b>	<b>-11.9</b>	<ul style="list-style-type: none"> <li>Development costs FYB206 - 16.7m</li> <li>Repayment Loan Bioeq AG +5m</li> </ul>	Current receivables	10.6
<b>Net cash from financing activities</b>	<b>56.7</b>	<ul style="list-style-type: none"> <li>+82.8m capital increase</li> <li>-20.5 m repayment of shareholder loan</li> <li>-4.8m repayment earn outs</li> </ul>	Revenue accrual (contract assets)	28.8
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>13.6</b>		Current liabilities / Accruals	-17.0
<b>Cash and cash equivalents as of Jan. 1, 2024</b>	<b>27.0</b>		<b>Working Capital</b>	<b>63.0</b>
<b>Cash and cash equivalents as of June 30, 2024</b>	<b>40.6</b>	<ul style="list-style-type: none"> <li>Thereof 25m as short-term investment</li> </ul>		





# OUTLOOK 2024 – PREPARE THE GROUND

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## 2024 Guidance raised for adjusted EBITDA & Working Capital



### 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

- 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: ~ € 850 million**
- **Designated Sponsors:**  
Oddo BHF Corporates & Markets AG  
M.M. Warburg & Co.

### Shareholder Structure

- ~58 % Anchor Investors incl. Athos KG, Active Ownership Capital, Wendeln & Cie. KG, Gedeon Richter, DSP
- ~42 % Free Float\*



\*\*per definition of Deutsche Börse

### International Analyst Coverage



## Exciting newsflow expected in the next 9 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  
Eylea® Biosimilar-  
Candidate  
FYB203 in the EU



Approval of  
Stelara® Biosimilar-  
Candidate  
FYB202 in the US



Approval of  
Stelara® Biosimilar-  
Candidate  
FYB202 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



**WE ARE HAPPY TO ANSWER  
YOUR QUESTIONS**

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[www.formycon.com](http://www.formycon.com)

