



November 13, 2023  
15:00 (CET)

# Formycon AG

## Earnings Call 9M 2023

A circular inset image showing a close-up of a human eye with a light blue iris and dark eyelashes.

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## Welcome to our Q3 call!

### Formycon Management Team



**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



## Vision & Mission

Pioneering Work in  
Biosimilar Development

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

**Formycon AG**  
The Biosimilar Experts

## Vision & Mission

Pioneering Work in  
Biosimilar Development

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# Improving Patient Access to Vital Medicines



**Formycon AG**  
The Biosimilar Experts

## Strong and broad Biosimilar-Pipeline

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

	Reference Product	Indication	Pre-Clinical	Technical Proof of Similarity	Phase I	Phase III	Approval	Ownership	Next Data Event	Originator Patent Status	Reference Sales*	Market Entry / expected	Commercialization Partner
<b>FYB</b> 201	<b>Lucentis®</b> (Genentech Inc.)	Ophthalmology						50% owned	Approvals CA, AUS, ++	Expired US: 06/2020, EU: 07/2022	\$2.9bn	 2022	Coherus [US]   teva [ex-US]   mspharma [MENA]
<b>FYB</b> 202	<b>Stelara®</b> (Johnson & Johnson)	Immunology						Fully owned	Submission EU , US	Patent Expiration** US: 09/2023, EU: 07/2024	\$9.7bn	04/2025 (US) 2025 (EU)	FRESENIUS KABI [Key global Markets]
<b>FYB</b> 203	<b>Eylea®</b> (Regeneron Pharm.)	Ophthalmology						Outlicensed	Submission US , EU	Patent Expiration** US: 05/2024, EU: 11/2025	\$9.5bn	2025	Coherus [US]
<b>FYB</b> 206	<b>Keytruda®</b> (Merck Sharp & Dohme)	Immuno-Oncology						Fully owned		Patent Expiration** US: 05/2029, EU: 09/2030	\$20.9bn	2028 onwards***	
<b>FYB</b> 208	undisclosed	Immunology						Fully owned		Patent Expiration** Undisclosed	} \$10.0bn	> 2028	
<b>FYB</b> 209	undisclosed	Immunology						Fully owned				> 2028	



## Highlights 2023 – Late-stage Programs reached multiple important milestones



### Lucentis® Biosimilar [Ranibizumab]

- FYB201 is out-performing biosimilar competition in US and Europe.
- In UK, Ongavia® has reached a market share of over 50%.
- Worldwide more than 200,000 doses sold since launch.
- YTD > 70 Mio. US\$ revenue in US by sales partner Coherus reaching market share of 29% of the overall US ranibizumab market.
- Launched in US, as well as 14 European countries and first country in Middle East.
- Submissions on-going in other relevant markets like Australia, Brazil, Saudi Arabia etc.



### Stelara® Biosimilar Candidate [Ustekinumab]

- Global out-licensing deal signed with Fresenius Kabi for commercialization of FYB202. Formycon expects significant development and regulatory milestone payments under the agreement.
- Settlement with J&J sets US market entry date to no later than April 15, 2025 within the first launch group of biosimilars.
- EMA accepted the Marketing Authorization Application (MAA) end of September 2023.
- US submission well on track (2023).



### Eylea® Biosimilar Candidate [Aflibercept]

- Successful completion of Phase III clinical trial.
- Biologics License application (BLA) submitted to the FDA end of June 2023 and file acceptance granted by FDA (FDA action date June 28, 2024).
- Binding term sheet for US commercialization partnership with Coherus.
- EMA Filing well on schedule for Q4/2023.

## Highlights 2023 – 2nd wave of Projects showing good progress



### Keytruda® Biosimilar Candidate [Pembrolizumab]

- FYB206 is in an advanced preclinical development stage and is expected to enter clinical trials during 2024.
- Clinical program aligned with relevant regulatory agencies in the course of scientific advices.
- Development of manufacturing process well advanced, leading to successful GMP-production at scale.



### Undisclosed Biosimilar Candidates

- Undisclosed immunology Biosimilar candidates FYB208 and FYB209 are both in a technical development stage.
- Cell line development at an advanced stage.
- Selection of reputed CDMOs (contract development and manufacturing organizations) for both programs well advanced.



# PERFORMANCE 9M/2023

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## Statement of comprehensive Income reflects successful Transformation



### 9M 2023 vs. 9M 2022

In € K	9M 2023	9M 2022	Change in %	Remarks
<b>Revenue</b>	<b>60,222</b>	<b>28,231</b>	+113.3 %	<ul style="list-style-type: none"> <li>Record revenues at Formycon</li> <li>Revenue consist of success payments (Fresenius), FYB201 licensing revenues (2,2m€) and services for FYB201 &amp; FYB203</li> </ul>
<b>Cost of sales</b>	<b>-38,702</b>	<b>-18,925</b>	+104.5 %	<ul style="list-style-type: none"> <li>Increase due to development cost for FYB201 &amp; FYB203</li> <li>Partial recording of FYB202 development cost</li> </ul>
<b>R&amp;D expenses</b>	<b>-7,679</b>	<b>-9,566</b>	-19.7 %	<ul style="list-style-type: none"> <li>Consider together with CapEx</li> <li>2023: FYB207, FYB208 &amp; FYB209</li> </ul>
<b>Other expenses</b>	<b>-8,605</b>	<b>-10,684</b>	-19,5 %	<ul style="list-style-type: none"> <li>Cost of ATHOS transaction (2022)</li> </ul>
<b>EBITDA</b>	<b>5,236</b>	<b>-10,944</b>	--	<ul style="list-style-type: none"> <li>Mainly driven by significant revenue increase</li> </ul>
<b>Comprehensive income (loss) for the period</b>	<b>74,255</b>	<b>61,106</b>	+21.5 %	<ul style="list-style-type: none"> <li>Against EBITDA:</li> <li>+106m decrease in fair value of earn out obligation</li> <li>- 39m adjustment of participation in Bioeq AG</li> <li>- 1,7m at equity (2023)</li> <li>- 7,1m deferred taxes (2023)</li> </ul>
<b>Capitalized development costs</b>	<b>13,507</b>	<b>15,080</b>	-10,4 %	<ul style="list-style-type: none"> <li>Mainly FYB206, shifted from R&amp;D in Capex</li> </ul>

## Statement of financial Position – further stabilising



### 9M 2023 *vs.* Dec. 31, 2022

In € K	9M 2023	Dec. 31, 2022	Change in %	Remarks
<b>Non-current assets</b>	<b>799,349</b>	<b>823,195</b>	-3.0%	<ul style="list-style-type: none"> <li>• Capitalisation FYB206</li> <li>• Adjustment Bioeq AG</li> </ul>
<b>Cash and cash equivalents</b>	<b>35,631</b>	<b>9,820</b>	+262.8%	<ul style="list-style-type: none"> <li>• +68m net capital increase</li> <li>• +25m FYB202 success payments</li> <li>• -20m loan repayment</li> <li>• - Continued investments in development pipeline</li> </ul>
<b>Other current assets</b>	<b>42,803</b>	<b>20,682</b>	+107.4%	<ul style="list-style-type: none"> <li>• +10m milestone for FYB202</li> <li>• +11m prepayment and deferral of sales</li> </ul>
<b>Equity capital</b>	<b>500,539</b>	<b>356,580</b>	+40.4%	<ul style="list-style-type: none"> <li>• +70m capital increase</li> <li>• +70m Net result</li> </ul>
<b>Non-current liabilities</b>	<b>304,449</b>	<b>446,451</b>	-31.8%	<ul style="list-style-type: none"> <li>• -34m reclassification to „current“</li> <li>• -115m decrease earn-outs</li> <li>• +7m deferred taxes</li> </ul>
<b>Current liabilities</b>	<b>72,796</b>	<b>50,666</b>	+43.7%	<ul style="list-style-type: none"> <li>• +34m reclassification from non-current</li> <li>• +10m accrual</li> <li>• -20m shareholder loan repayment</li> </ul>



## Group asset Structure as of September 30, 2023

### Total equity and liabilities

**€ 877,784K**

+ € 24,087K

+ 3%

### Equity

**€ 500,539K**

+ € 143,959K

+40%

### Liabilities

**€ 377,245K**

- € 119,872K

-24%

### Equity Ratio

**57.0%**

+15%

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

**91%**

-5%

### Cash & Cash Equivalents

**€ 35,631K**

+ € 25,811K

+263%

## Guidance 2023 fully on track

### Guidance Update for Fiscal year 2023 current forecast

#### Revenue

**75 to 85**

€ million

#### EBITDA

**-15 to -5**

€ million

#### Working Capital

**15 to 25**

€ million

#### Net income

**-20 to -30** vs. **50 to 60**

€ million

#### Net income

**50 to 60**

€ million

- **Guidance:**
  - + Topline and EBITA guidance unchanged
  - + Significant Increase in net income

### Key financial Figures 9M 2023

#### Revenue

**60.2**

€ million

#### EBITDA

**5.2**

€ million

#### Working Capital

**41.3**

€ million

#### Net income

**74.3**

€ million

- **Revenue increase:**
  - + FYB202 success payments
  - + Development compensation (esp. FYB203)
  - + Share of FYB201 sales proceeds
- **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:**
  - + 106m fair value of earn out obligation
  - + At Equity valuation of Bioeq AG
  - 39m adjustment of participation in Bioeq AG

### Forecast 2023 as of April 2023

#### Revenue

Significant  
increase  
(2022: 42.5)

€ million

#### EBITDA

At prior-year  
level  
(2022: -15.9)

€ million

#### Working Capital

At prior-year  
level  
(2022: 14.0)

€ million

#### Net income

At prior-year level  
excluding non-  
recurring item  
(2022: 36.0)

€ million

## Formycon on the Stock Market

- Listed on **Frankfurt Stock Exchange** since June 2012 / SME segment **“Scale”** (Open Market)
- **Registered capital: € 16,038,775**  
Shares outstanding: 16,038,775 (w/o par value)
- **Market price / Market capitalization: ~ € 900 million**
- **Research coverage:** Jefferies, Kepler Cheuvreux, Hauck & Aufhäuser Privatbankiers, B. Metzler seel. Sohn & Co. KGaA, First Berlin Equity Research, Alster Research, M. M. Warburg (since Sept. 23)

### 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



## Outlook – operational, regulatory and commercial news flow to be expected ...



### **Lucentis® Biosimilar** [Ranibizumab]

- Product launches in further attractive markets planned for 2023/2024: Saudi Arabia, Middle East, Canada, Brazil etc.



### **Stelara® Biosimilar Candidate** [Ustekinumab]

- Regulatory submissions in the US and further territories with subsequent file acceptance period



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

- EU-regulatory submission
- License negotiations with commercial partners in 2024



### **Keytruda® Biosimilar Candidate** [Pembrolizumab]

- Further at scale manufacturing for clinical supply
- Intense preparations for start of clinical program



### **Undisclosed Biosimilar Candidates**

- Selection of best clone
- Development of manufacturing process at reputed CDMOs

*to be continued ...*

## 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**

**WE ARE HAPPY TO ANSWER  
YOUR QUESTIONS**

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

