



August 30, 2023
15:00 (CEST)

Formycon AG

Earnings Call H1 2023

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

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Welcome to our H1 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

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

Formycon AG
The Biosimilar Experts

Vision & Mission

Pioneering Work in
Biosimilar Development


























Improving Patient Access to Vital Medicines



Formycon AG
The Biosimilar Experts

Strong and broad 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
	Lucentis® (Genentech Inc.)	Ophthalmology						50% owned	Approvals CA, AUS, +++	Expired US: 06/2020, EU: 07/2022	\$2.9bn	 2022	 [US]  [ex-US]  [MENA]
	Stelara® (Johnson & Johnson)	Immunology						Fully owned	Submission US, EU	Patent Expiration** US: 09/2023, EU: 07/2024	\$9.7bn	04/2025 (US) 2025 (EU)	 [Key global Markets]
	Eylea® (Regeneron Pharmaceuticals)	Ophthalmology						Outlicensed	Submission US ✓, EU (soon)	Patent Expiration** US: 05/2024, EU: 11/2025	\$9.5bn	2025	 [US]
	Keytruda® (Merck Sharp & Dohme)	Immuno-Oncology						Fully owned		Patent Expiration** US: 05/2029, EU: 09/2030	\$20.9bn	2028 onwards***	
 	undisclosed	Immunology						Fully owned		Patent Expiration** Undisclosed	≈ \$10.0bn	> 2028	
	Innovative SARS-CoV-2 Blocker	Covid-19						Fully owned					

Highlights H1 2023 – launched and late-stage Projects well on track



Lucentis® Biosimilar [Ranibizumab]

- FYB201 is out-performing biosimilar competition in US and Europe.
- In the UK, Ongavia® has reached a market share of over 40%.
- Steep uptake in the US: Strong performance of CIMERLI™ after assignment of reimbursement code (Q-Code) on April 1, 2023.
- Current US-market share of 17%.
- Launched in 10 European countries and first country in Middle East.



Stelara® Biosimilar Candidate [Ustekinumab]

- Clinical development successfully completed with positive results of Phase I clinical trial.
- 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.



Eylea® Biosimilar Candidate [Aflibercept]

- Commercialization partnership for US market with Coherus BioSciences, Inc. (binding term sheet signed in January).
- Successful completion of Phase III clinical trial.
- Biologics License application submitted to the FDA end of June 2023 and file acceptance granted by FDA (FDA action date June 28, 2024).

Lucentis® is a registered trademark of Genentech, Inc.
Stelara® is a registered trademark of Johnson & Johnson
Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.
Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd.
CIMERLI™ is a trademark of Coherus BioSciences, Inc.

Highlights H1 2023 – 2nd wave of Projects accelerating



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.



Innovative COVID-19 Drug

- Re-evaluation of the project due to major changes in the external (post-pandemic) environment.
- Formycon will continue the project in a resource-sparing way: pursue patent applications, scientific advice meetings, and potential opportunities for outside funding
- Aim: moving FYB207 into a strategic development partnership. Currently, no self-financed clinical studies are planned.



Undisclosed Biosimilar Candidates

- Undisclosed immunology Biosimilar candidates FYB208 and FYB209 are both in a technical development stage.
- Cell line development with promising clone candidates at a very advanced stage.
- Selection of CDMO (contract development and manufacturing organizations) for both programs well advanced.

PERFORMANCE H1 2023

Statement of comprehensive Income reflects Transformation



H1 2023 vs. H1 2022

In € K	H1 2023	H1 2022	Change in %	Remarks
Revenue	43,789	17,644	+148.2 %	<ul style="list-style-type: none"> Record revenues at Formycon Revenues consist of success payments (Fresenius), FYB201 licensing revenues and services for FYB201 & FYB203
Cost of sales	-26,153	-12,317	-+112.3 %	<ul style="list-style-type: none"> Increase due to development cost for FYB201 & FYB203 Partial recording of FYB202 development cost
R&D expenses	-5,170	-7,933	-34.9 %	<ul style="list-style-type: none"> Consider together with CapEx 2023: FYB207, FYB208 & FYB209
Other expenses	-6,108	-5,909	-4 %	<ul style="list-style-type: none"> Cost of ATHOS transaction (2022) vs. increase of capacity and personnel over time
EBITDA	7,262	-7,581	--	<ul style="list-style-type: none"> Mainly driven by significant revenue increase
Comprehensive income (loss) for the period	1,804	80,031	--	<ul style="list-style-type: none"> Against EBITDA: +89.9m one-off in 2022 +8.9m financial results (2023) -6.2m at equity (2023) - 7,3m deferred taxes (2023)
Capitalized development costs	12,147	2,040	+495.4 %	<ul style="list-style-type: none"> Mainly FYB206, shifted from R&D in 2022

Statement of financial Position – further stabilising



H1 2023 vs. Dec. 31, 2022

In € K	H1 2023	Dec. 31, 2022	Change in %	Remarks
Non-current assets	829,459	823,195	+0.8%	<ul style="list-style-type: none"> • Capitalisation FYB206
Cash and cash equivalents	36,865	9,820	+275.4%	<ul style="list-style-type: none"> • +68m net capital increase • +10m FYB202 contract signature • -20m loan repayment • -Continued investments in development pipeline
Other current assets	46,530	20,682	+125.0%	<ul style="list-style-type: none"> • +15m receivable for FYB202 Phase I • +10m prepayment and deferral of sales
Equity capital	427,416	356,851	+19.9%	<ul style="list-style-type: none"> • +70m capital increase
Non-current liabilities	403,442	446,451	-9.6%	<ul style="list-style-type: none"> • -35m reclassification to „current“ • -8m decrease earn-outs
Current liabilities	82,086	50,665	+62.0%	<ul style="list-style-type: none"> • +35m reclassification from non-current • +10m accrual • -20m shareholder loan repayment

Statement of Cash-Flows and Working Capital

H1 2023

In € K	H1 2023	Remarks
Net cash from operating activities	-8,331	<ul style="list-style-type: none"> +7.3m EBITDA -15.0m receivables outstanding Fresenius
Net cash from investing activities	-12,330	<ul style="list-style-type: none"> Development costs FYB206
Net cash from financing activities	47,706	<ul style="list-style-type: none"> +68.3m capital increase -20.1m repayment of shareholder loan
Net increase (decrease) in cash and cash equivalents	27,045	
Cash and cash equivalents as of Jan. 1, 2023	9,820	
Cash and cash equivalents as of June 30, 2023	36,865	<ul style="list-style-type: none"> Thereof 20m as short-term investment

Working Capital	June 30, 2023
Cash and cash equivalents	36,865
Current receivables	30,968
Revenue accrual (contract assets)	8,187
Current liabilities / Accruals	-19,721
Revenue accrual (contract liabilities)	-1,336
Working Capital	54,963

Group asset Structure as of June 30, 2023

Total equity and liabilities

€ 912,944K

+ € 59,247K

+7%

Equity

€ 427,416K

+ € 70,835K

+20%

Liabilities

€ 485,528K

- € 11,588K

-2%

Equity Ratio

46.8%

+5%

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

91%

-5%

Cash & Cash Equivalents

€ 36,865K

+ € 27,045K

+275%

Guidance 2023 fully on track

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

€ million

Key financial
Figures
H1 2023

Revenue

43.8

€ million

EBITDA

7.3

€ million

Working Capital

55.0

€ million

Net income

1.8

€ million

Forecast
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

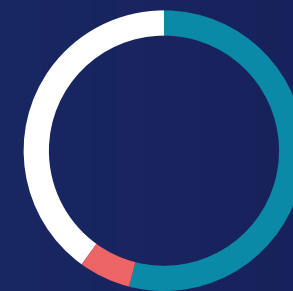
- **Guidance:**
+ Concretized in figures (corridors)
+ Slightly increased
- **Revenue increase:**
+ Share of FYB201 sales proceeds
+ FYB202 success payments
- **EBITDA:**
- Investments in FYB207, FYB208 and FYB209
+ Revenue from FYB201 and FYB202
- **Working Capital:**
- Investments in FYB202 and FYB206
- Repayment of shareholder loan (Q1)
+ Proceeds of capital increase (Q1)
- **Net income:**
- Non-recurring item (€ 89.9m) in fiscal year 2022
for FYB202 GmbH & Co. KG (non-cash)
± Revaluations of conditional purchase
+ At Equity valuation of Bioeq AG

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

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 H2 2023 – operational, regulatory and commercial news flow to be expected ...



Lucentis® Biosimilar [Ranibizumab]

- Product launches in further attractive markets planned for 2023: Belgium, Saudi Arabia, Middle East.



Stelara® Biosimilar Candidate [Ustekinumab]

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



Eylea® Biosimilar Candidate [Aflibercept]

- EU-regulatory submission
- License negotiations with commercial partners



Keytruda® Biosimilar Candidate [Pembrolizumab]

- Further at scale manufacturing for clinical supply
- Detailed plan for 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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