

Formycon (FYB GY) | Pharma/Healthcare

September 04, 2023

H1/23 results - accelerating FYB201 contribution

We confirm our Buy recommendation following the recent release of H1/23 results: Sales came in at EUR 44m, implying y-o-y growth of 148% - this strong growth was mainly driven by (milestone) payments from Fresenius Kabi related to FYB202. However, FYB201 also contributed - e.g. license sales in H1/23 amounted to EUR 1.2m (vs. EUR 330k in FY 2022). In this context, please note that given the JV structure between Formycon and Polpharma, a portion of global marketing proceeds are booked at equity and hence, do not effect the topline. In our view, the FYB201 contribution should further accelerate over the course of 2023 - marketing partner Coherus already achieved a market share of 17% in 9M. The EBITDA amounted to EUR 7m (vs. H1/22: EUR -8m) - this clear stepup was driven by higher sales (e.g. milestone payments) which are not offset by direct costs. Following the successful capital increase in February, Formycon's liquidity position remains stable with cash & equivalents of EUR 37m. Overall, we believe that the news flow should remain positive - next major milestones are the market launch of FYB201 in additional geos, the submission of the BLA for FYB202 and the start of clinical trials for FYB206 (incl. discussions with potential commercial partners). Prospects remain promising in our view.

Changes in estimates: We lowered our (sales) estimates reflecting (a) that a large portion of FYB201 sales are booked at equity - accounting effect and (b) that we assume that FYB202 will be launched slightly later (e.g. settlement with Johnson & Johnson to launch FYB202 no later than April 2025). We continue to value Formycon shares based on our rNPV approach and derive a new PT of EUR 97.

Fundamentals (in EUR m) ¹	2020	2021	2022	2023e	2024e	2025e
Sales	34	37	42	80	70	114
EBITDA	-5	-12	-16	-10	-2	28
EBIT	-6	-13	-18	-12	-5	23
EPS adj. (EUR)	-0.54	-1.22	2.62	-1.24	0.60	2.40
DPS (EUR)	0.00	0.00	0.00	0.00	0.00	0.00
BVPS (EUR)	6.16	5.08	26.00	25.30	25.91	28.31
Net Debt incl. Provisions	-42	-25	33	-6	16	-14
Ratios ¹	2020	2021	2022	2023e	2024e	2025e
EV/EBITDA	-112.9	-50.5	-76.5	-101.0	-484.7	34.7
EV/EBIT	-94.8	-47.0	-68.8	-78.0	-190.0	41.6
P/E adj.	-98.8	-48.4	33.0	-48.8	100.4	25.2
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	-14.1	-33.5	-37.5	-11.9	-2.9	24.1
EBIT margin (%)	-16.7	-36.1	-41.7	-15.4	-7.4	20.1
Net debt/EBITDA	8.8	2.1	-2.1	0.6	-7.9	-0.5
PBV	8.6	11.6	3.3	2.4	2.3	2.1

¹Sources: Bloomberg, Metzler Research

Buy

 **unchanged**

Price*

EUR 60.50

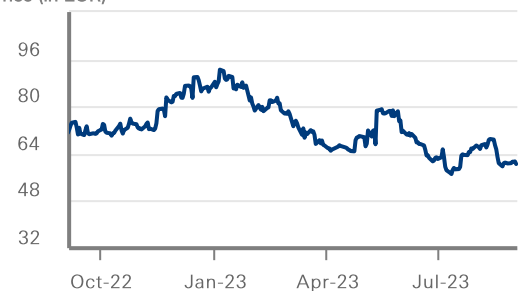
Price target

EUR 97.00 (114.00)

* XETRA trading price at the close of the previous day unless stated otherwise in the Disclosures

Market Cap (EUR m) ¹	970
Enterprise Value (EUR m) ¹	964
Free Float (%) ¹	39.7

Price (in EUR)¹



Performance (in %) ¹	1m	3m	12m
Share	-9.6	-15.7	-19.3
Rel. to Prime All Share	-8.9	-14.8	-32.6

Changes in estimates (in %) ¹	2023e	2024e	2025e
Sales	12.4	-36.2	-55.5
EBIT	38.0	-192.6	-74.3
EPS	10.0	322.6	-40.0

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company note

Review of H1/23 results

Recently, Formycon released its H1/23 results. Key highlights were the following:

- In H1/23, sales (which include in addition to Formycon AG also the fully consolidated subsidiaries Formycon Project 201 GmbH, FYB202 Project GmbH, Formycon Project 203 GmbH, Bioeq GmbH and the 50% stake in Bioeq AG) considerably increased to EUR 43.8m, implying a y-o-y growth of 148%. This was strongly impacted by (milestone) payments from Fresenius Kabi related to FYB202 (Formycon's biosimilar candidate for Stelara) - e.g. EUR 10m as consideration for the transfer of license and EUR 14m for the achievement of development milestones.
- In addition, Formycon also received biosimilar license sales for FYB201 (**As a reminder:** The U.S. Food and Drug Administration (FDA) approved FYB201 on August 3 2022 as the first biosimilar interchangeable with Lucentis (and for all five indications) in the US. Approval by the European Commission followed on August 26 2022). License sales in H1/23 amounted to EUR 1.2m (vs. EUR 330k in FY 2022). In this context, please note that a portion of global marketing proceeds are booked at equity and hence, do only affect net income, not the topline. The FYB201 contribution should further accelerate over the course of the year - in the US, a product-specific Q-Code was assigned to CIMERLI effective April 2023, already resulting in a clear step-up in sales (e.g. marketing partner Coherus reported CIMERLI sales in Q2/23 of USD 27m vs. USD 6m in Q1/23). Coherus has also already achieved a market share of 17% within nine months.
- The EBITDA amounted to EUR 7.3m (vs. H1/22: EUR -7.6m) - this clear step-up was driven by higher sales (e.g. milestone payments) which are not offset by direct costs.
- Depreciation & amortization in H1/23 amounted to EUR 0.9m - consequently the EBIT came in at EUR 6.4m (vs. H1/22: EUR -8.5m).
- The net income in the first half of the year came in at EUR 1.8m, strongly impacted by **(a)** a pro-rata loss of EUR 6m related to the at-equity consolidation in Bioeq AG, **(b)** a gain of EUR 9m related to the fair value valuation of the contingent purchase price component to ATHOS for the acquired assets of FYB201 and FYB202, and finally **(c)** a deferred tax expense in the amount of EUR 7m.
- As part of the successful capital increase in February this year in the amount of EUR 70m (910k shares placed at an issue price of EUR 77 per share), cash and cash equivalents increased to EUR 37m (not yet including the EUR 15m payment from Fresenius Kabi). Formycon plans to use the proceeds for the further development of FYB202, FYB206, FYB208, FYB209 and the expansion of the biosimilar pipeline. In H1/23, EUR 20m of the shareholder loan was already repaid (leaving another EUR 20m drawn and outstanding). Overall, Formycon's liquidity and financial position remains stable in our view.

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H1/23 sales impacted by payments from Fresenius Kabi; cash position remains stable

EUR m

	FY 2020	H1/21	H2/21	FY 2021	H1/22	H2/22	FY 2022	H1/23	FY 2023 Guidance	Metzler FY 2023e
Sales	34	20	17	37	18	25	43	44	75 - 85	80
Growth y-o-y (in %)	3	23	-6	8	-13	49	16	148	n/a	89
EBITDA	-5	-10	-3	-12	-8	-8	-16	7	-5 to -15	-10
Margin %	-14	-48	-16	-34	-43	-33	-37	17	n/a	-12
EBIT	-6	-10	-3	-13	-9	-9	-18	6	n/a	-12
Margin %	-17	-50	-19	-36	-48	-37	-42	15	n/a	-15
Net Income	-6	-10	-3	-13	80	-44	36	2	-20 to -30	-20
Margin %	-17	-50	-19	-36	455	-177	85	4	n/a	-25
Cash & equivalents	42	34	25	25	18	10	10	37	n/a	20

Source: Metzler Research, company data

Guidance for FY 2023 released

- Furthermore, Formycon released a detailed quantitative guidance for FY 2023: The company expects sales between EUR 75m and 85m, in combination with an EBITDA between EUR -5m and -15m and a net income between EUR -20m and -30m.
- Our (updated) estimates are in line with the company guidance. For H2/2023, we expect a further acceleration of FYB201 (license) sales. Earnings in H2/23 should be clearly impacted by higher expenses for FYB202 (biosimilar candidate for Stelara), FYB206 (biosimilar candidate for Keytruda), FYB208 (undisclosed) and FYB209 (undisclosed).
- We continue to believe that profits should increase considerably with the introduction of FYB202 and FYB203 at the latest.

Operational outlook for H2/2023

In the H1/23 conference call, management also gave an outlook on the pipeline for the second half of the year. In our view, the pipeline remains attractive and corresponding news flow should clearly remain positive over the next months:

- **FYB201 (biosimilar for Lucentis):** The launch of FYB201 has been successful - in the US (marketed by Coherus), CIMERLI has reached a market share of 17% within nine months. In the UK (marketed by Teva), Ongavia has reached a market share of 40%. In the course of 2023, the launch in further markets is planned, e.g. Belgium, Saudi Arabia and Middle East, which should result in further accelerating (license) sales.
- **FYB202 (biosimilar candidate for Stelara):** Recently, a settlement with Johnson & Johnson in the US has been reached, which allows Fresenius Kabi and Formycon to launch FYB202 (once approved by the FDA) no later than April 2025. Formycon plans to submit the Biologics License Application (BLA) in H2/23.

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- **FYB203 (biosimilar candidate for Eylea):** A few days ago, Formycon and Klinge Biopharma announced that the FDA has accepted the BLA for FYB203 - target action date is June 2024. Focus in H2/23 will be on the EU-regulatory submission and further license negotiations with commercial partners outside the US (**Note:** Coherus has signed a binding term sheet for FYB203 in the US - announced in January this year).
- **FYB206 (biosimilar candidate for Keytruda):** In the H1/23 conference call, management confirmed that FYB206 is progressing well - and is expected to enter clinical trials next year. Key focus now on a detailed plan for the clinical program and discussions with potential (commercial) partners.
- **FYB208 & FYB209:** Both are still undisclosed - but progressing well. In H2/23, Formycon will work on the development of the manufacturing process at reputed CDMO's.

Current pipeline process

	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		Coherus [US] teva rtspharma [sa 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)	PRESENIUS SAR® [Key Global Markets]
	Eylea® (Regeneron Pharmaceuticals)	Ophthalmology						Outlicensed	Submission US ✓, EU (soon)	Patent Expiration** US: 05/2024, EU: 11/2025	\$9.5bn	2025	Coherus [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					

Sources: Company data

company note

Pipeline - outlook for H2/23



Sources: Company data

Further conference call statements

Finally, we like to highlight the following statements during the H1/23 conference call:

Re-evaluation of FYB207

- FYB201 - at equity (costs):** Given the Joint Venture structure between Formycon and Polpharma, a portion of global marketing proceeds are booked at equity and hence, do only affect net income, not the topline. In H1/23, Formycon booked a loss of EUR 6m, reflecting JV-related costs (e.g. D&A, admin etc.). However, for FY 2023, management expects a positive EUR 3m contribution at equity - implying EUR 9m in H2/23.
- FYB206 - commercial partners:** Management sees a good interest in the product and initial discussions have already been held. While the company does not want to "rush" into a deal, finding a partner in a more early stage would be beneficial to assure a strong global partnership.
- FYB207 - re-evaluation:** Management highlighted that FYB207 (Covid-19 drug) has been re-evaluated. Formycon will continue the project in a resource-sparing way. Self-financed clinical studies are no longer planned. In our view this decision makes sense - WHO has recently lifted the global Covid-19 health emergency. Hence, focusing on the biosimilar pipeline appears much more attractive at this point in time we believe.

Valuation - Risk-adjusted NPV approach

We continue to value Formycon shares based on our risk-adjusted net present value approach. We have defined probabilities for each stage of development, thus, being able to value each of Formycon's pipeline products separately. Our main pa-

Parameters are:

- **WACC:** We are using a discount rate (WACC) of 12.1% which is based on the following factors: Risk-free rate of 2.0%, market risk premium of 6.5% and Beta of 1.6.
- **Terminal growth rate:** For the terminal value calculation of each project, we are using a terminal growth rate of -10%. Overall, we assumed that after ~10 years of marketing of the biosimilar, the overall life cycle of the product will be impacted by alternative treatment methods, leading to a gradual decline of sales.

Based on minor model adjustments and lowered short-term estimates (later than assumed launch of FYB202, lower sales from FYB207 following re-evaluation etc.), we derive a new PT of EUR 97 and confirm our Buy recommendation:

rNPV Analysis - Summary

Pipeline	Value / Costs
rNPV of FYB201 US (EURm)	175
rNPV of FYB201 Europe (EURm)	290
rNPV of FYB202 US (EURm)	696
rNPV of FYB202 Europe (EURm)	409
rNPV of FYB203 US (EURm)	284
rNPV of FYB203 Europe (EURm)	151
rNPV of FYB206 US (EURm)	689
rNPV of FYB206 Europe (EURm)	344
rNPV of FYB207 US (EURm)	61
rNPV of FYB207 Europe (EURm)	34
Total rNPV (EURm)	3,132
Unallocated costs* (EURm)	1,576
Enterprise Value (EURm)	1,556
Net debt (cash) (EURm)	-6
Equity Value (EURm)	1,561
Shares outstanding (m)	16
Target Price (EUR)	97

* including COGS, Personnel, Taxes and Capex
Source: Metzler Research

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Sensitivity analysis

In EUR

WACC (in %)	Terminal sales growth (in %)						
	-16	-14	-12	-10	-8	-6	-4
10.6	105	108	111	115	120	126	133
11.1	100	102	105	109	113	118	125
11.6	95	97	100	103	107	111	117
12.1	90	92	94	97	101	105	110
12.6	85	87	89	92	95	99	103
13.1	81	83	85	87	90	93	97
13.6	77	78	80	82	85	88	92

Sources: Metzler Research

company note

Key Data

Company profile

CEO: Dr. Stefan Glombitza

CFO: Enno Spillner

Martinsried (Planegg)

Formycon, headquartered in Martinsried-Planegg (Germany) is a leading developer of biosimilars with a focus on ophthalmology and immunology. The current pipeline includes four biosimilars: FYB201 (biosimilar for Lucentis), FYB202 (biosimilar for Stelara), FYB203 (biosimilar for Eylea) and FYB206 (biosimilar for Keytruda). In addition, with FYB207, Formycon has developed an innovative antiviral drug for the treatment of Covid-19 based on a long-acting ACE2-Ig-Gc fusion molecule.

Major shareholders

ATHOS (26.7%), Wendeln & Cie. (14.9%), Active Ownership Corporations (6.7%), DSP Beteiligungsgesellschaft (5.5%), Founder and management (6.5%)

Key figures

P&L (in EUR m)	2020	%	2021	%	2022	%	2023e	%	2024e	%	2025e	%
Sales	34	3.2	37	8.0	42	15.0	80	88.9	70	-12.6	114	63.1
EBITDA	-5	-253.6	-12	-157.5	-16	-28.6	-10	40.0	-2	78.7	28	n.m.
EBITDA margin (%)	-14.1	-242.5	-33.5	-138.4	-37.5	-11.8	-11.9	68.2	-2.9	75.6	24.1	931.0
EBIT	-6	-152.0	-13	-132.8	-18	-33.0	-12	30.3	-5	58.0	23	543.0
EBIT margin (%)	-16.7	-144.1	-36.1	-115.6	-41.7	-15.7	-15.4	63.1	-7.4	51.9	20.1	371.6
Financial result	-0	-302.7	-0	-57.0	54	n.m.	4	-93.5	18	412.0	30	68.5
EBT	-6	-153.7	-14	-131.4	37	371.1	-9	-124.1	13	246.0	53	314.9
Taxes	0	n.m.	0	126.1	-1	n.m.	11	n.m.	3	-70.8	15	364.6
Tax rate (%)	1.6	n.a.	-0.2	n.a.	-1.7	n.a.	-125.0	n.a.	25.0	n.a.	28.0	n.a.
Net income	-6	-148.8	-14	-135.6	37	375.1	-20	-153.4	10	148.7	39	298.3
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
Net Income after minorities	-6	-158.7	-13	-127.4	36	367.1	-20	-155.2	10	148.7	39	298.3
Number of shares outstanding (m)	11	10.5	11	0.0	14	24.2	16	16.9	16	0.0	16	0.0
EPS adj. (EUR)	-0.54	-134.2	-1.22	-127.4	2.62	315.1	-1.24	-147.2	0.60	148.7	2.40	298.3
DPS (EUR)	0.00	n.a.	0.00	n.a.	0.00	n.a.	0.00	n.a.	0.00	n.a.	0.00	n.a.
Dividend yield (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
Cash Flow (in EUR m)	2020	%	2021	%	2022	%	2023e	%	2024e	%	2025e	%
Gross Cash Flow	-5	-244.7	-12	-163.0	-15	-23.4	1	109.7	-5	-454.0	13	339.8
Increase in working capital	-1	n.a.	-1	n.a.	1	n.a.	-5	n.a.	-3	n.a.	-2	n.a.
Capital expenditures	1	14.1	1	5.6	27	n.m.	15	-43.0	11	-31.0	10	-2.1
D+A/Capex (%)	79.2	n.a.	77.3	n.a.	6.7	n.a.	18.4	n.a.	30.0	n.a.	44.4	n.a.
Free cash flow (Metzler definition)	-5	-83.1	-12	-132.2	-43	-249.6	-9	79.4	-12	-39.9	4	134.8
Free cash flow yield (%)	-0.9	n.a.	-1.9	n.a.	-3.7	n.a.	-0.9	n.a.	-1.3	n.a.	0.4	n.a.
Dividend paid	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cash flow (post dividend)	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Balance sheet (in EUR m)	2020	%	2021	%	2022	%	2023e	%	2024e	%	2025e	%
Assets	76	41.2	66	-12.3	761	n.m.	811	6.5	818	0.9	856	4.6
Goodwill	0	-36.3	0	0.0	488	n.m.	488	0.0	488	0.0	488	0.0
Shareholders' equity	68	41.1	56	-17.6	357	535.9	406	13.8	415	2.4	454	9.3
Equity/total assets (%)	90.0	n.a.	84.5	n.a.	46.8	n.a.	50.1	n.a.	50.8	n.a.	53.0	n.a.
Net Debt incl. Provisions	-42	-88.6	-25	40.0	33	229.4	-6	-118.0	16	372.1	-14	-184.8
thereof pension provisions	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Gearing (%)	-62.3	n.a.	-45.3	n.a.	9.2	n.a.	-1.5	n.a.	3.9	n.a.	-3.0	n.a.
Net debt/EBITDA	8.8	n.a.	2.1	n.a.	-2.1	n.a.	0.6	n.a.	-7.9	n.a.	-0.5	n.a.

Sources: Bloomberg, Metzler Research

company note

Disclosures

Recommendation history

Recommendations for each financial instrument or issuer - mentioned in this document - published by Metzler in the past twelve months

Date of dissemination	Metzler recommendation *		Current price **	Price target *	Author ***
	Previous	Current			
Issuer/Financial Instrument (ISIN): Formycon (DE000A1EWVY8)					
11.05.2023	Buy	Buy	72.00 EUR	114.00 EUR	Diedrich, Tom
20.01.2023	Buy	Buy	85.80 EUR	124.00 EUR	Diedrich, Tom
31.10.2022	Buy	Buy	74.20 EUR	87.00 EUR	Diedrich, Tom
19.09.2022	Buy	Buy	70.80 EUR	85.00 EUR	Diedrich, Tom
07.09.2022	Buy	Buy	71.10 EUR	85.00 EUR	Diedrich, Tom

* Effective until the price target and/or investment recommendation is updated (FI/FX recommendations are valid solely at the time of publication)

** XETRA trading price at the close of the previous day unless stated otherwise herein

*** All authors are financial analysts

Formycon

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company note

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company note

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