

Formycon (FYB GY) | Pharma/Healthcare

November 20, 2023

Q3/23: Further step ahead

Formycon made a big further step ahead during Q3/23 with a 55% y/y revenue increase to EUR16.4m. For 9M23 revenues now stand at EUR60.2m after EUR28.2m for 9M22. The sharp increase during the nine months period basically reflects the progressing commercialization of Formycons most advanced biosimilars, FYB 201, in a corporation with Bioeq and FYB 202, together with Fresenius Kabi. Marketing proceeds for FYB201, success payments for FYB202 but also development compensations for FYB203 were relevant components of year-to-date revenues. After the sharp y/y increase in Q3, Formycon appears to be well on track to end-up in the EUR75-85m revenue guidance for the full year. Although group EBITDA for 9M23 is still in positive territory at EUR5,2m (9m22 EUR-10,9m) management sticks to its loss guidance on that level of EUR-5,0 to -15,0m. The expectation of a sharp decline in earnings in Q4, despite the further revenue expansion reflects the groups steady investments into its further establishment as a full-scale, independent biosimilar group. Applications for FYB202 and FYB203 with the FDA/EMA are still planned for the end of 2003. The kick-off of the clinical programme for FYB206 as well as the beginning development process for two further candidates (FYB208/209) is on the agenda as well. All those initiatives take its toll on near term profitability. All in all, we see the group progressing well towards the achievement of its mid-term plans.

Valuation: To accurately reflect the further progression of FYB's development and its likely break-even after FY25, we value the shares with a DCF-approach and retain our target price unchanged.

Fundamentals (in EUR m) ¹	2020	2021	2022	2023e	2024e	2025e
Sales	34	37	42	75	70	98
EBITDA	-5	-13	-16	-12	-10	29
EBIT	-7	-14	-18	-15	-13	25
EPS adj. (EUR)	-0.61	-1.20	2.62	3.68	0.49	2.90
DPS (EUR)	0.00	n.a.	n.a.	n.a.	n.a.	n.a.
BVPS (EUR)	6.16	5.08	26.00	30.35	30.68	33.58
Net Debt incl. Provisions	-35	-19	352	216	231	200
Ratios ¹	2020	2021	2022	2023e	2024e	2025e
EV/EBITDA	-106.6	-50.4	-96.9	-102.5	-125.8	41.3
EV/EBIT	-84.1	-45.2	-86.8	-81.6	-97.6	47.8
P/E adj.	-87.0	-49.0	33.0	16.8	127.3	21.4
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	-15.0	-34.3	-37.3	-15.6	-13.9	29.3
EBIT margin (%)	-19.1	-38.2	-41.7	-19.6	-17.9	25.3
Net debt/EBITDA	6.8	1.5	-22.2	-18.4	-23.7	6.9
PBV	8.6	11.6	3.3	2.0	2.0	1.8

¹Sources: Bloomberg, Metzler Research

Buy

 **unchanged**

Price*

EUR 61.90

Price target

EUR 97.00 (unchanged)

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

Market Cap (EUR m) ¹	988
Enterprise Value (EUR m) ¹	1,204
Free Float (%) ¹	39.7

Price (in EUR)¹



Performance (in %) ¹	1m	3m	12m
Share	18.6	1.8	-21.7
Rel. to Prime All Share	10.1	0.2	-28.2
Changes in estimates (in %) ¹	2023e	2024e	2025e
Sales	-6.2	0.0	-14.0
EBIT	-19.4	-141.3	8.4
EPS	397.0	-19.3	20.7

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Key events after nine months (9M23)

After the actual start of the marketing-process of Formycon's most matured biosimilar (FYB 201) the group's establishment among the global biosimilar corporations is progressing steadily - and according to plans. Group revenues expanded over 55% in Q3 vs a year before. A mixture of success payments from its partner Fresenius Kabi (FYB202) and marketing proceeds for the Lucentis-biosimilar (FYB201) mainly contributed to group sales. Compensation payments for development services for the out-licensed FYB203 molecule added to the group-level as well.

Considerable operating swing

As product-related revenues expanded and costs for the further maturation of the product pipeline and the molecular portfolio are biased towards Q4/23, group EBITDA stayed in positive territory. For 9M23, Formycon reported EUR5,2m EBITDA after a negative EUR10,9m for 9M22. This implies a loss on the EBITDA-line in Q3/23 of EUR2,06m in Q3/23 and EUR-3,32m a year before.

The acquisition of a 50% stake from ATHOS in FYB201 transfers a considerable portion of related earnings to the atEquity result. Hence, as long as FYB201-related revenues and earnings dominate group results, any judgement of the operational success needs to include the atEquity result. Adding the EUR4,4m atEquity result to core operating earnings, we would assume Formycon was in positive territory in Q3/23, even after depreciation. (EBIT+ atEquity).

FYB201 is gaining momentum

The commercialisation of Formycon's most existing relevant product, FYB201 (ranibizumab/Lucentis) is progressing well. The groups US-based commercialisation partner Coherus sold over 100,000 doses from the product launch roughly one year ago (Oct22). Total sales since the launch across all markets amount to more than 200,000 doses. The biosimilar achieved a market share of 29% of the overall ranibizumab-market in the US as of Q3/23. Based on that increase, Formycon received direct license payments of EUR2,2m during 9M23.

Tougher competition in the US triggers an impairment

As Formycon is partnering with Bioeq, a considerable flow of current revenues and earnings only shows up on the atEquity-line. The groups significant EUR4,4m atEquity result in Q3/23 is largely due to the marketing success of FYB201. The fact that Formycon recorded a negative EUR1,7m amount at equity for 9M23 illustrates the sharp positive swing in results over recent months, related to FYB201.

Looking further ahead, the launch of the biosimilar into further markets promises to further enlarge its revenue- and earnings contribution over coming quarters. So far, the biosimilar is available in 14 European countries, the US and one country in the Middle East.

Changed competitive landscape for now limited to the US

The success of ranibizumab biosimilars in the US seems to have motivated, Roche which is commercializing Lucentis in the US, to launch a new drug into the US market that is almost priced at the biosimilars level. Apparently, Roche plans to regain market share in the ophthalmologic market. Corresponding price cuts for Lucentis biosimilars reduced managements revenue- and earnings projections over the expected life-cycle of its ranibizumab biosimilar (FYB201).

As a consequence, Formycon lowered the book value of its 50% stake in Bioeq AG (impairment) by EUR39m. On the other hand, reduced projections for revenues and earnings lowered the earn-out liability to ATHOS by EUR106m. Both non-cash

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actions cause the upgrade of the financial income guidance from a negative EUR -20m to -EUR30m range to a positive EUR50,0-60,0m bandwidth.

Biosimilars can be a tough market

The revaluation of the business model for FYB201 in Q3 illustrates how competitive the biosimilar market can be and how fast conditions can change. The decision by Roche to re-enter the market with a modified version of Lucentis, though at a substantially lower price, could have considerable consequences for the biosimilar players. The success of the biosimilar basically depends on a certain rebate compared with the originator drug. The expectation of lower prices for FYB201 largely caused the revaluation in Q3/23. While the balance of both non-cash valuation effects are positive for Formycons reported earnings, future revenues from the biosimilar might be lower than initially expected.

No impact on the molecular portfolio

Fortunately, the worsened business conditions affect the biosimilar where Formycon shares the economic risks and opportunities with its JV-partner Polpharma. With the exception of FYB203 which is outlicensed to Klinge Biopharma, the group is the sole owner of its entire remaining molecule portfolio. As each drug and its biosimilar have different characteristics, perspectives of Formycon's remaining portfolio and pipeline are not impacted by the situation. For now, the revaluation affects the US only which currently accounts for 50% of FYB201 sales. The further roll-out into other markets, and the existing business in Europe is not impacted for now.

Guidance modification for 2023 due to non-cash items

Management retains the EUR75,0 - 85,0 m revenue guidance unchanged. Revenues from the marketing of FYB201, success payments for FYB202 and remunerations for development services (FYB203) continue to dominate the top-line. The EBITDA range of EUR-5,0m to ,15,0m remains unchanged as well. The maintenance of that part of the guidance and no indication of any change in atEquity earnings suggest that Formycon's core operating KPIs are progressing according to plan.

As explained above, the devaluation of the earn-out obligation for FYB201 and the corresponding impairment of the stake in Bioeq triggers the sharp swing in Formycons financial income and hence is the reason for the raised net income guidance for the running year.

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Further outlook

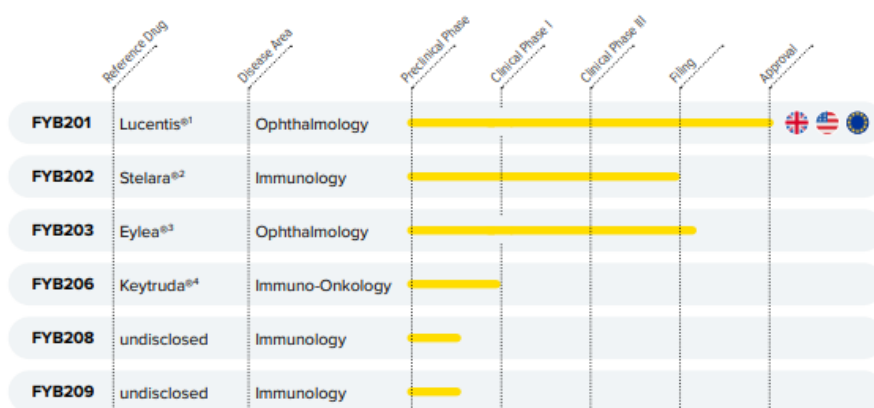
Solid quarter

Looking further ahead, the group is progressing with the development and roll-out of its pipeline according to plans. Applications for the regulatory approval in the US (FDA) and Europe (EMA) for FYB202 and FYB203 are planned for Q4/23. The clinical development of FYB206 is also supposed to start next year. The further expansion of its pipeline with the kick-off of the development of FYB208/209 progress accordingly.

No spill-over expected for now

To summarize, Q3 came in as expected regarding the core operational development of Formycon's pipeline, as well as the progress with its single available product in the market, FYB201. The modification of the FY23 guidance and our own scenario adjustments only reflect a non-cash valuation issue. However, the much more challenging market conditions for that biosimilar need to be monitored closely as they could spill-over to other ranibizumab markets in the future. We would not expect any cross-read beyond FYB201 and hence, keep our operating scenario unchanged.

Pipeline for a broader biosimilar portfolio



Source: Formycon, Metzler Research

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DCF model & sensitivity

	2022	2023	2024	2025	2026	2027	2028	2029	TV Year
Year	0	1	2	3	4	5	6	7	
Discounting period	0.01	1.01	2.01	3.01	4.01	5.01	6.01	7.01	8.01
Sales	42.5	75.3	70.2	98.4	201.8	181.6	208.8	240.1	254.6
Sales growth (%)		77.1	-6.8	40.2	105.1	-10.0	15.0	15.0	6.0
Operating margin (%)	139.1	-5.1	14.1	63.0	46.8	30.0	30.0	30.0	20.0
Operating profit (incl at Equity)	59.1	-3.9	9.9	62.0	94.4	54.5	62.6	72.0	50.9
Taxes	0.6	-13.5	2.6	15.5	23.6	10.9	12.5	14.4	10.2
Tax rate (%)	1.7	-30.0	25.0	25.0	25.0	20.0	20.0	20.0	20.0
Depreciation	1.9	3.0	2.8	3.9	4.0	3.6	4.2	4.8	5.1
Amortisation (ppa etc.)									
Gross cash flow	0.5	-12.0	10.8	32.5	74.9	47.2	54.3	62.4	45.8
Capex	0.55	0.98	0.91	1.48	4.0	3.6	4.2	4.8	5.1
Change in working capital	-0.2	-4.3	-2.5	-6.5					
Free cash flow	-0.2	-17.3	7.4	24.6	70.8	43.6	50.1	57.6	40.7
Discounted free cash flow	-0.2	-16.1	6.4	19.8	53.2	30.5	32.6	34.9	
Sum of DCF	161								
TV	1747								
Net Debt	352								
Fair' Equity value	1556								
Number of shares	16.0								
Fair' value per share	97.0								

Current share price 62.7
Upside 55%

		WACC	
Sales growth (%), years 3-7	15.0	Capex/sales (%), TV year	2.0
Sales growth (%), TV year	6.0	Depreciation/Capex (%)	100
Operating margin (%), years 3-7	30.0	Beta	1.16
Operating margin (%), TV year	20.0	LT debt interest rate (%)	4.5
Tax rate (%), years 3-7	20	Risk Free Rate (%)	2.0
Capex/Sales (%), years 3-7	2.0	Market Risk Premium (%)	6.5
		Cost of debt (%)	3.6
		Cost of equity (%)	9.5
		Equity	484.3
		Financial Debt	268.0
		Total capital	752.3
		WACC (%)	7.4

Sensitivity analysis

Sensitivity of DCF value per share to a +/- 5% change in key assumptions	DCF		Market risk		TV sales		TV Ebit	
	beta	value	premium	value	growth	value	margin	value
-5%	1.10	119.0	6.18%	117.6	5.73%	77.2	19.0%	91.8
base case	1.16	97.0	6.50%	97.0	6.03%	97.0	20.0%	97.0
+5%	1.22	81.0	6.83%	81.3	6.33%	127.7	21.0%	102.3

Source: Bloomberg, Metzler Research

Formycon is progressing well in its establishment among global biosimilar groups. Unsurprisingly, the rather early stage of its portfolio roll-out requires substantial upfront investments and hence, does not yet allow the generation of positive operating earnings. As the group seems to have all prerequisites to become a profitable player and even a full-scale pharma-group in the second half of the decade, we value FYB shares with a DCF approach.

We expect the group to become EBITDA positive from 2025e and to almost double in size by 2029e. As a huge portion of operating earnings during the lifecycle of FYB201 appear on the atEquity level, we add those figures to operating earnings in the DCF model. Overall, the share's sensitivity to variations in growth rates is considerable. The same holds true for the sensitivity to changes in risk parameters and interest rates, due to the groups relatively high indebtedness level.

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Peer group valuation

P/E	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23e</u>	<u>24e</u>	<u>25e</u>
Formycon	-130.7	-37.9	-49.9	26.7	17.0	128.7	21.6
Celltrion	76.4	92.7	48.4	42.1	34.7	31.1	27.0
Sandoz					11.5	10.0	8.0
Alvotech							24.4
AVG ex FMY	76.4	92.7	48.4	42.1	23.1	20.6	19.8
Ev/Ebitda	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23e</u>	<u>24e</u>	<u>25e</u>
Formycon	-208.7	-42.6	-51.2	-82.7	-103.4	-127.0	41.7
Celltrion	43.0	54.0	27.9	25.7	21.3	18.5	16.3
Sandoz					6.4	5.7	4.9
Alvotech						31.1	10.2
AVG ex FMY	43.0	54.0	27.9	25.7	13.9	18.4	10.5
P/CF	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23e</u>	<u>24e</u>	<u>25e</u>
Formycon	-672.0	-65.9	-64.8	-65.7	207.8	-105.5	58.0
Celltrion	79.8	49.2	140.3	30.6	25.7	23.0	21.0
Sandoz					15.7	11.9	10.8
Alvotech						18.1	9.8
AVG ex FMY	79.8	49.2	140.3	30.6	20.7	17.7	13.9
P/Book	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23e</u>	<u>24e</u>	<u>25e</u>
Formycon	6.4	3.8	11.9	2.7	2.1	2.0	1.9
Celltrion	8.3	14.5	6.9	5.34	5.0	4.3	3.8
Sandoz					1.3	1.2	1.2
Alvotech					-	-	-
AVG ex FMY	8.3	14.5	6.9	5.3	3.1	2.8	2.5

Source: Bloomberg, Metzler Research

We would use peer-group multiples for Formycon only as a rough indication for possible fair-value levels of FYB shares as neither of the mentioned players is at a comparable stage of its life-cycle (Celltrion, Alvotech) or has other activities in its portfolio (Sandoz) that limit the comparability with Formycon shares.

Moreover, shares of corporations that have yet to reach operational profitability typically trade at more elevated levels vs shares of those groups at a more mature stage and with a profitability track-record.

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-IgG-Fc 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	3.4	37	6.8	42	16.1	75	77.1	70	-6.8	98	40.2
Gross profit on sales	8	n.a.	10	27.5	12	19.4	15	26.5	16	5.9	58	261.0
Gross margin (%)	23.1	-76.9	27.6	19.4	28.4	2.9	20.3	-28.6	23.0	13.6	59.3	157.5
EBITDA	-5	-279.2	-13	-143.5	-16	-26.2	-12	25.9	-10	17.2	29	396.8
EBITDA margin (%)	-15.0	-266.6	-34.3	-128.1	-37.3	-8.8	-15.6	58.2	-13.9	11.2	29.3	311.7
EBIT	-7	-187.8	-14	-114.0	-18	-26.6	-15	16.7	-13	15.1	25	298.9
EBIT margin (%)	-19.1	-178.2	-38.2	-100.5	-41.7	-9.1	-19.6	53.0	-17.9	8.9	25.3	241.9
Financial result	-0	-289.7	-0	-101.0	54	n.m.	60	10.3	23	-61.7	37	61.5
EBT	-7	-189.0	-14	-113.8	37	357.6	45	23.4	10	-77.0	62	495.8
Taxes	0	894.2	-1	n.m.	1	165.9	-14	n.m.	3	119.2	15	495.8
Tax rate (%)	-1.3	n.a.	6.5	n.a.	1.7	n.a.	-30.0	n.a.	25.0	n.a.	25.0	n.a.
Net income	-7	-191.6	-13	-97.5	36	370.8	59	63.1	8	-86.7	46	495.8
Minority interests	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Income after minorities	-7	-193.8	-13	-97.5	36	370.8	59	63.1	8	-86.7	46	495.8
Number of shares outstanding (m)	0	-100.0	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
EPS adj. (EUR)	-0.61	-165.9	-1.20	-97.5	2.62	318.1	3.68	40.2	0.49	-86.8	2.90	495.8
DPS (EUR)	0.00	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	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	-4	-182.3	-10	-164.3	-15	-42.9	5	132.9	-10	-298.0	17	281.8
Increase in working capital	0	n.a.	-2	n.a.	-0	n.a.	-4	n.a.	-2	n.a.	-6	n.a.
Capital expenditures	-1	-150.5	-0	22.9	-1	-39.8	-1	-77.6	-1	6.8	-1	-61.8
D+A/Capex (%)	-270.1	n.a.	-363.5	n.a.	-337.9	n.a.	-307.7	n.a.	-307.7	n.a.	-266.7	n.a.
Free cash flow (Metzler definition)	-4	-36.0	-13	-217.7	-15	-21.7	-0	97.1	-13	n.m.	9	172.2
Free cash flow yield (%)	-0.7	n.a.	-1.9	n.a.	-1.3	n.a.	-0.0	n.a.	-1.3	n.a.	0.9	n.a.
Dividend paid	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
Free cash flow (post dividend)	-4	n.a.	-13	-217.7	-15	-21.7	-0	97.1	-13	n.m.	9	172.2
Balance sheet (in EUR m)	2020	%	2021	%	2022	%	2023e	%	2024e	%	2025e	%
Assets	76	41.2	66	-12.3	761	n.m.	887	16.5	897	1.1	942	4.9
Goodwill	0	-36.3	0	0.0	488	n.m.	488	0.0	495	1.3	505	2.0
Shareholders' equity	68	41.1	56	-17.6	357	535.9	484	35.8	492	1.6	539	9.4
Equity/total assets (%)	90.0	n.a.	84.5	n.a.	46.8	n.a.	54.6	n.a.	54.8	n.a.	57.2	n.a.
Net Debt incl. Provisions	-35	-56.3	-19	47.1	352	n.m.	216	-38.5	231	6.7	200	-13.3
thereof pension provisions	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
Gearing (%)	-51.6	n.a.	-33.1	n.a.	98.6	n.a.	44.7	n.a.	46.9	n.a.	37.1	n.a.
Net debt/EBITDA	6.8	n.a.	1.5	n.a.	-22.2	n.a.	-18.4	n.a.	-23.7	n.a.	6.9	n.a.

Sources: Bloomberg, Metzler Research

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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)					
04.09.2023	Buy	Buy	60.50 EUR	97.00 EUR	Diedrich, Tom
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

* 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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