

Formycon AG

Germany / Biopharmaceuticals
 Xetra
 Bloomberg: FYB GR
 ISIN: DE000A1EWVY8

FYB202 approval in
 EU and US

RATING
PRICE TARGET
 Return Potential
 Risk Rating

BUY
€ 82.00
 50.2%
 High

RAISING PRICE TARGET ON EARLIER FYB202 US LAUNCH DATE

Formycon and its commercialisation partner, Fresenius Kabi, announced the approval of the Stelara biosimilar FYB202 in both the EU and the US on 27 September. In its most recent corporate presentation, Formycon flagged decisions by the EU and US regulatory authorities on whether to approve FYB202 for early Q4/24 and September 2024 respectively. The timing of the announcements was thus widely anticipated in the market. The unexpected element in the news on FYB202 was the announcement that Formycon/Fresenius Kabi now have the right to market FYB202 in the US no later than 22 February 2025 (previously no later than 15 April). As far as we can ascertain, there have been no changes in competitors' launch dates and so Formycon/Fresenius Kabi will be joint third (previously fifth) in a queue of seven companies seeking to launch a Stelara biosimilar in the US market between 1 January and 15 May next year. We think this earlier launch date perceptibly improves FYB202's market share prospects and so have raised our forecasts, and the price target for the Formycon share from €80 to €82. We maintain our Buy recommendation.

FYB202 potentially a much bigger value driver for Formycon than either FYB201 or FYB203 Stelara generated worldwide sales of USD10.9bn in 2023. This compares with USD3.6bn of sales for Lucentis in 2021, the last year before the launch of biosimilars of the drug, which included Formycon's FYB201. Furthermore, Formycon will earn a royalty of 30-45% on FYB202 sales. The current royalty on FYB201 sales is 7-8%. Worldwide sales of Eylea amounted to USD9.2bn in 2023 but here again, the mid-single to low-double-digit royalty rate on Formycon's FYB203 biosimilar (launch expected in 2025) is much lower than for FYB202.

We assume H1/25 EU launch date for FYB202 Formycon and its competitors have reached agreement with Stelara's developer, Johnson & Johnson, as to the timing of their respective biosimilar launches in the US. Currently expected launch dates are shown in figure 1 overleaf. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2022	2023	2024E	2025E	2026E	2027E
Revenue (€m)	42.5	77.7	62.3	110.5	243.7	222.2
Y-o-y growth	16.1%	82.8%	-19.8%	77.3%	120.6%	-8.8%
EBITDA (€m)	-15.9	1.5	-23.7	46.9	189.5	159.2
EBITDA margin	-37.3%	2.0%	-38.0%	42.4%	77.8%	71.6%
Net income (€m)	36.0	75.8	-27.2	36.2	177.9	117.2
EPS (diluted) (€)	2.59	4.72	-1.54	2.03	9.98	6.57
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-55.9	-27.2	-52.7	-67.5	115.5	83.7
Net gearing	-2.8%	-5.4%	-12.8%	-8.4%	-17.8%	-22.0%
Liquid assets (€m)	9.8	27.0	71.2	49.9	137.3	195.2

RISKS

Product failures, failure to obtain funding, loss of key personnel.

COMPANY PROFILE

Formycon AG is a Munich, Germany based pharmaceuticals company specialising in the development of biosimilars, i.e. generic versions of biotechnology products.

MARKET DATA

As of 30 Sep 2024

Closing Price	€ 54.60
Shares outstanding	17.66m
Market Capitalisation	€ 964.07m
52-week Range	€ 38.15 / 66.90
Avg. Volume (12 Months)	9,092

Multiples	2023	2024E	2025E
P/E	11.7	n.a.	27.3
EV/Sales	12.2	15.2	8.6
EV/EBITDA	624.8	n.a.	20.2
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2024

Liquid Assets	€ 40.62m
Current Assets	€ 95.88m
Intangible Assets	€ 569.46m
Total Assets	€ 947.78m
Current Liabilities	€ 45.60m
Shareholders' Equity	€ 576.30m

SHAREHOLDERS

Athos KG	24.3%
Wendeln & Cie. KG	13.6%
Gedeon Richter Plc	9.0%
Active Ownership S.a.r.l.	6.0%
Free Float and other	47.1%



Formycon has agreed an EU launch date with J&J, but this has not been disclosed. We assume H1/25.

Figure 1: Competitive landscape for Stelara biosimilars

Company	US launch date no later than	FDA approval status	EC approval status
Amgen	01/01/2025	Yes	Yes
Alvotech	21/02/2025	Yes	Yes
Biocon	22/02/2025	BLA accepted	Marketing authorisation application under review
Formycon	22/02/2025	Yes	Yes
Samsung Bioepis	22/02/2025	Yes	Yes
Celltrion	07/03/2025	BLA submitted July 23	Yes
Intas Pharma	15/05/2025	BLA accepted 04/01/2024	Marketing authorisation application under review

Source: companies

Figure 2: Changes to our forecasts

in € 000s	2024E			2025E			2026E			2027E		
	Old	New	Δ	Old	New	Δ	Old	New	Δ	Old	New	Δ
Revenues	62.30	62.30	0.0%	108.57	110.49	1.8%	232.70	243.69	4.7%	212.12	222.16	4.7%
EBITDA	-23.70	-23.70	-	44.97	46.89	4.3%	178.50	189.48	6.2%	149.12	159.16	6.7%
margin	-38.0%	-38.0%	-	41.4%	42.4%	-	76.7%	77.8%	-	70.3%	71.6%	-
Adjusted EBITDA	-3.70	-3.70	-	59.97	61.89	3.2%	193.50	204.48	5.7%	164.12	174.16	6.1%
margin	-5.9%	-5.9%	-	55.2%	56.0%	-	83.2%	83.9%	-	77.4%	78.4%	-

Source: First Berlin Equity Research estimates

Buy recommendation maintained; price target raised from €80 to €82 We think the earlier than previously expected launch of Stelara in the US perceptibly increases the drug's market share prospects, We have increased our US Stelara royalty forecasts by 10% and our price target for the Formycon share from €80 to €82. We maintain our Buy recommendation.

Figure 3: Valuation model

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Royalties	PACME Margin ²⁾	Discount Factor	Patent Life ³⁾	Time to Market
FYB201	nAMD,DR (ex-US)	€39M	199K	€5,921	€1,178M	20%	€10M	15%	10%	n.a.	-
FYB201	nAMD,DR (US)	€62M	82K	€9,845	€807M	20%	€12M	15%	10%	na.	-
FYB202	Pso,CrD (ex-US)	€309M	62K	€34,240	€2,123M	12%	€63M	3%	12%	n.a.	1 year
FYB202	Pso,CrD (US)	€566M	69K	€55,067	€3,800M	12%	€120M	33%	12%	n.a.	1 year
FYB203	nAMD,DR (ex-US)	€23M	425K	€4,486	€1,906M	12%	€6M	9%	2%	n.a.	2 years
FYB203	nAMD,DR (US)	€36M	411K	€7,591	€3,120M	12%	€9M	9%	12%	na.	1 year
FYB206	multiple cancer types (ex-US)	€601M	65K	€79,625	€5,176M	12%	€661M	33%	14%	n.a.	7 years
FYB206	multiple cancer types (US)	€1,089M	59K	€138,393	€8,165M	12%	€999M	33%	14%	n.a.	5 years
FYB208	n.a.	€119M									
FYB209	n.a.	€101M									
FYB210	n.a.	€85M									
PACME PV		€3,030M									
Costs PV ⁴⁾		€1,757M									
NPV		€1,273M									
Proforma net Cash		€175M									
Fair Value		€1,448M									
Proforma share count		17,657K									
Fair Value Per Share		€82.00									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market.

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.

This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model).

3) Remaining patent life after the point of approval.

4) Includes company-level R&D, G&A, Financing Costs, CapEx and Taxes; COGS and S&M are factored into the PACME margin for each project.

Source: First Berlin Equity Research estimates



Figure 4: Changes to our valuation model

	Old	New	Delta
NPV	€1,238M	€1,273M	2.8%
Proforma net Cash	€175M	€175M	0.0%
Fair Value	€1,413M	€1,448M	2.5%
Share Count	17,657K	17,657K	0.0%
Fair value per share	€80.00	€82.00	2.5%

Source: First Berlin Equity Research estimates



INCOME STATEMENT

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Revenue	42.5	77.7	62.3	110.5	243.7	222.2
Cost of sales	-30.4	-54.4	-58.2	-43.7	-37.8	-43.6
Gross profit	12.1	23.3	4.1	66.7	205.9	178.6
R&D expenses	-16.9	-9.2	-14.6	-10.8	-9.2	-10.7
Selling expenses	-1.4	-0.8	-2.6	-1.9	-1.6	-1.9
Administrative expenses	-11.4	-13.3	-12.9	-9.5	-8.1	-9.5
Net other op. expenses	0.0	-0.4	0.0	0.0	0.0	0.0
Operating income (EBIT)	-17.7	-0.4	-26.0	44.5	187.0	156.5
Equity participations	76.8	-19.4	20.0	15.0	15.0	15.0
Dividends from Bioeq	0.0	0.0	0.0	0.0	0.0	15.0
Net financial result	-22.5	98.8	-21.2	-23.2	-24.1	-23.3
Pre-tax income (EBT)	36.6	79.1	-27.2	36.2	177.9	163.2
Income taxes	-0.6	-3.3	0.0	0.0	0.0	-46.0
Net income / loss	36.0	75.8	-27.2	36.2	177.9	117.2
Diluted EPS (in €)	2.59	4.72	-1.54	2.03	9.98	6.57
EBITDA	-15.9	1.5	-23.7	46.9	189.5	159.2
Adjusted EBITDA	-28.8	13.3	-3.7	61.9	204.5	174.2
Ratios						
Gross margin on revenue	28.4%	30.0%	6.6%	60.4%	84.5%	80.4%
EBIT margin on revenue	-41.7%	-0.5%	-41.7%	40.3%	76.7%	70.5%
Net margin on revenue	84.7%	97.6%	-43.6%	32.8%	73.0%	52.7%
Tax rate	1.7%	4.1%	0.0%	0.0%	0.0%	28.2%
Expenses as % of revenue						
Cost of sales	71.6%	70.0%	93.4%	39.6%	15.5%	19.6%
R&D expenses	39.8%	11.8%	23.5%	9.8%	3.8%	4.8%
Selling expenses	3.4%	1.1%	4.1%	1.7%	0.7%	0.9%
Administrative expenses	26.9%	17.1%	20.7%	8.6%	3.3%	4.3%
Y-Y Growth						
Revenues	16.1%	82.8%	-19.8%	77.3%	120.6%	-8.8%
Operating income	n.m.	n.m.	n.m.	n.m.	320.3%	-16.3%
Net income/ loss	n.m.	110.6%	n.m.	n.m.	391.0%	-34.1%



BALANCE SHEET

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Assets						
Current assets, total	30.5	67.1	81.1	70.2	199.8	251.8
Cash and cash equivalents	9.8	27.0	71.2	49.9	137.3	195.2
Other liquid assets	0.0	0.0	0.0	0.0	0.0	0.0
Inventories	0.6	0.5	0.4	0.5	1.6	1.5
Receivables	14.3	11.6	7.5	16.7	51.3	46.4
Contract assets	1.2	16.6	0.8	1.8	5.5	5.0
Other current assets	4.6	11.5	1.2	1.3	4.1	3.7
Non-current assets, total	823.2	823.2	882.2	928.8	1,019.2	1,109.5
Investment participation Bioeq AG	186.4	167.0	187.7	202.7	217.7	232.7
Loan to associate Bioeq AG	92.3	90.9	53.8	0.0	0.0	0.0
Property, plant & equipment	2.6	3.0	3.5	4.1	4.7	5.3
Right of use assets	8.9	9.3	9.7	10.1	10.5	10.8
Goodwill & other intangibles	533.0	552.9	627.5	712.0	786.4	860.7
Prepaid expenses	0.0	0.0	0.0	0.0	0.0	0.0
Deferred tax assets	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	853.7	890.4	963.2	999.1	1,219.0	1,361.3
Shareholders' equity & debt						
Current liabilities, total	50.7	69.3	69.8	55.5	99.7	125.8
Current lease obligations	0.9	1.2	1.2	1.3	1.4	1.4
Accounts payable	11.3	16.3	23.4	21.9	65.2	45.6
Tax liability	0.0	0.0	0.0	0.0	0.0	46.0
Provisions	0.0	0.4	0.0	0.0	0.0	0.0
Shareholder loan	20.8	20.5	0.0	0.0	0.0	0.0
Conditional purchase price payments	14.9	27.2	29.8	31.7	31.3	31.1
Other current liabilities	2.7	3.8	15.4	0.5	1.8	1.7
Long-term liabilities, total	446.5	318.3	336.7	350.6	348.4	347.5
Non-current lease obligations	7.6	7.8	8.2	8.6	9.0	9.5
Provisions	0.0	0.0	0.0	0.0	0.0	0.0
Shareholder loan	20.0	0.0	0.0	0.0	0.0	0.0
Conditional purchase price payments	299.3	187.7	205.5	219.0	215.9	214.6
Other liabilities	0.0	0.0	0.1	0.2	0.6	0.6
Deferred tax liabilities	119.5	122.8	122.8	122.8	122.8	122.8
Shareholders' equity	356.6	502.8	556.8	593.0	770.9	888.0
Total consolidated equity and debt	853.7	890.4	963.2	999.1	1,219.0	1,361.3
Key figures						
Current ratio (x)	0.60	0.97	1.16	1.27	2.00	2.00
Quick ratio (x)	0.59	0.96	1.16	1.26	1.99	1.99
Financial leverage (%)	-2.8	-5.4	-12.8	-8.4	-17.8	-22.0
Book value per share (€)	23.67	31.35	31.53	33.58	43.66	50.29
Return on equity (ROE)	17.5%	17.6%	-5.1%	6.3%	26.1%	14.1%



CASH FLOW STATEMENT

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Net profit	36.0	75.8	-27.2	36.2	177.9	117.2
Depreciation and amortisation	1.9	1.9	2.3	2.4	2.5	2.6
Net finance income	-54.3	-79.4	-20.6	-15.0	-15.0	-15.0
Effect of stock options	0.5	1.6	0.0	0.0	0.0	0.0
Net loss (gain) from disposal of non-current assets	0.0	0.0	0.0	0.0	0.0	0.0
Other non-cash transactions	0.0	0.0	0.0	0.0	0.0	0.0
Income tax expense	0.6	3.3	0.0	0.0	0.0	46.0
Change in working capital	-3.4	-12.8	49.1	-26.8	2.9	-13.9
Change in other financial assets/liabilities	0.2	0.0	21.5	23.5	25.1	24.7
Income taxes paid	-0.3	-0.2	0.0	0.0	0.0	0.0
Operating cash flow	-18.9	-9.8	25.1	20.4	193.4	161.6
CAPEX	-37.1	-17.4	-77.8	-87.8	-77.9	-78.0
Free cash flow	-55.9	-27.2	-52.7	-67.5	115.5	83.7
Repayment of Bioeq loan	0.0	0.0	37.2	53.8	0.0	0.0
Earnout	0.0	0.0	-1.1	-8.1	-28.5	-26.3
Equity financing, net	1.8	68.8	80.8	0.0	0.0	0.0
Shareholder loan	40.0	-23.1	-20.5	0.0	0.0	0.0
Loan	0.0	0.0	0.0	0.0	0.0	0.0
Payment of lease liabilities	-0.9	-1.2	0.5	0.5	0.5	0.5
Interest received/(paid)	-0.1	0.0	0.0	0.0	0.0	0.0
Net cash from financing activities	40.7	44.4	96.9	46.1	-28.0	-25.8
Net cash flows	-15.2	17.2	44.2	-21.4	87.4	57.9
Cash and liquid assets, start of the year	25.0	9.8	27.0	71.2	49.9	137.3
Cash and liquid assets, end of the year	9.8	27.0	71.2	49.9	137.3	195.2
EBITDA/share (in €)	-1.2	0.1	-1.4	2.7	10.7	9.0
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	-18.9%	848.5%	-16.4%
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	-27.6%
EBITDA/share	n.m.	n.m.	n.m.	n.m.	304.1%	-16.0%

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Anschrift:

First Berlin Equity Research GmbH
Friedrichstr. 34
10117 Berlin
Germany

Vertreten durch den Geschäftsführer: Martin Bailey

Telefon: +49 (0) 30-80 93 9 680

Fax: +49 (0) 30-80 93 9 687

E-Mail: info@firstberlin.com

Amtsgericht Berlin Charlottenburg HR B 103329 B

UST-Id.: 251601797

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First Berlin Equity Research GmbH

Authored by: Simon Scholes, Analyst

All publications of the last 12 months were authored by Simon Scholes.

Company responsible for preparation: First Berlin Equity Research GmbH, Friedrichstraße 69, 10117 Berlin

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Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy ¹	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

¹ The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	17 April 2013	€3.50	Buy	€7.30
2...38	↓	↓	↓	↓
39	14 April 2022	€67.30	Buy	€89.00
40	11 July 2022	€74.20	Buy	€97.00
41	30 August 2022	€76.80	Buy	€103.00
42	7 September 2022	€70.40	Buy	€103.00
43	23 September 2022	€70.40	Buy	€130.00
44	21 August 2023	€60.40	Buy	€105.00
45	13 June 2024	€48.20	Buy	€80.00
46	19 August 2024	€49.15	Buy	€80.00
47	Today	€54.60	Buy	€82.00

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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Legally required information regarding

- key sources of information in the preparation of this research report
- valuation methods and principles
- sensitivity of valuation parameters

can be accessed through the following internet link: <https://firstberlin.com/disclaimer-english-link/>

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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