

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Update

RATING**PRICE TARGET**

Return Potential

Risk Rating

ADD**€ 78.00**

24.2%

High

RESUBMISSION OF FYB201 BLA IS LIKELY ON TRACK

Last November Formycon announced that it would resubmit the BLA (Biologics License Application) for its Lucentis biosimilar FYB201 to the FDA during H1 2021. For competitive reasons Formycon did not notify the market of the first submission of the FYB201 BLA in December 2019. Similar considerations no doubt prompted Samsung Bioepis not to disclose the autumn 2020 BLA submission for its Lucentis biosimilar SB11 until it was accepted for filing in November after initial review by the FDA. The time between filing of a BLA and acceptance for filing after initial FDA review is two to two and a half months. As Formycon has not notified the market to the contrary, we assume that the FYB201 BLA resubmission is on track. We expect Formycon to inform the market once the FDA has accepted the BLA for filing after the initial review period. Formycon *did* announce submission of a market authorisation application for FYB201 to the EMA (European Medicines Agency) last week, and also that Teva Pharmaceutical Industries will commercialise FYB201 in Europe, Canada, Israel and New Zealand. As announced in November 2019, Coherus is the US marketing partner for FYB201. Meanwhile, Q1/21 results were close to our expectations and we have left our forecasts unchanged. We maintain our price target of €78.00 but lower the recommendation from Buy to Add as the upside is now lower than 25%.

Teva has strong existing commitment to biosimilars Teva Pharmaceutical Industries (Teva) is the leading generic pharmaceutical company in both Europe and the US and is rapidly growing its activities in biosimilars. The acquisition of the FYB201 distribution rights for Europe, Canada, Israel and New Zealand is only the latest step in Teva's expansion of this area of its business. Over the past two years it has launched truxima, a biosimilar of rituxan, and herzuma, a biosimilar of herceptin in the US. In addition, in August 2020 Teva concluded an agreement with the biopharmaceutical company Alvotech for the exclusive commercialisation in the US of five biosimilar product candidates. We assume a mid-2022 timing for the launch of FYB201 in both the US and the EU. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2017	2018	2019	2020	2021E	2022E
Revenue (€m)	29.00	42.99	33.16	34.23	45.00	62.48
Y-o-y growth	48.5%	48.2%	-22.9%	3.2%	31.5%	38.8%
EBIT (€m)	-1.54	7.13	-2.27	-5.73	-11.02	2.40
EBIT margin	-5.3%	16.6%	-6.9%	-16.7%	-24.5%	3.8%
Net income (€m)	-1.58	7.10	-2.29	-5.93	-11.02	2.40
EPS (diluted) (€)	-0.17	0.76	-0.23	-0.58	-0.98	0.21
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-4.66	-3.73	-7.19	-5.70	-13.21	-2.40
Net gearing	-60.6%	-37.0%	-46.4%	-62.1%	-69.5%	-68.3%
Liquid assets (€m)	15.48	12.31	22.35	42.25	62.01	66.61

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, e.g. generic versions of biotechnology products.

MARKET DATA

As of 02 Jul 2021

Closing Price	€ 62.80
Shares outstanding	11.05m
Market Capitalisation	€ 693.72m
52-week Range	€ 22.30 / 78.00
Avg. Volume (12 Months)	22,743

Multiples	2020	2021E	2022E
P/E	n.a.	n.a.	301.9
EV/Sales	19.2	14.6	10.5
EV/EBIT	n.a.	n.a.	274.2
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2020

Liquid Assets	€ 42.25m
Current Assets	€ 50.51m
Intangible Assets	€ 0.50m
Total Assets	€ 75.60m
Current Liabilities	€ 5.02m
Shareholders' Equity	€ 68.04m

SHAREHOLDERS

Institutional Investors	50.0%
Founders and Management	15.0%
Free Float	35.0%



As figure 1 below shows, Lucentis' US patent expired in June 2020 and its EU patent expires in July 2022.

Figure 1: Patent expiry date of Formycon biosimilar candidates' reference products

Market	Formycon biosimilar candidate (reference product)		
	FYB201 (Lucentis)	FYB202 (Stelara)	FYB203 (Eylea)
US	6/2020	9/2023	5/2024
EU	7/2022	7/2024	5/2025

Source: Companies

Figure 2: Q1/21 results versus our forecasts

in EURm	Q1 21A	Q1 21E	Delta	Q1 20A	Delta
Revenue	9.40	10.00	-6.0%	7.20	30.6%
EBITDA	-1.70	-2.00	n.m.	0.40	n.m.
margin	-18.1%	-20.0%	-	5.6%	-
EBIT	-1.90	-2.20	n.m.	0.20	n.m.
margin	-20.2%	-22.0%	-	2.8%	-
Net income	-2.00	-2.30	n.m.	0.20	n.m.
margin	-21.3%	-23.0%	-	2.8%	-

Source: Formycon; First Berlin Equity Research estimates

Q1/21 results were close to our expectations. As in Q1/20 and FY2020 revenue stemmed from fees for development work on the out-licensed biosimilar candidates FYB201 and FYB203 and also from payments for the provision of development services to the FYB202 joint venture. Q1/21 revenue was up 30.6% on the prior year period and management expects FY2021 revenue to be above the 2020 level. Formycon has also continued to invest in the development of the unpartnered pipeline projects FYB206 and FYB207. FYB206 is a preclinical biosimilar project whose reference product Formycon has not yet announced. The COVID-19 drug, FYB207, is expected to enter the clinic in Q4 this year. The end Q1/21 liquidity position of €35.3m in cash and equivalents and €10.7m in receivables will allow Formycon to continue developing FYB206 and also advance FYB207 beyond the preclinical phase.

Price target of €78.0 maintained, recommendation lowered from Buy to Add As Q1/21 results were close to our expectations, we have left our forecasts unchanged. We maintain our price target of €78.00 but lower the recommendation from Buy to Add as the upside is now lower than 25%.



Figure 3: Pipeline valuation model

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin ²⁾	Discount Factor	Patent Life ³⁾	Time to Market
FYB201	nAMD,DR (ex-US)	€63M	342K	€5,250	€1,794M	17%	€189M	9%	13%	n.a.	2 years
FYB201	nAMD,DR (US)	€57M	172K	€9,068	€1,560M	17%	€184M	9%	13%	n.a.	2 years
FYB202	Pso,CrD (ex-US)	€122M	93K	€27,500	€2,552M	17%	€492M	9%	13%	n.a.	3 years
FYB202	Pso,CrD (US)	€273M	121K	€44,750	€5,421M	17%	€1,044M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (ex-US)	€107M	548K	€4,859	€2,664M	17%	€480M	9%	13%	n.a.	4 years
FYB203	nAMD,DR (US)	€214M	534K	€8,591	€4,587M	17%	€818M	9%	13%	n.a.	3 years
FYB205,6x	n.a.	€261M									
FYB207	COVID-19 (ex-US)	€241M	201K	€20,000	€4,020M	10%	€40M	18%	16%	20	2 years
FYB207	COVID-20 (US)	€91M	75K	€20,000	€1,508M	10%	€152M	18%	16%	20	2 years
PACME PV		€1,428M									
Costs PV ⁴⁾		€648M									
NPV		€779M									
Downpayments and Milestones		€39M									
Proforma net Cash		€82M									
Fair Value		€901M									
Proforma share count		11,546K									
Fair Value Per Share		€78.00									

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



INCOME STATEMENT

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
Revenue	29.0	43.0	33.2	34.2	45.0	62.5
Increase/decrease in unfinished products	0.4	0.6	0.8	0.6	0.0	0.0
Total output	29.4	43.6	32.3	34.8	45.0	62.5
Other operating income	0.1	0.1	0.8	0.4	0.0	0.0
Cost of goods sold	-21.2	-25.8	-21.3	-26.1	-37.0	-40.0
Gross profit	8.4	17.9	11.7	9.2	8.0	22.5
Personnel costs	-6.3	-7.0	-9.1	-10.0	-12.5	-13.4
Depreciation and amortisation	-0.8	-0.9	-0.9	-0.9	-0.9	-0.9
Other operating expenses	-2.8	-3.0	-4.0	-4.0	-5.6	-5.7
Operating income (EBIT)	-1.5	7.1	-2.3	-5.7	-11.0	2.4
Net financial result	0.0	0.0	0.0	-0.1	0.0	0.0
Pre-tax income (EBT)	-1.6	7.1	-2.3	-5.8	-11.0	2.4
Income taxes	0.0	0.0	0.0	0.1	0.0	0.0
Net income / loss	-1.6	7.1	-2.3	-5.9	-11.0	2.4
Diluted EPS (in €)	-0.17	0.76	-0.23	-0.58	-0.98	0.21
EBITDA	-0.8	8.0	-1.4	-4.8	-10.1	3.3
Ratios						
Gross margin on output	28.4%	41.0%	36.3%	26.3%	17.8%	36.0%
EBIT margin on output	-5.2%	16.4%	-7.0%	-16.5%	-24.5%	3.8%
EBITDA margin on output	-2.6%	18.4%	-4.2%	-13.8%	-22.4%	5.3%
Net margin on output	-5.4%	16.3%	-7.1%	-17.0%	-24.5%	3.8%
Tax rate	-0.2%	0.0%	-0.3%	-1.6%	0.0%	0.0%
Expenses as % of output						
Cost of goods sold	-72.0%	-59.2%	-66.1%	-74.8%	-82.2%	-64.0%
Personnel costs	-21.5%	-16.1%	-28.1%	-28.8%	-27.8%	-21.5%
Depreciation and amortisation	-2.7%	-2.1%	-2.8%	-2.6%	-2.1%	-1.5%
Net other operating exp.	-9.1%	-6.5%	-10.0%	-10.2%	-12.4%	-9.1%
Y-Y Growth						
Revenues	48.5%	48.2%	-22.9%	3.2%	31.5%	38.8%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
Assets						
Current assets, total	26.6	18.7	28.1	50.5	71.5	83.0
Cash and cash equivalents	4.5	7.3	22.1	42.0	61.8	66.4
Other liquid assets	11.0	5.0	0.2	0.2	0.2	0.2
Receivables	10.5	5.2	4.9	6.9	9.0	15.6
Inventories	0.6	1.2	0.4	1.2	0.5	0.6
Other current assets	0.1	0.1	0.4	0.1	0.1	0.1
Non-current assets, total	4.2	20.9	25.5	25.1	25.5	25.8
Investment participations	0.0	16.0	20.7	20.7	20.7	20.7
Property, plant & equipment	3.3	3.5	3.7	3.5	3.4	3.4
Goodwill & other intangibles	0.9	0.8	0.6	0.5	0.4	0.3
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.2
Deferred tax assets	0.0	0.5	0.4	0.3	0.9	1.2
Total assets	30.8	39.6	53.6	75.6	97.0	108.8
Shareholders' equity & debt						
Current liabilities, total	3.4	3.3	2.8	5.0	3.8	5.9
Accounts payable	1.8	2.7	2.2	4.5	3.2	5.0
Other current liabilities	1.7	0.6	0.6	0.5	0.6	0.9
Long-term liabilities, total	1.8	3.1	2.6	2.5	4.1	5.4
Provisions	1.3	2.6	1.9	2.1	3.6	5.0
Other liabilities	0.6	0.5	0.7	0.4	0.5	0.4
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	25.5	33.2	48.2	68.0	89.2	97.5
Total consolidated equity and debt	30.8	39.6	53.6	75.6	97.0	108.8
Key figures						
Current ratio (x)	7.75	5.64	10.15	10.06	18.93	14.13
Quick ratio (x)	7.59	5.27	10.00	9.82	18.81	14.02
Financial leverage (%)	-60.6	-37.0	-46.4	-62.1	-69.5	-68.3
Book value per share (€)	2.78	3.37	4.82	285.29	298.55	325.73
Return on equity (ROE)	-6.8%	24.2%	-5.6%	-10.2%	-14.0%	2.6%



CASH FLOW STATEMENT

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
EBIT	-1.5	7.1	-2.3	-5.7	-11.0	2.4
Depreciation and amortisation	0.8	0.9	0.9	0.9	0.9	0.9
EBITDA	-0.8	8.0	-1.4	-4.8	-10.1	3.3
Changes in working capital	-3.4	5.3	0.6	-0.5	-2.4	-4.9
Other adjustments	0.0	0.0	-0.7	0.2	0.0	0.0
Operating cash flow	-4.2	13.3	-1.5	-5.1	-12.5	-1.6
CAPEX	-0.5	-17.0	-5.7	-0.6	-0.7	-0.8
Free cash flow	-4.7	-3.7	-7.2	-5.7	-13.2	-2.4
Debt financing, net	0.0	0.6	0.0	0.0	0.0	0.0
Equity financing, net	6.2	0.0	17.3	25.8	29.0	0.0
Grants	0.0	0.0	0.0	0.0	4.0	7.0
Other changes in cash	0.0	0.0	0.0	-0.2	0	0
Net cash flows	1.5	-3.2	10.0	19.9	19.8	4.6
Cash and liquid assets, start of the year	14.0	15.5	12.3	22.4	42.2	62.0
Cash and liquid assets, end of the year	15.5	12.3	22.4	42.2	62.0	66.6
EBITDA/share (in €)	-0.1	0.9	-0.1	-0.5	-0.9	0.3
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

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...29	↓	↓	↓	↓
30	26 April 2020	€19.75	Buy	€39.00
31	19 May 2020	€24.70	Buy	€39.00
32	23 June 2020	€23.10	Buy	€39.00
33	23 September 2020	€30.40	Buy	€39.00
34	14 October 2020	€33.00	Buy	€43.00
35	7 January 2021	€61.00	Buy	€78.00
36	26 March 2021	€62.60	Add	€78.00
37	20 May 2021	€56.80	Buy	€78.00
38	Today	€62.80	Add	€78.00

INVESTMENT HORIZON

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

UPDATES

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