

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

2019 annual report

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 39.00**

57.9%

High

ON TRACK FOR FIRST ROYALTIES FROM 2021/22

Formycon's 2019 results were close to our forecasts. Revenue was €33.2m (FBe: €35.0m; 2018: €43.0m) while EBIT came in at €2.3m (FBe: €2.0m; 2018: €7.1m). The 2018 numbers were boosted by an €8.5m credit relating to FYB's investment in FYB202 during 2013-16. As in 2018, revenue stemmed from fees for development work on the outlicensed biosimilar candidates FYB201 and FYB203 and also from payments for the provision of development services to the FYB202 joint venture. Costs related to the development work on these projects as well as on Formycon's unpartnered biosimilar candidates. We expect an increasing volume of clinical development work on FYB202 and FYB203 to push revenues to €40m this year while increased investment in preclinical projects widens the EBIT loss to €4m. However, resubmission of the FYB201 Biologics License Application remains on track for H2/20, which suggests that the company will enter the royalty phase from 2021/22. We maintain our Buy recommendation and price target of €39.0.

FYB201 BLA resubmission, FYB202/FYB203 phase III starts all by end 2020

Guidance on the progress of Formycon's three most advanced biosimilar candidates remains unchanged. Resubmission of the BLA for FYB201 (reference product: Lucentis) by license partner Bioeq AG is scheduled during H2/20. Dosing of participants in the phase I trial of the Stelara biosimilar candidate, FYB202, began last October. The manufacturing process for the active ingredient has already been scaled up to a commercial level. Despite the SARS-CoV-2 pandemic, the start of the phase III trial is still scheduled for Q3/20. Formycon has also already scaled up the manufacturing process for FYB203 (reference product: Eylea) to a commercial level and the start of the phase III clinical trial is planned for mid-2020. The total market for the reference products of these three biosimilar candidates climbed by 14% to USD17.8bn in 2018. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018	2019	2020E
Revenue (€m)	16.92	19.53	29.00	42.99	33.16	40.00
Y-o-y growth	34.0%	15.4%	48.5%	48.2%	-22.9%	20.6%
EBIT (€m)	0.54	-4.07	-1.54	7.13	-2.27	-4.00
EBIT margin	3.2%	-20.8%	-5.3%	16.6%	-6.9%	-10.0%
Net income (€m)	0.58	-4.07	-1.58	7.10	-2.29	-4.00
EPS (diluted) (€)	0.06	-0.45	-0.17	0.76	-0.23	-0.40
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.10	-6.40	-4.66	-3.73	-7.19	-6.53
Net gearing	-81.6%	-66.9%	-60.6%	-37.0%	-46.4%	-36.5%
Liquid assets (€m)	20.30	13.97	15.48	12.31	22.35	15.83

RISKS

Product failures, lack of funding, change in regulatory environment, new product innovations making biosimilars obsolete

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 18 May 2020

Closing Price	€ 24.70
Shares outstanding	10.00m
Market Capitalisation	€ 247.00m
52-week Range	€ 16.65 / 34.60
Avg. Volume (12 Months)	8,451

Multiples	2018	2019	2020E
P/E	32.6	n.a.	n.a.
EV/Sales	5.2	6.8	5.6
EV/EBIT	31.5	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2019

Liquid Assets	€ 22.35m
Current Assets	€ 28.06m
Intangible Assets	€ 0.63m
Total Assets	€ 53.56m
Current Liabilities	€ 2.77m
Shareholders' Equity	€ 48.21m

SHAREHOLDERS

Institutional Investors	50.0%
Founders and Management	20.0%
Free Float	30.0%

**Figure 1: FY 2019 results versus our forecasts**

in EURm	FY-19A	FY 19E	Delta	FY 18A	Delta
Revenue	33.16	35.00	-5.3%	42.99	-22.9%
EBIT	-2.27	-2.00	n.m.	7.13	n.m.
margin	-6.8%	-5.7%	-	0.00	-
Net income	-2.29	-1.97	n.m.	7.10	n.m.
margin	-6.9%	-5.6%	-	16.5%	-
EPS (€)	-0.23	-0.20	n.m.	0.76	n.m.

Source: Formycon; First Berlin Equity Research estimates

Not much news from competing biosimilar candidates since our last note in March In our studies of 7 February and 26 March, we described the progress of leading competing biosimilar candidates. The only significant development since the end of March is NeuClone's announcement on 7 April that it had completed subject visits in the phase I clinical trial of its Stelara biosimilar, NeuLara. However, NeuClone have not given any timeline for the start of a phase III trial. Meanwhile, Samsung Bioepis have not yet submitted a BLA for their Lucentis biosimilar SB11, and Momenta Mylan have still to complete recruitment for the phase III trial of the Eylea biosimilar M710.

Figure 2: 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

Antibody-based SARS-CoV-2 drugs under development In late April Formycon announced that it has antibody-based SARS-CoV-2 drugs in preclinical development. Results of preclinical development are expected in Q4/20. Depending on the outcome of the preclinical phase, clinical testing could be initiated in Q3 2021. Preclinical development is likely to cost €0.3m-€0.5m which Formycon will finance itself. The company anticipates being able to access grant funding to finance clinical development which is expected to cost €10m-13m. Given the urgent need for SARS-Cov-2 therapies, clinical development is likely to be fast-track. The advantages of an antibody over a vaccine are that an antibody provides immediate protection, whereas with a vaccine two weeks are required to build immunity, and also that not all vaccinated persons develop immunity.

Price target unchanged at €39.0. Buy recommendation maintained FYB205 is an as yet unpartnered biosimilar project in the preclinical phase for which the reference product has not yet been made public. On 15 May Formycon announced the existence of FYB206 – a further unpartnered biosimilar project in the preclinical phase whose reference product has yet to be made public. Formycon has further pipeline biosimilar candidates, details of which have also not yet been made public. Formycon raised €17.3m in new equity capital in 2019 and had a net cash and other securities position of €22.4m at the end of 2019. The company thus has ample funds for further pipeline development. However, pending further news of the reference products behind FYB205, FYB206 and other projects, we leave our valuation of these biosimilar candidates unchanged. Given the very crowded field of drug candidates for SARS-CoV-2, we have also not included this project in our valuation, which remains unchanged at €39.0 per share. We maintain our Buy recommendation.



Figure 3: Changes to our forecasts

in €m	2020E		Delta
	Old	New	
Revenues	38.00	40.00	5.3%
EBIT	-2.00	-4.00	n.a.
margin	neg.	neg.	-
Net income	-1.96	-4.00	n.a.
margin	neg.	neg.	-
EPS (diluted, in €)	-0.20	-0.40	n.a.

Source: First Berlin Equity Research estimates

Figure 4: 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)	€115M	327K	€5,250	€1,716M	17%	€331M	9%	13%	n.a.	3 Years
FYB201	nAMD,DR (US)	€112M	144K	€9,068	€1,305M	17%	€339M	9%	8%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€52M	56K	€27,500	€1,532M	17%	€484M	9%	16%	n.a.	5 Years
FYB202	Pso,CrD (US)	€114M	47K	€44,750	€2,115M	17%	€1,080M	9%	16%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€53M	417K	€4,859	€2,024M	17%	€558M	9%	16%	n.a.	6 Years
FYB203	nAMD,DR (US)	€86M	392K	€8,591	€3,365M	17%	€830M	9%	16%	n.a.	5 Years
FYB205,6,x	n.a.	€85M									
PACME PV		€616M									
Costs PV ⁴⁾		€288M									
NPV		€328M									
Downpayments and Milestones		€40M									
Proforma net Cash		€22M									
Fair Value		€390M									
Share Count		10,000K									
Fair Value Per Share		€39.00									

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 and CapEx; 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	2015A	2016A	2017A	2018A	2019A	2020E
Revenue	16.9	19.5	29.0	43.0	33.2	40.0
Increase/decrease in unfinished products	0.0	0.0	0.4	0.6	0.8	0.0
Total output	16.9	19.5	29.4	43.6	32.3	40.0
Other operating income	0.2	0.1	0.1	0.1	0.8	0.2
Cost of goods sold	-8.9	-15.4	-21.2	-25.8	-21.3	-27.8
Gross profit	8.3	4.3	8.4	17.9	11.7	12.4
Personnel costs	-3.9	-5.1	-6.3	-7.0	-9.1	-11.0
Depreciation and amortisation	-0.9	-0.7	-0.8	-0.9	-0.9	-0.8
Other operating expenses	-2.9	-2.6	-2.8	-3.0	-4.0	-4.6
Operating income (EBIT)	0.5	-4.1	-1.5	7.1	-2.3	-4.0
Net financial result	0.0	0.0	0.0	0.0	0.0	0.0
Pre-tax income (EBT)	0.6	-4.1	-1.6	7.1	-2.3	-4.0
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net income / loss	0.6	-4.1	-1.6	7.1	-2.3	-4.0
Diluted EPS (in €)	0.06	-0.45	-0.17	0.76	-0.23	-0.40
EBITDA	1.5	-3.4	-0.8	8.0	-1.4	-3.2
Ratios						
Gross margin on output	48.9%	21.9%	28.4%	41.0%	36.3%	31.0%
EBIT margin on output	3.2%	-20.8%	-5.2%	16.4%	-7.0%	-10.0%
EBITDA margin on output	8.7%	-17.3%	-2.6%	18.4%	-4.2%	-7.9%
Net margin on output	3.4%	-20.8%	-5.4%	16.3%	-7.1%	-10.0%
Tax rate	-0.2%	0.1%	-0.2%	0.0%	-0.3%	0.0%
Expenses as % of output						
Cost of goods sold	-52.5%	-78.8%	-72.0%	-59.2%	-66.1%	-69.4%
Personnel costs	-22.8%	-26.1%	-21.5%	-16.1%	-28.1%	-27.4%
Depreciation and amortisation	-5.5%	-3.6%	-2.7%	-2.1%	-2.8%	-2.1%
Net other operating exp.	-16.0%	-12.6%	-9.1%	-6.5%	-10.0%	-11.1%
Y-Y Growth						
Revenues	34.5%	15.4%	48.5%	48.2%	-22.9%	20.6%
Operating income	-38.1%	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	-32.9%	n.m.	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EURm	2015A	2016A	2017A	2018A	2019A	2020E
Assets						
Current assets, total	23.3	20.7	26.6	18.7	28.1	24.3
Cash and cash equivalents	0.6	3.0	4.5	7.3	22.1	12.0
Other liquid assets	19.7	11.0	11.0	5.0	0.2	3.8
Receivables	2.8	5.2	10.5	5.2	4.9	6.4
Inventories	0.2	0.6	0.6	1.2	0.4	2.0
Other current assets	0.0	0.9	0.1	0.1	0.4	0.1
Non-current assets, total	3.8	4.5	4.2	20.9	25.5	26.0
Investment participations	0.0	0.0	0.0	16.0	20.7	20.7
Property, plant & equipment	2.6	3.4	3.3	3.5	3.7	4.0
Goodwill & other intangibles	1.1	1.0	0.9	0.8	0.6	0.4
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.1
Deferred tax assets	0.0	0.0	0.0	0.5	0.4	0.8
Total assets	27.1	25.2	30.8	39.6	53.6	50.3
Shareholders' equity & debt						
Current liabilities, total	1.3	2.6	3.4	3.3	2.8	3.4
Accounts payable	0.6	2.3	1.8	2.7	2.2	2.8
Other current liabilities	0.7	0.3	1.7	0.6	0.6	0.6
Long-term liabilities, total	0.9	1.7	1.8	3.1	2.6	3.6
Provisions	0.7	0.7	1.3	2.6	1.9	3.2
Other liabilities	0.3	1.0	0.6	0.5	0.7	0.4
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	24.9	20.9	25.5	33.2	48.2	43.3
Deferred income	0.0	0.0	0.0	0.0	0.0	0.0
Total consolidated equity and debt	27.1	25.2	30.8	39.6	53.6	50.3
Key figures						
Current ratio (x)	17.45	7.91	7.75	5.64	10.15	7.23
Quick ratio (x)	17.28	7.67	7.59	5.27	10.00	6.64
Financial leverage (%)	-81.6	-66.9	-60.6	-37.0	-46.4	-36.5
Book value per share (€)	2.74	2.30	2.78	3.37	4.82	224.41
Return on equity (ROE)	3.0%	-17.8%	-6.8%	24.2%	-5.6%	-8.7%



CASH FLOW STATEMENT

All figures in EURm	2015A	2016A	2017A	2018A	2019A	2020E
EBIT	0.5	-4.1	-1.5	7.1	-2.3	-4.0
Depreciation and amortisation	0.9	0.7	0.8	0.9	0.9	0.8
EBITDA	1.5	-3.4	-0.8	8.0	-1.4	-3.2
Changes in working capital	-1.1	-1.7	-3.4	5.3	0.6	-2.4
Other adjustments	0.1	0.1	0.0	0.0	-0.7	0.0
Operating cash flow	0.5	-5.0	-4.2	13.3	-1.5	-5.6
CAPEX	-0.6	-1.4	-0.5	-17.0	-5.7	-0.9
Free cash flow	-0.1	-6.4	-4.7	-3.7	-7.2	-6.5
Debt financing, net	0.0	0.0	0.0	0.6	0.0	0.0
Equity financing, net	11.2	0.1	6.2	0.0	17.3	0.0
Other changes in cash	0.0	0.0	0.0	0.0	0.0	0.0
Net cash flows	11.1	-6.3	1.5	-3.2	10.0	-6.5
Cash and liquid assets, start of the year	9.2	20.3	14.0	15.5	12.3	22.4
Cash and liquid assets, end of the year	20.3	14.0	15.5	12.3	22.4	15.8
EBITDA/share (in €)	0.2	-0.4	-0.1	0.9	-0.1	-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	-26.8%	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.

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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...28	↓	↓	↓	↓
29	7 June 2019	€32.00	Buy	€51.00
30	11 November 2019	€32.40	Buy	€51.00
31	7 February 2020	€28.10	Buy	€39.00
32	26 March 2020	€19.75	Buy	€39.00
37	Today	€24.70	Buy	€39.00

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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- sensitivity of valuation parameters

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