

# Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Q1/20 results

**RATING****PRICE TARGET**

Return Potential

Risk Rating

**BUY****€ 39.00**

68.8%

High

## DEVELOPMENT PROGRAMMES ON TRACK

Formycon's Q1/20 results were close to our forecasts and the company budget. As in 2019, 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. Q1/20 revenue at €7.2m was 24% below the prior year figure of €9.5m, but revenue will pick up during the remaining quarters of the year in connection with the start of the FYB202 and FYB203 phase III trials. Management is guiding for full year revenue of €35-40m compared with the 2019 figure of €33.2m. Meanwhile, resubmission of the FYB201 Biologics License Application remains on schedule 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 by year-end

As Formycon confirmed in mid-May, resubmission of the BLA for FYB201 (reference product: Lucentis) by license partner Bioeq AG is scheduled during H2/20. The manufacturing process for the active ingredient of the Stelara biosimilar candidate, FYB202, 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 imminent.

### Q1/20 reference product sales up 10% despite negative pandemic influence

Figure 2 overleaf shows Q1/20 sales development of the FYB201, FYB202 and FYB203 reference products - respectively Lucentis, Stelara and Eylea. Novartis and Roche state that Lucentis sales fell during Q1/20 because of SARS-CoV-2-related disruption of ophthalmology practices. The strong rise in Stelara sales was driven by FDA approval of the drug for ulcerative colitis last autumn and increasing use in Crohn's disease. Eylea sales were up in Q1/20 but Regeneron states that the pandemic reduced demand for the drug from April. (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 22 Jun 2020

Closing Price	€ 23.10
Shares outstanding	10.00m
Market Capitalisation	€ 231.00m
52-week Range	€ 16.65 / 34.60
Avg. Volume (12 Months)	8,199

Multiples	2018	2019	2020E
P/E	30.5	n.a.	n.a.
EV/Sales	4.9	6.3	5.2
EV/EBIT	29.5	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: Q1/20 results versus our forecasts**

in EURm	Q1 20A	Q1 20E	Delta	Q1 19A	Delta
Revenue	7.20	8.00	-10.0%	9.50	-24.2%
EBITDA	0.40	0.00	n.m.	0.50	-20.0%
<i>margin</i>	5.6%	0.0%	-	5.3%	-
EBIT	0.20	-0.20	n.m.	0.20	0.0%
<i>margin</i>	2.8%	-2.5%	-	2.1%	-
Net income	0.20	-0.20	n.m.	0.20	0.0%
<i>margin</i>	2.8%	-2.5%	-	2.1%	-
EPS (€)	0.02	-0.02	n.m.	0.02	0.0%

Source: Formycon; First Berlin Equity Research estimates

In our recent studies we have described the progress of competing biosimilar candidates. The most significant news since the end of April in our view is the early May announcement from the Swedish biosimilar developer Xbrane and its partner Stada that commercialisation of their Lucentis biosimilar Xlucane in the US and Canada will be the responsibility of Bausch and Lomb. Xbrane is currently recruiting patients for Xlucane's phase III trial. Xbrane hopes to launch the product in the US in mid-2022.

**Figure 2: Q1/20 revenues of Formycon biosimilar candidates' reference products**

USDm	Q1/20	Q1/19	Delta
Lucentis	862	964	-10.6%
Stelara	1,819	1,405	29.5%
Eylea	1,854	1,744	6.3%
Total	4,535	4,113	10.3%

Source: Companies

**Price target unchanged at €39.0. Buy recommendation maintained** Formycon raised €17.3m in new equity capital in 2019 and had a net cash and other securities position of €21.1m at the end of Q1/20. The company thus has ample funds for further pipeline development. In May Formycon announced the existence of FYB206 – an 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. However, pending further news of the reference products behind FYB206 and other projects, we leave our valuation of these biosimilar candidates unchanged. Our forecasts are unchanged following the Q1/20 results, and we maintain our Buy recommendation and price target of €39.0.



Figure 3: Pipeline valuation model

Compound	Project <sup>1)</sup>	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin <sup>2)</sup>	Discount Factor	Patent Life <sup>3)</sup>	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 <sup>4)</sup>		€288M									
NPV		€328M									
Downpayments and Milestones		€40M									
Proforma net Cash		€21M									
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
<b>Revenue</b>	<b>16.9</b>	<b>19.5</b>	<b>29.0</b>	<b>43.0</b>	<b>33.2</b>	<b>40.0</b>
Increase/decrease in unfinished products	0.0	0.0	0.4	0.6	0.8	0.0
<b>Total output</b>	<b>16.9</b>	<b>19.5</b>	<b>29.4</b>	<b>43.6</b>	<b>32.3</b>	<b>40.0</b>
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
<b>Gross profit</b>	<b>8.3</b>	<b>4.3</b>	<b>8.4</b>	<b>17.9</b>	<b>11.7</b>	<b>12.4</b>
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
<b>Operating income (EBIT)</b>	<b>0.5</b>	<b>-4.1</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.3</b>	<b>-4.0</b>
Net financial result	0.0	0.0	0.0	0.0	0.0	0.0
<b>Pre-tax income (EBT)</b>	<b>0.6</b>	<b>-4.1</b>	<b>-1.6</b>	<b>7.1</b>	<b>-2.3</b>	<b>-4.0</b>
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net income / loss</b>	<b>0.6</b>	<b>-4.1</b>	<b>-1.6</b>	<b>7.1</b>	<b>-2.3</b>	<b>-4.0</b>
<b>Diluted EPS (in €)</b>	<b>0.06</b>	<b>-0.45</b>	<b>-0.17</b>	<b>0.76</b>	<b>-0.23</b>	<b>-0.40</b>
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.4</b>	<b>-3.2</b>
<b>Ratios</b>						
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%
<b>Expenses as % of output</b>						
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%
<b>Y-Y Growth</b>						
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
<b>Assets</b>						
<b>Current assets, total</b>	<b>23.3</b>	<b>20.7</b>	<b>26.6</b>	<b>18.7</b>	<b>28.1</b>	<b>24.3</b>
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
<b>Non-current assets, total</b>	<b>3.8</b>	<b>4.5</b>	<b>4.2</b>	<b>20.9</b>	<b>25.5</b>	<b>26.0</b>
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
<b>Total assets</b>	<b>27.1</b>	<b>25.2</b>	<b>30.8</b>	<b>39.6</b>	<b>53.6</b>	<b>50.3</b>
<b>Shareholders' equity &amp; debt</b>						
<b>Current liabilities, total</b>	<b>1.3</b>	<b>2.6</b>	<b>3.4</b>	<b>3.3</b>	<b>2.8</b>	<b>3.4</b>
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
<b>Long-term liabilities, total</b>	<b>0.9</b>	<b>1.7</b>	<b>1.8</b>	<b>3.1</b>	<b>2.6</b>	<b>3.6</b>
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
<b>Minority interests</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Shareholders' equity</b>	<b>24.9</b>	<b>20.9</b>	<b>25.5</b>	<b>33.2</b>	<b>48.2</b>	<b>43.3</b>
Deferred income	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total consolidated equity and debt</b>	<b>27.1</b>	<b>25.2</b>	<b>30.8</b>	<b>39.6</b>	<b>53.6</b>	<b>50.3</b>
<b>Key figures</b>						
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
<b>EBIT</b>	<b>0.5</b>	<b>-4.1</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.3</b>	<b>-4.0</b>
Depreciation and amortisation	0.9	0.7	0.8	0.9	0.9	0.8
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.4</b>	<b>-3.2</b>
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
<b>Operating cash flow</b>	<b>0.5</b>	<b>-5.0</b>	<b>-4.2</b>	<b>13.3</b>	<b>-1.5</b>	<b>-5.6</b>
CAPEX	-0.6	-1.4	-0.5	-17.0	-5.7	-0.9
<b>Free cash flow</b>	<b>-0.1</b>	<b>-6.4</b>	<b>-4.7</b>	<b>-3.7</b>	<b>-7.2</b>	<b>-6.5</b>
<b>Debt financing, net</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.6</b>	<b>0.0</b>	<b>0.0</b>
<b>Equity financing, net</b>	<b>11.2</b>	<b>0.1</b>	<b>6.2</b>	<b>0.0</b>	<b>17.3</b>	<b>0.0</b>
Other changes in cash	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net cash flows</b>	<b>11.1</b>	<b>-6.3</b>	<b>1.5</b>	<b>-3.2</b>	<b>10.0</b>	<b>-6.5</b>
Cash and liquid assets, start of the year	9.2	20.3	14.0	15.5	12.3	22.4
<b>Cash and liquid assets, end of the year</b>	<b>20.3</b>	<b>14.0</b>	<b>15.5</b>	<b>12.3</b>	<b>22.4</b>	<b>15.8</b>
<b>EBITDA/share (in €)</b>	<b>0.2</b>	<b>-0.4</b>	<b>-0.1</b>	<b>0.9</b>	<b>-0.1</b>	<b>-0.3</b>
<b>Y-Y Growth</b>						
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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#### 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 <sup>1</sup>	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%

<sup>1</sup> 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
33	19 May 2020	€24.70	Buy	€39.00
37	Today	€23.10	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.

#### SUBJECT TO CHANGE

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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/>

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