

# Formycon AG

Germany / Biopharmaceuticals  
 Xetra  
 Bloomberg: FYB GR  
 ISIN: DE000A1EWWY8

Resubmission of  
 FYB201 BLA

**RATING**  
**BUY**

**PRICE TARGET**  
**€ 39.00**

Return Potential 38.8%  
 Risk Rating High

## FDA REQUESTS DATA ON NEW FYB201 PROCESSING LOCATION

Formycon's licensing partner, Bioeq, is to withdraw the biologics license application (BLA) for FYB201 which it submitted in December, and plans to resubmit it in a few months time. The withdrawal follows a request from the FDA for additional data following the transfer of a piece of processing equipment to a new location at the original site. In H1/2018 Formycon had expected submission of the FYB201 BLA in late 2018/H1 2019 and marketing authorisation approval in the US in 2020. However, temporary problems in manufacturing sufficient quantities of FYB201 delayed the BLA submission until December 2019. The need to resubmit the BLA suggests that FYB201 will not now be approved in the US until the second half of 2021. Before the latest announcement, we had expected early 2021. Launch schedule delays create uncertainty as to whether FYB201 or its closest competing product, Samsung Bioepis' SB11, will reach the US market first. To take account of this uncertainty, we have reduced our market share forecasts for FYB201 in both the U.S. and other territories from 21% to 17%. Formycon is set to participate in large markets. The reference products of FYB201, FYB202 and FYB203 generated worldwide aggregate sales of USD15.6bn in 2018. However, we raise the discount factor on forecast FYB201 cashflows from 12% to 13% and for FYB202, FYB203 and FYB205 cashflows from 15% to 16% to reflect the fact that on recent evidence, approval processes for the company's biosimilar candidates are not progressing as smoothly as we previously modelled. Our new price target is €39.00 (previously: €51.00). We maintain our Buy recommendation.

**FDA requests additional data as part of FYB201 BLA review process**  
 Formycon's licensing partner, Bioeq, submitted a BLA for FYB201 in December 2019. However, on 4 February Formycon announced that the FDA has requested additional data as part of the BLA review process. The request relates to the transfer of processing equipment by the contract manufacturing organisation (CMO) to a different location to that at which drug substance qualification was completed. (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018	2019E	2020E
Revenue (€m)	16.92	19.53	29.00	42.99	35.00	38.00
Y-o-y growth	34.0%	15.4%	48.5%	48.2%	-18.6%	8.6%
EBIT (€m)	0.54	-4.07	-1.54	7.13	-2.00	-2.00
EBIT margin	3.2%	-20.8%	-5.3%	16.6%	-5.7%	-5.3%
Net income (€m)	0.58	-4.07	-1.58	7.10	-1.97	-1.96
EPS (diluted) (€)	0.06	-0.45	-0.17	0.76	-0.20	-0.20
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.10	-6.40	-4.66	-3.73	-7.29	-3.47
Net gearing	-81.6%	-66.9%	-60.6%	-37.0%	-45.0%	-39.5%
Liquid assets (€m)	20.30	13.97	15.48	12.31	21.46	17.99

### 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 06 Feb 2020

Closing Price	€ 28.10
Shares outstanding	10.00m
Market Capitalisation	€ 281.00m
52-week Range	€ 27.70 / 36.30
Avg. Volume (12 Months)	6,734

Multiples	2018	2019E	2020E
P/E	37.1	n.a.	n.a.
EV/Sales	6.1	7.5	6.9
EV/EBIT	36.6	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

### STOCK OVERVIEW



### COMPANY DATA

As of 30 Jun 2019

Liquid Assets	€ 7.96m
Current Assets	€ 28.26m
Intangible Assets	€ 0.72m
Total Assets	€ 54.01m
Current Liabilities	€ 2.13m
Shareholders' Equity	€ 49.81m

### SHAREHOLDERS

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



The transfer of equipment was made at the request of a national European health authority and followed the CMO's allocation of more space at the original FYB201 processing location to another product. Formycon and Bioeq estimate that it will take four months to generate the data required by the FDA. Bioeq have withdrawn the BLA and plan to resubmit it once the necessary data have been gathered. Both Formycon and Bioeq emphasise that the FDA's request for additional data relates to the new processing location and not to the quality of the drug substance.

**FYB201 US launch likely to be delayed from early 2021 to the second half of 2021** We expect Formycon to resubmit the BLA for FYB201 to the FDA in Q3. The FDA will then have 60 days to determine whether the BLA is complete. If we assume that the FDA accepts the BLA as complete, the standard decision period on whether or not to grant approval is a further 10 months. This suggests that Formycon is unlikely to be able to launch FYB201 in the US before the second half of 2021. The furthest advanced competing Lucentis biosimilar is Samsung Bioepis' SB11. The phase III trial of SB11 was completed on 9 December 2019. Samsung Bioepis has not yet filed a BLA for SB11. As figure 1 shows, so far the company has filed BLAs for five biosimilars. The BLA for SB8 is still under review by the FDA. The average period between phase III completion and FDA submission for the first five Samsung Bioepis biosimilars was 10 months. This suggests that Samsung Bioepis could file the BLA for SB11 in September. On the basis of standard FDA timelines, approval could be forthcoming in late 2021.

**Figure 1: Timegap between Samsung Bioepis biosimilar phase III completions and BLA submissions**

Biosimilar	Reference Drug	Phase III completion date	BLA submission date	Date of FDA approval
SB4	Etanercept	October 2015	May 2017	April 2019
SB2	Remicade	September 2015	March 2016	January 2017
SB5	Humira	October 2015	August 2016	July 2019
SB3	Herceptin	February 2017	October 2017	December 2018
SB8	Avastin	October 2018	September 2019	n.a.
SB11	Lucentis	December 2019	n.a.	n.a.

Source: FDA, Samsung Biologics, [clinicaltrials.gov](https://clinicaltrials.gov)

**Buy recommendation maintained but price target reduced from €51.00 to €39.00** We have adjusted our model to take account of the uncertainty as to whether FYB201 or its closest competing product, Samsung Bioepis' SB11, will reach the US market first. We have reduced our market share forecasts for FYB201 in both the US and other territories from 21% to 17%. We also raise the discount factor for FYB201 from 12% to 13% and for FYB202, FYB203 and FYB205 from 15% to 16% to reflect the fact that on recent evidence, approval processes for Formycon's biosimilar candidates are not progressing as smoothly as we previously expected. Our new price target is €39.00 (previously: €51.00). We maintain our Buy recommendation.



Figure 2: 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)	€114M	327K	€5,250	€1,716M	17%	€330M	9%	13%	n.a.	3 Years
FYB201	nAMD,DR (US)	€112M	144K	€9,068	€1,305M	17%	€337M	9%	8%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€48M	56K	€27,500	€1,532M	17%	€453M	9%	16%	n.a.	5 Years
FYB202	Pso,CrD (US)	€125M	47K	€44,750	€2,115M	17%	€1,054M	9%	16%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€53M	417K	€4,859	€2,024M	17%	€567M	9%	16%	n.a.	6 Years
FYB203	nAMD,DR (US)	€88M	392K	€8,591	€3,365M	17%	€753M	9%	16%	n.a.	4 Years
FYB205	n.a.	€84M									
PACME PV		€624M									
Costs PV <sup>4)</sup>		€294M									
NPV		€330M									
Downpayments and Milestones		€39M									
Proforma net Cash		€20M									
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

Figure 3: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	€768M	€624M	-18.7%
Costs PV	€318M	€294M	-7.5%
NPV	€449M	€330M	-26.5%
PV downpayments and milestones	€40M	€39M	-1.4%
Proforma net Cash	€20M	€20M	-0.7%
Fair Value	€510M	€390M	-23.5%
Share Count	10,000K	10,000K	0.0%
Fair value per share	€51.00	€39.00	-23.5%

Source: First Berlin Equity Research estimates



## INCOME STATEMENT

All figures in EURm	2015A	2016A	2017A	2018A	2019E	2020E
<b>Revenue</b>	<b>16.9</b>	<b>19.5</b>	<b>29.0</b>	<b>43.0</b>	<b>35.0</b>	<b>38.0</b>
Increase/decrease in unfinished products	0.0	0.0	0.4	0.6	0.0	0.0
<b>Total output</b>	<b>16.9</b>	<b>19.5</b>	<b>29.4</b>	<b>43.6</b>	<b>35.0</b>	<b>38.0</b>
Other operating income	0.2	0.1	0.1	0.1	0.2	0.2
Cost of goods sold	-8.9	-15.4	-21.2	-25.8	-24.2	-26.3
<b>Gross profit</b>	<b>8.3</b>	<b>4.3</b>	<b>8.4</b>	<b>17.9</b>	<b>11.0</b>	<b>11.9</b>
Personnel costs	-3.9	-5.1	-6.3	-7.0	-9.0	-9.8
Depreciation and amortisation	-0.9	-0.7	-0.8	-0.9	-0.7	-0.8
Other operating expenses	-2.9	-2.6	-2.8	-3.0	-3.2	-3.3
<b>Operating income (EBIT)</b>	<b>0.5</b>	<b>-4.1</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.0</b>	<b>-2.0</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>-2.0</b>	<b>-2.0</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>-2.0</b>	<b>-2.0</b>
<b>Diluted EPS (in €)</b>	<b>0.06</b>	<b>-0.45</b>	<b>-0.17</b>	<b>0.76</b>	<b>-0.20</b>	<b>-0.20</b>
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.3</b>	<b>-1.2</b>
<b>Ratios</b>						
Gross margin on output	48.9%	21.9%	28.4%	41.0%	31.3%	31.3%
EBIT margin on output	3.2%	-20.8%	-5.2%	16.4%	-5.7%	-5.3%
EBITDA margin on output	8.7%	-17.3%	-2.6%	18.4%	-3.6%	-3.1%
Net margin on output	3.4%	-20.8%	-5.4%	16.3%	-5.6%	-5.2%
Tax rate	-0.2%	0.1%	-0.2%	0.0%	0.0%	0.0%
<b>Expenses as % of output</b>						
Cost of goods sold	-52.5%	-78.8%	-72.0%	-59.2%	-69.1%	-69.1%
Personnel costs	-22.8%	-26.1%	-21.5%	-16.1%	-25.8%	-25.8%
Depreciation and amortisation	-5.5%	-3.6%	-2.7%	-2.1%	-2.1%	-2.1%
Net other operating exp.	-16.0%	-12.6%	-9.1%	-6.5%	-8.7%	-8.2%
<b>Y-Y Growth</b>						
Revenues	34.5%	15.4%	48.5%	48.2%	-18.6%	8.6%
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	2019E	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>27.8</b>	<b>26.0</b>
Cash and cash equivalents	0.6	3.0	4.5	7.3	14.0	11.4
Other liquid assets	19.7	11.0	11.0	5.0	7.5	6.6
Receivables	2.8	5.2	10.5	5.2	4.9	6.1
Inventories	0.2	0.6	0.6	1.2	1.4	1.9
Other current assets	0.0	0.9	0.1	0.1	0.1	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>26.0</b>	<b>26.1</b>
Investment participations	0.0	0.0	0.0	16.0	21.1	21.1
Property, plant & equipment	2.6	3.4	3.3	3.5	3.5	3.8
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	0.7	0.8
<b>Total assets</b>	<b>27.1</b>	<b>25.2</b>	<b>30.8</b>	<b>39.6</b>	<b>53.8</b>	<b>52.2</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>2.9</b>	<b>3.2</b>
Accounts payable	0.6	2.3	1.8	2.7	2.5	2.7
Other current liabilities	0.7	0.3	1.7	0.6	0.5	0.5
<b>Long-term liabilities, total</b>	<b>0.9</b>	<b>1.7</b>	<b>1.8</b>	<b>3.1</b>	<b>3.2</b>	<b>3.5</b>
Provisions	0.7	0.7	1.3	2.6	2.8	3.0
Other liabilities	0.3	1.0	0.6	0.5	0.4	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>47.7</b>	<b>45.5</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>53.8</b>	<b>52.2</b>
<b>Key figures</b>						
Current ratio (x)	17.45	7.91	7.75	5.64	9.46	8.16
Quick ratio (x)	17.28	7.67	7.59	5.27	8.99	7.56
Financial leverage (%)	-81.6	-66.9	-60.6	-37.0	-45.0	-39.5
Book value per share (€)	2.74	2.30	2.78	3.37	4.77	229.15
Return on equity (ROE)	3.0%	-17.8%	-6.8%	24.2%	-4.9%	-4.2%



## CASH FLOW STATEMENT

All figures in EURm	2015A	2016A	2017A	2018A	2019E	2020E
<b>EBIT</b>	<b>0.5</b>	<b>-4.1</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.0</b>	<b>-2.0</b>
Depreciation and amortisation	0.9	0.7	0.8	0.9	0.7	0.8
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.3</b>	<b>-1.2</b>
Changes in working capital	-1.1	-1.7	-3.4	5.3	-0.4	-1.4
Other adjustments	0.1	0.1	0.0	0.0	0.0	0.0
<b>Operating cash flow</b>	<b>0.5</b>	<b>-5.0</b>	<b>-4.2</b>	<b>13.3</b>	<b>-1.6</b>	<b>-2.6</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>-7.3</b>	<b>-3.5</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>16.4</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>9.1</b>	<b>-3.5</b>
Cash and liquid assets, start of the year	9.2	20.3	14.0	15.5	12.3	21.5
<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>21.5</b>	<b>18.0</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>-0.1</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.

**FIRST BERLIN 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...27	↓	↓	↓	↓
28	27 March 2018	€28.95	Buy	€53.00
29	7 June 2019	€32.00	Buy	€51.00
30	11 November 2019	€32.40	Buy	€51.00
31	Today	€28.10	Buy	€39.00

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First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular the German Securities Trading Act [WpHG], Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and the German Ordinance on the Analysis of Financial Instruments [FinAnV] into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

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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 <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.

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- valuation methods and principles
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