

# Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Covid-19 Update

**RATING****PRICE TARGET**

Return Potential

Risk Rating

**BUY****€ 39.00**

97.5%

High

## 25% SHARE PRICE FALL SINCE LATE FEBRUARY IS UNWARRANTED

We believe that the 25% decline in Formycon's share price since late February when covid-19 began to affect financial markets greatly overstates the impact of the virus on the company's prospects. In fact one could argue that recent news that Lucentis' successor product Beovu has caused serious side effects among 14 patients means that newsflow over the past six weeks is on balance positive for Formycon's ophthalmology franchise (FYB201 and FYB203). The company's general position remains excellent with three late stage products whose remaining development is fully funded by strong and stable partnerships. The balance sheet has a cash position of ca. €25m and no debt. Cash burn and funding requirements relate only to the early stage pipeline which consists of further biosimilar candidates for blockbuster reference products. We maintain our Buy recommendation and price target of €39.00.

**Covid-19 will presumably also affect Samsung Bioepis BLA submission** In February Formycon's licensing partner Bioeq announced that it would need to resubmit the BLA (biologics license application) for the Lucentis biosimilar FYB201, which was originally submitted in December 2019. The requirement to resubmit the BLA followed 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 our February note we pencilled in the BLA resubmission for Q3/20, but we gather from talking to management that while the target is still Q3/20, resubmission may slip into Q4/20. However, covid-19 presumably also affects Samsung Bioepis whose Lucentis biosimilar candidate SB11 is FYB201's main competitor. Samsung Bioepis have also still to submit a BLA for SB11 and so we see no negative impact of covid-19 on FYB201's competitive position.

**Beovu side effects are positive for Formycon's ophthalmology franchise** 14 patients using Novartis' recently (October 2019) FDA-approved Beovu for wet age-related macular degeneration have suffered severe inflammation of the blood vessels in their eyes. (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.

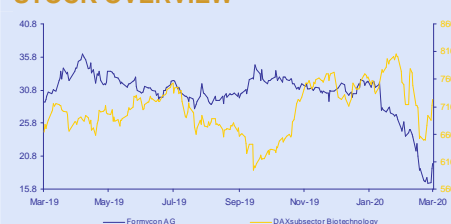
### MARKET DATA

As of 25 Mar 2020

Closing Price	€ 19.75
Shares outstanding	10.00m
Market Capitalisation	€ 197.50m
52-week Range	€ 16.65 / 36.30
Avg. Volume (12 Months)	7,975

Multiples	2018	2019E	2020E
P/E	22.0	n.a.	n.a.
EV/Sales	3.4	4.2	3.8
EV/EBIT	20.5	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%



**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	05/2024
EU	7/2022	7/2024	5/2025

Source: Companies

Novartis had positioned Beovu as the successor to Lucentis and the new drug's safety issues enhance the prospects of both the Lucentis biosimilar candidate FYB201 and the Eylea biosimilar candidate FYB203, which constitute Formycon's ophthalmology franchise.

**Patents likely to be decisive issue in competition between FYB203 and M710** Covid-19 may also hinder the start of recruitment for the FYB203 phase III trial, which is scheduled for mid-/Q3 2020. The most advanced competing Eylea biosimilar candidate is M710 which is being co-developed by Momenta Pharmaceuticals (headquartered in Cambridge, Massachusetts) and Mylan N.V. (headquartered in Pittsburgh, Pennsylvania). Recruitment to the M710 phase III trial started in August 2018. Primary completion (i.e. completion of recruitment) was planned for the end of February this year but Momenta/Mylan have not yet indicated whether recruitment has actually been completed. Final results are expected in December. Formycon's FYB201 phase trial lasted 28 months (February 2016 - June 2018) while the Momenta/Mylan phase III trial of M710 is also expected to take 28 months (August 2018 to December 2020). The FYB203 phase III trial is likely to enrol fewer participants than the FYB201 phase III trial. Based on fewer participants and experience gained in the course of the FYB201 trial, Formycon's management believe that the FYB203 phase III trial can be completed in under two years. Eylea's US patent expires in May 2024. If we assume six months to one year for submission of the FYB203 BLA, and a further year until FDA approval, FYB203 could reach the US market in time for Eylea's patent expiry. However, this schedule is admittedly tight. Using the same basis of calculation, FDA approval of M710 could be forthcoming some months ahead of Eylea's US patent expiry. But Momenta/Mylan have not yet explained how M710 will circumvent Eylea's formulation patent which runs until 2027. Formycon filed a patent application for an alternative liquid formulation VEGF (vascular endothelial growth factor) antagonist in June 2017. News as to whether this patent has been granted is likely in the near term. In our view the patent issue has a greater bearing on FYB203's competitive position versus M710 than any delay in recruitment to the FYB203 trial.

**Despite covid-19-related phase I trial delay, we expect FYB202 to reach major markets ahead of NeuLara** Dosing of participants in the phase I trial of the Stelara biosimilar candidate, FYB202, began last October. Covid-19 may also slow completion of recruitment for this trial. The most advanced competing Stelara biosimilar candidate is NeuLara, which is under development at the Australian company, NeuClone. The NeuLara phase I trial began in mid-October and recruitment was completed in December. However, we do not believe this will necessarily give NeuLara an advantage over FYB202. The NeuLara phase I trial is taking place under the Clinical Trial Notification (CTN) scheme of the Australian Therapeutic Goods Administration (TGA). Meanwhile, Formycon and its partners have held scientific advice meetings with the FDA and the EMA at which development steps up to submission of the marketing authorisation dossier were discussed. Given the greater depth of consultation between Formycon, its partners and the regulatory authorities in the US and Europe, we still expect FYB202 to reach major markets ahead of NeuLara.

**Buy recommendation maintained at €39.00 price target** We have made only minor changes to our valuation model and continue to see fair value for the Formycon share at €39.00. 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)	€116M	327K	€5,250	€1,716M	17%	€335M	9%	13%	n.a.	3 Years
FYB201	nAMD,DR (US)	€113M	144K	€9,068	€1,305M	17%	€342M	9%	3%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€49M	56K	€27,500	€1,532M	17%	€460M	9%	16%	n.a.	5 Years
FYB202	Pso,CrD (US)	€113M	47K	€44,750	€2,115M	17%	€1,071M	9%	16%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€54M	417K	€4,859	€2,024M	17%	€576M	9%	16%	n.a.	6 Years
FYB203	nAMD,DR (US)	€79M	392K	€8,591	€3,365M	17%	€765M	9%	16%	n.a.	5 Years
FYB205	n.a.	€85M									
PACME PV		€610M									
Costs PV <sup>4)</sup>		€284M									
NPV		€326M									
Downpayments and Milestones		€39M									
Proforma net Cash		€25M									
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	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	225.95
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...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	Today	€19.75	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.

#### RISK ASSESSMENT

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

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**SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Lurgiallee 12, 60439 Frankfurt**

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