

# Formycon AG

Germany / Biopharmaceuticals  
 Xetra  
 Bloomberg: FYB GR  
 ISIN: DE000A1EWWY8

FYB201 achieves  
 primary endpoint of  
 phase III trial

**RATING**  
**PRICE TARGET**

Return Potential  
 Risk Rating

**BUY**  
**€ 52.00**  
 37.2%  
 High

## SUCCESS OF FYB201 PHASE III TRIAL IS A MAJOR MILESTONE

FYB201 has achieved the primary endpoint of its phase III trial, thereby keeping Formycon on track to reach its target that its biosimilar products will be the first to market following the expiry of the patents on their reference products from 2020 onwards. We have raised our price target from €48.00 to €52.00 to reflect the reduction in risk entailed by this news. We maintain our Buy recommendation.

**Success of FYB201 phase III trial** Formycon has announced that based on interim results FYB201 has achieved the primary endpoint of its phase III trial. The primary endpoint of the trial is confirmation of comparable efficacy between FYB201 and the reference product, Lucentis, in the indication neovascular age-related macular degeneration. FYB201 is the furthest advanced of the biosimilar candidates Formycon is currently developing. Bioeq GmbH began recruitment of patients for a global phase III trial with the compound in February 2016. The last patient in the trial, in which patients are treated for a total of 48 weeks, is expected to complete treatment later in the current quarter. We expect the release of final results from the trial during Q3 of this year and the submission of a Biologics License Application (BLA) to the FDA in either Q4 2018 or Q1 2019. Patent expiry for Lucentis is June 2020 in the US and January 2022 in the EU. Formycon's management expects that the company's biosimilar products will be the first to market following the expiry of the patents on their reference products from 2020 onwards. The news that FYB201 has achieved the primary endpoint of its phase III trial keeps Formycon on track to achieve this goal.

**Combined Lucentis/Eylea sales up 9.3% in 2017** Formycon is focused on the "third wave" of biosimilars, i.e. on biosimilars whose reference products go off patent after 2020. Besides FYB201, the company currently has three other biosimilars under development as shown in figure 1 overleaf. The reference product for FYB203 is Eylea. (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017E	2018E	2019E
Revenue (€m)	12.67	17.15	19.66	28.20	29.30	24.20
Y-o-y growth	29.7%	35.4%	14.6%	43.4%	3.9%	-17.4%
EBIT (€m)	0.87	0.54	-4.07	0.11	0.15	-4.67
EBIT margin	6.9%	3.1%	-20.7%	0.4%	0.5%	-19.3%
Net income (€m)	0.86	0.58	-4.07	0.29	0.36	-4.50
EPS (diluted) (€)	0.10	0.06	-0.45	0.03	0.04	-0.48
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.63	-0.24	-6.40	1.87	-1.01	-5.82
Net gearing	-70.4%	-81.6%	-66.9%	-81.2%	-76.5%	-65.1%
Liquid assets (€m)	9.22	20.30	13.97	21.34	20.34	14.51

### 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 specializing in the development of biosimilars, e.g. generic versions of biotechnology products.

### MARKET DATA

As of 02 May 2018

Closing Price	€ 37.90
Shares outstanding	9.34m
Market Capitalisation	€ 354.13m
52-week Range	€ 28.30 / 39.32
Avg. Volume (12 Months)	11,823

Multiples	2016	2017E	2018E
P/E	n.m.	n.m.	n.m.
EV/Sales	17.3	12.0	11.6
EV/EBIT	n.m.	n.m.	n.m.
Div. Yield	0.0%	0.0%	0.0%

### STOCK OVERVIEW



### COMPANY DATA

As of 30 Jun 2017

Liquid Assets	€ 14.42m
Current Assets	€ 16.84m
Intangible Assets	€ 0.89m
Total Assets	€ 21.25m
Current Liabilities	€ 1.60m
Shareholders' Equity	€ 17.98m

### SHAREHOLDERS

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


**Figure 1: Formycon's current product pipeline**

PRODUCT CANDIDATE	ORIGINATOR (INN)	DISEASE AREA	PARTNER	PRECLINICAL PHASE	CLINICAL PHASE	
					PHASE I	PHASE III
FYB201	Lucentis® (ranibizumab)	Ophthalmology	Bioeq IP AG			
FYB202	Stelara® (ustekinumab)	Immunology	Aristo Pharma GmbH			
FYB203	Eylea® (aflibercept)	Ophthalmology	Santo Holding GmbH			
FYB205	Undisclosed	Undisclosed	not partnered			

Source: Formycon

Like Lucentis, Eylea is an intraocular anti-VEGF (vascular endothelial growth factor) drug indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. Combined sales of Lucentis and Eylea climbed 9.3% during 2017 to USD9.3bn (2016: USD8.5bn). This figure corresponds to ca. 90% of the value of the intraocular anti-VEGF market.

**Stelara sales up 17.5% in 2017** The reference product for FYB202 is Stelara. Stelara is a human interleukin-12 and -23 antagonist indicated for psoriasis, psoriatic arthritis and Crohn's disease. Stelara's worldwide sales rose 17.5% to USD4.0bn in 2017 (2016: USD3.4bn). Stelara's growth during 2017 was in part attributable to FDA approval of the drug for Crohn's Disease in H2/16. Stelara's sales growth should receive further impetus from its expected launch for ulcerative colitis in 2018/19.

**We expect clinical development of FYB202 and FYB203 from 2019** Patent expiry for Eylea is June 2023 in the US and May 2025 in the EU. For Stelara patent protection expires in September 2023 in the US and in July 2024 in the EU. FYB202 and FYB203 are currently at the preclinical stage. We expect clinical development of these products to begin in 2019. Formycon has not yet revealed FYB205's reference product.

**Low double digit royalties on FYB201 and FYB203** Formycon concluded partnerships for FYB201 and FYB203 in 2013 and 2015 respectively. The partnership agreements for FYB201 and FYB203 entail a mid-single digit upfront payment to Formycon and funding of all development, production and marketing costs of the Formycon biosimilar by the partner. Formycon's expected sales participation (royalties) is in the double digit percentage range (depending on certain marketing and manufacturing milestones). The cumulative royalty income to Formycon from these partnerships is expected to exceed €100m for each product.

**Under FYB202 JV deal Formycon receives up to 24.9% of revenues** In December 2017 Formycon founded a joint venture for the development of FYB202 with Aristo Pharma GmbH, a subsidiary of Santo Holding GmbH. The structure of the FYB202 deal differs from those concluded for FYB201 and FYB203. Under the FYB202 deal Formycon will bear 24.9% of development costs but will also participate in up to 24.9% of worldwide marketing revenues.

**Maintaining Buy recommendation with price target of €52.00 (previously: €48.00)** Our pipeline valuation model is adjusted to reflect the reduction in risk entailed by the news that FYB201 has achieved the primary endpoint of its phase III trial. We also now use a USD:EUR FX rate of 1.20 (previously: 1.10). We now see fair value for the Formycon share at €52.00 (previously: €48.00). 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)	€131M	270K	€4,813	€1,299M	17%	€357M	12%	12%	n.a.	4 Years
FYB201	nAMD,DR (US)	€158M	113K	€8,313	€939M	17%	€354M	12%	12%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€53M	40K	€25,208	€1,008M	17%	€343M	2%	15%	n.a.	6 Years
FYB202	Pso,CrD (US)	€108M	57K	€41,021	€2,338M	17%	€774M	12%	15%	n.a.	5 Years
FYB203	nAMD,DR (ex-US)	€55M	197K	€4,454	€877M	17%	€241M	12%	15%	n.a.	7 Years
FYB203	nAMD,DR (US)	€153M	212K	€7,875	€1,670M	17%	€630M	12%	15%	n.a.	5 Years
FYB205	n.a.	€89M									
<b>PACME PV</b>		<b>€747M</b>									
<b>Costs PV<sup>4)</sup></b>		<b>€312M</b>									
<b>NPV</b>		<b>€435M</b>									
Downpayments and Milestones		€30M									
Net Cash		€21M									
Fair Value		€486M									
Share Count		9,344K									
<b>Fair Value Per Share</b>		<b>€52.04</b>									

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

Figure 3: Changes to our pipeline valuation model

	Old	New	Delta
<b>PACME PV</b>	<b>€673.0M</b>	<b>€747.2M</b>	<b>11.0%</b>
<b>Costs PV</b>	<b>€271.0M</b>	<b>€312.3M</b>	<b>15.2%</b>
<b>NPV</b>	<b>€402.0M</b>	<b>€434.9M</b>	<b>8.2%</b>
<b>Downpayments and Milestones PV</b>	<b>€29.0M</b>	<b>€30.0M</b>	<b>3.6%</b>
<b>Net Cash</b>	<b>€20.0M</b>	<b>€21.3M</b>	<b>6.7%</b>
<b>Fair Value</b>	<b>€450.0M</b>	<b>€486.3M</b>	<b>8.1%</b>
<b>Share Count</b>	<b>9,344K</b>	<b>9,344K</b>	<b>0.0%</b>
<b>Price Target</b>	<b>€48.16</b>	<b>€52.04</b>	<b>8.1%</b>

Source: First Berlin Equity Research



## INCOME STATEMENT

All figures in EURm	2015A	2016A	2017E	2018E	2019E
<b>Revenue</b>	<b>17.2</b>	<b>19.7</b>	<b>28.2</b>	<b>29.3</b>	<b>24.2</b>
Increase/decrease in unfinished products	0.0	0.0	0.0	0.0	0.0
<b>Total output</b>	<b>17.2</b>	<b>19.7</b>	<b>28.2</b>	<b>29.3</b>	<b>24.2</b>
Cost of goods sold	-11.1	-17.9	-21.9	-22.1	-22.4
<b>Gross profit</b>	<b>6.1</b>	<b>1.7</b>	<b>6.3</b>	<b>7.2</b>	<b>1.8</b>
Personnel costs	-3.2	-3.4	-3.5	-4.0	-3.0
Depreciation and amortisation	-0.9	-0.7	-0.8	-1.0	-1.4
Other operating income	0.1	0.1	0.1	0.1	0.1
Other operating expenses	-1.5	-1.8	-2.0	-2.2	-2.2
<b>Operating income (EBIT)</b>	<b>0.5</b>	<b>-4.1</b>	<b>0.1</b>	<b>0.1</b>	<b>-4.7</b>
Net financial result	0.0	0.0	0.2	0.2	0.2
<b>Pre-tax income (EBT)</b>	<b>0.6</b>	<b>-4.1</b>	<b>0.3</b>	<b>0.4</b>	<b>-4.5</b>
Income taxes	0.0	0.0	0.0	0.0	0.0
<b>Net income / loss</b>	<b>0.6</b>	<b>-4.1</b>	<b>0.3</b>	<b>0.4</b>	<b>-4.5</b>
<b>Diluted EPS (in €)</b>	<b>0.06</b>	<b>-0.45</b>	<b>0.03</b>	<b>0.04</b>	<b>-0.48</b>
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>0.9</b>	<b>1.1</b>	<b>-3.3</b>
<b>Ratios</b>					
Gross margin on output	35.4%	8.8%	22.3%	24.6%	7.4%
EBIT margin on output	3.1%	-20.7%	0.4%	0.5%	-19.3%
EBITDA margin on output	8.6%	-17.2%	3.2%	3.8%	-13.6%
Net margin on output	3.4%	-20.7%	1.0%	1.2%	-18.6%
Tax rate	-0.2%	0.1%	0.0%	0.0%	0.0%
<b>Expenses as % of output</b>					
Cost of goods sold	-64.6%	-91.2%	-77.7%	-75.4%	-92.6%
Personnel costs	-18.7%	-17.3%	-12.4%	-13.7%	-12.4%
Depreciation and amortisation	-5.4%	-3.6%	-2.8%	-3.2%	-5.7%
Net other operating exp.	-8.2%	-8.6%	-6.7%	-7.2%	-8.7%
<b>Y-Y Growth</b>					
Revenues	35.4%	14.6%	43.4%	3.9%	-17.4%
Operating income	-38.1%	n.m.	n.m.	35.9%	n.m.
Net income/ loss	-32.9%	n.m.	n.m.	24.9%	n.m.



## BALANCE SHEET

All figures in EURm	2015A	2016A	2017E	2018E	2019E
<b>Assets</b>					
<b>Current assets, total</b>	<b>23.3</b>	<b>20.7</b>	<b>27.0</b>	<b>28.1</b>	<b>20.9</b>
Cash and cash equivalents	0.6	3.0	1.4	1.5	1.2
Other liquid assets	19.7	11.0	19.9	18.9	13.3
Receivables	2.8	5.2	4.2	5.9	4.8
Inventories	0.2	0.6	0.6	0.7	0.6
Other current assets	0.0	0.9	0.8	1.2	1.0
<b>Non-current assets, total</b>	<b>3.8</b>	<b>4.5</b>	<b>3.5</b>	<b>4.4</b>	<b>6.2</b>
Shares in affiliated companies	0.0	0.0	0.0	0.0	0.0
Loans to affiliated companies	0.0	0.0	0.0	0.0	0.0
Property, plant & equipment	2.6	3.4	2.5	3.5	5.6
Goodwill & other intangibles	1.1	1.0	0.8	0.7	0.5
Other assets	0.1	0.1	0.2	0.2	0.1
<b>Total assets</b>	<b>27.1</b>	<b>25.2</b>	<b>30.5</b>	<b>32.5</b>	<b>27.1</b>
<b>Shareholders' equity &amp; debt</b>					
<b>Current liabilities, total</b>	<b>1.6</b>	<b>3.6</b>	<b>3.1</b>	<b>4.1</b>	<b>3.4</b>
Accounts payable	0.6	2.3	2.0	2.6	2.2
Other current liabilities	1.0	1.3	1.1	1.5	1.2
<b>Long-term liabilities, total</b>	<b>0.7</b>	<b>0.7</b>	<b>1.1</b>	<b>1.8</b>	<b>1.5</b>
Provisions	0.7	0.7	1.1	1.2	1.0
Other liabilities	0.0	0.0	0.0	0.6	0.5
<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>Shareholders' equity</b>	<b>24.9</b>	<b>20.9</b>	<b>26.3</b>	<b>26.6</b>	<b>22.3</b>
<b>Total consolidated equity and debt</b>	<b>27.1</b>	<b>25.2</b>	<b>30.5</b>	<b>32.5</b>	<b>27.1</b>
<b>Key figures</b>					
Current ratio (x)	14.52	5.79	8.70	6.85	6.18
Quick ratio (x)	14.38	5.61	8.52	6.67	6.00
Financial leverage (%)	-81.6	-66.9	-81.2	-76.5	-65.1
Book value per share (€)	2.74	2.30	2.86	2.89	2.42
Return on equity (ROE)	3.0%	-17.8%	1.2%	1.4%	-18.4%



## CASH FLOW STATEMENT

All figures in EURm	2015A	2016A	2017E	2018E	2019E
<b>EBIT</b>	<b>0.5</b>	<b>-4.1</b>	<b>0.1</b>	<b>0.1</b>	<b>-4.7</b>
Depreciation and amortisation	0.9	0.7	0.8	1.0	1.4
<b>EBITDA</b>	<b>1.5</b>	<b>-3.4</b>	<b>0.9</b>	<b>1.1</b>	<b>-3.3</b>
Changes in working capital	-1.1	-1.7	0.5	-0.5	0.6
Other adjustments	0.1	0.1	0.2	0.2	0.2
<b>Operating cash flow</b>	<b>0.5</b>	<b>-5.0</b>	<b>1.6</b>	<b>0.8</b>	<b>-2.6</b>
CAPEX	-0.6	-1.4	0.3	-1.8	-3.3
<b>Free cash flow</b>	<b>-0.1</b>	<b>-6.4</b>	<b>1.9</b>	<b>-1.0</b>	<b>-5.8</b>
<b>Debt financing, net</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Equity financing, net</b>	<b>11.2</b>	<b>0.1</b>	<b>5.5</b>	<b>0.0</b>	<b>0.0</b>
Other changes in cash	0.0	0.0	0.0	0.0	0.0
<b>Net cash flows</b>	<b>11.1</b>	<b>-6.3</b>	<b>7.4</b>	<b>-1.0</b>	<b>-5.8</b>
Cash and liquid assets, start of the year	9.2	20.3	14.0	21.3	20.3
<b>Cash and liquid assets, end of the year</b>	<b>20.3</b>	<b>14.0</b>	<b>21.3</b>	<b>20.3</b>	<b>14.5</b>
<b>EBITDA/share (in €)</b>	<b>0.2</b>	<b>-0.4</b>	<b>0.1</b>	<b>0.1</b>	<b>-0.4</b>
<b>Y-Y Growth</b>					
Operating cash flow	n.m.	n.m.	n.m.	-53.0%	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	-26.8%	n.m.	n.m.	20.3%	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...19	↓	↓	↓	↓
20	4 May 2017	€28.30	Buy	€45.00
21	29 August 2017	€33.43	Buy	€48.00
22	2 October 2017	€34.80	Buy	€48.00
23	Today	€37.90	Buy	€52.00

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**INFORMATION PURSUANT TO SECTION 34B OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO THE GERMAN ORDINANCE ON THE ANALYSIS OF FINANCIAL INSTRUMENTS [FINANV]**

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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In accordance with Section 34b Paragraph 1 of the German Securities Trading Act [WpHG] and Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) financial analyses may only be passed on or publicly distributed if circumstances or relations which may cause conflicts of interest among the authors, the legal entities responsible for such preparation or companies associated with them are disclosed along with the financial analysis.

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First Berlin notes that it has concluded a contract with the issuer to prepare financial analyses and is paid for that by the issuer. First Berlin makes the financial analysis simultaneously available for all interested security financial services companies. First Berlin thus believes that it fulfils the requirements of section 64 WpHG for minor non-monetary benefits.

### 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:

**STRONG BUY:** An expected favourable price trend of more than 50% combined with sizeable confidence in the quality and forecast security of management.

**BUY:** An expected favourable price trend of more than 25% percent.

**ADD:** An expected favourable price trend of between 0% and 25%.

**REDUCE:** An expected negative price trend of between 0% and -15%.

**SELL:** An expected negative price trend of more than -15%.

#### 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.

### INVESTMENT HORIZON

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

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