

# Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Q2 results

**RATING****PRICE TARGET**

Return Potential

Risk Rating

**BUY****€45.00**

145.9%

High

## PLANNING TO BE 1<sup>ST</sup> TO MARKET AFTER REFERENCE PRODUCT PATENT EXPIRY

Q2/16 revenues and net profit were below the figures booked in Q1/16 and Q2/15 due to a dip in partner-financed development spending on FYB201 and FYB203. However, expenditure on both these projects is due to pick up in the second half of this year and management has maintained its guidance for full year revenues of “over €20m”. Meanwhile, the product portfolio, which now encompasses four biosimilar product candidates, continues to develop according to plan. Formycon plans that its biosimilar products will be the first to market following the expiry of the patents on their reference products. We have adjusted our valuation model to take account of the addition of FYB205 to the pipeline. In addition, news that Pfizer has returned the rights to Pfenex’ Lucentis biosimilar, PF582, suggests to us that Formycon’s lead over a significant competitor is widening. We now see fair value for the Formycon share at **€45.00** (previously: **€42.00**). We maintain our Buy recommendation.

**Spending on FYB201, FYB203 to pick up in H2; FY guidance maintained**  
 Formycon’s Q2/16 report showed a 63.4% decline in total revenues to €2.5m (Q2/15: €6.9m) while the net result came in at €-1.0m (Q2/15: €2.1m). Q2/16 sales and net profit were also below figures of €6.3m and €-0.2m respectively booked in the first quarter of this year. The reason for the decline in sales and profit figures in Q2/16 compared with Q2/15 and Q1/16 is that Formycon spent less on development of its outlicensed projects, FYB201 and FYB203, in Q2/16 than in the prior quarters and more on development of FYB202 and FYB205 which have not yet been partnered. Development of FYB201 and FYB203 is financed by Formycon’s licensing partners, respectively Bioeq IP AG and Santo, and appears on Formycon’s P&L as sales revenue. Formycon carries the cost of development of FYB202 and FYB205.

**FYB201 phase III trial had no P&L impact** FYB201 is the furthest advanced of the biosimilar candidates Formycon is currently developing. In October (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	0.41	12.67	17.15	19.00	36.60	31.50
Y-o-y growth	n.a.	2970.3%	35.4%	10.8%	92.6%	-13.9%
EBIT (€m)	-7.74	0.87	0.54	-2.28	3.22	-1.31
EBIT margin	-1876.5%	6.9%	3.1%	-12.0%	8.8%	-4.2%
Net income (€m)	-7.74	0.86	0.58	-2.09	3.41	-1.11
EPS (diluted) (€)	-0.90	0.10	0.06	-0.23	0.38	-0.12
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	0.00	-0.63	-0.24	-2.20	1.71	-0.39
Net gearing	-74.5%	-70.4%	-81.6%	-79.8%	-78.0%	-79.3%
Liquid assets (€m)	10.38	9.22	20.30	18.10	19.81	19.42

### 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 20 Sep 2016

Closing Price	€ 18.30
Shares outstanding	9.06m
Market Capitalisation	€ 165.85m
52-week Range	€ 14.76 / 24.86
Avg. Volume (12 Months)	11,129

Multiples	2015	2016E	2017E
P/E	283.1	n.a.	48.6
EV/Sales	8.6	7.8	4.0
EV/EBIT	275.4	n.a.	45.9
Div. Yield	0.0%	0.0%	0.0%

### STOCK OVERVIEW



### COMPANY DATA

As of 30 Jun 2016

Liquid Assets	€ 17.79m
Current Assets	€ 21.54m
Intangible Assets	€ 1.10m
Total Assets	€ 25.43m
Current Liabilities	€ 0.49m
Shareholders' Equity	€ 23.70m

### SHAREHOLDERS

Founders	23.5%
Institutional Investors	50.0%
Free Float	26.5%



2015 Formycon announced that the compound's reference product is Lucentis (Ranibizumab). Lucentis is indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. Worldwide sales were USD3.7bn in 2015. bioeq GmbH began recruitment of patients for a global phase III trial with FYB201 in February 2016. As bioeq GmbH is the sponsor of the trial, it had no impact on Formycon's P&L during the first half of 2016.

**Figure 1: Q2/16 results vs. our forecasts**

in EURm	Q2/16A	Q2/16E	Delta	Q2/15A	Delta
Sales	2.51	4.50	-44.2%	6.86	-63.4%
Net income	-0.99	-0.15	n.m.	2.10	n.m.
margin	-39.4%	-3.3%	-	30.6%	-

Source: Formycon; First Berlin Equity Research estimates

**Planning to be first to market after reference product patent expiry** We expect completion of recruitment for the phase III trial next year and filing of an NDA (new drug application) for FYB201 in the US towards the end of 2018. The patent on Lucentis expires in June 2020 in the US and in January 2022 in the EU. Formycon plans that FYB201 (as well as its other biosimilar product candidates) will be the first biosimilar products on the market following the expiry of the patents on their reference products.

**Formycon developing biosimilars for 90% of intraocular anti-VEGF market by value**

FYB202, FYB203 and FYB205 are currently in preclinical development. Formycon has not yet made public the reference products for FYB202 and FYB205, but in March 2016 revealed that the reference product for FYB203 is Eylea (Aflibercept). Like Lucentis, Eylea is an intraocular anti-VEGF (vascular endothelial growth factor) drug. VEGFs promote the growth of blood vessels. When injected directly into the vitreous humour of the eye, anti-VEGF drugs such as Lucentis and Eylea work by causing regression of the abnormal blood vessels thereby reducing both leakage of exudate and hemorrhaging as well as improving vision. Eylea is also indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. It is the main competitor to Lucentis and in 2015 generated worldwide sales of USD4.1bn. Patent expiry dates for Eylea are June 2023 in the US and May 2025 in the EU. In FYB201 and FYB203, Formycon thus has biosimilars under development corresponding to ca. 90% of the value of the intraocular anti-VEGF (vascular endothelial growth factor) market. Formycon first announced the development of FYB202 in Q2 2014 and of FYB205 in May 2016.

**Revenues to pick up in H2 as development work on FYB201 and FYB203 gathers pace**

Management has indicated in the Q2 report that development work on FYB201 and FYB203 will gather pace again in the second half of 2016 and that revenues will accordingly pick up. The company has retained its full 2016 sales guidance of "over €20m" on the basis of increasing revenues from these partnered projects. We are leaving our full year sales forecast unchanged at €19m, but have adjusted our net profit forecast down to €-2.1m from €-0.6m as we do not expect the profit which Formycon generates on development work on FYB201 and FYB203 to outweigh the ongoing costs of the development of FYB202 and FYB205.

**We maintain our Buy recommendation and raise our price target to €45.00 (previously: €42.00)**

We have adjusted our valuation model to take account of the addition of FYB205 to the product pipeline. FYB205 is currently unpartnered and so will add to Formycon's net costs over the next few years. In addition, news that Pfizer has returned the rights to Pfenex' Lucentis biosimilar, PF582, suggests to us that Formycon's lead over Pfenex will widen. On this basis, we now raise our expectation for FYB201's share of post-patent expiry Lucentis revenues from 15% to 20%. We now see fair value for the Formycon share at €45.00 (previously: €42.00). We maintain our Buy recommendation.



Figure 2: Changes to our forecasts

in €m	2016E			2017E			2018E		
	Old	New	Delta	Old	New	Delta	Old	New	Delta
Revenues*	19.00	19.00	0.0%	36.60	36.60	0.0%	31.50	31.50	0.0%
EBITDA	-0.30	-1.30	-	6.20	4.20	-32.3%	1.70	-0.30	-
margin	neg.	neg.	-	neg.	11.5%	-	5.4%	-1.0%	-
Net income	-0.60	-2.09	-	5.60	3.41	-39.0%	1.20	-1.11	-
margin	neg.	neg.	-	neg.	9.3%	-	neg.	-3.5%	-
EPS (diluted, in €)	-0.07	-0.23	-	0.62	0.38	-39.2%	0.13	-0.12	-

\* including other operating income such as upfront and milestone payments

Source: First Berlin Equity Research

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)	€66M	270K	€5,250	€1,418M	17%	€403M	2%	15%	n.a.	6 Years
FYB201	nAMD,DR (US)	€84M	113K	€9,068	€1,025M	17%	€409M	12%	5%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€62M	197K	€4,859	€957M	17%	€272M	12%	15%	n.a.	9 Years
FYB203	nAMD,DR (US)	€187M	212K	€8,591	€1,821M	17%	€728M	12%	15%	n.a.	7 Years
FYB202 & FYB205	n.a.	€224M									
PACME PV		€624M									
Costs PV <sup>4)</sup>		€243M									
NPV		€382M									
Milestones		€4M									
Net Cash		€18M									
Fair Value		€404M									
Share Count		9,060K									
Fair Value Per Share		€44.55									

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 4: Changes to our pipeline valuation model

	Old	New	Delta
NPV	€362.7M	€381.9M	5.3%
Milestones PV	€0.0M	€4.0M	n.m.
Net Cash	€20.0M	€17.8M	-11.1%
Fair Value	€382.7M	€403.7M	5.5%
Share Count	9,060K	9,060K	0.0%
Price Target	€42.25	€44.55	5.5%

Source: First Berlin Equity Research



## INCOME STATEMENT

All figures in EURm	2014A	2015A	2016E	2017E	2018E
<b>Revenue</b>	<b>12.7</b>	<b>17.2</b>	<b>19.0</b>	<b>36.6</b>	<b>31.5</b>
Increase/decrease in unfinished products	0.0	0.0	0.0	0.0	0.0
<b>Total output</b>	<b>12.7</b>	<b>17.2</b>	<b>19.0</b>	<b>36.6</b>	<b>31.5</b>
Cost of goods sold	-5.9	-11.1	-15.2	-27.0	-25.7
<b>Gross profit</b>	<b>6.8</b>	<b>6.1</b>	<b>3.8</b>	<b>9.6</b>	<b>5.8</b>
Personnel costs	-2.9	-3.2	-3.4	-3.5	-4.0
Depreciation and amortisation	-1.1	-0.9	-1.0	-1.0	-1.0
Other operating income	0.0	0.1	0.1	0.1	0.1
Other operating expenses	-1.9	-1.5	-1.8	-2.0	-2.2
<b>Operating income (EBIT)</b>	<b>0.9</b>	<b>0.5</b>	<b>-2.3</b>	<b>3.2</b>	<b>-1.3</b>
Net financial result	0.0	0.0	0.2	0.2	0.2
<b>Pre-tax income (EBT)</b>	<b>0.9</b>	<b>0.6</b>	<b>-2.1</b>	<b>3.4</b>	<b>-1.1</b>
Income taxes	0.0	0.0	0.0	0.0	0.0
<b>Net income / loss</b>	<b>0.9</b>	<b>0.6</b>	<b>-2.1</b>	<b>3.4</b>	<b>-1.1</b>
<b>Diluted EPS (in €)</b>	<b>0.10</b>	<b>0.06</b>	<b>-0.23</b>	<b>0.38</b>	<b>-0.12</b>
<b>EBITDA</b>	<b>1.9</b>	<b>1.5</b>	<b>-1.3</b>	<b>4.2</b>	<b>-0.3</b>
<b>Ratios</b>					
Gross margin on output	53.4%	35.4%	20.0%	26.2%	18.4%
EBIT margin on output	6.9%	3.1%	-12.0%	8.8%	-4.2%
EBITDA margin on output	15.3%	8.6%	-6.8%	11.5%	-1.0%
Net margin on output	6.8%	3.4%	-11.0%	9.3%	-3.5%
Tax rate	-0.2%	-0.2%	0.0%	0.0%	0.0%
<b>Expenses as % of output</b>					
Cost of goods sold	-46.6%	-64.6%	-80.0%	-73.8%	-81.6%
Personnel costs	-22.8%	-18.7%	-17.9%	-9.6%	-12.7%
Depreciation and amortisation	-8.5%	-5.4%	-5.1%	-2.7%	-3.2%
Net other operating exp.	-15.2%	-8.2%	-8.9%	-5.2%	-6.7%
<b>Y-Y Growth</b>					
Revenues	2970.3%	35.4%	10.8%	92.6%	-13.9%
Operating income	n.m.	-38.1%	n.m.	n.m.	n.m.
Net income/ loss	n.m.	-32.9%	n.m.	n.m.	n.m.



## BALANCE SHEET

All figures in EURm	2014A	2015A	2016E	2017E	2018E
<b>Assets</b>					
<b>Current assets, total</b>	<b>12.8</b>	<b>23.3</b>	<b>21.4</b>	<b>26.3</b>	<b>25.0</b>
Cash and cash equivalents	0.3	0.6	1.0	1.8	1.6
Other liquid assets	8.9	19.7	17.1	18.0	17.8
Receivables	3.3	2.8	3.0	5.9	5.0
Inventories	0.3	0.2	0.3	0.5	0.5
Other current assets	0.0	0.0	0.0	0.0	0.0
<b>Non-current assets, total</b>	<b>4.1</b>	<b>3.8</b>	<b>3.9</b>	<b>4.3</b>	<b>4.6</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	2.7	2.6	2.9	3.3	3.8
Goodwill & other intangibles	1.3	1.1	0.9	0.7	0.6
Other assets	0.0	0.1	0.1	0.2	0.2
<b>Total assets</b>	<b>16.9</b>	<b>27.1</b>	<b>25.3</b>	<b>30.5</b>	<b>29.5</b>
<b>Shareholders' equity &amp; debt</b>					
<b>Current liabilities, total</b>	<b>3.3</b>	<b>1.6</b>	<b>1.9</b>	<b>3.6</b>	<b>3.1</b>
Accounts payable	2.3	0.6	0.7	1.4	1.2
Other current liabilities	1.0	1.0	1.2	2.3	1.9
<b>Long-term liabilities, total</b>	<b>0.5</b>	<b>0.7</b>	<b>0.8</b>	<b>1.5</b>	<b>1.9</b>
Provisions	0.5	0.7	0.8	1.5	1.3
Other liabilities	0.0	0.0	0.0	0.0	0.6
<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>13.1</b>	<b>24.9</b>	<b>22.7</b>	<b>25.4</b>	<b>24.5</b>
<b>Total consolidated equity and debt</b>	<b>16.9</b>	<b>27.1</b>	<b>25.3</b>	<b>30.5</b>	<b>29.5</b>
<b>Key figures</b>					
Current ratio (x)	3.94	14.52	11.35	7.22	7.97
Quick ratio (x)	3.83	14.38	11.20	7.07	7.82
Financial leverage (%)	-70.4	-81.6	-79.8	-78.0	-79.3
Book value per share (€)	1.52	2.74	2.50	2.80	2.70
Return on equity (ROE)	6.4%	3.0%	-8.8%	14.2%	-4.5%



## CASH FLOW STATEMENT

All figures in EURm	2014A	2015A*	2016E	2017E	2018E
<b>EBIT</b>	<b>0.9</b>	<b>0.5</b>	<b>-2.3</b>	<b>3.2</b>	<b>-1.3</b>
Depreciation and amortisation	1.1	0.9	1.0	1.0	1.0
<b>EBITDA</b>	<b>1.9</b>	<b>1.5</b>	<b>-1.3</b>	<b>4.2</b>	<b>-0.3</b>
Changes in working capital	-2.0	-1.1	-0.1	-1.4	1.1
Other adjustments	0.0	0.1	0.2	0.2	0.2
<b>Operating cash flow</b>	<b>0.0</b>	<b>0.5</b>	<b>-1.2</b>	<b>2.9</b>	<b>0.9</b>
CAPEX	-0.6	-0.6	-1.0	-1.2	-1.3
<b>Free cash flow</b>	<b>-0.6</b>	<b>-0.1</b>	<b>-2.2</b>	<b>1.7</b>	<b>-0.4</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>0.0</b>	<b>11.2</b>	<b>0.0</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>-0.6</b>	<b>11.1</b>	<b>-2.2</b>	<b>1.7</b>	<b>-0.4</b>
Cash and liquid assets, start of the year	0.9	9.2	20.3	18.1	19.8
<b>Cash and liquid assets, end of the year</b>	<b>0.3</b>	<b>20.3</b>	<b>18.1</b>	<b>19.8</b>	<b>19.4</b>
<b>EBITDA/share (in €)</b>	<b>0.2</b>	<b>0.2</b>	<b>-0.1</b>	<b>0.5</b>	<b>0.0</b>
<b>Y-Y Growth</b>					
Operating cash flow	n.a.	n.m.	n.m.	n.m.	-67.8%
Free cash flow	n.a.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.a.	-26.8%	n.m.	n.m.	n.m.

\* Compared to the prior year, the definition of cash and liquid resources was changed to also include holdings of short-term securities, thus limiting comparability to the prior year.

**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...14	↓	↓	↓	↓
15	18 January 2016	€19.86	Buy	€42.00
16	8 March 2016	€22.11	Buy	€42.00
17	21 April 2016	€21.36	Buy	€42.00
18	Today	€18.30	Buy	€45.00

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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:

**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.

#### UPDATES

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