

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

2016 results

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 45.00**

59.0%

High

PORTFOLIO DEVELOPMENT PROGRESSING RAPIDLY

Revenues jumped from €11.8m after nine months to €19.7m at the full year stage as partner-financed development work on FYB201 and FYB203 gathered pace. The 2016 revenue number was close to management guidance of €20m and our forecast of €19m. However, EBIT of €4.1m was below our forecast of €2.3m because of higher spending on development of the unpartnered FYB202 and FYB205 than we had modelled. Formycon's product portfolio continues to develop rapidly and 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. Success-based payments are expected to be in the triple digit millions of Euro over the lifetime of each of Formycon's biosimilars. We maintain our Buy recommendation and price target of €45.00.

Revenue growth driven by partner-financed development spending
 Formycon's 2016 results showed a 14.6% increase in total revenue to €19.7m (2015: €17.2m). The increase reflects higher partner-financed development spending. FYB201 has been licensed out to Bioeq IP AG since late 2013, but FYB203 was only licensed out to Santo Holding GmbH in Q2 2015. Both FYB201 and FYB203 were thus under partner-financed development for the whole of 2016, whereas in 2015 FYB203 was not outlicensed until late May. Stripping out the upfront payment (we estimate this at €5m) made by Santo to Formycon on conclusion of the FYB203 licensing deal in Q2 2015 shows that underlying partner-financed development spending rose by over 50%.

End 2017 liquid assets position of €14m EBIT came in at €4.1m (2015: €0.5m). The loss stems from higher development spending on the so far unpartnered biosimilar product candidates, FYB202 and FYB205. Formycon had liquid assets including securities of €14.0m at the end of 2016 (2015: €20.3m) Including short term receivables, this figure was €19.2m (2015: €23.1m). (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016	2017E	2018E
Revenue (€m)	0.41	12.67	17.15	19.66	36.60	31.50
Y-o-y growth	n.a.	2970.3%	35.4%	14.6%	86.1%	-13.9%
EBIT (€m)	-7.74	0.87	0.54	-4.07	3.22	-1.31
EBIT margin	-1876.5%	6.9%	3.1%	-20.7%	8.8%	-4.2%
Net income (€m)	-7.74	0.86	0.58	-4.07	3.38	-1.14
EPS (diluted) (€)	-0.90	0.10	0.06	-0.45	0.37	-0.13
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	0.00	-0.63	-0.24	-6.40	3.41	-1.45
Net gearing	-74.5%	-70.4%	-81.6%	-66.9%	-73.9%	-70.5%
Liquid assets (€m)	10.38	9.22	20.30	13.97	17.38	15.92

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 03 May 2017

Closing Price	€ 28.30
Shares outstanding	9.06m
Market Capitalisation	€ 256.48m
52-week Range	€ 17.48 / 29.20
Avg. Volume (12 Months)	10,878

Multiples	2016	2017E	2018E
P/E	n.a.	75.8	n.a.
EV/Sales	12.3	6.6	7.7
EV/EBIT	n.a.	75.2	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2016

Liquid Assets	€ 13.97m
Current Assets	€ 20.67m
Intangible Assets	€ 0.99m
Total Assets	€ 25.19m
Current Liabilities	€ 3.57m
Shareholders' Equity	€ 20.89m

SHAREHOLDERS

Founders	23.5%
Institutional Investors	50.0%
Free Float	26.5%


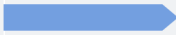

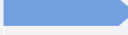
**Figure 1: 2016 results versus our forecasts**

in EURm	FY/16A	FY/16E	Delta	FY/15A	Delta
Total revenue	19.66	19.00	3.5%	17.15	14.6%
EBIT	-4.07	-2.28	n.m.	0.54	n.m.
margin	n.m.	n.m.	-	3.1%	-
Net income	-4.07	-2.09	n.m.	0.58	n.m.
margin	-20.7%	-11.0%	-	3.4%	-
EPS (€)	-0.45	-0.23	n.m.	0.06	n.m.

Source: Formycon; First Berlin Equity research estimates

Filing of FYB201 NDA scheduled towards end 2018 FYB201 is the furthest advanced of the biosimilar candidates Formycon is currently developing. In October 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 USD3.3bn in 2016 (2015: USD3.7bn). bioeq GmbH began recruitment of patients for a global phase III trial with FYB201 in February 2016. We expect completion of recruitment for the phase III trial later this year and filing of an NDA (new drug application) for FYB201 in the US towards the end of 2018. FYB202, FYB203 and FYB205 are currently in preclinical development. Figure 2 below shows Formycon's current product pipeline.

Figure 2: 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	Undisclosed	Undisclosed	not partnered			
FYB203	Eylea® (Aflibercept)	Ophthalmology	Santo Holding GmbH			
FYB205	Undisclosed	Undisclosed	not partnered			

Source: Formycon

Sales of FYB201 and FYB203 reference products rose 9.2% to USD8.5bn in 2016

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. It is the main competitor to Lucentis and in 2016 generated worldwide sales of USD5.2bn (2015: USD4.1bn). In 2016 combined sales of the reference products for FYB201 and FYB203 - Lucentis and Eylea - grew 9.2% to USD8.5bn (2015: USD7.7bn).

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

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. Eylea is also indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. In FYB201 and FYB203, Formycon has biosimilars under development corresponding to ca. 90% of the value of the intraocular anti-VEGF (vascular endothelial growth factor) market.



Planning to be first to market after reference product patent expiry The patent on Lucentis expires in June 2020 in the US and in January 2022 in the EU. Patent expiry dates for Eylea are June 2023 in the US and May 2025 in the EU. Formycon plans that FYB201 and FYB203 (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.

We maintain our Buy recommendation and price target of €45.00 Company guidance for 2017 is for revenue of €25m. However, this number only includes development work on FYB201 and FYB203. Management points out that 2017 revenue could be higher if a partnership deal is concluded for FYB202. Our 2017 revenue forecast of €36.6m assumes a deal for FYB202. Our 2018 revenue forecast is €5m lower than the 2017 figure because of the absence of the €5m upfront payment in connection with the FYB202 partnership deal we assume for 2017. We maintain our Buy recommendation and price target of €45.00.

Figure 3: Pipeline valuation model

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin ²⁾	Discount Factor	Patent Life ³⁾	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)	€87M	113K	€9,068	€1,025M	17%	€407M	12%	5%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€64M	197K	€4,859	€957M	17%	€271M	12%	15%	n.a.	9 Years
FYB203	nAMD,DR (US)	€193M	212K	€8,591	€1,821M	17%	€724M	12%	15%	n.a.	7 Years
FYB202 & FYB205	n.a.	€229M									
PACME PV		€639M									
Costs PV ⁴⁾		€249M									
NPV		€390M									
Milestones		€4M									
Net Cash		€14M									
Fair Value		€408M									
Share Count		9,060K									
Fair Value Per Share		€45.03									

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



INCOME STATEMENT

All figures in EURm	2014A	2015A	2016A	2017E	2018E
Revenue	12.7	17.2	19.7	36.6	31.5
Increase/decrease in unfinished products	0.0	0.0	0.0	0.0	0.0
Total output	12.7	17.2	19.7	36.6	31.5
Cost of goods sold	-5.9	-11.1	-17.9	-27.0	-25.7
Gross profit	6.8	6.1	1.7	9.6	5.8
Personnel costs	-2.9	-3.2	-3.4	-3.5	-4.0
Depreciation and amortisation	-1.1	-0.9	-0.7	-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
Operating income (EBIT)	0.9	0.5	-4.1	3.2	-1.3
Net financial result	0.0	0.0	0.0	0.2	0.2
Pre-tax income (EBT)	0.9	0.6	-4.1	3.4	-1.1
Income taxes	0.0	0.0	0.0	0.0	0.0
Net income / loss	0.9	0.6	-4.1	3.4	-1.1
Diluted EPS (in €)	0.10	0.06	-0.45	0.37	-0.13
EBITDA	1.9	1.5	-3.4	4.2	-0.3
Ratios					
Gross margin on output	53.4%	35.4%	8.8%	26.2%	18.4%
EBIT margin on output	6.9%	3.1%	-20.7%	8.8%	-4.2%
EBITDA margin on output	15.3%	8.6%	-17.2%	11.5%	-1.0%
Net margin on output	6.8%	3.4%	-20.7%	9.2%	-3.6%
Tax rate	-0.2%	-0.2%	0.1%	0.0%	0.0%
Expenses as % of output					
Cost of goods sold	-46.6%	-64.6%	-91.2%	-73.8%	-81.6%
Personnel costs	-22.8%	-18.7%	-17.3%	-9.6%	-12.7%
Depreciation and amortisation	-8.5%	-5.4%	-3.6%	-2.7%	-3.2%
Net other operating exp.	-15.2%	-8.2%	-8.6%	-5.2%	-6.7%
Y-Y Growth					
Revenues	2970.3%	35.4%	14.6%	86.1%	-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	2016A	2017E	2018E
Assets					
Current assets, total	12.8	23.3	20.7	24.7	24.3
Cash and cash equivalents	0.3	0.6	3.0	1.8	1.6
Other liquid assets	8.9	19.7	11.0	15.5	14.3
Receivables	3.3	2.8	5.2	5.5	6.3
Inventories	0.3	0.2	0.6	0.7	0.8
Other current assets	0.0	0.0	0.9	1.1	1.3
Non-current assets, total	4.1	3.8	4.5	4.3	4.6
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	3.4	3.3	3.8
Goodwill & other intangibles	1.3	1.1	1.0	0.8	0.7
Other assets	0.0	0.1	0.1	0.2	0.2
Total assets	16.9	27.1	25.2	29.0	28.9
Shareholders' equity & debt					
Current liabilities, total	3.3	1.6	3.6	4.0	4.4
Accounts payable	2.3	0.6	2.3	2.6	2.8
Other current liabilities	1.0	1.0	1.3	1.5	1.6
Long-term liabilities, total	0.5	0.7	0.7	1.5	1.9
Provisions	0.5	0.7	0.7	1.5	1.3
Other liabilities	0.0	0.0	0.0	0.0	0.6
Minority interests	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	13.1	24.9	20.9	23.5	22.6
Total consolidated equity and debt	16.9	27.1	25.2	29.0	28.9
Key figures					
Current ratio (x)	3.94	14.52	5.79	6.13	5.50
Quick ratio (x)	3.83	14.38	5.61	5.95	5.32
Financial leverage (%)	-70.4	-81.6	-66.9	-73.9	-70.5
Book value per share (€)	1.52	2.74	2.31	2.60	2.49
Return on equity (ROE)	6.4%	3.0%	-17.8%	15.2%	-5.0%



CASH FLOW STATEMENT

All figures in EURm	2014A	2015A	2016A	2017E	2018E
EBIT	0.9	0.5	-4.1	3.2	-1.3
Depreciation and amortisation	1.1	0.9	0.7	1.0	1.0
EBITDA	1.9	1.5	-3.4	4.2	-0.3
Changes in working capital	-2.0	-1.1	-1.7	-0.3	0.0
Other adjustments	0.0	0.1	0.1	0.2	0.2
Operating cash flow	0.0	0.5	-5.0	4.1	-0.1
CAPEX	-0.6	-0.6	-1.4	-0.7	-1.3
Free cash flow	-0.6	-0.1	-6.4	3.4	-1.5
Debt financing, net	0.0	0.0	0.0	0.0	0.0
Equity financing, net	0.0	11.2	0.1	0.0	0.0
Other changes in cash	0.0	0.0	0.0	0.0	0.0
Net cash flows	-0.6	11.1	-6.3	3.4	-1.5
Cash and liquid assets, start of the year	0.9	9.2	20.3	14.0	17.4
Cash and liquid assets, end of the year	0.3	20.3	14.0	17.4	15.9
EBITDA/share (in €)	0.2	0.2	-0.4	0.5	0.0
Y-Y Growth					
Operating cash flow	n.a.	n.m.	n.m.	n.m.	n.m.
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.

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...16	↓	↓	↓	↓
17	21 April 2016	€21.36	Buy	€42.00
18	21 September 2016	€18.30	Buy	€45.00
19	27 November 2016	€18.68	Buy	€45.00
20	Today	€28.30	Buy	€45.00

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