

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWWY8

**Preliminary 2015
results**
RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€42.00**

96.6%

High

PORTFOLIO DEVELOPMENT PROGRESSING RAPIDLY

Preliminary 2015 results were in line with company guidance for a positive net profit. Development of Formycon's portfolio of biosimilars continues to progress rapidly. The company is currently developing three biosimilar products, marketing of which is expected to begin in the US and EU from 2020 once the patents on the reference products expire. FYB201 (now in phase III) and FYB203 (preclinical stage) were licensed out to Santo in December 2013 and May 2015 respectively. FYB201's reference product is Lucentis (2015 worldwide sales of USD3.5bn) while FYB203's reference product is Eylea (2015 worldwide sales of USD4.1bn). Formycon has yet to reveal FYB202's reference product, but stated in the preliminary results press release that a partnership agreement with respect to this compound could be forthcoming as early as this year. We continue to expect that FYB201, FYB202 and FYB203 will each achieve lifetime success-based payments in the triple digit millions of Euros. We maintain our Buy recommendation and price target of €42.00.

2015 guidance for positive net profit achieved Formycon (FYB) published preliminary 2016 results showing a 34% increase in sales to €16.9m (2014: €12.6m), EBITDA of €1.5m (2014: €1.9m) and net profit of €0.6m (2014: €0.9m) 2014 revenues were based primarily on the license and development agreement with Santo Holding (Santo) for FYB201. Sales rose in 2015 because FYB signed a second license and development agreement with Santo for FYB203. Full year revenues and profits were somewhat below our forecast (see figure 2 overleaf) as the holiday period meant that fewer development hours were booked in Q4/15 than Q3/15. However, the company succeeded in reaching its full year guidance for a positive net profit. Publication of the 2015 annual report is scheduled for May/June.

€11.1m in new equity in April; FYB203 license agreement in May FYB has made rapid progress with the development of its biosimilar portfolio over the past year. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015P	2016E	2017E	2018E
Revenue (€m)	0.41	12.67	16.90	19.00	36.60	31.50
Y-o-y growth	n.a.	2970.3%	33.4%	12.4%	92.6%	-13.9%
EBIT (€m)	-7.74	0.87	0.50	-0.82	5.38	0.97
EBIT margin	-1876.5%	6.9%	3.0%	-4.3%	14.7%	3.1%
Net income (€m)	-7.74	0.86	0.57	-0.62	5.60	1.19
EPS (diluted) (€)	-0.90	0.10	0.06	-0.07	0.62	0.13
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	0.00	-0.63	0.53	-0.67	3.64	1.82
Net gearing	-74.5%	-62.1%	-78.7%	-78.3%	-77.6%	-80.0%
Liquid assets (€m)	10.38	9.20	20.28	19.62	23.26	25.08

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 Apr 2016

Closing Price	€ 21.36
Shares outstanding	9.06m
Market Capitalisation	€ 193.59m
52-week Range	€ 14.76 / 31.89
Avg. Volume (12 Months)	16,297

Multiples	2015P	2016E	2017E
P/E	334.8	n.a.	34.6
EV/Sales	10.3	9.1	4.7
EV/EBIT	347.4	n.a.	32.2
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2015

Liquid Assets	€ 20.56m
Current Assets	€ 24.83m
Intangible Assets	€ 1.23m
Total Assets	€ 28.69m
Current Liabilities	€ 2.35m
Shareholders' Equity	€ 25.76m

SHAREHOLDERS

Founders	23.5%
Institutional Investors	50.0%
Free Float	26.5%



After having raised a gross €11.1m of new equity in April 2015 to finance further portfolio development, the following month FYB announced a license and development agreement with Santo for FYB203. The agreement triggered an immediate payment from Santo to FYB of several million Euro.

Initiation of pivotal phase III trial with FYB201 in October In October FYB initiated a pivotal phase III clinical trial with FYB201 and also revealed that the compound's reference product is Lucentis. Lucentis is indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. Worldwide sales were USD3.5bn in 2015. The phase III trial is designed to confirm FYB201's biosimilarity to Lucentis and was developed in consultation with the FDA in the United States and the European Medicines Agency (EMA). The trial is expected to support registration in both regions and will entail enrolment of 650 patients at more than 75 centres worldwide. At the end of February 2016, FYB announced that FYB203's reference product is Eylea. Eylea is indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. Worldwide 2015 sales were USD4.1bn. In FYB201 and FYB203, FYB has biosimilars under development corresponding to ca. 90% of the value of the intraocular anti-VEGF (vascular endothelial growth factor) market.

Alternative delivery/formulation patents to act as moats for FYB201/FYB203 FYB also stated earlier this year that it has applied for patents for alternative methods of delivery and formulation for FYB201 and FYB203 to those used in conjunction with Lucentis and Eylea. Grant of these patents will ensure market access for FYB while acting as obstacles to competitors.

We bring forecast timing of FYB202 partnership agreement forward to 2017 from 2018 FYB is guiding towards 2016 revenues of over €20m. This number is based on further development revenues in respect of FYB201 and FYB203 and also possibly on a partnership agreement regarding FYB's third biosimilar project, FYB202. We had previously modelled a FYB202 partnership agreement in 2018. We now bring forward the timing of this agreement to 2017. This is the explanation for the changes to our 2017 and 2018 forecasts. However, as our existing 2016 revenue forecast of €19m is close to management guidance, we leave this figure unchanged for the time being.

Figure 1: 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%	16.00	36.60	128.8%	30.80	31.50	2.3%
EBITDA	-0.30	-0.30	-	-2.50	6.20	-	17.00	1.70	-90.0%
margin	neg.	neg.	-	neg.	16.9%	-	55.2%	5.4%	-
Net income	-1.00	-0.62	-	-3.20	5.60	-	-3.20	1.19	-
margin	neg.	neg.	-	neg.	15.3%	-	neg.	3.8%	-
EPS (diluted, in €)	-0.11	-0.07	-	-0.35	0.62	-	1.77	0.13	-92.6%

* including other operating income such as upfront and milestone payments

Source: First Berlin Equity Research

We maintain our Buy recommendation and price target of €42.00 The main assumptions underlying our pipeline valuation model are unchanged on our previous DCF model and are as follows:

- pricing will be 30% lower after patent expiry of the reference products
- FYB's licensing partners will gain >15% market share
- FYB agrees on a royalty rate of 10-12% Our valuation shows a pipeline NPV of €363m. Including net cash of €20m, we see fair value of €33m corresponding to a price target of €42.00 and a Buy rating.

**Figure 2: Preliminary 2015 results vs. our forecasts**

in EURm	2015A	2015E	Delta	2014A	Delta
Sales	16.90	19.50	-13.3%	12.58	34.3%
EBITDA	1.47	1.70	-13.5%	1.94	-24.2%
margin	8.7%	8.7%	-	15.4%	-
Net income	0.57	1.00	-43.0%	0.86	-33.7%
margin	3.4%	5.1%	-	6.8%	-

Source: Formycon; First Berlin Equity Research estimates

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)	€82M	270K	€5,250	€1,418M	17%	€403M	2%	15%	n.a.	6 Years
FYB201	nAMD,DR (US)	€83M	113K	€9,068	€1,025M	17%	€409M	12%	5%	n.a.	4 Years
FYB202	n.a.	€150M									
FYB203	nAMD,DR (ex-US)	€33M	197K	€4,859	€957M	17%	€272M	12%	15%	n.a.	9 Years
FYB203	nAMD,DR (US)	€96M	212K	€8,591	€1,821M	17%	€728M	12%	5%	n.a.	7 Years
PACME PV		€443M									
Costs PV ⁴⁾		-€81M									
Net Cash		€20M									
Fair Value		€383M									
Share Count		9,060K									
Fair Value Per Share		€42.25									

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	2013A	2014A	2015P	2016E	2017E	2018E
Revenue	0.4	12.7	16.9	19.0	36.6	31.5
Increase/decrease in unfinished products	0.0	0.0	0.0	0.0	0.0	0.0
Total output	0.4	12.7	16.9	19.0	36.6	31.5
Cost of goods sold	-1.5	-5.9	-10.8	-14.2	-25.0	-23.7
Gross profit	-1.1	6.8	6.1	4.8	11.6	7.8
Personnel costs	-2.9	-2.9	-3.2	-3.4	-3.5	-4.0
Depreciation and amortisation	-1.1	-1.1	-1.0	-0.5	-0.8	-0.7
Other operating income	0.0	0.0	0.1	0.1	0.1	0.1
Other operating expenses	-2.7	-1.9	-1.5	-1.8	-2.0	-2.2
Operating income (EBIT)	-7.7	0.9	0.5	-0.8	5.4	1.0
Net financial result	0.0	0.0	0.1	0.2	0.2	0.2
Pre-tax income (EBT)	-7.7	0.9	0.6	-0.6	5.6	1.2
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net income / loss	-7.7	0.9	0.6	-0.6	5.6	1.2
Diluted EPS (in €)	-0.90	0.10	0.06	-0.07	0.62	0.13
EBITDA	-6.6	1.9	1.5	-0.3	6.2	1.7
Ratios						
Gross margin on output	n.m.	53.4%	35.9%	25.3%	31.7%	24.8%
EBIT margin on output	n.m.	6.9%	3.0%	-4.3%	14.7%	3.1%
EBITDA margin on output	n.m.	15.3%	8.7%	-1.6%	16.9%	5.4%
Net margin on output	n.m.	6.8%	3.4%	-3.3%	15.3%	3.8%
Tax rate	n.m.	-0.2%	0.0%	0.0%	0.0%	-2.0%
Expenses as % of output						
Cost of goods sold	n.m.	-46.6%	-64.1%	-74.7%	-68.3%	-75.2%
Personnel costs	n.m.	-22.8%	-18.9%	-17.9%	-9.6%	-12.7%
Depreciation and amortisation	n.m.	-8.5%	-5.7%	-2.7%	-2.2%	-2.3%
Net other operating exp.	n.m.	-15.2%	-8.3%	-8.9%	-5.2%	-6.7%
Y-Y Growth						
Revenues	n.a.	2970.3%	33.4%	12.4%	92.6%	-13.9%
Operating income	n.a.	n.m.	-42.6%	n.m.	n.m.	-81.9%
Net income/ loss	n.a.	n.m.	-33.7%	n.m.	n.m.	-78.7%



BALANCE SHEET

All figures in EURm	2013A	2014A	2015P	2016E	2017E	2018E
Assets						
Current assets, total	10.9	12.0	25.1	24.3	30.7	33.1
Cash and cash equivalents	0.9	0.3	0.8	1.0	1.8	1.6
Other liquid assets	9.5	8.9	19.4	18.7	21.4	23.5
Receivables	0.0	2.4	4.2	4.0	6.2	6.6
Inventories	0.3	0.3	0.5	0.6	1.1	1.3
Other current assets	0.2	0.0	0.0	0.1	0.1	0.1
Non-current assets, total	6.2	5.8	5.4	5.8	7.6	7.7
Shares in affiliated companies	0.0	0.1	0.1	0.1	0.1	0.1
Loans to affiliated companies	1.7	1.7	1.7	1.7	1.7	1.7
Property, plant & equipment	3.0	2.7	2.4	2.9	4.8	5.0
Goodwill & other intangibles	1.6	1.3	1.2	1.1	1.0	0.9
Other assets	0.0	0.0	0.1	0.1	0.1	0.1
Total assets	17.1	17.7	30.4	30.1	38.3	40.8
Shareholders' equity & debt						
Current liabilities, total	2.7	2.4	4.0	4.2	6.9	7.6
Accounts payable	2.5	1.4	2.5	2.4	3.7	3.9
Other current liabilities	0.2	1.0	1.5	1.9	3.2	3.6
Long-term liabilities, total	0.5	0.5	0.7	0.8	1.5	1.9
Provisions	0.5	0.5	0.7	0.8	1.5	1.3
Other liabilities	0.0	0.0	0.0	0.0	0.0	0.6
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	13.9	14.8	25.8	25.1	30.0	31.4
Total consolidated equity and debt	17.1	17.7	30.4	30.1	38.3	40.8
Key figures						
Current ratio (x)	4.03	4.95	6.30	5.74	4.47	4.37
Quick ratio (x)	3.93	4.80	6.18	5.59	4.31	4.20
Financial leverage (%)	-74.5	-62.1	-78.7	-78.3	-77.6	-80.0
Book value per share (€)	1.61	1.72	2.84	2.77	3.31	3.46
Return on equity (ROE)	n.a.	6.0%	2.8%	-2.4%	20.3%	3.9%



CASH FLOW STATEMENT

All figures in EURm	2014A	2015P	2016E	2017E	2018E
EBIT	0.9	0.5	-0.8	5.4	1.0
Depreciation and amortisation	1.1	1.0	0.5	0.8	0.7
EBITDA	1.9	1.5	-0.3	6.2	1.7
Changes in working capital	-2.6	-0.5	0.3	-0.1	0.8
Other adjustments	0.6	0.1	0.2	0.2	0.2
Operating cash flow	0.0	1.1	0.2	6.3	2.7
CAPEX	-0.6	-0.5	-0.9	-2.6	-0.9
Free cash flow	-0.6	0.5	-0.7	3.6	1.8
Debt financing, net	0.0	0.0	0.0	0.0	0.0
Equity financing, net	0.0	10.6	0.0	0.0	0.0
Other changes in cash	-0.6	0.0	0.0	0.0	0.0
Net cash flows	-1.2	11.1	-0.7	3.6	1.8
Cash and liquid assets, start of the year	10.4	9.2	20.3	19.6	23.3
Cash and liquid assets, end of the year	9.2	20.3	19.6	23.3	25.1
EBITDA/share (in €)	0.2	0.2	0.0	0.7	0.2
Y-Y Growth					
Operating cash flow	n.a.	n.m.	-77.6%	2531.1%	-57.0%
Free cash flow	n.a.	n.m.	n.m.	n.m.	-49.9%
EBITDA/share	n.a.	-26.9%	n.m.	n.m.	-72.6%

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	12 November 2015	€23.54	Buy	€42.00
16	18 January 2016	€19.86	Buy	€42.00
17	8 March 2016	€22.11	Buy	€42.00
18	Today	€21.36	Buy	€42.00

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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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