

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWWY8

2017 annual report

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 52.00**

36.3%

High

LOOKING FORWARD TO THE ROARING TWENTIES

The 2017 annual report released yesterday showed a 48.6% increase in revenue to €29.0m (FBe: €28.2m; 2016: €19.5m) while the operating loss narrowed to €-1.5m (FBe: €0.1m; 2016: €-4.1m). Meanwhile, last week's news that FYB201 has achieved the primary endpoint of its phase III trial keeps 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 maintain our price target of €52.00 and our Buy recommendation.

FYB202 JV payment also contributed to 2017 revenues 2017 revenue stemmed largely from the reimbursement of development costs of FYB201 and FYB203 by Bioeq IP AG and Santo Holding respectively. The increase in revenues was attributable to a higher volume of development work on these products and also to the foundation of the FYB202 joint venture with Aristo Pharma. Formycon received a payment which was booked as revenue in return for contributing the project rights to the joint venture company.

Comfortable financial position In July 2017 Formycon raised gross proceeds of €6.0m through a private placement transaction. The proceeds are being used to fund the co-investment in FYB202 and the ongoing development of the biosimilar drug portfolio. The private placement helped raise Formycon's end 2017 cash and liquid assets position to €15.5m (2016: €14.0m). Including short-term receivables the liquid assets position at end 2017 was €26.0m (2016: €19.2m). We expect an aggregate net cash outflow in 2018 and 2019 of €0.9m. The following year should see the company clearly in the black as revenues are generated from the launch of FYB201 on the US market. Formycon's financial position thus looks comfortable.

Success of FYB201 trial Formycon last week announced that based on interim results FYB201 had achieved the primary endpoint of its phase III trial. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€m)	12.59	16.92	19.53	29.00	29.30	24.20
Y-o-y growth	29.7%	34.5%	15.4%	48.5%	1.0%	-17.4%
EBIT (€m)	0.87	0.54	-4.07	-1.54	0.15	-4.67
EBIT margin	6.9%	3.2%	-20.8%	-5.3%	0.5%	-19.3%
Net income (€m)	0.86	0.58	-4.07	-1.58	0.33	-4.49
EPS (diluted) (€)	0.10	0.06	-0.45	-0.17	0.04	-0.48
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.63	-0.10	-6.40	-4.66	5.16	-6.11
Net gearing	-70.4%	-81.6%	-66.9%	-60.6%	-79.5%	-67.0%
Liquid assets (€m)	9.22	20.30	13.97	15.48	20.64	14.53

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 07 May 2018

Closing Price	€ 38.15
Shares outstanding	9.34m
Market Capitalisation	€ 356.47m
52-week Range	€ 28.85 / 39.32
Avg. Volume (12 Months)	11,839

Multiples	2017	2018E	2019E
P/E	n.a.	1082.1	n.a.
EV/Sales	12.8	12.7	15.4
EV/EBIT	n.a.	2498.0	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2017

Liquid Assets	€ 15.48m
Current Assets	€ 26.36m
Intangible Assets	€ 0.86m
Total Assets	€ 30.83m
Current Liabilities	€ 3.44m
Shareholders' Equity	€ 25.54m

SHAREHOLDERS

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

Figure 1: 2017 results versus our forecasts

in EURm	2017A	2017E	Delta	2016A	Delta
Revenue	29.03	28.20	2.9%	19.53	48.6%
EBIT	-1.54	0.11	n.m.	-4.07	n.m.
margin	n.m.	n.m.	-	n.m.	-
Net income	-1.58	0.29	n.m.	-4.07	n.m.
margin	n.m.	n.m.	-	n.m.	-
EPS (€)	-0.17	0.03	n.m.	-0.45	n.m.

Source: Formycon; First Berlin Equity research estimates

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 2 below. The reference product for FYB203 is Eylea.

Figure 2: 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® (afibercept)	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 We continue to see fair value for the Formycon share at €52.00. We maintain our Buy recommendation.

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)	€131M	327K	€4,813	€1,573M	17%	€272M	12%	12%	n.a.	4 Years
FYB201	nAMD,DR (US)	€166M	144K	€8,313	€1,197M	17%	€295M	12%	12%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€53M	56K	€25,208	€1,404M	17%	€475M	2%	15%	n.a.	6 Years
FYB202	Pso,CrD (US)	€108M	47K	€41,021	€1,938M	17%	€936M	12%	15%	n.a.	5 Years
FYB203	nAMD,DR (ex-US)	€55M	417K	€4,454	€1,856M	17%	€549M	2%	15%	n.a.	7 Years
FYB203	nAMD,DR (US)	€153M	392K	€7,875	€3,085M	17%	€1,329M	2%	15%	n.a.	5 Years
FYB205	n.a.	€87M									
PACME PV		€753M									
Costs PV ⁴⁾		€313M									
NPV		€440M									
Downpayments and Milestones		€30M									
Net Cash		€15M									
Fair Value		€486M									
Share Count		9,344K									
Fair Value Per Share		€52.00									

Source: First Berlin Equity Research



INCOME STATEMENT

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
Revenue	12.6	16.9	19.5	29.0	29.3	24.2
Increase/decrease in unfinished products	0.0	0.0	0.0	0.4	0.0	0.0
Total output	12.6	16.9	19.5	29.4	29.3	24.2
Other operating income	0.1	0.2	0.1	0.1	0.1	0.1
Cost of goods sold	-5.9	-8.9	-15.4	-21.2	-22.3	-22.5
Gross profit	6.8	8.3	4.3	8.4	7.1	1.8
Personnel costs	-2.9	-3.9	-5.1	-6.3	-4.0	-3.0
Depreciation and amortisation	-1.1	-0.9	-0.7	-0.8	-1.0	-1.4
Other operating expenses	-1.9	-2.9	-2.6	-2.8	-2.1	-2.2
Operating income (EBIT)	0.9	0.5	-4.1	-1.5	0.1	-4.7
Net financial result	0.0	0.0	0.0	0.0	0.2	0.2
Pre-tax income (EBT)	0.9	0.6	-4.1	-1.6	0.3	-4.5
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net income / loss	0.9	0.6	-4.1	-1.6	0.3	-4.5
Diluted EPS (in €)	0.10	0.06	-0.45	-0.17	0.04	-0.48
EBITDA	1.9	1.5	-3.4	-0.8	1.1	-3.3
Ratios						
Gross margin on output	53.7%	48.9%	21.9%	28.4%	24.2%	7.4%
EBIT margin on output	6.9%	3.2%	-20.8%	-5.2%	0.5%	-19.3%
EBITDA margin on output	15.4%	8.7%	-17.3%	-2.6%	3.8%	-13.6%
Net margin on output	6.8%	3.4%	-20.8%	-5.4%	1.1%	-18.6%
Tax rate	-0.2%	-0.2%	0.1%	-0.2%	0.0%	0.0%
Expenses as % of output						
Cost of goods sold	-47.0%	-52.5%	-78.8%	-72.0%	-76.1%	-93.0%
Personnel costs	-23.0%	-22.8%	-26.1%	-21.5%	-13.7%	-12.4%
Depreciation and amortisation	-8.5%	-5.5%	-3.6%	-2.7%	-3.2%	-5.7%
Net other operating exp.	-14.4%	-16.0%	-12.6%	-9.1%	-6.8%	-8.7%
Y-Y Growth						
Revenues	2949.5%	34.5%	15.4%	48.5%	1.0%	-17.4%
Operating income	n.m.	-38.1%	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	-32.9%	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
Assets						
Current assets, total	12.8	23.3	20.7	26.6	27.1	20.0
Cash and cash equivalents	0.3	0.6	3.0	4.5	1.5	1.2
Other liquid assets	8.9	19.7	11.0	11.0	19.2	13.3
Receivables	3.3	2.8	5.2	10.5	5.9	4.8
Inventories	0.3	0.2	0.6	0.6	0.6	0.6
Other current assets	0.0	0.0	0.9	0.1	0.1	0.0
Non-current assets, total	4.1	3.8	4.5	4.2	4.4	6.2
Shares in affiliated companies	0.0	0.0	0.0	0.0	0.0	0.0
Loans to affiliated companies	0.0	0.0	0.0	0.0	0.0	0.0
Property, plant & equipment	2.7	2.6	3.4	3.3	3.5	5.6
Goodwill & other intangibles	1.3	1.1	1.0	0.9	0.7	0.5
Other assets	0.0	0.1	0.1	0.1	0.2	0.1
Total assets	16.9	27.1	25.2	30.8	31.5	26.3
Shareholders' equity & debt						
Current liabilities, total	3.3	1.3	2.6	3.4	3.8	3.1
Accounts payable	2.3	0.6	2.3	1.8	2.1	1.7
Other current liabilities	1.0	0.7	0.3	1.7	1.8	1.5
Long-term liabilities, total	0.5	0.9	1.7	1.8	1.7	1.4
Provisions	0.5	0.7	0.7	1.3	1.2	1.0
Other liabilities	0.0	0.3	1.0	0.6	0.6	0.5
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	13.1	24.9	20.9	25.5	26.0	21.7
Total consolidated equity and debt	16.9	27.1	25.2	30.8	31.5	26.3
Key figures						
Current ratio (x)	3.94	17.45	7.91	7.75	7.13	6.37
Quick ratio (x)	3.83	17.28	7.67	7.59	6.97	6.17
Financial leverage (%)	-70.4	-81.6	-66.9	-60.6	-79.5	-67.0
Book value per share (€)	1.52	2.74	2.30	2.78	2.82	2.36
Return on equity (ROE)	6.4%	3.0%	-17.8%	-6.8%	1.3%	-18.9%



CASH FLOW STATEMENT

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
EBIT	0.9	0.5	-4.1	-1.5	0.1	-4.7
Depreciation and amortisation	1.1	0.9	0.7	0.8	1.0	1.4
EBITDA	1.9	1.5	-3.4	-0.8	1.1	-3.3
Changes in working capital	-2.0	-1.1	-1.7	-3.4	4.9	0.3
Other adjustments	0.0	0.1	0.1	0.0	0.2	0.2
Operating cash flow	0.0	0.5	-5.0	-4.2	6.2	-2.8
CAPEX	-0.6	-0.6	-1.4	-0.5	-1.1	-3.3
Free cash flow	-0.6	-0.1	-6.4	-4.7	5.2	-6.1
Debt financing, net	0.0	0.0	0.0	0.0	0.0	0.0
Equity financing, net	0.0	11.2	0.1	6.2	0.0	0.0
Other changes in cash	0.0	0.0	0.0	0.0	0.0	0.0
Net cash flows	-0.6	11.1	-6.3	1.5	5.2	-6.1
Cash and liquid assets, start of the year	0.9	9.2	20.3	14.0	15.5	20.6
Cash and liquid assets, end of the year	0.3	20.3	14.0	15.5	20.6	14.5
EBITDA/share (in €)	0.2	0.2	-0.4	-0.1	0.1	-0.4
Y-Y Growth						
Operating cash flow	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.a.	-26.8%	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...20	↓	↓	↓	↓
21	29 August 2017	€33.43	Buy	€48.00
22	2 October 2017	€34.80	Buy	€48.00
23	3 May 2018	€37.90	Buy	€52.00
24	Today	€38.15	Buy	€52.00

Authored by: Simon Scholes, Analyst

Company responsible for preparation:

First Berlin Equity Research GmbH

Mohrenstraße 34
10117 Berlin

Tel. +49 (0)30 - 80 93 96 94 Fax +49 (0)30 - 80 93 96 87

info@firstberlin.com

www.firstberlin.com

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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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%.

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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.

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Legally required information regarding

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

can be accessed through the following internet link: <http://firstberlin.com/disclaimer-english-link/>

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