

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Update

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 53.00**

78.2%

High

NEAR-TERM NEWSFLOW TO KEEP FOCUS ON PORTFOLIO POTENTIAL

During the past two weeks, Formycon (FYB) has reported Q3/18 results and provided an update on the development of its pipeline of biosimilar candidates. In the Q3/18 report management raised FY/18 sales guidance from €36-40m to “slightly over €40m”. The change reflects a higher than expected volume of development work on FYB’s partnered biosimilar candidates. FY/18 net profit guidance is now “about €7m”. Previous guidance was for “a clearly positive result” and our forecast was €4.2m. We gather that tax differences in the FYB202 joint venture company played a role here. FYB already reported in May that FYB201 had achieved the primary endpoint of its phase III trial. This week FYB additionally stated that the phase III study showed comparable results with regard to efficacy, safety and immunogenicity between FYB201 and the reference product Lucentis. The final phase III study report will be available in December 2018 and filing of a biologics license application (BLA) with the FDA is planned for H1/19. The next few months may also see the closing of a contract between the development partner for FYB201 (Bioeq IP AG) and a marketing partner for FYB201 on the U.S. market. Meanwhile, FYB202 (reference product Stelara) is expected to enter the clinical phase from mid-2019 and scientific advice briefing books are being prepared so as to align the future development strategy for FYB203 (also preclinical; reference product Eylea) with both the FDA and EMA. In our view FYB is on track to achieve its goal that its biosimilar products will be the first to market following expiry of the patents on their reference products from 2020 onwards. We maintain our Buy recommendation and price target of €53.00.

€8.5m credit helped 9M/18 results 9M/18 and Q3/18 revenues were above our forecasts (see figure 1 overleaf) because the latter were based on the company’s old, lower guidance. 9M/18 sales were up 114.4% at €32.4m (9M/17: €15.1m) and rose 11.5% in Q3/18 to €7.8m (Q3/17: €7.0m). The difference between the 9M/18 and Q3/18 growth rates is attributable to an €8.5m credit booked in H1/18 relating to FYB’s investment in FYB202 during 2013-16. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€m)	12.59	16.92	19.53	29.00	40.50	24.20
Y-o-y growth	29.7%	34.5%	15.4%	48.5%	39.6%	-40.2%
EBIT (€m)	0.87	0.54	-4.07	-1.54	7.66	-4.67
EBIT margin	6.9%	3.2%	-20.8%	-5.3%	18.9%	-19.3%
Net income (€m)	0.86	0.58	-4.07	-1.58	7.02	-4.69
EPS (diluted) (€)	0.10	0.06	-0.45	-0.17	0.75	-0.50
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.63	-0.10	-6.40	-4.66	-5.93	-5.18
Net gearing	-70.4%	-81.6%	-66.9%	-60.6%	-29.5%	-15.0%
Liquid assets (€m)	9.22	20.30	13.97	15.48	9.55	4.37

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 21 Nov 2018

Closing Price	€ 29.75
Shares outstanding	9.42m
Market Capitalisation	€ 280.32m
52-week Range	€ 26.50 / 38.75
Avg. Volume (12 Months)	7,067

Multiples	2017	2018E	2019E
P/E	n.a.	39.6	n.a.
EV/Sales	9.3	6.6	11.1
EV/EBIT	n.a.	35.0	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2018

Liquid Assets	€ 11.81m
Current Assets	€ 21.84m
Intangible Assets	€ 0.78m
Total Assets	€ 42.20m
Current Liabilities	€ 5.93m
Shareholders' Equity	€ 33.13m

SHAREHOLDERS

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

**Figure 1: Q3/18 and 9M/18 results versus our forecasts**

in EURm	Q3-18A	Q3-18E	Delta	Q3-17A	Delta	9M-18A	9M-18E	Delta	9M-17A	Delta
Revenue	7.83	7.00	11.9%	7.02	11.5%	32.42	31.59	2.6%	15.12	114.4%
EBITDA	0.71	-0.75	n.m.	-1.75	n.m.	9.34	7.88	18.5%	-4.25	n.m.
margin	9.1%	-10.7%	-	n.m.	-	28.8%	24.9%	-	n.m.	-
EBIT	0.47	-1.00	n.m.	-1.95	n.m.	8.70	7.23	20.3%	-4.84	n.m.
margin	6.0%	-14.3%	-	0.00	-	26.8%	n.m.	-	0.00	-
Net income	0.47	-1.00	n.m.	-1.98	n.m.	8.06	6.59	22.3%	-4.89	n.m.
margin	6.0%	-14.3%	-	n.m.	-	24.9%	n.m.	-	n.m.	-

Source: Formycon AG, First Berlin Equity Research estimates

This was prior to the foundation of the FYB202 J.V. with Aristo at the end of 2017. FYB's revenues currently derive primarily from reimbursement of the development work it carries out on its partnered products, FYB201, FYB202 and FYB203. We expect royalties on the sale of these products to begin flowing from mid-2020 as the patents on their reference products start to expire. FYB's cash position amounted to €12.0m at the end of September.

Primary and secondary endpoints of FYB201 phase III trial reached The primary endpoint of the FYB201 phase III trial was confirmation of comparable efficacy between FYB201 and the reference product, Lucentis, in the indication neovascular age-related macular degeneration. FYB reported in May that FYB201 had achieved this endpoint. The trial also had eight secondary endpoints covering comparability of FYB201 and Lucentis with respect to efficacy, safety and immunogenicity. This week FYB reported that these endpoints were also reached.

Clinical testing of FYB202 expected from mid-2019 FYB201 is the furthest advanced of FYB's biosimilar candidates. FYB202 and FYB203 are currently at the preclinical stage. However this week, FYB reported that substance process development and manufacturing scale-up for FYB202 are at an advanced stage and that clinical testing is expected to start in mid-2019 following consultation with the FDA and EMA. Substance process development and scale-up are also at an advanced stage for FYB203 and FYB is currently preparing scientific advice briefing books ahead of consultations with the FDA and EMA on future development strategy.

FYB201 progression freeing up capacity at FYB The progression of FYB201 towards filing of a BLA is freeing up capacity at FYB for development of other biosimilar product candidates. FYB205, whose reference product FYB has not so far published, may benefit from this. FYB205 is an early stage project which has progressed up to initial cell line screening. Management also states that the company is exploring other as yet unspecified biosimilar targets.

We maintain our Buy recommendation and price target of €53.00 The next few months should see ample newsflow on FYB's biosimilar portfolio, but particularly from FYB201. The final FYB201 phase III study report will be available in December 2018 and filing of a BLA with the FDA is planned for H1/19. The next few months may also see the closing of a contract between the development partner for FYB201 (Bioeq IP AG) and a marketing partner for FYB201 on the U.S. market. In our view FYB is on track to achieve its goal that its biosimilar products will be the first to market following expiry of the patents on their reference products from 2020 onwards.



Figure 2 shows changes to our forecasts. These relate primarily to the increase in guidance announced in the Q3/18 report and do not significantly affect our price target which is unchanged at €53.00. We maintain our Buy recommendation.

Figure 2: Changes to our forecasts

in €m	Old	2018E New	Delta	Old	2019E New	Delta
Revenues	36.00	40.50	12.5%	24.20	24.20	0.0%
EBIT	4.00	7.66	91.5%	-4.67	-4.67	n.m.
margin	11.1%	neg.	-	neg.	neg.	-
Net income	4.19	7.02	67.4%	-4.48	-4.69	n.m.
margin	neg.	neg.	-	neg.	neg.	-
EPS (diluted, in €)	0.45	0.75	66.9%	-0.48	-0.50	n.m.

Source: 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)	€162M	327K	€4,813	€1,573M	17%	€339M	12%	12%	n.a.	4 Years
FYB201	nAMD,DR (US)	€144M	144K	€8,313	€1,197M	17%	€258M	12%	12%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€44M	56K	€25,208	€1,404M	17%	€272M	2%	15%	n.a.	6 Years
FYB202	Pso,CrD (US)	€62M	47K	€41,021	€1,938M	17%	€375M	12%	5%	n.a.	5 Years
FYB203	nAMD,DR (ex-US)	€89M	417K	€4,454	€1,856M	17%	€611M	2%	15%	n.a.	7 Years
FYB203	nAMD,DR (US)	€153M	392K	€7,875	€3,085M	17%	€884M	12%	15%	n.a.	5 Years
FYB205	n.a.	€97M									
PACME PV		€753M									
Costs PV ⁴⁾		€292M									
NPV		€460M									
Downpayments and Milestones		€28M									
Net Cash		€12M									
Fair Value		€500M									
Share Count		9,443K									
Fair Value Per Share		€53.00									

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 estimates



INCOME STATEMENT

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
Revenue	12.6	16.9	19.5	29.0	40.5	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	40.5	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	-23.1	-18.0
Gross profit	6.8	8.3	4.3	8.4	17.5	6.3
Personnel costs	-2.9	-3.9	-5.1	-6.3	-7.0	-8.0
Depreciation and amortisation	-1.1	-0.9	-0.7	-0.8	-0.9	-0.9
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	7.7	-4.7
Net financial result	0.0	0.0	0.0	0.0	0.0	0.0
Pre-tax income (EBT)	0.9	0.6	-4.1	-1.6	7.6	-4.7
Income taxes	0.0	0.0	0.0	0.0	0.6	0.0
Net income / loss	0.9	0.6	-4.1	-1.6	7.0	-4.7
Diluted EPS (in €)	0.10	0.06	-0.45	-0.17	0.75	-0.50
EBITDA	1.9	1.5	-3.4	-0.8	8.5	-3.8
Ratios						
Gross margin on output	53.7%	48.9%	21.9%	28.4%	43.3%	26.1%
EBIT margin on output	6.9%	3.2%	-20.8%	-5.2%	18.9%	-19.3%
EBITDA margin on output	15.4%	8.7%	-17.3%	-2.6%	21.1%	-15.6%
Net margin on output	6.8%	3.4%	-20.8%	-5.4%	17.3%	-19.4%
Tax rate	-0.2%	-0.2%	0.1%	-0.2%	8.0%	0.0%
Expenses as % of output						
Cost of goods sold	-47.0%	-52.5%	-78.8%	-72.0%	-56.9%	-74.3%
Personnel costs	-23.0%	-22.8%	-26.1%	-21.5%	-17.3%	-33.1%
Depreciation and amortisation	-8.5%	-5.5%	-3.6%	-2.7%	-2.2%	-3.7%
Net other operating exp.	-14.4%	-16.0%	-12.6%	-9.1%	-4.9%	-8.7%
Y-Y Growth						
Revenues	2949.5%	34.5%	15.4%	48.5%	39.6%	-40.2%
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	18.3	13.5
Cash and cash equivalents	0.3	0.6	3.0	4.5	2.0	1.2
Other liquid assets	8.9	19.7	11.0	11.0	7.5	3.2
Receivables	3.3	2.8	5.2	10.5	8.1	8.5
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	20.4	20.5
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	3.6	3.9
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	0.1	0.1
Investment participations	0.0	0.0	0.0	0.0	16.0	16.0
Total assets	16.9	27.1	25.2	30.8	38.8	34.0
Shareholders' equity & debt						
Current liabilities, total	3.3	1.3	2.6	3.4	3.2	3.1
Accounts payable	2.3	0.6	2.3	1.8	1.6	1.7
Other current liabilities	1.0	0.7	0.3	1.7	1.6	1.5
Long-term liabilities, total	0.5	0.9	1.7	1.8	3.1	1.7
Provisions	0.5	0.7	0.7	1.3	2.4	1.0
Other liabilities	0.0	0.3	1.0	0.6	0.7	0.7
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	13.1	24.9	20.9	25.5	32.4	29.2
Deferred income	0.0	0.0	0.0	0.0	0.0	0.0
Total consolidated equity and debt	16.9	27.1	25.2	30.8	38.8	34.0
Key figures						
Current ratio (x)	3.94	17.45	7.91	7.75	5.66	4.29
Quick ratio (x)	3.83	17.28	7.67	7.59	5.47	4.10
Financial leverage (%)	-70.4	-81.6	-66.9	-60.6	-29.5	-15.0
Book value per share (€)	1.52	2.74	2.30	2.78	3.52	3.17
Return on equity (ROE)	6.4%	3.0%	-17.8%	-6.8%	24.2%	-15.2%



CASH FLOW STATEMENT

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
EBIT	0.9	0.5	-4.1	-1.5	7.7	-4.7
Depreciation and amortisation	1.1	0.9	0.7	0.8	0.9	0.9
EBITDA	1.9	1.5	-3.4	-0.8	8.5	-3.8
Changes in working capital	-2.0	-1.1	-1.7	-3.4	2.3	-0.4
Other adjustments	0.0	0.1	0.1	0.0	0.4	0.0
Operating cash flow	0.0	0.5	-5.0	-4.2	11.2	-4.2
CAPEX	-0.6	-0.6	-1.4	-0.5	-17.1	-1.0
Free cash flow	-0.6	-0.1	-6.4	-4.7	-5.9	-5.2
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	-5.9	-5.2
Cash and liquid assets, start of the year	0.9	9.2	20.3	14.0	15.5	9.5
Cash and liquid assets, end of the year	0.3	20.3	14.0	15.5	9.5	4.4
EBITDA/share (in €)	0.2	0.2	-0.4	-0.1	0.9	-0.4
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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...23	↓	↓	↓	↓
24	8 May 2018	€38.15	Buy	€52.00
25	6 June 2018	€36.75	Buy	€53.00
26	14 September 2018	€32.25	Buy	€53.00
27	Today	€29.75	Buy	€53.00

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Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

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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:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy ¹	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

¹ The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

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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.

INVESTMENT HORIZON

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

UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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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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