

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWVY8

Q2 results

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 53.00**

64.3%

High

FYB201 ON TRACK FOR 2020 U.S. LAUNCH

Q2/18 revenue of €10.9m (Q2/17: €4.6m) and EBIT of €1.6m (Q2/17: -2.2m) were well above our forecasts of €6.0m and €0.7m respectively because development on FYB202 carried out in Q1/18 was not invoiced until Q2/18. Reported Q1/18 revenue of €13.7m and EBIT of €6.7m were boosted by a €8.5m credit relating to past investment in FYB202. Stripping out this credit Q1/18 revenue and EBIT would have been €5.2m and €1.8m respectively. We had expected figures close to this level in Q2/18. But the fact that the service contract with FYB202 partner Aristo Pharma was not signed until Q2/18 meant that Q2/18 revenue and profit benefited from development work done by Formycon on FYB202 in Q1/18. H1/18 revenue was €24.6m (H1/17: €8.0m). Management has raised full year revenue guidance from €35m to €34-40m implying average quarterly revenues during H2/18 of €5.7m to €7.7m. Full year profit guidance is now for "a clearly positive result" (previously: "a significantly positive result"). We have revised up our 2018 revenue forecast to €36.0m (previously: €35.0m) but have not altered our net profit forecast of €4.2m. Our projections for subsequent years are unchanged as is our price target at €53.0. We maintain our Buy recommendation.

FYB201 approval package under preparation for submission to FDA/EMA

In early May, Formycon announced that based on interim results, FYB201 had achieved the primary endpoint of its phase III trial. 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. Formycon and its FYB201 partner Bioeq are currently preparing documents for submission to the FDA and EMA with objective of regulatory approval and market launch. 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. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€m)	12.59	16.92	19.53	29.00	36.00	24.20
Y-o-y growth	29.7%	34.5%	15.4%	48.5%	24.1%	-32.8%
EBIT (€m)	0.87	0.54	-4.07	-1.54	4.00	-4.67
EBIT margin	6.9%	3.2%	-20.8%	-5.3%	11.1%	-19.3%
Net income (€m)	0.86	0.58	-4.07	-1.58	4.19	-4.48
EPS (diluted) (€)	0.10	0.06	-0.45	-0.17	0.45	-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	5.35	-2.90
Net gearing	-70.4%	-81.6%	-66.9%	-60.6%	-62.5%	-61.1%
Liquid assets (€m)	9.22	20.30	13.97	15.48	20.82	17.92

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 13 Sep 2018

Closing Price	€ 32.25
Shares outstanding	9.34m
Market Capitalisation	€ 301.34m
52-week Range	€ 28.85 / 38.75
Avg. Volume (12 Months)	8,008

Multiples	2017	2018E	2019E
P/E	n.a.	71.9	n.a.
EV/Sales	10.0	8.0	12.0
EV/EBIT	n.a.	n.a.	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: Q2/18 results versus our forecasts**

in EURm	Q2-18A	Q2-18E	Delta	Q2-17A	Delta
Revenue	10.90	6.00	81.7%	4.63	135.4%
EBITDA	1.75	-0.70	n.m.	-1.99	n.m.
<i>margin</i>	16.1%	n.m.		n.m.	
EBIT	1.55	-0.70	n.m.	-2.19	n.m.
<i>margin</i>	14.2%	n.m.	-	0.00	-
Net income	0.92	-0.70	n.m.	-2.20	n.m.
<i>margin</i>	8.4%	n.m.	-	n.m.	-

Source: Formycon; First Berlin Equity Research estimates

Focus on “third wave” of biosimilars 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 products for FYB202 and FYB203 are respectively Stelara and Eylea. 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. Patent protection for Eylea expires in June 2023 in the US and in May 2025 in the EU. Combined sales of Lucentis and Eylea climbed 12.8% during H1/18 to USD4.9bn (H1/17: USD4.3bn). This figure corresponds to ca. 90% of the value of the intraocular anti-VEGF market. 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. Worldwide sales rose 33.0% to USD2.4bn in H1/18 (H1/17: USD1.8bn). Patent protection for Stelara expires in September 2023 in the US and in July 2024 in the EU.

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

We expect clinical development of FYB202 and FYB203 from 2019 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.

FYB201 and FYB203 royalties in double digit percentage range (depending on certain marketing and manufacturing milestones) 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.

We maintain our Buy recommendation and €53.0 price target Management has raised full year revenue guidance from €35m to €36-40m implying average quarterly revenues during H12/18 of €5.7m to €7.7m. Full year profit guidance is now for "a clearly positive result" (previously: "a significantly positive result"). We have revised up our 2018 revenue forecast to €36.0m (previously: €35.0m) but have not altered our net profit forecast of €4.2m. Our projections for subsequent years are unchanged as is our price target at €53.0. We maintain our Buy recommendation.

Figure 3: Changes to our forecasts

in €m	2018E			2019E		
	Old	New	Delta	Old	New	Delta
Revenues	35.00	36.00	2.9%	24.20	24.20	0.0%
EBIT	4.00	4.00	0.0%	-4.67	-4.67	n.m.
margin	11.4%	neg.	-	neg.	neg.	-
Net income	4.19	4.19	0.1%	-4.48	-4.48	n.m.
margin	neg.	neg.	-	neg.	neg.	-
EPS (diluted, in €)	0.45	0.45	-0.2%	-0.48	-0.48	n.m.

Source: First Berlin Equity Research estimates

Figure 4: 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⁾		€306M									
NPV		€447M									
Downpayments and Milestones		€28M									
Net Cash		€17M									
Fair Value		€491M									
Share Count		9,344K									
Fair Value Per Share		€52.57									

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	2017A	2018E	2019E
Revenue	12.6	16.9	19.5	29.0	36.0	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	36.0	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	-18.0
Gross profit	6.8	8.3	4.3	8.4	13.8	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	-0.8	-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	4.0	-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	4.2	-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	4.2	-4.5
Diluted EPS (in €)	0.10	0.06	-0.45	-0.17	0.45	-0.48
EBITDA	1.9	1.5	-3.4	-0.8	4.8	-3.8
Ratios						
Gross margin on output	53.7%	48.9%	21.9%	28.4%	38.5%	26.1%
EBIT margin on output	6.9%	3.2%	-20.8%	-5.2%	11.1%	-19.3%
EBITDA margin on output	15.4%	8.7%	-17.3%	-2.6%	13.5%	-15.6%
Net margin on output	6.8%	3.4%	-20.8%	-5.4%	11.6%	-18.5%
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%	-61.8%	-74.3%
Personnel costs	-23.0%	-22.8%	-26.1%	-21.5%	-19.4%	-33.1%
Depreciation and amortisation	-8.5%	-5.5%	-3.6%	-2.7%	-2.3%	-3.7%
Net other operating exp.	-14.4%	-16.0%	-12.6%	-9.1%	-5.6%	-8.7%
Y-Y Growth						
Revenues	2949.5%	34.5%	15.4%	48.5%	24.1%	-32.8%
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	28.8	23.4
Cash and cash equivalents	0.3	0.6	3.0	4.5	1.8	1.2
Other liquid assets	8.9	19.7	11.0	11.0	19.0	16.7
Receivables	3.3	2.8	5.2	10.5	7.2	4.8
Inventories	0.3	0.2	0.6	0.6	0.7	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	11.4	10.5
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	4.3	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	6.3	4.4
Total assets	16.9	27.1	25.2	30.8	40.2	33.9
Shareholders' equity & debt						
Current liabilities, total	3.3	1.3	2.6	3.4	4.7	3.1
Accounts payable	2.3	0.6	2.3	1.8	2.5	1.7
Other current liabilities	1.0	0.7	0.3	1.7	2.2	1.5
Long-term liabilities, total	0.5	0.9	1.7	1.8	2.1	1.4
Provisions	0.5	0.7	0.7	1.3	1.4	1.0
Other liabilities	0.0	0.3	1.0	0.6	0.7	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	33.3	29.3
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	40.2	33.9
Key figures						
Current ratio (x)	3.94	17.45	7.91	7.75	6.16	7.44
Quick ratio (x)	3.83	17.28	7.67	7.59	6.00	7.25
Financial leverage (%)	-70.4	-81.6	-66.9	-60.6	-62.5	-61.1
Book value per share (€)	1.52	2.74	2.30	2.78	3.63	3.19
Return on equity (ROE)	6.4%	3.0%	-17.8%	-6.8%	14.2%	-14.3%



CASH FLOW STATEMENT

All figures in EURm	2014A	2015A	2016A	2017A	2018E	2019E
EBIT	0.9	0.5	-4.1	-1.5	4.0	-4.7
Depreciation and amortisation	1.1	0.9	0.7	0.8	0.8	0.9
EBITDA	1.9	1.5	-3.4	-0.8	4.8	-3.8
Changes in working capital	-2.0	-1.1	-1.7	-3.4	4.4	0.8
Other adjustments	0.0	0.1	0.1	0.0	-2.2	2.1
Operating cash flow	0.0	0.5	-5.0	-4.2	7.1	-0.9
CAPEX	-0.6	-0.6	-1.4	-0.5	-1.7	-2.0
Free cash flow	-0.6	-0.1	-6.4	-4.7	5.3	-2.9
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	5.3	-2.9
Cash and liquid assets, start of the year	0.9	9.2	20.3	14.0	15.5	20.8
Cash and liquid assets, end of the year	0.3	20.3	14.0	15.5	20.8	17.9
EBITDA/share (in €)	0.2	0.2	-0.4	-0.1	0.5	-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...22	↓	↓	↓	↓
23	3 May 2018	€34.80	Buy	€52.00
24	8 May 2018	€38.15	Buy	€52.00
25	6 June 2018	€36.75	Buy	€53.00
26	Today	€32.25	Buy	€53.00

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First Berlin notes that it has concluded a contract with the issuer to prepare financial analyses and is paid for that by the issuer. First Berlin makes the financial analysis simultaneously available for all interested security financial services companies. First Berlin thus believes that it fulfils the requirements of section 64 WpHG for minor non-monetary benefits.

PRICE TARGET DATES

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.

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

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.

SUBJECT TO CHANGE

The opinions contained in the financial analysis reflect the assessment of the author on the day of publication of the financial analysis. The author of the financial analysis reserves the right to change such opinion without prior notification.

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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