Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

Q3/2016 results

RATING	**BUY**
PRICE TARGET	**€45.00**
Return Potential	141.0%
Risk Rating	High

4 BIOSIMILARS EACH EXPECTED TO GENERATE TRIPLE DIGIT FEES

As was the case in Q2/16, Q3/16 revenues and net profit were below the figures booked in Q1/16 and the prior year quarter due to a dip in partner-financed development spending on FYB201 and FYB203. However, expenditure on both these projects is due to pick up in the final quarter of this year and management has maintained its guidance for full year revenues of €20m. Meanwhile, the product portfolio, which now encompasses four biosimilar product candidates, continues to develop according to plan. Formycon plans that its 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.

Spending on FYB201, FYB203 to pick up in Q4; FY guidance maintained Formycon's Q3/16 report showed a 38.8% decline in total revenues to €3.0m (Q3/15: €4.9m) while the net result came in at €-1.4m (Q2/15: €0.0m). Both Q3/16 and Q2/16 revenue and net profit were well below figures of €6.3m and €-0.2m respectively booked in the first quarter of this year. The reason for the decline in sales and profit in Q2/16 and Q3/16 compared with Q1/16 and the prior year quarter is that Formycon spent less on development of its outlicensed projects, FYB201 and FYB203, in the second and third quarter of the current year and more on development of FYB202 and FYB205 which have not yet been partnered. Development of FYB201 and FYB203 is financed by Formycon's licensing partners, respectively Bioeq IP AG and Santo, and appears on Formycon's P&L as sales revenue. Formycon carries the cost of development of FYB202 and FYB205.

Filing of FYB201 NDA scheduled towards end 2018 FYB201 is the furthest advanced of the biosimilar candidates Formycon is currently developing. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	0.41	12.67	17.15	19.00	36.60	31.50
Y-o-y growth	n.a.	2970.3%	35.4%	10.8%	92.6%	-13.9%
EBIT (€m)	-7.74	0.87	0.54	-2.28	3.22	-1.31
EBIT margin	-1876.5%	6.9%	3.1%	-12.0%	8.8%	-4.2%
Net income (€m)	-7.74	0.86	0.58	-2.09	3.41	-1.11
EPS (diluted) (€)	-0.90	0.10	0.06	-0.23	0.38	-0.12
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	0.00	-0.63	-0.24	-2.20	1.71	-0.39
Net gearing	-74.5%	-70.4%	-81.6%	-79.8%	-78.0%	-79.3%
Liquid assets (€m)	10.38	9.22	20.30	18.10	19.81	19.42

RISKS

Product failures, lack of funding, change in regulatory environment, new product innovations making biosimilars obsolete

COMPANY PROFILE

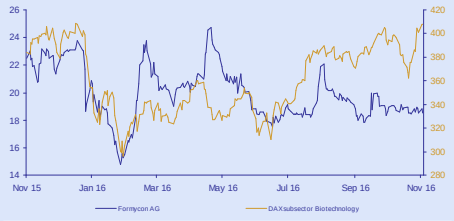
Formycon AG is a Munich, Germany based pharmaceuticals company specializing in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

As of 16 Nov 2016	
Closing Price	€ 18.68
Shares outstanding	9.06m
Market Capitalisation	€ 169.25m
52-week Range	€ 14.76 / 24.75
Avg. Volume (12 Months)	9,977

Multiples	2015	2016E	2017E
P/E	288.9	n.a.	49.6
EV/Sales	8.9	8.1	4.2
EV/EBIT	285.0	n.a.	47.5
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2016*	
Liquid Assets	€ 17.79m
Current Assets	€ 21.54m
Intangible Assets	€ 1.10m
Total Assets	€ 25.43m
Current Liabilities	€ 0.49m
Shareholders' Equity	€ 23.70m

*30 Sep balance sheet not published

SHAREHOLDERS

Founders	23.5%
Institutional Investors	50.0%
Free Float	26.5%

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Figure 1: Q3/16 results vs. our forecasts

in EURm	Q3/16A	Q3/16E	Delta	Q3/15A	Delta	9M/16A	9M15A	Delta
Sales	2.97	4.50	-50.0%	4.85	-38.8%	11.83	14.71	-19.6%
Net income	-1.39	-1.20	-	-0.02	n.m.	-2.57	1.51	n.m.
margin	*-46.8%*	*-26.7%*	-	*-0.4%*	-	*neg.*	*neg.*	-

Source: Formycon; First Berlin Equity Research estimates

In October 2015 Formycon announced that the compound's reference product is Lucentis (Ranibizumab). Lucentis is indicated for opthalmic conditions including age-related macular degeneration and diabetic macular edema. Worldwide sales were USD3.7bn in 2015. 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 next 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	CLINICAL PHASE 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

Formycon developing biosimilars for 90% of intraocular anti-VEGF market by value 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. 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 opthalmic conditions including age-related macular degeneration and diabetic macular edema. It is the main competitor to Lucentis and in 2015 generated worldwide sales of USD4.1bn. 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 Management has indicated that development work on FYB201 and FYB203 will gather pace again in Q4 2016 and that revenues will accordingly pick up. The company has retained its full 2016 sales guidance of €20m on the basis of increasing revenues from these partnered projects.

We are leaving our full year sales forecast of €19m as well as our net profit forecast of €-2.1m unchanged as we do not expect the profit which Formycon generates on development work on FYB201 and FYB203 to outweigh the ongoing costs of the development of FYB202 and FYB205. 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	12%	15%	n.a.	6 Years
FYB201	nAMD,DR (US)	€84M	113K	€9,068	€1,025M	17%	€409M	12%	15%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€62M	197K	€4,859	€957M	17%	€272M	12%	15%	n.a.	9 Years
FYB203	nAMD,DR (US)	€187M	212K	€8,591	€1,821M	17%	€728M	12%	15%	n.a.	7 Years
FYB202 & FYB205	n.a.	€224M									
PACME PV		€624M									
Costs PV[4)]		€243M									
NPV		€382M									
Milestones		€4M									
Net Cash		€18M									
Fair Value		€404M									
Share Count		9,060K									
Fair Value Per Share		€44.55									

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	2016E	2017E	2018E
Revenue	**12.7**	**17.2**	**19.0**	**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**	**19.0**	**36.6**	**31.5**
Cost of goods sold	-5.9	-11.1	-15.2	-27.0	-25.7
Gross profit	**6.8**	**6.1**	**3.8**	**9.6**	**5.8**
Personnel costs	-2.9	-3.2	-3.4	-3.5	-4.0
Depreciation and amortisation	-1.1	-0.9	-1.0	-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**	**-2.3**	**3.2**	**-1.3**
Net financial result	0.0	0.0	0.2	0.2	0.2
Pre-tax income (EBT)	**0.9**	**0.6**	**-2.1**	**3.4**	**-1.1**
Income taxes	0.0	0.0	0.0	0.0	0.0
Net income / loss	**0.9**	**0.6**	**-2.1**	**3.4**	**-1.1**
Diluted EPS (in €)	**0.10**	**0.06**	**-0.23**	**0.38**	**-0.12**
EBITDA	**1.9**	**1.5**	**-1.3**	**4.2**	**-0.3**
Ratios					
Gross margin on output	53.4%	35.4%	20.0%	26.2%	18.4%
EBIT margin on output	6.9%	3.1%	-12.0%	8.8%	-4.2%
EBITDA margin on output	15.3%	8.6%	-6.8%	11.5%	-1.0%
Net margin on output	6.8%	3.4%	-11.0%	9.3%	-3.5%
Tax rate	-0.2%	-0.2%	0.0%	0.0%	0.0%
Expenses as % of output					
Cost of goods sold	-46.6%	-64.6%	-80.0%	-73.8%	-81.6%
Personnel costs	-22.8%	-18.7%	-17.9%	-9.6%	-12.7%
Depreciation and amortisation	-8.5%	-5.4%	-5.1%	-2.7%	-3.2%
Net other operating exp.	-15.2%	-8.2%	-8.9%	-5.2%	-6.7%
Y-Y Growth					
Revenues	2970.3%	35.4%	10.8%	92.6%	-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	2016E	2017E	2018E
Assets					
Current assets, total	**12.8**	**23.3**	**21.4**	**26.3**	**25.0**
Cash and cash equivalents	0.3	0.6	1.0	1.8	1.6
Other liquid assets	8.9	19.7	17.1	18.0	17.8
Receivables	3.3	2.8	3.0	5.9	5.0
Inventories	0.3	0.2	0.3	0.5	0.5
Other current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets, total	**4.1**	**3.8**	**3.9**	**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	2.9	3.3	3.8
Goodwill & other intangibles	1.3	1.1	0.9	0.7	0.6
Other assets	0.0	0.1	0.1	0.2	0.2
Total assets	**16.9**	**27.1**	**25.3**	**30.5**	**29.5**
Shareholders' equity & debt					
Current liabilities, total	**3.3**	**1.6**	**1.9**	**3.6**	**3.1**
Accounts payable	2.3	0.6	0.7	1.4	1.2
Other current liabilities	1.0	1.0	1.2	2.3	1.9
Long-term liabilities, total	**0.5**	**0.7**	**0.8**	**1.5**	**1.9**
Provisions	0.5	0.7	0.8	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**	**22.7**	**25.4**	**24.5**
Total consolidated equity and debt	**16.9**	**27.1**	**25.3**	**30.5**	**29.5**

Key figures					
Current ratio (x)	3.94	14.52	11.35	7.22	7.97
Quick ratio (x)	3.83	14.38	11.20	7.07	7.82
Financial leverage (%)	-70.4	-81.6	-79.8	-78.0	-79.3
Book value per share (€)	1.52	2.74	2.50	2.80	2.70
Return on equity (ROE)	6.4%	3.0%	-8.8%	14.2%	-4.5%

CASH FLOW STATEMENT

All figures in EURm	2014A	2015A*	2016E	2017E	2018E
EBIT	**0.9**	**0.5**	**-2.3**	**3.2**	**-1.3**
Depreciation and amortisation	1.1	0.9	1.0	1.0	1.0
EBITDA	**1.9**	**1.5**	**-1.3**	**4.2**	**-0.3**
Changes in working capital	-2.0	-1.1	-0.1	-1.4	1.1
Other adjustments	0.0	0.1	0.2	0.2	0.2
Operating cash flow	**0.0**	**0.5**	**-1.2**	**2.9**	**0.9**
CAPEX	-0.6	-0.6	-1.0	-1.2	-1.3
Free cash flow	**-0.6**	**-0.1**	**-2.2**	**1.7**	**-0.4**
Debt financing, net	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Equity financing, net	**0.0**	**11.2**	**0.0**	**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**	**-2.2**	**1.7**	**-0.4**
Cash and liquid assets, start of the year	0.9	9.2	20.3	18.1	19.8
Cash and liquid assets, end of the year	**0.3**	**20.3**	**18.1**	**19.8**	**19.4**
EBITDA/share (in €)	**0.2**	**0.2**	**-0.1**	**0.5**	**0.0**

Y-Y Growth					
Operating cash flow	n.a.	n.m.	n.m.	n.m.	-67.8%
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.

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Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	17 April 2013	€3.50	Buy	€7.30
2...15	↓	↓	↓	↓
16	8 March 2016	€22.11	Buy	€42.00
17	21 April 2016	€21.36	Buy	€42.00
18	21 September 2016	€18.30	Buy	€45.00
19	Today	€18.68	Buy	€45.00

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- **key sources of information in the preparation of this research report**
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- **sensitivity of valuation parameters**

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