Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

Update

RATING	**BUY**
PRICE TARGET	**€ 48.00**
Return Potential	43.6%
Risk Rating	High

RAISING PRICE TARGET ON FYB202 PARTNERSHIP DEAL

Since our last update in early May, Formycon has revealed that the reference product for FYB202 (the third of the four biosimilar drugs it has under development) is Stelara. Stelara is indicated for psoriasis, psoriatic arthritis and Crohn's disease. Worldwide sales rose 17.3% to USD1.8bn in H1/17. The consultancy Evaluate Pharma expects worldwide sales of USD4.5bn for the drug in 2022. Formycon signed a binding term sheet for the conclusion of a partnership deal for FYB202 in July. The structure of the FYB202 partnership differs from those concluded for FYB201 and FYB203. The main features of the FYB201 and FYB203 partnership deals are partner funding of all development, production and marketing costs of the biosimilar with Formycon participating in sales following launch via a low double digit percentage royalty. Under the FYB202 deal Formycon will bear 30% of development costs but will also participate in up to 30% of worldwide marketing revenues. Formycon's product portfolio continues to develop rapidly and 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. Success-based payments are expected to be in the triple digit millions of Euro over the lifetime of each of Formycon's biosimilars. We have adjusted our valuation model to reflect the partnership deal for FYB202 and now see fair value at €48.00 per share (previously: €45.00). We maintain our Buy recommendation.

Worldwide biosimilars market CAGR of 27.4% projected to 2025 Relative to forecast future growth, the biosimilars market is still in its infancy. The worldwide market was worth USD3.4bn in 2016. The consultancy Quintiles IMS expects the market to grow at a CAGR of over 45% to more than USD15bn by 2020 and projects a CAGR of 27.4% for the period 2016-2025 to USD30bn.

Over 30 biosimilars currently approved in Europe The EU accounted for around 80% of 2016 biosimilar sales. The EU is currently the largest market for biosimilars because it established a legislative framework…(please turn over)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016	2017E	2018E
Revenue (€ m)	0.41	12.67	17.15	19.66	28.20	29.30
Y-o-y growth	n.a.	2970.3%	35.4%	14.6%	43.4%	3.9%
EBIT (€ m)	-7.74	0.87	0.54	-4.07	0.11	0.15
EBIT margin	-1876.5%	6.9%	3.1%	-20.7%	0.4%	0.5%
Net income (€ m)	-7.74	0.86	0.58	-4.07	0.29	0.36
EPS (diluted) (€)	-0.90	0.10	0.06	0.00	0.03	0.04
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	0.00	-0.63	-0.24	-6.40	1.87	-1.01
Net gearing	-74.5%	-70.4%	-81.6%	-66.9%	-81.2%	-76.5%
Liquid assets (€ m)	10.38	9.22	20.30	13.97	21.34	20.34

RISKS

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

COMPANY PROFILE

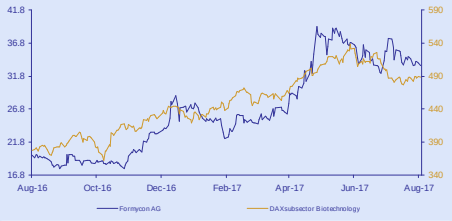
Formycon AG is a Munich, Germany based pharmaceuticals company specializing in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

As of 28 Aug 2017	
Closing Price	€ 33.43
Shares outstanding	9.29m
Market Capitalisation	€ 310.57m
52-week Range	€ 17.85 / 39.32
Avg. Volume (12 Months)	13,825

Multiples	2016	2017E	2018E
P/E	n.a.	1072.4	869.2
EV/Sales	14.8	10.3	9.9
EV/EBIT	n.a.	2651.2	1951.4
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2016	
Liquid Assets	€ 13.97m
Current Assets	€ 20.67m
Intangible Assets	€ 0.99m
Total Assets	€ 25.19m
Current Liabilities	€ 3.57m
Shareholders' Equity	€ 20.89m

SHAREHOLDERS

Founders	20.0%
Institutional Investors	50.0%
Free Float	30.0%

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…as early as 2003. The EU approved its first biosimilar in 2006. Over 30 biosimilars have been approved in the EU since then.

43 biosimilars currently in clinical development in the US By contrast the U.S. did not pass its Biologics Price Competition and Innovation Act until 2010 and the first biosimilar was only approved two years ago. Five biosimilars have so far been approved in the U.S. However, the U.S. biosimilar market can be expected to close the gap on Europe over the next five years as filings for approval with the FDA accelerate. The FDA has so far accepted 17 dossiers for review of which it has approved five. A further 17 filings are expected to be made by the end of this year. 43 biosimilars are in clinical development in the U.S. – the majority of which are in phase III. Branded biologics targeted by biosimilar developers include Abbvie's Humira (indications include rheumatic arthritis, Crohn's disease, psoriasis), Amgen's Neulasta (indications include rheumatic arthritis, Crohn's disease, psoriasis), Roches' Avastin (indications include colorectal, lung, breast, kidney, ovary, cervical cancers), Herceptin (indications include breast and stomach cancers) and Rituxan (indications include stimulation of white blood cell production during chemotherapy). Together these products represented a market of USD20bn in 2016.

Combined Lucentis/Eylea sales reached USD4.4bn in H1/17 Formycon is focused on the "third wave" of biosimilars, i.e on biosimilars whose reference products go off patent after 2020. The company currently has four biosimilars under development as shown in figure 1 below. The reference products for FYB201 and FYB203 are respectively Lucentis and Eylea. Lucentis and Eylea are intraocular anti-VEGF (vascular endothelial growth factor) drugs which are indicated for opthalmic conditions including age-related macular degeneration and diabetic macular edema. Combined sales of Lucentis and Eylea climbed 6.5% during H1/17 to USD4.4bn (H1/16: USD4.1bn). This figure corresponds to ca. 90% of the value of the intraocular anti-VEGF market.

Figure 1: Formycon's current product pipeline

Product candidate	Originator (INN)	Disease area	Partner	Clinical Phase
FYB201	Lucentis Ranibizumab	Opthalmology	Bioeq IP AG	Phase III
FYB202	Stelara Ustekinumab	Psoriasis, psioratic arthritis Crohn's disease	Santo Holding GmbH	Preclinical
FYB203	Eylea Aflibercept	Opthalmology	Santo Holding GmbH	Preclinical
FYB205	Undisclosed	Undisclosed	not partnered	Preclinical

Source: Formycon

Stelara sales forecast to reach USD4.5bn by 2022 In May of this year Formycon announced that 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 17.3% to USD1.8bn in H1/17 (H1/16: USD1.5bn). Stelara is one of five drugs indicated for psoriasis and psoriatic arthritis with worldwide annual sales of over USD1bn (see figure 2 below). Stelara's growth during H1/17 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. The drug offers first in class potential as a treatment alternative for ulcerative colitis due to the ineffectiveness of anti-TNF and anti-IL17 treatments. The consultancy Evaluate Pharma expects worldwide sales of USD4.5bn for Stelara in 2022.

Figure 2: Stelara and leading peers

Drug (INN)	Originator	Disease areas	H1 2017 sales USDm
Cosentyx Sekukinumab	Novartis	Psoriasis, psioratic arthritis Crohn's disease	900
Enbrel Etanercept	Amgen	Psoriasis, psioratic arthritis rheumatoid arthritis	3,852
Humira Adalimumab	AbbVie	Psoriasis, psioratic arthritis rheumatoid arthritis, Crohn's disease, ulcerative colitis	8,834
Remicade Infliximab	Johnson & Johnson	Psoriasis, psioratic arthritis Crohn's disease	3,202
Stelara Ustekinumab	Johnson & Johnson	Psoriasis, psioratic arthritis Crohn's disease	1,806

Source: Companies

Completion of FYB201 phase III recruitment expected by end Q3 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. We expect completion of recruitment by the end of the current quarter and filing of an NDA (new drug application) for FYB201 in the US towards the end of 2018. Patent expiry for Lucentis is June 2020 in the US and January 2022 in the EU. For Stelara patent protection expires in September 2023 in the US and in July 2024 in the EU. Patent expiry for Eylea is June 2023 in the US and May 2025 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.

Cumulative royalty income expected to top €100m for each of FYB201 and FYB203 Formycon concluded partnerships for FYB201 and FYB203 in 2013 and 2015 respectively. The partnership agreements for FYB201 and FYB203 entailed a mid single digit upfront payment to Formycon, funding of all development, production and marketing costs of the Formycon biosimilar by the partner and Formycon's participation in sales following launch via a low double digit royalty. The cumulative royalty income to Formycon from these partnerships is expected to exceed €100m for each product.

FYB202 partnership and capital raise announced in July In July 2017 Formycon announced a partnership for FYB202 with Santo Holding GmbH. The structure of the FYB202 partnership differs from those concluded for FYB201 and FYB203. Under the FYB202 deal Formycon will bear 30% of development costs but will also participate in up to 30% of worldwide marketing revenues. In the same month Formycon also announced the closing of a private placement transaction generating gross proceeds of €6m through the issue of 190,500 shares at €31.50 per share. The proceeds will be used to fund the co-investment in FYB202 and the ongoing development of the biosimilar drug portfolio.

Maintaining Buy recommendation with price target of €48.00 (previously: €45.00) We have adjusted our pipeline valuation model to reflect the FYB202 partnership and the July capital raise (see figures 3 and 4 below). We now see fair value for the Formycon share at €48.00 (previously: €45.00). We maintain our Buy recommendation.

Figure 3: Pipeline valuation

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.	5 Years
FYB201	nAMD,DR (US)	€86M	113K	€9,068	€1,025M	17%	€407M	12%	15%	n.a.	3 Years
FYB202	Pso,CrD (ex-US)	€41M	40K	€27,500	€1,101M	17%	€391M	12%	15%	n.a.	7 Years
FYB202	Pso,CrD (US)	€142M	57K	€44,750	€2,572M	17%	€890M	12%	15%	n.a.	6 Years
FYB203	nAMD,DR (ex-US)	€58M	197K	€4,859	€957M	17%	€271M	12%	15%	n.a.	8 Years
FYB203	nAMD,DR (US)	€193M	212K	€8,591	€1,821M	17%	€724M	12%	15%	n.a.	6 Years
FYB205	n.a.	€87M									
PACME PV		€673M									
Costs PV[4)]		€271M									
NPV		€402M									
Downpayments and Milestones		€29M									
Net Cash		€20M									
Fair Value		€450M									
Share Count		9,290K									
Fair Value Per Share		€48.44									

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

Figure 4: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	**€639.0M**	**€672.8M**	**5.3%**
Costs PV	€249.0M	€271.3M	8.9%
NPV	**€390.0M**	**€401.5M**	**3.0%**
Downpayments and Milestones PV	€4.0M	€28.5M	n.m.
Net Cash	€14.0M	€20.0M	42.9%
Fair Value	€408.0M	€450.0M	10.3%
Share Count	9,060K	9,290K	2.5%
Price Target	**€45.03**	**€48.44**	**7.6%**

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EURm	2014A	2015A	2016A	2017E	2018E
Revenue	**12.7**	**17.2**	**19.7**	**28.2**	**29.3**
Increase/decrease in unfinished products	0.0	0.0	0.0	0.0	0.0
Total output	**12.7**	**17.2**	**19.7**	**28.2**	**29.3**
Cost of goods sold	-5.9	-11.1	-17.9	-21.9	-22.1
Gross profit	**6.8**	**6.1**	**1.7**	**6.3**	**7.2**
Personnel costs	-2.9	-3.2	-3.4	-3.5	-4.0
Depreciation and amortisation	-1.1	-0.9	-0.7	-0.8	-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**	**-4.1**	**0.1**	**0.1**
Net financial result	0.0	0.0	0.0	0.2	0.2
Pre-tax income (EBT)	**0.9**	**0.6**	**-4.1**	**0.3**	**0.4**
Income taxes	0.0	0.0	0.0	0.0	0.0
Net income / loss	**0.9**	**0.6**	**-4.1**	**0.3**	**0.4**
Diluted EPS (in €)	**0.10**	**0.06**	**0.00**	**0.03**	**0.04**
EBITDA	**1.9**	**1.5**	**-3.4**	**0.9**	**1.1**
Ratios					
Gross margin on output	53.3%	35.4%	8.8%	22.3%	24.6%
EBIT margin on output	6.9%	3.1%	-20.7%	0.4%	0.5%
EBITDA margin on output	15.3%	8.6%	-17.2%	3.2%	3.8%
Net margin on output	6.8%	3.4%	-20.7%	1.0%	1.2%
Tax rate	-0.2%	-0.2%	0.1%	0.0%	0.0%
Expenses as % of output					
Cost of goods sold	-46.7%	-64.6%	-91.2%	-77.7%	-75.4%
Personnel costs	-22.9%	-18.7%	-17.3%	-12.4%	-13.7%
Depreciation and amortisation	-8.5%	-5.4%	-3.6%	-2.8%	-3.2%
Net other operating exp.	-15.0%	-8.2%	-8.6%	-6.7%	-7.2%
Y-Y Growth					
Revenues	2970.3%	35.4%	14.6%	43.4%	3.9%
Operating income	n.m.	-38.1%	n.m.	n.m.	35.9%
Net income/ loss	n.m.	-32.9%	n.m.	n.m.	24.9%

BALANCE SHEET

All figures in EURm	2014A	2015A	2016A	2017E	2018E
Assets					
Current assets, total	**12.8**	**23.3**	**20.7**	**27.0**	**28.1**
Cash and cash equivalents	0.3	0.6	3.0	1.4	1.5
Other liquid assets	8.9	19.7	11.0	19.9	18.9
Receivables	3.3	2.8	5.2	4.2	5.9
Inventories	0.3	0.2	0.6	0.6	0.7
Other current assets	0.0	0.0	0.9	0.8	1.2
Non-current assets, total	**4.1**	**3.8**	**4.5**	**3.5**	**4.4**
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	3.4	2.5	3.5
Goodwill & other intangibles	1.3	1.1	1.0	0.8	0.7
Other assets	0.0	0.1	0.1	0.2	0.2
Total assets	**16.9**	**27.1**	**25.2**	**30.5**	**32.5**
Shareholders' equity & debt					
Current liabilities, total	**3.3**	**1.6**	**3.6**	**3.1**	**4.1**
Accounts payable	2.3	0.6	2.3	2.0	2.6
Other current liabilities	1.0	1.0	1.3	1.1	1.5
Long-term liabilities, total	**0.5**	**0.7**	**0.7**	**1.1**	**1.8**
Provisions	0.5	0.7	0.7	1.1	1.2
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**	**20.9**	**26.3**	**26.6**
Total consolidated equity and debt	**16.9**	**27.1**	**25.2**	**30.5**	**32.5**
Key figures					
Current ratio (x)	3.94	14.52	5.79	8.70	6.85
Quick ratio (x)	3.83	14.38	5.61	8.52	6.67
Financial leverage (%)	-70.4	-81.6	-66.9	-81.2	-76.5
Book value per share (€)	1.52	2.74	2.30	2.86	2.90
Return on equity (ROE)	6.4%	3.0%	-17.8%	1.2%	1.4%

CASH FLOW STATEMENT

All figures in EURm	2014A	2015A	2016A	2017E	2018E
EBIT	**0.9**	**0.5**	**-4.1**	**0.1**	**0.1**
Depreciation and amortisation	1.1	0.9	0.7	0.8	1.0
EBITDA	**1.9**	**1.5**	**-3.4**	**0.9**	**1.1**
Changes in working capital	-2.0	-1.1	-1.7	0.5	-0.5
Other adjustments	0.0	0.1	0.1	0.2	0.2
Operating cash flow	**0.0**	**0.5**	**-5.0**	**1.6**	**0.8**
CAPEX	-0.6	-0.6	-1.4	0.3	-1.8
Free cash flow	**-0.6**	**-0.1**	**-6.4**	**1.9**	**-1.0**
Debt financing, net	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Equity financing, net	**0.0**	**11.2**	**0.1**	**5.5**	**0.0**
Other changes in cash	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Net cash flows	**-0.6**	**11.1**	**-6.3**	**7.4**	**-1.0**
Cash and liquid assets, start of the year	0.9	9.2	20.3	14.0	21.3
Cash and liquid assets, end of the year	**0.3**	**20.3**	**14.0**	**21.3**	**20.3**

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...17	↓	↓	↓	↓
18	21 September 2016	€18.30	Buy	€45.00
19	27 November 2016	€18.68	Buy	€45.00
20	4 May 2017	€28.30	Buy	€45.00
21	Today	€33.43	Buy	€48.00

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First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

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The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

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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