Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

Coherus will market FYB201 in the U.S.

RATING	**BUY**
PRICE TARGET	**€ 51.00**
Return Potential	57.4%
Risk Rating	High

COHERUS' SUCCESS WITH UDENYCA BODES WELL FOR FYB201

The U.S. biosimilars company Coherus has signed an exclusive marketing and distribution agreement for the U.S. with respect to Formycon's furthest advanced biosimilar candidate, FYB201. Coherus' recent success suggests that this deal will work very well for Formycon. This year Coherus secured a 19% unit share of the U.S. pegfilgrastim market for its biosimilar Udenyca within only nine months of the product's January 2019 launch. Udenyca is a biosimilar of Amgen's Neulasta, which had U.S. sales of USD3.9bn in 2018. The deep and rapid inroads into the pegfilgrastim market made by Coherus with Udenyca suggest that it will be a strong marketing partner for Formycon's FYB201 biosimilar whose reference product, Lucentis, generated U.S. sales of USD1.7bn in 2018. FYB201's U.S. launch is planned for 2021 and Formycon will earn staggered royalties which enter double digits on its sales and so stands to benefit directly from Coherus' marketing prowess. The launch of FYB201 in Europe is planned for 2022 and will be followed by the launches of FYB202 (reference product: Stelara; worldwide 2018 sales: USD5.2bn) and FYB203 (reference product: Eylea; worldwide 2018 sales: USD6.7bn) in both the U.S. and Europe between 2023 and 2025. We maintain our Buy recommendation and price target of €51.00.

FYB201 Biologics License Application submission to FDA later this quarter
Bioeq, the owner of the global commercialisation rights to FYB201, has signed an exclusive marketing and distribution agreement with Coherus BioSciences (Coherus) for FYB201 in the U.S. Bioeq plans to file the Biologics License Application for FYB201 with the FDA later this quarter and Coherus expects to launch FYB201 in the U.S. in 2021. Lucentis goes off patent in the U.S. in June 2020.

Coherus eyeing additional market share beyond 20% with Udenyca in 2020
Amgen's Neulasta (pegfilgrastim) is used to stimulate the production of white blood cells to fight infection in patients undergoing chemotherapy. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018	2019E	2020E
Revenue (€ m)	16.92	19.53	29.00	42.99	35.00	38.00
Y-o-y growth	34.0%	15.4%	48.5%	48.2%	-18.6%	8.6%
EBIT (€ m)	0.54	-4.07	-1.54	7.13	-2.00	-2.00
EBIT margin	3.2%	-20.8%	-5.3%	16.6%	-5.7%	-5.3%
Net income (€ m)	0.58	-4.07	-1.58	7.10	-1.97	-1.96
EPS (diluted) (€)	0.06	-0.45	-0.17	0.76	-0.20	-0.20
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-0.10	-6.40	-4.66	-3.73	-7.29	-3.47
Net gearing	-81.6%	-66.9%	-60.6%	-37.0%	-45.0%	-39.5%
Liquid assets (€ m)	20.30	13.97	15.48	12.31	21.46	17.99

RISKS

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

COMPANY PROFILE

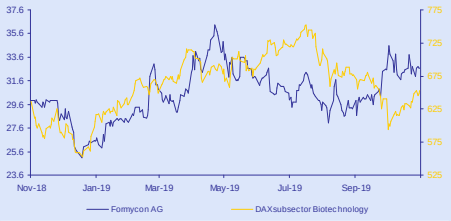
Formycon AG is a Munich, Germany based pharmaceuticals company specialising in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

	As of 08 Nov 2019
Closing Price	€ 32.40
Shares outstanding	10.00m
Market Capitalisation	€ 324.00m
52-week Range	€ 25.05 / 36.30
Avg. Volume (12 Months)	5,960

Multiples	2018	2019E	2020E
P/E	42.8	n.a.	n.a,.
EV/Sales	7.1	8.7	8.0
EV/EBIT	42.6	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

	As of 30 Jun 2019
Liquid Assets	€ 7.96m
Current Assets	€ 28.26m
Intangible Assets	€ 0.72m
Total Assets	€ 54.01m
Current Liabilities	€ 2.13m
Shareholders' Equity	€ 49.81m

SHAREHOLDERS

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

Analyst: Simon Scholes, Tel. +49 (0)30 - 80 93 96 94

Its U.S. patent expired in October 2015, and on 2 November 2018 Udenyca was the second pegfilgrastim biosimilar approved by the FDA. The first was Mylan's Fulphila, but by the end of August 2019, this product had achieved a market share of only ca. 3%. Coherus did not begin the full scale launch of Udenyca until 3 January 2019, but by the end of September it had already achieved a unit market share of 19%. In its Q3 report; Coherus states that its aim is to exit 2019 with a pegfilgrastim market share of 20% or greater, and gain additional market share beyond 20% in 2020.

6 November: an eventful day in the biosimilars sector The Bioeq/Coherus announcement came on the same day as a similar agreement announced between Formycon's competitor, Samsung Bioepis, and Biogen. This deal includes both the opthalmology biosimilar candidates which Samsung Bioepis currently has under development - SB11 in phase III for which the reference product is Lucentis and SB15 (preclinical) for which the reference product is Eylea. Completion of the SB11 phase III trial is scheduled for the end of this month. The FYB201 phase III trial was completed in June 2018. This suggests that FYB201 will reach the U.S. market ahead of SB11. Formycon's Eylea biosimilar candidate, FYB203, is currently also at the preclinical stage but Formycon expects the phase III trial to begin in mid-2020. Samsung Bioepis has not announced a schedule for the start of the clinical phase of SB15 development. Also on 6 November, the FDA approved a third pegfilgrastim biosimilar – Sandoz' Ziextenzo. Coherus expects to gain further market share with Udenyca despite competition from Sandoz.

Momenta/Mylan Eylea biosimilar phase III trial has started in advance of FYB203 trial As we wrote in June, the most advanced competing Eylea biosimilar candidate is M710 which is being co-developed by Momenta Pharmaceuticals (headquartered in Cambridge, Massachussetts) and Mylan N.V. (headquartered in Pittsburgh, Pennsylvania). Recruitment to the phase III trial of M710 started in August 2018. Completion of the trial is scheduled for December 2020. We continue to assume that both M710 and Formycon's Eylea biosimilar candidate will reach the U.S. market market soon after patent expiry of the reference product in November 2023.

Coherus has Eylea biosimilar in preclinical development but has not given clinical timeline Prior to the conclusion of the agreement with Bioeq, Coherus had its own Lucentis biosimilar (CHS-2020) in preclinical development. Coherus states that the agreement with Bioeq will allow it to divert resources previously earmarked for CHS-2020 to development of its own Eylea biosimilar candidate (CHS-3351). CHS-3351 is also currently in preclinical development, but Coherus has not announced a timeline for the transition to the clinic.

FYB's Stelara biosimilar, FYB202, is well placed to reach market before competition In late October Formycon announced the start of the phase I trial of its Stelara biosimilar candidate, FYB202. The most advanced competing Stelara biosimilar candidate is NeuLara, which is under development at the Australian company, NeuClone. The phase I trial of NeuLara bagan in mid-October. The Neulara phase I trial is taking place under the Clinical Trial Notification (CTN) scheme of the Australian Therapeutic Goods Administration (TGA). Meanwhile, FYB has held scientific advice meetings with the FDA and the EMA at which development steps up to submission of the marketing authorisation dossier were discussed. Given the greater depth of FYB's consultation with the regulatory authorities in the U.S. and Europe, we think FYB202 will reach major markets ahead of NeuLara.

Buy recommendation maintained at an unchanged price target of €51.00 The marketing agreement with Coherus for FYB201 in the U.S. strengthens our confidence that Formycon will play a major role on the biosimilar market. We maintain our Buy recommendation and price target of €51.00.

Figure 1: 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)	€158M	327K	€5,250	€1,716M	21%	€414M	9%	12%	n.a.	3 Years
FYB201	nAMD,DR (US)	€156M	144K	€9,068	€1,305M	21%	€416M	9%	12%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€56M	56K	€27,500	€1,532M	17%	€472M	9%	15%	n.a.	5 Years
FYB202	Pso,CrD (US)	€141M	47K	€44,750	€2,115M	17%	€1,099M	9%	15%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€61M	417K	€4,859	€2,024M	17%	€591M	9%	15%	n.a.	6 Years
FYB203	nAMD,DR (US)	€99M	392K	€8,591	€3,365M	17%	€785M	9%	15%	n.a.	4 Years
FYB205	n.a.	€96M									
PACME PV		€768M									
Costs PV[4)]		€318M									
NPV		€449M									
Downpayments and Milestones		€40M									
Proforma net Cash		€20M									
Fair Value		€510M									
Share Count		10,000K									
Fair Value Per Share		€51.00									

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	2015A	2016A	2017A	2018A	2019E	2020E
Revenue	**16.9**	**19.5**	**29.0**	**43.0**	**35.0**	**38.0**
Increase/decrease in unfinished products	0.0	0.0	0.4	0.6	0.0	0.0
Total output	**16.9**	**19.5**	**29.4**	**43.6**	**35.0**	**38.0**
Other operating income	0.2	0.1	0.1	0.1	0.2	0.2
Cost of goods sold	-8.9	-15.4	-21.2	-25.8	-24.2	-26.3
Gross profit	**8.3**	**4.3**	**8.4**	**17.9**	**11.0**	**11.9**
Personnel costs	-3.9	-5.1	-6.3	-7.0	-9.0	-9.8
Depreciation and amortisation	-0.9	-0.7	-0.8	-0.9	-0.7	-0.8
Other operating expenses	-2.9	-2.6	-2.8	-3.0	-3.2	-3.3
Operating income (EBIT)	**0.5**	**-4.1**	**-1.5**	**7.1**	**-2.0**	**-2.0**
Net financial result	0.0	0.0	0.0	0.0	0.0	0.0
Pre-tax income (EBT)	**0.6**	**-4.1**	**-1.6**	**7.1**	**-2.0**	**-2.0**
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net income / loss	**0.6**	**-4.1**	**-1.6**	**7.1**	**-2.0**	**-2.0**
Diluted EPS (in €)	**0.06**	**-0.45**	**-0.17**	**0.76**	**-0.20**	**-0.20**
EBITDA	**1.5**	**-3.4**	**-0.8**	**8.0**	**-1.3**	**-1.2**
Ratios						
Gross margin on output	48.9%	21.9%	28.4%	41.0%	31.3%	31.3%
EBIT margin on output	3.2%	-20.8%	-5.2%	16.4%	-5.7%	-5.3%
EBITDA margin on output	8.7%	-17.3%	-2.6%	18.4%	-3.6%	-3.1%
Net margin on output	3.4%	-20.8%	-5.4%	16.3%	-5.6%	-5.2%
Tax rate	-0.2%	0.1%	-0.2%	0.0%	0.0%	0.0%
Expenses as % of output						
Cost of goods sold	-52.5%	-78.8%	-72.0%	-59.2%	-69.1%	-69.1%
Personnel costs	-22.8%	-26.1%	-21.5%	-16.1%	-25.8%	-25.8%
Depreciation and amortisation	-5.5%	-3.6%	-2.7%	-2.1%	-2.1%	-2.1%
Net other operating exp.	-16.0%	-12.6%	-9.1%	-6.5%	-8.7%	-8.2%
Y-Y Growth						
Revenues	34.5%	15.4%	48.5%	48.2%	-18.6%	8.6%
Operating income	-38.1%	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	-32.9%	n.m.	n.m.	n.m.	n.m.	n.m.

BALANCE SHEET

All figures in EURm	2015A	2016A	2017A	2018A	2019E	2020E
Assets						
Current assets, total	**23.3**	**20.7**	**26.6**	**18.7**	**27.8**	**26.0**
Cash and cash equivalents	0.6	3.0	4.5	7.3	14.0	11.4
Other liquid assets	19.7	11.0	11.0	5.0	7.5	6.6
Receivables	2.8	5.2	10.5	5.2	4.9	6.1
Inventories	0.2	0.6	0.6	1.2	1.4	1.9
Other current assets	0.0	0.9	0.1	0.1	0.1	0.1
Non-current assets, total	**3.8**	**4.5**	**4.2**	**20.9**	**26.0**	**26.1**
Investment participations	0.0	0.0	0.0	16.0	21.1	21.1
Property, plant & equipment	2.6	3.4	3.3	3.5	3.5	3.8
Goodwill & other intangibles	1.1	1.0	0.9	0.8	0.6	0.4
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.1
Deferred tax assets	0.0	0.0	0.0	0.5	0.7	0.8
Total assets	**27.1**	**25.2**	**30.8**	**39.6**	**53.8**	**52.2**
Shareholders' equity & debt						
Current liabilities, total	**1.3**	**2.6**	**3.4**	**3.3**	**2.9**	**3.2**
Accounts payable	0.6	2.3	1.8	2.7	2.5	2.7
Other current liabilities	0.7	0.3	1.7	0.6	0.5	0.5
Long-term liabilities, total	**0.9**	**1.7**	**1.8**	**3.1**	**3.2**	**3.5**
Provisions	0.7	0.7	1.3	2.6	2.8	3.0
Other liabilities	0.3	1.0	0.6	0.5	0.4	0.4
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Shareholders' equity	**24.9**	**20.9**	**25.5**	**33.2**	**47.7**	**45.5**
Deferred income	0.0	0.0	0.0	0.0	0.0	0.0
Total consolidated equity and debt	**27.1**	**25.2**	**30.8**	**39.6**	**53.8**	**52.2**
Key figures						
Current ratio (x)	17.45	7.91	7.75	5.64	9.46	8.16
Quick ratio (x)	17.28	7.67	7.59	5.27	8.99	7.56
Financial leverage (%)	-81.6	-66.9	-60.6	-37.0	-45.0	-39.5
Book value per share (€)	2.74	2.30	2.78	3.37	4.77	218.67
Return on equity (ROE)	3.0%	-17.8%	-6.8%	24.2%	-4.9%	-4.2%

CASH FLOW STATEMENT

All figures in EURm	2015A	2016A	2017A	2018A	2019E	2020E
EBIT	**0.5**	**-4.1**	**-1.5**	**7.1**	**-2.0**	**-2.0**
Depreciation and amortisation	0.9	0.7	0.8	0.9	0.7	0.8
EBITDA	**1.5**	**-3.4**	**-0.8**	**8.0**	**-1.3**	**-1.2**
Changes in working capital	-1.1	-1.7	-3.4	5.3	-0.4	-1.4
Other adjustments	0.1	0.1	0.0	0.0	0.0	0.0
Operating cash flow	**0.5**	**-5.0**	**-4.2**	**13.3**	**-1.6**	**-2.6**
CAPEX	-0.6	-1.4	-0.5	-17.0	-5.7	-0.9
Free cash flow	**-0.1**	**-6.4**	**-4.7**	**-3.7**	**-7.3**	**-3.5**
Debt financing, net	**0.0**	**0.0**	**0.0**	**0.6**	**0.0**	**0.0**
Equity financing, net	**11.2**	**0.1**	**6.2**	**0.0**	**16.4**	**0.0**
Other changes in cash	0.0	0.0	0.0	0.0	0.0	0.0
Net cash flows	**11.1**	**-6.3**	**1.5**	**-3.2**	**9.1**	**-3.5**
Cash and liquid assets, start of the year	9.2	20.3	14.0	15.5	12.3	21.5
Cash and liquid assets, end of the year	**20.3**	**14.0**	**15.5**	**12.3**	**21.5**	**18.0**
EBITDA/share (in €)	**0.2**	**-0.4**	**-0.1**	**0.9**	**-0.1**	**-0.1**
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	-26.8%	n.m.	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...26	↓	↓	↓	↓
27	22 November 2018	€29.75	Buy	€53.00
28	27 March 2018	€28.95	Buy	€53.00
29	7 June 2019	€32.00	Buy	€51.00
30	Today	€32.40	Buy	€51.00

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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First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular the German Securities Trading Act [WpHG], Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and the German Ordinance on the Analysis of Financial Instruments [FinAnV] into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

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PRICE TARGET DATES

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

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

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/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Lurgiallee 12, 60439 Frankfurt

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