Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

Update

RATING	**BUY**
PRICE TARGET	**€ 103.00**
Return Potential	34.1%
Risk Rating	High

BUY FOR NEAR-TERM SHARE PRICE CATALYSTS

On 26 August Formycon announced the approval of its Lucentis biosimilar, FYB201, by the European Commission. The news was expected as the EMA's Committee for Medicinal Products for Human Use (CHMP) recommended approval of the drug in late June. EU approval of FYB201 follows approval of the drug by the FDA on 2 August and by the UK's MHRA in mid-May. The US launch is scheduled for early October. Teva, the marketing partner for FYB201 in the EU, plans to launch the drug as soon as possible. We gather that the likely timing is also early October. The Formycon share price has retreated 12% since the all-time high of €87 on 16 August. The peak at €87 coincided with the announcement that FYB202 phase 3 topline results had demonstrated the drug candidate's efficacy to be comparable to its Stelara reference product. We expect Formycon to generate a steady flow of further positive news over the next few months. This includes the strong probability that initial FYB201 sales figures in the US and EU will demonstrate leadership over the main competing Lucentis biosimilar, Samsung Bioepis' BYOOVIZ . In addition, before the end of this year, we expect topline results from the phase 3 trial of FYB203 (reference product Eylea), the disclosure of the FYB206 reference product, as well as the announcement of marketing partners for FYB202 and FYB203. FYB202 and FYB206 are both fully owned by Formycon. This means that the announcement of the FYB202 licensing partner is likely to be accompanied by an upfront payment to Formycon. Meanwhile, the royalty on FYB206 sales is likely to be nearer that on FYB202 (ca. 33%) than on FYB201 (ca. 15%), which is still 50% controlled by Bioeq AG. We advise investors to make use of the recent recoil in the Formycon share price to add to positions. We have raised our price target from €97 to €103 to reflect the approval of FYB201 in both the US and EU and the positive FYB202 topline phase 3 results. We maintain our Buy recommendation. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2020	2021	2022E	2023E	2024E	2025E
Revenue (€ m)	34.23	36.97	45.35	79.30	161.56	484.30
Y-o-y growth	3.2%	8.0%	22.7%	74.9%	103.7%	199.8%
EBIT (€ m)	-4.81	-12.39	-4.31	22.70	104.06	448.30
EBIT margin	-14.1%	-33.5%	-9.5%	28.6%	64.4%	92.6%
Net income (€ m)	-5.93	-13.47	-5.28	21.65	100.93	316.88
EPS (diluted) (€)	-0.58	-1.22	-0.39	1.44	6.70	21.03
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-5.70	-15.43	-12.17	13.89	82.58	232.22
Net gearing	-62.1%	-44.9%	-25.2%	-37.5%	-65.3%	-73.5%
Liquid assets (€ m)	42.25	25.18	13.01	26.90	109.48	341.70

RISKS

Product failures, failure to obtain funding, loss of key personnel.

COMPANY PROFILE

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

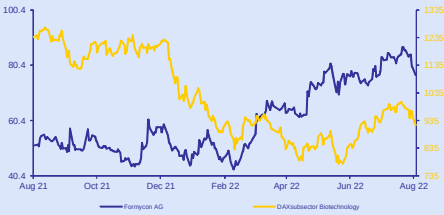
MARKET DATA

As of 29 Aug 2022

Closing Price	€ 76.80
Shares outstanding	15.06m
Market Capitalisation	€ 1156.97m
52-week Range	€ 42.65 / 87.00
Avg. Volume (12 Months)	10,143

Multiples	2021	2022E	2023E
P/E	n.a.	n.a.	51.6
EV/Sales	29.5	24.1	13.8
EV/EBIT	n.a.	n.a.	48.1
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2021

Liquid Assets	€ 25.18m
Current Assets	€ 37.99m
Intangible Assets	€ 0.79m
Total Assets	€ 66.33m
Current Liabilities	€ 5.59m
Shareholders' Equity	€ 56.07m

SHAREHOLDERS

Family Offices	43.0%
Institutional Investors	23.0%
Founders and Management	7.0%
Free Float	27.0%

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

BYOOVIZ only approved for 3 of 5 Lucentis indications in US Samsung Bioepis' Lucentis biosimilar, BYOOVIZ, was approved by the EMA and FDA in August and September 2021 respectively. In the UK, US and EU FYB201 is approved for all Lucentis indications. These include neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), myopic choroidal neovascularisation (mCNV), diabetic retinopathy (DR) and diabetic macular edema (DME). BYOOVIZ is approved in the EU for all five Lucentis indications but in the US only for the first three. In the US, AMD, RVO and mCNV are treated using a 10mg/mL solution of the drug. A 6mg/mL solution is used for DR and DME. BYOOVIZ is not indicated for DR and DME in the US because a 6mg/mL solution of the drug has not yet been approved. In recent years the 6mg/mL solution has accounted for 25% of the US market.

In the US FYB201 has the additional advantage over BYOOVIZ of interchangeability The FDA also approved FYB201 as a biosimilar interchangeable with Lucentis. This designation was not granted to BYOOVIZ. The significance of interchangeability is that a biosimilar product with this status may be substituted without the intervention of the health care professional who prescribed the reference product. In addition, the first biosimilar with interchangeability status compared to its reference product is entitled to one year of exclusivity of the interchangeability designation from the time of first commercial marketing. We expect the interchangeability of FYB201 and its greater range of indications to secure the drug the leading position among Lucentis biosimilars in the US.

We expect FYB201 to be the first Lucentis biosimilar to reach the European market Samsung Bioepis announced the commercial availability of BYOOVIZ through major distributors in the US from 1 July. The company has not commented on the timing of the product's European launch. We expect that FYB201 will be the first Lucentis biosimilar to reach the European market.

FYB203 phase 3 topline data due by the end of this year The last patient in the phase 3 trial of Formycon's Eylea biosimilar candidate, FYB203, was enrolled in April. Data on the primary efficacy endpoint are expected by the end of this year. The estimated completion date of the phase 3 trial according to ClinicalTrials.gov is June 2023.

Announcement of FYB206 reference molecule by the end of this year Formycon has stated it will announce details of the FYB206 reference molecule later this year. The FYB206 biosimilar programme is progressing according to plan and a comprehensive data package is currently being compiled in order to closely coordinate further programme steps in scientific advice meetings with the EMA and FDA. Scaling up of the manufacturing process to commercial scale is planned for the end of 2022. FYB206 is fully owned by Formycon. This suggests that the royalty on FYB206 sales will be nearer to FYB202 (ca. 33%), which is also fully owned by Formycon, than to FYB201 (ca. 15%). The latter drug is 50% controlled by Bioeq AG.

We expect announcement of FYB202 and FYB203 marketing partners by end 2022 We expect Formycon to announce the marketing partners for FYB202 and FYB203 before the end of this year. When Coherus acquired the US marketing rights to FYB201 in late 2019, it made an upfront/milestone payment of €10m to Bioeq AG, which at the time held full control of the drug candidate's marketing rights. The marketing rights to FYB202 are fully controlled by Formycon. This suggests that the announcement of the FYB202 marketing partner is likely to be accompanied by an upfront payment to Formycon, although we have not included this item in our forecasts. The marketing rights to FYB203 are controlled by Klinge Biopharma GmbH and so we do not expect Formycon to receive an upfront payment in this case.

Price target raised from €97 to €103. Buy recommendation maintained Given the likely steady flow of positive news over the next few months, we advise investors to make use of the recent recoil in the Formycon share price to add to positions. We have revised up our price target from €97 to €103 to reflect the approval of FYB201 in both the US and EU and the positive FYB202 topline phase 3 results. We maintain our Buy recommendation.

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)	€355M	199K	€9,862	€1,964M	20%	€371M	15%	10%	n.a.	1 year
FYB201	nAMD,DR (US)	€245M	82K	€16,436	€1,355M	20%	€256M	15%	10%	n.a.	1 year
FYB202	Pso,CrD (ex-US)	€483M	62K	€46,943	€2,905M	12%	€396M	33%	13%	n.a.	2 years
FYB202	Pso,CrD (US)	€785M	69K	€78,237	€5,398M	12%	€638M	33%	13%	n.a.	2 years
FYB203	nAMD,DR (ex-US)	€126M	425K	€7,691	€3,265M	12%	€456M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (US)	€224M	411K	€12,818	€5,265M	12%	€723M	9%	13%	n.a.	3 years
FYB206	n.a.	€135M									
FYB207	COVID-19 (ex-US)	€128M	149K	€20,000	€2,976M	12%	€510M	18%	16%	20	2 years
FYB207	COVID-19 (US)	€122M	142K	€20,000	€2,836M	12%	€486M	18%	16%	20	2 years
FYB208	n.a.	€101M									
FYB209	n.a.	€101M									
PACME PV		€2,804M									
Costs PV[4)]		€1,283M									
NPV		€1,520M									
Proforma net Cash		€31M									
Fair Value		€1,552M									
Proforma share count		15,065K									
Fair Value Per Share		€103.00									

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, CapEx and Taxes; COGS and S&M are factored into the PACME margin for each project.

Source: First Berlin Equity Research estimates

Figure 2: Changes to our pipeline valuation model

	Old	New	Delta
NPV	€1,430M	€1,520M	**6.3%**
Proforma net Cash	€31M	€31M	1.0%
Fair Value	€1,461M	€1,552M	6.2%
Share Count	15,065K	15,065K	0.0%
Fair value per share	€97.00	€103.00	**6.2%**

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in EURm	2020A	2021A	2022E	2023E	2024E	2025E
Revenue	**34.2**	**37.0**	**45.3**	**79.3**	**161.6**	**484.3**
Increase/decrease in unfinished products	0.6	0.4	0.0	0.0	0.0	0.0
Total output	**34.8**	**37.3**	**45.3**	**79.3**	**161.6**	**484.3**
Other operating income	0.4	3.2	8.8	2.4	0.0	0.0
Cost of goods sold	-26.1	-36.3	-40.4	-39.7	-36.9	-23.1
Gross profit	**9.2**	**5.7**	**13.8**	**42.0**	**124.6**	**461.2**
Personnel costs	-10.0	-13.0	-15.1	-16.3	-17.6	-11.0
Other operating expenses	-4.0	-5.1	-3.0	-3.0	-3.0	-1.8
EBITDA	**-4.8**	**-12.4**	**-4.3**	**22.7**	**104.1**	**448.3**
Depreciation and amortisation	-0.9	-0.9	-1.0	-1.1	-1.1	-1.1
Operating income (EBIT)	**-5.7**	**-13.3**	**-5.3**	**21.6**	**103.0**	**447.2**
Net financial result	-0.1	-0.2	0.0	0.0	0.0	0.0
Pre-tax income (EBT)	**-5.8**	**-13.5**	**-5.3**	**21.6**	**103.0**	**447.2**
Income taxes	-0.1	0.0	0.0	0.0	-2.1	-130.3
Net income / loss	**-5.9**	**-13.5**	**-5.3**	**21.6**	**100.9**	**316.9**
Diluted EPS (in €)	**-0.58**	**-1.22**	**-0.39**	**1.44**	**6.70**	**21.03**
Ratios						
Gross margin on output	26.3%	15.3%	30.3%	53.0%	77.1%	95.2%
EBIT margin on output	-16.5%	-35.7%	-11.6%	27.3%	63.7%	92.3%
EBITDA margin on output	-13.8%	-33.2%	-9.5%	28.6%	64.4%	92.6%
Net margin on output	-17.0%	-36.1%	-11.6%	27.3%	62.5%	65.4%
Tax rate	1.7%	-0.2%	0.0%	0.0%	-2.0%	-29.1%
Expenses as % of output						
Cost of goods sold	-74.8%	-97.3%	-89.1%	-50.0%	-22.9%	-4.8%
Personnel costs	-28.8%	-34.8%	-33.2%	-20.6%	-10.9%	-2.3%
Depreciation and amortisation	-2.6%	-2.5%	-2.1%	-1.3%	-0.7%	-0.2%
Net other operating exp.	-10.2%	-5.1%	12.8%	-0.8%	-1.8%	-0.4%
Y-Y Growth						
Revenues	3.2%	8.0%	22.7%	74.9%	103.7%	199.8%
Operating income	n.m.	n.m.	n.m.	n.m.	375.7%	334.2%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	366.2%	214.0%

BALANCE SHEET

All figures in EURm	2020A	2021A	2022E	2023E	2024E	2025E
Assets						
Current assets, total	**50.5**	**38.0**	**32.9**	**55.3**	**158.3**	**476.3**
Cash and cash equivalents	42.0	25.0	12.9	26.8	109.3	341.5
Other liquid assets	0.2	0.2	0.2	0.2	0.2	0.2
Receivables	6.9	7.7	13.5	19.8	40.4	121.1
Inventories	1.2	1.9	1.8	2.0	1.9	3.9
Other current assets	0.1	3.2	4.5	6.6	6.5	9.7
Non-current assets, total	**25.1**	**28.3**	**28.0**	**28.5**	**28.9**	**31.5**
Investment participations	20.7	23.7	23.7	23.7	23.7	23.7
Property, plant & equipment	3.5	3.3	3.3	3.6	3.4	3.4
Goodwill & other intangibles	0.5	0.7	0.6	0.6	0.6	0.6
Prepaid expenses	0.1	0.3	0.4	0.6	1.3	3.9
Deferred tax assets	0.3	0.3	0.0	0.0	0.0	0.0
Total assets	**75.6**	**66.3**	**60.9**	**83.7**	**187.2**	**507.8**
Shareholders' equity & debt						
Current liabilities, total	**5.0**	**5.6**	**5.8**	**6.9**	**9.2**	**12.1**
Accounts payable	4.5	4.7	4.9	5.6	6.5	8.2
Other current liabilities	0.5	0.9	0.9	1.3	2.7	3.9
Long-term liabilities, total	**2.5**	**4.7**	**3.6**	**5.2**	**10.3**	**30.6**
Provisions	2.1	4.3	3.2	4.8	9.7	29.1
Other liabilities	0.4	0.4	0.3	0.4	0.6	1.5
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Shareholders' equity	**68.0**	**56.1**	**51.5**	**71.7**	**167.7**	**465.2**
Total consolidated equity and debt	**75.6**	**66.3**	**60.9**	**83.7**	**187.2**	**507.8**
Key figures						
Current ratio (x)	10.06	6.79	5.67	8.01	17.19	39.34
Quick ratio (x)	9.82	6.46	5.35	7.72	16.98	39.02
Financial leverage (%)	-62.1	-44.9	-25.2	-37.5	-65.3	-73.5
Book value per share (€)	388.29	429.73	348.37	381.77	415.84	450.59
Return on equity (ROE)	-10.2%	-21.7%	-9.8%	35.1%	84.3%	100.1%

CASH FLOW STATEMENT

All figures in EURm	2020A	2021A	2022E	2023E	2024E	2025E
EBIT	**-5.7**	**-13.3**	**-5.3**	**21.6**	**103.0**	**447.2**
Depreciation and amortisation	0.9	0.9	1.0	1.1	1.1	1.1
EBITDA	**-4.8**	**-12.4**	**-4.3**	**22.7**	**104.1**	**448.3**
Changes in working capital	-0.5	-4.1	-7.0	-7.5	-18.5	-84.7
Taxes paid	0.0	0.0	0.0	0.0	-2.1	-130.3
Other adjustments	0.2	2.3	0.0	0.0	0.0	0.0
Operating cash flow	**-5.1**	**-14.2**	**-11.3**	**15.2**	**83.5**	**233.3**
CAPEX	-0.6	-1.3	-0.9	-1.3	-0.9	-1.1
Free cash flow	**-5.7**	**-15.4**	**-12.2**	**13.9**	**82.6**	**232.2**
Debt financing, net	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Equity financing, net	**25.8**	**1.5**	**0.0**	**0.0**	**0.0**	**0.0**
Other changes in cash	-0.2	0	0	0	0	0
Net cash flows	**19.9**	**-17.1**	**-12.2**	**13.9**	**82.6**	**232.2**
Cash and liquid assets, start of the year	22.4	42.2	25.2	13.0	26.9	109.5
Cash and liquid assets, end of the year	**42.2**	**25.2**	**13.0**	**26.9**	**109.5**	**341.7**
EBITDA/share (in €)	**-0.5**	**-1.1**	**-0.3**	**1.5**	**6.9**	**29.8**
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	449.9%	179.5%
Free cash flow	n.m.	n.m.	n.m.	n.m.	494.3%	181.2%
EBITDA/share	n.m.	n.m.	n.m.	n.m.	358.3%	330.8%

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Anschrift:
First Berlin Equity Research GmbH
Mohrenstr. 34
10117 Berlin
Germany

Vertreten durch den Geschäftsführer: Martin Bailey

Telefon: +49 (0) 30-80 93 9 680
Fax: +49 (0) 30-80 93 9 687
E-Mail: info@firstberlin.com

Amtsgericht Berlin Charlottenburg HR B 103329 B
UST-Id.: 251601797
Ggf. Inhaltlich Verantwortlicher gem. § 6 MDStV
First Berlin Equity Research GmbH

Authored by: Simon Scholes, Analyst
All publications of the last 12 months were authored by Simon Scholes.

Company responsible for preparation: First Berlin Equity Research GmbH, Mohrenstraße 34, 10117 Berlin

The production of this recommendation was completed on 30 August 2022 at 11:09

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

INFORMATION PURSUANT TO SECTION 85 (1) SENTENCE 1 OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO ART. 20 (1) OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO ART. 37 OF COMMISSION DELEGATED REGULATION (EU) NO 2017/565 (MIFID) II.

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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.

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...32	↓	↓	↓	↓
33	14 October 2020	€33.00	Buy	€43.00
34	7 January 2021	€61.00	Buy	€78.00
35	26 March 2021	€62.60	Add	€78.00
36	20 May 2021	€56.80	Buy	€78.00
37	5 July 2021	€62.80	Add	€78.00
38	23 September 2021	€50.20	Buy	€78.00
39	14 April 2022	€67.30	Buy	€89.00
40	11 July 2022	€74.20	Buy	€97.00
41	Today	€76.80	Buy	€103.00

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: https://firstberlin.com/disclaimer-english-link/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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