

Formycon AG

Germany / Biopharmaceuticals
 Xetra
 Bloomberg: FYB GR
 ISIN: DE000A1EWWY8

FYB206 reference
 product is Keytruda

RATING
PRICE TARGET
 Return Potential
 Risk Rating

BUY
€ 130.00
 84.4%
 High

DEVELOPING A BIOSIMILAR FOR THE DECADE'S NO.1 DRUG

Formycon has announced that the previously undisclosed reference product for FYB206 is the Merck & Co. drug, Keytruda. Indications include advanced melanoma, lung and other types of cancer. Keytruda's worldwide sales were USD17.2bn in 2021, up nearly 20% on 2020 and 89% higher than sales of Stelara (FYB202's reference product). Stelara is itself one of the top ten best-selling drugs worldwide with 2021 sales of USD9.1bn, and is now Formycon's second largest biosimilar reference product. Importantly, Formycon fully owns the development and commercialisation rights for FYB206. Similarly to FYB202, for which Formycon also has full control of the rights, royalties could be in excess of 30%. Given Keytruda's pre-eminent position in its portfolio, Merck & Co. has erected defences around the drug consisting of over 50 patents. Key substance patents expire in the US in 2028 but some production/process patents do not expire until 2036. In the course of developing FYB206, Formycon has created important IP, and patent applications have been filed in order to overcome the Keytruda patent wall. We had previously conservatively assumed that FYB206 reference product sales would be similar in size to those of the FYB201 reference product, Lucentis (2021 sales: USD3.6bn). News that the actual reference product is Keytruda, prompts us to raise our price target from €103 to €130. We maintain our Buy recommendation.

Keytruda expected to become world's biggest drug with sales >USD25bn
 Keytruda belongs to a class of drugs known as immune checkpoint inhibitors used for cancer immunotherapy. It is a humanised antibody that binds to human PD-1 receptors to help activate the body's own immune response to fight cancer. Sales growth has been driven by approvals to treat an expanding list of different cancer types. Keytruda received FDA approval for seven new indications in each of 2021 and 2020. As of early 2022, the full prescribing list covered 19 indications with more in the pipeline. Keytruda is expected to become the highest grossing drug in the world later this decade with sales in excess of USD25bn. (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%
EBITDA (€m)	-4.81	-12.39	-4.31	22.70	104.06	448.30
EBITDA margin	-14.1%	-33.5%	-9.5%	28.6%	64.4%	92.6%
Net income (€m)	-5.93	-13.47	84.72	21.65	100.93	316.88
EPS (diluted) (€)	-0.58	-1.22	6.22	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%	-11.0%	-19.5%	-46.8%	-64.3%
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 22 Sep 2022

Closing Price	€ 70.50
Shares outstanding	15.06m
Market Capitalisation	€ 1062.06m
52-week Range	€ 42.65 / 87.00
Avg. Volume (12 Months)	10,626

Multiples	2021	2022E	2023E
P/E	n.a.	11.3	49.0
EV/Sales	28.2	23.0	13.1
EV/EBITDA	n.a.	n.a.	45.9
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%



We expect FYB206 to enter the clinic in 2024 FYB206 is currently in the late preclinical stage. Formycon is consulting with the EMA and FDA as to the next steps in its development. We expect clinical development to begin in 2024. Development of the manufacturing process is also at an advanced stage, and GMP manufacturing capacities have been secured.

Keytruda antibody patents expire in the US in 2028 Keytruda patents begin to expire in the US in 2028 and the EU in 2030. For comparison, the patents on Stelara and Eylea (FYB203 reference product) expire during 2023-25. According to The Initiative for Medicines, Access, & Knowledge (I-MAK), 129 patents had been filed for Keytruda as of June 2020, of which 53 were granted. 50% of these patent applications were filed after the drug's first FDA approval in September 2014. Merck & Co. filed patents covering the anti-PD-1 antibody, pembrolizumab (the non-proprietary name for Keytruda) in 2008. These are to set to expire in the US in 2028. Several of the patents granted since 2014 relate to production and process methods. Some of these patents do not expire until 2036. As we have seen above, Formycon has taken several steps to overcome these barriers.

We raise the price target from €103 to €130 and maintain our Buy recommendation

So far Celltrion (South Korea), NeuClone (Australia), PlantForm (Canada) and Xbrane (Sweden) have announced the development of Keytruda biosimilars. Given the size of the reference market and the still lengthy period until Keytruda patents expire, we think it likely that further competitors will emerge. In valuing FYB206, we have assumed parameters similar to those for Stelara, i.e. 40% discount to current reference product pricing, 12% market share and 33% royalty rate. We had previously conservatively assumed that FYB206 reference product sales would be similar in size to those of the FYB201 reference product, Lucentis (2021 sales: USD3.6bn). News that the actual reference product is the much larger Keytruda, prompts us to raise our price target from €103 to €130. We maintain our Buy recommendation.

Figure 1: Pipeline valuation model

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Royalties	PACME Margin ²⁾	Discount Factor	Patent Life ³⁾	Time to Market
FYB201	nAMD,DR (ex-US)	€355M	199K	€9,862	€1,964M	20%	€56M	5%	10%	n.a.	1 year
FYB201	nAMD,DR (US)	€245M	82K	€16,436	€1,355M	20%	€38M	15%	0%	n.a.	1 year
FYB202	Pso,CrD (ex-US)	€486M	62K	€46,943	€2,905M	12%	€131M	33%	13%	n.a.	2 years
FYB202	Pso,CrD (US)	€784M	69K	€78,237	€5,398M	12%	€211M	33%	13%	n.a.	2 years
FYB203	nAMD,DR (ex-US)	€126M	425K	€7,691	€3,265M	12%	€39M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (US)	€224M	411K	€12,818	€5,265M	12%	€65M	9%	8%	n.a.	3 years
FYB206	multiple cancer types (ex-US)	€183M	65K	€103,000	€6,746M	12%	€392M	33%	16%	n.a.	7 years
FYB206	multiple cancer types (US)	€359M	59K	€150,000	€8877M	12%	€573M	33%	16%	n.a.	9 years
FYB207	COVID-19 (ex-US)	€128M	149K	€20,000	€2,976M	12%	€92M	18%	16%	20	2 years
FYB207	COVID-19 (US)	€122M	142K	€20,000	€2,836M	12%	€87M	18%	16%	20	2 years
FYB208	n.a.	€101M									
FYB209	n.a.	€101M									
PACME PV		€3,212M									
Costs PV ⁴⁾		€1,283M									
NPV		€1,929M									
Proforma net Cash		€29M									
Fair Value		€1,958M									
Proforma share count		15,065K									
Fair Value Per Share		€130.00									

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	€1,522M	€1,929M	26.7%
Proforma net Cash	€29M	€29M	1.4%
Fair Value	€1,551M	€1,958M	26.3%
Share Count	15,065K	15,065K	0.0%
Fair value per share	€103.00	€130.00	26.2%

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	90.0	0.0	0.0	0.0
Pre-tax income (EBT)	-5.8	-13.5	84.7	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	84.7	21.6	100.9	316.9
Diluted EPS (in €)	-0.58	-1.22	6.22	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%	186.8%	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.	-74.4%	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	94.4	94.8	95.3	97.9
Investment participations	20.7	23.7	0.0	0.0	0.0	0.0
Financial assets	0.0	0.0	90.0	90.0	90.0	90.0
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	127.2	150.1	253.5	574.2
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	117.9	138.0	234.0	531.5
Total consolidated equity and debt	75.6	66.3	127.2	150.1	253.5	574.2
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	-11.0	-19.5	-46.8	-64.3
Book value per share (€)	516.11	579.94	476.04	527.13	579.23	632.39
Return on equity (ROE)	-10.2%	-21.7%	97.4%	16.9%	54.3%	82.8%



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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PRICE TARGET DATES

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

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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...34	↓	↓	↓	↓
35	26 March 2021	€62.60	Buy	€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	30 August 2022	€76.80	Buy	€103.00
42	7 September 2022	€70.40	Buy	€103.00
43	Today	€70.50	Buy	€130.00

INVESTMENT HORIZON

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