

Formycon AG

Germany / Biopharmaceuticals
 Xetra
 Bloomberg: FYB GR
 ISIN: DE000A1EWWY8

New data on FYB207
 vs. SARS-CoV-2
 mutations

RATING
PRICE TARGET

Return Potential
 Risk Rating

ADD
€ 78.00
 24.6%
 High

THE HARDER THEY COME, THE HARDER THEY FALL

Formycon has published new results from in vitro tests of its ACE2 IgG-Fc antibody fusion protein drug candidate FYB207 against SARS-CoV-2. These indicate that FYB207 is even more effective against recent more infectious mutations of SARS-CoV-2, such as the British variant B.1.1.7, than against earlier less infectious variants. A study published in December 2020 already indicated that FYB207's efficacy is undiminished by spike protein mutations. Spike protein mutations threaten the efficacy of vaccines and the vast majority of antibodies against SARS-CoV-2. FYB207's efficacy is unaffected by spike protein mutations because the ACE2 component of FYB207 binds the protein spike before it can reach the patient's native ACE2 receptors which are the entry point for the virus. If the spike protein does mutate to escape ACE2 neutralisation via decreasing affinity, it will become less pathogenic. The combination of the absence of compulsory vaccination and the 2-10% of the population who are immuno-compromised suggest that new SARS-CoV-2 infections will continue at a significant level indefinitely. We continue to assume an annual total of 275,000 SARS-CoV-2-related hospitalisations in Europe and the US combined from 2022. FYB207's strong performance profile suggests that robust pricing (average of €20,000 per patient) and a market share of 10% are achievable. We expect a phase I/II trial of FYB207 to begin in Q4 this year. Providing that the outcome of this trial is favourable, we expect Formycon to request an Emergency Use Authorisation (EUA) for FYB207. A successful phase I/II trial of FYB207 and an EUA could see the drug reach the market in late 2022. We maintain our price target of €78.00 but lower the recommendation from Buy to Add to reflect share price appreciation since our last study of 7 January. (p.t.o.)

Tested against three variants... FYB207 was tested in vitro against three variants of SARS-CoV-2 in order of increasing infectiousness: (I) SARS-CoV-2-Jan, isolated at the start of the COVID-19 outbreak in Germany in January 2020 and directly related to the first outbreak in Wuhan, China, (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2016	2017	2018	2019	2020E	2021E
Revenue (€m)	19.53	29.00	42.99	33.16	40.00	45.00
Y-o-y growth	15.4%	48.5%	48.2%	-22.9%	20.6%	12.5%
EBIT (€m)	-4.07	-1.54	7.13	-2.27	-4.00	-7.72
EBIT margin	-20.8%	-5.3%	16.6%	-6.9%	-10.0%	-17.2%
Net income (€m)	-4.07	-1.58	7.10	-2.29	-4.00	-7.72
EPS (diluted) (€)	-0.45	-0.17	0.76	-0.23	-0.39	-0.82
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-6.40	-4.66	-3.73	-7.19	-4.77	-10.42
Net gearing	-66.9%	-60.6%	-37.0%	-46.4%	-62.0%	-68.3%
Liquid assets (€m)	13.97	15.48	12.31	22.35	42.05	60.60

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 25 Mar 2021

Closing Price	€ 62.60
Shares outstanding	11.05m
Market Capitalisation	€ 691.51m
52-week Range	€ 19.05 / 78.00
Avg. Volume (12 Months)	22,248

Multiples	2019	2020E	2021E
P/E	n.a.	n.a.	n.a.
EV/Sales	19.6	16.2	14.4
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2020

Liquid Assets	€ 20.23m
Current Assets	€ 26.45m
Intangible Assets	€ 0.53m
Total Assets	€ 52.18m
Current Liabilities	€ 3.60m
Shareholders' Equity	€ 46.83m

SHAREHOLDERS

Institutional Investors	50.0%
Founders and Management	15.0%
Free Float	35.0%

(II) SARS-CoV-2-April, which was isolated when the virus first proliferated in Europe in April 2020, and (III) the British variant, SARS-CoV-2 variant B.1.1.7, first detected in the UK in September 2020, which is associated with increased infectivity and mortality, and is now the predominant SARS-CoV-2 variant in Europe.

...performs best against the more infectious and harmful British variant The quantity of FYB207 required to achieve 50% inhibition of the virus was 4.7 nanomolars in the Wuhan variant, 1.3 nanomolars in the April 2020 variant, and 0.6 nanomolars in the British variant. These results underline the very positive profile of FYB207 relative to competing SARS-CoV-2 antibodies indicated by the December 2020 study. There are dozens of SARS-CoV-2 antibodies under development, but most of these target the spike protein and so are vulnerable to mutation-induced viral escape. So far we have only been able to find three competing antibody fusion proteins (see figure 1).

Figure 1: Competing SARS-CoV-2/COVID-19 antibody fusion protein drug candidates

Company	Drug name	Type	Stage
Henlius	HLX71	ACE-2-Fc fusion protein	IND approval in US
Sorrento Therapeutics	STI-4398	ACE-2-Fc fusion protein	Preclinical
Systimmune	SI-F019	ACE-2-Fc fusion protein	Preclinical

Source: COVID-19 tracker, companies

Price target of €78.00 maintained, but recommendation lowered from Buy to Add The in vitro test results are very encouraging but Formycon still has to test FYB207 in humans. A phase 1/2 trial is due to start in Q4 this year. The elderly, the obese and allergy sufferers are disproportionately represented among the 2-10% of the population which are immunocompromised. We expect SARS-CoV-2 to remain endemic in this group even when the pandemic is over. Providing that the outcome of the phase 1/2 trial is favourable, we expect Formycon to request an EUA for FYB207. A successful phase I/II trial of FYB207 and an EUA could see the drug reach the market in late 2022. We expect that Formycon will seek partners for manufacturing and marketing of FYB207, but that it will orchestrate the clinical trial(s) of FYB207 independently. On this basis, we expect the royalty rate for FYB207 to be 18% rather than the 9% we model for FYB201, FYB202 and FYB203. We maintain our price target of €78.00 but lower the recommendation from Buy to Add to reflect share price appreciation since our last study of 7 January.

Figure 2: 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)	€96M	374K	€5,250	€1,963M	17%	€306M	9%	13%	n.a.	2 years
FYB201	nAMD,DR (US)	€90M	195K	€9,068	€1,767M	17%	€308M	9%	13%	n.a.	2 years
FYB202	Pso,CrD (ex-US)	€110M	88K	€27,500	€2,418M	17%	€446M	9%	13%	n.a.	3 years
FYB202	Pso,CrD (US)	€260M	121K	€44,750	€5,395M	17%	€996M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (ex-US)	€114M	614K	€4,859	€2,983M	17%	€515M	9%	13%	n.a.	4 years
FYB203	nAMD,DR (US)	€200M	521K	€8,591	€4,479M	17%	€765M	9%	8%	n.a.	3 years
FYB205,6,x	n.a.	€261M									
FYB207	COVID-19 (ex-US)	€241M	201K	€20,000	€4,020M	10%	€40M	18%	16%	20	2 years
FYB207	COVID-20 (US)	€91M	75K	€20,000	€1,508M	10%	€152M	18%	16%	20	2 years
PACME PV		€1,464M									
Costs PV ⁴⁾		€674M									
NPV		€790M									
Downpayments and Milestones		€38M									
Proforma net Cash		€69M									
Fair Value		€897M									
Share Count		11,500K									
Fair Value Per Share		€78.00									

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



INCOME STATEMENT

All figures in EURm	2016A	2017A	2018A	2019A	2020E	2021E
Revenue	19.5	29.0	43.0	33.2	40.0	45.0
Increase/decrease in unfinished products	0.0	0.4	0.6	0.8	0.0	0.0
Total output	19.5	29.4	43.6	32.3	40.0	45.0
Other operating income	0.1	0.1	0.1	0.8	0.2	0.2
Cost of goods sold	-15.4	-21.2	-25.8	-21.3	-27.8	-34.0
Gross profit	4.3	8.4	17.9	11.7	12.4	11.2
Personnel costs	-5.1	-6.3	-7.0	-9.1	-11.0	-12.7
Depreciation and amortisation	-0.7	-0.8	-0.9	-0.9	-0.8	-0.7
Other operating expenses	-2.6	-2.8	-3.0	-4.0	-4.6	-5.6
Operating income (EBIT)	-4.1	-1.5	7.1	-2.3	-4.0	-7.7
Net financial result	0.0	0.0	0.0	0.0	0.0	0.0
Pre-tax income (EBT)	-4.1	-1.6	7.1	-2.3	-4.0	-7.7
Income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net income / loss	-4.1	-1.6	7.1	-2.3	-4.0	-7.7
Diluted EPS (in €)	-0.45	-0.17	0.76	-0.23	-0.40	-0.82
EBITDA	-3.4	-0.8	8.0	-1.4	-3.2	-7.1
Ratios						
Gross margin on output	21.9%	28.4%	41.0%	36.3%	31.0%	24.9%
EBIT margin on output	-20.8%	-5.2%	16.4%	-7.0%	-10.0%	-17.2%
EBITDA margin on output	-17.3%	-2.6%	18.4%	-4.2%	-7.9%	-15.7%
Net margin on output	-20.8%	-5.4%	16.3%	-7.1%	-10.0%	-17.2%
Tax rate	0.1%	-0.2%	0.0%	-0.3%	0.0%	0.0%
Expenses as % of output						
Cost of goods sold	-78.8%	-72.0%	-59.2%	-66.1%	-69.4%	-75.6%
Personnel costs	-26.1%	-21.5%	-16.1%	-28.1%	-27.4%	-28.2%
Depreciation and amortisation	-3.6%	-2.7%	-2.1%	-2.8%	-2.1%	-1.5%
Net other operating exp.	-12.6%	-9.1%	-6.5%	-10.0%	-11.1%	-11.9%
Y-Y Growth						
Revenues	15.4%	48.5%	48.2%	-22.9%	20.6%	12.5%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EURm	2016A	2017A	2018A	2019A	2020E	2021E
Assets						
Current assets, total	20.7	26.6	18.7	28.1	49.0	70.1
Cash and cash equivalents	3.0	4.5	7.3	22.1	12.0	4.5
Other liquid assets	11.0	11.0	5.0	0.2	30.1	56.1
Receivables	5.2	10.5	5.2	4.9	6.4	9.0
Inventories	0.6	0.6	1.2	0.4	0.4	0.5
Other current assets	0.9	0.1	0.1	0.4	0.1	0.1
Non-current assets, total	4.5	4.2	20.9	25.5	26.0	26.5
Investment participations	0.0	0.0	16.0	20.7	20.7	20.7
Property, plant & equipment	3.4	3.3	3.5	3.7	4.0	4.5
Goodwill & other intangibles	1.0	0.9	0.8	0.6	0.4	0.3
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.1
Deferred tax assets	0.0	0.0	0.5	0.4	0.8	0.9
Total assets	25.2	30.8	39.6	53.6	75.0	96.6
Shareholders' equity & debt						
Current liabilities, total	2.6	3.4	3.3	2.8	3.6	3.8
Accounts payable	2.3	1.8	2.7	2.2	3.0	3.2
Other current liabilities	0.3	1.7	0.6	0.6	0.6	0.6
Long-term liabilities, total	1.7	1.8	3.1	2.6	3.6	4.1
Provisions	0.7	1.3	2.6	1.9	3.2	3.6
Other liabilities	1.0	0.6	0.5	0.7	0.4	0.5
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders' equity	20.9	25.5	33.2	48.2	67.8	88.7
Deferred income	0.0	0.0	0.0	0.0	0.0	0.0
Total consolidated equity and debt	25.2	30.8	39.6	53.6	75.0	96.6
Key figures						
Current ratio (x)	7.91	7.75	5.64	10.15	13.76	18.56
Quick ratio (x)	7.67	7.59	5.27	10.00	13.63	18.44
Financial leverage (%)	-66.9	-60.6	-37.0	-46.4	-62.0	-68.3
Book value per share (€)	2.30	2.78	3.37	4.82	308.86	339.55
Return on equity (ROE)	-17.8%	-6.8%	24.2%	-5.6%	-6.9%	-9.9%



CASH FLOW STATEMENT

All figures in EURm	2016A	2017A	2018A	2019A	2020E	2021E
EBIT	-4.1	-1.5	7.1	-2.3	-4.0	-7.7
Depreciation and amortisation	0.7	0.8	0.9	0.9	0.8	0.7
EBITDA	-3.4	-0.8	8.0	-1.4	-3.2	-7.1
Changes in working capital	-1.7	-3.4	5.3	0.6	-0.7	-2.4
Other adjustments	0.1	0.0	0.0	-0.7	0.0	0.0
Operating cash flow	-5.0	-4.2	13.3	-1.5	-3.8	-9.4
CAPEX	-1.4	-0.5	-17.0	-5.7	-0.9	-1.0
Free cash flow	-6.4	-4.7	-3.7	-7.2	-4.8	-10.4
Debt financing, net	0.0	0.0	0.6	0.0	0.0	1.0
Equity financing, net	0.1	6.2	0.0	17.3	24.5	29.0
Other changes in cash	0.0	0.0	0.0	0.0	0.0	-1.0
Net cash flows	-6.3	1.5	-3.2	10.0	19.7	18.6
Cash and liquid assets, start of the year	20.3	14.0	15.5	12.3	22.4	42.1
Cash and liquid assets, end of the year	14.0	15.5	12.3	22.4	42.1	60.6
EBITDA/share (in €)	-0.4	-0.1	0.9	-0.1	-0.3	-0.7
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	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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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

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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

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

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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...28	↓	↓	↓	↓
29	11 November 2019	€32.40	Buy	€51.00
30	7 February 2020	€28.10	Buy	€39.00
31	26 March 2020	€19.75	Buy	€39.00
32	19 May 2020	€24.70	Buy	€39.00
33	23 June 2020	€23.10	Buy	€39.00
34	23 September 2020	€30.40	Buy	€39.00
35	14 October 2020	€32.00	Buy	€43.00
36	7 January 2021	€61.00	Buy	€78.00
37	Today	€62.60	Add	€78.00

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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