Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

2020 annual report

RATING	**BUY**
PRICE TARGET	**€ 78.00**
Return Potential	37.3%
Risk Rating	High

ABUNDANT NEAR-TERM NEWSFLOW

Formycon's FY2020 results showed revenue of €34.2m (FBe: €40.0m; 2019: €33.2m) while EBIT came in at €-5.7m (FBe: €-4.0m; 2019: €-2.3m). As in 2019, revenue stemmed from fees for development work on the out-licensed biosimilar candidates FYB201 and FYB203 and also from payments for the provision of development services to the FYB202 joint venture. Revenue was slightly below the guided range of €35-40m. Net profit guidance was for a negative figure of unspecified magnitude. Management tells us that the slight shortfall between reported revenue and the guided range is not due to any delay in the underlying development programmes but rather connected to the timing of the issue of invoices from service providers. Pipeline development remains on track. Management continues to expect submission to the FDA of the Biologics License Application for FYB201 (reference product: Lucentis) by the end of this quarter. Subject to FDA approval, FYB201 will generate its first royalty income in 2022. The phase 3 trials of FYB202 (reference product: Stelara) and FYB203 (reference product: Eylea) began in September 2020 and July 2020 respectively. According to clinicaltrials.gov, the estimated primary completion date for the FYB202 phase 3 trial is September 2021, and August 2021 for the FYB203 phase 3 trial. Aggregate revenue of the FYB201, FYB202 and FYB203 reference products rose 8% in 2020 to USD19.2bn (2019: USD17.8bn). Meanwhile, FYB207, Formycon's ACE2 IgG-Fc antibody fusion protein drug candidate against SARS-CoV-2, is expected to enter the clinic in Q4 this year. In December 2020 Formycon announced that in vitro tests showed that FYB207 effectively binds SARS-CoV-2 and completely prevents infection of cells. Results released in March this year 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. We maintain our price target of €78.0, but raise the recommendation from Add to Buy to reflect upside potential of over 25%. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2017	2018	2019	2020	2021E	2022E
Revenue (€ m)	29.00	42.99	33.16	34.23	45.00	62.48
Y-o-y growth	48.5%	48.2%	-22.9%	3.2%	31.5%	38.8%
EBIT (€ m)	-1.54	7.13	-2.27	-5.73	-11.02	2.40
EBIT margin	-5.3%	16.6%	-6.9%	-16.7%	-24.5%	3.8%
Net income (€ m)	-1.58	7.10	-2.29	-5.93	-11.02	2.40
EPS (diluted) (€)	-0.17	0.76	-0.23	-0.58	-0.98	0.21
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-4.66	-3.73	-7.19	-5.70	-13.21	-2.40
Net gearing	-60.6%	-37.0%	-46.4%	-62.1%	-69.5%	-68.3%
Liquid assets (€ m)	15.48	12.31	22.35	42.25	62.01	66.61

RISKS

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

COMPANY PROFILE

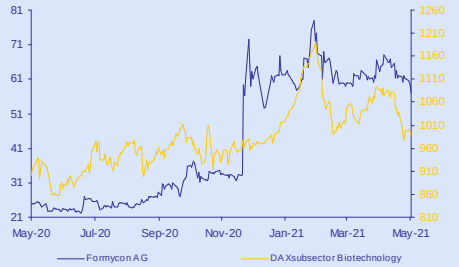
Formycon AG is a Munich, Germany based pharmaceuticals company specialising in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

	As of 19 May 2021
Closing Price	€ 56.80
Shares outstanding	11.05m
Market Capitalisation	€ 627.44m
52-week Range	€ 22.30 / 78.00
Avg. Volume (12 Months)	22,189

Multiples	2020	2021E	2022E
P/E	n.a.	n.a.	273.1
EV/Sales	17.1	13.0	9.4
EV/EBIT	n.a.	n.a.	243.7
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

	As of 31 Dec 2020
Liquid Assets	€ 42.25m
Current Assets	€ 50.51m
Intangible Assets	€ 0.50m
Total Assets	€ 75.60m
Current Liabilities	€ 5.02m
Shareholders' Equity	€ 68.04m

SHAREHOLDERS

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

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Figure 1: FY 2020 results versus our forecasts

in EURm	FY 20A	FY 20E	Delta	FY 19A	Delta
Revenue	34.20	40.00	-14.5%	33.20	3.0%
EBITDA	-4.80	-3.20	n.m.	-1.40	n.m
margin	-14.0%	-8.0%	-	-4.2%	-
EBIT	-5.70	-4.00	n.m.	-2.30	n.m.
margin	-16.7%	-10.0%	-	-6.9%	-
Net income	-5.90	-4.00	n.m.	-2.30	n.m.
margin	-17.3%	-10.0%	-	-6.9%	-

Source: Formycon; First Berlin Equity Research estimates

FYB201 EU marketing authorisation application also likely in near term Formycon has announced that it will submit an application for marketing authorisation of FYB201 to the EMA soon after the BLA submission to the FDA. We assume a mid-2022 timing for the launch of FYB201 in both the US and the EU. As figure 2 below shows, Lucentis' EU patent expires in July 2022. Our 2022 revenue forecast incorporates €11m of royalty income on sales of FYB201 in the US and EU. Formycon announced in November 2019 that Coherus Biosciences will be the exclusive distributor of FYB201 in the US. In the 2020 annual report, Formycon stated that its FYB201 licensing partner, Bioeq, is responsible for selecting a distributor for Europe and that this process is at an advanced stage.

Figure 2: Patent expiry date of Formycon biosimilar candidates' reference products

	Formycon biosimilar candidate (reference product)		
Market	FYB201 (Lucentis)	FYB202 (Stelara)	FYB203 (Eylea)
US	6/2020	9/2023	05/2024
EU	7/2022	7/2024	5/2025

Source: Companies

Growing royalties to allow advancement of projects to a later stage without a partner Formycon has not yet announced the reference product for FYB206, which is an early-stage product in the company's development pipeline. As we discussed in our note of 14 October last year, a biosimilar candidate is largely de-risked once the regulatory authorities have accepted the equivalence between the biosimilar and the reference product. This is achieved through the submission of an analytical package confirming that the biosimilar candidate is highly similar to the reference product in terms of its physicochemical and biological characterisation. If the analytical package indicates a high degree of similarity, clinical benefit can be largely assumed. Subsequent clinical studies then serve essentially to confirm the findings of the analytical package and eliminate residual risk. With biosimilars it is the analytical package, not the phase 3 trial which is truly pivotal. This is shown by the fact that so far, no biosimilar candidate has failed in a phase 3 trial.

Figure 3: Timing of partnership deals/regulatory clearance for start of clinical development

Biosimilar candidate	Reference product	Partner	Date of partnership deal	Date of FDA clearance for start of clinical development
FYB201	Lucentis	Bioeq AG	December 2013	July 2015
FYB202	Stelara	Aristo Pharma GmbH	December 2017	February 2019
FYB203	Eylea	Klinge Biopharma GmbH	May 2015	September 2019

Source: Formycon AG

As figure 3 shows, Formycon concluded partnerships with respect to FYB201, FYB202 and FYB203 well in advance of the submission of the analytical data package. Last October following the closing of the Active Ownership Group private placement, Formycon indicated that the proceeds (€25.75m gross) would be used to advance non-partnered pipeline projects such as FYB206 through the analytical package stage without reliance on a partner.

The company reiterated this point in the 2020 annual report with respect to the additional financial latitude, provided, subject to regulatory approval, by FYB201 royalties from 2022, and by FYB202 and FYB203 royalties from 2023 and 2024 respectively. This opens up the possibility of better deal terms than for biosimilar candidates partnered before the analytical package submission stage and is the reason why our royalty rate assumption for FYB206 is 18% compared with 9% for FYB201, FYB202 and FYB203.

FYB207 SARS-Cov-2 antiviral circumvents spike protein mutation Formycon's ACE2 IgG-Fc antibody fusion protein drug candidate against SARS-CoV-2 is expected to enter the clinic in Q4 this year. The most common target for antiviral drugs targeting SARS-CoV-2 is the spike protein on the surface of the virus. However, this mode of action is vulnerable to spike protein mutation. The ACE2 component of Formycon's recently announced ACE2 IgG-Fc fusion protein binds the spike before it can reach the patient's native ACE2 receptors which are the entry point for the virus. The problem of spike protein mutation is circumvented because any mutation of the virus which reduces its affinity to ACE2 will also reduce its pathogenicity. The elderly, the obese and allergy sufferers are disproportionately represented among the 2-10% of the population who are immuno-compromised. We expect SARS-CoV-2 to remain endemic in this group even when the pandemic is over. FYB207's strong performance profile suggests that robust pricing (average of €20,000) and a market share of 10% are achievable.

Price target of €78.0 maintained, but recommendation raised from Add to Buy We maintain our price target of €78.0, but raise the recommendation from Add to Buy to reflect upside potential of over 25%.

Figure 4: 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)	€63M	342K	€5,250	€1,794M	17%	€189M	9%	13%	n.a.	2 years
FYB201	nAMD,DR (US)	€57M	172K	€9,068	€1,560M	17%	€184M	9%	13%	n.a.	2 years
FYB202	Pso,CrD (ex-US)	€122M	93K	€27,500	€2,552M	17%	€492M	9%	13%	n.a.	3 years
FYB202	Pso,CrD (US)	€273M	121K	€44,750	€5,421M	17%	€1,044M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (ex-US)	€107M	548K	€4,859	€2,664M	17%	€480M	9%	13%	n.a.	4 years
FYB203	nAMD,DR (US)	€214M	534K	€8,591	€4,587M	17%	€818M	9%	13%	n.a.	3 years
FYB205,6x	n.a.	€261M									
FYB207	COVID-19 (ex-US)	€241M	201K	€20,000	€4,020M	10%	€402M	18%	16%	20	2 years
FYB207	COVID-20 (US)	€91M	75K	€20,000	€1,508M	10%	€152M	18%	16%	20	2 years
PACME PV		€1,428M									
Costs PV[4)]		€648M									
NPV		€779M									
Downpayments and Milestones		€39M									
Proforma net Cash		€82M									
Fair Value		€901M									
Proforma share count		11,546K									
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	2017A	2018A	2019A	2020A	2021E	2022E
Revenue	**29.0**	**43.0**	**33.2**	**34.2**	**45.0**	**62.5**
Increase/decrease in unfinished products	0.4	0.6	0.8	0.6	0.0	0.0
Total output	**29.4**	**43.6**	**32.3**	**34.8**	**45.0**	**62.5**
Other operating income	0.1	0.1	0.8	0.4	0.0	0.0
Cost of goods sold	-21.2	-25.8	-21.3	-26.1	-37.0	-40.0
Gross profit	**8.4**	**17.9**	**11.7**	**9.2**	**8.0**	**22.5**
Personnel costs	-6.3	-7.0	-9.1	-10.0	-12.5	-13.4
Depreciation and amortisation	-0.8	-0.9	-0.9	-0.9	-0.9	-0.9
Other operating expenses	-2.8	-3.0	-4.0	-4.0	-5.6	-5.7
Operating income (EBIT)	**-1.5**	**7.1**	**-2.3**	**-5.7**	**-11.0**	**2.4**
Net financial result	0.0	0.0	0.0	-0.1	0.0	0.0
Pre-tax income (EBT)	**-1.6**	**7.1**	**-2.3**	**-5.8**	**-11.0**	**2.4**
Income taxes	0.0	0.0	0.0	0.1	0.0	0.0
Net income / loss	**-1.6**	**7.1**	**-2.3**	**-5.9**	**-11.0**	**2.4**
Diluted EPS (in €)	**-0.17**	**0.76**	**-0.23**	**-0.58**	**-0.98**	**0.21**
EBITDA	**-0.8**	**8.0**	**-1.4**	**-4.8**	**-10.1**	**3.3**
Ratios						
Gross margin on output	28.4%	41.0%	36.3%	26.3%	17.8%	36.0%
EBIT margin on output	-5.2%	16.4%	-7.0%	-16.5%	-24.5%	3.8%
EBITDA margin on output	-2.6%	18.4%	-4.2%	-13.8%	-22.4%	5.3%
Net margin on output	-5.4%	16.3%	-7.1%	-17.0%	-24.5%	3.8%
Tax rate	-0.2%	0.0%	-0.3%	-1.6%	0.0%	0.0%
Expenses as % of output						
Cost of goods sold	-72.0%	-59.2%	-66.1%	-74.8%	-82.2%	-64.0%
Personnel costs	-21.5%	-16.1%	-28.1%	-28.8%	-27.8%	-21.5%
Depreciation and amortisation	-2.7%	-2.1%	-2.8%	-2.6%	-2.1%	-1.5%
Net other operating exp.	-9.1%	-6.5%	-10.0%	-10.2%	-12.4%	-9.1%
Y-Y Growth						
Revenues	48.5%	48.2%	-22.9%	3.2%	31.5%	38.8%
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	2017A	2018A	2019A	2020A	2021E	2022E
Assets						
Current assets, total	**26.6**	**18.7**	**28.1**	**50.5**	**71.5**	**83.0**
Cash and cash equivalents	4.5	7.3	22.1	42.0	61.8	66.4
Other liquid assets	11.0	5.0	0.2	0.2	0.2	0.2
Receivables	10.5	5.2	4.9	6.9	9.0	15.6
Inventories	0.6	1.2	0.4	1.2	0.5	0.6
Other current assets	0.1	0.1	0.4	0.1	0.1	0.1
Non-current assets, total	**4.2**	**20.9**	**25.5**	**25.1**	**25.5**	**25.8**
Investment participations	0.0	16.0	20.7	20.7	20.7	20.7
Property, plant & equipment	3.3	3.5	3.7	3.5	3.4	3.4
Goodwill & other intangibles	0.9	0.8	0.6	0.5	0.4	0.3
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.2
Deferred tax assets	0.0	0.5	0.4	0.3	0.9	1.2
Total assets	**30.8**	**39.6**	**53.6**	**75.6**	**97.0**	**108.8**
Shareholders' equity & debt						
Current liabilities, total	**3.4**	**3.3**	**2.8**	**5.0**	**3.8**	**5.9**
Accounts payable	1.8	2.7	2.2	4.5	3.2	5.0
Other current liabilities	1.7	0.6	0.6	0.5	0.6	0.9
Long-term liabilities, total	**1.8**	**3.1**	**2.6**	**2.5**	**4.1**	**5.4**
Provisions	1.3	2.6	1.9	2.1	3.6	5.0
Other liabilities	0.6	0.5	0.7	0.4	0.5	0.4
Minority interests	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Shareholders' equity	**25.5**	**33.2**	**48.2**	**68.0**	**89.2**	**97.5**
Total consolidated equity and debt	**30.8**	**39.6**	**53.6**	**75.6**	**97.0**	**108.8**
Key figures						
Current ratio (x)	7.75	5.64	10.15	10.06	18.93	14.13
Quick ratio (x)	7.59	5.27	10.00	9.82	18.81	14.02
Financial leverage (%)	-60.6	-37.0	-46.4	-62.1	-69.5	-68.3
Book value per share (€)	2.78	3.37	4.82	285.29	298.55	325.73
Return on equity (ROE)	-6.8%	24.2%	-5.6%	-10.2%	-14.0%	2.6%

CASH FLOW STATEMENT

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
EBIT	**-1.5**	**7.1**	**-2.3**	**-5.7**	**-11.0**	**2.4**
Depreciation and amortisation	0.8	0.9	0.9	0.9	0.9	0.9
EBITDA	**-0.8**	**8.0**	**-1.4**	**-4.8**	**-10.1**	**3.3**
Changes in working capital	-3.4	5.3	0.6	-0.5	-2.4	-4.9
Other adjustments	0.0	0.0	-0.7	0.2	0.0	0.0
Operating cash flow	**-4.2**	**13.3**	**-1.5**	**-5.1**	**-12.5**	**-1.6**
CAPEX	-0.5	-17.0	-5.7	-0.6	-0.7	-0.8
Free cash flow	**-4.7**	**-3.7**	**-7.2**	**-5.7**	**-13.2**	**-2.4**
Debt financing, net	**0.0**	**0.6**	**0.0**	**0.0**	**0.0**	**0.0**
Equity financing, net	**6.2**	**0.0**	**17.3**	**25.8**	**29.0**	**0.0**
Grants	**0.0**	**0.0**	**0.0**	**0.0**	**4.0**	**7.0**
Other changes in cash	0.0	0.0	0.0	-0.2	0	0
Net cash flows	**1.5**	**-3.2**	**10.0**	**19.9**	**19.8**	**4.6**
Cash and liquid assets, start of the year	14.0	15.5	12.3	22.4	42.2	62.0
Cash and liquid assets, end of the year	**15.5**	**12.3**	**22.4**	**42.2**	**62.0**	**66.6**
EBITDA/share (in €)	**-0.1**	**0.9**	**-0.1**	**-0.5**	**-0.9**	**0.3**
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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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...29	↓	↓	↓	↓
30	7 February 2020	€28.10	Buy	€39.00
31	26 April 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	€33.00	Buy	€43.00
36	7 January 2021	€61.00	Buy	€78.00
37	26 March 2021	€62.60	Add	€78.00
38	Today	€56.80	Buy	€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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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/

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