Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

Q1 results/update

RATING	**BUY**
PRICE TARGET	**€ 51.00**
Return Potential	59.4%
Risk Rating	High

THE CENTRAL VISION IS CLEAR

Q1/19 results showed revenue of €9.5m (Q1/18: €13.7m) while EBIT came in at €0.2m (Q1/18: €6.7m). Prior year numbers were helped by credits of €8.5m at the sales level and €6.7m at the EBIT level relating to Formycon's (FYB) investment in FYB202 during 2013-16. On 4 June FYB announced that it has still to receive €12.3m of the €17.3m gross proceeds due from the March share issue to M&H Equity. Management are optimistic that M&H Equity will transfer the outstanding funds. However, if the money is not forthcoming the most likely solution would be to place the unpaid shares with another institution as the shares have already been entered into the commercial register (Handelsregister) and it is difficult to reverse this. FYB's cash position at end Q1/19 was €9.2m. FYB's management have emphasised that they expect no impact on current or planned development activities, most of which are financed through long term development partnerships. Given that we expect cash consumption of €2-3m during the remainder of this year, the company's financial position looks solid even without receipt of the outstanding funds from M&H Equity. In its May pipeline update, FYB announced that the FYB202 phase I clinical trial is due to start in mid-2019 and that the start of the FYB203 phase III trial is scheduled for mid-2020. However, FDA approval of FYB201 is now not expected until 2021. FYB had previously been aiming for 2020 to facilitate launch of the product soon after patent expiry of the reference product, Lucentis, in June 2020. The delay relates to problems in manufacturing sufficient quantities of FYB201, which in the meantime have been resolved. Despite the delay, we still expect FYB201 to be the first Lucentis biosimilar to reach the U.S. market. We maintain our Buy recommendation but lower the price target from €53.0 to €51.0 to reflect the later launch of FYB201 than we had previously modelled.

Full year 2019 revenue guidance of €35m The Q1/19 report features full-year management revenue guidance of €35m. The revenue expectation is based on reimbursement of development work…(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

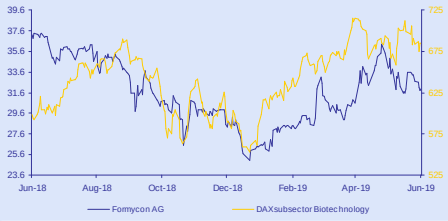
Formycon AG is a Munich, Germany based pharmaceuticals company specialising in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

	As of 06 Jun 2019
Closing Price	€ 32.00
Shares outstanding	10.00m
Market Capitalisation	€ 320.00m
52-week Range	€ 25.05 / 37.35
Avg. Volume (12 Months)	6,389

Multiples	2018	2019E	2020E
P/E	42.3	n.a.	n.a.
EV/Sales	7.2	8.9	8.2
EV/EBIT	43.6	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

	As of 31 Dec 2018
Liquid Assets	€ 12.31m
Current Assets	€ 18.75m
Intangible Assets	€ 0.78m
Total Assets	€ 39.62m
Current Liabilities	€ 3.33m
Shareholders' Equity	€ 33.24m

SHAREHOLDERS

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

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…for the licensed-out projects (FYB201 and FYB203) and FYB202, which FYB is developing within the context of a joint venture with Aristo Pharma GmbH. 2019 revenue is expected to come in below last year's €43.0m because of the inclusion of the FYB202 investment credit in the 2018 topline. In line with guidance given in the annual report published in May, we now expect net income to be slightly negative.

Figure 1: Q1/19 results versus our forecasts

in EURm	Q1-19A	Q1-19E	Delta	Q1-18A
Revenue	9.50	10.00	-5.0%	13.70
EBITDA	0.50	-0.90	n.m.	6.90
margin	5.3%	-9.0%	-	n.m.
EBIT	0.20	-1.20	n.m.	6.70
margin	2.1%	-12.0%	-	0.00
Net income	0.20	-1.20	n.m.	6.70
margin	2.1%	-12.0%	-	*n.m.*
EPS (€)	0.02	-0.13	n.m.	0.72

Source: Formycon; First Berlin Equity Research estimates

Q1/19 results close to our expectations Q1/19 results were quite close to our expectations even though our forecasts were based on the full year 2019 revenue forecast of €40.5m in our last report of 27 March.

Financial position solid even if outstanding funds from M&H are not received In the March press release announcing the issue to M&H Equity, FYB stated that the proceeds would be used to "expand the pipeline and develop the company's own biosimilar projects". This statement implied use of funds to develop those of FYB's biosimilar candidates which are so far unpartnered, in particular FYB205. FYB205, whose reference product FYB has not so far been published, is an early stage project which has progressed up to initial cell line screening. During Q1/19 FYB injected a further €5.1m into the FYB202 joint venture company, thereby taking its total investment to around €21.0m. We expect this to be the single biggest unreimbursed investment undertaken by FYB this year. FYB's cash position at end Q1/19 was €9.2m. Given that we expect cash consumption of €2-3m during the remainder of this year, the company's financial position looks solid even without receipt of the outstanding funds from M&H Equity. Management have emphasised that they expect no impact on current or planned development activities, most of which are financed through long term development partnerships.

Update on development portfolio In May FYB provided an update on its development portfolio. Submission of the biologics application (BLA) for FYB201 to the FDA is now expected for the beginning of Q4 this year and marketing authorisation approval in the U.S. and the EU in 2021. Management had previously expected the submission of the BLA during late 2018/H1 2019 and marketing authorisation approval in the U.S. in 2020. From talking to management, we gather that problems in manufacturing sufficient quantities of FYB201 caused the delay. These problems have now been resolved. Figure 2 overleaf shows patent expiry dates for the development portfolio's reference products. We estimate that combined Q1/19 sales of the reference products so far announced by FYB climbed by ca. 15% in constant currency terms.

Figure 2: Patent expiry dates for development portfolio's reference products

FYB biosimilar candidate	Reference product	Main indication(s)	Reference product patent expiry dates
FYB201	Lucentis	wet macular degeneration	U.S. 06/2020 & EU 7/2022
FYB202	Stelara	psoriasis, Crohn's disease	U.S. 09/2023 & EU 7/2024
FYB203	Eylea	wet macular degeneration	U.S. 11/2023 & EU 05/2025
FYB205	to be announced	n.a.	n.a.

Source: companies

FYB is the only company to have successfully concluded a phase III trial of a Lucentis biosimilar candidate. The FYB201 phase III trial was completed in June 2018. As figure 3 shows, the furthest advanced competing Lucentis biosimilar candidates have still to complete phase III. Although FYB201 is now scheduled to reach the U.S. market in 2021 rather than in 2020, we still expect it to be the first Lucentis biosimilar to be launched.

Figure 3: Furthest advanced competing Lucentis biosimilar candidates

Company	Biosimilar candidate	Phase III start dates	Forecast phase III completion dates
Samsung Bioepis	SB11	March 2018	November 2019
Xbrane	Xlucane	April 2019	February 2021

Source: companies

FYB202 in pole position among Stelara biosimilar candidates The FYB202 phase I clinical trial is due to start in mid-2019. The most advanced competing Stelara biosimilar candidate is NeuLara, which is being developed by the Australian company, NeuClone. A phase I trial of NeuLara is scheduled to start in H2/2019. The Neulara phase I trial will take place in Australia 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 authorization dossier were discussed. Given that the FYB202 phase I trial is starting ahead of the NeuLara phase I trial and 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.

Momenta/Mylan Eylea biosimilar phase III trial has started in advance of FYB203 trial The FYB203 phase III clinical trial is scheduled to start in mid-2020. 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 assume that both FYB203 and M710 will reach the U.S. market soon after patent expiry of the reference product in November 2023.

We maintain our Buy recommendation but lower the price target from €53.0 to €51.0 As figure 4 overleaf shows, we have altered our 2019 forecasts to take account of the guidance given in the annual and Q1 reports. For the first time we show full 2020 forecasts featuring revenue of €38m and net profit of €-2.0m. We maintain our Buy recommendation but lower the price target to €51.0 (previously: €53.0) to reflect the launch of FYB201 on the U.S. market in 2021 rather than in 2020 as we had previously forecast.

Figure 4: Changes to our forecasts

in €m	2019E Old	2019E New	2019E Delta	2020E New
Revenues	40.00	35.00	-12.5%	38.00
EBIT	-4.67	-2.00	-	-2.00
margin	*neg.*	*neg.*	-	*neg.*
Net income	-4.69	-1.97	-	-1.96
margin	*neg.*	*neg.*	-	*neg.*
EPS (diluted, in €)	-0.50	-0.20	-	-0.20

Source: First Berlin Equity Research estimates

Figure 5: 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)	€166M	327K	€4,813	€1,573M	17%	€324M	12%	12%	n.a.	3 Years
FYB201	nAMD,DR (US)	€164M	144K	€8,313	€1,197M	17%	€326M	12%	12%	n.a.	2 Years
FYB202	Pso,CrD (ex-US)	€44M	56K	€25,208	€1,404M	17%	€278M	12%	15%	n.a.	5 Years
FYB202	Pso,CrD (US)	€64M	47K	€41,021	€1,938M	17%	€368M	12%	15%	n.a.	4 Years
FYB203	nAMD,DR (ex-US)	€77M	417K	€4,454	€1,856M	17%	€557M	12%	15%	n.a.	6 Years
FYB203	nAMD,DR (US)	€126M	392K	€7,875	€3,085M	17%	€740M	12%	15%	n.a.	4 Years
FYB205	n.a.	€97M									
PACME PV		€739M									
Costs PV[4]		€277M									
NPV		€462M									
Downpayments and Milestones		€29M									
Proforma net Cash		€22M									
Fair Value		€512M									
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

Figure 6: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	€775M	€739M	**-4.7%**
Costs PV	€300M	€277M	-7.7%
NPV	€475M	€462M	**-2.8%**
PV downpayments and milestones	€29M	€29M	-1.0%
Proforma net Cash	€26M	€22M	-17.3%
Fair Value	€530M	€512M	-3.4%
Share Count	10,000K	10,000K	0.0%
Fair value per share	€53.00	€51.00	**-3.8%**

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	241.42
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...25	↓	↓	↓	↓
26	14 September 2018	€32.25	Buy	€53.00
27	22 November 2018	€29.75	Buy	€53.00
28	27 March 2019	€28.95	Buy	€53.00
29	Today	€32.00	Buy	€51.00

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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.

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- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
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