

Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWWY8

Q1 2018 results

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 53.00**

44.2%

High

FORMYCON RECEIVES €8.5M CREDIT FOR PAST INVESTMENT IN FYB202

Formycon's Q1/18 results were well above our expectations because the company booked an €8.5m credit in revenue and profits relating to past investment in FYB202. Sales came in at €13.7m (FBe: €5.0m; Q1/17: €3.4m while EBIT was €6.7m (FBe: €0.0m; Q1/17: €-0.7m). Formycon and Aristo Pharma GmbH formed a joint venture to further develop FYB202 at the end of 2017. Formycon's share of the J.V. is 24.9%. The €8.5m credit reflects the development work carried out by Formycon during 2013-16 – i.e. prior to the J.V.'s foundation. Formycon will be able to deduct €8.5m from its 24.9% share of future development spending in FYB202, but will be entitled to a 24.9% share of licensing and marketing revenues generated by the J.V. We are raising our price target to €53.0 (previously: €52.0) to reflect the present value of the €8.5m reduction in Formycon's funding obligation to the J.V. We maintain our Buy recommendation.

FYB will make €8.5m in cash savings during FYB202 development The reference product for FYB202 is Stelara. Stelara is a human interleukin-12 and -23 antagonist indicated for psoriasis, psoriatic arthritis and Crohn's disease. Worldwide sales rose 17.5% to USD4.0bn in 2017 (2016: USD3.4bn). Patent protection for Stelara expires in September 2023 in the US and in July 2024 in the EU. In Q4/17 Formycon booked a single digit sum in return for contributing the project rights to the FYB202 joint venture company. Formycon received the cash associated with this transaction during Q1/18. This was the main reason for the decline in Formycon's receivables from €10.5m at the end of December to €3.2m at the end of March. The €8.5m credit booked in Q1/18 is a non-cash item but Formycon will make €8.5m in cash savings relative to its 24.9% share of spending on FYB202 during the development of the compound.

Focus on "third wave" of biosimilars Formycon is focused on the "third wave" of biosimilars, i.e. on biosimilars whose reference products go off patent after 2020. Besides FYB202, the company currently has three other biosimilars under development as shown in figure 2 overleaf. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

| | 2014 | 2015 | 2016 | 2017 | 2018E | 2019E |
|--------------------|--------|--------|--------|--------|--------|--------|
| Revenue (€m) | 12.59 | 16.92 | 19.53 | 29.00 | 35.00 | 24.20 |
| Y-o-y growth | 29.7% | 34.5% | 15.4% | 48.5% | 20.7% | -30.9% |
| EBIT (€m) | 0.87 | 0.54 | -4.07 | -1.54 | 4.00 | -4.67 |
| EBIT margin | 6.9% | 3.2% | -20.8% | -5.3% | 11.4% | -19.3% |
| Net income (€m) | 0.86 | 0.58 | -4.07 | -1.58 | 4.19 | -4.48 |
| EPS (diluted) (€) | 0.10 | 0.06 | -0.45 | -0.17 | 0.45 | -0.48 |
| DPS (€) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| FCF (€m) | -0.63 | -0.10 | -6.40 | -4.66 | 5.56 | -3.10 |
| Net gearing | -70.4% | -81.6% | -66.9% | -60.6% | -63.0% | -61.1% |
| Liquid assets (€m) | 9.22 | 20.30 | 13.97 | 15.48 | 21.04 | 17.94 |

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 specializing in the development of biosimilars, e.g. generic versions of biotechnology products.

MARKET DATA

As of 05 Jun 2018

| | |
|-------------------------|-----------------|
| Closing Price | € 36.75 |
| Shares outstanding | 9.34m |
| Market Capitalisation | € 343.39m |
| 52-week Range | € 28.85 / 39.00 |
| Avg. Volume (12 Months) | 9,632 |

| Multiples | 2017 | 2018E | 2019E |
|------------|------|-------|-------|
| P/E | n.a. | 81.9 | n.a. |
| EV/Sales | 12.4 | 10.3 | 14.9 |
| EV/EBIT | n.a. | 90.0 | n.a. |
| Div. Yield | 0.0% | 0.0% | 0.0% |

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2017

| | |
|----------------------|----------|
| Liquid Assets | € 15.48m |
| Current Assets | € 26.36m |
| Intangible Assets | € 0.86m |
| Total Assets | € 30.83m |
| Current Liabilities | € 3.44m |
| Shareholders' Equity | € 25.54m |

SHAREHOLDERS

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



The reference products for FYB201 and FYB203 are respectively Lucentis and Eylea. Lucentis and Eylea are intraocular anti-VEGF (vascular endothelial growth factor) drugs which are indicated for ophthalmic conditions including age-related macular degeneration and diabetic macular edema. Combined sales of Lucentis and Eylea climbed 9.3% during 2017 to USD9.3bn (2016: USD8.5bn). This figure corresponds to ca. 90% of the value of the intraocular anti-VEGF market.

Figure 1: Q1/18 results versus our forecasts

| in EURm | Q1-18A | Q1-18E | Delta | Q1-17E | Delta |
|------------|--------|--------|--------|--------|--------|
| Revenue | 13.69 | 5.00 | 173.8% | 3.38 | 305.0% |
| EBIT | 6.68 | 0.00 | n.m. | -0.70 | n.m. |
| margin | n.m. | n.m. | - | n.m. | - |
| Net income | 6.67 | 0.00 | n.m. | -0.71 | n.m. |
| margin | n.m. | n.m. | - | n.m. | - |
| EPS (€) | 0.71 | 0.00 | n.m. | -0.08 | n.m. |

Source: Formycon; First Berlin Equity Research estimates

Success of FYB201 phase III trial In early May, Formycon announced that based on interim results FYB201 had achieved the primary endpoint of its phase III trial. The primary endpoint of the trial is confirmation of comparable efficacy between FYB201 and the reference product, Lucentis, in the indication neovascular age-related macular degeneration. FYB201 is the furthest advanced of Formycon's biosimilar candidates. Bioeq GmbH began recruitment of patients for a global phase III trial with the compound in February 2016. The last patient in the trial, in which patients are treated for a total of 48 weeks, is expected to complete treatment later in the current quarter. We expect the release of final results from the trial during Q3 of this year and the submission of a Biologics License Application (BLA) to the FDA in either Q4 2018 or Q1 2019. Patent expiry for Lucentis is June 2020 in the US and January 2022 in the EU. Formycon's management expects that the company's biosimilar products will be the first to market following the expiry of the patents on their reference products from 2020 onwards. News that FYB201 has achieved the primary endpoint of its phase III trial keeps Formycon on track to achieve this goal.

Figure 2: Formycon's current product pipeline

| PRODUCT CANDIDATE | ORIGINATOR (INN) | DISEASE AREA | PARTNER | PRECLINICAL PHASE | CLINICAL PHASE | |
|-------------------|----------------------------|---------------|--------------------|-------------------|----------------|-----------|
| | | | | | PHASE I | PHASE III |
| FYB201 | Lucentis® (ranibizumab) | Ophthalmology | Bioeq IP AG | | | |
| FYB202 | Stelara® (ustekinumab) | Immunology | Aristo Pharma GmbH | | | |
| FYB203 | Eylea® (afibercept) | Ophthalmology | Santo Holding GmbH | | | |
| FYB205 | Undisclosed | Undisclosed | not partnered | | | |

Source: Formycon



We expect clinical development of FYB202 and FYB203 from 2019 Patent protection for Eylea expires in June 2023 in the US and in May 2025 in the EU. FYB202 and FYB203 are currently at the preclinical stage. We expect clinical development of these products to begin in 2019. Formycon has not yet revealed FYB205's reference product.

Low double digit royalties on FYB201 and FYB203 Formycon concluded partnerships for FYB201 and FYB203 in 2013 and 2015 respectively. The partnership agreements for FYB201 and FYB203 entail a mid-single digit upfront payment to Formycon and funding of all development, production and marketing costs of the Formycon biosimilar by the partner. Formycon's expected sales participation (royalties) is in the double digit percentage range (depending on certain marketing and manufacturing milestones). The cumulative royalty income to Formycon from these partnerships is expected to exceed €100m for each product.

Under FYB202 JV deal Formycon receives up to 24.9% of revenues In December 2017 Formycon founded a joint venture for the development of FYB202 with Aristo Pharma GmbH, a subsidiary of Santo Holding GmbH. The structure of the FYB202 deal differs from those concluded for FYB201 and FYB203. Under the FYB202 deal Formycon will bear 24.9% of development costs but will also participate in up to 24.9% of worldwide marketing revenues.

Price target raised to €53.0 (previously: €52.0), Buy recommendation maintained 2018 revenue guidance given in the 2017 annual report published in early May was for a slight rise above the 2017 level of €29.0m. Management stated that 2018 profitability would be influenced by investments in non-outlicensed projects (FYB202 and FYB205). In the light of the Q1/18 results, Formycon is now guiding towards revenues of €35.0m and a significantly positive result. Changes to our forecasts are shown in figure 3 below. We are raising our price target to €53.0 (previously: €52.0) to reflect the present value of the €8.5m reduction in Formycon's funding obligation to the J.V. We maintain our Buy recommendation.

Figure 3: Changes to our forecasts

| in €m | 2018E | | | 2019E | | |
|---------------------|-------|-------|---------|-------|-------|-------|
| | Old | New | Delta | Old | New | Delta |
| Revenues | 29.30 | 35.00 | 19.5% | 24.20 | 24.20 | 0.0% |
| EBIT | 0.15 | 4.00 | 2566.7% | -4.67 | -4.67 | n.m. |
| margin | neg. | neg. | - | neg. | neg. | - |
| Net income | 0.33 | 4.19 | 1171.0% | -4.48 | -4.48 | n.m. |
| margin | neg. | neg. | - | neg. | neg. | - |
| EPS (diluted, in €) | 0.04 | 0.45 | 1022.6% | -0.48 | -0.48 | n.m. |

Source: First Berlin Equity Research estimates



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) | €162M | 327K | €4,813 | €1,573M | 17% | €339M | 12% | 12% | n.a. | 4 Years |
| FYB201 | nAMD,DR (US) | €144M | 144K | €8,313 | €1,197M | 17% | €258M | 12% | 12% | n.a. | 2 Years |
| FYB202 | Pso,CrD (ex-US) | €44M | 56K | €25,208 | €1,404M | 17% | €272M | 2% | 15% | n.a. | 6 Years |
| FYB202 | Pso,CrD (US) | €62M | 47K | €41,021 | €1,938M | 17% | €375M | 12% | 5% | n.a. | 5 Years |
| FYB203 | nAMD,DR (ex-US) | €89M | 417K | €4,454 | €1,856M | 17% | €611M | 2% | 15% | n.a. | 7 Years |
| FYB203 | nAMD,DR (US) | €153M | 392K | €7,875 | €3,085M | 17% | €884M | 12% | 15% | n.a. | 5 Years |
| FYB205 | n.a. | €97M | | | | | | | | | |
| PACME PV | | €753M | | | | | | | | | |
| Costs PV ⁴⁾ | | €306M | | | | | | | | | |
| NPV | | €447M | | | | | | | | | |
| Downpayments and Milestones | | €28M | | | | | | | | | |
| Net Cash | | €17M | | | | | | | | | |
| Fair Value | | €491M | | | | | | | | | |
| Share Count | | 9,344K | | | | | | | | | |
| Fair Value Per Share | | €52.58 | | | | | | | | | |

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

Figure 5: Changes to our pipeline valuation

| | Old | New | Delta |
|--------------------------------|--------|--------|-------|
| PACME PV | €753M | €753M | -0.1% |
| Costs PV | €313M | €306M | -2.3% |
| NPV | €440M | €447M | 1.4% |
| Downpayments and Milestones PV | €30M | €28M | -6.9% |
| Net Cash | €15M | €17M | 7.2% |
| Fair Value | €486M | €491M | 1.1% |
| Share Count | 9,344K | 9,344K | 0.0% |
| Fair value per share | €52.00 | €52.58 | 1.1% |

Source: First Berlin Equity Research



INCOME STATEMENT

| All figures in EURm | 2014A | 2015A | 2016A | 2017A | 2018E | 2019E |
|--|-------------|-------------|--------------|--------------|-------------|--------------|
| Revenue | 12.6 | 16.9 | 19.5 | 29.0 | 35.0 | 24.2 |
| Increase/decrease in unfinished products | 0.0 | 0.0 | 0.0 | 0.4 | 0.0 | 0.0 |
| Total output | 12.6 | 16.9 | 19.5 | 29.4 | 35.0 | 24.2 |
| Other operating income | 0.1 | 0.2 | 0.1 | 0.1 | 0.1 | 0.1 |
| Cost of goods sold | -5.9 | -8.9 | -15.4 | -21.2 | -21.3 | -18.0 |
| Gross profit | 6.8 | 8.3 | 4.3 | 8.4 | 13.8 | 6.3 |
| Personnel costs | -2.9 | -3.9 | -5.1 | -6.3 | -7.0 | -8.0 |
| Depreciation and amortisation | -1.1 | -0.9 | -0.7 | -0.8 | -0.8 | -0.9 |
| Other operating expenses | -1.9 | -2.9 | -2.6 | -2.8 | -2.1 | -2.2 |
| Operating income (EBIT) | 0.9 | 0.5 | -4.1 | -1.5 | 4.0 | -4.7 |
| Net financial result | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | 0.2 |
| Pre-tax income (EBT) | 0.9 | 0.6 | -4.1 | -1.6 | 4.2 | -4.5 |
| Income taxes | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income / loss | 0.9 | 0.6 | -4.1 | -1.6 | 4.2 | -4.5 |
| Diluted EPS (in €) | 0.10 | 0.06 | -0.45 | -0.17 | 0.45 | -0.48 |
| EBITDA | 1.9 | 1.5 | -3.4 | -0.8 | 4.8 | -3.8 |
| Ratios | | | | | | |
| Gross margin on output | 53.7% | 48.9% | 21.9% | 28.4% | 39.5% | 26.1% |
| EBIT margin on output | 6.9% | 3.2% | -20.8% | -5.2% | 11.4% | -19.3% |
| EBITDA margin on output | 15.4% | 8.7% | -17.3% | -2.6% | 13.8% | -15.6% |
| Net margin on output | 6.8% | 3.4% | -20.8% | -5.4% | 12.0% | -18.5% |
| Tax rate | -0.2% | -0.2% | 0.1% | -0.2% | 0.0% | 0.0% |
| Expenses as % of output | | | | | | |
| Cost of goods sold | -47.0% | -52.5% | -78.8% | -72.0% | -60.8% | -74.3% |
| Personnel costs | -23.0% | -22.8% | -26.1% | -21.5% | -20.0% | -33.1% |
| Depreciation and amortisation | -8.5% | -5.5% | -3.6% | -2.7% | -2.4% | -3.7% |
| Net other operating exp. | -14.4% | -16.0% | -12.6% | -9.1% | -5.7% | -8.7% |
| Y-Y Growth | | | | | | |
| Revenues | 2949.5% | 34.5% | 15.4% | 48.5% | 20.7% | -30.9% |
| Operating income | n.m. | -38.1% | n.m. | n.m. | n.m. | n.m. |
| Net income/ loss | n.m. | -32.9% | n.m. | n.m. | n.m. | n.m. |



BALANCE SHEET

| All figures in EURm | 2014A | 2015A | 2016A | 2017A | 2018E | 2019E |
|---|-------------|-------------|-------------|-------------|-------------|-------------|
| Assets | | | | | | |
| Current assets, total | 12.8 | 23.3 | 20.7 | 26.6 | 28.8 | 23.4 |
| Cash and cash equivalents | 0.3 | 0.6 | 3.0 | 4.5 | 1.8 | 1.2 |
| Other liquid assets | 8.9 | 19.7 | 11.0 | 11.0 | 19.3 | 16.7 |
| Receivables | 3.3 | 2.8 | 5.2 | 10.5 | 7.0 | 4.8 |
| Inventories | 0.3 | 0.2 | 0.6 | 0.6 | 0.7 | 0.6 |
| Other current assets | 0.0 | 0.0 | 0.9 | 0.1 | 0.1 | 0.0 |
| Non-current assets, total | 4.1 | 3.8 | 4.5 | 4.2 | 11.2 | 10.5 |
| Shares in affiliated companies | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Loans to affiliated companies | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Property, plant & equipment | 2.7 | 2.6 | 3.4 | 3.3 | 4.2 | 5.6 |
| Goodwill & other intangibles | 1.3 | 1.1 | 1.0 | 0.9 | 0.7 | 0.5 |
| Other assets | 0.0 | 0.1 | 0.1 | 0.1 | 6.3 | 4.4 |
| Total assets | 16.9 | 27.1 | 25.2 | 30.8 | 40.1 | 34.0 |
| Shareholders' equity & debt | | | | | | |
| Current liabilities, total | 3.3 | 1.3 | 2.6 | 3.4 | 4.6 | 3.1 |
| Accounts payable | 2.3 | 0.6 | 2.3 | 1.8 | 2.5 | 1.7 |
| Other current liabilities | 1.0 | 0.7 | 0.3 | 1.7 | 2.1 | 1.5 |
| Long-term liabilities, total | 0.5 | 0.9 | 1.7 | 1.8 | 2.1 | 1.4 |
| Provisions | 0.5 | 0.7 | 0.7 | 1.3 | 1.4 | 1.0 |
| Other liabilities | 0.0 | 0.3 | 1.0 | 0.6 | 0.7 | 0.5 |
| Minority interests | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Shareholders' equity | 13.1 | 24.9 | 20.9 | 25.5 | 33.4 | 29.4 |
| Deferred income | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total consolidated equity and debt | 16.9 | 27.1 | 25.2 | 30.8 | 40.1 | 34.0 |
| Key figures | | | | | | |
| Current ratio (x) | 3.94 | 17.45 | 7.91 | 7.75 | 6.33 | 7.45 |
| Quick ratio (x) | 3.83 | 17.28 | 7.67 | 7.59 | 6.18 | 7.26 |
| Financial leverage (%) | -70.4 | -81.6 | -66.9 | -60.6 | -63.0 | -61.1 |
| Book value per share (€) | 1.52 | 2.74 | 2.30 | 2.78 | 3.63 | 3.19 |
| Return on equity (ROE) | 6.4% | 3.0% | -17.8% | -6.8% | 14.2% | -14.3% |



CASH FLOW STATEMENT

| All figures in EURm | 2014A | 2015A | 2016A | 2017A | 2018E | 2019E |
|--|-------------|-------------|-------------|-------------|-------------|-------------|
| EBIT | 0.9 | 0.5 | -4.1 | -1.5 | 4.0 | -4.7 |
| Depreciation and amortisation | 1.1 | 0.9 | 0.7 | 0.8 | 0.8 | 0.9 |
| EBITDA | 1.9 | 1.5 | -3.4 | -0.8 | 4.8 | -3.8 |
| Changes in working capital | -2.0 | -1.1 | -1.7 | -3.4 | 4.5 | 0.7 |
| Other adjustments | 0.0 | 0.1 | 0.1 | 0.0 | -2.1 | 2.1 |
| Operating cash flow | 0.0 | 0.5 | -5.0 | -4.2 | 7.2 | -1.0 |
| CAPEX | -0.6 | -0.6 | -1.4 | -0.5 | -1.6 | -2.1 |
| Free cash flow | -0.6 | -0.1 | -6.4 | -4.7 | 5.6 | -3.1 |
| Debt financing, net | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Equity financing, net | 0.0 | 11.2 | 0.1 | 6.2 | 0.0 | 0.0 |
| Other changes in cash | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net cash flows | -0.6 | 11.1 | -6.3 | 1.5 | 5.6 | -3.1 |
| Cash and liquid assets, start of the year | 0.9 | 9.2 | 20.3 | 14.0 | 15.5 | 21.0 |
| Cash and liquid assets, end of the year | 0.3 | 20.3 | 14.0 | 15.5 | 21.0 | 17.9 |
| EBITDA/share (in €) | 0.2 | 0.2 | -0.4 | -0.1 | 0.5 | -0.4 |
| Y-Y Growth | | | | | | |
| Operating cash flow | n.a. | n.m. | n.m. | n.m. | n.m. | n.m. |
| Free cash flow | n.a. | n.m. | n.m. | n.m. | n.m. | n.m. |
| EBITDA/share | n.a. | -26.8% | 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...21 | ↓ | ↓ | ↓ | ↓ |
| 22 | 2 October 2017 | €34.80 | Buy | €48.00 |
| 23 | 3 May 2018 | €34.80 | Buy | €52.00 |
| 24 | 8 May 2018 | €38.15 | Buy | €52.00 |
| 25 | Today | €36.75 | Buy | €53.00 |

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BUY: An expected favourable price trend of more than 25% percent.

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