# Formycon AG

Germany / Biopharmaceuticals Xetra Bloomberg: FYB GR ISIN: DE000A1EWVY8

Update

RATING	BUY
PRICE TARGET	€ 80.00
Return Potential	66.0%
Risk Rating	High

# ALL STILL TO PLAY FOR

The Formycon share price has fallen by more than 40% since the beginning of 2023, mainly because of lower than expected royalty income from the first Formycon medicine to reach the market, the Lucentis biosimilar, FYB201. However, FYB201 which was launched in the EU, UK and US in 2022, is only the first of six biosimilars which we expect Formycon to have launched by the end of this decade. Forthcoming biosimilars have higher reference product sales and royalty rates than FYB201. In our view, the most important near-term launch (subject to approval, in both the EU and US in 2025) will be of the Stelara biosimilar, FYB202. Stelara generated worldwide sales of USD10.9bn in 2023. This compares with USD3.6bn of sales for Lucentis in 2021, the last year before the launch of biosimilars of the drug. Furthermore, Formycon will earn a royalty of 30-40% on FYB202 sales. The current royalty on FYB201 sales is 7-8%. There will be more competition on the Stelara biosimilar market than on the Lucentis biosimilar market. But critically, unlike Roche whose 2022 launch of the Lucentis successor product, Vabysmo, coincided with the introduction of Lucentis biosimilars, Johnson & Johnson do not have a near-term successor product to Stelara. We expect Formycon to generate triple digit royalties from FYB202 are early as 2026. This compares with our total 2026 royalty forecast for FYB201 (including both top-line and at-equity revenues) of ca. €15m. We think the current share price weakness is an opportunity to pick up Formycon stock cheaply ahead of the lucrative FYB202 launch. We maintain our Buy recommendation but have lowered the price target to €80 (previously: €105), mainly to reflect downward revisions to our FYB201 forecasts as well as a more conservative view on FYB203 (Formycon's Eylea biosimilar), for which we model first revenues from next year.

**Milestone payments drove 2023 revenue growth** 2023 revenues jumped 82.8% to  $\in$ 77.7m (2022:  $\in$ 42.5m). The increase was entirely due to  $\in$ 37.4m of milestone payments (2022:  $\in$ 0m) in connection with the marketing agreement for FYB202 concluded with Fresenius in February 2023. (p.t.o.)

# **FINANCIAL HISTORY & PROJECTIONS**

	2022	2023	2024E	2025E	2026E	2027E
Revenue (€m)	42.50	77.70	62.30	108.57	232.70	212.12
Y-o-y growth	16.1%	82.8%	-19.8%	74.3%	114.3%	-8.8%
EBITDA (€m)	-15.87	1.52	-23.70	44.97	178.50	149.12
EBITDA margin	-37.3%	2.0%	-38.0%	41.4%	76.7%	70.3%
Net income (€m)	35.99	75.80	-37.30	34.18	166.79	109.75
EPS (diluted) (€)	2.59	4.72	-2.11	1.92	9.36	6.16
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-55.95	-27.23	-77.62	-43.32	103.12	74.68
Net gearing	-2.8%	-5.4%	-8.5%	-8.5%	-16.9%	-20.6%
Liquid assets (€m)	9.82	27.04	46.25	49.31	126.04	176.48

### **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, i.e. generic versions of biotechnology products.

MARKET DA	ТА	As of 12	2 Jun 2024		
Closing Price			€ 48.20		
Shares outstand	ding		17.66m		
Market Capitalis	sation	€	851.06m		
52-week Range	•	€ 38.15 / 69.20			
Avg. Volume (1	2 Months)		9,176		
Multiples	2023	2024E	2025E		
P/E	10.2	n.a.	25.1		
EV/Sales	11.0	13.7	7.9		
EV/EBITDA	562.1	n.a.	19.0		
Div. Yield	0.0%	0.0%	0.0%		

# STOCK OVERVIEW



COMPANY DATA	As of 31 Dec 2023
Liquid Assets	€ 27.04m
Current Assets	€ 67.15m
Intangible Assets	€ 552.94m
Total Assets	€ 890.36m
Current Liabilities	€ 69.31m
Shareholders' Equity	€ 502.75m
SHAREHOLDERS	
Athos KG	24.3%
Wendeln & Cie. KG	13.6%
Gedeon Richter Plc	9.0%
Active Ownership S.a.r.l.	6.0%
Free Float and other	47.1%

Revenues from partners in connection with development work carried out by Formycon on FYB202 and FYB203 fell €6m to €36.2m (2022: €42.2m) due to the approval of FYB201 in the UK, EU and US during 2022. Royalties on sales of FYB201, primarily from the US, came in at €4.2m (2022: €0.3m). Further significant royaty income from FYB201 was also included in the associates line in connection with Formycon's 50% stake in Bioeq AG. FYB202 milestone income pushed EBITDA to €1.5m (2022: €15.9m). For the first time, Formycon published an adjusted EBITDA figure to reflect its share in Bioeq's income. 2023 adjusted EBITDA of €13.3m included €11.8m in "investment gain from Bioeq AG."

FYB201 earn-out written down 31.6% in FYB201 balance sheet Formycon's 2023 balance sheet shows a €99.5m (31.6%) reduction from €314m to €215m in the present value of the earn-out payable to Athos in connection with future income generated by the Lucentis biosimilar, FYB201. The reduction in the PV of the FYB201 earnout reflects a downward revision of management's assessment of future income from the product as well as a higher discount rate due to the general increase in the level of interest rates. Roche launched Vabysmo, a successor product to Lucentis, in early 2022 at a large discount to Lucentis. Vabysmo also represents an improvement on Lucentis in that the required dosage frequency is lower. Vabysmo sales reached USD2.6bn in 2023 as it gained market share from Lucentis. As figure 1 shows, annual US sales of Lucentis fell by ca. two thirds from ca. USD1.5bn to ca. USD500m over the two year period to end 2023. In the Rest of the World annual sales fell by ca. one third from USD2.2bn to USD1.5bn. We think the decline was partly due to the introduction of biosimilars such as FYB201, but mainly due to the launch of Vabysmo. Formycon's 2023 annual report also showed a €31.2m (16.9%) impairment in the value of Formycon's investment in Bioeq AG from €184.7m to €153.5m - again reflecting a downward revision of expectations of future income generated by FYB201. Formycon included the €68.3m sum of the €99.5m earn-out reduction and the €31.2m impairment in net income, which came in at €75.8m (2022: €36.0m). The prior year figure benefitted from an exceptional item of €66.9m (the sum of an €89.7m upward revaluation of Formycon's stake in FYB202 following the Athos transaction and a €22.8m upward revaluation of the FYB201 earn-out liability).

**FYB201 royalty income to rise this year due sales ramp in US, Europe, new launches** Formycon is guiding towards sales of €55m-65m and EBITDA of €-15m to €-25m for 2024. Sales are expected to be fall compared with 2023 largely because of lower FYB202 milestone payments, as part of the milestone payments originally expected for 2024 were booked in 2023. Payments from partners for development work on FYB201 and FYB203 are also expected to be lower than last year because of progress made in these projects (FYB201 approved by the FDA in 2022, FYB203 expected to be granted FDA approval later this month). Management expects the decline in these two items to be counteracted to some extent by increasing royalty income from FYB201as sales ramp up further in the EU, UK and US and the product is launched in Canada, Latin America and the MENA region.

**Clinical phase of FYB206 development has just started** The expected decline in EBITDA stems in part from lower revenue, and in part from increasing development costs for FYB208 and FYB209 whose reference products Formycon has still to disclose. Development work will also start on a new project, FYB210 (reference product also undisclosed). In addition, Formycon is continuing development work on FYB206, a biosimilar of Keytruda, which with 2023 sales of UD25bn, is the best-selling drug in the world. On 13 June Formycon announced the inclusion of the first patient in a phase 1 trial of FYB206. The trial investigates the pharmacokinetic equivalence of FYB206 with Keytruda as part of a preventive therapy for patients who have had a malignant melanoma (black skin cancer) completely surgically removed. Recruitment of a parallel phase III trial investigating the safety and efficacy of FYB206 compared with Keytruda in patients with non-small cell lung cancer is expected to start very soon.

As Formycon has demonstrated technical proof of similarity between FYB206 and Keytruda, development costs will be capitalised rather than expensed, and so will not impact EBITDA.

Adjusted EBITDA has replaced net profit as a key performance indicator Formycon stated in the 2023 results press release that it has replaced net profit as a key performance indicator with adjusted EBITDA. The reason for the move is the volatility of net profit due to fluctuations in the value of the FYB201 earn-out. The company did not show net profit in its Q1/24 figures and has not given net profit guidance for FY/24.

USDm	FY 22	Q1 23	Q2 23	Q3 23	Q4 23	FY 23	Q1 24
Lucentis			QZ 23	QJ 23	Q4 23	1123	Get 24
US	1,061	180	147	110	72	509	57
%Δ	-28.3%	-35.0%	-55.0%	-53.5%	-67.2%	-52.0%	-68.6%
ROW	1,874	416	395	363	301	1,475	314
%Δ	-13.2%	-20.0%	-21.2%	-20.2%	-20.0%	-21.3%	-24.5%
%∆ Total	2,935	-20.078 <b>596</b>	-21.270 542	473	373	1,984	-24.376 <b>371</b>
	-19.4%	-25.2%	-34.5%	-31.6%	-39.6%	-32.4%	-37.8%
%Δ	-13.470	-23.2 /0	-J-+.J /0	-51.076	-33.076	-32.470	-57.076
Vabysmo							
US	539	389	476	602	670	2,137	744
%Δ	n.a.	1612.1%	474.5%	282.9%	144.3%	296.7%	91.1%
ROW	77	78	108	140	169	495	225
%Δ	n.a.	n.a.	1202.0%	546.1%	261.9%	543.1%	189.7%
Total	616	467	584	743	839	2,632	969
% <b>Δ</b>	26.2%	1954.5%	540.6%	314.9%	161.4%	327.5%	107.6%
/0 Δ	20.270	1004.070	040.070	014.070	101.470	021.070	107.070
Eylea							
US	6,264	1,434	1,500	1,448	1,338	5,720	1,202
%Δ	8.1%	-5.5%	-7.5%	-11.1%	-10.6%	-8.7%	-16.2%
ROW*	3,395	847	886	872	890	3,495	n.a.
%Δ	-1.6%	-2.5%	1.8%	6.7%	6.1%	2.9%	n.a.
Total	9,659	2,281	2,386	2,320	2,228	9,215	n.a.
%Δ	4.5%	-4.4%	-4.2%	-5.2%	-4.6%	-4.6%	n.a.
Eylea HD							
US	0	0	0	43	123	166	200
%Δ	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
ROW*	0	0	0	0	0	0	n.a.
%Δ	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total	0	0	0	43	123	166	n.a.
%Δ	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Stelara							
US	6,388	1,451	1,817	1,912	1,786	6,966	1,396
%Δ	21.9%	5.2%	5.0%	15.5%	10.1%	9.0%	-3.8%
ROW	3,335	993	981	951	967	3,892	1,055
%Δ	35.2%	9.2%	13.0%	19.9%	26.4%	16.7%	6.2%
Total	9,723	2,444	2,797	2,864	2,753	10,858	2,451
%Δ	26.2%	6.8%	7.6%	<b>16.9%</b>	15.3%	11.7%	0.3%
Keytruda							
US	12,686	3,485	3,863	3,794	3,972	15,114	4,119
%Δ	29.9%	25.4%	20.8%	13.9%	17.5%	19.1%	18.2%
ROW	8,251	2,310	2,408	2,543	2,636	9,897	2,828
%Δ	11.2%	13.8%	17.2%	21.4%	27.3%	19.9%	22.4%
Total	20,937	5,795	6,271	6,337	6,608	25,011	6,947
%Δ	21.8%	20.5%	19.4%	<b>16.8%</b>	21.2%	19.5%	19.9%

Figure 1: Reference products and competitors: recent sales development

Source: Companies

Q1/24 sales down due to no FYB202 milestone, but FYB201 royalty income up Formycon's Q1/24 report showed sales of  $\in$ 17.7m (Q1/23:  $\in$ 32.4m) and EBITDA of  $\in$ -5.5m (Q1/23:  $\in$ 6.0m) respectively. Prior year sales benefitted from a  $\in$ 10m milestone in connection with the conclusion of the global marketing agreement for FYB202 with Fresenius Kabi in February 2023.

Income from development services for the two partnered projects FYB201 and FYB203 was also higher in Q1/23 than in Q1/24. FYB201 royalties amounted to  $\leq$ 1.9m (Q1/23:  $\leq$ 0.3m). Like the FY/23 numbers, the Q1/24 P&L included further significant royalty income from FYB201 in the associates line in connection with Formycon's 50% stake in Bioeq AG.

rigure 2. Q 1/24 and r 1/25 results								
€000	FY/22	Q1/23	FY/23	Q1/24				
Total revenues	42,497	32,400	77,696	17,700				
Δ	16.1%	300.0%	82.8%	-45.4%				
of which:								
FYB201 royalties	329	300	4,159	1,900				
Revenues from FYB201/203 partners	42,168	22,100	36,181	15,800				
FYB202 milestone	0	10,000	37,356	0				
EBITDA	-15,866	6,000	1,518	-5,500				
Adjusted EBITDA	-28,798	-400	13,329	-1,200				
Net profit	35,992	-12,400	75,795	n.a.				

## Figure 2: Q1/24 and FY/23 results

Source: Formycon

FDA approvals of FYB203 and FYB202 expected in June 2024, late 2024/early 2025 respectively Formycon submitted applications for regulatory approval of FYB202 (Stelara biosimilar; 2023 reference product sales: USD10.9bn ) and FYB203 (Eylea biosimilar; 2023 reference product sales: USD9.2bn) in both the EU and US last year. Formycon expects FDA approval of FYB202 in late 2024/early 2025 and has concluded an agreement with the reference product rights holder, Johnson & Johnson, allowing commercialisation no later than 15 April 2025. Formycon and its FYB202 marketing partner, Fresenius Kabi, will share the post-commercialisation value of the drug approximately equally. This implies a royalty rate of 30-40% (we assume 33%). In addition, Formycon booked success payments in connection with the regulatory progess made by FYB202 of €37.5m in 2023. Management has indicated that further milestone payments (estimated in the mid-double digit million euros) will become payable upon approval of FYB202 in the US and EU. We assume a figure of €30m split equally been 2024 and 2025. The FDA target action date for FYB203 is June 2024. Regulatory approval for FYB203 from the EMA is expected at the beginning of 2025. The royalty rate for FYB203 is initially mid-single digit, rising to low-double digit as sales grow.

**Regeneron legal proceedings against Eylea biosimilar developers ongoing** In mid-May 2024 Formycon announced that its marketing partner for FYB203 in the MENA region will be MS Pharma, which is already responsible for marketing FYB201 in the MENA region. Formycon has still to announce a marketing partner for FYB203 for the US and EU. We believe the absence of an announcement for these markets relates to the legal dispute between Formycon and Regeneron, the developer of the reference product, Eylea. In late November 2023 Regeneron filed a patent infringement lawsuit against Formycon. Figure 3 gives an overview of Formycon's competitors on the market for Eylea biosimilars. Regeneron's proceedings against Formycon are one of six US actions brought by Regeneron regarding Eylea biosimilars, with the other actions involving Amgen, Biocon, Celltrion, Samsung Bioepis (2 actions). The proceedings are located in the Northern District of West Virginia and are ongoing. A scheduling conference was held on 17 May 2024, the transcript for which is not yet publicly accessible. Eylea's composition of matter patent expired in the US in June 2023 and expires in the EU in May 2025. We gather that the ongoing patent dispute relates to formulation of the drug. The formulation patent expires in June 2027 in both the US and EU.

Company	Status phase III	FDA submission/ approval
Alvotech	Start (07/22)	-
Amgen	Primary endpoint met (Q3/2022)	US file acceptance (11/2023)
Biocon	Completed	US filing (10/2021), EU approval (07/2023)
Celltrion	Positive 24-week results (Q4/023)	US filing (07/2023)
Formycon	Completed	US file acceptance (08/2023); target action date June 2024
Samsung Bioepis	Last patient in (Q2/2022)	n/a
Sandoz	First patient out (05/2023)	n/a

Source: companies

**US Eylea sales down 16.2% y-o-y in Q1/24 following Eylea HD launch** Regeneron has launched Eylea HD (High Dose), a high dose, longer acting formulation of Eylea. Eylea HD was approved in the US and EU in August and November 2023 respectively. Figure 4 compares dosages for FYB201, Lucentis, Vabysmo, Eylea and Eylea HD in the indications age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), myopic choroidal neovascularisation (mCNV). Fewer doses of Eylea HD are required than of Eylea. Although, as figure 4 shows, the difference between the two drugs in this respect is not nearly as large as between Vabysmo and Lucentis, in Q1/24 Eylea sales in the US were down USD232m or 16.2% y-o-y at USD1,202m, whereas combined Eylea and Eylea HD sales were down only 2.3% at USD1,402m. Regeneron's Eylea/Eylea HD marketing partner for the Rest of the World did not disclose the split between Eylea/Eylea HD sales in Q1/24.

## Figure 4: Dosage instructions for FYB201, Lucentis, Eylea, Eylea HD, Vabysmo

	AMD	RVO	DME	DR	mCNV
FYB201	0.5mg once a month	0.5mg (0.05ml) once a month	0.3mg (0.05ml) once a month	0.3mg (0.05ml) once a month	0.5mg (0.05ml) once a month
Lucentis	0.5mg once a month	0.5mg (0.05ml) once a month	0.3mg (0.05ml) once a month	0.3mg (0.05ml) once a month	0.5mg (0.05ml) once a month
Eylea	2mg every 4 weeks for first 3	2mg every 4 weeks for first 3	2mg every 4 weeks for first 3	2mg every 4 weeks for first 3	2mg every 4 weeks for first 3
	months, then 2mg	months, then 2mg	months, then 2mg	months, then 2mg	months, then 2mg
	every 8 weeks	every 8 weeks	every 8 weeks	every 8 weeks	every 8 weeks
Eylea HD	8mg every 4 weeks for first		8mg every 4 weeks for first	8mg every 4 weeks for first	
	3 months, then 8mg	n.a.	3 months, then 8mg	3 months, then 8mg	n.a.
	every 8 to 16 weeks		every 8 to 16 weeks	every 8 to 12 weeks	
Vabysmo	6mg every 4 weeks for first 4 doses		6mg every 4 weeks for at least		
	then weeks 28 and 44 or	n.a.	first 4 doses, then up to 8 weeks	n.a.	n.a.
	weeks 24,36 and 48 or				
	weeks 20,28,36 and 44				

#### Source: FDA

As mentioned above, Formycon announced an exclusive global marketing agreement for FYB202 with Fresenius Kabi in early February 2023. Formycon retains semi-exclusive commercialization rights for Germany as well as rights for parts of the MENA region and Latin America. As figure 5 shows, Formycon is likely to be one of a group of six companies launching Stelara biosimilars during the first half of 2025.

#### Figure 5: Competitive landscape for Stelara biosimilars

Company	US launch date no later than	FDA approval status
Amgen	01/01/2025	Yes
Alvotech	21/02/2025	Yes
Samsung	22/02/2025	Not yet communicated
Celltrion	07/03/2025	BLA submitted June 23
Formycon	15/04/2025	Expected 2024/early 2025
Intas Pharma	15/05/2025	BLA accepted 04.01.24

Source: companies

**Fresenius Kabi is currently marketing three biosimilars in the US** Fresenius Kabi entered the biosimilars business in 2017 through the acquisition of Merck KGaA's biosimilars pipeline. The Merck pipeline included a phase 3 adalimumab biosimilar candidate and two other biosimilar candidates for pegfilgrastim and tocilizumab respectively. As figure 6 shows, all three of these biolsimilar candidates have since been approved by the FDA and are currently being marketed in the US by Fresenius Kabi.

Reference product	Originator	Global 2023 originator sales (USD bn)	Brand name	Indication	Acquired from	Developed	FDA approval	Marketing
Self-developed								
Adalimumab	Abbvie	14.4	Idacio	Rheumatism, Crohn's	Merck	Kabi	13.12.2022	Kabi
Pegfilgrastim	Amgen	6.2	Stimufend	Neutropenia	Merck	Kabi	01.09.2022	Kabi
Tocilizumab	Roche	2.8	Tyenne	Rheumatoid arthritis	Merck	Kabi	05 03.2024	Kabi
Denosumab	Amgen	6.2	n.a.	Osteoporosis	self-developed	Kabi	phase III	Kabi
Out-licensed								
Rituximab	Biogen	4.1	Redditux	Autoimmune diseases, cancer	mAbxience	mAbxience	pending	Dr Reddy (India)
Bevacizumab	Roche	6.7	ALYMSYS	Cancer, AMD	mAbxience	mAbxience	13.04.2022	Amneal (US/India)
In-licensed								
Ustekinumab	J&J	10.9	n.a.	Plaque psoriasis, Crohn's	Formycon	Formycon	late 2024/early 2025	Kabi

## Figure 6: Fresenius Kabi's biosimilars portfolio

Source: Fresenius Kabi

In 2022 Fresenius Kabi acquired mAbxience which has two commercialised biosimilars (rituximab and bevacizumab) as well as several biosimilar candidates in the areas of immunology and oncology. mAbxience was founded in 2010 as the biotechnology area of the Argentinian company, Insud Pharma S.L. Fresenius also has a self-developed biosimilar of denosumab in phase 3.

Fresenius Kabi aims to grow Biopharmaceuticals segment sales by 65%-120% by 2026 Fresenius Kabi's biosimilars business is the largest operation within its Biopharmaceuticals segment. The segment's other business is contract development and manufacturing services. Segment sales climbed 93% in 2023 to €363m (2022: €188m) due to the successful market introductions in Europe and the US of Idacio and Stimufend. Segment EBIT was breakeven in Q1/24. Fresenius has stated that its "ambition" is to grow Biopharmaceuticals sales to €600m-€800m by 2026. Fresenius has not given 2026 margin guidance for the segment. But presumably the division will be clearly profitable if the sales goal is reached.

**J&J/Protagonist's oral psoriasis drug unlikely to reach the market before 2029** As we have pointed out above, Johnson & Johnson does not have a near-term second generation product for Stelara. However, together with its partner Protagonist Therapeutics, the company is currently conducting four phase 3 trials of JNJ-2213. According to Johnson & Johnson and Protagonist, JNJ-2113 has the potential to be the first-in-class targeted oral peptide designed to selectively block the IL-23 receptor. Interleukin 23 (IL-23) is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. The pathologic binding of IL-23 to IL-23 receptor can trigger chronic diseases that are associated with inflammation, including psoriasis and ulcerative colitis. The four phase 3 trials are scheduled to complete during 2027. This suggests that, subject to approval, JNJ-2113 could reach the market in 2029.

We maintain our Buy recommendation but lower the price target to €80 (previously: €105) Changes to our forecasts mainly reflect downward revisions to our FYB201 forecasts as well as a more conservative view on FYB203 (Formycon's Eylea biosimilar) following the launch of Eylea HD. However as figure 8 overleaf shows, we also assume that FYB202 will be subject to a higher degree of price erosion from 2028 onwards than in our previous note of August 2023. We maintain our Buy recommendation but lower the price target to €80 (previously: €105).

# Figure 7: Forecast revenue and development costs 2022-2030

in €000's	2022A	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenues	42,497	77,696	62,299	108,571	232,704	212,118	217,023	273,566	357,710
% ⊿	n.a.	82.8%	-19.8%	74.3%	114.3%	<b>-8.8%</b>	2.3%	<b>26.1%</b>	<b>30.8%</b>
of which:									
Development fees from partners	42,168	36,182	20,208	0	0	0	0	0	0
Milestones	0	37,356	35,000	48,000	38,000	33,000	33,000	33,000	10,000
Royalties	329	4,159	7,091	60,571	194,704	179,118	184,023	240,566	347,710
by product:									
FYB201 (reference product: Lucentis)	329	4,159	7,091	7,291	7,771	7,989	7,886	7,289	6,742
FYB202 (reference product: Stelara)	0	0	0	45,002	171,510	157,120	163,248	154,195	128,167
FYB203 (reference product: Eylea)	0	0	0	8,278	15,423	14,009	12,889	11,858	11,110
FYB206 (reference product: Keytruda)	0	0	0	0	0	0	0	32,713	117,899
FYB207 (COVID antiviral)	0	0	0	0	0	0	0	0	0
FYB208 (reference product: t.b.a.)	0	0	0	0	0	0	0	34,511	49,281
FYB209 (reference product: t.b.a.)	0	0	0	0	0	0	0	0	34,511
Development costs	951,854	111,485	161,000	148,600	129,205	138,000	110,000	98,000	77,000
% Δ	n.a.	<b>-88.3%</b>	44.4%	-7.7%	<b>-13.1%</b>	<b>6.8%</b>	-20.3%	-10.9%	-21.4%
of which:									
Expensed	58,363	76,178	86,000	63,600	54,205	63,000	65,000	68,000	56,000
% ∆	n.a.		12.9%	-26.0%	-14.8%	16.2%	3.2%	4.6%	-17.6%
by product:									
FYB201	11,676	11,275	5,000	0	0	0	0	0	0
FYB202	3,092	24,185	20,000	7,500	5,000	0	0	0	0
FYB203	26,287	26,456	10,000	1,000	1,000	1,000	0	0	0
FYB206	6,130	0	0	0	0	0	0	0	0
FYB207	6,699	2,847	0	0	0	0	0	0	0
FYB208	1,001	3,346	8,000	0	0	0	0	0	0
FYB209	1,251	4,072	4,000	8,000	0	0	0	0	0
FYB210			1,000	2,000	2,000	7,000	9,000	12,000	0
Other	2,227	3,997	38,000	45,100	46,205	55,000	56,000	56,000	56,000
of which:									
Capitalised	893,491	35,307	75,000	85,000	75,000	75,000	45,000	30,000	21,000
% Δ		-96.0%	112.4%	13.3%	-11.8%	0.0%	-40.0%	n.a.	n.a.
by product:									
FYB201	291,639	14,111	0	0	0	0	0	0	0
FYB202	615,424	3,717	0	0	0	0	0	0	0
FYB206	5,733	16,073	75,000	50,000	30,000	20,000	11,000	6,000	1,000
FYB208	0	0	0	27,000	25,000	30,000	12,000	12,000	10,000
FYB209	0	0	0	8,000	20,000	25,000	22,000	12,000	10,000
Other	-19,305	1,406	0	0	0	0	0	0	0
EBITDA	-15,866	1,518	-23,701	44,971	178,499	149,118	152,023	205,566	301,710

Source: Formycon, First Berlin Equity Research estimates

# Figure 8: Changes to our royalty forecasts by product

€ 000's	2024E	2025E	2026E	2027E	2028E	2029E	2030E
FYB201 new	7,091	7,291	7,771	7,989	7,886	7,289	6,742
FYB201 old	9,955	14,108	16,272	18,026	22,604	24,712	27,181
change (%)	-28.8%	-48.3%	-52.2%	-55.7%	-65.1%	-70.5%	-75.2%
FYB202 new	0	45,002	171,510	157,120	163,248	154,195	128,167
FYB202 old	0	33,664	60,171	110,501	200,425	255,605	260,781
change (%)	n.a.	33.7%	185.0%	42.2%	-18.5%	-39.7%	-50.9%
FYB203 new	0	8,278	15,423	14,009	12,889	11,858	11,110
FYB203 old	0	13,409	25,365	48,947	60,624	72,749	74,204
change (%)	n.a.	-38.3%	-39.2%	-71.4%	-78.7%	-83.7%	-85.0%
FYB206 new	0	0	0	0	0	32,713	117,899
FYB206 old	0	0	0	0	0	23,988	148,244
change (%)	n.a.	n.a.	n.a.	n.a.	n.a.	36.4%	-20.5%
FYB208 new	0	0	0	0	0	34,511	49,281
FYB208 old	0	0	0	0	0	34,511	70,402
change (%)	n.a.	n.a.	n.a.	n.a.	n.a.	0.0%	-30.0%
FYB209 new	0	0	0	0	0	0	34,511
FYB209 old	0	0	0	0	0	0	34,511
change (%)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0%

Source: First Berlin Equity Research estimates

# Figure 9: Valuation model

Compound	Project <sup>1)</sup>	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Royalties	PACME Margin <sup>2)</sup>	Discount Factor	Patent Life <sup>3)</sup>	Time to Market
FYB201	nAMD,DR (ex-US)	€39M	199K	€5,921	€1,178M	20%	€10M	1 <b>5</b> %	10%	n.a.	-
FYB201	nAMD,DR (US)	€62M	82K	€9,845	€807M	20%	€12M	15%	10%	na.	-
FYB202	Pso,CrD (ex-US)	€309M	62K	€34,240	€2,123M	12%	€63M	<b>3</b> %	12%	n.a.	1 year
FYB202	Pso,CrD (US)	€514M	69K	€55,067	€3,800M	12%	€109M	33%	12%	n.a.	1 year
FYB203	nAMD,DR (ex-US)	€23M	425K	€4,486	€1,906M	12%	€6M	9%	2%	n.a.	2 years
FYB203	nAMD,DR (US)	€36M	411K	€7,591	€3,120M	12%	€9M	9%	12%	na.	1 year
FYB206	multiple cancer types (ex-US)	€621M	65K	€79,625	€5,176M	12%	€661M	33%	14%	n.a.	7 years
FYB206	multiple cancer types (US)	€1,125M	59K	€138,393	€8,165M	12%	€999M	33%	14%	n.a.	5 years
FYB208	n.a.	€119M									
FYB209	n.a.	€101M									
FYB210	n.a.	€85M									
PACME PV		€3,034M									
Costs PV <sup>4)</sup>		€1,741M									
NPV		€1,293M									
Proforma net	Cash	€120M									
Fair Value		€1,413M									
Proforma sha	re count	17,657K									
Fair Value Pe	er Share	€80.00									

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 10: Changes to our valuation model

	Old	New	Delta
NPV	€1,508M	€1,293M	-14.3%
Proforma net Cash	€176M	€120M	-32.1%
Fair Value	€1,684M	€1,413M	-16.1%
Share Count	16,039K	17,657K	10.1%
Fair value per share	€105.00	€80.00	-23.8%

Source: First Berlin Equity Research estimates

# **INCOME STATEMENT**

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Revenue	42.5	77.7	62.3	108.6	232.7	212.1
Cost of sales	-30.4	-54.4	-58.2	-43.7	-37.8	-43.6
Gross profit	12.1	23.3	4.1	64.8	194.9	168.5
R&D expenses	-16.9	-9.2	-14.6	-10.8	-9.2	-10.7
Selling expenses	-1.4	-0.8	-2.6	-1.9	-1.6	-1.9
Administrative expenses	-11.4	-13.3	-12.9	-9.5	-8.1	-9.5
Net other op. expenses	0.0	-0.4	0.0	0.0	0.0	0.0
Operating income (EBIT)	-17.7	-0.4	-26.0	42.6	176.0	146.5
Equity participations	76.8	-19.4	10.0	15.0	15.0	15.0
Dividends from Bioeq	0.0	0.0	0.0	0.0	0.0	15.0
Net financial result	-22.5	98.8	-21.3	-23.4	-24.2	-23.7
Pre-tax income (EBT)	36.6	79.1	-37.3	34.2	166.8	152.8
Income taxes	-0.6	-3.3	0.0	0.0	0.0	-43.1
Net income / loss	36.0	75.8	-37.3	34.2	166.8	109.8
Diluted EPS (in €)	2.59	4.72	-2.11	1.92	9.36	6.16
EBITDA	-15.9	1.5	-23.7	45.0	178.5	149.1
Adjusted EBITDA	-28.8	13.3	-13.7	60.0	193.5	164.1
Ratios						
Gross margin on revenue	28.4%	30.0%	6.6%	59.7%	83.8%	79.5%
EBIT margin on revenue	-41.7%	-0.5%	-41.7%	39.2%	75.6%	69.1%
Net margin on revenue	84.7%	97.6%	-59.9%	31.5%	71.7%	51.7%
Tax rate	1.7%	4.1%	0.0%	0.0%	0.0%	28.2%
Expenses as % of revenue						
Cost of sales	71.6%	70.0%	93.4%	40.3%	16.2%	20.5%
R&D expenses	39.8%	11.8%	23.5%	10.0%	4.0%	5.0%
Selling expenses	3.4%	1.1%	4.1%	1.8%	0.7%	0.9%
Administrative expenses	26.9%	17.1%	20.7%	8.8%	3.5%	4.5%
Y-Y Growth						
Revenues	16.1%	82.8%	-19.8%	74.3%	114.3%	-8.8%
Operating income	n.m.	n.m.	n.m.	n.m.	313.5%	-16.8%

# **BALANCE SHEET**

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Assets						
Current assets, total	30.5	67.1	56.0	69.0	184.9	229.7
Cash and cash equivalents	9.8	27.0	46.2	49.3	126.0	176.5
Other liquid assets	0.0	0.0	0.0	0.0	0.0	0.0
Inventories	0.6	0.5	0.4	0.5	1.5	1.4
Receivables	14.3	11.6	7.4	16.1	48.2	43.6
Contract assets	1.2	16.6	0.8	1.7	5.2	4.7
Other current assets	4.6	11.5	1.2	1.3	3.9	3.5
Non-current assets, total	823.2	823.2	872.2	918.8	1,009.2	1,099.5
Investment participation Bioeq AG	186.4	167.0	177.7	192.7	207.7	222.7
Loan to associate Bioeq AG	92.3	90.9	53.8	0.0	0.0	0.0
Property, plant & equipment	2.6	3.0	3.5	4.1	4.7	5.3
Right of use assets	8.9	9.3	9.7	10.1	10.5	10.8
Goodw ill & other intangibles	533.0	552.9	627.5	712.0	786.4	860.7
Prepaid expenses	0.0	0.0	0.0	0.0	0.0	0.0
Deferred tax assets	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	853.7	890.4	928.2	987.8	1,194.1	1,329.3
Shareholders' equity & debt						
Current liabilities, total	50.7	69.3	44.9	56.1	96.4	121.3
Current lease obligations	0.9	1.2	1.2	1.3	1.4	1.4
Accounts payable	11.3	16.3	13.4	22.6	61.7	43.6
Tax liability	0.0	0.0	0.0	0.0	0.0	43.1
Provisions	0.0	0.4	0.0	0.0	0.0	0.0
Shareholder loan	20.8	20.5	0.0	0.0	0.0	0.0
Loan	0.0	0.0	0.0	0.0	0.0	0.0
Conditional purchase price payments	14.9	27.2	29.8	31.7	31.5	31.5
Other current liabilities	2.7	3.8	0.5	0.5	1.7	1.6
Long-term liabilities, total	446.5	318.3	336.7	350.8	350.1	350.6
Non-current lease obligations	7.6	7.8	8.2	8.6	9.0	9.5
Provisions	0.0	0.0	0.0	0.0	0.0	0.0
Shareholder loan	20.0	0.0	0.0	0.0	0.0	0.0
Loan	0.0	0.0	0.0	0.0	0.0	0.0
Conditional purchase price payments	299.3	187.7	205.5	219.2	217.7	217.8
Other liabilities	0.0	0.0	0.1	0.2	0.6	0.5
Deferred tax liabilities	119.5	122.8	122.8	122.8	122.8	122.8
Shareholders' equity	356.6	502.8	546.6	580.8	747.6	857.4
Total consolidated equity and debt	853.7	890.4	928.2	987.8	1,194.1	1,329.3
Key figures						
Current ratio (x)	0.60	0.97	1.25	1.23	1.92	1.89
Quick ratio (x)	0.59	0.96	1.24	1.22	1.90	1.88
Financial leverage (%)	-2.8	-5.4	-8.5	-8.5	-16.9	-20.6
Book value per share (€)	23.67	31.35	30.96	32.90	42.34	48.56
Return on equity (ROE)	17.5%	17.6%	-7.1%	6.1%	25.1%	13.7%

# **CASH FLOW STATEMENT**

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Net profit	36.0	75.8	-37.3	34.2	166.8	109.8
Depreciation and amortisation	1.9	1.9	2.3	2.4	2.5	2.6
Net finance income	-54.3	-79.4	-10.6	-15.0	-15.0	-15.0
Effect of stock options	0.5	1.6	0.0	0.0	0.0	0.0
Net loss (gain) from disposal of non-current assets	0.0	0.0	0.0	0.0	0.0	0.0
Other non-cash transactions	0.0	0.0	0.0	0.0	0.0	0.0
Income tax expense	0.6	3.3	0.0	0.0	0.0	43.1
Change in w orking capital	-3.4	-12.8	24.3	-0.6	1.6	-12.7
Change in other financial assets/liabilities	0.2	0.0	21.5	23.5	25.1	24.9
Income taxes paid	-0.3	-0.2	0.0	0.0	0.0	0.0
Operating cash flow	-18.9	-9.8	0.2	44.5	181.0	152.6
CAPEX	-37.1	-17.4	-77.8	-87.8	-77.9	-78.0
Free cash flow	-55.9	-27.2	-77.6	-43.3	103.1	74.7
Repayment of Bioeq loan	0.0	0.0	37.2	53.8	0.0	0.0
Earnout	0.0	0.0	-1.1	-7.8	-26.9	-24.8
Equity financing, net	1.8	68.8	80.8	0.0	0.0	0.0
Shareholder loan	40.0	-23.1	-20.5	0.0	0.0	0.0
Loan	0.0	0.0	0.0	0.0	0.0	0.0
Payment of lease liabilities	-0.9	-1.2	0.5	0.5	0.5	0.5
Interest received/(paid)	-0.1	0.0	0.0	0.0	0.0	0.0
Net cash from financing activities	40.7	44.4	96.9	46.4	-26.4	-24.2
Net cash flows	-15.2	17.2	19.2	3.1	76.7	50.4
Cash and liquid assets, start of the year	25.0	9.8	27.0	46.2	49.3	126.0
Cash and liquid assets, end of the year	9.8	27.0	46.3	49.3	126.0	176.5
EBITDA/share (in €)	-1.2	0.1	-1.4	2.5	10.1	8.4
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	27171.9%	306.6%	-15.7%
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	-27.6%
EBITDA/share	n.m.	n.m.	n.m.	n.m.	296.9%	-16.5%

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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			2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy <sup>1</sup>	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%

<sup>1</sup> 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  $\leq 0 - \leq 2$  billion, and Category 2 companies have a market capitalisation of  $> \leq 2$  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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#### **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
236	Ļ	Ļ	Ļ	Ļ
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	23 September 2022	€70.40	Buy	€130.00
44	21 August 2023	€60.40	Buy	€105.00
45	Today	€48.20	Buy	€80.00

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- 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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