Formycon AG

Germany / Biopharmaceuticals
Xetra
Bloomberg: FYB GR
ISIN: DE000A1EWVY8

News on FYB201, FYB202 and FYB206

RATING	**BUY**
PRICE TARGET	**€ 46.00**
Return Potential	54.1%
Risk Rating	High

REACTION TO PRICE EROSION NEWS LOOKS OVERDONE

On 17 February Formycon informed the market that price pressure in the U.S. on FYB201 (Lucentis biosimilar, launched in late 2022) and on FYB202 (Stelara biosimilar, U.S. launch imminent) is higher than it previously expected. Formycon also announced that after consultation with the FDA the completion of the FYB206 (Keytruda biosimilar) phase 3 trial will not be necessary for the drug candidate's approval. In its 2024 accounts Formycon intends to write FYB201 and FYB202 down by high single digit to low double digit €m and high double digit to low triple digit €m amounts respectively. The reduction in the investment stemming from the elimination of the FYB206 phase 3 trial is likely to amount to a high double digit €m sum. We had previously assumed annual average price erosion of 40% for Formycon's biosimilars relative to their reference products. We now raise this figure to 52%. We also raise the average discount rate for cashflows generated by the biosimilar portfolio by an average 7% to 13.6% to account for increased uncertainty over future price erosion. The net impact of the reduced investment in FYB206, and higher price erosion and discount rate assumptions, lowers our price target from €82 to €46. We think the market's reaction to the 17 February press release is overdone. We maintain our Buy recommendation.

FYB202 is Formycon's most important near-term value driver Formycon's most important near-term value driver is the Stelara biosimilar, FYB202, which was approved by both the FDA and the EMA in September last year and whose U.S. launch is imminent. Stelara generated worldwide sales of USD10.4bn in 2024. 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%. However, as figure 1 overleaf indicates, there is very strong competition on the Stelara biosimilar market and we believe that this is the main driver behind the severe price erosion versus the reference product which Formycon is currently experiencing on the U.S. market. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2022	2023	2024E	2025E	2026E	2027E
Revenue (€ m)	42.5	77.7	61.1	63.9	184.2	169.1
Y-o-y growth	16.1%	82.8%	-21.4%	4.6%	188.1%	-8.2%
EBITDA (€ m)	-15.9	1.5	-16.7	0.3	130.0	106.1
EBITDA margin	-37.3%	2.0%	-27.3%	0.5%	70.6%	62.7%
Net income (€ m)	36.0	75.8	-89.6	-20.1	110.3	63.0
EPS (diluted) (€)	2.59	4.72	-5.06	-1.09	5.61	3.20
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-55.9	-27.2	-53.6	-33.8	64.8	30.3
Net gearing	-2.8%	-5.4%	-8.1%	-10.1%	-15.4%	-15.7%
Liquid assets (€ m)	9.8	27.0	40.1	53.1	98.0	110.1

RISKS

Product failures, failure to obtain funding, loss of key personnel.

COMPANY PROFILE

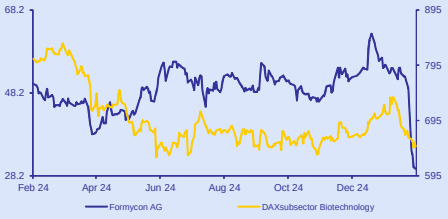
Formycon AG is a Munich, Germany based pharmaceuticals company specialising in the development of biosimilars, i.e. generic versions of biotechnology products.

MARKET DATA

As of 21 Feb 2025	
Closing Price	€ 29.85
Shares outstanding	17.66m
Market Capitalisation	€ 527.06m
52-week Range	€ 29.85 / 62.50
Avg. Volume (12 Months)	14,314

Multiples	2023	2024E	2025E
P/E	6.3	n.a.	n.a.
EV/Sales	6.5	8.3	7.9
EV/EBITDA	332.1	n.a.	1575.9
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2024	
Liquid Assets	€ 40.62m
Current Assets	€ 95.88m
Intangible Assets	€ 569.46m
Total Assets	€ 947.78m
Current Liabilities	€ 45.60m
Shareholders' Equity	€ 576.30m

SHAREHOLDERS

Athos KG	24.3%
Wendeln & Cie. KG	13.6%
Gedeon Richter	9.0%
Active Ownership	6.0%
Free Float and other	47.1%

Analyst: Simon Scholes, Tel. +49 (0)30 - 80 93 96 94

Figure 1: Competitive landscape for Stelara biosimilars

Company	US launch date no later than	FDA approval status	EC approval status
Amgen	01/01/2025	Yes	Yes
Alvotech	21/02/2025	Yes	Yes
Biocon	22/02/2025	Yes	Yes
Formycon	22/02/2025	Yes	Yes
Samsung Bioepis	22/02/2025	Yes	Yes
Celltrion	07/03/2025	Yes	Yes
Intas Pharma	15/05/2025	Yes	Yes

Source: companies

FYB202 booked in Formycon's 2022 and 2023 accounts at ca. €530m Following the Athos transaction in 2022, FYB202 was booked in Formycon's 2022 and 2023 annual reports at ca. €530m. A €100m writedown implies a reduction in this figure of ca. 20%. We had previously assumed price erosion of 40% for Formycon's biosimilars relative to their reference products. On the basis of price erosion 20% above this figure, we now model price erosion of 52% on the basis of the following calculation: 100%-((100%-40%)*0.8).

Writedown on FYB201 much smaller than on FYB202 Since launch in 2022, FYB201 has achieved a share of over 50% of the U.S. ranibizumab market (Lucentis and its biosimilars). However, the value of this market was much diminished during 2022-2024 by Roche's 2022 launch of Vabysmo, a successor product to Lucentis, and by subsequent heavy discounting of Lucentis. In addition, Formycon's royalty on FYB201 at 7%-8% is much lower than on FYB202 (30%-40%). Hence, higher than expected discounting causes a much smaller writedown on FYB201 than on FYB202.

Elimination of phase 3 FYB206 trial does not necessarily imply earlier market launch Formycon began phase 1 and phase 3 trials of FYB206 (Keytruda biosimilar) in June and July last year respectively. In the press release of 17 February, Formycon announced that after consultation with the FDA, the phase 3 trial will no longer be necessary. This is expected to save a high double digit million € sum and also shorten the path to approval. However, investors should bear in mind that Keytruda exclusivity does not expire in the U.S. until 2029 and in Europe until 2030. The phase 3 trial was scheduled to complete in 2027 and so Formycon would probably have been ready to launch in time for expiry of U.S. exclusivity even if a phase 3 trial had been necessary. It is possible that competitors in the Keytruda biosimilar space will also be able to dispense with a phase 3 trial. The main advantage to Formycon of no FYB206 phase 3 trial would therefore appear to be saved money rather than competitive advantage.

We model cashflow from milestones of €35m in 2025, and a €50m equity capital raise Management indicated during the analysts' call on 17 February that the company's current view of its cash runway is that it extends to Q2/26. This statement does not include potential milestones from partnering drug candidates such as FYB206. We model cashflow from milestones of €35m in 2025. In view of lower than previously expected 2025 royalty income from FYB201 and FYB202 we now think fresh equity capital will be necessary later this year, and model a €50m raise.

Figure 2: Changes to our forecasts

	2024E			2025E			2026E			2027E		
in € 000s	Old	New	Δ	Old	New	Δ	Old	New	Δ	Old	New	Δ
Revenues	61.10	61.10	0.0%	110.49	63.92	-42.1%	243.69	184.18	-24.4%	222.16	169.06	-23.9%
EBITDA	-16.70	-16.70	-	46.89	0.32	-99.3%	189.48	129.98	-31.4%	159.16	106.06	-33.4%
margin	*-27.3%*	*-27.3%*	-	*42.4%*	*0.5%*	-	*77.8%*	*70.6%*	-	*71.6%*	*62.7%*	-
Adjusted EBITDA	3.90	3.90	-	61.89	5.32	-91.4%	204.48	137.48	-32.8%	174.16	113.56	-34.8%
margin	*6.4%*	*6.4%*	-	*56.0%*	*8.3%*	-	*83.9%*	*74.6%*	-	*78.4%*	*67.2%*	-
Net profit	-19.60	-89.56	-	36.00	-20.15	-	178.00	110.34	-38.0%	117.20	62.98	-46.3%
margin	*-32.1%*	*-146.6%*	-	*32.6%*	*-31.5%*	-	*73.0%*	*59.9%*	-	*52.8%*	*37.3%*	-

Source: First Berlin Equity Research estimates

Writedowns do not affect 2024 sales and EBITDA KPIs The writedowns on FYB201 and FYB202 will not impact 2024 sales, EBITDA and adjusted EBITDA. We leave our forecasts for these KPIs unchanged. However, as figure 2 above shows, we have reduced our 2024 net profit forecast by €70m. This reduction is comprised of a €110m reduction in the book values of FYB201 and FYB202 (€10m for FYB201 and €100m for FYB202) and a €40m reduction in the value of the earnout liabilities stemming from the Athos transaction concluded in 2022. In the 2023 annual report the total value of the FYB201 and FYB202 earnout liabilities was €215m. The writedowns are non-cash and do not directly impact the cashflow statement.

Buy recommendation maintained but price target reduced from €82 to €46 The reduction in our revenue forecasts for 2025-2027 reflect lower estimated royalty income from FYB201, FYB202 and FYB203 (Eylea biosimilar). The gap between our EBITDA and adjusted EBITDA forecasts for 2025-2027 narrows because this consists primarily of equity accounted income in Formycon's 50% stake in Bioeq AG. Bioeq AG has a stake in FYB201, and so is also impacted by reduced royalty income from this drug. We maintain our Buy recommendation but have reduced the price target from €82 to €46.

Figure 3: Valuation model

Compound	Project[1]	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Royalties	PACME Margin[2]	Discount Factor	Patent Life[3]	Time to Market
FYB201	nAMD,DR (ex-US)	€36M	199K	€5,921	€1,178M	20%	€10M	15%	11%	n.a.	-
FYB201	nAMD,DR (US)	€39M	82K	€9,845	€807M	20%	€12M	15%	11%	n.a.	-
FYB202	Pso,CrD (ex-US)	€185M	62K	€34,240	€2,123M	12%	€43M	33%	13%	n.a.	-
FYB202	Pso,CrD (US)	€364M	69K	€55,067	€3,800M	12%	€86M	33%	13%	n.a.	-
FYB203	nAMD,DR (ex-US)	€19M	425K	€4,486	€1,906M	12%	€5M	9%	11%	n.a.	-
FYB203	nAMD,DR (US)	€25M	411K	€7,591	€3,120M	12%	€7M	9%	13%	n.a.	-
FYB206	multiple cancer types (ex-US)	€481M	65K	€79,625	€5,176M	12%	€528M	33%	14%	n.a.	5 years
FYB206	multiple cancer types (US)	€871M	59K	€138,393	€8,165M	12%	€799M	33%	14%	n.a.	4 years
FYB208	n.a.	€80M									
FYB209	n.a.	€68M									
FYB210	n.a.	€56M									
PACME PV		€2,225M									
Costs PV[4]		€1,477M									
NPV		€748M									
Proforma net Cash		€159M									
Fair Value		€907M									
Proforma share count		19,507K									
Fair Value Per Share		€46.49									

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 4: Changes to our valuation model

NPV	Old €1,273M	New €748M	Delta -41.2%
Proforma net Cash	€175M	€159M	-9.3%
Fair Value	€1,448M	€907M	-37.4%
Share Count	17,657K	19,507K	10.5%
Fair value per share	**€82.01**	**€46.49**	**-43.3%**

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Revenue	**42.5**	**77.7**	**61.1**	**63.9**	**184.2**	**169.1**
Cost of sales	-30.4	-54.4	-43.8	-43.7	-37.6	-43.4
Gross profit	**12.1**	**23.3**	**17.3**	**20.2**	**146.6**	**125.6**
R&D expenses	-16.9	-9.2	-17.5	-10.8	-9.2	-10.7
Selling expenses	-1.4	-0.8	-1.2	-1.9	-1.6	-1.9
Administrative expenses	-11.4	-13.3	-17.6	-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**	**-19.0**	**-2.0**	**127.6**	**103.6**
Equity participations	76.8	-19.4	20.6	5.0	7.5	7.5
Dividends from Bioeq	0.0	0.0	0.0	0.0	0.0	7.5
Net financial result	-22.5	98.8	-21.2	-23.1	-24.7	-25.2
Pre-tax income (EBT)	**36.6**	**79.1**	**-89.6**	**-20.1**	**110.3**	**93.4**
Income taxes	-0.6	-3.3	0.0	0.0	0.0	-30.4
Net income / loss	**36.0**	**75.8**	**-89.6**	**-20.1**	**110.3**	**63.0**
Diluted EPS (in €)	**2.59**	**4.72**	**-5.06**	**-1.09**	**5.61**	**3.20**
EBITDA	**-15.9**	**1.5**	**-16.7**	**0.3**	**130.0**	**106.1**
Adjusted EBITDA	**-28.8**	**13.3**	**3.9**	**5.3**	**137.5**	**113.6**
Ratios						
Gross margin on revenue	28.4%	30.0%	28.3%	31.7%	79.6%	74.3%
EBIT margin on revenue	-41.7%	-0.5%	-31.1%	-3.2%	69.3%	61.3%
Net margin on revenue	84.7%	97.6%	-146.6%	-31.5%	59.9%	37.3%
Tax rate	1.7%	4.1%	0.0%	0.0%	0.0%	32.6%
Expenses as % of revenue						
Cost of sales	71.6%	70.0%	71.7%	68.3%	20.4%	25.7%
R&D expenses	39.8%	11.8%	28.6%	16.9%	5.0%	6.3%
Selling expenses	3.4%	1.1%	2.0%	3.0%	0.9%	1.1%
Administrative expenses	26.9%	17.1%	28.8%	14.9%	4.4%	5.6%
Y-Y Growth						
Revenues	16.1%	82.8%	-21.4%	4.6%	188.1%	-8.2%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	-18.8%
Net income/ loss	n.m.	110.6%	n.m.	n.m.	n.m.	-42.9%

BALANCE SHEET

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Assets						
Current assets, total	**30.5**	**67.1**	**70.5**	**81.0**	**178.5**	**184.0**
Cash and cash equivalents	9.8	27.0	40.1	53.1	98.0	110.1
Other liquid assets	0.0	0.0	0.0	0.0	0.0	0.0
Inventories	0.6	0.5	2.4	2.6	7.4	6.8
Receivables	14.3	11.6	14.1	12.1	35.0	32.1
Contract assets	1.2	16.6	1.6	1.7	5.0	4.6
Other current assets	4.6	11.5	12.2	11.5	33.2	30.4
Non-current assets, total	**823.2**	**823.2**	**814.0**	**856.5**	**917.5**	**995.5**
Investment participation Bioeq AG	186.4	167.0	188.3	193.3	200.8	208.3
Loan to associate Bioeq AG	92.3	90.9	85.9	85.9	85.9	85.9
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
Goodwill & other intangibles	533.0	552.9	526.6	563.2	615.7	685.2
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**	**884.5**	**937.5**	**1,096.0**	**1,179.5**
Shareholders' equity & debt						
Current liabilities, total	**50.7**	**69.3**	**51.2**	**56.6**	**98.7**	**112.6**
Current lease obligations	0.9	1.2	1.2	1.3	1.4	1.4
Accounts payable	11.3	16.3	18.3	21.1	58.9	41.8
Tax liability	0.0	0.0	0.0	0.0	0.0	30.4
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
Conditional purchase price payments	14.9	27.2	29.7	32.3	32.9	33.8
Other current liabilities	2.7	3.8	1.8	1.9	5.5	5.1
Long-term liabilities, total	**446.5**	**318.3**	**337.0**	**354.7**	**360.7**	**367.4**
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
Conditional purchase price payments	299.3	187.7	205.4	222.7	227.2	233.6
Other liabilities	0.0	0.0	0.5	0.6	1.7	1.5
Deferred tax liabilities	119.5	122.8	122.8	122.8	122.8	122.8
Shareholders' equity	**356.6**	**502.8**	**496.4**	**526.3**	**636.6**	**699.6**
Total consolidated equity and debt	**853.7**	**890.4**	**884.5**	**937.5**	**1,096.0**	**1,179.5**
Key figures						
Current ratio (x)	0.60	0.97	1.38	1.43	1.81	1.63
Quick ratio (x)	0.59	0.96	1.33	1.39	1.73	1.57
Financial leverage (%)	-2.8	-5.4	-8.1	-10.1	-15.4	-15.7
Book value per share (€)	23.67	31.35	28.11	26.98	32.63	35.86
Return on equity (ROE)	17.5%	17.6%	-17.9%	-3.9%	19.0%	9.4%

CASH FLOW STATEMENT

All figures in EURm	2022A	2023A	2024E	2025E	2026E	2027E
Net profit	**36.0**	**75.8**	**-89.6**	**-20.1**	**110.3**	**63.0**
Depreciation and amortisation	1.9	1.9	2.3	2.3	2.4	2.5
Net finance income	-54.3	-79.4	-21.3	-5.0	-7.5	-7.5
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/impairments	0.0	0.0	70.0	0.0	0.0	0.0
Income tax expense	0.6	3.3	0.0	0.0	0.0	30.4
Change in w orking capital	-3.4	-12.8	10.4	5.3	-10.0	-11.1
Change in other financial assets/liabilities	0.2	0.0	21.5	23.5	25.5	26.0
Income taxes paid	-0.3	-0.2	0.0	0.0	0.0	0.0
Operating cash flow	**-18.9**	**-9.8**	**-6.7**	**6.0**	**120.7**	**103.3**
CAPEX	-37.1	-17.4	-46.9	-39.8	-55.9	-73.0
Free cash flow	**-55.9**	**-27.2**	**-53.6**	**-33.8**	**64.8**	**30.3**
Repayment of Bioeq loan	0.0	0.0	5.0	0.0	0.0	0.0
Earnout	0.0	0.0	-1.2	-3.7	-20.4	-18.7
Equity financing, net	1.8	68.8	82.8	50.0	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**	**66.6**	**46.8**	**-19.9**	**-18.2**
Net cash flows	**-15.2**	**17.2**	**13.0**	**12.9**	**44.9**	**12.1**
Cash and liquid assets, start of the year	25.0	9.8	27.0	40.1	53.1	98.0
Cash and liquid assets, end of the year	**9.8**	**27.0**	**40.1**	**53.1**	**98.0**	**110.1**
EBITDA/share (in €)	**-1.2**	**0.1**	**-1.0**	**0.0**	**6.7**	**5.4**
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	1906.9%	-14.4%
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	-53.2%
EBITDA/share	n.m.	n.m.	n.m.	n.m.	37961.2%	-18.4%

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Anschrift:
First Berlin Equity Research GmbH
Friedrichstr. 34
10117 Berlin
Germany

Vertreten durch den Geschäftsführer: Martin Bailey

Telefon: +49 (0) 30-80 93 9 680
Fax: +49 (0) 30-80 93 9 687
E-Mail: info@firstberlin.com

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First Berlin Equity Research GmbH

Authored by: Simon Scholes, Analyst
All publications of the last 12 months were authored by Simon Scholes.

Company responsible for preparation: First Berlin Equity Research GmbH, Friedrichstraße 69, 10117 Berlin

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

INFORMATION PURSUANT TO SECTION 85 (1) SENTENCE 1 OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO ART. 20 (1) OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO ART. 37 OF COMMISSION DELEGATED REGULATION (EU) NO 2017/565 (MIFID) II.

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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		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...40	↓	↓	↓	↓
41	30 August 2022	€76.80	Buy	€103.00
42	7 September 2022	€70.40	Buy	€103.00
43	23 September 2022	€70.50	Buy	€130.00
44	21 August 2023	€60.40	Buy	€105.00
45	13 June 2024	€48.20	Buy	€80.00
46	19 August 2024	€49.15	Buy	€80.00
47	1 October 2024	€54.60	Buy	€82.00
48	11 December 2024	€51.90	Buy	€82.00
49	Today	€29.85	Buy	€46.00

INVESTMENT HORIZON

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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/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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