

# Formycon AG

Germany / Biopharmaceuticals

Xetra

Bloomberg: FYB GR

ISIN: DE000A1EWWY8

H1 2021 results

**RATING****PRICE TARGET**

Return Potential

Risk Rating

**BUY****€ 78.00**

55.4%

High

## ACCELERATING DEVELOPMENT OF FYB207 PRODUCTION PROCESS

H1/21 revenue of €20.3m (FBe €21.0m; H1/20: €16.5m) was close to our forecast and stemmed from fees for development work on the outlicensed biosimilar candidates FYB201 (reference product: Lucentis) and FYB203 (reference product: Eylea) as well as payments for the provision of development services to the FYB202 joint venture (reference product: Stelara). However, the EBITDA loss widened from €-1.7m in Q1/21 to €8.0m in Q2/21 and H1/21 EBITDA of €-9.7m (H1/20: €0.9m) was below our estimate of €-5.0m. The higher loss in Q2/21 was due to increased investment in both the covid-19 drug candidate FYB207 ahead of the start of clinical trials in H1/22 and the biosimilar candidate FYB206 (reference product not yet disclosed). We expect spending on FYB206 and FYB 207 to be below the Q2 level during Q3 and Q4 and now see full year EBITDA at €-15.1m (previously: €-10.1m). Formycon has already produced material at a pilot scale for pre-clinical in vivo studies of FYB207 and begun scale-up to large scale GMP-based (Good Manufacturing Practice) production for clinical trial supply. The company has also set up the entire infrastructure for conducting pre-clinical in vivo studies and starting clinical development with experienced contract companies. We expect a successful application for an Emergency Use Authorisation to see the product reach the market in 2023. Cash and equivalents were a healthy €33.6m at the end of H1/21. Higher H1/21 sales of Eylea than we had modelled prompt us to raise our valuation of FYB203. This cancels out the impact of the 2021 forecast reduction on our valuation. Our 2022 numbers are broadly unchanged. We raise the recommendation from Add to Buy, as the upside to our unchanged price target of €78.00 is now over 25%.

**FYB201 approval in both US and EU likely in mid-2022** Formycon and its license partner Bioeq announced the submission of a marketing authorisation application for FYB201 to the EMA on 29 June and of a biologics license application (BLA) for FYB201 to the FDA on 5 August. (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

	2017	2018	2019	2020	2021E	2022E
Revenue (€m)	29.00	42.99	33.16	34.23	45.00	63.04
Y-o-y growth	48.5%	48.2%	-22.9%	3.2%	31.5%	40.1%
EBIT (€m)	-1.54	7.13	-2.27	-5.73	-16.02	2.96
EBIT margin	-5.3%	16.6%	-6.9%	-16.7%	-35.6%	4.7%
Net income (€m)	-1.58	7.10	-2.29	-5.93	-16.02	2.96
EPS (diluted) (€)	-0.17	0.76	-0.23	-0.58	-1.43	0.25
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-4.66	-3.73	-7.19	-5.70	-18.21	-1.93
Net gearing	-60.6%	-37.0%	-46.4%	-62.1%	-66.8%	-67.3%
Liquid assets (€m)	15.48	12.31	22.35	42.25	54.51	63.78

### 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, e.g. generic versions of biotechnology products.

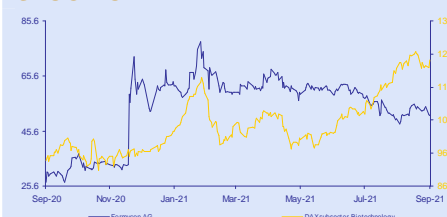
### MARKET DATA

As of 22 Sep 2021

Closing Price	€ 50.20
Shares outstanding	11.05m
Market Capitalisation	€ 554.53m
52-week Range	€ 27.10 / 78.00
Avg. Volume (12 Months)	23,259

Multiples	2020	2021E	2022E
P/E	n.a.	n.a.	198.2
EV/Sales	15.2	11.6	8.3
EV/EBIT	n.a.	n.a.	176.2
Div. Yield	0.0%	0.0%	0.0%

### STOCK OVERVIEW



### COMPANY DATA

As of 30 Jun 2021

Liquid Assets	€ 33.63m
Current Assets	€ 44.07m
Intangible Assets	€ 0.72m
Total Assets	€ 70.94m
Current Liabilities	€ 9.47m
Shareholders' Equity	€ 58.81m

### SHAREHOLDERS

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

**Figure 1: H1/21 results versus our forecasts**

in EURm	H1 21A	H1 21E	Delta	H1 20A	Delta
Revenue	20.3	21.0	-3.3%	16.5	23.0%
EBITDA	-9.7	-5.0	n.m.	-0.9	n.m.
<i>margin</i>	neg.	neg.	-	neg.	-
EBIT	-10.2	-5.5	n.m.	-1.4	n.m.
<i>margin</i>	neg.	neg.	-	neg.	-
Net income	-10.2	-5.5	n.m.	-1.4	n.m.
<i>margin</i>	neg.	neg.	-	neg.	-
EPS (€)	-0.92	-0.50	n.m.	-0.14	n.m.

Source: Formycon; First Berlin Equity Research estimates

We expect the FDA to notify Formycon whether or not it has accepted the BLA in October. Providing that the approval processes run smoothly, approval of FYB201 in both the US and EU should be forthcoming by mid-2022.

**Timing of launch of Samsung Bioepis' Lucentis biosimilar unclear** Samsung Bioepis is Formycon's closest competitor with respect to the development of a Lucentis biosimilar. Samsung Bioepis' Lucentis biosimilar candidate, SB11, was approved by the EMA on 18 August and by the FDA on 20 September. However, in its press release on the FDA approval, Samsung Bioepis stated that "Pursuant to a global license agreement entered into with Genentech, Samsung Bioepis"... "will have freedom to market SB11 in the United States as of June 2022, i.e., before expiration of Genentech's applicable SPCs, and elsewhere in other territories after expiration of Genentech's SPCs." During the period of their validity, SPCs (supplementary protection certificates) block manufacturing of competing drugs. FYB201 will be manufactured in Poland by Polpharma. Lucentis is not patented in Poland and so the SPCs do not apply. It is unclear from Samsung's press release whether the company will be able to manufacture SB11 for stock ahead of mid-2022, which is the likely timing of the FYB201 launch in both the EU and the US. However, the press release suggests that marketing of SB11 outside the US will not take place until after mid-2022.

**Figure 2: H1/21 revenues of Formycon biosimilar candidates' reference products**

USDm	H1/21	H1/20	Delta
Lucentis	1,819	1,642	10.8%
Stelara	4,422	3,516	25.8%
Eylea	4,438	3,609	23.0%
Total	10,678	8,767	21.8%

Source: Companies

**Aggregate reference product sales up 22% in H1/21** Figure 2 above shows H1/21 sales development of the FYB201, FYB202 and FYB203 reference products - respectively Lucentis, Stelara and Eylea. Roche reported that ongoing covid-19 restrictions crimped sales of Lucentis in the US, but this was outweighed by strong development in Europe and China. On the latter market, sales were boosted by strong growth following National Reimbursement Drug Listing in Q4 2019. Stelara sales benefitted from continued strong uptake of the drug for Crohn's disease and ulcerative colitis in both the US and Europe. Eylea sales were driven by robust demand in both the US and Europe.

**We still expect FYB207 to reach the market in 2023** Formycon announced in December 2020 that its ACE2 antibody fusion protein-based covid-19 therapy candidate effectively binds SARs-CoV-2 and completely prevents infection of cells.



Clinical trials were scheduled to start in Q4 of this year, but in August Formycon announced the expansion of preclinical testing to optimise the drug candidate's efficacy. Clinical trials are now expected to start in H1/22. Based on the expectation of a successful phase I/II trial and Emergency Use Authorisation application, we still expect the drug to reach the market in 2023.

**Price target unchanged at €78.00. Recommendation raised from Add to Buy** Higher H1/21 sales of Eylea than we had modelled prompt us to raise our valuation of FYB203. This cancels out the impact of the 2021 forecast reduction on our valuation (see figure 3 below). Our 2022 numbers are broadly unchanged. We raise the recommendation from Add to Buy as the upside to our unchanged price target of €78.00 is now over 25%.

**Figure 3: Changes to our forecasts**

in €m	2021E			2022E		
	Old	New	Delta	Old	New	Delta
Revenues	45.00	45.00	0.0%	62.50	63.04	0.9%
EBITDA	-10.10	-15.07	n.a.	3.30	3.90	18.3%
margin	neg.	neg.	-	5.3%	6.2%	-
EBIT	-11.00	-16.02	n.a.	2.40	2.96	23.2%
margin	neg.	neg.	-	3.8%	4.7%	-
Net profit	-11.00	-16.02	n.a.	2.40	2.96	23.2%
margin	neg.	neg.	-	3.8%	4.7%	-
EPS (diluted, in €)	-0.98	-1.43	n.a.	0.21	0.25	20.6%

Source: First Berlin Equity Research estimates

**Figure 4: Pipeline valuation model**

Compound	Project <sup>1)</sup>	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin <sup>2)</sup>	Discount Factor	Patent Life <sup>3)</sup>	Time to Market
FYB201	nAMD,DR (ex-US)	€48M	260K	€5,250	€1,364M	10%	€129M	9%	13%	n.a.	1 year
FYB201	nAMD,DR (US)	€82M	231K	€9,068	€2,091M	10%	€254M	9%	13%	n.a.	1 year
FYB202	Pso,CrD (ex-US)	€116M	93K	€27,500	€2,552M	16%	€478M	9%	13%	n.a.	3 years
FYB202	Pso,CrD (US)	€260M	121K	€44,750	€5,421M	16%	€1,016M	9%	13%	n.a.	3 years
FYB203	nAMD,DR (ex-US)	€116M	548K	€4,859	€2,664M	16%	€601M	9%	13%	n.a.	4 years
FYB203	nAMD,DR (US)	€254M	582K	€8,591	€5,000M	16%	€1,127M	9%	13%	n.a.	3 years
FYB205,6x	n.a.	€261M									
FYB207	COVID-19 (ex-US)	€241M	201K	€20,000	€4,020M	10%	€40M	18%	16%	20	2 years
FYB207	COVID-19 (US)	€91M	75K	€20,000	€1,508M	10%	€152M	18%	16%	20	2 years
<b>PACME PV</b>		<b>€1,469M</b>									
<b>Costs PV<sup>4)</sup></b>		<b>€671M</b>									
<b>NPV</b>		<b>€797M</b>									
Downpayments and Milestones		€38M									
Proforma net Cash		€75M									
Fair Value		€911M									
Proforma share count		11,675K									
<b>Fair Value Per Share</b>		<b>€78.00</b>									

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 5: Changes to our pipeline valuation model**

	Old	New	Delta
<b>NPV</b>	<b>€779M</b>	<b>€797M</b>	<b>2.4%</b>
<b>PV downpayments and milestones</b>	<b>€39M</b>	<b>€38M</b>	<b>-2.9%</b>
<b>Proforma net Cash</b>	<b>€82M</b>	<b>€75M</b>	<b>-8.2%</b>
<b>Fair Value</b>	<b>€901M</b>	<b>€911M</b>	<b>1.1%</b>
<b>Share Count</b>	<b>11,566K</b>	<b>11,675K</b>	<b>0.9%</b>
<b>Fair value per share</b>	<b>€78.00</b>	<b>€78.00</b>	<b>0.0%</b>

Source: First Berlin Equity Research estimates



## INCOME STATEMENT

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
<b>Revenue</b>	<b>29.0</b>	<b>43.0</b>	<b>33.2</b>	<b>34.2</b>	<b>45.0</b>	<b>63.0</b>
Increase/decrease in unfinished products	0.4	0.6	0.8	0.6	0.0	0.0
<b>Total output</b>	<b>29.4</b>	<b>43.6</b>	<b>32.3</b>	<b>34.8</b>	<b>45.0</b>	<b>63.0</b>
Other operating income	0.1	0.1	0.8	0.4	0.0	0.0
Cost of goods sold	-21.2	-25.8	-21.3	-26.1	-40.0	-40.0
<b>Gross profit</b>	<b>8.4</b>	<b>17.9</b>	<b>11.7</b>	<b>9.2</b>	<b>5.0</b>	<b>23.0</b>
Personnel costs	-6.3	-7.0	-9.1	-10.0	-13.5	-13.4
Depreciation and amortisation	-0.8	-0.9	-0.9	-0.9	-0.9	-0.9
Other operating expenses	-2.8	-3.0	-4.0	-4.0	-6.6	-5.7
<b>Operating income (EBIT)</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.3</b>	<b>-5.7</b>	<b>-16.0</b>	<b>3.0</b>
Net financial result	0.0	0.0	0.0	-0.1	0.0	0.0
<b>Pre-tax income (EBT)</b>	<b>-1.6</b>	<b>7.1</b>	<b>-2.3</b>	<b>-5.8</b>	<b>-16.0</b>	<b>3.0</b>
Income taxes	0.0	0.0	0.0	0.1	0.0	0.0
<b>Net income / loss</b>	<b>-1.6</b>	<b>7.1</b>	<b>-2.3</b>	<b>-5.9</b>	<b>-16.0</b>	<b>3.0</b>
<b>Diluted EPS (in €)</b>	<b>-0.17</b>	<b>0.76</b>	<b>-0.23</b>	<b>-0.58</b>	<b>-1.43</b>	<b>0.25</b>
<b>EBITDA</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.4</b>	<b>-4.8</b>	<b>-15.1</b>	<b>3.9</b>
<b>Ratios</b>						
Gross margin on output	28.4%	41.0%	36.3%	26.3%	11.1%	36.5%
EBIT margin on output	-5.2%	16.4%	-7.0%	-16.5%	-35.6%	4.7%
EBITDA margin on output	-2.6%	18.4%	-4.2%	-13.8%	-33.5%	6.2%
Net margin on output	-5.4%	16.3%	-7.1%	-17.0%	-35.6%	4.7%
Tax rate	-0.2%	0.0%	-0.3%	-1.6%	0.0%	0.0%
<b>Expenses as % of output</b>						
Cost of goods sold	-72.0%	-59.2%	-66.1%	-74.8%	-88.9%	-63.5%
Personnel costs	-21.5%	-16.1%	-28.1%	-28.8%	-30.0%	-21.3%
Depreciation and amortisation	-2.7%	-2.1%	-2.8%	-2.6%	-2.1%	-1.5%
Net other operating exp.	-9.1%	-6.5%	-10.0%	-10.2%	-14.6%	-9.0%
<b>Y-Y Growth</b>						
Revenues	48.5%	48.2%	-22.9%	3.2%	31.5%	40.1%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



## BALANCE SHEET

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
<b>Assets</b>						
<b>Current assets, total</b>	<b>26.6</b>	<b>18.7</b>	<b>28.1</b>	<b>50.5</b>	<b>64.0</b>	<b>80.3</b>
Cash and cash equivalents	4.5	7.3	22.1	42.0	54.2	63.5
Other liquid assets	11.0	5.0	0.2	0.2	0.3	0.3
Receivables	10.5	5.2	4.9	6.9	9.0	15.8
Inventories	0.6	1.2	0.4	1.2	0.5	0.6
Other current assets	0.1	0.1	0.4	0.1	0.1	0.1
<b>Non-current assets, total</b>	<b>4.2</b>	<b>20.9</b>	<b>25.5</b>	<b>25.1</b>	<b>25.5</b>	<b>25.8</b>
Investment participations	0.0	16.0	20.7	20.7	20.7	20.7
Property, plant & equipment	3.3	3.5	3.7	3.5	3.4	3.4
Goodwill & other intangibles	0.9	0.8	0.6	0.5	0.4	0.3
Prepaid expenses	0.1	0.1	0.1	0.1	0.1	0.2
Deferred tax assets	0.0	0.5	0.4	0.3	0.9	1.3
<b>Total assets</b>	<b>30.8</b>	<b>39.6</b>	<b>53.6</b>	<b>75.6</b>	<b>89.5</b>	<b>106.1</b>
<b>Shareholders' equity &amp; debt</b>						
<b>Current liabilities, total</b>	<b>3.4</b>	<b>3.3</b>	<b>2.8</b>	<b>5.0</b>	<b>3.8</b>	<b>5.9</b>
Accounts payable	1.8	2.7	2.2	4.5	3.2	5.0
Other current liabilities	1.7	0.6	0.6	0.5	0.6	0.9
<b>Long-term liabilities, total</b>	<b>1.8</b>	<b>3.1</b>	<b>2.6</b>	<b>2.5</b>	<b>4.1</b>	<b>5.4</b>
Provisions	1.3	2.6	1.9	2.1	3.6	5.0
Other liabilities	0.6	0.5	0.7	0.4	0.5	0.4
<b>Minority interests</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Shareholders' equity</b>	<b>25.5</b>	<b>33.2</b>	<b>48.2</b>	<b>68.0</b>	<b>81.7</b>	<b>94.7</b>
<b>Total consolidated equity and debt</b>	<b>30.8</b>	<b>39.6</b>	<b>53.6</b>	<b>75.6</b>	<b>89.5</b>	<b>106.1</b>
<b>Key figures</b>						
Current ratio (x)	7.75	5.64	10.15	10.06	16.94	13.55
Quick ratio (x)	7.59	5.27	10.00	9.82	16.83	13.44
Financial leverage (%)	-60.6	-37.0	-46.4	-62.1	-66.8	-67.3
Book value per share (€)	2.78	3.37	4.82	291.47	305.43	333.68
Return on equity (ROE)	-6.8%	24.2%	-5.6%	-10.2%	-21.4%	3.4%



## CASH FLOW STATEMENT

All figures in EURm	2017A	2018A	2019A	2020A	2021E	2022E
<b>EBIT</b>	<b>-1.5</b>	<b>7.1</b>	<b>-2.3</b>	<b>-5.7</b>	<b>-16.0</b>	<b>3.0</b>
Depreciation and amortisation	0.8	0.9	0.9	0.9	0.9	0.9
<b>EBITDA</b>	<b>-0.8</b>	<b>8.0</b>	<b>-1.4</b>	<b>-4.8</b>	<b>-15.1</b>	<b>3.9</b>
Changes in working capital	-3.4	5.3	0.6	-0.5	-2.4	-5.0
Other adjustments	0.0	0.0	-0.7	0.2	0.0	0.0
<b>Operating cash flow</b>	<b>-4.2</b>	<b>13.3</b>	<b>-1.5</b>	<b>-5.1</b>	<b>-17.5</b>	<b>-1.1</b>
CAPEX	-0.5	-17.0	-5.7	-0.6	-0.7	-0.8
<b>Free cash flow</b>	<b>-4.7</b>	<b>-3.7</b>	<b>-7.2</b>	<b>-5.7</b>	<b>-18.2</b>	<b>-1.9</b>
<b>Debt financing, net</b>	<b>0.0</b>	<b>0.6</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Equity financing, net</b>	<b>6.2</b>	<b>0.0</b>	<b>17.3</b>	<b>25.8</b>	<b>29.0</b>	<b>0.0</b>
<b>Grants</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>1.5</b>	<b>11.2</b>
Other changes in cash	0.0	0.0	0.0	-0.2	0	0
<b>Net cash flows</b>	<b>1.5</b>	<b>-3.2</b>	<b>10.0</b>	<b>19.9</b>	<b>12.3</b>	<b>9.3</b>
Cash and liquid assets, start of the year	14.0	15.5	12.3	22.4	42.2	54.5
<b>Cash and liquid assets, end of the year</b>	<b>15.5</b>	<b>12.3</b>	<b>22.4</b>	<b>42.2</b>	<b>54.5</b>	<b>63.8</b>
<b>EBITDA/share (in €)</b>	<b>-0.1</b>	<b>0.9</b>	<b>-0.1</b>	<b>-0.5</b>	<b>-1.3</b>	<b>0.3</b>
<b>Y-Y Growth</b>						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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**ASSET VALUATION SYSTEM**

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

**ASSET RECOMMENDATION**

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy <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 €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

**RISK ASSESSMENT**

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

**RECOMMENDATION & PRICE TARGET HISTORY**

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	17 April 2013	€3.50	Buy	€7.30
2...29	↓	↓	↓	↓
30	19 May 2020	€24.70	Buy	€39.00
31	23 June 2020	€23.10	Buy	€39.00
32	23 September 2020	€30.40	Buy	€39.00
33	14 October 2020	€33.00	Buy	€43.00
34	7 January 2021	€61.00	Buy	€78.00
35	26 March 2021	€62.60	Add	€78.00
36	20 May 2021	€56.80	Buy	€78.00
37	5 July 2021	€62.80	Add	€78.00
38	Today	€50.20	Buy	€78.00

**INVESTMENT HORIZON**

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.



### UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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#### Legally required information regarding

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

can be accessed through the following internet link: <https://firstberlin.com/disclaimer-english-link/>

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