PAION AG

Germany / Biotechnology
Frankfurt Prime Standard
Bloomberg: PA8 GR
ISIN: DE000A0B65S3

2018 Annual Report

RATING	**BUY**
PRICE TARGET	**€ 4.10**
Return Potential	88.5%
Risk Rating	High

FIRST REMIMAZOLAM REVENUES IN U.S. AND JAPAN LIKELY IN 2020

PAION filed for market approval of remimazolam in Japan in the indication general anaesthesia in December 2018 and management expects filing in the U.S. in the indication procedural sedation "shortly". This means that first revenues in remimazolam in the U.S. and Japan are likely in 2020. Meanwhile, the EU phase III clinical trial with remimazolam in general anaesthesia is on track and completion of patient recruitment is expected by the end of 2019. PAION's main priority over the next few years is to gain regulatory approval for remimazolam in as many countries for as many indications as possible. PAION estimates the peak sales opportunity for remimazolam at over USD500m annually for each of the three indications: procedural sedation, general anaesthesia and intensive care unit sedation. Final 2018 numbers were close to our expectations and also in line with company guidance. We maintain our Buy recommendation but lower the price target to €4.10 (previously: €4.30) to accommodate management's expectation that a further €10m in new equity capital (we had previously assumed only €5m) will be required ahead of filing for approval of remimazolam for general anaesthesia in the EU.

Further details on competitive advantage during conference call The two main incumbent products in the above-mentioned indications are midazolam which is used mainly in conscious sedation, and propofol which is used mainly in deep sedation. Remimazolam's advantage over midazolam is shorter onset/offset times and over propofol clinically meaningful lower cardiodepressive and respiratory depressant effects. The most valuable single indication/geography for remimazolam is procedural sedation in the U.S. where colonoscopies account for nearly half of the annual 43 million medical procedures in which sedation is used. In the U.S. colonoscopies are typically carried out in large outpatient clinics. PAION's management believes that the efficiencies stemming from remimazolam's shorter onset/offset times relative to midazolam amount to several USD100s per patient. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2016	2017	2018	2019E	2020E	2021E
Revenue (€ m)	4.26	5.81	2.77	8.00	37.45	47.11
Y-o-y growth	n.a.	36.4%	-52.4%	189.2%	368.2%	25.8%
EBIT (€ m)	-25.08	-15.87	-12.46	-10.50	17.20	17.93
EBIT margin	2.0%	3.0%	4.0%	5.0%	6.0%	7.0%
Net income (€ m)	-20.12	-12.09	-9.94	-8.48	19.63	16.78
EPS (diluted) (€)	-0.38	-0.20	-0.16	-0.13	0.31	0.26
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-11.78	-17.75	-12.83	-2.04	14.47	7.73
Net gearing	-120.7%	-98.5%	-82.7%	-112.3%	-93.1%	-79.9%
Liquid assets (€ m)	30.11	24.84	17.23	20.18	39.65	47.38

RISKS

Risks to our price target include but are not limited to: drug development, finding development partners on favourable terms, financial, and legal risks.

COMPANY PROFILE

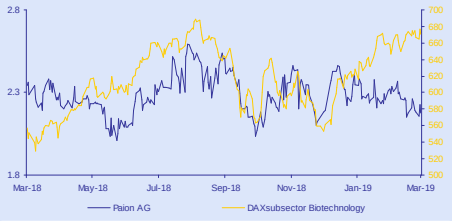
PAION is a specialty pharmaceutical company headquartered in Aachen (Germany) with operations in Cambridge (United Kingdom). PAION's lead substance, remimazolam, is an intravenous ultra-short-acting benzodiazepine anaesthetic that has completed phase III clinical development for procedural sedation.

MARKET DATA

As of 27 Mar 2019	
Closing Price	€ 2.17
Shares outstanding	63.86m
Market Capitalisation	€ 138.89m
52-week Range	€ 2.01 / 2.60
Avg. Volume (12 Months)	57,390

Multiples	2018	2019E	2020E
P/E	n.a.	n.a.	7.1
EV/Sales	44.0	15.2	3.2
EV/EBIT	n.a.	n.a.	7.1
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2018	
Liquid Assets	€ 28.73m
Current Assets	€ 35.13m
Intangible Assets	€ 2.65m
Total Assets	€ 37.58m
Current Liabilities	€ 10.21m
Shareholders' Equity	€ 27.37m

SHAREHOLDERS

Cosmo Pharmaceuticals	9.1%
TIAA-CREF	3.0%
Free Float	87.9%

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Faster time to full recovery also equates to a better experience not only for patients but also for persons (typically friends or relatives) accompanying the patients to and from the procedure.

2018 results were close to our expectations and in line with guidance Final 2018 P&L numbers were close to our expectations and also in line with company guidance (see figure 1 below). The largest component of 2018 revenue of €2.8m (FBe: €3.0m; 2017: €5.8m) was €2.0m stemming from the licensing agreement for remimazolam in Japan with Mundipharma. A further €0.5m came from PAION's South Korean partner, Hana Pharm, and was triggered by filing for market approval of remimazolam in Japan. The remaining €0.3m related to the license agreement for China with Yichang Humanwell and stemmed from filing for market approval in that country. 2017 revenues were almost all accounted for by recognition of the remaining €5.7m of the €10.0m upfront payment received from Cosmo in 2016 following the conclusion of the licensing deal for remimazolam in the US.

Figure 1: FY/18 results vs. our forecasts

in EURm	FY/18A	FY/18E	Delta	FY/17A	Delta
Total revenue*	2.77	3.00	-7.7%	5.81	-52.3%
R&D expenses	12.17	13.00	-6.4%	17.85	-31.8%
S,G&A expenses	3.41	3.75	-9.1%	3.83	-11.0%
EBT	-12.45	-13.73	9.3%	-15.85	21.5%
Tax credit	2.51	2.50	0.4%	3.76	-33.2%
Net income	-9.94	-11.23	11.5%	-12.09	17.8%
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (dil., in EUR)	-0.16	-0.18	11.5%	-0.20	17.8%

* including other operating income such as milestone payments

Source: PAION, First Berlin Equity Research estimates

Net loss narrowed in 2018 due to lower R&D costs R&D was again clearly the biggest expense item in the P&L but fell 31.8% to €12.2m (2017: €17.9m) because costs for phase III and particularly phase I trials in connection with the U.S. development programme were higher in the previous year. Lower R&D expenses were the main reason why the company's net loss narrowed to €9.9m (2017: a net loss of €12.1m) despite lower revenue.

Filing for approval of remimazolam in multiple countries PAION's licensing partners filed for approval of remimazolam for procedural sedation in China and for general anaesthesia in Japan in November and December 2018 respectively. Filing for approval of remimazolam in the US for procedural sedation is expected "shortly".

PAION's Canadian licensing partner, Pharmascience, is expected to use the US market approval dossier as the basis for filing for market approval in Canada while TR-Pharm (remimazolam licensee for Turkey, the Middle East and North Africa) plans to file for market approval in Turkey based on the U.S. or Japanese dossier. The Russian remimazolam licensee, R-Pharm, completed a phase III trial in general anaesthesia in November 2018 and plans to file for approval later this year.

In South Korea recruitment for a phase III trial of remimazolam in general anaesthesia was completed in October 2018. Local partner Hana Pharm expects to file for approval in 2020 following establishment of a production process.

Completion of EU phase III trial recruitment in general anaesthesia by end 2019 Management expect patient recruitment for the EU phase III trial of remimazolam in general anaesthesia to be completed by the end of 2019. Positive results from the EU phase III trial together with data from the EU phase II trial (completed in 2014) and the Japanese phase II/III trial (completed in 2013) are expected to suffice for filing for approval in general anaesthesia.

EU filing for approval in procedural sedation likely without further trials PAION's management discussed data from the US phase III clinical development programme of remimazolam for procedural sedation at a pre-submission meeting with the EMA in February 2019. Based on this meeting, PAION now expects to be able to file for approval of remimazolam in procedural sedation in the EU without carrying out any further trials. During the conference call following the results, management stated that it expected to be able to give guidance on the timing of filing for approval of remimazolam in the EU in procedural sedation by the end of H1 2019.

First remimazolam revenues in U.S. and Japan likely in 2020 Our previous 2019 revenue forecast of €17.6m was based on the assumptions of a milestone payment from Cosmo for filing for approval in the U.S., a milestone payment from Mundipharma for market approval in Japan, as well as first remimazolam product revenues in Japan. In the 2018 annual report, management guided towards revenues of "about €8m" for 2019 comprised of a €7.5m milestone from the U.S. filing and €0.5m from TR-Pharm in connection with the transfer of the Japanese filing dossier translated into English or transfer of the U.S. filing dossier. Management further stated that market approval in China and Japan (following filing for approval in November 2018 and December 2018 respectively) could in both cases happen by "the end of 2019 at the earliest". Market approval in the US is expected in 2020. Management's 2019 guidance does not include any milestones or product revenues with respect to either China or Japan.

Figure 2: Management 2019 guidance

in EURm	FY/19 Guidance
Total revenue*	ca. €8m
R&D expenses	ca. €13-€15m
S,G&A expenses	ca. €4-€5m
Tax credits	ca. €2m
Net result	ca. €-7 to €-10m

* including other op. income such as milestone payments

Source: PAION

Management guidance regarding the 2019 P&L is shown above in figure 2. R&D expenses are expected to rise to €13-15m as recruitment of the EU phase III trial in general anaesthesia progresses. Meanwhile S,G&A expenses are also expected to rise to €4-5m due to pre-commercial activities prior to the launch of remimazolam in multiple territories. We have adjusted our forecasts to take account of management guidance for 2019 as well as our current expectations regarding market approval timings and milestones. We also show detailed 2021 forecasts for the first time.

Figure 3: Changes to our forecasts

	2019E			2020E			2021E
in EURm	Old	New	Δ	Old	New	Δ	New
Revenues	1.84	0.00	-100.0%	21.99	12.90	-41.3%	42.56
Other operating income	15.80	8.00	-49.4%	8.00	24.55	206.9%	4.55
Total revenues	17.64	8.00	-54.6%	29.99	37.45	24.9%	47.11
EBIT	-6.26	-10.50	-67.7%	5.79	17.20	196.9%	17.93
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
Net income	-3.04	-8.48	-178.5%	9.01	19.63	117.8%	16.78
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
EPS (dil., in EUR)	-0.05	-0.13	-178.5%	0.14	0.31	117.8%	0.26

Source: PAION, First Berlin Equity Research estimates

Buy recommendation maintained but price target lowered to €4.10 (previously: €4.30)
PAION had cash and cash equivalents of €17.2m at the end of 2018 (2017: €24.8m). Management stated in the 2018 annual report that the company's cash reach extends until mid-2020. The assumptions underlying this statement include expected U.K. tax credits on R&D expenses and the milestone payment expected in connection with filing for market approval in the U.S. As we have seen above, PAION's management expects recruitment for the EU phase III trial in general anaesthesia to be complete by the end of this year. PAION has not given any further guidance regarding the timeline for general anaesthesia in the EU but we believe filing for approval in 2021 and first revenues in 2022 are reasonable assumptions. Management has stated that a further €10m will be required until filing for approval for general anaesthesia in the EU. We have incorporated this guidance into our model which now features a €5m capital raise in both 2019 and 2020 (previously 2019 only). PAION also points out in the 2018 annual report that additional funds will be required in coming years for planned own commercialisation in selected European markets as well as for planned development of remimazolam for the indication ICU sedation. However, we expect that future revenues and milestones will be sufficient to cover these costs. We maintain our Buy recommendation but lower the price target to €4.10 (previously: €4.30) to reflect the higher requirement for new equity capital than we had previously modelled.

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
Remimazolam	PS EU	€111.5M	15,144K	€14	€208.6M	25%	€69.9M	60%	15%	15	2 Years
Remimazolam	PS US	€150.6M	20,000K	€20	€400.0M	50%	€257.5M	20%	15%	13	1 Year
Remimazolam	PS CAN	€7.0M	1,056K	€20	€21.1M	50%	€13.6M	18%	15%	13	1 Year
Remimazolam	GA EU	€181.6M	15,144K	€40	€605.8M	20%	€162.3M	60%	15%	15	3 Years
Remimazolam	GA US	€71.8M	23,925K	€40	€957.0M	20%	€246.5M	20%	15%	13	4 Years
Remimazolam	GA JAP	€80.6M	10,000K	€40	€400.0M	25%	€134.0M	18%	15%	15	1 Year
Remimazolam	GA CHN	€15.8M	51,000K	€28	€1,405.0M	10%	€188.2M	10%	15%	15	4 Years
Remimazolam	PS CHN	€15.1M	33,260K	€10	€346.5M	10%	€46.4M	10%	15%	15	1 Year
Remimazolam	GA KOR	€7.6M	3,750K	€28	€103.3M	25%	€34.6M	10%	15%	15	2 Years
Remimazolam	GA CIS/MENA/TUR	€66.2M	55,247K	€28	€1,566.6M	10%	€209.9M	12%	15%	15	1 Year
Remimazolam	ICU US	€16.1M	1,561K	€250	€390.2M	25%	€125.6M	20%	15%	13	5 Years
Remimazolam	ICU EU	€66.5M	2,439K	€167	€406.5M	25%	€136.8M	60%	15%	15	4 Years
Remimazolam	ICU Japan	€4.3M	606K	€167	€101.0M	25%	€33.8M	18%	15%	15	5 Years
PACME PV		€794.5M									
Costs PV (4)		€585.1M									
NPV		€209.5M									
Milestones PV		€41.0M									
Pro forma net cash		€26.2M									
Fair Value		€276.7M									
Pro forma share count		68,228K									
Price Target		€4.10									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

PS EU = Procedural Sedation in the EU
PS US = Procedural Sedation in the US
PS CAN = Procedural Sedation in Canada
GA EU = General Anaesthesia in the EU
GA US = General Anaesthesia in the US
GA JAP = General Anaesthesia in Japan
GA CHN = General Anaesthesia in China
GA KOR = General Anaesthesia in South Korea
GA CIS/MENA/TUR = General Anaesthesia in the Commonwealth of Independent States, Middle East & North Africa, and Turkey
ICU US = General Anaesthesia in Intensive Care Units in the US
ICU EU = General Anaesthesia in Intensive Care Units in the EU
Other projects: GGF2 (HF) and Solulin (HPH)
HF = Heart Failure
HPH = Haemophilia

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), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs, CapEx and working capital; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

Figure 5: Changes to pipeline valuation model

	Old	New	Delta
NPV	**€212.4M**	**€209.5M**	**-1.4%**
Milestones PV	€45.9M	€41.0M	-10.7%
Pro Forma Net Cash	€24.4M	€26.2M	7.6%
Fair Value	€282.7M	€276.7M	-2.1%
Diluted Share Count	€65.9M	€68.2M	3.6%
Fair Value Per Share	**€4.30**	**€4.10**	**-4.7%**

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Net revenues	**0**	**0**	**0**	**0**	**12,902**	**42,560**
Other op. inc. (including milestones)	**4,262**	**5,811**	**2,766**	**8,000**	**24,550**	**4,550**
Total revenue	**4,262**	**5,811**	**2,766**	**8,000**	**37,452**	**47,110**
Cost of goods sold	**0**	**0**	**0**	**0**	**0**	**4,407**
Gross profit	**4,262**	**5,811**	**2,766**	**8,000**	**37,452**	**42,703**
S,G&A	5,129	3,828	3,408	4,500	5,250	9,776
R&D	23,408	17,854	12,167	14,000	15,000	15,000
Other operating income (expense)	-807	-2	354	0	0	0
Operating income (EBIT)	**-25,082**	**-15,872**	**-12,455**	**-10,500**	**17,202**	**17,927**
Net financial result	21	20	8	21	29	44
Pre-tax income (EBT)	**-25,061**	**-15,852**	**-12,447**	**-10,479**	**17,231**	**17,971**
Income taxes	4,944	3,759	2,510	2,000	2,400	-1,194
Net income / loss	**-20,118**	**-12,093**	**-9,937**	**-8,479**	**19,631**	**16,777**
Diluted EPS	**-0.38**	**-0.20**	**-0.16**	**-0.13**	**0.31**	**0.26**
EBITDA	**-24,758**	**-15,626**	**-12,265**	**-10,360**	**17,342**	**18,067**
Ratios						
EBIT margin	n.m.	n.m.	n.m.	n.m.	45.9%	38.1%
EBITDA margin	n.m.	n.m.	n.m.	n.m.	46.3%	38.4%
Net margin	n.m.	n.m.	n.m.	n.m.	52.4%	35.6%
Cash Coverage of Expenses						
Cash / G&A	5.9x	6.5x	5.1x	4.5x	7.6x	7.6x
Cash / R&D	1.3x	1.4x	1.4x	1.4x	2.6x	3.2x
Y-Y Growth						
Total revenue	5851.0%	36.4%	-52.4%	189.2%	368.2%	25.8%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	4.2%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	-14.5%

BALANCE SHEET

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Assets						
Current assets, total	**35,128**	**29,357**	**22,037**	**23,682**	**49,458**	**66,365**
Cash and cash equivalents	30,111	24,839	17,227	20,182	39,654	47,381
Short-Term Investments	0	0	0	0	0	0
Receivables	0	37	1,500	0	1,935	4,731
Inventories	0	0	0	0	4,119	10,502
Other current assets	5,017	4,481	3,311	3,500	3,750	3,750
Non-current assets, total	**2,855**	**2,529**	**2,286**	**2,166**	**2,046**	**1,966**
Property, plant & equipment	167	114	74	44	14	24
Goodwill & other intangibles	2,688	2,415	2,212	2,122	2,032	1,942
Other Assets	0	0	0	0	0	0
Total assets	**37,984**	**31,885**	**24,323**	**25,848**	**51,504**	**68,331**
Shareholders' equity & debt						
Current Liabilities, Total	**13,040**	**6,656**	**3,501**	**7,875**	**8,926**	**9,035**
Convertible bond	0	0	0	0	0	0
Short-term debt	0	0	0	0	0	0
Accounts payable	6,353	5,921	2,218	7,000	8,000	8,000
Milestone	5,730	0	0	0	0	0
Provisions	555	391	630	0	26	85
Other current liabilities	403	344	654	875	900	950
Longterm liabilities, total	**0**	**0**	**0**	**0**	**0**	**0**
Convertible bond	0	0	0	0	0	0
Long-term debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Deferred revenue	0	0	0	0	0	0
Shareholders' equity	**24,943**	**25,229**	**20,822**	**17,973**	**42,578**	**59,296**
Total consolidated equity and debt	**37,984**	**31,885**	**24,323**	**25,848**	**51,504**	**68,331**
Ratios						
Current ratio (x)	2.69	4.41	6.29	3.01	5.54	7.35
Quick ratio (x)	2.69	4.41	6.29	3.01	5.08	6.18
Net gearing	-120.7%	-98.5%	-82.7%	-112.3%	-93.1%	-79.9%
Book value per share (€)	0.45	0.41	0.33	0.28	0.67	0.93
Return on equity (ROE)	-66.5%	-48.2%	-43.2%	-43.7%	64.8%	32.9%

CASH FLOW STATEMENT

All figures in EUR '000	2016	2017	2018	2019E	2020E	2021E
Net result	**-20,118**	**-12,093**	**-9,939**	**-8,479**	**19,631**	**16,777**
Depreciation and amortization	759	347	255	140	140	140
Changes in working capital	1,137	-911	-4,647	6,314	-5,279	-9,130
Milestone	5,730	-5,730	0	0	0	0
Net taxes received	585	838	0	0	0	0
Other items	321	-170	1,518	0	0	0
Operating cash flow	**-11,586**	**-17,720**	**-12,813**	**-2,025**	**14,492**	**7,787**
CAPEX	-192	-25	-13	-20	-20	-60
Free cash flow	**-11,778**	**-17,745**	**-12,826**	**-2,045**	**14,472**	**7,727**
Debt financing, net	**0**	**0**	**0**	**0**	**0**	**0**
Convertible bond financing, net	**0**	**0**	**0**	**0**	**0**	**0**
Equity financing, net	**9,212**	**12,494**	**5,214**	**5,000**	**5,000**	**0**
Other changes in cash	**-2**	**-22**	**0**	**0**	**0**	**0**
Net cash flows	**-2,568**	**-5,273**	**-7,612**	**2,955**	**19,472**	**7,727**
Cash, start of the year	32,680	30,111	24,839	17,227	20,182	39,654
Cash, end of the year	**30,111**	**24,839**	**17,227**	**20,182**	**39,654**	**47,381**

Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

FIRST BERLIN RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	2 April 2012	€0.79	Buy	€2.00
2...35	↓	↓	↓	↓
36	4 July 2017	€3.04	Buy	€4.40
37	10 April 2018	€2.23	Buy	€4.30
38	20 November 2018	€2.40	Buy	€4.30
39	Today	€2.17	Buy	€4.10

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INFORMATION PURSUANT TO SECTION 34B OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO 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 THE GERMAN ORDINANCE ON THE ANALYSIS OF FINANCIAL INSTRUMENTS [FINANV]

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

ASSET RECOMMENDATION

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

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

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.

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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**

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