# MOLOGEN AG

Germany / Pharmaceutical/Biotechnology
Primary Exchange: Frankfurt
Bloomberg: MGN GR
ISIN: DE0006637200

Q3/16 results

| | |
|---|---|
| **RATING** | **BUY** |
| **PRICE TARGET** | **€11.30** |
| Return Potential | 655.3% |
| Risk Rating | High |

## LEFITOLIMOD (MGN1703) IN 4 CLINICAL TRIALS; FIRST FILING IN 2019/20

**Lower R&D expenses than we had modelled meant that Q3/16 EBIT came in at €-4.5m (Q3/15: €-6.3m) - €1.9m above our forecast of €-6.4m. Mologen continues to implement the "Next Level" corporate realignment programme which is refocusing the company on products which are close to the market while halting/suspending development of most earlier stage products. "Next Level" aims to accelerate the commercialisation of the company's lead drug candidate, the Toll-like receptor 9 (TLR9) agonist and immune surveillance reactivator, lefitolimod (MGN1703), while flexibilising costs before this is achieved. Lefitolimod (MGN1703) is the subject of four clinical trials – in metastatic colorectal cancer (mCRC), small-cell lung cancer, HIV, and a combination trial with the immune checkpoint inhibitor, Yervoy. The market for mCRC alone is worth over USD10bn. We expect Mologen to file an application for approval with the FDA in this indication in 2019/20. We have revised our 2016 EBIT forecast up to reflect the likelihood that R&D spending this year will not be as high as we previously forecast. However, adjustments to our long term taxation assumptions cause us to leave our price target unchanged at €11.30. We maintain our Buy recommendation.**

**Q3/16 result above our forecast** Q3/16 EBIT at €-4.5m (FBe: €-6.4m; Q3/15: €-6.3m) was above our forecast (see figure 1 overleaf) mainly because R&D spending at €3.5m (Q3/15: €-5.2m) was €2.0m lower than we had expected. R&D expenditure after nine months was €10.5m (9M/15 €10.4m). Management has confirmed that R&D spending will also be higher for the full year. EBIT was also affected by costs, which we estimate at €0.5m, in connection with the personnel reduction entailed by the "Next Level" programme and by recruitment of new staff in clinical development in H2/15. Management tells us that total personnel reduction costs in connection with "Next Level" will be around €0.5m in H2 2016. Management and employees numbered 63 persons at the end of March 2016. (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

| | 2013 | 2014 | 2015 | 2016E | 2017E | 2018E |
|---|---|---|---|---|---|---|
| Revenue (€m) | 0.23 | 0.01 | 0.04 | 0.03 | 0.00 | 36.36 |
| Y-o-y growth | 278.3% | -94.7% | 225.0% | -35.9% | -100.0% | n.a. |
| EBIT (€m) | -10.86 | -17.10 | -20.54 | -21.77 | -24.33 | 12.71 |
| EBIT margin | n.a. | n.a. | n.a. | n.a. | n.a. | 35.0% |
| Net income (€m) | -10.83 | -17.08 | -20.54 | -21.79 | -24.48 | 12.56 |
| EPS (diluted) (€) | -0.70 | -1.02 | -0.99 | -0.89 | -0.81 | 0.28 |
| DPS (€) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| FCF (€m) | -9.01 | -15.70 | -15.18 | -23.69 | -23.88 | 12.73 |
| Net gearing | -58.4% | -101.9% | -126.1% | -128.2% | -166.4% | -121.9% |
| Liquid assets (€m) | 8.77 | 13.56 | 24.59 | 17.04 | 12.06 | 24.79 |

### RISKS

Risks to our price target include but are not limited to development, partnering, financial, and regulatory risks.

### COMPANY PROFILE

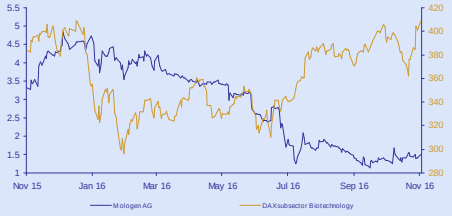
MOLOGEN is an R&D-stage biotechnology company based in Berlin. The firm focuses on innovative DNA-based and cell-based drug development for the treatment of diseases with unmet medical need. The company's furthest developed products are MGN1703 for the treatment of colorectal carcinoma, small cell lung cancer and HIV. In addition a combination study of MGN1703 with Yervoy is being performed.

### MARKET DATA

| As of 14 Nov 2016 | |
|---|---|
| Closing Price | € 1.50 |
| Shares outstanding | 33.95m |
| Market Capitalisation | € 50.79m |
| 52-week Range | € 1.15 / 4.85 |
| Avg. Volume (12 Months) | 43,914 |

| Multiples | 2015 | 2016E | 2017E |
|---|---|---|---|
| P/E | n.a. | n.a. | n.a. |
| EV/Sales | 725.6 | 1132.0 | 0.0 |
| EV/EBIT | n.a. | n.a. | n.a. |
| Div. Yield | 0.0% | 0.0% | 0.0% |

### STOCK OVERVIEW




### COMPANY DATA

| As of 30 Sep 2016 | |
|---|---|
| Liquid Assets | € 10.19m |
| Current Assets | € 11.09m |
| Intangible Assets | € 0.07m |
| Total Assets | € 11.26m |
| Current Liabilities | € 8.35m |
| Shareholders' Equity | € 4.91m |

### SHAREHOLDERS

| | |
|---|---|
| Global Derivative Trading GmbH | 29.0% |
| Deutsche Balaton AG | 5.0% |
| Baloise Group | 4.0% |
| Deutscher Ring Krankenvers. a.G. | 4.0% |
| IPConcept | 3.0% |
| Free float | 55.0% |

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We expect Mologen to end 2016 with a headcount of around 46 persons, thereby creating a more flexible cost structure at the company.

**Figure 1: Q3/16 results vs. our forecasts**

| in €m | Q3 16A | Q2-16E | Delta | Q3-15A | Delta | 9M 2016 | 9M 2015 | Delta |
|---|---|---|---|---|---|---|---|---|
| Sales* | 0.03 | 0.00 | - | 0.00 | - | 0.04 | 0.05 | -22.2% |
| EBIT | -4.46 | -5.00 | - | -6.35 | - | -14.31 | -13.25 | - |
| *margin* | *neg.* | *neg.* | - | *neg.* | - | *neg.* | *neg.* | |
| Net income | -4.46 | -5.00 | - | -6.35 | - | -14.31 | -13.25 | - |
| *margin* | *neg.* | *neg.* | - | *neg.* | - | *neg.* | *neg.* | |
| EPS (in €) | -0.20 | -0.22 | - | -0.28 | - | -0.63 | -0.66 | - |

* including other operating income

*Source: First Berlin Equity Research; Mologen AG*

As described in our note of 22 July, under “Next Level” Mologen is focusing development resources on its lead drug candidate lefitolimod (MGN1703) and the next generation of this product – EnanDIM. The overarching goal of “Next Level” is to accelerate the commercialisation of lefitolimod (MGN1703), while flexibilising costs before this is achieved.

**Completion of IMPALA phase III recruitment in mCRC Q1 2017** Lefitolimod (MGN1703) is currently the subject of four clinical trials. Mologen continues to recruit patients for its phase III IMPALA pivotal study with lefitolimod (MGN1703) in metastatic colorectal cancer (mCRC). Patient recruitment for IMPALA began in September 2014 and is scheduled to be completed in Q1 2017. Mologen intends to evaluate the data within approximately 24 months of completion of recruitment. Some uncertainty remains as to the precise timing as the primary end point is overall survival. Filing for approval with the FDA is likely in 2019/20.

**IMPULSE topline phase II results in small cell lung cancer expected in H1 2017** Enrolment of 100 patients to the IMPULSE phase II trial with lefitolimod (MGN1703) in small cell lung cancer was completed in autumn 2015. The primary endpoint of the study is overall survival. Mologen intends to start the primary analyses by the end of 2016 and publish topline results in the first half of 2017. Mologen plans to present the results next June at the ASCO (American Society of Clinical Oncologists) annual meeting in Chicago.

**TEACH phase I results in HIV due in H1/17** An early stage trial with HIV patients carried out at the Aarhus University Hospital in Denmark in 2015 suggests that lefitolimod (MGN1703) could play a role in the kick and kill concept of HIV eradication. In the first phase of the trial, patients received one month of treatment. In the extension phase, patients will be treated with lefitolimod (MGN1703) for six months. Topline results of the study are expected in the first half of 2017. The so-called TEACH trial is the first time that lefitolimod (MGN1703) has been evaluated in patients with diseases other than cancer and is being conducted within the framework of a collaborative agreement with Mologen.

**Completion of recruitment for combination trial with Yervoy scheduled for 2018** In January 2016, Mologen concluded a cooperation agreement with the MD Anderson Cancer Center at the University of Texas to conduct a phase 1 trial of lefitolimod (MGN1703) with the immune checkpoint inhibitor Yervoy. The trial started in mid-July 2016 and will include around 50 to 60 patients. Completion of recruitment is scheduled for 2018 with publication of results the followng year. The trial with Yervoy will be the first time that lefitolimod (MGN1703) has been evaluated in combination with a checkpoint inhibitor and may be the first of several studies of lefitolimod (MGN1703) in combination with other anti-cancer drugs.

**€13.6m rights issue successfully completed** Mologen recently successfully completed a 1 for 2 rights issue raising gross proceeds of €13.6m. We expect the company to raise a further €2.5m later this month through the issue of a convertible bond to its largest shareholder, Global Derivative Trading (GDT). The presumed total proceeds of €16.1m will be used to implement the “Next Level” strategy.

Holders of 75% of the shares, including the largest shareholder, GDT, took up their rights. The private placement of shares not subscribed in the rights issue was oversubscribed. Mologen acquired a new significant shareholder, IPConcept (holds a stake of 3%), in the course of the capital raise. IPConcept is based in Luxembourg and is a subsidiary of DZ Bank. A further capital raise is likely to be required by the end of the second half of 2017. However, the strength of the interest shown in the recent financing round bodes well for the success of capital market activity next year.

**Encouraging preclinical data on EnanDIM** In September Mologen announced data from a preclinical study in mice on the lefitolimod (MGN1703) successor product, EnanDIM. In vivo data showed that EnanDIM can reduce tumour growth and thus prolong survival. Previous results showed that EnanDIM molecules broadly activate immune cells in vitro and revealed no signs of toxicity after the administration of maximal feasible doses in vivo.

**EnanDIM clinical development phase expected to begin in ca. 18 months** EnanDIM is being aggressively developed towards the clinical trial stage. Clinical phase I is expected to begin in around 18 months. From the conference call following the publication of the Q3 results, we gather that EnanDIM may also be developed for the HIV indication. Both lefitolimod (MGN1703) and EnanDIM belong to the family of TLR9 agonists. In contrast to lefitolimod, EnanDIM is a family of linear molecules which can be adapted to distinct functional properties, e.g. stimulating different parts of the immune system. The lefitolimod (MGN1703) molecule is a closed dumbbell-shaped structure whereas the EnanDIM molecule is linear. The EnanDIM molecule combines the advantages of lefitolimod's (MGN1703) natural DNA components in terms of safety and tolerability with its linear structure. This makes EnanDIM easier and more cost effective to produce than lefitolimod (MGN1703). Importantly, market exclusivity for EnanDIM in the indications cancer/infectious diseases runs until 2035 in both the EU and US compared with 2030 in the EU and 2028 in the US for lefitolimod (MGN1703) in the indication metastatic colorectal cancer.

**Search for partner for lefitolimod (MGN1703) continues** Mologen has appointed a specialist biotechnology consultancy firm to assist in the search for a partner for lefitolimod (MGN1703). According to management, talks with interested parties have intensified in recent months. We assume the conclusion in 2018 of a partnership with a pharmaceutical company for further development of lefitolimod (MGN1703) and an associated milestone payment of USD40m (€36.4m).

**Figure 2: Changes to our forecasts**

| | 2016E | | | 2017E | | | 2018E | | |
|---|---|---|---|---|---|---|---|---|---|
| in €m | Old | New | Delta | Old | New | Delta | Old | New | Delta |
| Sales* | 0.00 | 0.03 | - | 0.00 | 0.00 | - | 36.36 | 36.36 | 0.0% |
| EBIT | -26.32 | -21.77 | - | -24.33 | -24.33 | - | 12.71 | 12.71 | 0.0% |
| *margin* | *neg.* | *neg.* | - | *neg.* | *neg.* | - | *35.0%* | *35.0%* | - |
| Net income | -26.35 | -21.79 | - | -24.48 | -24.48 | - | 12.56 | 12.56 | 0.0% |
| *margin* | *neg.* | *neg.* | - | *neg.* | *neg.* | - | *34.5%* | *34.5%* | - |
| EPS (in €) | -1.07 | -0.89 | - | -0.81 | -0.81 | - | 0.28 | 0.28 | 0.3% |

* including other operating income and upfront/milestone payment(s)

*Source: First Berlin Equity Research*

**We maintain our Buy recommendation and price target of €11.30** We have revised up our 2016 EBIT forecast (see figure 2) to reflect the likelihood that R&D spending this year will not be as high as we previously forecast. The numbers for 2017 and 2018 are unaltered. However, adjustments to our long term taxation assumptions cause us to leave our price target unchanged at €11.30. We maintain our Buy recommendation and price target of €11.30.

## Figure 3: Pipeline valuation

| 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| MGN1703 | CRC-EU | €258M | 165K | €38,182 | €6,300M | 10% | €825M | 18% | 15% | 10 | 4 Years |
| MGN1703 | CRC-US | €241M | 105K | €63,636 | €6,682M | 10% | €840M | 18% | 15% | 8 | 4 years |
| MGN1703 | SCLC-EU | €55M | 23K | €27,273 | €614M | 50% | €397M | 15% | 15% | 10 | 4 years |
| MGN1703 | SCLC-US | €51M | 14K | €45,455 | €650M | 50% | €404M | 15% | 15% | 8 | 4 years |
| MGN1601 | RCC-EU | €116M | 41K | €38,182 | €1,581M | 30% | €1,141M | 25% | 15% | 10 | 9 years |
| MGN1601 | RCC-US | €113M | 26K | €63,636 | €1,674M | 25% | €1,110M | 25% | 15% | 12 | 9 years |
| PACME PV | | €835M | | | €17,500M | | €3,715M | | | | |
| Costs PV[4)] | | €444M | | | | | | | | | |
| NPV | | €391M | | | | | | | | | |
| Milestones PV | | €101M | | | | | | | | | |
| Profrma net cash | | €39M | | | | | | | | | |
| Fair Value | | €530M | | | | | | | | | |
| Proforma share count | | 46,928K | | | | | | | | | |
| Price Target | | €11.30 | | | | | | | | | |

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), 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 and CapEx; COGS and S&M are factored into the PACME margin for each project

*Source: First Berlin Equity Research*

# INCOME STATEMENT

| All figures in EUR '000 | 2013 | 2014 | 2015 | 2016E | 2017E | 2018E |
|---|---|---|---|---|---|---|
| **Net product revenues** | **227** | **12** | **39** | **25** | **0** | **0** |
| **Milestone & upfront payments** | **0** | **0** | **0** | **0** | **0** | **36,364** |
| **Total revenue** | **227** | **12** | **39** | **25** | **0** | **36,364** |
| **Cost of materials** | **2,904** | **8,687** | **11,011** | **12,111** | **12,000** | **12,000** |
| **Gross profit** | **-2,677** | **-8,675** | **-10,972** | **-12,086** | **-12,000** | **-12,000** |
| **PACME** (incl. milestone & upfront payments) | **-2,677** | **-8,675** | **-10,972** | **-12,086** | **-12,000** | **24,364** |
| Depreciation | 1,014 | 110 | 121 | 383 | 150 | 180 |
| Personnel costs | 4,364 | 5,113 | 5,074 | 5,667 | 5,200 | 5,500 |
| Other operating income (expense) | -2,803 | -3,199 | -4,372 | -3,631 | -6,975 | -5,970 |
| **Operating income (EBIT)** | **-10,858** | **-17,097** | **-20,539** | **-21,767** | **-24,325** | **12,714** |
| Net financial result | 30 | 19 | 3 | -25 | -153 | -153 |
| **Pre-tax income (EBT)** | **-10,828** | **-17,078** | **-20,536** | **-21,792** | **-24,478** | **12,560** |
| **Net income / loss** | **-10,828** | **-17,078** | **-20,536** | **-21,792** | **-24,478** | **12,560** |
| **Diluted EPS** (in EUR) | **-0.70** | **-1.02** | **-0.99** | **-0.89** | **-0.81** | **0.28** |
| **EBITDA** | **-9,844** | **-16,987** | **-20,418** | **-21,384** | **-24,175** | **12,894** |
| **Ratios** | | | | | | |
| EBIT margin on PACME | n.m. | n.m. | n.m. | n.m. | n.m. | n.m. |
| EBITDA margin on PACME | n.m. | n.m. | n.m. | n.m. | n.m. | n.m. |
| Net margin on PACME | n.m. | n.m. | n.m. | n.m. | n.m. | n.m. |
| **Expenses as % of PACME** | | | | | | |
| Personnel costs | n.m. | n.m. | n.m. | n.m. | n.m. | 22.6% |
| **Y-Y Growth** | | | | | | |
| Total revenues | 278.3% | -94.7% | 225.0% | -35.9% | n.m. | n.m. |
| 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 EUR '000 | 2013 | 2014 | 2015 | 2016E | 2017E | 2018E |
|---|---|---|---|---|---|---|
| **Assets** | | | | | | |
| **Current assets, total** | **15,480** | **14,613** | **25,981** | **18,442** | **13,473** | **26,449** |
| Cash and cash equivalents | 8,765 | 13,563 | 24,592 | 17,042 | 12,063 | 24,794 |
| Short-term Investments | 6,000 | 0 | 0 | 0 | 0 | 0 |
| Receivables | 0 | 0 | 0 | 0 | 0 | 0 |
| Inventories | 33 | 30 | 28 | 30 | 40 | 200 |
| Other current assets | 682 | 1,020 | 1,361 | 1,370 | 1,370 | 1,455 |
| **Non-current assets, total** | **457** | **440** | **414** | **425** | **415** | **1,300** |
| Property, plant & equipment | 220 | 234 | 239 | 280 | 300 | 900 |
| Goodwill & other intangibles | 237 | 206 | 175 | 145 | 115 | 400 |
| Other assets | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total assets** | **15,937** | **15,053** | **26,395** | **18,867** | **13,888** | **27,749** |
| **Shareholders' equity & debt** | | | | | | |
| **Current liabilities, total** | **943** | **1,747** | **6,886** | **5,010** | **5,610** | **6,910** |
| Short-term debt | 19 | 10 | 8 | 10 | 10 | 10 |
| Accounts payable | 554 | 1,315 | 6,390 | 4,500 | 5,000 | 6,000 |
| Other current liabilities | 370 | 422 | 488 | 500 | 600 | 900 |
| **Long-term liabilities, total** | **10** | **8** | **6** | **2,555** | **2,560** | **2,590** |
| Convertible bond | 0 | 0 | 0 | 2,540 | 2,540 | 2,540 |
| Long term debt | 0 | 0 | 0 | 0 | 0 | 0 |
| Deferred revenue | 10 | 8 | 6 | 15 | 20 | 50 |
| **Shareholders' equity** | **14,984** | **13,298** | **19,503** | **11,302** | **5,718** | **18,249** |
| **Total consolidated equity and debt** | **15,937** | **15,053** | **26,395** | **18,867** | **13,888** | **27,749** |
| **Ratios** | | | | | | |
| Current ratio (x) | 16.42 | 8.36 | 3.77 | 3.68 | 2.40 | 3.83 |
| Quick ratio (x) | 16.38 | 8.35 | 3.77 | 3.67 | 2.39 | 3.80 |
| Net gearing | -58.4% | -101.9% | -126.1% | -128.2% | -166.4% | -121.9% |
| Book value per share (€) | 0.97 | 0.78 | 0.86 | 0.37 | 0.19 | 0.41 |
| Net cash | 8,746 | 13,553 | 24,584 | 14,492 | 9,513 | 22,244 |
| Return on equity (ROE) | -54.3% | -120.8% | -125.2% | -141.5% | -287.6% | 104.8% |

# CASH FLOW STATEMENT

| All figures in EUR '000 | 2013 | 2014 | 2015 | 2016E | 2017E | 2018E |
|---|---|---|---|---|---|---|
| **EBIT** | **-10,858** | **-17,097** | **-20,539** | **-21,767** | **-24,325** | **12,714** |
| Depreciation and amortization | 1,014 | 110 | 121 | 383 | 150 | 180 |
| **EBITDA** | **-9,844** | **-16,987** | **-20,418** | **-21,384** | **-24,175** | **12,894** |
| Changes in working capital | -146 | -93 | 4,786 | -1,889 | 590 | 1,055 |
| Other adjustments | 1,121 | 1,475 | 546 | -268 | -153 | -153 |
| **Operating cash flow** | **-8,869** | **-15,605** | **-15,086** | **-23,541** | **-23,738** | **13,796** |
| CAPEX | -145 | -93 | -95 | -151 | -140 | -1,065 |
| **Free cash flow** | **-9,014** | **-15,698** | **-15,181** | **-23,692** | **-23,878** | **12,731** |
| **Debt financing, net** | **0** | **0** | **0** | **0** | **0** | **0** |
| **Equity financing, net** | **8** | **14,495** | **26,207** | **13,600** | **18,900** | **0** |
| **Convertible bond** | | | | **2,540** | | |
| Changes in other financial assets | **-6,000** | **6,000** | **0** | **0** | **0** | **0** |
| Other Changes in Cash | **-6** | **1** | **3** | **2** | **0** | **0** |
| **Net cash flows** | **-15,012** | **4,798** | **11,029** | **-7,550** | **-4,978** | **12,731** |
| Cash, start of the year | 23,777 | 8,765 | 13,563 | 24,592 | 17,042 | 12,063 |
| **Cash, end of the year** | **8,765** | **13,563** | **24,592** | **17,042** | **12,063** | **24,794** |
| **EBITDA/share** | **-0.64** | **-1.01** | **-0.98** | **-0.87** | **-0.80** | **0.29** |
| | | | | | | |
| **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 | 9 January 2013 | €12.14 | Buy | €26.70 |
| 2...15 | ↓ | ↓ | ↓ | ↓ |
| 16 | 22 July 2016 | €1.36 | Buy | €11.60 |
| 17 | 16 August 2016 | €1.96 | Buy | €11.60 |
| 18 | 1 November 2016 | €1.42 | Buy | €11.30 |
| 19 | Today | €1.50 | Buy | €11.30 |

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First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular the German Securities Trading Act [WpHG], Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and the German Ordinance on the Analysis of Financial Instruments [FinAnV] into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

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

ADD: An expected favourable price trend of between 0% and 25%.

REDUCE: An expected negative price trend of between 0% and -15%.

SELL: An expected negative price trend of more than -15%.

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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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