MOLOGEN AG

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

"Next Level" programme

RATING	**BUY**
PRICE TARGET	**€11.60**
Return Potential	752.9%
Risk Rating	High

ACCELERATING COMMERCIALISATION, FLEXIBILISING COSTS

In early June Mologen announced a corporate realignment - "Next Level" - which aims to refocus the company on those products which are close to the market while halting/suspending development of most earlier stage products. Mologen is also shuttering production for clinical supply and parts of its research activities and outsourcing the discontinued functions to subcontractors. Only those employees responsible for basic research are leaving the company. Mologen will retain the more senior employees within research and production who will use their know-how to initiate, control and monitor the outsourcing of these activities. Furthermore, the company has appointed a specialist biotechnology consultancy firm to assist in the search for partners for its most advanced product, the Toll-like receptor 9 (TLR9) agonist and immune surveillance reactivator, lefitolimod (MGN1703). The focus on lefitolimod (MGN1703) means that Mologen will further develop the next generation of this product – EnanDIM – which is currently still a pre-clinical molecule family. The overarching goal is clearly to accelerate the commercialisation of lefitolimod (MGN1703) while flexibilising costs before this is achieved. Following discussions with management, we now expect Mologen to conclude a partnership for lefitolimod (MGN1703) in 2018 (previously: 2017). We maintain our Buy recommendation but reduce the price target to €11.60 (previously: €16.50). The two main reasons for our price target reduction are higher dilution than we previously assumed from the share issue which we expect towards the end of this year, as well as the launch of MGN1601 two years later than projected in our study of 6 April.

Completion of IMPALA phase III recruitment in mCRC in H2/16 Lefitolimod (MGN1703) is currently the subject of four clinical trials (see figure 1 overleaf). 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 by the end of 2016. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	0.23	0.01	0.04	0.00	0.00	36.36
Y-o-y growth	278.3%	-94.7%	225.0%	n.a.	100.0%	200.0%
EBIT (€m)	-10.86	-17.10	-20.54	-26.32	-23.93	12.71
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	100.0%
Net income (€m)	-10.83	-17.08	-20.54	-26.32	-23.93	12.71
EPS (diluted) (€)	-0.70	-1.02	-0.99	-1.16	-0.49	0.26
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-9.01	-15.70	-15.18	-28.22	-23.32	12.88
Net gearing	-58.4%	-101.9%	-126.1%	-111.3%	-189.4%	-123.6%
Liquid assets (€m)	8.77	13.56	24.59	31.37	8.05	20.93

RISKS

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

COMPANY PROFILE

MOLOGEN is a 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 and MGN1601 for the treatment of renal cell carcinoma.

MARKET DATA

As of 21 Jul 2016

Closing Price	€ 1.36
Shares outstanding	22.63m
Market Capitalisation	€ 30.78m
52-week Range	€ 1.30 / 5.08
Avg. Volume (12 Months)	20,239

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	n.a.
EV/Sales	273.8	n.a.	n.a.
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 31 Mar 2016

Liquid Assets	€ 20.12m
Current Assets	€ 21.08m
Intangible Assets	€ 0.22m
Total Assets	€ 21.53m
Current Liabilities	€ 6.48m
Shareholders' Equity	€ 15.04m

SHAREHOLDERS

Global Derivative Trading GmbH	24.0%
Baloise Holding AG	6.0%
Deutscher Ring Krankenvers. a.G.	6.0%
Salvator Vermögensverw.. GmbH	5.0%
Deutsche Balaton AG	5.0%
Other and free float	59.0%

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The primary endpoint is overall survival using lefitolimod (MGN1703) as a "switch-maintenance" therapy for patients with metastatic CRC. Secondary endpoints include progression-free survival, toxicity, safety and quality of life. The study will comprise 540 patients in eight European countries including the five largest European markets. Mologen intends to evaluate the data within 12 to 24 months of completion of recruitment.

IMPULSE topline phase II results in small cell lung cancer expected in early 2017 Meanwhile Mologen completed enrolment of 100 patients to the IMPULSE phase II trial with lefitolimod (MGN1703) in small cell lung cancer 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 at the beginning of 2017.

Figure 1: Lefitolimod (MGN 1703) - clinical trials schedule

	IMPALA (mCRC)- Pivotal study	**IMPULSE (SCLC)-** Randomised study	**TEACH (HIV)-** Phase 1	**Combination trial-** Phase 1
2014	First patient in (FPI)	First patient in (FPI)		
2015		Recruitment completed	Start/end of first phase	
2016	Recruitment completed	Start of primary analysis	Initial results of first phase; start extension	First patient in (FPI)
2017		Results	Results	
2018	Start primary endpoint analysis (OS)			End of recruitment
2019	Results*			Start of primary analysis

mCRC metastatic colorectal cancer | SCLC small cell lung cancer | * timing of read out depends on dynamics of overall survival

Source: Mologen

TEACH phase I results in HIV due in H1/17 In June 2015 the Aarhus University Hospital in Denmark started an early stage trial to test whether immunotherapy with lefitolimod (MGN 1703) can activate the innate and adaptive immune systems in HIV patients so as to enhance killing of HIV-infected cells. In March 2016 Mologen announced the extension of the so-called TEACH trial of lefitolimod (MGN1703) with HIV patients following promising initial results. During the initial phase of the trial lefitolimod (MGN1703) led to the activation of plasmacytoid dendritic cells, natural killer cells and T cells in HIV positive patients during antiretroviral therapy. There are thus grounds to believe 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. Final results of the study are expected in the first half of 2017. The TEACH study 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. The initial aim of the combination study is to find the highest tolerable dose of lefitolimod (MGN1703) that can be given in combination with Yervoy to patients with advanced tumors. Safety will also be investigated. The trial in addition aims to evaluate the efficacy of the two therapies in combination in an expansion phase. The trial with Yervoy will be the first time that lefitolimod (MGN1703) has been evaluated in combination with a checkpoint inhibitor. The trial may be the first of several of lefitolimod (MGN1703) in combination with other anti-cancer drugs.

THE "NEXT LEVEL" PROGRAMME

"Next Level" entails halting/suspension of most early-stage product development
The "Next Level" strategy announced in June entails a sharpening of Mologen's focus on its most advanced product, lefitolimod (MGN1703). The company's organisational structures are being adjusted to prepare a potential market entry of lefitolimod. To this end, management has decided to sell or spin off the non-viral vector system MIDGE and products developed on this platform. The affected compounds include the prophylactic and therapeutic vaccines against leishmaniasis (MGN1331) and against hepatitis B (MGN1333), both of which are at the preclinical phase. MGN1404, which was the subject of a phase I trial in the indication malignant melanoma, is also affected. We have not included proceeds from a potential sale or spin off in our valuation.

Figure 2: Target portfolio - focus on lefitolimod (MGN 1703) and next generation compounds EnanDIM

Platform	Compound	Indications	PC PH1 PH2 PH3	Study	Cooperation partners
DNA-based TLR) agonists (ISR)	**Lefitolimod (MGN1703)**	• Metastatic colorectal cancer (mCRC) • Small cell lung cancer (SCLC) • HIV • Advanced solid malignancies		IMPALA IMPULSE TEACH Lefitolimod & Yervoy	- - Aarhus University Hospital MD Anderson Cancer Center
	EnanDIM	• Cancer anti-infective therapies			
Therapeutic Vaccine (cell-line)	MGN 1601	• Renal Cancer		On hold: backup compound	

ISR Immune Surveillance Reactivator | **PC** pre-clinical

Source: Mologen

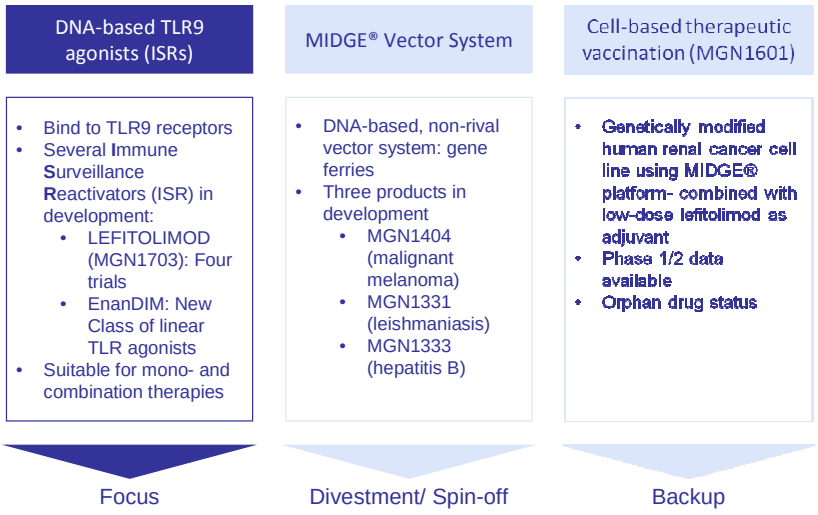
In addition, Mologen has also decided to suspend development of MGN1601, a cell-based therapeutic vaccine against renal cancer. The MGN1601 cell line is genetically modified using MIDGE technology and combined with low-dose lefitolimod as an adjuvant. Mologen completed ASET, a phase I/II trial with MGN1601, in September 2013. Monotherapy with MGN1601 proved to be safe and was well tolerated, while treatment of a subgroup of patients with the compound produced favourable overall survival data.

The results of ASET were good enough to prompt management to plan a phase II study of MGN1601 in combination with another drug. Management has stated that if lefitolimod (MGN1703) or the entire lefitolimod product group is successfully out-licensed, MGN1601 would be a good basis for continuation of the business model. Figure 2 shows the planned restructuring of the existing portfolio and the target portfolio, while figure 3 illustrates the clinical status of the different compounds within the target portfolio.

Most early stage research will be halted/suspended… In keeping with the discontinuation/suspension of most of its early stage product development, Mologen will reduce the headcount of its research department. The positions affected will be in basic research. Translational research will not be affected. Mologen is retaining the "brains" within its research department. These remaining employees will define structure and coordinate research work on lefitolimod (MGN1703) and EnanDIM, large parts of which will be outsourced to contract research organisations.

…clinical supply production to be outsourced Mologen plans to outsource production for clinical supply. The outsourcing of production will also allow an upscaling of production in preparation for market entry. The headcount of the production team will also be reduced, but here too those employees with critical know-how will remain within the company. The remaining staff will be responsible for the development of a production strategy for market supply which will entail upscaling of production through a contract manufacturing organisation as well as documentation of the supply chain. This information will be part of the package submitted to the authorities at the time of filing for approval of lefitolimod (MGN 1703).

Figure 3: Target portfolio – clinical status of TLR 9 product family and MGN 1601



Source: Mologen

Headcount reduction will amount to around 25% of end March total Management and employees at Mologen numbered 63 persons at the end of March 2016. We expect the measures described above to reduce the headcount to around 46 persons and create a more flexible cost structure at Mologen. We estimate the one-time cost of personnel restructuring measures at €0.5m. It is likely that provisions for these costs will be taken in the Q2 report which is due on 11 August.

We project a reduction in the fixed cost base of €1m annually. Management has indicated that the corporate realignment will not have any major impact on the 2016 guidance which is for an increase in cash consumption compared with 2015 as recruitment for the IMPALA phase III trial with lefitolimod (MGN1703) reaches its final stages. Cash consumption during 2015 amounted to €15.2m.

We now expect a €35m (previously €25m) equity issue by the end of this year We have made only minor changes to our P&L forecast for 2016 as we expect cost savings stemming from the reduction in head count to be largely absorbed by redundancy payments. However, to ensure that the company's cash reach extends until the time of the partnership/milestone payment we now expect for 2018, we pencil in a €35m equity raise for the end of this year (previously €25m). For 2017 we assume a €1m reduction in personnel costs but a €1.5m rise in other operating expenses associated with the outsourced costs of clinical production and more importantly preparations for the eventual upscaling of production.

We now expect a partnership in 2018 (previously: 2017) Following discussions with management, we now expect the conclusion of a partnership with a pharmaceutical company for further development of lefitolimod (MGN1703) and an associated milestone payment of USD40m (€36.4m) in 2018 (previously: 2017) Our forecast timing of the market introduction of lefitolimod (MGN1703) in the indications mCRC and small cell lung cancer in 2020 remains unchanged.

We assume that Mologen will resume development of MGN1601 following the conclusion of the lefitolimod (MGN1703) partnership. This pushes back our forecast of the timing of the launch of MGN1601 in the indication renal cancer from 2023 to 2025.

We maintain our Buy recommendation with a price target of €11.60 (previously: €16.50) As mentioned above, our 2016 P&L forecast is largely unchanged but our 2017 EBIT forecast is now nearly €37m lower because we have pushed the timing of the receipt of the milestone payment into 2018 from 2017. Following discussions with Mologen's management we have lengthened the forecast period of exclusivity enjoyed by lefitolimod (MGN1703) in the indication mCRC from 2026 to 2030 in the EU and from 2026 to 2028 in the US. In the indication small cell lung cancer we have lengthened the forecast period of exclusivity in the EU from 2027 to 2030 and in the US from 2027 to 2028. For MGN 1601 we expect exclusivity to last for ten years after launch in the EU i.e. to 2035 and for twelve years after launch in the US i.e. until 2037.

The extensions to the exclusivity periods described above raise our pipeline NPV estimate by 18.6%. However, the issue of €35m of new equity instead of the €25m we had previously assumed and the issue of these new shares at €1.36 rather than at €3.50 as we modelled in our last study of 6 April, weigh on our valuation. We maintain our Buy recommendation but lower the price target to €11.60 (previously: €16.50).

Figure 4: Changes to our forecasts

	2016E			2017E			2018E
in €m	Old	New	Delta	Old	New	Delta	
Sales*	0.00	0.00	-	36.36	0.00	-100.0%	36.36
EBIT	-26.12	-26.32	-	12.94	-23.93	-	12.71
margin	*neg.*	*neg.*	-	*35.6%*	*neg.*	-	*35.0%*
Net income	-25.86	-26.32	-	13.51	-23.93	-	12.71
margin	*neg.*	*neg.*	-	*37.2%*	*neg.*	-	*neg.*
EPS (in €)	-1.14	-1.16	-	0.45	-0.49	-	0.26

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

Source: First Berlin Equity Research

Figure 5: 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)]		€446M									
NPV		€389M									
Milestones PV		€101M									
Profrma net cash		€53M									
Fair Value		€543M									
Proforma share count		46,824K									
Price Target		€11.59									

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

Figure 6: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	**€707.6M**	**€835.1M**	**18.0%**
Costs PV (4)	€379.9M	€446.1M	17.4%
NPV	**€327.9M**	**€389.0M**	**18.6%**
Milestones PV	€103.8M	€100.7M	-3.0%
Net Cash	€47.2M	€53.0M	12.3%
Fair Value	€478.9M	€542.7M	13.3%
Share Count	29,077K	46,824K	61.0%
Price Target	**€16.47**	**€11.59**	**-29.6%**

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Net product revenues	**227**	**12**	**39**	**0**	**0**	**0**
Milestone & upfront payments	**0**	**0**	**0**	**0**	**0**	**36,364**
Total revenue	**227**	**12**	**39**	**0**	**0**	**36,364**
Cost of materials	**2,904**	**8,687**	**11,011**	**15,000**	**12,000**	**12,000**
Gross profit	**-2,677**	**-8,675**	**-10,972**	**-15,000**	**-12,000**	**-12,000**
PACME (incl. milestone & upfront payments)	**-2,677**	**-8,675**	**-10,972**	**-15,000**	**-12,000**	**24,364**
Depreciation	1,014	110	121	140	150	180
Personnel costs	4,364	5,113	5,074	5,900	4,800	5,500
Other operating income (expense)	-2,803	-3,199	-4,372	-5,280	-6,975	-5,970
Operating income (EBIT)	**-10,858**	**-17,097**	**-20,539**	**-26,320**	**-23,925**	**12,714**
Net financial result	30	19	3	0	0	0
Pre-tax income (EBT)	**-10,828**	**-17,078**	**-20,536**	**-26,320**	**-23,925**	**12,714**
Net income / loss	**-10,828**	**-17,078**	**-20,536**	**-26,320**	**-23,925**	**12,714**
Diluted EPS (in EUR)	**-0.70**	**-1.02**	**-0.99**	**-1.16**	**-0.49**	**0.26**
EBITDA	**-9,844**	**-16,987**	**-20,418**	**-26,180**	**-23,775**	**12,894**
Ratios						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	199.4%	52.2%
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	198.1%	52.9%
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	199.4%	52.2%
Expenses as % of PACME						
Personnel costs	n.m.	n.m.	n.m.	n.m.	-40.0%	22.6%
Y-Y Growth						
Total revenues	278.3%	-94.7%	225.0%	n.m.	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**	**32,774**	**9,459**	**22,588**
Cash and cash equivalents	8,765	13,563	24,592	31,374	8,049	20,933
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**	**33,199**	**9,874**	**23,888**
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**	**15**	**20**	**50**
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**	**28,174**	**4,244**	**16,928**
Total consolidated equity and debt	**15,937**	**15,053**	**26,395**	**33,199**	**9,874**	**23,888**
Ratios						
Current ratio (x)	16.42	8.36	3.77	6.54	1.69	3.27
Quick ratio (x)	16.38	8.35	3.77	6.54	1.68	3.24
Net gearing	-58.4%	-101.9%	-126.1%	-111.3%	-189.4%	-123.6%
Book value per share (€)	0.97	0.78	0.86	0.58	0.09	0.35
Net cash	8,746	13,553	24,584	31,364	8,039	20,923
Return on equity (ROE)	-54.3%	-120.8%	-125.2%	-110.4%	-147.6%	120.1%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
EBIT	**-10,858**	**-17,097**	**-20,539**	**-26,320**	**-23,925**	**12,714**
Depreciation and amortization	1,014	110	121	140	150	180
EBITDA	**-9,844**	**-16,987**	**-20,418**	**-26,180**	**-23,775**	**12,894**
Changes in working capital	-146	-93	4,786	-1,889	590	1,055
Other adjustments	1,121	1,475	546	0	0	0
Operating cash flow	**-8,869**	**-15,605**	**-15,086**	**-28,069**	**-23,185**	**13,949**
CAPEX	-145	-93	-95	-151	-140	-1,065
Free cash flow	**-9,014**	**-15,698**	**-15,181**	**-28,220**	**-23,325**	**12,884**
Debt financing, net	**0**	**0**	**0**	**0**	**0**	**0**
Equity financing, net	**8**	**14,495**	**26,207**	**35,000**	**0**	**0**
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**	**6,782**	**-23,325**	**12,884**
Cash, start of the year	23,777	8,765	13,563	24,592	31,374	8,049
Cash, end of the year	**8,765**	**13,563**	**24,592**	**31,374**	**8,049**	**20,933**
EBITDA/share	**-0.64**	**-1.01**	**-0.98**	**-1.16**	**-0.49**	**0.26**
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	21 May 2015	€4.75	Buy	€21.50
17	21 August 2015	€4.59	Buy	€21.50
18	6 April 2016	€3.78	Buy	€16.50
19	Today	€1.36	Buy	€11.60

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