MOLOGEN AG

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

Update

RATING	**BUY**
PRICE TARGET	**€ 11.30**
Return Potential	268.6%
Risk Rating	High

NEWSFLOW KEEPS PARTNERSHIP HOPES RAISED

Mologen's lead drug candidate, the immunomodulator, lefitolimod, is currently the object of four clinical trials - in metastatic colorectal cancer (mCRC), small-cell lung cancer (SCLC), HIV, and a phase I combination trial with the immune checkpoint inhibitor, Yervoy. The market for mCRC alone is worth over USD10bn. We expect Mologen to file applications for approval with the EMA and FDA in this indication in 2019/20. Talks with interested parties, including several from Asia, have intensified in recent months. Recent and imminent newsflow may make lefitolimod more attractive to potential partners. Topline results from the IMPULSE phase II trial of lefitolimod with SCLC patients released on 24 April showed overall survival benefit in comparison to the control arm in two important subgroups – patients with a low count of activated B cells and patients with reported Chronic Obstructive Pulmonary Disease. Meanwhile, data released so far from the TEACH study suggest that lefitolimod can be used in HIV as well as cancer therapy. Headline results from this study are due in mid-2017. In addition, preclinical studies in murine tumour models published in late January indicate that lefitolimod is effective in combination with anti-PD1/anti-PD-L1 antibody-based checkpoint inhibitors. Yervoy, which is currently the subject of the Mologen/MD Anderson Center trial at the University of Texas, uses CTLA4 antibodies and is a representative of the other major checkpoint inhibitor type. We maintain our Buy recommendation and price target of €11.30.

Completion of IMPALA recruitment imminent Mologen continues to recruit patients for its phase III IMPALA pivotal study with lefitolimod in mCRC. The primary endpoint is overall survival using lefitolimod as a "switch-maintenance" therapy for patients with mCRC. 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. Patient recruitment for IMPALA began in September 2014. Completion of recruitment is expected over the next few weeks. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016	2017E	2018E
Revenue (€ m)	0.23	0.01	0.04	0.07	0.00	36.36
Y-o-y growth	278.3%	-94.7%	225.0%	89.7%	-100.0%	n.a.
EBIT (€ m)	-10.86	-17.10	-20.54	-20.98	-24.29	12.80
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	35.2%
Net income (€ m)	-10.83	-17.08	-20.54	-21.00	-24.72	12.38
EPS (diluted) (€)	-0.70	-1.02	-0.99	-0.85	-0.82	0.28
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-9.01	-15.70	-15.18	-19.30	-24.51	12.88
Net gearing	-58.4%	-101.9%	-126.1%	-155.4%	-213.1%	-139.9%
Liquid assets (€ m)	8.77	13.56	24.59	20.52	19.91	32.80

RISKS

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

COMPANY PROFILE

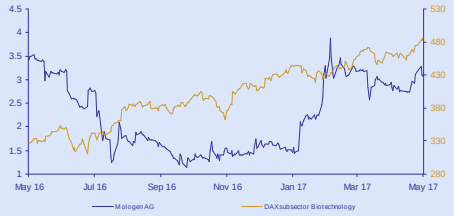
MOLOGEN is a biopharmaceutical company based in Berlin specialising in the clinical development of innovative DNA-based and cell-based drugs in the fields of oncology and infectious diseases. The company's furthest developed product is lefitolimod for the treatment of metastatic colorectal carcinoma, small cell lung cancer and HIV. In addition a combination study of lefitolimod with Yervoy is being performed.

MARKET DATA

As of 04 May 2017	
Closing Price	€ 3.07
Shares outstanding	33.95m
Market Capitalisation	€ 104.08m
52-week Range	€ 1.15 / 3.89
Avg. Volume (12 Months)	120,561

Multiples	2016	2017E	2018E
P/E	n.a.	n.a.	10.9
EV/Sales	1157.9	n.a.	2.4
EV/EBIT	n.a.	n.a.	6.7
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2016	
Liquid Assets	€ 20.52m
Current Assets	€ 21.30m
Intangible Assets	€ 0.00m
Total Assets	€ 21.36m
Current Liabilities	€ 7.40m
Shareholders' Equity	€ 11.84m

SHAREHOLDERS

Global Derivative Trading GmbH	29.0%
Deutsche Balaton AG	5.0%
Deutscher Ring Krankenvers. a.G.	4.0%
Baloise Group	4.0%
Free float	58.0%

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Mologen originally expected to admit the last patient to the trial at the end of 2016, but recruitment was slowed by weaker enrolment during the summer. 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 endpoint is overall survival. Filing for approval with the EMA and the FDA is likely in 2019/20.

IMPULSE topline phase II results The IMPULSE phase II trial with lefitolimod includes 102 patients with Extensive Disease SCLC showing at least partial response to four cycles of first-line chemotherapy. The primary endpoint is overall survival (OS), in the total patient population. Topline results released on 24 April showed that the study did not meet its primary endpoint, OS. This is not surprising, as SCLC is a very challenging indication. However, the study did demonstrate overall survival benefit in comparison to the control arm in two important subgroups – patients with a low count of activated B cells (hazard ratio 0.59, 95% confidence interval 0.29-1.21) and patients with reported Chronic Obstructive Pulmonary Disease (hazard ratio 0.54, 95% confidence interval 0.21-1.38). Around 50% and 25% of the patients in the study respectively belong to these groups.

TEACH phase I results in HIV due in mid-2017 An early stage trial with HIV patients carried out at the Aarhus University Hospital in Denmark in 2015 suggests that lefitolimod 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, 13 patients will be treated with lefitolimod for six months. The so-called TEACH trial is the first time that lefitolimod has been evaluated in patients with diseases other than cancer and is being conducted within the framework of a collaborative agreement with Mologen.Topline results of the study are expected in mid-2017.

Lefitolimod potential against HIV reservoir in the intestine In February Aarhus University Hospital presented new data on the TEACH study at the Conference on Retroviruses and Opportunistic Infections in Seattle, USA. The data showed for the first time that lefitolimod can induce a local antiviral immune response in sigmoid colon biopsies of HIV-infected patients undergoing antiretroviral treatment. In addition, lefitolimod did not induce unwanted inflammation. One of the problems with conventional antiretroviral therapy of HIV is that latent HIV reservoirs are not eliminated. These latent HIV reservoirs can be found throughout the body, including in the brain, lymph nodes, blood and the digestive tract. The data presented by the Aarhus University Hospital indicate lefitolimod's potential to be used in HIV eradication processes.

Completion of recruitment for combination trial with Yervoy likely in 2018 In January 2016, Mologen concluded a cooperation agreement with the MD Anderson Cancer Center at the University of Texas to conduct a phase I trial of lefitolimod 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 likely in 2018 with publication of results around a year later. The trial with Yervoy will be the first time that lefitolimod has been evaluated in combination with a checkpoint inhibitor and may be the first of several studies of lefitolimod in combination with other anti-cancer drugs.

USD2.75m grant from Gilead to fund lefitolimod combination trial in HIV In early January 2017 lefitolimod received further validation as a combination therapy when the Aarhus University Hospital received a USD2.75m grant from Gilead Sciences to fund a combination trial of the drug in HIV. The planned trial will evaluate lefitolimod in combination with novel virus-neutralising antibodies developed by Rockefeller University, New York, US. The grant made to Aarhus University Hospital is one of 12 made by Gilead Sciences in the context of its USD22m HIV cure grants programme.

Combination study of lefitolimod with anti-PD-1 and anti-PD-L1 antibody-based checkpoint inhibitors The checkpoint inhibitor, Yervoy, which is the subject of the ongoing Mologen/MD Anderson combination trial uses anti-CTLA4 antibodies to treat cancer. In late January 2017 Mologen released results of studies in murine tumour models investigating the combination of lefitolimod with checkpoint inhibitors based on anti-PD-1 and anti-PD-L1 antibodies. The two other most widely used checkpoint inhibitor drugs, Opdivo and Keytruda, are anti-PD-1 antibodies. Data from these studies showed that lefitolimod can substantially improve the antitumour effect of these antibodies, thus extending survival in mouse models.

Search for partner for lefitolimod (MGN1703) continues Mologen appointed a specialist biotechnology consultancy firm in mid-2016 to assist in the search for a partner for lefitolimod. According to management, talks with interested parties, including several from Asia, have intensified in recent months. We assume the conclusion in 2018 of a partnership with a pharmaceutical company for further development of lefitolimod and an associated milestone payment of USD40m (€36.4m).

Figure 1: 2016 results versus our forecasts

in €m	FY-16A	FY-16E	Delta	FY-15A	Delta
Sales**	0.07	0.03	133.3%	0.04	75.0%
EBIT	-20.99	-21.77	-	-20.54	-
margin	*neg.*	*neg.*	-	*neg.*	-
Net income	-21.00	-21.79	-	-20.54	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (in €)	-0.85	-0.89	-	-0.99	-

Source: First Berlin Equity Research; Mologen AG

We maintain our Buy recommendation and price target of €11.30 Mologen's 2016 results were close to our forecasts (see figure 1). The end 2016 cash position amounted to €20.5m (2015: €24.6m). The operating cash outflow was €19.3m (2015: €15.1m). Management has indicated that this figure will be higher in 2017 due to the continuation of the IMPALA study, the outsourcing and upscaling of production in preparation for market entry, as well as continued efforts towards outlicensing and partnering. Our model features proceeds of €23.9m from capital raising activities in 2017. We are leaving our forecasts largely unchanged on our study of 15 February and maintain our Buy recommendation and price target of €11.30.

Figure 2: 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	3 Years
MGN1703	CRC-US	€241M	105K	€63,636	€6,682M	10%	€840M	18%	15%	8	3 Years
MGN1703	SCLC-EU	€55M	23K	€27,273	€614M	50%	€397M	15%	15%	10	3 Years
MGN1703	SCLC-US	€51M	14K	€45,455	€650M	50%	€404M	15%	15%	8	3 Years
MGN1601	RCC-EU	€116M	41K	€38,182	€1,581M	30%	€1,141M	25%	15%	10	8 years
MGN1601	RCC-US	€113M	26K	€63,636	€1,674M	25%	€1,110M	25%	15%	12	8 years
PACME PV		€835M			€17,500M		€4,718M				
Costs PV[4)]		€433M									
NPV		€402M									
Milestones PV		€101M									
Profrma net cash		€40M									
Fair Value		€543M									
Proforma share count		47,977K									
Price Target		€11.31									

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; Mologen AG

INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016	2017E	2018E
Net product revenues	**227**	**12**	**39**	**74**	**0**	**0**
Milestone & upfront payments	**0**	**0**	**0**	**0**	**0**	**36,364**
Total revenue	**227**	**12**	**39**	**74**	**0**	**36,364**
Cost of materials	**2,904**	**8,687**	**11,681**	**11,780**	**14,500**	**14,000**
Gross profit	**-2,677**	**-8,675**	**-11,642**	**-11,706**	**-14,500**	**-14,000**
PACME (incl. milestone & upfront payments)	**-2,677**	**-8,675**	**-11,642**	**-11,706**	**-14,500**	**22,364**
Depreciation	1,014	110	121	408	117	90
Personnel costs	4,364	5,113	5,074	5,453	5,200	5,500
Other operating income (expense)	-2,803	-3,199	-3,702	-3,418	-4,475	-3,970
Operating income (EBIT)	**-10,858**	**-17,097**	**-20,539**	**-20,985**	**-24,292**	**12,804**
Net financial result	30	19	3	-18	-427	-428
Pre-tax income (EBT)	**-10,828**	**-17,078**	**-20,536**	**-21,003**	**-24,719**	**12,376**
Net income / loss	**-10,828**	**-17,078**	**-20,536**	**-21,003**	**-24,719**	**12,376**
Diluted EPS (in EUR)	**-0.70**	**-1.02**	**-0.99**	**-0.85**	**-0.82**	**0.28**
EBITDA	**-9,844**	**-16,987**	**-20,418**	**-20,577**	**-24,175**	**12,894**
Ratios						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	57.3%
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	57.7%
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	55.3%
Expenses as % of PACME						
Personnel costs	n.m.	n.m.	n.m.	n.m.	n.m.	24.6%
Y-Y Growth						
Total revenues	278.3%	-94.7%	225.0%	89.7%	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	2016	2017E	2018E
Assets						
Current assets, total	**15,480**	**14,613**	**25,981**	**21,300**	**20,698**	**34,353**
Cash and cash equivalents	8,765	13,563	24,592	20,520	19,915	32,799
Short-term Investments	6,000	0	0	0	0	0
Receivables	0	0	0	33	0	0
Inventories	33	30	28	13	40	100
Other current assets	682	1,020	1,361	734	743	1,455
Non-current assets, total	**457**	**440**	**414**	**62**	**50**	**70**
Property, plant & equipment	220	234	239	25	50	70
Goodwill & other intangibles	237	206	175	37	0	0
Other assets	0	0	0	0	0	0
Total assets	**15,937**	**15,053**	**26,395**	**21,362**	**20,748**	**34,423**
Shareholders' equity & debt						
Current liabilities, total	**943**	**1,747**	**6,886**	**7,404**	**7,610**	**8,910**
Short-term debt	19	10	8	3	10	10
Accounts payable	554	1,315	6,390	6,530	7,000	8,000
Other current liabilities	370	422	488	871	600	900
Long-term liabilities, total	**10**	**8**	**6**	**2,121**	**7,138**	**7,168**
Convertible bond	0	0	0	2,119	7,118	7,118
Long term debt	0	0	0	0	0	0
Deferred revenue	10	8	6	2	20	50
Shareholders' equity	**14,984**	**13,298**	**19,503**	**11,837**	**6,000**	**18,345**
Total consolidated equity and debt	**15,937**	**15,053**	**26,395**	**21,362**	**20,748**	**34,423**
Ratios						
Current ratio (x)	16.42	8.36	3.77	2.88	2.72	3.86
Quick ratio (x)	16.38	8.35	3.77	2.88	2.71	3.84
Net gearing	-58.4%	-101.9%	-126.1%	-155.4%	-213.1%	-139.9%
Book value per share (€)	0.97	0.78	0.86	0.39	0.20	0.42
Net cash	8,746	13,553	24,584	18,398	12,787	25,671
Return on equity (ROE)	-54.3%	-120.8%	-125.2%	-134.0%	-277.2%	101.7%

CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016	2017E	2018E
EBIT	**-10,858**	**-17,097**	**-20,539**	**-20,985**	**-24,292**	**12,804**
Depreciation and amortization	1,014	110	121	408	117	90
EBITDA	**-9,844**	**-16,987**	**-20,418**	**-20,577**	**-24,175**	**12,894**
Changes in working capital	-146	-93	4,786	1,127	196	528
Other adjustments	1,121	1,475	546	198	-427	-428
Operating cash flow	**-8,869**	**-15,605**	**-15,086**	**-19,252**	**-24,406**	**12,994**
CAPEX	-145	-93	-95	-44	-105	-110
Free cash flow	**-9,014**	**-15,698**	**-15,181**	**-19,296**	**-24,511**	**12,884**
Debt financing, net	**18**	**-9**	**-2**	**-5**	**7**	**0**
Equity financing, net	**8**	**14,495**	**26,207**	**12,706**	**18,900**	**0**
Convertible bond	**0**	**0**	**0**	**2,535**	**4,999**	**0**
Changes in other financial assets	**-6,000**	**6,000**	**0**	**-18**	**0**	**0**
Other Changes in Cash	**-24**	**10**	**5**	**6**	**0**	**0**
Net cash flows	**-15,012**	**4,798**	**11,029**	**-4,072**	**-605**	**12,884**
Cash, start of the year	23,777	8,765	13,563	24,592	20,520	19,915
Cash, end of the year	**8,765**	**13,563**	**24,592**	**20,520**	**19,915**	**32,799**
EBITDA/share	**-0.64**	**-1.01**	**-0.98**	**-0.84**	**-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	1 November 2016	€1.42	Buy	€11.30
17	15 November 2016	€1.50	Buy	€11.30
18	15 February 2017	€3.28	Buy	€11.30
19	Today	€3.07	Buy	€11.30

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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:

STRONG BUY: An expected favourable price trend of more than 50% combined with sizeable confidence in the quality and forecast security of management.

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**

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

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