MOLOGEN AG

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

Update

RATING	**BUY**
PRICE TARGET	**€11.30**
Return Potential	244.3%
Risk Rating	High

COMBINATION THERAPY POTENTIAL RAISES PARTNERING HOPES

Studies in murine tumour models have investigated the combination of lefitolimod with checkpoint inhibitors, in this case anti-PD-1 and anti-PD-L1 antibodies. The data shows that lefitolimod can substantially improve the antitumour effect of these antibodies thus extending survival in the mouse model. The two main shortcomings of checkpoint inhibitors are that they only work in a minority of patients and that they have considerable side effects. The combination of checkpoint inhibitors with other immunotherapies is widely regarded as the key to raising response rates. This view is supported by the positive results of the recent lefitolimod combination studies in mice showing the potential of lefitolimod for combination strategies. Moreover lefitolimod has good safety and tolerability characteristics as it is produced exclusively from natural DNA components without any chemical modification. In our view, recent newsflow increases the likelihood of a partnership with a large established pharmaceutical company. Lefitolimod is the subject of four ongoing clinical trials - in metastatic colorectal cancer (mCRC), small-cell lung cancer (SCLC), 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 applications for approval with the EMA and FDA in this indication in 2019/20. We maintain our Buy recommendation and price target of €11.30.

Positive results in combination with antibodies targeting PD-1/PD-L1 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 with Yervoy. This trial started in mid-July 2016 and will include around 50 to 60 patients. Completion of recruitment is scheduled for early 2018 with publication of results in 2019. Mologen has used mouse studies to prove the concept of combining lefitolimod with checkpoint inhibitors. Results recently presented at the Annual 2017 Gastrointestinal Cancer Symposium at San Francisco were based on these studies. (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	12.73
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	12.28
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	13.05
Net gearing	-58.4%	-101.9%	-126.1%	-128.2%	-166.4%	-125.6%
Liquid assets (€m)	8.77	13.56	24.59	17.04	17.06	30.11

RISKS

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

COMPANY PROFILE

MOLOGEN is a Berlin-based biotechnology company 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 colorectal carcinoma, small cell lung cancer and HIV. In addition a combination study of lefitolimod with Yervoy is being performed.

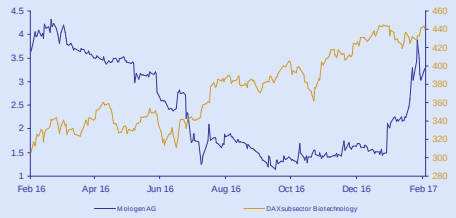
MARKET DATA

As of 14 Feb 2017

Closing Price	€ 3.28
Shares outstanding	33.95m
Market Capitalisation	€ 111.41m
52-week Range	€ 1.15 / 4.33
Avg. Volume (12 Months)	101,433

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	n.a.
EV/Sales	2418.1	3772.2	n.a.
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%
Deutscher Ring Krankenvers. a.G.	4.0%
Baloise Group	4.0%
Free float	58.0%

Analyst: Simon Scholes, Tel. +49 (0)30 - 80 93 96 94

Study with colorectal cancer and lymphoma murine tumour models Murine tumour models were used during the studies, a colon carcinoma model (using the CT26 cell line) and a lymphoma model (using the A20 cell line). In the CT26 model intraperitoneal injection of PD-L1 antibodies had no effect on tumour growth, but peritumoural injection of lefitolimod slowed tumour growth. Tumour growth was further inhibited by the combination, resulting in prolonged survival of the mice. The positive combinatory effect was even more pronounced in the lymphoma A20 model, where intraperitoneal PD-1 antibodies or intratumoural lefitolimod alone each showed an anti-tumour effect which was clearly increased with the combination of both. Overall, the data suggest promising potential for the combination of lefitolimod with checkpoint inhibitors and bode well for the outcome of the ongoing phase I trial with Yervoy.

Further validation of lefitolimod as combination therapy from Gilead grant Mologen's partner, the Aarhus University Hospital in Denmark, is currently conducting a phase I trial to determine whether immunotherapy with lefitolimod can activate the innate and adaptive immune systems in HIV patients so as to enhance killing of HIV-infected cells. In early January 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.

Additional ca. €5.0m in convertible bond funding Before Christmas Mologen announced the issue of a convertible bond to raise ca. €5.0m with a 6% coupon. The bond matures on 19 January 2025 and is convertible into up to 3.125m shares at a conversion price of €1.60. The convertible issue was made soon after the completion in October of a 1 for 2 rights issue which raised gross proceeds of €13.6m and the issue of a €2.5m convertible (6% coupon, convertible into up to 1.69m shares at a conversion price of €1.50). The proceeds will be used to fund further development of lefitolimod and its successor product, EnanDIM.

Dr Matthias Baumann MD to join Mologen as CMO Mologen has announced that Dr Matthias Baumann will join the company as Chief Medical Officer (CMO) on 1 May. Dr Baumann is currently CMO at Noxxon Pharma AG (Noxxon), a Berlin-based biotech company focused on cancer therapies. At Noxxon Dr Baumann manages the planning and implementation of preclinical and clinical development programs. Prior to joining Noxxon, Dr Baumann served as Chief Scientific Officer and Managing Director of the German-based company FOCUS Clinical Drug Development GmbH, a contract research organization (CRO) specialised in early clinical studies and exploratory development. In this role he was responsible for progressing drug candidates from the preclinical stage to clinical proof of concept. Before working for FOCUS, Dr Baumann held various research and development roles at Roche and Boehringer Mannheim as well as in academic research in the fields of oncology and immunology.

We maintain our Buy recommendation and our price target of €11.30 The Mologen share has more than doubled over the past month on newsflow which has focused investor attention on lefitolimod's potential as a combination therapy and raised hopes of a partnership with a large pharmaceutical company (which we model in 2018). Lefitolimod is the subject of four clinical trials - in metastatic colorectal cancer (mCRC), small-cell lung cancer (SCLC), 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 applications for approval with the EMA and FDA in this indication in 2019/20. We maintain our Buy recommendation and price target of €11.30.

Figure 1: 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)]		€436M									
NPV		€399M									
Milestones PV		€101M									
Profrma net cash		€39M									
Fair Value		€538M									
Proforma share count		47,679K									
Price Target		€11.29									

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	165
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**	**12,729**
Net financial result	30	19	3	-25	-153	-453
Pre-tax income (EBT)	**-10,828**	**-17,078**	**-20,536**	**-21,792**	**-24,478**	**12,275**
Net income / loss	**-10,828**	**-17,078**	**-20,536**	**-21,792**	**-24,478**	**12,275**
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**	**18,473**	**31,664**
Cash and cash equivalents	8,765	13,563	24,592	17,042	17,063	30,109
Short-term Investments	6,000	0	0	0	0	0
Receivables	0	0	0	0	0	0
Inventories	33	30	28	30	40	100
Other current assets	682	1,020	1,361	1,370	1,370	1,455
Non-current assets, total	**457**	**440**	**414**	**425**	**415**	**800**
Property, plant & equipment	220	234	239	280	300	400
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**	**18,888**	**32,464**
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**	**7,560**	**7,590**
Convertible bond	0	0	0	2,540	7,540	7,540
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**	**17,964**
Total consolidated equity and debt	**15,937**	**15,053**	**26,395**	**18,867**	**18,888**	**32,464**
Ratios						
Current ratio (x)	16.42	8.36	3.77	3.68	3.29	4.58
Quick ratio (x)	16.38	8.35	3.77	3.67	3.29	4.57
Net gearing	-58.4%	-101.9%	-126.1%	-128.2%	-166.4%	-125.6%
Book value per share (€)	0.97	0.78	0.86	0.37	0.19	0.40
Net cash	8,746	13,553	24,584	14,492	9,513	22,559
Return on equity (ROE)	-54.3%	-120.8%	-125.2%	-141.5%	-287.6%	103.7%

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**	**12,729**
Depreciation and amortization	1,014	110	121	383	150	165
EBITDA	**-9,844**	**-16,987**	**-20,418**	**-21,384**	**-24,175**	**12,894**
Changes in working capital	-146	-93	4,786	-1,889	590	1,155
Other adjustments	1,121	1,475	546	-268	-153	-453
Operating cash flow	**-8,869**	**-15,605**	**-15,086**	**-23,541**	**-23,738**	**13,596**
CAPEX	-145	-93	-95	-151	-140	-550
Free cash flow	**-9,014**	**-15,698**	**-15,181**	**-23,692**	**-23,878**	**13,046**
Debt financing, net	**0**	**0**	**0**	**0**	**0**	**0**
Equity financing, net	**8**	**14,495**	**26,207**	**13,600**	**18,900**	**0**
Convertible bond	**0**	**0**	**0**	**2,540**	**5,000**	**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**	**-7,550**	**22**	**13,046**
Cash, start of the year	23,777	8,765	13,563	24,592	17,042	17,063
Cash, end of the year	**8,765**	**13,563**	**24,592**	**17,042**	**17,063**	**30,109**
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	€3.28	Buy	€11.30

Authored by: Simon Scholes, Analyst

Company responsible for preparation:

First Berlin Equity Research GmbH
Mohrenstraße 34
10117 Berlin

Tel. +49 (0)30 - 80 93 96 94 Fax +49 (0)30 - 80 93 96 87

info@firstberlin.com
www.firstberlin.com

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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

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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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