MOLOGEN AG

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

Update

RATING	**BUY**
PRICE TARGET	**€ 13.30**
Return Potential	447.3%
Risk Rating	High

ESMO UNDERSCORES LEFITOLIMOD'S IMMUNOTHERAPEUTIC POTENTIAL

Mologen released important additional information from recent trials with lefitolimod at last week's ESMO conference in Madrid. Topline results of the IMPULSE phase II trial of lefitolimod with 102 small cell lung cancer (SCLC) patients published in April showed overall survival signals 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. The former group comprised 38 (43%) of a total of 88 patients for whom B cell data was available. The latter group numbered 25 of the 102 participants in the study. The B cell-related data is particularly interesting as it has positive implications for lefitolimod's efficacy against cancers other than SCLC. Cancer immunotherapy looks at tumours as "hot" or "cold" depending on how densely they are infiltrated by T cells. T cells are the main driver of the adaptive immune response. Mologen published data from studies of lefitolimod in combination with anti-PD1/anti-PD-L1 antibody-based checkpoint inhibitors in murine tumour models in January. Additional data from these studies presented at ESMO showed that monotherapy with lefitolimod in a CT26 colon carcinoma model resulted in increased infiltration of the tumour by T Cells and reduced tumour growth. In late August Mologen announced the signing of a binding term sheet for a collaboration with the Chinese company, iPharma Ltd., regarding the development, manufacture and commercialisation of lefitolimod in China. iPharma will pay €3m to Mologen upfront and invest €2m in Mologen within 12 months of the final license agreement as well as make milestone payments. The total package could amount to €100m. We have adjusted our valuation model to account for the iPharma deal and now see fair value for the Mologen share at €13.30 (previously: €11.30). We maintain our Buy recommendation.

Aditional IMPULSE data released at ESMO 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. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€ m)	0.01	0.04	0.07	3.04	18.18	0.00
Y-o-y growth	-0.9%	2.3%	0.9%	40.0%	5.0%	-1.0%
EBIT (€ m)	-17.10	-20.54	-20.98	-20.81	-5.33	-23.63
EBIT margin	n.a.	n.a.	n.a.	n.a.	-0.3%	n.a.
Net income (€ m)	-17.08	-20.54	-21.00	-21.27	-5.79	-24.09
EPS (diluted) (€)	-1.02	-0.99	-0.85	-0.62	-0.17	-0.70
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-15.70	-15.18	-19.30	-22.14	-5.40	-24.02
Net gearing	-101.9%	-126.1%	-155.4%	-202.2%	-124.6%	-991.4%
Liquid assets (€ m)	13.56	24.59	20.52	17.85	37.45	13.43

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 21 Sep 2017	
Closing Price	€ 2.43
Shares outstanding	34.29m
Market Capitalisation	€ 83.33m
52-week Range	€ 1.15 / 4.60
Avg. Volume (12 Months)	161,272

Multiples	2017	2018E	2019E
P/E	n.a.	n.a.	n.a.
EV/Sales	n.a.	4.1	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 Jun 2017	
Liquid Assets	€ 14.15m
Current Assets	€ 15.01m
Intangible Assets	€ 0.00m
Total Assets	€ 15.06m
Current Liabilities	€ 6.64m
Shareholders' Equity	€ 1.82m

SHAREHOLDERS

Global Derivative Trading GmbH	<25.0%
Deutsche Balaton AG	5.0%
SIGNAL Krankenvers. a.G.	4.0%
Baloise Holding AG	4.0%
Free float	62.0%

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

The primary endpoint is overall survival (OS). 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 signals 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). At ESMO (European Society for Medical Oncology) Mologen released data on the size of these groups. The former group comprised 38 (43%) of a total of 88 patients for whom B cell data was available. The latter group numbered 25 of the 102 participants in the study. The B cell-related data is particularly interesting as it has positive implications for lefitolimod's efficacy against cancers other than SCLC. The size of the subgroups in the IMPULSE study are thought to be reflective of the overall patient population.

Lefitolimod raises T cell infiltration in murine tumour model The checkpoint inhibitor, ipilimumab (Yervoy) an anti-CTLA4 antibody is used as a combination partner for lefitolimod in the ongoing Mologen/MD Anderson trial in solid tumours. In 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.

The studies used 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. The combination of lefitolimod and aPD-L1 showed a mean tumour growth inhibition (TGI) of 48% 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. TGI for the combination was 99.1% compared to 45.9% with aPD-1. Overall, these 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.

Cancer immunotherapy looks at tumours as "hot" or "cold" or somewhere in between depending on how densely they are infiltrated by T cells. T cells are the main driver of the adaptive immune response. Mologen published first data from studies of lefitolimod in combination with anti-PD1/anti-PD-L1 antibody-based checkpoint inhibitors in murine tumour models in January. Additional data from these murine studies showed that monotherapy with lefitolimod in a CT26 colon carcinoma model resulted in increased infiltration of the tumour by T Cells and reduced tumour growth.

Signing of collaboration with iPharma Ltd. In late August, Mologen announced the signing of a binding term sheet for a collaboration with the Chinese company, iPharma Ltd., regarding the development, manufacture and commercialisation of its lead drug candidate, lefitolimod, in China as well as a potential co-development.

iPharma is a biotech company founded in 2016 as a JV between I-Bridge Capital and BioLineRx Ltd. I-Bridge Capital is a healthcare-focused venture capital firm founded by an ex-partner of Kleiner Perkins Caufield & Byers. BioLineRx Ltd. is an Israeli-based NASDAQ-listed biotech company focused on immuno-oncology.

The final agreement with iPharma (which is expected to be signed by the end of this year) will comprise two parts:

1: a license agreement including sublicense rights under which Mologen grants iPharma an exclusive license for the development, manufacturing and commercialisation of lefitolimod in oncology in China including Hong Kong and Macao, Taiwan and Singapore (the defined territories). Under the licensing agreement, Mologen would receive an upfront payment, milestone payments as well as royalties and an equity investment.

All costs relating to development, registration, marketing and commercialisation of lefitolimod in the defined territories would be covered by iPharma. iPharma will make an upfront payment to Mologen of €3m and an equity investment in Mologen of €2 m within a period of 12 months following the execution of the final license agreement. Mologen will also receive milestone payments on reaching predefined development steps, the market approval of the compound, and certain sales thresholds. The total package could amount to €100m. In addition Mologen would receive low double digit royalties on sales.

2: A co-development agreement under which the two parties shall jointly develop lefitolimod in one or more mutually agreed indications in oncology following a development plan to be agreed on and subject to further funding, in the defined territories and on a global level.

Cash reach to the beginning of 2018 H1/17 EBIT was €-10.5m (H1/16: €-9.8m). The operating loss widened because of a rise in R&D expense to €8.0m (H1/16: €7.1m) and higher business development expenses in connection with efforts to conclude a partnership/licensing agreement. Cash and cash equivalents were €14.2m at the end of June - down from €20.5m at the end of December. Cash burn during H1/17 amounted to €1.9m per month during H1/17 (H1/16: €1.5m). €5m in net proceeds from the issue of a convertible bond restricted the H1/17 cash outflow to €6.4m (H1/16: €9.3m). In management's view, the current cash position covers the company's financial requirements up to the beginning of 2018.

We maintain our Buy recommendation and raise the price target to €13.30 (previously: €11.30) We gather from the conference call held on the announcement of the collaboration with iPharma Ltd. for the Chinese market that management is negotiating partnership deals for other territories. As figure 1 overleaf shows, following the iPharma deal we take a more conservative stance on the likely size of upfront payments entailed by these agreements. We had previously assumed partnership-related upfront payments of USD40m in 2018 but have now lowered this figure to USD20m. We continue, however, to model partnership-related milestone payments of over USD100m in connection with the completion of phase III trials/approval/launch of lefitolimod on non-iPharma markets from 2019/20. Our pipeline valuation model (see figure 2 overleaf) also now incorporates expected milestone payments from the i-Pharma deal. The proforma share count rises because we now model a €25m equity capital raise in 2018 (previously no capital raise) to compensate for the lower forecast upfront payment. We now see fair value for the Mologen share at €13.30 (previously: €11.30). We maintain our Buy recommendation.

Figure 1: Changes to our forecasts

in €m	2017E Old	2017E New	2017E Delta	2018E Old	2018E New	2018E Delta	2019E New
Sales*	0.00	3.04	-	36.36	18.18	-50.0%	0.00
EBIT	-24.29	-20.81	-	12.80	-5.33	-	-23.63
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
Net income	-24.72	-21.27	-	12.38	-5.79	-	-24.09
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
EPS (in €)	-0.82	-0.62	-	0.28	-0.17	-	-0.70

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

Source: First Berlin Equity Research estimates

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	mCRC-EU	€270M	206K	€38,182	€7,872M	10%	€1,031M	18%	15%	10	4 Years
MGN1703	mCRC-US	€302M	131K	€63,636	€8,316M	10%	€1,045M	18%	15%	8	4 Years
MGN1703	SCLC-EU	€58M	24K	€27,273	€649M	50%	€420M	15%	15%	10	4 Years
MGN1703	SCLC-US	€54M	15K	€45,455	€685M	50%	€426M	15%	15%	8	4 Years
MGN1703	mCRC-PRC	€106M	247K	€26,727	€6,594M	10%	€1,130M	11%	20%	10	5 Years
MGN1703	SCLC-PRC	€39M	48K	€19,091	€913M	50%	€712M	11%	20%	10	5 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		€1,058M			€35,792M		€7,015M				
Costs PV[4]		€538M									
NPV		€521M									
Milestones PV		€151M									
Proforma net cash		€45M									
Fair Value		€716M									
Proforma share count		53,726K									
Price Target		€13.33									

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 estimates; Mologen AG

Figure 3: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	**€835.0M**	**€1,058.3M**	**26.7%**
Costs PV (4)	€433.0M	€537.5M	24.1%
NPV	**€402.0M**	**€520.8M**	**29.5%**
Milestones PV	€101.0M	€150.7M	49.2%
Proforma net cash	€40.0M	€44.5M	11.3%
Fair Value	€543.0M	€716.0M	31.9%
Share Count	47,977K	53,726K	12.0%
Price Target	**€11.32**	**€13.33**	**17.7%**

Source: First Berlin Equity Research estimates;

INCOME STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
Net product revenues	**12**	**39**	**74**	**36**	**0**	**0**
Milestone & upfront payments	**0**	**0**	**0**	**3,000**	**18,182**	**0**
Total revenue	**12**	**39**	**74**	**3,036**	**18,182**	**0**
Cost of materials	**8,687**	**11,681**	**11,780**	**14,500**	**14,000**	**14,000**
Gross profit	**-8,675**	**-11,642**	**-11,706**	**-14,464**	**-14,000**	**-14,000**
PACME (incl. milestone & upfront payments)	**-8,675**	**-11,642**	**-11,706**	**-11,464**	**4,182**	**-14,000**
Depreciation	110	121	408	117	90	0
Personnel costs	5,113	5,074	5,453	5,200	5,500	5,700
Other operating income (expense)	-3,199	-3,702	-3,418	-4,025	-3,925	-3,925
Operating income (EBIT)	**-17,097**	**-20,539**	**-20,985**	**-20,806**	**-5,333**	**-23,625**
Net financial result	19	3	-18	-462	-461	-461
Pre-tax income (EBT)	**-17,078**	**-20,536**	**-21,003**	**-21,268**	**-5,795**	**-24,086**
Net income / loss	**-17,078**	**-20,536**	**-21,003**	**-21,268**	**-5,795**	**-24,086**
Diluted EPS (in EUR)	**-1.02**	**-0.99**	**-0.85**	**-0.62**	**-0.17**	**-0.70**
EBITDA	**-16,987**	**-20,418**	**-20,577**	**-20,689**	**-5,243**	**-23,625**
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.	131.5%	n.m.
Y-Y Growth						
Total revenues	-94.7%	225.0%	89.7%	4002.7%	498.9%	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	2014	2015	2016	2017E	2018E	2019E
Assets						
Current assets, total	**14,613**	**25,981**	**21,300**	**18,710**	**38,326**	**13,456**
Cash and cash equivalents	13,563	24,592	20,520	17,852	37,451	13,426
Short-term Investments	0	0	0	0	0	0
Receivables	0	0	33	0	0	0
Inventories	30	28	13	20	25	30
Other current assets	1,020	1,361	734	838	850	0
Non-current assets, total	**440**	**414**	**62**	**52**	**42**	**25**
Property, plant & equipment	234	239	25	25	25	25
Goodwill & other intangibles	206	175	37	27	17	0
Other assets	0	0	0	0	0	0
Total assets	**15,053**	**26,395**	**21,362**	**18,762**	**38,368**	**13,481**
Shareholders' equity & debt						
Current liabilities, total	**1,747**	**6,886**	**7,404**	**6,600**	**7,000**	**6,200**
Short-term debt	10	8	3	0	0	0
Accounts payable	1,315	6,390	6,530	6,000	6,100	6,200
Other current liabilities	422	488	871	600	900	0
Long-term liabilities, total	**8**	**6**	**2,121**	**6,592**	**6,592**	**6,592**
Convertible bond	0	0	2,119	6,591	6,591	6,591
Long term debt	0	0	0	0	0	0
Deferred revenue	8	6	2	1	1	1
Shareholders' equity	**13,298**	**19,503**	**11,837**	**5,570**	**24,776**	**689**
Total consolidated equity and debt	**15,053**	**26,395**	**21,362**	**18,762**	**38,368**	**13,481**
Ratios						
Current ratio (x)	8.36	3.77	2.88	2.83	5.48	2.17
Quick ratio (x)	8.35	3.77	2.88	2.83	5.47	2.17
Net gearing	-101.9%	-126.1%	-155.4%	-202.2%	-124.6%	-991.4%
Book value per share (€)	0.78	0.86	0.39	0.16	0.72	0.02
Net cash	13,553	24,584	18,398	11,261	30,860	6,835
Return on equity (ROE)	-120.8%	-125.2%	-134.0%	-244.4%	-38.2%	-189.2%

CASH FLOW STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
EBIT	**-17,097**	**-20,539**	**-20,985**	**-20,806**	**-5,333**	**-23,625**
Depreciation and amortization	110	121	408	117	90	0
EBITDA	**-16,987**	**-20,418**	**-20,577**	**-20,689**	**-5,243**	**-23,625**
Changes in working capital	-93	4,786	1,127	-879	383	45
Other adjustments	1,475	546	198	-462	-461	-461
Operating cash flow	**-15,605**	**-15,086**	**-19,252**	**-22,030**	**-5,322**	**-24,041**
CAPEX	-93	-95	-44	-107	-80	17
Free cash flow	**-15,698**	**-15,181**	**-19,296**	**-22,137**	**-5,402**	**-24,024**
Debt financing, net	**-9**	**-2**	**-5**	**-3**	**0**	**0**
Equity financing, net	**14,495**	**26,207**	**12,706**	**15,000**	**25,000**	**0**
Convertible bond	**0**	**0**	**2,535**	**4,989**	**0**	**0**
Changes in other financial assets	**6,000**	**0**	**-18**	**0**	**0**	**0**
Other Changes in Cash	**10**	**5**	**6**	**-517**	**0**	**0**
Net cash flows	**4,798**	**11,029**	**-4,072**	**-2,668**	**19,598**	**-24,024**
Cash, start of the year	8,765	13,563	24,592	20,520	17,852	37,451
Cash, end of the year	**13,563**	**24,592**	**20,520**	**17,852**	**37,451**	**13,426**
EBITDA/share	**-1.01**	**-0.98**	**-0.84**	**-0.61**	**-0.15**	**-0.69**
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...16	↓	↓	↓	↓
17	15 November 2016	€1.50	Buy	€11.30
18	15 February 2017	€3.28	Buy	€11.30
19	5 May 2017	€3.07	Buy	€11.30
20	Today	€2.43	Buy	€13.30

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

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]

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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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

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%.

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.

INVESTMENT HORIZON

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UPDATES

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