MOLOGEN AG

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

Update

RATING	**BUY**
PRICE TARGET	**€ 5.70**
Return Potential	518.2%
Risk Rating	Speculative

LOOKING FORWARD TO 2020

Mologen's main value driver is the IMPALA phase III trial of its lead compound, the TLR9 agonist and immunomodulator, lefitolimod in metastatic colorectal cancer (mCRC). This indication is worth USD10bn - over 250x the company's current market capitalisation. The extreme discrepancy between Mologen's market valuation and the value of its main addressable market is partly explicable in terms of a challenging start to 2018. Last August Mologen announced its first partnering deal with the Chinese company, iPharma Ltd., regarding the development, manufacture and commercialisation of lefitolimod in China. The exclusivity period with iPharma expired at the end of 2017 and in February Mologen announced that it had agreed on a partnership with the US company, Oncologie on very similar terms to the iPharma deal conditional on a €3m initial payment. This payment was made in April. Meanwhile, publication of the annual report was delayed from 22 March to 25 April. Also in April, the company stated that the primary analysis date for the IMPALA study is April 2020. This suggests that filing for approval of lefitolimod in mCRC may not happen until 2021. Mologen had previously guided towards a filing date of 2019/20. Current cash reach is expected to be end-2018. In late April, CEO Mariola Söhngen announced that she will not renew her contract which expires at the end of October. We have lowered our price target from €13.10 to €5.70 and raised the risk rating from High to Speculative while maintaining our overall Buy rating. The higher level of dilution entailed by later filing than we previously modelled is one reason for the downgrade to our price target and risk rating. We also use higher discount rates in our valuation model to reflect the departure of the CEO and the worsening quality of the company's financing (€12m bond financing with conversion into shares at a 10% discount to VWAP).

Agreement with Oncologie Inc. In mid-February Mologen signed a Chinese licensing/global co-development agreement for lefitolimod with Oncologie Inc. (Oncologie). Oncologie is headquartered in Boston, US… (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018E	2019E	2020E
Revenue (€ m)	0.04	0.07	0.05	3.00	0.00	42.50
Y-o-y growth	230.0%	89.7%	-36.5%	n.a.	n.a.	n.a.
EBIT (€ m)	-20.54	-20.98	-18.71	-17.68	-20.19	22.17
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	52.2%
Net income (€ m)	-20.54	-21.00	-19.28	-18.06	-20.57	21.79
EPS (diluted) (€)	-0.99	-0.85	-0.56	-0.44	-0.33	0.29
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-15.18	-19.30	-19.11	-18.23	-21.46	15.94
Net gearing	-1.3%	-1.6%	0.2%	1.0%	-0.4%	-1.0%
Liquid assets (€ m)	24.59	20.52	6.52	8.30	1.84	24.77

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.

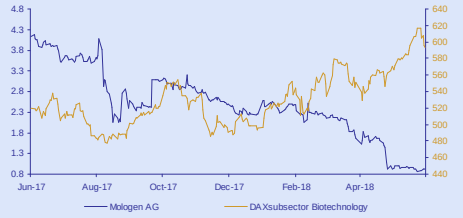
MARKET DATA

As of 01 Jun 2018

Closing Price	€ 0.92
Shares outstanding	37.69m
Market Capitalisation	€ 34.75m
52-week Range	€ 0.86 / 4.17
Avg. Volume (12 Months)	110,529

Multiples	2017	2018E	2019E
P/E	n.a.	n.a.	n.a.
EV/Sales	677.9	10.6	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 2018

Liquid Assets	€ 8.28m
Current Assets	€ 13.07m
Intangible Assets	€ 0.01m
Total Assets	€ 13.11m
Current Liabilities	€ 7.46m
Shareholders' Equity	€ 0.16m

SHAREHOLDERS

Global Derivative Trading GmbH	<25%
Deutsche Balaton AG	5%
SIGNAL Krankenvers. a.G.	4%
Baloise Holding AG	4%
Axxion S.A.	3%
Free float	59%

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

...and has operations in Shanghai. The agreement stipulated an initial payment to Mologen of €3m, which was received in April, and a €2m equity investment by Oncologie in Mologen within 12 months of signing. Subsequent milestones take total potential payments from the deal to over €100m. The agreement with Oncologie replaces a binding term sheet signed with iPharma in August 2017. The exclusivity period with iPharma ended in December and Mologen then opened negotiations with other parties. The result was the agreement with Oncologie. The terms of the agreement signed with Oncologie are very similar to the iPharma deal. Like the iPharma deal, the agreement with Oncologie comprises two parts – first an exclusive license for the development, manufacture and commercialisation of lefitolimod in China, Hong Kong and Macao, Taiwan and Singapore and second – a commitment for global co-development. The main difference between the two deals is Oncologie's emphasis on using planned novel biomarkers in combination with lefitolimod.

Primary analysis of IMPALA data expected in April 2020 Mologen completed recruitment of patients for its phase III IMPALA pivotal study with lefitolimod in mCRC in May 2017. The primary endpoint is overall survival using lefitolimod as a maintenance therapy for patients with mCRC. Secondary endpoints include progression-free survival, toxicity, safety and quality of life. The study comprises 549 patients in eight European countries including the five largest European markets. In April Mologen announced that it expects primary analysis of the data in April 2020. We have pushed back our assumption as to the timepoint of filing with the EMA and the FDA from 2019/20 to 2021.

Completion of recruitment for combination trial with Yervoy likely later this year 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, has a dose escalation and subsequent expansion component and may 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.

IMPULSE final evaluation confirms topline data The final evaluation of the IMPULSE phase II trial data confirmed topline data released in April 2017. The final study analysis included 103 patients with extensive-stage small cell lung cancer (ES-SCLC) showing at least partial response to four cycles of first-line chemotherapy. The primary endpoint of the trial was overall survival (OS). The study did not meet its primary endpoint, which is not surprising as ES-SCLC is a very challenging indication. However, the study did demonstrate an overall survival benefit in comparison to the control arm in two important subgroups – patients with a low count of activated B cells (hazard ratio 0.53, 95% confidence interval 0.26-1.08) and patients with reported Chronic Obstructive Pulmonary Disease (hazard ratio 0.48, 95% confidence interval 0.20-1.17). Mologen released data on the size of these groups at ESMO (European Society for Medical Oncology) in September 2017. 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 103 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 reflective of the overall patient population. Mologen is currently discussing potential further development of lefitolimod in ES-SCLC with clinical and scientific experts.

Lefitolimod could be combi partner in HIV for vaccines/monoclonal antibodies In August 2017 Mologen published results of the extension phase of the TEACH study of lefitolimod with HIV patients on ART (antiretroviral therapy). The study enrolled 12 patients and was carried out in cooperation with Aarhus University Hospital in Denmark. One of the primary endpoints of the study was quantification of the size of the HIV reservoir. Lefitolimod combined with ART did not show any detectable impact on the size of the viral reservoir.

However, the intervention did demonstrate sustained increases in activation of important immune cells (CD4 and CD8 cells) and also triggered maturation of other important immune cells (B cells) towards antibody producing cells. Lefitolimod was also safe and well tolerated in HIV patients on ART. Although the trial did not demonstrate the desired effect on the viral reservoir, the results do suggest that lefitolimod could be an important partner in combination with other HIV therapies such as monoclonal antibodies or vaccines.

One ART interruption patient showed viral control of 20 weeks vs. average two weeks The extension phase of the TEACH study included an antiretroviral treatment interruption (ATI) component. ATI is used to determine the size and reduction of latent infected cells which is measured via time to viral rebound. After viral rebound ART is reintroduced. One of the nine patients who took part in ATI showed viral control for more than 20 weeks, whereas the interval until viral rebound is generally two weeks. Mologen is very closely examining the results of lefitolimod treatment in this patient.

Gilead-financed combination trial of lefitolimod with HIV patients to start later in 2018 In January 2017, Aarhus University received a grant of USD2.75m from Gilead Sciences to fund a clinical trial of lefitolimod in combination with innovative virus-neutralizing antibodies in HIV positive patients using ART. The virus-neutralizing antibodies have been developed by Rockefeller University, New York, US. The trial, to be known as TITAN, is scheduled to start later this year.

Cash consumption to rise in 2018 despite lower R&D Mologen had cash and cash equivalents of €8.3m at the end of March 2018. Q1/18 results showed an operating cash outflow of €4.6m (Q1/17: €6.0m). The decline was due to reduced R&D spending. During Q1/17 Mologen was either recruiting for, or carrying out the IMPALA, IMPULSE and TEACH studies. During Q1/18 IMPALA was the focus of clinical activity. R&D spending is expected to remain below the 2017 level in 2018. However, overall cash consumption is expected to rise due to the preparation of production capacity at a contract manufacturer and regulatory activities. We forecast 2018 cash consumption of €21.2m (2017: €19.1m).

Mologen has put in place a raft of financing measures to cover this year's cash outflow.

In late October 2017, Mologen and the US investor Global Corporate Finance (GCF), signed a share subscription facility. The facility entails the issue of up to 3.43m new shares at 95% of 5-day VWAP. Timing of the issue tranches is at Mologen's discretion. The facility runs for up to 30 months. So far Mologen has issued 475,000 shares to GCF through this facility, generating gross proceeds of €1m.

On 20 February Mologen announced a €12m convertible bond subscription agreement with European High Growth Opportunities Securitization Fund (EHGO), a fund advised by Alpha Blue Ocean Advisors. The bonds will be issued in up to 24 tranches of €0.5m each with a waiting period of at least 10 trading days between each tranche. EHGO can convert the bonds at its discretion, conversion being mandatory upon the lapse of 12 months from the issuance of the relevant tranche. The conversion price is 90% of the Volume Weighted Average Price (VWAP) of Mologen's share price during the three trading days preceding the conversion (but at least 80% of the VWAP of Mologen's share price during the 10 trading days preceding the issuance of the bonds). The bonds do not accrue interest. Mologen has so far exercised two tranches, raising a total of €1m, both of which have been fully converted by EHGO.

In March Mologen announced the completion of a rights issue which raised the share capital by 2.36m shares or 6.78% to 37.13m shares. The issue was at €2.12 per share and raised gross proceeds of €5.0m.

We model the issue of a further 6.0m shares through a rights offering at a 10% discount to the current share price before the end of this year. Gross proceeds would be €5m.

Buy recommendation maintained, but price target lowered from €13.10 to €5.70 We maintain our Buy recommendation, but now take a more conservative view on the timing of upfront payments from partner agreements for the EU and US. We now do not assume these until 2020 and hence model additional share issuance to compensate for the later timing. Figure 1 shows the resulting changes to our forecasts. We no longer accord a valuation to the renal cancer vaccine, MGN1601, as development of this compound is currently shelved. Given the current low level of the share price, we expect Mologen to minimise dilution by concentrating resources on the IMPALA trial, preparation of production capacity and regulatory activities. We therefore push back our forecast of the timing of first revenues from ES-SCLC from 2021 to 2024. We also use higher discount rates in our valuation model to reflect the resignation of the CEO and the worsening quality of the company's financing (€12m in bonds which convert into shares at a 10% discount to VWAP). For the U.S. and EU markets we now use a discount rate of 17.5% (previously: 15%) while for China we use a discount rate of 22.5% (previously: 20%). These changes cause us to lower our price target from €13.10 to €5.70. We have also raised the risk rating from High to Speculative while maintaining our overall Buy rating.

Figure 1: Changes to our forecasts

	2018E			2019E			2020E
in €m	Old	New	Delta	Old	New	Delta	New
Sales*	18.18	3.00	-83.5%	0.00	0.00	-	42.50
EBIT	-9.30	-17.68	-	-27.69	-20.19	-	22.17
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
Net income	-9.76	-18.06	-	-28.15	-20.57	-	21.79
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*
EPS (in €)	-0.28	-0.44	-	-0.82	-0.33	-	0.29

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

Source: First Berlin Equity Research estimates

Figure 2: Pipeline valuation

	Old	New	Delta
PACME PV	**€1,058.3M**	**€534.4M**	**-49.5%**
Costs PV (4)	€541.4M	€204.3M	-62.3%
NPV	**€516.9M**	**€330.1M**	**-36.1%**
Milestones PV	€150.7M	€51.8M	-65.6%
Proforma net cash	€41.0M	€33.3M	-18.6%
Fair Value	€708.5M	€415.2M	-41.4%
Share Count	54,169K	72,852K	34.5%
Price Target	**€13.10**	**€5.70**	**-56.5%**

Source: First Berlin Equity Research estimates; Mologen AG

Figure 3: Changes to our pipeline valuation model

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	€193M	206K	€35,000	€7,216M	10%	€926M	18%	17.5%	8	4 Years
MGN1703	mCRC-US	€205M	131K	€58,333	€7,623M	10%	€978M	18%	17.5%	6	4 Years
MGN1703	SCLC-EU	€26M	24K	€25,000	€595M	50%	€392M	15%	17.5%	6	6 Years
MGN1703	SCLC-US	€23M	15K	€41,667	€628M	50%	€398M	15%	17.5%	4	6 Years
MGN1703	mCRC-PRC	€67M	247K	€24,500	€6,045M	10%	€1,164M	11%	22.5%	10	5 Years
MGN1703	SCLC-PRC	€20M	48K	€17,500	€837M	50%	€672M	11%	22.5%	10	5 Years
PACME PV		€534M			€32,809M		€6,698M				
Costs PV[4]		€204M									
NPV		€330M									
Milestones PV		€52M									
Proforma net cash		€33M									
Fair Value		€415M									
Proforma share count		72,852K									
Price Target		€5.70									

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

INCOME STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
Net product revenues	**39**	**74**	**47**	**0**	**0**	**0**
Milestone & upfront payments	**0**	**0**	**0**	**3,000**	**0**	**42,500**
Total revenue	**39**	**74**	**47**	**3,000**	**0**	**42,500**
Cost of materials	**11,681**	**11,780**	**9,752**	**10,500**	**11,000**	**11,000**
Gross profit	**-11,642**	**-11,706**	**-9,705**	**-10,500**	**-11,000**	**-11,000**
PACME (incl. milestone & upfront payments)	**-11,642**	**-11,706**	**-9,705**	**-7,500**	**-11,000**	**31,500**
Depreciation	121	408	49	55	63	128
Personnel costs	5,074	5,453	5,093	5,200	5,200	5,300
Other operating income (expense)	-3,702	-3,418	-3,860	-4,925	-3,925	-3,900
Operating income (EBIT)	**-20,539**	**-20,985**	**-18,707**	**-17,680**	**-20,188**	**22,173**
Net financial result	3	-18	-574	-380	-379	-379
Pre-tax income (EBT)	**-20,536**	**-21,003**	**-19,281**	**-18,060**	**-20,567**	**21,793**
Net income / loss	**-20,536**	**-21,003**	**-19,281**	**-18,060**	**-20,567**	**21,793**
Diluted EPS (in EUR)	**-0.99**	**-0.85**	**-0.56**	**-0.44**	**-0.33**	**0.29**
EBITDA	**-20,418**	**-20,577**	**-18,658**	**-17,625**	**-20,125**	**22,300**
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.	-69.3%	n.m.	n.m.
Y-Y Growth						
Total revenues	225.0%	89.7%	-36.5%	6283.0%	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	2015	2016	2017	2018E	2019E	2020E
Assets						
Current assets, total	**25,981**	**21,300**	**8,061**	**9,520**	**3,167**	**26,600**
Cash and cash equivalents	24,592	20,520	6,523	8,295	1,837	24,772
Short-term Investments	0	0	0	0	0	0
Receivables	0	33	13	0	0	0
Inventories	28	13	16	25	30	128
Other current assets	1,361	734	1,509	1,200	1,300	1,700
Non-current assets, total	**414**	**62**	**44**	**34**	**20**	**30**
Property, plant & equipment	239	25	27	17	20	30
Goodwill & other intangibles	175	37	17	17	0	0
Other assets	0	0	0	0	0	0
Total assets	**26,395**	**21,362**	**8,105**	**9,554**	**3,187**	**26,630**
Shareholders' equity & debt						
Current liabilities, total	**6,886**	**7,404**	**7,502**	**7,000**	**6,200**	**850**
Short-term debt	8	3	9	0	0	0
Accounts payable	6,390	6,530	4,400	6,100	6,200	0
Other current liabilities	488	871	3,093	900	0	850
Long-term liabilities, total	**6**	**2,121**	**5,474**	**5,420**	**5,420**	**5,419**
Convertible bond	0	2,119	5,419	5,419	5,419	5,419
Long term debt	0	0	0	0	0	0
Deferred revenue	6	2	55	1	1	0
Shareholders' equity	**19,503**	**11,837**	**-4,871**	**-2,866**	**-8,433**	**20,361**
Total consolidated equity and debt	**26,395**	**21,362**	**8,105**	**9,554**	**3,187**	**26,630**
Ratios						
Current ratio (x)	3.77	2.88	1.07	1.36	0.51	31.29
Quick ratio (x)	3.77	2.88	1.07	1.36	0.51	31.14
Net gearing	-126.1%	-155.4%	22.5%	100.4%	-42.5%	-95.1%
Book value per share (€)	0.86	0.39	-0.14	-0.07	-0.14	0.33
Net cash	24,584	18,398	1,095	2,876	-3,582	19,353
Return on equity (ROE)	-125.2%	-134.0%	-553.6%	466.9%	364.1%	365.4%

CASH FLOW STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
EBIT	**-20,539**	**-20,985**	**-18,707**	**-17,680**	**-20,188**	**22,173**
Depreciation and amortization	121	408	49	55	63	128
EBITDA	**-20,418**	**-20,577**	**-18,658**	**-17,625**	**-20,125**	**22,300**
Changes in working capital	4,786	1,127	-705	-180	-905	-5,848
Other adjustments	546	198	251	-380	-379	-379
Operating cash flow	**-15,086**	**-19,252**	**-19,112**	**-18,185**	**-21,409**	**16,073**
CAPEX	-95	-44	6	-45	-49	-138
Free cash flow	**-15,181**	**-19,296**	**-19,106**	**-18,230**	**-21,458**	**15,936**
Debt financing, net	**-2**	**-5**	**0**	**-9**	**0**	**0**
Equity financing, net	**26,207**	**12,706**	**477**	**15,012**	**8,000**	**7,000**
Convertible bond	**0**	**2,535**	**4,976**	**4,999**	**7,000**	**0**
Changes in other financial assets	**0**	**-18**	**0**	**0**	**0**	**0**
Other Changes in Cash	**5**	**6**	**-344**	**0**	**0**	**0**
Net cash flows	**11,029**	**-4,072**	**-13,997**	**1,772**	**-6,458**	**22,936**
Cash, start of the year	13,563	24,592	20,520	6,523	8,295	1,837
Cash, end of the year	**24,592**	**20,520**	**6,523**	**8,295**	**1,837**	**24,772**
EBITDA/share	**-0.98**	**-0.83**	**-0.55**	**-0.43**	**-0.33**	**0.30**
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...18	↓	↓	↓	↓
19	5 May 2017	€3.07	Buy	€11.30
20	22 September 2017	€2.43	Buy	€13.30
21	20 November 2017	€2.62	Buy	€13.10
22	Today	€0.92	Buy	€5.70

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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- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

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