

MOLOGEN AG

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

Q3 results

RATING
PRICE TARGET
 Return Potential
 Risk Rating

BUY
€ 13.10
 399.8%
 High

WEALTH OF TRIAL DATA SECURES CHINESE PARTNERSHIP DEAL

Mologen's lead drug candidate, the TLR9 agonist and immunomodulator, lefitolimod, is currently the object of two clinically active trials - in metastatic colorectal cancer (mCRC) 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. Mologen has also reported results from two further trials this year. The phase II small cell lung cancer (SCLC) trial showed positive results in two clinically relevant patient subgroups while data released so far from the extension phase of the TEACH study with HIV patients suggest that lefitolimod could be an important partner in combination with other HIV therapies such as monoclonal antibodies or vaccines. We believe that these and other data were instrumental in the August 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. The total package of upfront and milestone payments in connection with this deal could amount to €100m. In addition Mologen will receive low double digit royalties on sales. We expect one or more partnership deals for other territories in 2018. On 9 November, the US company Dynavax announced the FDA approval of its hepatitis B vaccine, HEPLISAV-B, which combines hepatitis B surface antigen with a TLR9 agonist. This news marks the first approval in the U.S. for a TLR9 agonist and supports our confidence in lefitolimod. We maintain our Buy recommendation but lower the price target from €13.30 to €13.10 to reflect higher technology transfer and production outsourcing costs than we previously modelled.

Q3 EBIT above our forecast Mologen's Q3 EBIT of €-4.0m (Q3/16: €4.5m) was better than our forecast of €-4.4m because of a decline in R&D expenses to €2.6m (Q3/16: €3.4m). The decline in R&D expense relates to the completion of recruitment for the IMPALA phase III trial of lefitolimod with mCRC patients in May. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€m)	0.01	0.04	0.07	3.05	18.18	0.00
Y-o-y growth	-0.9%	2.3%	0.9%	40.3%	5.0%	-1.0%
EBIT (€m)	-17.10	-20.54	-20.98	-16.87	-9.30	-27.69
EBIT margin	n.a.	n.a.	n.a.	n.a.	-0.5%	n.a.
Net income (€m)	-17.08	-20.54	-21.00	-17.33	-9.76	-28.15
EPS (diluted) (€)	-1.02	-0.99	-0.85	-0.51	-0.28	-0.82
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-15.70	-15.18	-19.30	-18.20	-9.37	-28.09
Net gearing	-101.9%	-126.1%	-155.4%	-159.9%	-124.6%	80.5%
Liquid assets (€m)	13.56	24.59	20.52	21.79	37.42	9.33

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 17 Nov 2017

Closing Price € 2.62
 Shares outstanding 34.29m
 Market Capitalisation € 89.88m
 52-week Range € 1.40 / 4.60
 Avg. Volume (12 Months) 170,497

Multiples	2017	2018E	2019E
P/E	n.a.	n.a.	n.a.
EV/Sales	27.8	4.7	0.0
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2017

Liquid Assets € 9.81m
 Current Assets € 10.93m
 Intangible Assets € 0.02m
 Total Assets € 10.97m
 Current Liabilities € 6.62m
 Shareholders' Equity € -2.19m

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%

However, management cautions against extrapolation of this number into 2018. In particular R&D costs are likely to rise in connection with the planned outsourcing and upscaling of production to market standard.

Figure 1: Q3/17 results versus our forecasts

in €m	Q3-17A	Q3-17E	Delta	Q3-16A	Delta
Sales	0.00	0.00	-	0.00	-
EBIT	-4.02	-4.80	-	-4.46	-
margin	neg.	neg.	-	neg.	-
Net income	-4.14	-4.90	-	-4.46	-
margin	neg.	neg.	-	neg.	-
EPS (in €)	-0.12	-0.14	-	-0.20	-

Source: First Berlin Equity Research; Mologen AG

Phase II SCLC, TEACH (HIV), checkpoint inhibitor combi results so far in 2017

Besides completion of IMPALA recruitment, clinical highlights of the year so far include presentation of the exploratory phase II trial top-line results of lefitolimod in SCLC patients (the IMPULSE trial) in April, and publication of the main results of the extension phase of the Ib/Ila TEACH trial of lefitolimod in HIV patients in August. In January 2017, Mologen also 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 most widely used checkpoint inhibitor drugs, Opdivo and Keytruda, are anti-PD-1 antibodies. 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 the checkpoint inhibitor, Yervoy.

IMPALA data likely in 2019 Mologen envisions evaluating the IMPALA data within approximately 24 months of completion of recruitment. Some uncertainty remains as to the precise timing of the primary read-out date due to the event-driven study design. Filing for approval with the EMA and the FDA is likely in 2019/20.

Positive IMPULSE results in two relevant subgroups Topline IMPULSE results released in 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 with 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 the ESMO conference in September (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 could be combi partner in HIV for vaccines/monoclonal antibodies In August 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.

Gilead to finance combination trial of lefitolimod with HIV patients 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 with HIV positive patients using ART. The trial is scheduled to start in 2018.

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. Full results of the IMPULSE and the TEACH extension trials will be presented in Q1/18 and at mid-year 2018 respectively.

GCF deal could generate proceeds of almost €10m at current share price Cash used in operating activities totalled €15.4m during the first nine months of 2017. Cash used in investing activities was minimal and so the free cash outflow was also €15.4m. This was financed by €5m in proceeds from a convertible bond issue in Q1/17 and a reduction in cash from €20.5m to €9.8m. Monthly cash burn averaged €18m during the first nine months of 2017. In 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 (10% of Mologen's current share capital) at 95% of 5-day VWAP. Timing of the issue tranches is at Mologen's discretion. The facility runs for up to 30 months and at the current share price could generate proceeds of up to €10.0m. The addition of the GCF facility to Mologen's current cash position extend the company's cash reach to mid-2018.

iPharma initial payment of €3m to be recognised in the full year result 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. Management expects the final agreement to close by the end of this year upon which Mologen will receive an initial payment from iPharma of €3m. iPharma will make a further equity investment in Mologen of €2m within 12 months of closing. 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 will receive low double digit royalties on sales.

We maintain our Buy recommendation but lower the price target from €13.30 to €13.10

Full year guidance given by Mologen at the time of the 2016 annual report was for an increase in R&D expenses and a decline in the operating result in the absence of a partnership deal. With R&D after the first nine months of 2017 at €10.6m (9M/16: €10.5m), and the closing of the iPharma deal expected before the end of the year (initial payment: €3m), management's view is now that the 2017 operating result could be "slightly above" the 2016 figure. Our last note of 22 September already incorporated the €3m upfront payment from iPharma expected before year-end, but also assumed a €2.5m increase in combined materials and personnel costs to €19.7m (2016: €172m) – due mainly to higher R&D spending. In our current forecast, we have reduced this number to €16.7m. This accounts for the increase in our 2017 EBIT forecast from €-20.8m to €-17.9m.



However, we have also raised our forecasts for material costs by €4m in both 2017 and 2018 to reflect the expense of technology transfer and production outsourcing in line with the “Next Level” strategy. The net effect of these changes is to lower our price target to €13.10 (previously: €13.30). We maintain our Buy recommendation.

Figure 2: Changes to our forecasts

in €m	Old	2017E New	Delta	Old	2018E New	Delta	Old	2019E New	Delta
Sales*	3.04	3.05	0.5%	18.18	18.18	0.0%	0.00	0.00	-
EBIT	-20.81	-16.87	-	-5.33	-9.30	-	-23.69	-27.69	-
margin	neg.	neg.	-	neg.	neg.	-	neg.	neg.	-
Net income	-21.27	-17.33	-	-5.79	-9.76	-	-24.09	-28.15	-
margin	neg.	neg.	-	neg.	neg.	-	neg.	neg.	-
EPS (in €)	-0.62	-0.51	-	-0.17	-0.28	-	-0.70	-0.82	-

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

Source: First Berlin Equity Research estimates

Figure 3: 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%	18%	10	4 Years
MGN1703	mCRC-US	€302M	131K	€63,636	€8,316M	10%	€1,045M	18%	18%	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%	0	8 years
MGN1601	RCC-US	€113M	26K	€63,636	€1,674M	25%	€1,110M	25%	15%	2	8 years
PACME PV		€1,058M			€35,792M		€7,015M				
Costs PV ⁴⁾		€541M									
NPV		€517M									
Milestones PV		€151M									
Proforma net cash		€41M									
Fair Value		€709M									
Proforma share count		54,169K									
Price Target		€13.08									

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 4: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	€1,058.3M	€1,058.3M	0.0%
Costs PV (4)	€537.5M	€541.4M	0.7%
NPV	€520.8M	€516.9M	-0.8%
Milestones PV	€150.7M	€150.7M	0.0%
Proforma net cash	€44.5M	€41.0M	-7.9%
Fair Value	€716.0M	€708.5M	-1.0%
Share Count	53,762K	54,169K	0.8%
Price Target	€13.32	€13.08	-1.8%

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	3,018	18,182	0
Total revenue	12	39	74	3,054	18,182	0
Cost of materials	8,687	11,681	11,780	10,562	18,000	18,000
Gross profit	-8,675	-11,642	-11,706	-10,526	-18,000	-18,000
PACME (incl. milestone & upfront payments)	-8,675	-11,642	-11,706	-7,508	182	-18,000
Depreciation	110	121	408	50	55	63
Personnel costs	5,113	5,074	5,453	5,180	5,500	5,700
Other operating income (expense)	-3,199	-3,702	-3,418	-4,135	-3,925	-3,925
Operating income (EBIT)	-17,097	-20,539	-20,985	-16,873	-9,298	-27,688
Net financial result	19	3	-18	-462	-461	-461
Pre-tax income (EBT)	-17,078	-20,536	-21,003	-17,334	-9,760	-28,149
Net income / loss	-17,078	-20,536	-21,003	-17,334	-9,760	-28,149
Diluted EPS (in EUR)	-1.02	-0.99	-0.85	-0.51	-0.28	-0.82
EBITDA	-16,987	-20,418	-20,577	-16,823	-9,243	-27,625
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.	3025.0%	n.m.
Y-Y Growth						
Total revenues	-94.7%	225.0%	89.7%	4027.0%	495.3%	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	22,644	38,294	9,362
Cash and cash equivalents	13,563	24,592	20,520	21,786	37,419	9,332
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	22,696	38,336	9,387
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	9,504	24,744	-3,405
Total consolidated equity and debt	15,053	26,395	21,362	22,696	38,336	9,387
Ratios						
Current ratio (x)	8.36	3.77	2.88	3.43	5.47	1.51
Quick ratio (x)	8.35	3.77	2.88	3.43	5.47	1.51
Net gearing	-101.9%	-126.1%	-155.4%	-159.9%	-124.6%	80.5%
Book value per share (€)	0.78	0.86	0.39	0.28	0.72	-0.10
Net cash	13,553	24,584	18,398	15,195	30,828	2,741
Return on equity (ROE)	-120.8%	-125.2%	-134.0%	-162.5%	-57.0%	-263.8%



CASH FLOW STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
EBIT	-17,097	-20,539	-20,985	-16,873	-9,298	-27,688
Depreciation and amortization	110	121	408	50	55	63
EBITDA	-16,987	-20,418	-20,577	-16,823	-9,243	-27,625
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	-18,163	-9,322	-28,041
CAPEX	-93	-95	-44	-40	-45	-46
Free cash flow	-15,698	-15,181	-19,296	-18,203	-9,367	-28,087
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	1,266	15,633	-28,087
Cash, start of the year	8,765	13,563	24,592	20,520	21,786	37,419
Cash, end of the year	13,563	24,592	20,520	21,786	37,419	9,332
EBITDA/share	-1.01	-0.98	-0.84	-0.49	-0.27	-0.81
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...17	↓	↓	↓	↓
18	15 February 2017	€3.28	Buy	€11.30
19	5 May 2017	€3.07	Buy	€11.30
20	22 September 2017	€2.43	Buy	€13.30
21	Today	€2.62	Buy	€13.10

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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.

CONFLICTS OF INTEREST

In accordance with Section 34b Paragraph 1 of the German Securities Trading Act [WpHG] and Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) financial analyses may only be passed on or publicly distributed if circumstances or relations which may cause conflicts of interest among the authors, the legal entities responsible for such preparation or companies associated with them are disclosed along with the financial analysis.

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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

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

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