

# Molgen

## Right time for a rights issue

With two late stage clinical studies ongoing with its cancer immunotherapy MGN1703, Molgen is seeking an injection of cash to ensure recruitment is completed and data from one of the trials are delivered in 2016. Phase II data from the 100-patient study in small-cell lung cancer next year could have a major bearing on partnering and financing options for completing the Phase III trial with MGN1703 in colorectal cancer, scheduled for 2017/18. With up to 5.7m shares on offer, priced at €5.00, we estimate net proceeds of €27m, sufficient into 2017, which takes in these key catalysts.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/13	0.2	(9.9)	(0.64)	0.0	N/A	N/A
12/14	0.0	(17.0)	(1.01)	0.0	N/A	N/A
12/15e	0.0	(18.1)	(1.07)	0.0	N/A	N/A
12/16e	0.0	(18.4)	(1.08)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding intangible amortisation, exceptional items.

## A rights issue...

Molgen is seeking to place 5.658m new shares, in a one-for-three rights issue to existing shareholders, at €5.00 per share. The company expects substantial uptake from existing shareholders, with the balance of shares to be offered to new international, institutional investors. This should help to broaden and strengthen the shareholder list, as happened in a similar placing in February 2014. Assuming full subscription, we estimate net proceeds of €27m (after ~5% issue expenses).

## ...at the right time...

With €13.6m in cash as of 31 December 2014, and R&D expenses set to increase again in 2015 on the €13.3m recorded in FY14 (+68% vs FY13), a financing was expected this year. While partnering MGN1703 remains a possibility in 2015, we suggest a relatively low probability ahead of the key trial milestones in 2016.

## ...with the right objective in mind

MGN1703 is undergoing a 540-patient Phase III (IMPALA) study in metastatic CRC and a 100-patient Phase II (IMPULSE) trial in SCLC. Recruitment into IMPULSE is expected to complete by the end of 2015, with initial overall survival data due in 2016, while IMPALA should be fully enrolled by end-2016. With the proposed capital raise extending the cash runway into 2017, Molgen should be able to deliver IMPULSE data and IMPALA recruitment in 2016, which in turn could have a positive impact on partnering/fresh financing options for MGN1703.

## Valuation: Raised to €345m on FX benefit

Our rNPV of Molgen's product portfolio (MGN1703 + MGN1601) has increased to €336m (vs €293m), primarily due to a positive currency swing (now 1.1 \$:€ vs 1.3 previously). Including estimated end-Q115 cash of €9m, our overall valuation is now €345m (vs €305m) or €20.35/share (vs €18/share). The successful completion of the IMPULSE (2016) and IMPALA (2017) studies with MGN1703 remain the key near- and longer-term valuation drivers.

FY14 and capital raise

Pharma & biotech

2 April 2015

**Price** €5.50  
**Market cap** €94m

Net cash (€m) at 31 December 2014	13.6
Shares in issue	17.0m
Free float	53%
Code	MGN
Primary exchange	Frankfurt Prime Standard
Secondary exchange	N/A

## Share price performance



%	1m	3m	12m
Abs	4.4	(5.3)	(49.0)
Rel (local)	(1.5)	(23.1)	(59.5)
52-week high/low	€12.0	€4.9	

## Business description

Molgen is a German biotech company developing novel cancer immunotherapies. The lead products are MGN1703 (TLR9 agonist) for metastatic colorectal cancer maintenance (Phase III) and SCLC (Phase II); and MGN1601, an allogeneic renal cancer cell vaccine (Phase I/II).

## Next events

MGN1703: final OS data from IMPACT Phase II (CRC)	Q215
Q115 results	12 May 2015
MGN1703: complete recruitment in IMPULSE Phase II (NSCLC)	Q415
MGN1601 Phase II plans	H215

## Analysts

Christian Glennie	+44 (0)20 3077 5727
Dr John Savin	+44 (0)20 3077 5735
Dr Mick Cooper	+44 (0)20 3077 5734

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

## Valuation

We have maintained the key assumptions for MGN1703 and MGN1601 within our valuation model, but after adjusting for the positive currency movement since our [last report](#) in December (now 1.1 \$:€ vs 1.3 previously), the portfolio value has increased to €336m (vs €293m).

Including estimated end-Q115 cash of €9m, and excluding the proposed capital raise, our overall valuation is now €345m (vs €305m) or €20.35/share (vs €18/share). Our sum-of-the-parts DCF model applies a standard 12.5% discount rate and our key assumptions and metrics are summarised in Exhibit 1.

**Exhibit 1: Mologen valuation metrics and assumptions**

Product	Status	Market launch	NPV (€m)	Peak sales (\$m)	Probability of success	Royalty estimate	rNPV (€m)	rNPV share (€)	Key assumptions
MGN1703 - CRC - US	Phase III-ready	2018	129	429	65%	25%	82	4.81	~135,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2023); \$50,000 treatment price; 2023 patent expiry
MGN1703 - CRC - EU	Phase III	2018	213	629	65%	25%	134	7.89	~345,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2023); \$30,000 treatment price; 2025 patent expiry
MGN1703 - CRC - Japan	Phase III-ready	2020	14	92	50%	15%	7	0.41	~40,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2025); \$40,000 treatment price; eight yrs exclusivity.
MGN1703 - SCLC - US	Phase II-ready	2020	38	223	30%	15%	11	0.67	~225,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 20% peak share (2023); \$50,000 price; 2023 patent expiry.
MGN1703 - SCLC - EU	Phase II	2020	23	236	30%	15%	1	0.03	~310,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 25% peak share (2025); \$30,000 price; 2025 patent expiry.
MGN1703 - SCLC - Japan	Phase II-ready	2022	3	27	25%	15%	1	0.05	~38,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 25% peak share (2025); \$40,000 price; eight yrs exclusivity.
MGN1601 - RCC - US	Phase II-ready	2022	277	390	25%	70% operating margin	62	3.66	~63,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2024); \$75,000 treatment price; 12yrs BLA exclusivity (2032).
MGN1601 - RCC - EU	Phase II-ready	2022	179	259	25%	70% operating margin	38	2.22	~75,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2024); \$50,000 treatment price; 10yrs BLA exclusivity (2030).
MGN1601 - RCC - Japan	Phase II-ready	2022	3	25	25%	15%	1	0.05	~6,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2025); \$60,000 treatment price; BLA exclusivity (2030).
<b>Portfolio value</b>			<b>880</b>				<b>336</b>	<b>19.79</b>	
Cash							9	0.56	End-Q115e net cash
<b>Total</b>							<b>345</b>	<b>20.35</b>	16.97m shares out (excludes 1.26m stock options)

Source: Edison Investment Research. Note: Cancer incidence rates from [SEER/American Cancer Society/Globocan](#).

MGN1703 contributes the most to the valuation, with the key near-term drivers the outcome of the IMPULSE Phase II study in SCLC and ultimately the IMPALA Phase III trial in mCRC. Positive results would prompt higher probabilities of success, leading to potentially significant valuation increases (see unadjusted NPV).

MGN1703 is an immunomodulating drug (TLR9 agonist), developed as a maintenance treatment for use after effective induction chemotherapy, to reduce tumour burden and help stimulate a response against free circulating tumour-associated antigens. We see this as a potentially unique position in the wider burgeoning field of cancer immunotherapy.

To date, Mologen has reported encouraging preliminary overall survival (OS) data from a Phase II (IMPACT) study with MGN1703 in mCRC, particularly in certain subgroups of patients that are the subject of further investigation in the IMPALA trial. For example, at a recent oncology conference (AACR Tumor Immunology and Immunotherapy Conference), Mologen presented IMPACT data, which showed a pronounced OS benefit (24.5 months) vs placebo (15.1 months) in patients who

responded to prior induction chemotherapy (albeit in relatively small patient numbers). This result underscores the ongoing Phase III IMPALA study design, which will only select chemo-responders.

We assume that a licensing partner will be secured on successful completion of the IMPALA study, hence the 25% royalty rate in CRC, whereas the SCLC programme will have completed Phase II, giving a more modest 15% royalty. In reality, the royalty rate may fall somewhere between the two levels. However, we have not included any upfront fees and/or milestones that would be expected on securing a partner and successful commercialisation of the product, which offers further potential upside to our valuation.

While we assume a deal on completion of IMPALA, we note that a partnership could be secured ahead of IMPALA study data in 2017/18 (for example, on the back of positive IMPULSE data in 2016); this potential partnering scenario was highlighted in the recent [deal](#) between Bristol-Myers Squibb and Bavarian Nordic over Prostavac (Bavarian's cancer vaccine candidate), which is still midway through a Phase III trial in prostate cancer. BMS paid \$60m upfront and is committed to paying up to \$915m in further clinical, regulatory and commercial milestones.

## Sensitivities

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The key sensitivities relate to the clinical performance of MGN1703 and the company's ability to secure the additional financing (beyond the current proposed capital raise), and/or an appropriate partner, to complete the full clinical programme for MGN1703. Results from the IMPULSE Phase II study in SCLC (H116) and the IMPALA Phase III trial in mCRC (2017/18) will have a major bearing on MGN1703's chances of regulatory approvals and commercial success.

## Financials

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Mologen's net loss widened to €17.1m in FY14 (vs €10.8m in FY13) primarily due to increased R&D expenses in FY14 in support of the IMPALA and IMPULSE studies. R&D costs, as classified by Mologen, increased 68% in FY14 to €13.3m, which is mainly derived from 'cost of materials' (€8.7m in FY14) and 'personnel expenses' (€5.1m in FY14), as reported in the income statement.

This left a cash balance at 31 December 2014 of €13.6m, sufficient to Q415, hence the proposed capital raise. We assume the total allocation of new shares (5,657,875) will be fully subscribed (by existing and new shareholders) at €5.00 per share, raising gross proceeds of €28.3m, or €26.9m in estimated net proceeds (assuming 5% issue expense). We include the capital raise in our model, which now indicates that Mologen will be funded into H117. Importantly, this would provide the company with a cash runway that takes in some important milestones in 2016, particularly the primary analysis of the IMPULSE study data in SCLC and completion of patient recruitment into the IMPALA trial.

**Exhibit 2: Financial summary**

	€000s	2011	2012	2013	2014	2015e	2016e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>							
<b>Revenue</b>		<b>137</b>	<b>60</b>	<b>227</b>	<b>12</b>	<b>30</b>	<b>40</b>
Cost of Sales		0	0	0	0	0	0
<b>Gross Profit</b>		<b>137</b>	<b>60</b>	<b>227</b>	<b>12</b>	<b>30</b>	<b>40</b>
Research and development (cost of materials)		(2,384)	(1,763)	(2,904)	(8,687)	(9,990)	(10,190)
Selling, general & administrative (personnel expenses)		(3,126)	(3,561)	(4,364)	(5,113)	(5,266)	(5,372)
Other operating income / expense		(1,929)	(2,464)	(2,803)	(3,199)	(2,882)	(2,880)
<b>EBITDA</b>		<b>(7,302)</b>	<b>(7,728)</b>	<b>(9,844)</b>	<b>(16,987)</b>	<b>(18,108)</b>	<b>(18,401)</b>
<b>Operating Profit (before GW and except.)</b>		<b>(7,358)</b>	<b>(7,782)</b>	<b>(9,923)</b>	<b>(17,059)</b>	<b>(18,135)</b>	<b>(18,431)</b>
Intangible Amortisation		(236)	(257)	(935)	(38)	(89)	(68)
Exceptionals/Other		0	0	0	0	0	0
<b>Operating Profit</b>		<b>(7,594)</b>	<b>(8,039)</b>	<b>(10,858)</b>	<b>(17,097)</b>	<b>(18,224)</b>	<b>(18,499)</b>
Net Interest		109	53	30	19	21	23
Other		0	0	0	0	0	0
<b>Profit Before Tax (norm)</b>		<b>(7,249)</b>	<b>(7,729)</b>	<b>(9,893)</b>	<b>(17,040)</b>	<b>(18,115)</b>	<b>(18,408)</b>
<b>Profit Before Tax (FRS 3)</b>		<b>(7,485)</b>	<b>(7,986)</b>	<b>(10,828)</b>	<b>(17,078)</b>	<b>(18,203)</b>	<b>(18,476)</b>
Tax		0	0	0	0	0	0
Deferred tax		0	0	0	0	0	0
<b>Profit After Tax (norm)</b>		<b>(7,249)</b>	<b>(7,729)</b>	<b>(9,893)</b>	<b>(17,040)</b>	<b>(18,115)</b>	<b>(18,408)</b>
<b>Profit After Tax (FRS 3)</b>		<b>(7,485)</b>	<b>(7,986)</b>	<b>(10,828)</b>	<b>(17,078)</b>	<b>(18,203)</b>	<b>(18,476)</b>
Average Number of Shares Outstanding (m)		12.3	13.9	15.4	16.8	17.0	17.0
<b>EPS - normalised (€)</b>		<b>(0.59)</b>	<b>(0.56)</b>	<b>(0.64)</b>	<b>(1.01)</b>	<b>(1.07)</b>	<b>(1.08)</b>
<b>EPS - FRS 3 (€)</b>		<b>(0.61)</b>	<b>(0.57)</b>	<b>(0.70)</b>	<b>(1.02)</b>	<b>(1.07)</b>	<b>(1.09)</b>
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>							
<b>Fixed Assets</b>		<b>1,523</b>	<b>1,328</b>	<b>457</b>	<b>440</b>	<b>432</b>	<b>443</b>
Intangible Assets		1,385	1,147	237	206	135	81
Tangible Assets		134	178	220	234	297	362
Other		4	3	0	0	0	0
<b>Current Assets</b>		<b>8,308</b>	<b>24,457</b>	<b>15,480</b>	<b>14,613</b>	<b>24,204</b>	<b>6,648</b>
Stocks		33	21	33	30	28	28
Debtors		6	3	0	0	0	0
Cash		7,476	23,777	14,765	13,563	23,156	5,600
Other		793	656	682	1,020	1,020	1,020
<b>Current Liabilities</b>		<b>(1,109)</b>	<b>(882)</b>	<b>(943)</b>	<b>(1,747)</b>	<b>(1,747)</b>	<b>(1,747)</b>
Creditors		(1,109)	(882)	(943)	(1,747)	(1,747)	(1,747)
Short term borrowings		0	0	0	0	0	0
<b>Long Term Liabilities</b>		<b>(11)</b>	<b>(9)</b>	<b>(10)</b>	<b>(8)</b>	<b>(8)</b>	<b>(8)</b>
Long term borrowings		0	0	0	0	0	0
Other long term liabilities		(11)	(9)	(10)	(8)	(8)	(8)
<b>Net Assets</b>		<b>8,711</b>	<b>24,894</b>	<b>14,984</b>	<b>13,298</b>	<b>22,881</b>	<b>5,336</b>
<b>CASH FLOW</b>							
<b>Operating Cash Flow</b>		<b>(6,296)</b>	<b>(6,946)</b>	<b>(8,869)</b>	<b>(15,605)</b>	<b>(17,174)</b>	<b>(17,448)</b>
Net Interest		0	0	0	0	0	0
Tax		0	0	0	0	0	0
Capex		(268)	(117)	(146)	(93)	(108)	(108)
Acquisitions/disposals		1	2	1	0	0	0
Financing		9,311	23,362	8	14,495	26,875	0
Dividends		0	0	0	0	0	0
Other		0	0	0	0	0	0
Net Cash Flow		2,748	16,301	(9,006)	(1,203)	9,593	(17,556)
<b>Opening net debt/(cash)</b>		<b>(4,722)</b>	<b>(7,476)</b>	<b>(23,777)</b>	<b>(14,765)</b>	<b>(13,563)</b>	<b>(23,156)</b>
HP finance leases initiated		0	0	0	0	0	0
Exchange rate movements		6	0	(6)	1	0	0
Other		0	0	0	0	0	0
<b>Closing net debt/(cash)</b>		<b>(7,476)</b>	<b>(23,777)</b>	<b>(14,765)</b>	<b>(13,563)</b>	<b>(23,156)</b>	<b>(5,600)</b>

Source: Mologen accounts; Edison Investment Research

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