Mologen

FY15 update

Lefitolimod trials on track

Pharma & biotech

Mologen's pipeline is focused around lead candidate lefitolimod (MGN1703). Patient enrolment for IMPALA, the pivotal Phase III study in metastatic colorectal cancer (mCRC), continues on track and we expect full enrolment by end 2016. Data due in H117 from the IMPULSE Phase II trial in lung cancer could trigger a licensing deal. FY15 net cash of €24.6m should ensure IMPALA patient recruitment by year-end 2016. We have lowered our valuation of Mologen to €337m, or €14.89 per share, on a more protracted market launch timeline across the product portfolio.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	0.0	(17.0)	(1.01)	0.0	N/A	N/A
12/15	0.0	(20.5)	(0.98)	0.0	N/A	N/A
12/16e	0.0	(24.9)	(1.20)	0.0	N/A	N/A
12/17e	0.0	(25.8)	(1.24)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

IMPALA and IMPULSE: Major inflection points near

Lefitolimod (MGN1703), an innovative DNA-based TLR9 agonist, is currently in four clinical trials. In January Mologen announced preliminary demographic data for the first 200 patients in its most advanced study, the 540-patient Phase III IMPALA trial in mCRC; full patient enrolment is expected by end 2016. Results from lefitolimod's Phase II IMPULSE trial in small cell lung cancer (SCLC), which completed patient enrolment in 2015, are expected in H117. This could potentially trigger a licensing deal and consequently additional funding options for lefitolimod.

TEACH study extension

Initial data for the use of lefitolimod to treat HIV patients (TEACH study) have demonstrated that it increases activation of key immune markers. Encouraged by this response, investigators have extended the patient dosing regimen. Dosing has been extended from one to six months; final results are now expected H117.

Combination therapy: Increasing the appeal

A combination study of Mologen's lead candidate lefitolimod with Yervoy (Bristol-Myers Squibb), an immune checkpoint inhibitor, has been announced. The combination of two immunotherapies has potential synergistic effects on survival. While Yervoy's safety record is a concern, lefitolimod has previously demonstrated a good safety profile; if this is maintained while increasing efficacy over the monotherapy, lefitolimod's licensing appeal increases.

Valuation: €337m (€14.89/share)

We have reduced our valuation of Mologen to €337m (vs €387m) or €14.89/share (vs €17). Our lower valuation is attributed to a change in market launch times across the product portfolio. Our model suggests a cash runway into 2017; we forecast additional illustrative financing of €30m in FY16.

13 April 2016

Price	**€3.73**
Market cap	**€84m**

Net cash (€m) at 31 December 2015	24.6
Shares in issue	22.6m
Free float	52%
Code	MGN
Primary exchange	Frankfurt Prime Standard
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(9.7)	(24.7)	(29.4)
Rel (local)	(9.1)	(23.0)	(10.5)
52-week high/low		€5.6	€3.4

Business description

Mologen is a German biotech company developing novel immunotherapies. The lead products are lefitolimod (TLR9 agonist) for metastatic colorectal cancer maintenance, SCLC and HIV; and MGN1601, an allogeneic renal cell vaccine.

Next events

First patient-in-combination trial	H116
Strategic review	H116
IMPALA recruitment completed	H216
IMPULSE: start analysis	Q416

Analysts

Dr Susie Jana +44 (0) 20 3077 5700

Daniel Wilkinson +44 (0)20 3077 5734

healthcare@edisongroup.com

Edison profile page

Mologen is a research client of Edison Investment Research Limited

Valuation

We have reduced our valuation of Mologen to €337m (€14.89/share); 60% of the reduction is due to the adjustment in market launch times relating to lefitolimod in its lead indication metastatic colorectal cancer (CRC). We now expect lefitolimod for CRC to launch in 2019 (vs 2018 previously) in the EU and 2020 (vs 2018) in the US. Timelines have also been extended across the portfolio to more realistically reflect launch expectations. We await the new management's strategy review in H116 for further insight into the launch timetables. Our other assumptions remain unchanged and our sum-of-the-parts DCF model remains at a standard 12.5% discount rate. We do not currently ascribe any value to the HIV indication or combination trial as we await further clarity on the deployment of cash resources from the expected portfolio review in H116. Our key assumptions and valuation metrics are summarised in Exhibit 1 below.

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	2020	103	301	65%	25%	65	2.86	~135,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2023); $50,000 treatment price; 2025 patent expiry
MGN1703: CRC - EU	Phase III	2019	211	613	65%	25%	135	5.97	~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	2021	13	81	50%	15%	7	0.29	~40,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2025); $40,000 treatment price; 8 yrs exclusivity
MGN1703: SCLC - US	Phase II-ready	2022	32	153	30%	15%	9	0.42	~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	2022	22	162	30%	15%	3	0.12	~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	2023	3	19	25%	15%	1	0.03	~38,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 25% peak share (2025); $40,000 price;
MGN1601: RCC - US	Phase II-ready	2023	248	344	25%	70% operating margin	57	2.54	~63,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2024); $75,000 treatment price; 12 yrs BLA exclusivity (2032)
MGN1601: RCC - EU	Phase II-ready	2023	158	229	25%	70% operating margin	35	1.54	~75,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2024); $50,000 treatment price; 10 yrs BLA exclusivity (2030)
MGN1601: RCC - Japan	Phase II-ready	2023	3	22	25%	15%	1	0.03	~6,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2025); $60,000 treatment price; BLA exclusivity (2030)
Portfolio value			793				312	13.80	
Cash							25	1.09	Net cash at 31 December 2015
Total							337	14.89	22.6m shares out

Source: Edison Investment Research. Note: Cancer incidence rates from SEER/American Cancer Society/Globocan.

Lefitolimod (MGN1703) across CRC and SCLC accounts for 65% of our total €337m valuation. The outcome of the IMPULSE Phase II study in SCLC and ultimately the IMPALA Phase III trial in mCRC are the key near-term drivers. Positive results would prompt higher probabilities of success, leading to potentially significant valuation increases (see unadjusted NPV).

Lefitolimod is an immunomodulating drug (TLR9 agonist) that broadly activates the immune system, enabling it to increase the recognition and combat of cancer cells. It is being developed as a maintenance treatment for use after effective induction chemotherapy to reduce tumour burden by building a specific response based on free circulating tumour-associated antigens.

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. These results have shaped the design of the IMPALA trial now underway. For example, only patients who

have responded to induction chemotherapy are eligible for the IMPALA trial, following the findings of a pronounced OS benefit (24.5 months) vs placebo (15.1 months) in these patients (albeit in relatively small patient numbers).

Our valuation assumes that a licensing partner will be secured on successful completion of the IMPALA study, with a 25% royalty rate in mCRC. Since the SCLC programme will have completed Phase II, we assume 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 2017).

For MGN1601, we assume Mologen will commercialise the product itself in the US and Europe, with a 15% COGS and 15% marketing costs, giving a 70% operating margin. A partner would be required in Japan/RoW and therefore royalties would be receivable (estimated at 15%).

Sensitivities: Clinical execution risk

The key sensitivities relate to the clinical performance of MGN1703 and the company's ability to secure the additional financing, and/or a partner, to complete the full clinical programme. Results from the IMPULSE and IMPALA studies will have a major bearing on MGN1703's chance of regulatory approvals and commercial success. We have made assumptions about the potential market opportunity available to MGN1703, which do not currently include significant stratification of patient populations. MGN1703 may be most active in certain subgroups, which could reduce the target patient pool. However, confirmed activity in a patient subset may result in a higher treatment price, greater reimbursement rates and more favourable economic terms from any partnership.

Future development of MGN1601 is dependent on funding and/or partnerships. At present MGN1703 is the priority, although we currently assume that with new management in place active development of MGN1601 may resume in 2016.

Financials

Cash at 31 December 2015 was €24.6m, which includes the capital raise in April 2015 when €28.3m gross (€26.2m net) was raised from the rights issue (one-for-three) of c 5.7m new shares at €5.00 per share. Our model suggests that current cash is sufficient to fund operations to early 2017, depending on the progress of the IMPULSE and IMPALA studies for MGN1703. Importantly, this provides a cash runway that accommodates 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. However, a funding gap remains in respect of the IMPALA study (primary endpoint estimated by end-2017). We estimate this to be in the €25-35m range and include an illustrative €30m financing, nominally attributed to debt, in our FY16 forecasts, to allow completion of the study. The size and timing of the financing may vary significantly and could be influenced by the outcome of the IMPULSE study (H216) and potential licensing deals.

A net loss of €20.5m as reported (vs €17.1m in 2014) primarily reflects increased R&D expenditure in FY15 of €16.8m (vs €13.3m in FY14). R&D expense, as classified by Mologen, is mainly derived from "cost of materials" of €11m (€8.7.m in FY14) and "personnel expenses" of €5.1m (€5.1.m in FY14), as reported in the income statement. Mologen continues to expect R&D increases in FY16, mainly in support of the IMPALA and IMPULSE trials, with this expected to drive a higher net loss

than in 2015. We forecast FY16 R&D (cost of materials) costs of €15.4m and SG&A (personnel expenses) of €5.2m. Our forecast net loss for FY16 is €24.9m.

Exhibit 2: Financial summary

€'000s	2013	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	227	12	39	40	50
Cost of Sales	0	0	0	0	0
Gross Profit	227	12	39	40	50
Research and development (cost of materials)	(2,904)	(8,687)	(11,011)	(15,415)	(16,186)
Selling, general & administrative (personnel expenses)	(4,364)	(5,113)	(5,074)	(5,175)	(5,227)
Other operating income / expense	(2,803)	(3,199)	(4,372)	(4,368)	(4,368)
EBITDA	(9,844)	(16,987)	(20,418)	(24,919)	(25,731)
Operating Profit (before GW and except.)	(9,923)	(17,059)	(20,499)	(24,943)	(25,762)
Intangible Amortisation	(935)	(38)	(40)	(88)	(53)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(10,858)	(17,097)	(20,539)	(25,030)	(25,815)
Net Interest	30	19	3	25	8
Other	0	0	0	0	0
Profit Before Tax (norm)	(9,893)	(17,040)	(20,496)	(24,918)	(25,755)
Profit Before Tax (FRS 3)	(10,828)	(17,078)	(20,536)	(25,006)	(25,807)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(9,893)	(17,040)	(20,496)	(24,918)	(25,755)
Profit After Tax (FRS 3)	(10,828)	(17,078)	(20,536)	(25,006)	(25,807)
Average Number of Shares Outstanding (m)	15.4	16.8	20.8	20.8	20.8
EPS - normalised (c)	(0.64)	(1.01)	(0.98)	(1.20)	(1.24)
EPS - FRS 3 (c)	(0.70)	(1.02)	(0.99)	(1.20)	(1.24)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	457	440	414	411	435
Intangible Assets	237	206	175	105	63
Tangible Assets	220	234	239	306	372
Other	0	0	0	0	0
Current Assets	15,480	14,613	25,981	31,523	6,248
Stocks	33	30	28	28	27
Debtors	0	0	0	0	0
Cash	14,765	13,563	24,592	30,134	4,860
Other	682	1,020	1,361	1,361	1,361
Current Liabilities	(943)	(1,747)	(6,886)	(6,886)	(6,886)
Creditors	(943)	(1,747)	(6,886)	(6,886)	(6,886)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(10)	(8)	(6)	(30,006)	(30,006)
Long term borrowings	0	0	0	(30,000)	(30,000)
Other long term liabilities	(10)	(8)	(6)	(6)	(6)
Net Assets	14,984	13,298	19,503	(4,958)	(30,209)
CASH FLOW					
Operating Cash Flow	(8,869)	(15,602)	(15,095)	(24,349)	(25,168)
Net Interest	0	3	0	0	0
Tax	0	(6)	12	0	0
Capex	(146)	(93)	(95)	(109)	(106)
Acquisitions/disposals	1	0	0	0	0
Financing	8	14,495	26,207	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(9,006)	(1,203)	11,029	(24,458)	(25,274)
Opening net debt/(cash)	(23,777)	(14,765)	(13,563)	(24,592)	(134)
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	(6)	1	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(14,765)	(13,563)	(24,592)	(134)	25,140

Source: Mologen accounts; Edison Investment Research

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand