EDISON

Mologen

H115 results and update

MGN1703 leading the way

Pharma & biotech

Mologen's lead product, MGN1703, is currently in three clinical trials for different indications. The €28.3m (gross) proceeds from the rights issue in April 2015 mean Mologen should have sufficient funds to reach full recruitment of IMPALA (Phase III in colorectal cancer) and top-line data from IMPULSE (Phase II in small-cell lung cancer). The IMPULSE data (H216) could have a positive impact on partnering or financing options for MGN1703. We value Mologen at €384m.

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)	(0.90)	0.0	N/A	N/A
15/16e	0.0	(20.0)	(0.96)	0.0	N/A	N/A

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

MGN1703: Multiple clinical trials underway

MGN1703 is an innovative DNA-based TLR9 agonist currently undergoing three clinical trials. IMPALA is a 540-pt pivotal study in metastatic colorectal cancer. Full enrolment is expected by end-2016 and data by end-2017. Recruitment for the IMPULSE Phase II study in small-cell lung cancer (100-pt) should complete by end-2015. This could see initial overall survival (OS) data in H216. Finally, in June 2015, enrolment began in the TEACH study to treat HIV. The study is being run by the Danish Aarhus University Hospital and is the first non-cancer study for MGN1703.

Funded through to key milestones

The €28.3m gross proceeds from the rights issue in April 2015 have provided sufficient funding to extend the cash runway into 2017, taking in some important milestones. This includes full enrolment of the IMPULSE and IMPALA studies (Q415 and Q416 respectively) and the initial data readout from IMPULSE in H216.

IMPULSE data in 2016 could trigger partnership

The IMPULSE data could have a major impact on partnering and financing options for MGN1703, potentially covering the cash shortfall required for the completion of IMPALA. In the near term, promising data from the TEACH study could lend support to the extension of MGN1703 beyond cancer applications. Further funding could also allow MGN1601, a renal cell cancer vaccine, to advance into Phase II.

Valuation: €384m (€17/share)

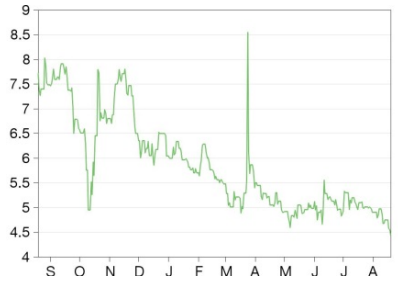
Our rNPV of Mologen's product portfolio (MGN1703 + MGN1601) has increased to €384m (vs €345m), primarily due to rolling the model forward and updating for €35m cash; this is diluted to €17/share (vs €20) based on the higher share count. We forecast illustrative additional financing of €30m in 2017 in respect of the IMPALA study.

20 August 2015

Price	**€4.45**
Market cap	**€101m**

Net cash (€m) at 30 June 2015	34.9
Shares in issue	22.6m
Free float	54%
Code	MGN
Primary exchange	Frankfurt Prime Standard
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(12.7)	(8.8)	(40.7)
Rel (local)	(4.6)	1.2	(48.2)
52-week high/low		€8.6	€4.6

Business description

Mologen is a German biotech company developing novel cancer immunotherapies. The lead products are MGN1703 (TLR9 agonist) for metastatic colorectal cancer maintenance and SCLC that has also recently started a study in HIV; and MGN1601, an allogeneic renal cancer cell vaccine.

Next events

MGN1703: complete recruitment in IMPULSE Phase II (SCLC)	Q415
MGN1703: data from TEACH Phase I/IIa (HIV)	Q415
MGN1703: final OS data from IMPACT Phase II (CRC)	H215
MGN1703: primary analysis of OS data from IMPULSE	H216

Analysts

Dr Lucy Codrington +44 (0)20 3681 2527

Christian Glennie +44 (0)20 3077 5727

healthcare@edisongroup.com

Edison profile page

Corporate update

In July, it was announced that Dr Mariola Söhngen will take over as CEO, with effect from 1 November 2015. Dr Söhngen is the co-founder of Paion AG, where she currently serves as chief medical officer. Following a transitional period, the current CEO, Dr Matthias Schroff will leave the company on 31 December 2015. The company is in the process of recruiting a new CFO to replace Jörg Petraß, who has decided not to extend his contract. He will leave on 31 December 2015.

Valuation

Our valuation of Mologen has increased to €384m (vs €345m) with rolling forward in time, and updating for end-H115 cash of €35m (including the €28m gross capital raise from the issue of c 5.7m new shares). Our per-share valuation is now diluted to €17/share (vs €20.35/share) based on the increased share count following the raise. Our key assumptions for MGN1703 and MGN1601 have been maintained. Our sum-of-the-parts DCF model applies a standard 12.5% discount rate. Our key assumptions and valuation 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	133	429	65%	25%	85	3.74	~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	221	629	65%	25%	140	6.16	~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	0.32	~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	39	223	30%	15%	12	0.52	~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	25	236	30%	15%	2	0.08	~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	0.04	~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	286	390	25%	70% operating margin	64	2.83	~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	185	259	25%	70% operating margin	39	1.72	~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	4	25	25%	15%	1	0.04	~6,000 RCC cases/yr; 35% advanced RCC; 15% peak penetration (2025); $60,000 treatment price; BLA exclusivity (2030).
Portfolio value			**910**				**349**	**15.44**	
Cash							35	1.54	End-H115 net cash
Total							**384**	**16.99**	20.6m 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. The outcome of the IMPULSE Phase II study in small-cell lung cancer (SCLC) and ultimately the IMPALA Phase III trial in metastatic colorectal cancer (mCRC) are the key near-term drivers. Positive results would prompt higher probabilities of success, leading to potentially significant valuation increases (see unadjusted NPV). Given the early stage of development, we do not include its use in HIV at present.

MGN1703 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 and help stimulate a response against 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 that are the subject of further investigation in the IMPALA trial. For example, only patients who have responded to induction chemotherapy are eligible for the IMPALA trial, following the finding 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 2016).

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

The key sensitivities relate to the clinical performance of MGN1703 and the company's ability to secure the additional financing and/or an appropriate partner to complete the full clinical programme for MGN1703. Results from the IMPULSE Phase II study in SCLC (H216) 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

Cash as of 30 June 2015 was €34.9m, which includes the capital raise in April 2015 when €28.3m gross (€26.8m 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 mid-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. There does, however, remain a funding gap, 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 new FY17 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 €6.9m (vs €7.9m in H114) primarily reflects reduced R&D expenditure in H115 of €5.2m (vs €5.9m in H114). R&D expense, as classified by Mologen, is mainly derived from "cost of materials" of €2.5m (€3.7m in H114) and "personnel expenses" of €2.6m (€2.7m in H114), as reported in the income statement. Mologen continues to expect R&D to increase in H215, mainly in support of the IMPALA and IMPULSE studies, with this expected to drive a higher net loss than in 2014 (€17.1m loss reported). Hence, at this stage, we have made no major changes to our FY15 R&D forecast (cost of materials) of €9.2m, even though this will require a large uptick in spend in

H215. Our estimated SG&A (personnel expenses) has increased slightly to €5.6m (vs €5.1m previously forecast). Our forecast net loss for FY15 has increased accordingly to €18.1m (from €17.3m), in line with management's reiterated financial outlook.

Exhibit 2: Financial summary

€'000s	2013	2014	2015e	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	227	12	54	40	50
Cost of Sales	0	0	0	0	0
Gross Profit	227	12	54	40	50
Research and development (cost of materials)	(2,904)	(8,687)	(9,217)	(11,060)	(8,295)
Selling, general & administrative (personnel expenses)	(4,364)	(5,113)	(5,617)	(5,729)	(5,787)
Other operating income / expense	(2,803)	(3,199)	(3,279)	(3,275)	(3,275)
EBITDA	(9,844)	(16,987)	(18,059)	(20,025)	(17,307)
Operating Profit (before GW and except.)	(9,923)	(17,059)	(18,082)	(20,050)	(17,335)
Intangible Amortisation	(935)	(38)	(87)	(77)	(46)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(10,858)	(17,097)	(18,169)	(20,127)	(17,382)
Net Interest	30	19	18	24	1
Other	0	0	0	0	0
Profit Before Tax (norm)	(9,893)	(17,040)	(18,063)	(20,025)	(17,334)
Profit Before Tax (FRS 3)	(10,828)	(17,078)	(18,150)	(20,103)	(17,380)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(9,893)	(17,040)	(18,063)	(20,025)	(17,334)
Profit After Tax (FRS 3)	(10,828)	(17,078)	(18,150)	(20,103)	(17,380)
Average Number of Shares Outstanding (m)	15.4	16.8	20.1	21.0	21.0
EPS - normalised (€)	(0.64)	(1.01)	(0.90)	(0.96)	(0.83)
EPS - FRS 3 (€)	(0.70)	(1.02)	(0.90)	(0.96)	(0.83)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	457	440	400	372	369
Intangible Assets	237	206	155	93	56
Tangible Assets	220	234	245	279	313
Other	0	0	0	0	0
Current Assets	15,480	14,613	24,768	5,405	18,756
Stocks	33	30	27	27	26
Debtors	0	0	0	0	0
Cash	14,765	13,563	24,109	4,748	18,098
Other	682	1,020	631	631	631
Current Liabilities	(943)	(1,747)	(3,216)	(3,216)	(3,216)
Creditors	(943)	(1,747)	(3,216)	(3,216)	(3,216)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(10)	(8)	(7)	(7)	(30,007)
Long term borrowings	0	0	0	0	(30,000)
Other long term liabilities	(10)	(8)	(7)	(7)	(7)
Net Assets	14,984	13,298	21,944	2,555	(14,099)
CASH FLOW					
Operating Cash Flow	(8,869)	(15,605)	(15,481)	(19,288)	(16,579)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(146)	(93)	(67)	(74)	(71)
Acquisitions/disposals	1	0	0	0	0
Financing	8	14,495	26,095	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(9,006)	(1,203)	10,546	(19,362)	(16,650)
Opening net debt/(cash)	(23,777)	(14,765)	(13,563)	(24,109)	(4,748)
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)	(24,109)	(4,748)	11,902

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