EDISON

Mologen

Post-interim results update

'Next Level' on track

Pharma & biotech

Mologen's interim results have confirmed the implementation of its 'Next Level' strategic review. This is focused on the development and commercialisation of lead candidate lefitolimod (oncology and HIV) across its four clinical trial programmes and the next-generation molecules EnanDIM (TLR9 agonist), effectively evolving Mologen into a more product-focused company. Partnering opportunities for lefitolimod are being actively sought. We anticipate Phase II IMPULSE (SCLC) data in early/mid-2017 and initial Phase III IMPALA (mCRC) data 24 months after final patient recruitment to drive the shares. We value Mologen at €201m (€8.87/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/14	0.0	(17.0)	(1.01)	0.0	N/A	N/A
12/15	0.0	(20.5)	(0.99)	0.0	N/A	N/A
12/16e	0.0	(24.9)	(1.10)	0.0	N/A	N/A
12/17e	0.0	(25.8)	(1.14)	0.0	N/A	N/A

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

'Next Level' evolution

To ensure evolution from a research-based to a product-oriented company, Mologen is focusing near-term efforts on developing lefitolimod (TLR9 agonist) for potential commercialisation; manufacturing efforts will be out-sourced to achieve suitable scale. Mologen's move to a more clinical development-focused company means preclinical R&D assets (MIDGE vector system) will be spun off or divested while MGN1601 (renal cancer vaccine) is on hold.

IMPULSE and IMPALA critical share price drivers

Focus in the near term will naturally centre on lefitolimod and its four ongoing clinical trial programmes; notably Phase III (IMPALA) and Phase II (IMPULSE) maintenance trials for mCRC and SCLC respectively. We anticipate IMPULSE (SCLC) data in early/mid-2017 and IMPALA (mCRC) initial data approximately 24 months after final patient recruitment to be the next major share price drivers. Additionally, during the past six months Mologen has extended the TEACH 'study (HIV) following positive initial results and has announced a collaboration with the MD Anderson Cancer center on recruitment of the first patient in the Phase I combination study with the immunotherapy ipilimumab (Yervoy) for advanced solid malignancies.

Valuation: €201m or €8.87 per share

Our valuation of Mologen remains at €201m or €8.87/share. We assume lefitolimod will be out-licensed in oncology in 2018 and have valued royalties accordingly; however, we do not model in any potential upfront or milestone payments. Our model suggests a cash runway into early 2017; we forecast additional illustrative financing of €30m in 2016. Following the AGM, Mologen has announced its intention to carry out a cash capital increase from authorised capital to extend the cash runway further; this is critical to fund lefitolimod's development out to 2018.

1 September 2016

Price	**€1.73**
Market cap	**€38m**
Net cash (€m) at 30 June 2016	15.3
Shares in issue	22.6m
Free float	55%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(6.7)	(48.4)	(61.6)
Rel (local)	(9.0)	(50.0)	(62.8)
52-week high/low		€5.1	€1.3

Business description

Mologen is a German biotech company developing novel immunotherapies. Lead product lefitolimod (TLR9 agonist) is being evaluated in metastatic colorectal cancer maintenance, small cell lung cancer maintenance, HIV and a combination trial in advanced solid malignancies.

Next events

IMPALA recruitment completed	End 2016/Q117
IMPULSE: Start analysis	Q416
IMPULSE data	H117
IMPALA initial data	24 months after final patient enrolment

Analysts

Dr Susie Jana +44 (0) 20 3077 5700

Daniel Wilkinson +44 (0)20 3077 5734

healthcare@edisongroup.com

Edison profile page

Lefitolimod commercialisation is key

'Next Level' aims to prepare Mologen's lead product candidate lefitolimod for a potential market approval. IMPALA (Phase III mCRC) and IMPULSE (Phase II SCLC) trials continue as planned, with completion of patient recruitment for IMPALA expected by end 2016/Q117 (results expected approximately 24 months after last patient enrolment) and the results of IMPULSE in H117. We assume the launch of lefitolimod in its first indication (the maintenance treatment of metastatic colorectal cancer) will be in 2020 for Europe and 2021 for the US; we model that out-licensing in oncology indications will be achieved in 2018. Outsourcing of manufacturing will enable Mologen to effectively ramp up its production capacity and potentially multi-source its supply line through contract manufacturing, further increasing the licensing appeal of lefitolimod if IMPALA and/or IMPULSE are positive. Earlier-stage trials include a Phase I TEACH study in HIV, which has started its expansion study (final results due in H117), while a Phase I combination trial with ipilimumab (Yervoy) in advanced malignancies has started enrolment (potential data readout by 2019) could increase the licensing appeal of lefitolimod in oncology if results are positive.

Outsourcing key to strategy

Mologen has recognised that it does not have the sufficient capabilities in house to ramp up the manufacturing of lefitolimod for a potential market launch. It will close in-house clinical supply manufacturing and look for a contract manufacturer with the capacity and expertise needed to deliver lefitolimod in market quantities. This enables a solid production line to be put in place, while controlling costs that would be incurred if Mologen invested in the expertise and facilities needed to internally scale production. Furthermore, multiple manufacturers could be used to enable protection of lefitolimod supply. Additionally, early-stage, in-house R&D will be outsourced as Mologen directs its attention to clinical assets. All outsourcing activities will be led by Mologen staff, ensuring expertise and knowledge is retained in house.

Building commercialisation expertise

Mologen has indicated that it is proactively searching for licensing partners and has brought in a consultancy firm specialising in biotechnology. The team is expected to aid the Executive Board in evaluating and assessing strategic options that have arisen from the 'Next Level' strategy. A key objective will be refining the business case around lefitolimod and how it is targeting and searching for licensing partners. As commercialisation opportunities near, we assume internal expertise will be brought on board to support this process. While headcount is initially being reduced (in R&D and manufacturing), we expect numbers to remain steady in the mid-term as commercial expertise is brought on board. The successful commercialisation of lefitolimod is key for Mologen's current strategy and the timing and terms will have a substantial impact on the company's future, with the results of both IMPALA and IMPULSE key to any future deal.

More detail on lefitolimod and the 'Next Level' strategy can be found in our July 2016 update; 'Next Level of development'.

Valuation

Our valuation of Mologen remains unchanged at €201m or €8.87/share. We assume lefitolimod will be out-licensed in oncology in 2018 and have valued royalties accordingly; however, we do not model in any potential upfront or milestone payments. Our model suggests a cash runway into early 2017; we forecast additional illustrative financing of €30m in 2016. Following the AGM Mologen has announced its intention to carry out a cash capital increase from authorized capital to extend the cash runway further; this is critical to fund lefitolimod's development out to 2018.

Full details of our valuation methodology and assumptions can be found in our July 2016 note.

Financials

Cash at 30 June 2016 was €15.3m, 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 the next six months, particularly the primary analysis of the IMPULSE study data in SCLC (expected H216 – data expected H117) and completion of patient recruitment in the IMPALA trial at end 2016/Q117. However, a funding gap remains in respect of the IMPALA study (primary endpoint estimated by end-2018). 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 for completion of the study. Mologen has announced that funding will be covered by existing authorised capital, together with existing authorisation to use conditional capital.

In terms of operating costs for H116, R&D expenses increased to €7.1m vs €5.2m in H115 translating to an in increase in operating losses (EBIT) of €9.8m vs €6.9m in H115. The increased R&D costs are expected to continue 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 remains unchanged at €24.9m.

Exhibit 1: 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	20.7	22.6	22.6
EPS - normalised (c)	(0.64)	(1.01)	(0.99)	(1.10)	(1.14)
EPS - FRS 3 (c)	(0.70)	(1.02)	(0.99)	(1.10)	(1.14)
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: Company 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