EDISON

Mologen

Corporate update

SCLC data - subgroup analysis hints at benefit

Pharma & biotech

Top-line data from Mologen's Phase II small cell lung cancer trial (IMPULSE) have been announced. Positive responses in two subgroups hint at a treatment-related benefit in certain subsets. However, the trial missed its primary endpoint of overall survival in the total study population. Additionally, in line with previous data, an agreeable safety profile was reported. We expect the data to further inform partnership discussions in the near term. The 'Next Level' strategy has now been implemented and the pipeline continues to move towards commercialisation. We value Mologen at €252m (€7.33/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	0.0	(20.5)	(0.99)	0.0	N/A	N/A
12/16	0.1	(20.8)	(0.91)	0.0	N/A	N/A
12/17e	0.0	(21.4)	(0.63)	0.0	N/A	N/A
12/18e	0.0	(15.9)	(0.47)	0.0	N/A	N/A

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

IMPULSE top-line data positive in certain subgroups

Mologen's Phase II SCLC trial (IMPULSE) demonstrated benefit in patients with a low count of activated B cells (hazard ratio: 0.59; 95% confidence interval [CI]: 0.29-1.21) and patients with chronic obstructive pulmonary disease (hazard ratio 0.54; 95% CI: 0.21-1.38). The large confidence intervals reported indicate the low powering of the subgroup analysis; as such, further trials and data will be needed to confirm the observations. The company reported a favourable safety profile.

Q117 Financials: Funded into early 2018

Q117 results highlight the continued progression of Mologen's clinical pipeline (IMPALA patient recruitment is complete). Costs of materials at €3.0m (Q116: €2.4m) increased slightly while personnel expenses at €1.2m (Q116: €1.3m) remained steady. A net loss of €5.2m was reported for Q116 (Q115: €4.5m). Recent bond issues alongside a capital increase will fund Mologen to early 2018, with data from IMPULSE and TEACH key to any further funding or partnerships in the short term.

Strategy: 'Next Level' implemented

In June 2016, Mologen announced its 'Next Level' strategy, which focused its resources on the lead TLR9 agonist lefitolimod and its EnanDIM platform. This focusing of the pipeline along with the outsourcing of basic research is complete and we expect Mologen to continue to prepare for the potential commercialisation of lefitolimod (identification of a contract manufacturer for lefitolimod is advanced).

Valuation: €252m (€7.33/share)

We have rolled forward our model, which has increased the portfolio value, but this was slightly offset by a reduction in value attributable to changes in assumption for the SCLC indication. Portfolio value has increased to €7.44/share versus €7.20/share previously. However, this is offset by a reduction in net cash (minus interest bearing debt), which is now modelled as of end-2017 at -€0.11/share (vs €0.47 previously). We value Mologen at €252m (€7.33/share).

16 May 2017

Price	**€3.67**
Market cap	**€126m**
Net cash (€m) at 31 March 2017	19.4
Shares in issue	34.2m
Free float	58%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	32.8	11.2	8.1
Rel (local)	25.6	2.4	(16.0)
52-week high/low		€3.8	€1.2

Business description

Mologen is a German biopharmaceutical company developing novel biopharmaceuticals. 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

IMPULSE full data presented	Q317
TEACH data	Mid-2017
IMPALA data	Mid-2019

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IMPULSE data: Top line delivers mixed results

IMPULSE is an exploratory Phase II trial in patients with small cell lung cancer (SCLC) that is testing the effect of lefitolimod as a maintenance treatment on overall survival. Patients must have achieved at least a partial response following platinum-based, first-line therapy. Participants in the trial are split between two treatments arms, with one arm receiving lefitolimod while the other arm receives local standard of care. With 102 patients enrolled in the trial, it is the largest single data package to date on lefitolimod and will further inform partnering and licensing discussions.

The recently announced top-line data did not meet the primary endpoint in the total patient population of overall survival. However, two pre-defined subgroups hinted at a potentially significant survival benefit. These were in patients with a low count of activated B cells (hazard ratio: 0.59; 95% confidence interval [CI]:0.29-1.21) and patients with chronic obstructive pulmonary disease (COPD) (hazard ratio 0.54; 95% CI: 0.21-1.38). While exact patient numbers in each group were not disclosed, approximately 50% of all patients had a low count of activated B cells and 25% had COPD. The low power of the exploratory subgroup analysis means confidence intervals are broad and statistically include the possibility that patients performed worse on lefitolimod. We do note that SCLC is a difficult indication to treat and the five-year relative survival rate in stage 1 patients is 31%, dropping off to 2% in stage 5 patients. Subsequently, the response in the subgroups is a positive development, but at this stage only exploratory in nature. As such, additional trials and further data are needed to confirm these initial data.

The most common adverse events (AEs) reported by the company were cough (25% vs 7.7% in control group) and headache (21.7% vs 5.1% in control group). The full data package will be presented at an upcoming scientific conference and the final readout is expected in Q118, approximately 24 months after patient enrolment. We have adjusted our valuation to account for the new data, a summary of which can be found in the valuation section of this report.

Outside of the IMPULSE trial, additional milestones are expected throughout 2017; the IMPALA (Phase III metastatic colorectal cancer) trial continues as planned – most recently, this has included the completion of patient recruitment (540 patients) (results are expected in 2019). The Phase I TEACH study in HIV has started its expansion study and final results are expected in late summer. The Danish Aarhus University Hospital, one of Mologen's partners, recently presented positive data from the ongoing trial that demonstrated lefitolimod induced an antiviral immune response without causing unwanted destructive tissue inflammation. Additionally at the start of the year, Aarhus University Hospital announced that it had received a $2.75m grant from Gilead. The grant is to fund a clinical trial with lefitolimod in combination with novel virus-neutralising antibodies developed by Rockefeller University. The two unique modes of action are hoped to act in a "kick-and-kill" manner, where latent virus is woken up ("kick") in the infected cells before being subsequently "killed" by the activated immune system; lefitolimod is believed to aid in both the "kick" and "kill" stages.

Finally a Phase I combination trial with ipilimumab (Yervoy) in advanced malignancies is enrolling (potential data readout by 2019) and positive results could increase the appeal of lefitolimod in oncology.

Preclinical data hints at potential with ICIs

Mologen's lead candidate lefitolimod (TLR9 agonist) demonstrated promising efficacy in mouse models when used in combination with a PD-1 or a PD-L1 immune checkpoint inhibitor (ICI). In an A20 lymphoma model, mean tumour growth inhibition (TGI) of 45.9% for PD-1 antibody treated and 49.8% for lefitolimod treated mice was observed. However, when used in combination the TGI increased dramatically to 99.1% and consequently at 60 days, survival was 100% compared with approximately 33% for the PD-1 antibody and lefitolimod when used as monotherapies. In a separate colon carcinoma (CT26) mouse model, a lefitolimod and a PD-L1 combination demonstrated a mean TGI of 48.4% compared with 27.6% for lefitolimod alone. The PD-L1 ICI had no effect on tumour growth when used as a monotherapy. This early pre-clinical data highlights the potential of ICI combinations with lefitolimod, however clinical data is needed in what is now a hotly contested sector.

The benefits of combining a TLR9 agonist with checkpoint inhibitors was further highlighted by recent data demonstrating the effect EnanDIM compounds (Mologen's next-generation TLR9 agonists) had on a colon carcinoma CT26 mouse model. EnanDIM532 and a PD-1 antibody demonstrated 28.3% and 57.0% TGI, respectively, when utilised as monotherapies, while the combination of both reduced tumour growth substantially, represented by 74.7% TGI.

Financials

Cash at 31 March 2017 was €19.4m, which includes the recent January bond issue of net €4.99m. Our model suggests that current cash is sufficient to fund operations into early 2018; this provides a cash runway that accommodates some important milestones, notably the presentation of the full data package from the SCLC IMPULSE trial. However, a funding gap remains in respect of the IMPALA study (primary endpoint estimated 24 months after the final patient is recruited).

In terms of operating costs for Q117 and 2016, the company reported that FY16 R&D expenses remained steady at €17.0m vs €16.8m for 2015. This translated to a small increase in operating loss (EBIT) of €21.0m vs €20.5m in FY15. Q117 R&D rose slightly to €3.9m versus €3.7m in Q117. We expect R&D costs to remain broadly similar for the rest of FY17 and this is reflected in a forecast EBIT loss of €21.0m. We anticipate personnel expenses to remain stable as increased outsourcing offsets the lower headcount (we forecast €5.2m in FY17, vs €5.5m in FY16). In FY18 we currently assume that lefitolimod will be out licensed in oncology indications; as such, a reduction in costs is expected, mainly in cost of materials (€7.4m in FY18e from €12.4m in FY17e). Additionally, we model €30m in illustrative debt for 2018 to fund the company. We note that the terms of any potential future licensing deal will heavily influence Mologen's financing needs, while we currently model the out licensing of lefitolimod in 2018; a delay or failure to achieve this could materially affect Mologen's future cash needs.

To fund the company through to its next major inflection points, Mologen has raised gross proceeds of €21.1m, through a capital increase and the issuance of two convertible bonds. The capital increase in October 2016 issued 11.3m new shares, raising gross €13.6m (net €12.7m). Subsequently two convertible bonds have been issued: one in November (€2.54m) and another recently in January (€4.99m); each has an eight-year maturity date and a 6% coupon, paid quarterly. The €2.54m bond has a conversion price of €1.50, while the €4.99m bond can be converted at €1.60. Mologen's largest shareholder, Global Derivate Trading (GDT), subscribed fully to the €2.54m bond and to approximately 73% of the €4.99m bond.

Our forecast net loss for FY17 has increased slightly to €21.4m (previously forecast at €20.7m).

Valuation

Our valuation of Mologen has changed to €252m or €7.33/share (previously €261m or €7.67/share). The value of the portfolio has increased, from €245m (€7.20/share) to €254m (€7.44/share); however, this is offset by a reduction in net cash (minus interest-bearing debt), which is now modelled as of end-2017 at -€0.11/share (vs €0.47 previously). The portfolio value has increased primarily due to rolling forward our model. However, this was offset by a slight reduction in the value we attribute to lefitolimod (in SCLC) following the IMPULSE data. We now assume a lower peak penetration in SCLC of 15% (vs 25% previously) due to its potential applicability in fewer patients than initially forecast. Additionally, due to the uncertainty of the next steps in development, we have lowered the probability of success to 15% across the board (vs 30% in the US/Europe and 25% in Japan). Lefitolimod in SCLC now represents €0.07/share of our rNPV. The majority of the portfolio value still remains in lefitolimod in CRC (Exhibit 1) where we have retained our assumptions.

Exhibit 1: Valuation assumptions

Product	Status	Market launch	NPV (€m)	Peak sales ($m)	Probability of success	Royalty estimate	rNPV (€m)	rNPV share (€)	Key assumptions
Lefitolimod - CRC - US	Phase III-ready	2021	101	308	65%	25%	64.5	1.89	~135,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $40,000 treatment price; 2028 patent expiry
Lefitolimod - CRC - EU	Phase III	2020	222	589	65%	25%	143.3	4.19	~345,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $30,000 treatment price; 2030 patent expiry
Lefitolimod - CRC - Japan	Phase III-ready	2021	31	198	50%	15%	15.3	0.45	~112,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $35,000 treatment price; 8yrs exclusivity
Lefitolimod - SCLC – US	Phase II-ready	2022	22	124	15%	15%	2.1	0.06	~225,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2027); $40,000 price; 2028 patent expiry
Lefitolimod - SCLC - EU	Phase II	2022	14	130	15%	15%	0.3	0.01	~310,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2028); $30,000 price; 2030 patent expiry
Lefitolimod - SCLC - Japan	Phase II-ready	2023	5	34	15%	15%	0.1	0.00	~38,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2028); $35,000 price; 8yrs exclusivity
Lefitolimod - HIV - WW	Phase I	2025	61	405	15%	15%	6.2	0.18	~ 36.7m cases (prevalence), 46% treated, 5% Peak share (2034), $20,000 price, Patent Expiry 2036 (Expected - Not yet granted)
Lefitolimod & ICI - ASM (SCLC used as model) - WW	Phase I	2028	54	511	15%	10%	7.5	0.22	~ 1.8m lung cancer cases worldwide, 12.50% SCLC, 5% peak share (2033), $30,000 price, Patent Expiry 2036 (Expected - not yet granted)
MGN1601 - RCC -US - on hold	Phase II ready	2027	118	198	10%	25%	10.3	0.30	~63,000 RCC cases/yr; 25% advanced RCC; 12.5% peak penetration (2032); $60,000 treatment price; 12yrs BLA exclusivity (2038)
MGN1601 - RCC - EU - on hold	Phase II ready	2027	64	116	10%	25%	4.7	0.14	~75,000 RCC cases/yr; 25% advanced RCC; 12.5% peak penetration (2032); $40,000 treatment price; 10yrs BLA exclusivity (2036)
MGN1601 - RCC - Japan - on hold	Phase II ready	2028	3	23	10%	25%	0.2	0.01	~17,000 Kidney Cancer cases/yr, 80% RCC, 25% Advanced RCC, 12.5% peak penetration (2032), $50,000 treatment price, 8 year BLA exclusivity (2036)
Portfolio value			695				254.4	7.44	7.44
Cash							(2.8)	(0.11)	Net debt at 31 December 2017
Total							251.6	7.33	34.2m shares outstanding

Source: Edison Investment Research

We assume lefitolimod will be out licensed in oncology in 2018 and have valued royalties accordingly; however, we do not model any potential upfront or milestone payments. Our model suggests a cash runway potentially into early 2018. For more details of our valuation methodologies please see our last outlook note, titled Next level of development.

Exhibit 2: Financial summary

€'000s	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	12	39	74	40	40
Cost of Sales	0	0	0	0	0
Gross Profit	12	39	74	40	40
Research and development (cost of materials)	(8,687)	(11,681)*	(11,780)	(12,369)	(7,421)
Selling, general & administrative (personnel expenses)	(5,113)	(5,074)	(5,453)	(5,180)	(4,662)
Other operating income / expense	(3,199)	(3,702)*	(3,418)	(3,444)	(3,444)
EBITDA	(16,987)	(20,418)	(20,577)	(20,953)	(15,488)
Operating Profit (before GW and except.)	(17,059)	(20,499)	(20,813)	(20,956)	(15,494)
Intangible Amortisation	(38)	(40)	(172)	(19)	(17)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(17,097)	(20,539)	(20,985)	(20,974)	(15,511)
Net Interest	19	3	(18)	(424)	(423)
Other	0	0	0	0	0
Profit Before Tax (norm)	(17,040)	(20,496)	(20,831)	(21,380)	(15,917)
Profit Before Tax (FRS 3)	(17,078)	(20,536)	(21,003)	(21,399)	(15,934)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(17,040)	(20,496)	(20,831)	(21,380)	(15,917)
Profit After Tax (FRS 3)	(17,078)	(20,536)	(21,003)	(21,399)	(15,934)
Average Number of Shares Outstanding (m)	16.8	20.7	23.0	34.2	34.2
EPS - normalised (c)	(1.01)	(0.99)	(0.91)	(0.63)	(0.47)
EPS - FRS 3 (c)	(1.02)	(0.99)	(0.91)	(0.63)	(0.47)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	440	414	62	97	121
Intangible Assets	206	175	37	33	20
Tangible Assets	234	239	25	64	101
Other	0	0	0	0	0
Current Assets	14,613	25,981	21,300	5,019	19,268
Stocks	30	28	13	13	13
Debtors	0	0	33	33	33
Cash	13,563	24,592	20,520	4,239	18,488
Other	1,020	1,361	734	734	734
Current Liabilities	(1,747)	(6,886)	(7,404)	(7,404)	(7,404)
Creditors	(1,747)	(6,886)	(7,404)	(7,404)	(7,404)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(8)	(6)	(2,121)	(7,072)	(37,072)
Long term borrowings	0	0	(2,119)	(7,070)	(37,070)
Other long term liabilities	(8)	(6)	(2)	(2)	(2)
Net Assets	13,298	19,503	11,837	(9,360)	(25,087)
CASH FLOW					
Operating Cash Flow	(15,602)	(15,095)	(19,270)	(20,751)	(15,280)
Net Interest	3	0	0	(424)	(424)
Tax	(6)	12	0	0	0
Capex	(93)	(95)	(57)	(56)	(47)
Acquisitions/disposals	0	0	13	0	0
Financing	14,495	26,207	12,706	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(1,203)	11,029	(6,608)	(21,232)	(15,751)
Opening net debt/(cash)	(14,765)	(13,563)	(24,592)	(18,401)	2,831
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	1	0	1	0	0
Other	0	0	416	0	0
Closing net debt/(cash)	(13,563)	(24,592)	(18,401)	2,831	18,582

Source: Edison Investment Research, Mologen. Note: Other long-term liabilities are convertible bonds.*Restated.

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