EDISON

Mologen

Corporate update

IMPALA the focus as funding gap remains

Pharma & biotech

Mologen's Phase III pivotal trial (IMPALA) in metastatic colorectal cancer (mCRC) is now the focus for investors as both the Phase II trial (IMPULSE) in small cell lung cancer (SCLC) and Phase I trial in HIV (TEACH) are now complete. The company recently announced the results of a statistical forecast that has predicted the primary analysis of the data will most likely occur in April 2020 (95% CI: +/- five months). Cash reach has been prolonged to the end of 2018 by recent financing arrangements, and the signing of a licence and co-development agreement with Oncologie, in addition to R&D cost reductions. A new study with lefitolimod in HIV (TITAN) is expected to be initiated by Aarhus University Hospital in 2018. We value Mologen at €243m (€6.5/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16	0.0	(20.8)	(0.84)	0.0	N/A	N/A
12/17	0.0	(19.3)	(0.56)	0.0	N/A	N/A
12/18e	3.0	(14.6)	(0.39)	0.0	N/A	N/A
12/19e	0.0	(17.1)	(0.45)	0.0	N/A	N/A

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

IMPULSE data interesting, focus now on IMPALA

Mologen has confirmed the initial top-line results for its 103-patient Phase II IMPULSE trial in SCLC. While it missed its primary end point, two predefined subgroups demonstrated improvements in overall survival hazard ratios. The company is currently assessing its future development options. Focus has now predominately switched to IMPALA, a 549-patient (enrolled), two-arm, randomised pivotal Phase III trial for the maintenance treatment of mCRC patients.

Oncologie: First licensing agreement signed

In February, Mologen signed a licence and co-development agreement with Oncologie potentially worth over €100m (€3m upfront), a €2m equity investment and low double-digit royalties. Previously, Mologen announced that it had signed deal terms with China-based iPharma; however, the deal was not completed.

Financials: Funding until year end

The initial payment of €3m from Oncologie in addition to recent financial arrangements has resulted in a cash reach to the end of 2018. Cash burn in Q118 was reduced to €4.6m (vs €6.0m), mainly as a result of reduction in R&D costs from the completion of the TEACH and IMPULSE studies. The initial payment from Oncologie helped reduce the pre-tax loss to €0.7m versus €5.1m in Q117.

Valuation: €243m (€6.5/share)

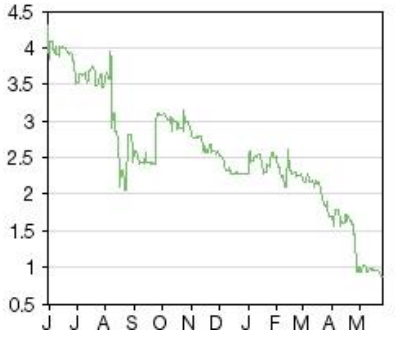
We value Mologen at €243m (€6.5/share) vs €256m (€7.43/share) previously. We have rolled forward our model, which is based on a risk-adjusted rNPV of lefitolimod across a range of indications and regions. Additionally, we have pushed back launches in both the EU and US for lefitolimod in CRC and SCLC to 2022 and 2024, respectively. We now also assume lefitolimod is out-licensed across indications in 2020 versus our previous assumption of 2018.

29 May 2018

Price	**€0.87**
Market cap	**€33m**

Net cash (€m) at 31 March 2018	2.8
Shares in issue	37.7m
Free float	59%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(6.5)	(60.9)	(80.3)
Rel (local)	(8.5)	(62.2)	(80.7)
52-week high/low		€4.4	€0.9

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

HY17 results	9 August 2018
IMPULSE full data presented at scientific conference	Autumn 2018
IMPALA primary analysis	H120

Analysts

Dr Daniel Wilkinson +44 (0)20 3077 5734

Dr Susie Jana +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

TLR9 in the headlines as IMPALA takes centre stage

In 2017, Mologen's exploratory Phase II SCLC IMPULSE trial and its Phase Ib/IIa HIV TEACH trial completed and investor attention is now focused on the most advanced clinical study, the Phase III IMPALA trial in mCRC. IMPALA, a Phase III trial testing lefitolimod as a maintenance treatment in 549 mCRC patients has completed enrolment (concluded in May 2017). It is a randomised, exploratory, non-blinded, two-arm study, with a primary end point of overall survival. In April, Mologen published a data-based prediction that has forecast when the primary analysis of IMPALA will occur. It has predicted that this will most likely occur in April 2020 with a 95% confidence interval of plus/minus five months. Previous forecasts had estimated initial data were to be expected in 2019. The time period was calculated based on patient data collected up to April 2018. Mologen plans to repeat this type of analysis in order to review and, if necessary, adapt its current forecast.

In April 2018, Mologen confirmed the top-line results presented in 2017 from the now-completed exploratory Phase II IMPULSE trial. Data demonstrated that it did not meet the primary end point of overall survival. However, it showed potential, non-statistically significant advantage in two pre-specified subgroups. Patients with a low number of activated B cells and patients with chronic obstructive pulmonary disease (COPD) demonstrated improvements in overall survival hazard ratios. Patients with a low number of activated B cells demonstrated a hazard ratio of 0.53 (95% confidence interval [CI]: 0.26–1.08) and patients with COPD (a common underlying disease for lung cancer) demonstrated a 0.48 hazard ratio (95% CI: 0.20–1.17). The trial was not powered for statistical significance in these subgroups. It should be kept in mind that SCLC is a difficult disease to treat and any potential benefit that could be provided is a positive. Mologen is currently assessing its options for future development.

Top-line data from TEACH, an exploratory, non-randomised Phase Ib/IIa trial testing lefitolimod in HIV-positive patients, failed the primary end point of reduction in viral reservoir in 12 patients receiving both antiretroviral therapy and lefitolimod. However, an increased duration of viral control above what is typically expected was observed in one patient out of nine after stopping ART. A new trial, designated TITAN, plans to test lefitolimod in combination with virus-neutralising antibodies and is planned to start in 2018. The trial will be run by Aarhus University Hospital in Denmark. In January 2017, Aarhus received a $2.75m grant from Gilead to fund the trial. The antibodies have been developed by Rockefeller University in New York.

We note TLR9 therapies, of which Mologen's lead candidate lefitolimod is one, continue to gain industry-wide traction; most recently, sector-wide attention was generated by a publication in the journal Science. In a preclinical study, it was demonstrated that a combination of a TLR9 agonist with an OX40 antibody cured mice of existing cancers. These and other immune combinations continue to gain traction and multiple approaches are being tested, including a Phase I trial run by MD Anderson Cancer Center, testing Mologen's lefitolimod with Yervoy (CTLA-4 inhibitor). Mologen additionally continues to progress its next-generation TLR9 agonists EnanDIM, with data most recently presented at AACR.

In April, it was announced that Dr Mariola Söhngen will be stepping down as the CEO as of 31 October. Mologen has begun the search for a successor.

Oncologie: First licensing agreement for lefitolimod

In February, Mologen signed a licence and co-development agreement with Oncologie potentially worth over €100m (€3m upfront), a €2m equity investment and double-digit royalties. Oncologie is a

Boston-headquartered, private oncology therapeutics company with operations additionally in Shanghai, China. Mologen had previously announced in 2017 that it had signed deal terms with China-based iPharma. After the end of an exclusivity period, Mologen entered discussions and negotiations with Oncologie. The contract comprises two parts.

First, a licence agreement through which Mologen grants Oncologie an exclusive licence for the development, manufacturing and commercialisation of lefitolimod in China, Hong Kong, Macao, Taiwan and Singapore. The second part is a global co-development partnership, which aims to utilise Oncologie's novel biomarkers. Both parties will share the economic returns from global joint development pursuant to both parties' contributions; however, all costs relating to development, registration, marketing and commercialisation of lefitolimod in any territory are to be covered by Oncologie.

Mologen has received an initial payment of €3m and a €2m equity investment by Oncologie is expected within 12 months of the initial payment. Additional development and commercialisation milestones are expected and total payments could be more than €100m. They are due on reaching predefined development steps as well as market approval. In addition, sales-related commercial milestones are defined. Finally, Mologen will receive low double-digit royalties on sales.

Valuation: €243m (€6.5/share)

We now value Mologen at €243m (€6.5/share) versus €256m (€7.43/share) previously. The valuation is based on a risk-adjusted, sum-of-the-parts DCF model, applying a standard 12.5% discount rate and including 31 March 2018 net cash of €2.8m. With the delay in anticipated data readout for IMPALA, we have pushed lefitolimod's forecast launch in mCRC back to 2022 from 2021 in the US and 2020 in the EU. We assume based on historic data that the creation of a regulatory package for the FDA/EMA is likely to take between eight and 12 months with the review of a regulatory submission taking 12 months. As such we assume a launch in both markets is most likely in early 2022, however variability in timings related to these aforementioned processes mean a launch as early as late 2021 could be possible.

With the uncertainties around the next stages of development for lefitolimod in SCLC, we have pushed back the launch dates to 2024 from 2022 in both the EU and the US. We no longer assume lefitolimod will be out-licensed in 2018 in the EU and the US. We now assume it will be out-licensed across indications in 2020 once IMPALA data have been published. We note that the terms of any potential future licensing deal for lefitolimod will heavily influence financing needs, while a delay or failure to achieve out-licensing could materially affect Mologen's long-term financial position.

At this time, we assume Mologen will be able to negotiate a higher royalty rate in mCRC and now assume this at 35% (versus 25% previously). We additionally assume that a partner will fund a Phase III trial for SCLC. A summary of our valuation assumptions can be seen in Exhibit 1. For a full breakdown of our valuation, please see our previously published outlook note (Lefitolimod trial readouts hint at future potential).

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	2022	111	303	65%	30%	70.5	1.87	~135,000 CRC cases/year; 25% metastatic + 5% regional; 60% chemo response; 25% peak share; $40,000 treatment price; 2028 patent expiry
Lefitolimod CRC – EU	Phase III	2022	207	572	65%	30%	133.1	3.53	~345,000 CRC cases/year; 25% metastatic + 5% regional; 60% chemo response; 25% peak share; $30,000 treatment price; 2030 patent expiry
Lefitolimod SCLC – US	Phase II-ready	2024	19	118	15%	15%	2.6	0.07	~225,000 lung cancer cases/year; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share; $40,000 price; 2028 patent expiry
Lefitolimod SCLC – EU	Phase II	2024	9	124	15%	15%	0.4	0.01	~310,000 lung cancer cases/year; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share; $30,000 price; 2030 patent expiry
Lefitolimod HIV – WW	Phase I	2025	72	405	15%	15%	7.5	0.19	~36.7m cases (prevalence); 46% treated; 5% peak share; $20,000 price; patent expiry 2036 (expected, not yet granted)
Lefitolimod & ICI – ASM (SCLC used as model) – WW	Phase I	2028	62	511	15%	15%	8.6	0.23	~1.8m lung cancer cases worldwide; 12.50% SCLC; 5% peak share; $30,000 price; patent expiry 2036 (expected, not yet granted)
Lefitolimod mCRC – China	Phase I	2028	70	203	5%	15%	18.1	0.48	~200,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 10% will receive additional treatment; 1% peak share; €5,000; patent expiry unknown
Portfolio value			810				240.52	6.38	
Cash							2.8	0.07	Net cash 31 March 2018
Total							**243**	**6.46**	**37.7m shares out**

Source: Edison Investment Research

Financials

Gross cash at 31 March 2018 was €8.3m (net cash €2.8m). Our model suggests that current cash is sufficient to fund operations to end 2018; a funding gap remains in respect of the IMPALA study and combination readout. Our model includes €20m of illustrative debt in 2019 to fill this funding gap.

In Q118, Mologen reported €3m in revenue from the Oncologie deal. Cost of materials in Q118 was reduced to €1.6m (vs €3.0m in Q118), mainly as a result of reduction in R&D costs from the completion of the TEACH and IMPULSE studies. We expect the trend in reduced R&D costs to continue with forecast cost of materials for FY18 of €8.3m versus €9.7m in 2017. We forecast a net loss for FY18 of €14.6m versus €19.3m in 2017.

To continue to fund the company, Mologen has engaged in a variety of funding activities in Q118.

In February, Mologen entered into an agreement with Luxembourg-based financing provider European High Growth Opportunities Securitization Fund (EHGO). Under this agreement, Mologen can, over a two-year period, require EHGO to subscribe to convertible bonds. The bonds can be issued in amounts of €500,000 in 24 tranches for a total of €12m. Bonds must be converted 12 months after issuance and they do no not accrue interest. As of Q118 results, two tranches have been exercised and both have been converted. We note existing shareholders will face some, albeit small, share dilution if future bonds are exercised. We assume a further six tranches are drawn down in 2018.

In March, Mologen announced a rights issue from authorised capital to national and international investors. 2,357,368 new shares were issued at a subscription price of €2.12. Overall, the company generated gross proceeds of around €5m. For details of all of Mologen's existing financial arrangements, including previously subscribed convertible bonds, please see our outlook note Lefitolimod trial readouts hint at future potential.

Exhibit 2: Financial summary

€000s	2015	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	39	74	47	3,000	40
Cost of Sales	0	0	0	0	0
Gross Profit	39	74	47	3,000	40
Research and development (cost of materials)	(11,681)	(11,780)	(9,752)	(8,289)	(7,875)
Selling, general & administrative (personnel expenses)	(5,074)	(5,453)	(5,093)	(5,042)	(4,992)
Other operating income / expense	(3,702)	(3,418)	(3,860)	(3,884)	(3,845)
EBITDA	(20,418)	(20,577)	(18,658)	(14,215)	(16,671)
Operating Profit (before amort. and except.)	(20,499)	(20,813)	(18,684)	(14,218)	(16,677)
Intangible Amortisation	(40)	(172)	(23)	(9)	(5)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(20,539)	(20,985)	(18,707)	(14,226)	(16,682)
Net Interest	3	(18)	(574)	(422)	(426)
Other	0	0	0	0	0
Profit Before Tax (norm)	(20,496)	(20,831)	(19,258)	(14,640)	(17,103)
Profit Before Tax (FRS 3)	(20,536)	(21,003)	(19,281)	(14,649)	(17,108)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(20,496)	(20,831)	(19,258)	(14,640)	(17,103)
Profit After Tax (FRS 3)	(20,536)	(21,003)	(19,281)	(14,649)	(17,108)
Average Number of Shares Outstanding (m)	20.7	24.7	34.3	37.7	37.7
EPS - normalised (c)	(0.99)	(0.84)	(0.56)	(0.39)	(0.45)
EPS - FRS 3 (c)	(0.99)	(0.85)	(0.56)	(0.39)	(0.45)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	414	62	44	66	89
Intangible Assets	175	37	17	10	6
Tangible Assets	239	25	27	56	83
Other	0	0	0	0	0
Current Assets	25,981	21,300	8,061	2,712	6,008
Stocks	28	13	16	16	16
Debtors	0	33	13	13	13
Cash	24,592	20,520	6,523	1,175	4,470
Other	1,361	734	1,509	1,509	1,509
Current Liabilities	(6,886)	(7,404)	(7,502)	(7,502)	(7,502)
Creditors	(6,390)	(6,530)	(4,400)	(4,400)	(4,400)
Short term borrowings	0	0	0	0	0
Other	(496)	(874)	(3,102)	(3,102)	(3,102)
Long Term Liabilities	(6)	(2,121)	(5,474)	(9,470)	(29,897)
Long term borrowings	0	(2,119)	(5,419)	(9,415)	(29,842)
Other long term liabilities	(6)	(2)	(55)	(55)	(55)
Net Assets	19,503	11,837	(4,871)	(14,194)	(31,302)
CASH FLOW					
Operating Cash Flow	(15,095)	(19,270)	(19,696)	(15,061)	(17,097)
Net Interest	0	18	574	424	427
Tax	12	0	0	0	0
Capex	(95)	(57)	(33)	(33)	(34)
Acquisitions/disposals	0	13	35	0	0
Financing	26,207	12,706	477	5,326	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	11,029	(6,590)	(18,643)	(9,344)	(16,705)
Opening net debt/(cash)	(13,563)	(24,592)	(18,401)	(1,104)	8,240
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	0	1	(8)	0	0
Other	0	398	1,354	0	(427)
Closing net debt/(cash)	(24,592)	(18,401)	(1,104)	8,240	25,372

Source: Mologen, Edison Investment Research.

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

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
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia