EDISON

Mologen

Q3 results

Financed to inflection points

Pharma & biotech

The recent completion of the €13.6m capital raise and the soon to be issued convertible bond of presumably €2.5m will enable Mologen, alongside its latest reported cash of €10.2m (at 30 September 2016), to reach key inflection points in the coming year. Analysis of its Phase II (IMPULSE) small cell lung cancer (SCLC) trial should begin by year end, with initial data expected to be presented in H117. Final data from the Phase I HIV study will be presented in mid-2017, while the ongoing Phase III trial (IMPALA) in metastatic colorectal cancer (mCRC) is expected to complete patient enrolment by Q117. We value Mologen at €261m or €7.67/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	(20.8)	(0.61)	0.0	N/A	N/A
12/17e	0.0	(20.7)	(0.61)	0.0	N/A	N/A

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

Presumed €16.1m raised in funding

Mologen recently raised gross proceeds of presumably €16.1m from the combination of a €13.6m completed equity raise and a €2.5m bond that will be issued in November. Share capital was increased by the addition of 11.3m shares from €22.6m to €33.9m. Additionally, Mologen will shortly issue a €2.5m convertible bond to its majority shareholder Global Derivative Trading GmbH which, in addition to the equity raise and last reported cash (€10.2m at 30 September 2016), will fund it through to potentially Q417.

IMPULSE data in sight

Mologen's increased cash balance will fund it to the presentation of key data in H117 from its Phase II SCLC trial (IMPULSE). The trial is studying the benefit of its lead product candidate lefitolimod as a maintenance treatment on overall survival of 100 patients in comparison with the current best standard therapy. Positive data could be a major inflection point for the company and the quality of the data will prove pivotal in any potential future deals or partnerships.

Pipeline progressing on track

IMPALA, a Phase III pivotal trial, is testing lefitolimod as a switch maintenance therapy in approximately 540 mCRC patients across eight European countries. Enrolment is expected to complete in Q117. Data are expected approximately 24 months after the final patient is recruited. Final data from TEACH, the Phase I/IIa trial of lefitolimod (+ antiretroviral treatment) in HIV patients are expected mid-2017.

Valuation: €261m or €7.67/share

Our overall valuation has increased (previously €201m or €8.87/share) due to rolling forward our model and the reduction in assumptions on FY16 costs following Q3 results. We have now included the capital raise and bond issue in our forecasts, which has caused a slight reduction in our per share valuation.

14 November 2016

Price	**€1.45**
Market cap	**€49m**

Net cash (€m) at 30 September 2016 (pre-fund raise)	10.2
Shares in issue	33.9m
Free float	55%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	4.5	(20.0)	(59.3)
Rel (local)	3.7	(19.4)	(58.3)
52-week high/low		€4.8	€1.2

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

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

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Key data approaches in 2017

IMPALA (Phase III mCRC) and IMPULSE (Phase II SCLC) trials continue as planned, with completion of patient recruitment for IMPALA expected by Q117 (results expected approximately 24 months after last patient enrolment) and the results of IMPULSE in H117. IMPULSE is a Phase II trial in patients with 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 current standard of care. With 102 patients enrolled in the trial, it will provide the largest single data package to date on lefitolimod and will be key to Mologen's ability to partner or license it.

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 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 mid-2017), while a Phase I combination trial with ipilimumab (Yervoy) in advanced malignancies has started enrolment (potential data readout by 2019) and could increase the licensing appeal of lefitolimod in oncology if results are positive.

'Next Level' implementation continues

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 Mologen to put in place a solid production line, while controlling the costs that would be incurred if it invested in the expertise and facilities needed to internally scale production. Furthermore, multiple manufacturers could be used to enable the 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 that expertise and knowledge is retained in house.

Mologen has indicated that it is actively 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 that internal expertise will be brought on board to support this process. While headcount is initially being reduced (announced at the Q3 results to be 25% of workforce [17 staff] 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 note, 'Next Level' of development.

Valuation

Our valuation of Mologen has changed to €261m or €7.67/share (previously €201m or €8.87/share). This increase in value is driven by rolling forward our model and a reduction in forecast costs. The continued implementation of the 'Next Level' strategy, as demonstrated in the Q3 results, has resulted in lower costs than previously forecast. We now expect cost of materials to be €11.6m and €12.1m in FY16 and FY17 respectively (previously €15.4m and €16.2m). Additionally, small changes in personnel costs have been made as a result of clarity around the exact numbers involved in headcount changes; this is mainly reflected in FY17, where personal costs are now €4.5m compared to our previous €5.2m.

We have now included the recently completed capital raise in our forecasts, which provides a cash runway into potentially Q417, while also diluting the value per share (11.3m new shares issued, taking outstanding share capital to €33.9m). We assume €13m net will remain of the gross €13.6m raised. Additionally, Mologen will issue a convertible bond with a total nominal value of presumably €2.54m and a maturity date of 29 October 2024 to its largest shareholder, Global Derivative Trading GmbH (GDT). The bond carries 6% fixed annual interest and can be converted into 1.7m shares at a €1.50 conversion price.

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 Q417. Our valuation methodology and assumptions remain unchanged and can be found in more detail in our July 2016 note.

Financials

Cash at 30 September 2016 was €10.2m, which does not include the recent capital increase and coming bond issue of presumably €16.1m gross. Our model suggests that current cash is sufficient to fund operations to potentially Q417, depending on the progress of the IMPULSE and IMPALA studies for lefitolimod. Importantly, this provides a cash runway that accommodates some important milestones in the next year, particularly the primary analysis of the IMPULSE study data in SCLC (data expected in H117) and completion of patient recruitment in the IMPALA trial in Q117. However, a funding gap remains in respect of the IMPALA study (primary endpoint estimated 24 months after final patient recruited).

In terms of operating costs for the first nine months of 2016 (9M16), R&D expenses increased slightly to €10.5m vs €10.4m for the first nine months of 2015 (9M15) translating to an in increase in operating loss (EBIT) of €14.3m vs €13.3m over the same nine-month period in 2016 and 2015 respectively. The increased R&D costs are expected to continue in FY16, mainly in support of the IMPALA and IMPULSE trials, which the company expects to drive a marginally higher net loss than in 2015. We predict other operating expenses to be slightly lower in FY16 (€3.94m) than previously forecast (€4.38m) due to changes in company structure following the ongoing implementation of the 'Next Level' strategy. Our forecast net loss for FY16 has decreased slightly to €21.2m (previously €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	40
Cost of Sales	0	0	0	0	0
Gross Profit	227	12	39	40	40
Research and development (cost of materials)	(2,904)	(8,687)	(11,011)	(11,562)	(12,140)
Selling, general & administrative (personnel expenses)	(4,364)	(5,113)	(5,074)	(5,328)	(4,529)
Other operating income / expense	(2,803)	(3,199)	(4,372)	(3,930)	(3,930)
EBITDA	(9,844)	(16,987)	(20,418)	(20,779)	(20,558)
Operating Profit (before GW and except.)	(9,923)	(17,059)	(20,499)	(20,803)	(20,589)
Intangible Amortisation	(935)	(38)	(40)	(350)	79
Exceptionals/Other	0	0	0	0	0
Operating Profit	(10,858)	(17,097)	(20,539)	(21,153)	(20,510)
Net Interest	30	19	3	0	(148)
Other	0	0	0	0	0
Profit Before Tax (norm)	(9,893)	(17,040)	(20,496)	(20,803)	(20,737)
Profit Before Tax (FRS 3)	(10,828)	(17,078)	(20,536)	(21,153)	(20,658)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(9,893)	(17,040)	(20,496)	(20,803)	(20,737)
Profit After Tax (FRS 3)	(10,828)	(17,078)	(20,536)	(21,153)	(20,658)
Average Number of Shares Outstanding (m)	15.4	16.8	20.7	24.5	33.9
EPS - normalised (c)	(0.64)	(1.01)	(0.99)	(0.61)	(0.61)
EPS - FRS 3 (c)	(0.70)	(1.02)	(0.99)	(0.62)	(0.61)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	457	440	414	149	277
Intangible Assets	237	206	175	(158)	(95)
Tangible Assets	220	234	239	306	372
Other	0	0	0	0	0
Current Assets	15,480	14,613	25,981	19,899	(331)
Stocks	33	30	28	28	27
Debtors	0	0	0	0	0
Cash	14,765	13,563	24,592	18,511	(1,720)
Other	682	1,020	1,361	1,361	1,361
Current Liabilities	(943)	(1,747)	(6,886)	(5,608)	(5,608)
Creditors	(943)	(1,747)	(6,886)	(5,608)	(5,608)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(10)	(8)	(6)	(2,546)	(2,546)
Long term borrowings	0	0	0	(2,540)	(2,540)
Other long term liabilities	(10)	(8)	(6)	(6)	(6)
Net Assets	14,984	13,298	19,503	11,894	(8,208)
CASH FLOW					
Operating Cash Flow	(8,869)	(15,602)	(15,095)	(21,512)	(20,150)
Net Interest	0	3	0	0	0
Tax	0	(6)	12	0	0
Capex	(146)	(93)	(95)	(109)	(80)
Acquisitions/disposals	1	0	0	0	0
Financing	8	14,495	26,207	13,000	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(9,006)	(1,203)	11,029	(8,621)	(20,230)
Opening net debt/(cash)	(23,777)	(14,765)	(13,563)	(24,592)	(15,971)
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)	(15,971)	4,260

Source: Mologen, Edison Investment Research

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