EDISON

Mologen

Corporate update

Retaining lefitolimod's value

Pharma & biotech

Mologen has announced that it has terminated negotiations with Oncologie and will retain rights to lefitolimod. With the lefitolimod IMPALA Phase III readout now expected in H219, focus will likely shift to securing a partner for lefitolimod once data are available from this pivotal trial. We have updated our valuation to reflect the termination of Oncologie negotiations. We now forecast that lefitolimod will be out-licensed post the IMPALA trial and assume similar deal terms to those Oncologie presented. We value Mologen at €169m (€18.2/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16	0.1	(20.8)	(4.22)	0.0	N/A	N/A
12/17	0.0	(19.3)	(2.81)	0.0	N/A	N/A
12/18e	3.0	(14.2)	(1.53)	0.0	N/A	N/A
12/19e	0.0	(17.0)	(1.84)	0.0	N/A	N/A

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

Negotiation for lefitolimod global rights terminated

Following a negotiation period between Mologen and Oncologie, a global deal was not reached, although the Greater China deal remains in place. Mologen states this was a result of new inferior deal terms being presented to what was originally agreed. Separately, Mologen announced an updated prediction on the timelines for its top-line Phase III IMPALA data readout; it is now forecast for H219 (vs H120 previously). The company now aims to out-license/sell lefitolimod post IMPALA data.

First data presented from lefitolimod/ICI combination

At SITC 2018, first clinical data was presented on the combination of the immune checkpoint inhibitor Yervoy and lefitolimod in patients with solid tumours. To date, 19 patients have been enrolled and no dose limiting toxicities were encountered at any dose level. The combination was generally well tolerated and safe. Two patients experienced stable disease for 45 weeks (primary peritoneal carcinoma) and 24 weeks (high-grade pancreatic neuroendocrine tumor), respectively (NCT02668770).

Financials: Short-term financing concerns

We forecast a reduction in FY18 revenue to €3.0m (from €6.0m) and FY19 revenue to €0.0m (€7.0m) as a result of the termination of the Oncologie deal. Q3 costs remained in line with expectations and we maintain FY18 R&D of €7.3m and SG&A of €5.5m. We forecast an FY18 net loss of €14.2m vs €11.1m. Estimated current gross cash of approximately €12m should fund Mologen until mid-2019. In addition, Mologen has announced plans for a new convertible bond of up to €2.7m and an equity capital raise (of up to 50% of the outstanding shares) is proposed.

Valuation: €169m (€18.2/share)

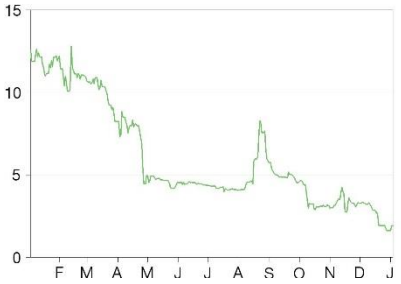
We value Mologen at €169m (€18.2/share) vs €188m (€16.6/share) previously, updated for the termination of the Oncologie negotiations; additionally, we have rolled forward our model, updated for FX and number of shares. We now forecast lefitolimod will be out-licensed post the IMPALA trial readout and that any potential future deal signed will have similar terms to those Oncologie originally presented.

4 January 2019

Price	**€1.90**
Market cap	**€18m**

Net cash (€m) at 30 September 2018 (not including €8.2m gross capital raise)	0.7
Shares in issue	9.3m
Free float	73%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(41.3)	(59.2)	(84.9)
Rel (local)	(35.4)	(51.9)	(81.1)

52-week high/low	€12.6	€1.6

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

FY18 results	21 March 2019
Yervoy + lefitolimod further data	2019
IMPALA top-line results	H219

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Edison profile page

Lefitolimod: Seeing it to the end

On 15 August 2018, Mologen signed a non-binding term sheet with Oncologie for the global assignment of lefitolimod. At the end of the exclusivity period on 15 November, Mologen terminated the negotiations as the companies had not reached a mutually satisfactory conclusion. Mologen states this was a result of new inferior deal terms being presented to them in the negotiation period. Original deal terms were valued at over €1bn in milestones (€200m in development milestones and up to €900m in commercial milestones), in addition to royalties on net sales. Approximately €23m of these milestones were in near-term considerations split across cash payments, convertible bonds and R&D funding.

To date, Mologen has received €5m from Oncologie, €3m as a result of the original Asia-focused deal signed in February 2018 and a €2m bond subscribed by Oncologie on 3 September 2018 (€9.702/share). While negotiations for the global deal have been terminated, the Asia-focused deal with Oncologie signed in February remains in place. The deal is potentially worth over €100m in milestones and double-digit royalties. We currently have no information regarding the strategy in this region. Mologen will now focus on financing itself to the completion of the IMPALA trial and the readout of top-line data, at which point it will then aim to out-license or sell lefitolimod.

Valuation: €169m (€18.2/share)

Our valuation of Mologen has decreased to €169m (€18.2/share) vs €188m (€16.6/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 estimated net cash of €5.2m (includes September end cash and €8.2m gross capital raise). The reduction in value is predominately driven by a push back in timelines of any potential deal and there is also a small negative impact on our valuation from the loss of near-term revenue from the Oncologie deal. We now forecast a new deal will be negotiated for lefitolimod in 2020. As we have little visibility on ongoing deal negotiations and any potential parties involved, we have assumed any new deal would have similar terms to the original Oncologie deal. While better terms could potentially be negotiated with the Phase III data in hand, negotiations will hinge on multiple factors including, but not limited to, Mologen's financial position, changes in market dynamics and advances in treatment paradigms.

Due to the aforementioned range of variables influencing any deal terms achieved, we have included a sensitivity analysis on our forecast milestone and royalty rate in the indication (Exhibit 1). Upside or downside to our base valuation will be reliant on the strength of the results from the IMPALA trial and any potential partners will likely focus on the magnitude of improvement in overall survival of lefitolimod arm versus the control arm.

Additionally, with an earlier expected readout of IMPALA in H219, we now forecast a launch in mCRC of 2021 (versus 2022 previously). For an overview of all our valuation assumptions, please see Exhibit 2. We have also updated our number of shares outstanding to reflect the €8.2m gross capital raise and have rolled forward our model and updated it for FX rates.

Exhibit 1: Effect of forecast royalty rate and milestones for lefitolimod in mCRC on Mologen's overall valuation

		Total EU + US milestones				
		c $100m	c $125m	c $150m	c $175m	c $200m
Average royalty rate	8%	125	130	136	140	144
	10%	142	147	152	156	161
	12%	158	163	**€169m**	172	177
	14%	175	179	185	189	193
	16%	191	196	201	205	210

Source: Edison Investment Research

Exhibit 2: 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	68	308	65%	12%	42.5	4.6	~135,000 CRC cases/year; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $40,000 treatment price; 2028 patent expiry, c $150m milestones in total across EU and US
Lefitolimod – CRC – EU	Phase III	2021	113	581	65%	12%	71.2	7.7	~345,000 CRC cases/year; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $30,000 treatment price; 2030 patent expiry, c $150m milestones in total across EU and US
Lefitolimod – SCLC –- US	Phase II-ready	2024	26	118	15%	12%	4.5	0.5	~225,000 lung cancer cases/year; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2027); $40,000 price; 2028 patent expiry, c $50m milestones in total across EU and US
Lefitolimod – SCLC – EU	Phase II	2024	17	124	15%	12%	3.2	0.3	~310,000 lung cancer cases/year; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2028); $30,000 price; 2030 patent expiry, c $50m milestones in total across EU and US
Lefitolimod – HIV – Worldwide (WW)	Phase I	2025	100	405	15%	12%	13.1	1.4	~36.7m cases/year (prevalence), 46% treated, 5% peak share (2034), $20,000 price, patent expiry 2036 (expected – not yet granted), c $130m milestones in total WW
Lefitolimod & ICI – ASM (SCLC used as model) – WW	Phase I	2028	73	511	15%	12%	10.9	1.2	~1.8m lung cancer cases WW, 12.50% SCLC, 5% peak share (2033), $30,000 price, patent expiry 2036 (expected, not yet granted), c $150m milestones WW total
Lefitolimod – mCRC – China	Phase I	2028	67	203	5%	12%	17.8	1.9	~200 CRC cases/year; 25% metastatic + 5% regional; 60% chemo response; 10% will receive additional treatment, 1% peak share (2033), €5,000 price, patent expiry unknown, c $100m milestones in total China
Portfolio value			717				163	17.6	
Cash							5.2	0.6	Net cash at 30 September 2018 + €8.2m gross capital raise (assume net €8m)
Total							169	18.2	9.27m shares out

Source: Edison Investment Research

Financials: Funded until mid-2019

We now forecast a reduction in FY18 revenue to €3.0m from €6.0m previously, and FY19 revenue to €0.0m from €7.0m previously, as a result of the termination of the Oncologie deal, mainly due to a loss of R&D funding. Q3 costs remained in line with expectations and we continue to forecast FY18 R&D of €7.3m and SG&A of €5.5m. For FY19, we forecast costs will remain relatively flat (R&D €6.9m and €5.5m) with a slight reduction in clinical trials costs as the IMPALA trial comes to completion. We now forecast an FY18 net loss of €14.2m vs €11.1m previously. Estimated current gross cash of approximately €12m (includes €8.2m gross capital raise) should fund Mologen until mid-2019.

Mologen has recently announced plans to issue a new convertible bond in January 2019 with a nominal value of €2.7m, a term of eight years and fixed interest rate of 6.0%. If the convertible bond is fully placed, the company expects to be financed until late summer 2019. In addition, Mologen has proposed an equity raise at a yet to be determined subscription price to increase the share capital by up to 50% of the current outstanding shares. There are currently no timelines for this proposed capital raise and we do not include this in our current forecasts. We note the proposed capital increase causes a natural stock overhang and would cause a dilution of our per share value of Mologen. To enable sufficient funding past the end of FY19, we have also modelled €15m of illustrative debt in 2019.

Mologen currently has a variety of debt instruments. In September 2018, the company issued a €2m convertible bond to Oncologie without subscription rights. The bond is 0% interest mandatory

convertible notes with a term of five years. The conversion price is a 10-day volume weighted average of the stock price plus a 30% premium. In February 2018, Mologen entered into an agreement with Luxembourg-based financing provider European High Growth Opportunities Securitization Fund (EHGO). Under this agreement, Mologen can require EHGO to subscribe to €500,000 in 24 tranches for a total of €12m convertible bonds over a two-year period. As of the Q118 results, two tranches have been exercised and both have been converted.

In November 2016 (2016/2024 bond: €2.54m) and in January 2017 (2017/2025 bond: €4.99m), two convertible bonds were placed. Terms of these were recently renegotiated with the 2016/2024 bond having its conversion price reduced to €2.74 from €7.50 and its interest rate increase to 8% (from 6%). In addition, the conversion price of the 2017/2025 bond was reduced to €2.46 from €7.61. A special right of termination has been included in the terms and conditions of both convertible bonds if the new terms are not implemented by 30 June 2019. The result of these negotiations will be submitted to vote by all bond creditors on 28 February 2019.

On 21 November, a consortium of investors, which together account for at least 5% of the share capital of the company, called for an EGM to be convened (to take place on 26 February 2019) to discuss a range of items – notably including a special audit, removal/election of board members and a new capital raise (agenda). Mologen recently announced (19 December) that the Executive Board and Supervisory Board of Mologen consider the reasons provided by the applicants for their proposed resolutions to be factually inaccurate and do not support the content of the proposed resolutions.

While we have modelled in €15m of illustrative debt in 2019 to enable funding past the end of FY19, we note any funding needs will be dependent on the results of the EGM on 26 February and the bond vote on 28 February.

Exhibit 3: Financial summary

€'000s	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	74	47	3,047	0
Cost of Sales	0	0	0	0
Gross Profit	74	47	3,047	0
Research and development (cost of materials)	(11,780)	(9,752)	(7,314)	(6,948)
Selling, general & administrative (personnel expenses)	(5,453)	(5,093)	(5,450)	(5,504)
Other operating income/expense	(3,418)	(3,860)	(3,884)	(3,845)
EBITDA	(20,577)	(18,658)	(13,600)	(16,297)
Operating Profit (before amort. and except.)	(20,813)	(18,684)	(13,603)	(16,301)
Intangible Amortisation	(172)	(23)	(9)	(5)
Exceptionals/Other	0	0	0	0
Operating Profit	(20,985)	(18,707)	(13,611)	(16,306)
Net Interest	(18)	(574)	(558)	(728)
Other	0	0	0	0
Profit Before Tax (norm)	(20,831)	(19,258)	(14,161)	(17,029)
Profit Before Tax (FRS 3)	(21,003)	(19,281)	(14,170)	(17,034)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(20,831)	(19,258)	(14,161)	(17,029)
Profit After Tax (FRS 3)	(21,003)	(19,281)	(14,170)	(17,034)
Year-End Shares Outstanding (m)	4.9	6.9	9.3	9.3
EPS - normalised (c)	(4.22)	(2.81)	(1.53)	(1.84)
EPS - FRS 3 (c)	(4.25)	(2.81)	(1.53)	(1.84)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	62	44	50	57
Intangible Assets	37	17	10	6
Tangible Assets	25	27	39	51
Other	0	0	0	0
Current Assets	21,300	8,061	8,599	9,987
Stocks	13	16	16	16
Debtors	33	13	13	13
Cash	20,520	6,523	7,061	8,450
Other	734	1,509	1,509	1,509
Current Liabilities	(7,404)	(7,502)	(6,182)	(6,182)
Creditors	(6,530)	(4,400)	(3,080)	(3,080)
Short term borrowings	0	0	0	0
Other	(874)	(3,102)	(3,102)	(3,102)
Long Term Liabilities	(2,121)	(5,474)	(7,055)	(25,485)
Long term borrowings	(2,119)	(5,419)	(7,000)	(25,430)
Other long term liabilities	(2)	(55)	(55)	(55)
Net Assets	11,837	(4,871)	(4,589)	(21,623)
CASH FLOW				
Operating Cash Flow	(19,270)	(19,696)	(16,038)	(17,025)
Net Interest	18	574	560	730
Tax	0	0	0	0
Capex	(57)	(33)	(17)	(16)
Acquisitions/disposals	13	35	0	0
Financing	12,706	477	13,048	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(6,590)	(18,643)	(2,447)	(16,311)
Opening net debt/(cash)	(24,592)	(18,401)	(1,104)	(61)
HP finance leases initiated	0	0	0	0
Exchange rate movements	1	(8)	0	0
Other	398	1,354	1,404	(529)
Closing net debt/(cash)	(18,401)	(1,104)	(61)	16,779

Source: Mologen accounts, Edison Investment Research

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