EDISON

MagForce

Interim results

2019 a pivotal year

Healthcare equipment & services

MagForce continues to implement its two-pillar strategy. A gross $9.0m capital raise secured by subsidiary MagForce USA in August will enable financing of the pivotal US prostate cancer trial to completion. In Europe, expansion outside Germany has started and a NanoActivator will be installed in Poland by the end of the year. Of the €9.2m reported revenue and other operating income in H118, €24k relates to EU glioblastoma multiforme (GBM) treatments, while the remainder (€8.8m) was non-cash income relating to hidden reserves as a result of the MagForce USA share transfer. We forecast revenues to pick up in 2019 following the roll-out of devices across Europe and a launch in the US (in late 2019). We value MagForce at €303.1m or €11.5/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	0.5	(7.2)	(0.28)	0.0	N/A	N/A
12/17	0.7	(7.5)	(0.28)	0.0	N/A	N/A
12/18e	0.3	(11.4)	(0.43)	0.0	N/A	N/A
12/19e	5.8	(9.1)	(0.34)	0.0	N/A	N/A

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

NanoTherm US prostate cancer trial funding secured

In August 2018, a gross capital increase of $9.0m from the issue of 866,666 new shares in MagForce USA (to a US investor) secured funding for the pivotal US prostate cancer trial. MagForce expects the first 10 patients in the trial to be treated by year-end 2018, and thus for preliminary data to be available early in 2019. Prostate cancer in the US presents a significant market opportunity, representing ~62% of our rNPV. The company forecasts that NanoTherm could be launched for the commercial treatment of prostate cancer patients in the US in Q419 (subject to FDA approval).

EU expansion and reimbursement required in GBM

Reported revenues of €24k for H118 reflect a drop-off in remunerated GBM treatments, markedly lower than our previous forecasts. This is a consequence of both a change in revenue recognition and a lower number of patients treated in Germany, stemming from a transition away from foreign, private to reimbursed treatments and expansion in Europe progressing slower than anticipated. With the installation of NanoActivators in Poland and other European countries outside Germany from 2018 onwards, we expect a sharp increase in treatment sales in these countries. Once reimbursement discussions in Germany have concluded, we expect a strong recovery in sales in Germany to follow in 2019.

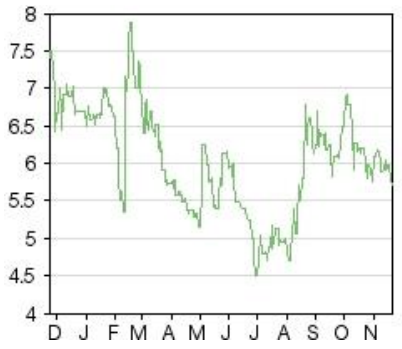
Valuation: €303.1m (€11.5/share)

Our revised valuation of MagForce is €303.1m or €11.5/share (previously €307.6m or €11.7/share), based on a risk-adjusted NPV analysis. The main factor in the slight reduction in valuation is changing the trajectory of EU GBM revenue forecasts, reflecting the delays in NanoActivator installations across the broader EU market and lower sales in Germany. We have rolled forward our model, updated FX rates and reflected the slight equity dilution in MagForce USA (-9pp).

21 November 2018

Price	**€5.70**
Market cap	**€150m**
	$1.14/€
Net debt (€m) at 30 June 2018	10.0
Shares in issue	26.3m
Free float	66.2%
Code	MF6
Primary exchange	Frankfurt (Xetra)
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(7.9)	(9.5)	(22.7)
Rel (local)	(3.9)	0.8	(8.7)
52-week high/low		€7.9	€4.5

Business description

MagForce is a German firm with the first European approved nanotechnology-based therapy to treat brain tumours. NanoTherm therapy consists of nanoparticle injection into the tumour, activated by an external magnetic field, producing heat and thermally destroying or sensitising the tumour.

Next events

NanoActivator installation in Poland	Q418
Preliminary readout from the US prostate cancer trial	Q119
FDA submission	Q319

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Revenues down for EU GBM treatments in 2018

In Europe, NanoTherm therapy is already approved via a CE mark to treat brain cancers, and the therapy can therefore be used to treat primary and recurrent brain tumours. MagForce reported revenues of €24k for this indication in H118, which is lower than revenues in previous years. Revenues from the sale of NanoTherm nanoparticles and usage of NanoActivator devices totalled €154k for FY17 and €176k for FY16. Reported revenues in H118 have been affected by multiple factors including:

- A change of revenue recognition in the period, reflecting the fact that reimbursement in Germany is not guaranteed and revenues will now be recorded once reimbursement has been settled (currently in negotiations).
- The lower revenue figure also reflects the later than anticipated expansion into Poland, with Polish patients delaying travelling to Germany for treatment given that the full cost of treatment (including hospitalisation and surgical costs) is likely to be much lower in Poland.
- Patients from the broader EU market (including Poland) were waiting around two months for cross-border reimbursement negotiations to conclude for treatment in Germany, but during this wait had progressed beyond the point where they would benefit from treatment.

To drive growth in sales, MagForce is focused on reimbursement discussions with various member states and rolling out NanoActivator devices (to enable NanoTherm therapy) into the broader European market. Access to the devices outside Germany remains a key factor in driving treatment numbers. Financing from the EIB announced in October 2017 (up to €35m) is enabling MagForce to roll out its devices across Europe and reach patients who were previously unable to travel across the border to Germany (where MagForce has three commercially operational devices). Installation of a NanoActivator in Lublin, Poland is now planned by year end 2018 and is a significant milestone for MagForce's European expansion plans. Management also highlights Spain and Italy as other key locations where there is likely to be sharp uptake from private patients; roll-out into these territories has been slightly more protracted than we had expected. Furthermore, the reimbursement process, which varies by country, is critical to MagForce establishing substantial revenue growth; reimbursement discussions currently taking place in Germany should conclude in early 2019.

EU sales forecasts

Our forecasts for Europe are based on the number of NanoActivators that MagForce could install in both Germany and other Europe states, along with clinical uptake based on usage per device. We have reviewed our forecasts and have changed our EU GBM sales trajectory to reflect flat sales growth in Germany in 2018. We have also pushed back our 2018 sales forecasts to reflect the slower than expected roll-out of devices in territories beyond Germany. The first device is to be installed by year-end 2018 (in Poland). We forecast three installations a year in 2019 onwards in Europe outside Germany. This roll-out profile is required to achieve our peak sales forecasts, which we maintain at €10m for GBM in Germany and €61m in broader Europe. These estimates suggest that NanoTherm therapy would be treating c 3,500 patients pa in Europe at peak levels (c 2025). This should be seen in the context that around 25,000 new cases of brain cancer are diagnosed per year in the EU5 (the UK, France, Germany, Italy and Spain).

NanoTherm US prostate launch set for late 2019

NanoTherm therapy is regulated as a device rather than a drug in the US, and therefore follows a medical device regulatory route to approval. As part of this pathway, in May 2015 MagForce filed an IDE with the US FDA, which was subsequently granted in February 2018. In July 2018, MagForce reported the initiation of its pivotal prostate cancer trial across two clinical sites where NanoActivators are installed (University of Washington in Seattle, Washington and CHRISTUS Santa Rosa Hospital in San Antonio, Texas). The $9m gross proceeds from the capital increase in MagForce USA have provided funding to complete the ongoing prostate cancer trial, and both completion and submission for FDA review are expected in H219. While we maintain our €235m peak sales forecasts for prostate in the US for 2025, we have delayed launch to late 2019.

The single-arm US prostate cancer trial aims to recruit up to 120 prostate cancer patients who have a prostate cancer Gleason score of 7[1] and are under active surveillance to assess NanoTherm therapy as focal treatment for prostate cancer. The study is structured such that 10 patients will be treated initially (before year-end 2018), and preliminary data accessed to demonstrate that NanoTherm is safe and there is no systemic translocation of the nanoparticles from the prostate. Enrolment of the subsequent 110 patients will then be used to demonstrate efficacy as defined by no recurrence of tumour in a follow-up biopsy. The therapy aims to destroy localised tumours in the prostate of patients by focal ablation. By ablating the prostate cancer focally, MagForce anticipates that patients will be able to maintain active surveillance and avoid definitive treatments such as surgery or whole gland radiotherapy, which is associated with side effects such as impairment in urinary functions (incontinence) and sexual functions (impotence).

With a relatively quick turnaround time in determining whether the primary endpoint has been met (biopsy to confirm reduction of prostate cancer lesions), a six- to nine-month turnaround after the preliminary safety results (expected Q119) is conceivable, providing that trial recruitment proceeds as planned. Based on this, the data available in Q319 should be sufficient to support a pre-market approval application for the device (based on the larger NanoActivators), with smaller pNanoActivators approved towards the end of the clinical trial, either by being included in the clinical data package or via the 510k route (using the original NanoActivator as the predicate device). While the GBM indication is reliant on the larger NanoActivators for activation of the NanoTherm nanoparticles, the more localised prostate cancer can be treated by the pNanoActivators (smaller ambulatory machines that resemble a dentist's chair), thereby widening outreach to the US patient pool in the longer term.

We assume regulatory approval and first sales of treatments from Q419, assuming timely recruitment of the remaining 110 patients is achieved in H119. We assume that all future device sales will be of the smaller (and substantially cheaper) pNanoActivators and that devices will be provided via third-party leasing, MagForce will collect revenues from the sale of the pNanoActivators to the leasing provider. MagForce believes it will have 20 pNanactivators installed by Q419, and we conservatively assume that each prostate NanoActivator could treat around 30 patients per year in 2019. As a smaller quantity of nanoparticles will likely be required in prostate cancer, we assume a lower vial price of around a quarter of GBM, ie around $7k per vial. This price would position NanoTherm competitively with brachytherapy and each prostate NanoActivator could therefore generate revenues. Our estimates for peak sales of combined NanoTherm therapy and pNanoActivator sales of $268m (€235m) are based on annual roll-out of 20-35 devices per year from 2019, with 200 patients treated per device at peak in 2025.

[1] Grade 7 Gleason score defines a moderately growing tumour in the prostate that can be readily operated on.

NanoTherm overview

The destruction or treatment of cancerous cells with heat, commonly through laser or microwave irradiation, is well established. Current techniques can often be intrusive and can be hampered by unfocused heat distribution. NanoTherm therapy is utilised to ablate cancerous cells at the core of a tumour, while generating lower temperatures in the hyperthermia region at the edges of the tumour, minimising healthy cell damage. The NanoTherm therapy has three main components:

- NanoTherm consists of magnetic nanoparticles suspended in a liquid (ferrofluid) that are injected directly into tumour tissue. The nanoparticles consist of an iron oxide core with a patented aminosilane coating. These nanoparticles are activated with an alternating magnetic field, which generates heat that either kills or sensitises the tumour cells.
- NanoPlan is a software package that calculates the strength of magnetic field needed for the magnetic nanoparticles to reach the required temperature. The software takes into account the size and location of the tumour and the distribution of nanoparticles to determine the strength of the magnetic field. This information is critical for the correct application of the technology and is fed in from either magnetic resonance imaging (MRI) or positron emission tomography (PET) data.
- NanoActivator is a freestanding, room-sized device that generates and applies a magnetic field to a patient. This magnetic field induces an oscillation in the iron oxide nanoparticles, which in turn generate heat. To measure the exact temperature change, a thermometry catheter is inserted into the tumour via a minimally invasive surgical procedure alongside the administration of the nanoparticles.

Financials

MagForce AG is the parent company of the MagForce group, which consists of five companies: MagForce AG, MagForce USA, MagForce USA Holding GmbH, MagForce Ventures GmbH and MT MedTech Engineering GmbH. The company is not required to report consolidated financial statements under HGB accounting standards.

MagForce reported net profit of €4.1m in H118 (H117: €3.0m loss). Revenues from sales decreased for H118 to €24k (H117: €683k), and are a reflection that revenues in Europe continue to be affected by a lengthy reimbursement process (carried out on a per-patient basis) and a change in revenue recognition. Other operating income, reported at €9.1m in H118 (H117: €605k), was largely attributed to the transfer of 975,000 shares in MagForce USA to MagForce USA Holding GmbH on 25 June 2018, and consequent realisation of hidden reserves of €8.8m at the parent company level (MagForce AG). This is a non-cash item of a non-operating nature. Cost of materials decreased to €364k (H117: €574k) due to the lower use of raw materials, supplies and purchased goods. Personnel expenses were in line y-o-y at €1.7m. We have updated our 2018 forecasts to include the €8.8m as non-operating income, which reduces our forecast operating loss for 2018 to €1.8m from €8.0m. However, we highlight the potential one-time impact and forecast a higher operating loss of €8.2m in 2019. Exhibit 1 summarises the key changes to our forecasts.

MagForce reported cash and cash equivalents at 30 June 2018 of €5.3m. In January 2018, the first €10.0m tranche of the €35.0m loan facility with the EIB (secured in October 2017) was disbursed with a five-year maturity (with interest, €10.4m is owed). In May 2018, the €400k loan granted from Lipps & Associates was repaid with interest (the loan was due on 30 June 2019 and had a 5% interest rate). Interest repayments of €83k were made for the €5m convertible bond issued in March 2017 (the bond has a maturity of three years, an interest rate of 5% pa and a conversion price of €5/share). As at 30 June 2018, MagForce had net debt of €10m (H117: €0.4m).

Exhibit 1: Summary of our forecast changes for 2018 and 2019

€m	2018 old	2018 new	2019 old	2019 new
Revenues	2.898	0.345	7.107	5.819
Other operating income	0	8.769	0	0
EBITDA	(7.613)	(10.244)	(6.646)	(7.822)
Operating profit/(loss)	(7.977)	(1.810)	(7.068)	(8.195)
PBT - normalised	(8.788)	(11.391)	(7.943)	(9.070)
PBT - reported	(8.790)	(2.624)	(7.943)	(9.070)
EPS (€) - normalised	(0.33)	(0.43)	(0.30)	(0.34)
EPS (€) - reported	(0.33)	(0.10)	(0.30)	(0.34)

Source: Edison Investment Research

Valuation

Our updated valuation is €303.1m or €11.5/share (previously €307.6m or €11.7 per share) based on a risk-adjusted NPV analysis. The main factor in the slight reduction in valuation is pushing back our EU revenue forecasts (for GBM) by a year, reflecting the delay in NanoActivator installations in the broader EU market and lower sales in Germany. We have rolled forward our model and updated it to reflect H118 results, net debt of €10.0m at 30 June 2018 and updated FX exchange rates. We have also reflected dilution in the US subsidiary to reflect MagForce's 68% stake (previously 77%). We value only treating glioblastoma multiforme (GBM) in the EU and prostate cancer in the US. While we recognise MagForce's intention to treat additional indications in each region, we do not currently value these opportunities. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 2.

Exhibit 2: MagForce risk-adjusted NPV valuation

Product	Indication	Launch	Peak sales (€m)	Peak sales ($m)	NPV (€m)	Probability	MagForce AG beneficial interest	rNPV (€m)	rNPV/share (€/share)
NanoTherm EU	GBM - Germany	2016	10	11	29.6	100%	100%	29.6	1.1
	GBM - Broader Use	2019	61	69	89.2	100%	100%	89.2	3.4
NanoTherm US	Prostate Cancer	2019	235	268	345.3	80%	68%	187.5	7.1
Net debt (AG), H118					(10.0)	100%	100%	(10.0)	(0.4)
Net cash (US)					10.0	100%	68%	6.8	0.3
Valuation					464.1			303.1	11.5

Source: Edison Investment Research. Note: peak sales are rounded to the nearest €5m/$5m for original currency.

Exhibit 3: Financial summary

€'000s	2015	2016	2017	2018e	2019e
December	HGB	HGB	HGB	HGB	HGB
PROFIT & LOSS					
Revenue	2,576	474	716	345	5,819
Cost of Sales	(2,959)	(574)	(974)	(3,713)	(6,031)
Gross Profit	(383)	(101)	(258)	(3,368)	(212)
EBITDA	(4,421)	(6,554)	(6,739)	(10,244)	(7,822)
Operating Profit (before amort. and except.)	(4,871)	(7,456)	(7,410)	(10,577)	(8,195)
Intangible Amortisation	(5)	(5)	(1)	(2)	(0)
Exceptionals	3,000	0	0	0	0
Other	0	0	0	8,769	0
Operating Profit	(1,876)	(7,461)	(7,411)	(1,810)	(8,195)
Net Interest	329	231	(53)	(814)	(875)
Profit Before Tax (norm)	(4,542)	(7,225)	(7,463)	(11,391)	(9,070)
Profit Before Tax (reported)	(1,547)	(7,230)	(7,464)	(2,624)	(9,070)
Tax	(0)	(1)	(1)	0	0
Profit After Tax (norm)	(4,542)	(7,226)	(7,464)	(11,391)	(9,070)
Profit After Tax (reported)	(1,547)	(7,231)	(7,465)	(2,624)	(9,070)
Average Number of Shares Outstanding (m)	25.6	26.0	26.3	26.3	26.3
EPS - normalised (c)	(17.7)	(27.8)	(28.3)	(43.2)	(34.4)
EPS - (reported) (€)	(0.06)	(0.28)	(0.28)	(0.10)	(0.34)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	19,533	18,742	20,672	29,117	30,519
Intangible Assets	7	3	1	0	0
Tangible Assets	4,494	3,706	3,589	3,267	4,668
Investments	15,033	15,033	17,082	25,851	25,851
Current Assets	5,325	1,536	1,360	2,801	4,991
Stocks	81	71	301	305	496
Debtors	91	71	85	189	3,188
Cash	1,393	614	666	2,000	1,000
Other	3,760	780	307	307	307
Current Liabilities	(1,779)	(4,431)	(3,747)	(3,592)	(5,092)
Creditors	(1,779)	(4,431)	(3,747)	(3,592)	(5,092)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(197)	(197)	(5,091)	(15,876)	(27,038)
Long term borrowings	0	0	(5,012)	(15,798)	(26,960)
Other long term liabilities	(197)	(197)	(79)	(78)	(78)
Net Assets	22,881	15,650	13,193	12,450	3,380
CASH FLOW					
Operating Cash Flow	(8,808)	(1,078)	(7,930)	(10,507)	(9,512)
Net Interest	329	231	(53)	(814)	(875)
Tax	(0)	(1)	(1)	0	0
Capex	(1,357)	(115)	(553)	(10)	(1,775)
Acquisitions/disposals	0	0	0	0	0
Financing	0	0	5,000	0	0
Dividends	0	0	0	0	0
Net Cash Flow	(9,837)	(963)	(3,538)	(11,331)	(12,162)
Opening net debt/(cash)	(11,153)	(1,393)	(614)	4,347	13,798
HP finance leases initiated	0	0	0	0	0
Other	77	184	(1,423)	1,880	(0)
Closing net debt/(cash)	(1,393)	(614)	4,347	13,798	25,960

Source: Company accounts, Edison Investment Research

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