EDISON

MagForce

Corporate update

US NanoTherm IDE approval a major milestone

Healthcare equipment & services

MagForce has received IDE approval to start its first pivotal clinical trial evaluating NanoTherm focal ablation therapy for prostate cancer in the US. This is a major milestone for the company. Prostate cancer in the US presents a significant market opportunity (representing ~60% of our rNPV) and makes sense strategically as a first US indication. The start of this trial will broaden the geographic and therapeutic reach of NanoTherm therapy beyond Europe, where it is already approved for brain cancer. Our updated valuation is €302.6m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	2.6	(4.5)	(0.18)	0.0	N/A	N/A
12/16	0.5	(7.2)	(0.28)	0.0	N/A	N/A
12/17e	0.8	(7.0)	(0.26)	0.0	N/A	N/A
12/18e	2.9	(8.8)	(0.33)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. Figures above do not include MagForce USA.

Prostate IDE approved: US trials to initiate shortly

The original investigational device exemption (IDE) was filed in May 2015 and during 2016 and 2017 MagForce USA updated its preclinical NanoTherm study data to meet FDA standards. Importantly, ahead of the IDE approval, MagForce USA has installed two NanoActivators in two different clinical sites (Seattle and San Antonio). Patient recruitment for focal ablation therapy in 120 advanced to intermediate-risk prostate cancer patients should start promptly (within months). NanoTherm could be approved and launched for treatment of prostate cancer patients by the end 2019.

EU multi-strategy approach to drive uptake

In October 2017 MagForce announced financing from the European Investment Bank (EIB) of up €35m. This funding will in part enable MagForce to roll out its NanoTherm devices across Europe and reach patients who were previously reluctant to travel across the border to Germany (where MagForce has six devices installed and three used commercially) for glioblastoma multiforme (GBM) treatment. Key to the roll-out will be achieving reimbursement in selected European countries. Efforts to raise both clinicians' and patients' awareness of the therapy will additionally determine the success of the devices in these new territories.

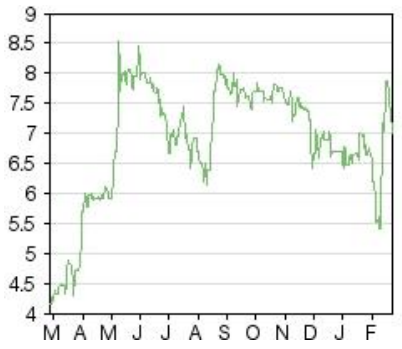
Valuation: rNPV revised to €302.6m or €11.5/share

Our valuation has increased to €302.6m (from €226m). We have raised our NanoTherm US prostate launch peak sales to $268m, but have deferred launch by a year to end 2019. We step up success probability rates of NanoTherm US prostate (from 70% to 80%) and NanoTherm GBM in Europe (outside Germany) from 65% to 100%. Valuation has also been affected by updating the FX rate ($1.23/€ vs $1.11/€ previously) and rolling forward our DCF. Following the EIB financing, we expect three NanoActivators to be launched in three countries in FY18 to serve broader EU glioblastoma. We now forecast initial sales from 2018.

23 February 2018

Price	**€7.01**
Market cap	**€185m**
	$1.23/€
Net debt (€m) at 30 June 2017	0.7
Shares in issue	26.3m
Free float	70%
Code	MF6X
Primary exchange	Frankfurt (Xetra)
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	1.0	(4.5)	64.7
Rel (local)	9.1	(0.3)	58.6
52-week high/low		€9.1	€4.2

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

US prostate cancer trial start	Q218
Further NanoActivator installations	2018

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Edison profile page

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US IDE approval a major milestone

NanoTherm therapy is regulated as a device rather than as a drug in the US, and therefore follows a medical device regulatory route through to approval. As part of this pathway, in May 2015 MagForce filed an IDE with the US FDA. During 2016 and 2017 MagForce worked with the FDA to update preclinical study data conducted a decade earlier to current FDA standards and addressed concerns with regards to hemocompatibility, pyrogenicity, biocompatibility/toxicity and migration of nanoparticles. While the IDE approval has taken longer than anticipated, it has now been granted and MagForce USA is in a position to start patient recruitment promptly. The opportunity in US prostate is a key component of our valuation (~60% of risk-adjusted NPV). The company believes there are potentially 50,000 to 100,000 men in active surveillance programmes in prostate cancer in the US who could benefit from this focal therapy.

Two NanoActivators ready and waiting to begin pivotal trials

In November 2015, MagForce announced that the first NanoActivator (a magnetic field device in which NanoTherm therapy is used to ablate cancer lesions) had been installed in the US in Seattle, Washington. A second machine was installed in 2017 at CHRISTUS Santa Rosa Hospital in San Antonio, Texas where Dr Ian M Thompson Jr, MD, the co-principal investigator, is based. The clinical site incorporates a clinical office and the NanoActivator treatment centre. Both of these NanoActivators were used to collect the preclinical data for FDA submission. MagForce anticipates that the study will initiate in the next few months. It expects the single-arm trial to recruit up to 120 prostate cancer patients [who have grade 7 (Gleason score) prostate cancer and are under active surveillance] to assess NanoTherm therapy as focal treatment for prostate cancer. Grade 7 defines a moderate growing tumour, one that can be readily operated on. Focal therapy aims to destroy localised tumours in the prostate in patients with intermediate-risk prostate cancer (those patients who are not severe enough to warrant aggressive therapy and instead are under active surveillance to monitor the tumour). 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 and sexual functions. Clinical endpoints include evaluation of adverse effects and impact on overall survival.

Paving way for a late 2019 launch

Assuming the trial takes around 12-15 months to complete, data could become available in 2019. This should be sufficient to support a pre-market approval application for the device (based on the larger NanoActivators), with the 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). We assume approval and first sales of the pNanoActivators from Q419, allowing time for filing and regulatory review following data in 2019. We assume that after the installation of the three larger NanoActivators (potentially by the end of 2018) all future device sales will be the smaller pNanoActivators. While GBM indication is reliant on the larger and much more costly NanoActivators for NanoTherm administration, the more localised prostate cancer can be treated by the pNanoActivators (smaller ambulatory machines that resemble a dentist's chair), developed by MagForce to fit into the smaller clinic setting thereby widening outreach to the US patient pool in the longer term. For more details, see our May 2017 outlook note Steady progress.

After lung cancer, prostate cancer is the most common cancer among men. In 2012, there were 1.1 million reported new cases of prostate cancer worldwide, with 307.5 thousand deaths. Treatment of prostate cancer depends on the progression of the disease; for localised cancer, surgery is

commonly used, with chemo, radiation, hormone and biologic therapy combinations also used for more advanced cases. Prostate cancer has surgical treatment rates of around one in 10 patients, representing a significant patient population. Surgical treatments commonly involve a radical prostatectomy: the complete removal of the prostate including surrounding tissue. Two types exist: retropubic (incision in the abdomen) or perineal (incision in the area between the scrotum and anus) prostatectomy. Common problems after surgery include impotence, inguinal hernia (bulging of fat/small intestine through weak muscle) and leakage of urine.

US prostate peak sales potential of $268m (€218m)

Following discussions with management we have revisited our US prostate peak sales assumptions. Based on the proposed design of the pNanoActivators, we assume it will be possible to install 20-40 devices per year in the US at peak (from 20-30). However, we note that this number is difficult to predict at this stage and will depend on successful uptake of the device (driven by the clinical trial data and the size of the salesforce). We conservatively assume each prostate NanoActivator could treat around 200 patients per year (MagForce believes that a 35-40% utilisation rate of 500 patients per machine is plausible). A smaller quantity of nanoparticles will likely be required in prostate cancer, hence we assume a lower vial price of around a quarter of that used for GBM, ie around $7k per vial (our previous assumption was $6k). This price would position NanoTherm competitively with brachytherapy radioactive seeds. Each prostate NanoActivator could therefore generate revenues of almost $1.4m per year, leading to a potential opportunity of $268m (€218m).

Broader European expansion in the future

In Europe, NanoTherm therapy is already approved via a CE mark to treat brain cancers, and NanoTherm therapy can therefore be used to treat primary and recurrent brain tumours. MagForce is focused on attracting patients from across the brain cancer spectrum, rather than just on recurrent disease, thereby enlarging the patient population that could benefit from this treatment.

In October 2017 MagForce announced financing from the EIB of up €35m. This funding will enable MagForce to roll out its NanoTherm devices across Europe and reach patients who were previously reluctant to travel across the border to Germany (where MagForce has six devices installed, three used commercially) for glioblastoma treatment. Access to the devices remains a key factor in driving treatment numbers. However, efforts to raise both clinicians' and patients' awareness of the therapy will ultimately determine the success of the devices in these new territories. We expect that MagForce will look to accelerate installations of NanoActivators outside Germany this year (three NanoActivators will be installed in Poland, Spain and Italy), as physicians gain more experience of the therapy and more data become available. The reimbursement process, which varies by country, is critical.

GBM in Europe could be a c €60m opportunity

Our European revenue forecasts are based on the number of NanoActivators that MagForce could install in Germany and Europe. With the understanding gained from marketing in Germany that seriously ill GBM patients are reluctant to travel across borders, the placement of devices throughout Europe is vital in driving revenues. We assume peak sales of c €60m in the broader EU, assuming that 20-25 machines are installed over the next five to 10 years, and we expect the first revenues to begin to be booked in FY18. We reduce our 2017 and 2018 sales forecasts to reflect a slower than expected roll-out of devices. We expect three of the NanoActivators in Germany to be redeployed across separate European countries in FY18. These estimates suggest that NanoTherm therapy would be treating fewer than 4,000 GBM patients pa in Europe in the future at peak levels. This should be seen in the context of around 25k new cases of brain cancer in the EU5

(the UK, France, Germany, Italy and Spain) per year. GBMs can be divided into two types: the more common faster growing primary tumours and the slower but still aggressive secondary tumours. Primary tumours make up about 90% of all GBMs and are the focus of MagForce's NanoTherm therapy.

Prostate cancer development is a distinct possibility

With the NanoTherm nanoparticle-based therapy for cancer prostate cancer now advancing into a pivotal clinical trial in the US, this indication could also be developed in Europe, using data from the US to help secure approval. At this early stage, we attribute no value to prostate cancer in Europe due to the company's focus on GBM in Europe and no information on timelines for this indication in the US.

NanoTherm therapy

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 suffer from unfocused heat distribution. Cancer cells are more susceptible to heat than healthy cells; while dependent on cell type, it is generally believed that healthy cells can survive at temperatures around 42°C, temperatures at which cancerous cells undergo necrosis (cell death). Temperature increases of up to approximately 43°C result in hyperthermia-associated cell death, while temperatures above 43°C result in thermoablation, which causes irreversible destruction of both healthy and cancerous cells. MagForce's NanoTherm therapy is utilised to ablate cancerous cells at the core of a tumour, while generating lower temperatures in the hyperthermia region on the edges of the tumour, minimising healthy cell damage. The NanoTherm therapy consists of three main components: NanoTherm, NanoPlan and NanoActivator.

NanoTherm: Ferrofluid injected directly into the tumour

NanoTherm consists of magnetic nanoparticles suspended in a liquid (ferrofluid) that are injected directly into tumour tissue. These nanoparticles are activated with an alternating magnetic field; this activation generates heat. The nanoparticles consist of an iron oxide core with a patented aminosilane coating. These nanoparticles are suspended in water and form a colloidal dispersion.

The structure and stability of nanoparticles is dependent on their size and morphology. Different synthesis techniques may generate particles of similar size but varying magnetic properties. Manufacturing of nanoparticles produces a distribution of sizes; minimising this range allows more control over key properties and is vital in delivering consistent treatment.

The applied magnetic field from the NanoActivator is converted to heat by the hysteresis of the magnetic nanoparticles. Magnetic hysteresis produces heat, which is undesirable in most applications. However, this effect can be taken advantage of in the treatment of tumours.

Thermal distribution of the nanoparticle heat can vary depending on the type of tissue, heating time and nanoparticle composition. A balance between heat generation in the particles and the flow to the surrounding tissues must be achieved. Along with the heterogeneity of tissues, nanoparticle distribution will vary across the compartments of a tumour. Once injected into the tumour, the nanoparticles aggregate and have been shown to remain where they have been injected. These nanoparticles are then exposed to a magnetic field of enough strength to produce heat. This heat either kills the tumour cells or sensitises them to other treatments (radiotherapy/chemotherapy).

NanoPlan and NanoActivator

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 or positron tomography 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 that either kills or sensitises the tumour cells. 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. Alongside the original NanoActivator, MagForce is developing a more compact version for specific use in the US prostate market.

GBM study data

Data from the largest trial to date utilising NanoTherm therapy was published in 2010. A total of 66 GBM patients were enrolled in a single-arm study in two centres. The trial utilised a combination of NanoTherm therapy and radiotherapy. The primary endpoint was overall survival following diagnosis of first tumour recurrence, with the secondary endpoint being overall survival after primary tumour diagnosis. The primary endpoint demonstrated a 13.4-month median overall survival, while secondary endpoint data demonstrated a 23.2-month median overall survival. No control arm was present in the study so it is difficult to compare both endpoints with other treatments. However, a review of therapeutic options demonstrates that the median overall survival for patients treated after reoccurrence falls between six and 12 months, and for patients after initial tumour diagnoses between 15 and 18 months. A trial cited by MagForce as a historical control demonstrated that the median survival for 573 newly diagnosed patients utilising a combination of radiotherapy and temozolomide was 14.6 months.

Valuation

Our valuation has been increased to €302.6m (from €226m). The main changes to our assumptions are:

- Raising our peak forecasts for NanoTherm US prostate sales (as explained above) to $268m from $213m and deferring launch by one year to end 2019 (we delay revenues and associated R&D and S&M costs accordingly)
- Increasing the success probability rates of NanoTherm US prostate (from 70% to 80%) and NanoTherm GBM in Europe (outside Germany) from 65% to 100%. Following the EIB financing, we model that three NanoActivators are launched in three countries to serve broader EU glioblastoma. We now forecast initial sales from 2018 (delayed by one year) and increase the probability to 100% to reflect increased confidence of a launch this year. However, we reduce our 2017 and 2018 sales forecasts to reflect a slower than expected roll-out of devices.
- The valuation has also been affected by updating the FX rate ($1.23/€ vs $1.11/€ previously) and rolling forward our DCF.

Our valuation is based on a risk-adjusted NPV analysis. It is centred on NanoTherm therapy, risk-adjusted to reflect the current development status and the respective core strategies for the EU and US. We value only GBM in the EU and prostate cancer in the US. While we recognise MagForce's future intention to treat additional indications in each region, we do not currently value these opportunities.

Our valuation takes into account €0.7m net debt for MagForce AG at end June 2017, in addition to including estimated net cash held in MagForce USA (which is not specifically disclosed in the financial statements). We use a $1.23/€ spot rate. Note that while we value MagForce USA as per company reporting, it is not consolidated into our financial model. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 1.

Exhibit 1: MagForce risk-adjusted NPV valuation

Product	Indication	Launch	Peak sales (€m)	Peak sales ($m)	NPV (€m)	Probability	MagForce beneficial interest	rNPV (€m)	rNPV/ share (€)
NanoTherm EU	GBM - Germany	2016	10	12	28.6	100%	100%	28.6	1.1
	GBM - broader use	2018	60	74	89.0	100%	100%	89.0	3.4
NanoTherm US	Prostate cancer	2019	210	268	289.2	80%	77%	178.0	6.8
Net debt (AG)					(0.7)	100%	100%	(0.7)	(0.0)
Net cash (US)					10.0	100%	77%	7.7	0.3
Valuation					**416.1**			**302.6**	**11.5**

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

MagForce's net debt as of 30 June 2017 was €0.7m (cash in hand, bank balances and checks reported at €7.7m). In February 2017, Lipps & Associates LLC granted a loan of €400k to MagForce. The loan is due on 30 June 2019 and has a 5% interest rate. In June 2017, a further €3.0m was loaned to MagForce at 4% interest, also due on 30 June 2019. In March 2017, a €5m convertible bond was issued with a maturity of three years, an interest rate of 5% pa and a conversion price of €5/share. In June, MagForce raised €5m via a capital raise with M&G International Investments, placing 0.7m shares at €6.94. Post period MagForce agreed a €35m loan from the EIB, of which €10m was available for immediate drawdown.

Exhibit 2: Financial summary

€'000s	2015	2016	2017e	2018e
December	HGB	HGB	HGB	HGB
PROFIT & LOSS				
Revenue	2,576	474	828	2,898
Cost of Sales	(2,959)	(574)	(2,528)	(3,935)
Gross Profit	(383)	(101)	(1,700)	(1,037)
EBITDA	(4,421)	(6,554)	(6,243)	(7,613)
Operating Profit (before amort. and except.)	(4,871)	(7,456)	(6,560)	(7,969)
Intangible Amortisation	(5)	(5)	(2)	(0)
Exceptionals	3,000	0	0	0
Other	0	0	0	0
Operating Profit	(1,876)	(7,461)	(6,562)	(7,969)
Net Interest	329	231	(391)	(814)
Profit Before Tax (norm)	(4,542)	(7,225)	(6,951)	(8,783)
Profit Before Tax (reported)	(1,547)	(7,230)	(6,954)	(8,783)
Tax	(0)	(1)	0	0
Profit After Tax (norm)	(4,542)	(7,226)	(6,951)	(8,783)
Profit After Tax (reported)	(1,547)	(7,231)	(6,954)	(8,783)
Average Number of Shares Outstanding (m)	25.6	26.0	26.3	26.3
EPS - normalised (€)	(0.18)	(0.28)	(0.26)	(0.33)
EPS - normalised and fully diluted (€)	(0.18)	(0.28)	(0.26)	(0.33)
EPS - (reported) (€)	(0.06)	(0.28)	(0.26)	(0.33)
Dividend per share (€)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	19,533	18,742	18,847	19,778
Intangible Assets	7	3	0	0
Tangible Assets	4,494	3,706	3,814	4,745
Investments	15,033	15,033	15,033	15,033
Current Assets	5,325	1,536	18,301	9,154
Stocks	81	71	208	323
Debtors	91	71	454	1,588
Cash	1,393	614	16,860	6,463
Other	3,760	780	780	780
Current Liabilities	(1,779)	(4,431)	(4,397)	(4,965)
Creditors	(1,779)	(4,431)	(4,397)	(4,965)
Short term borrowings	0	0	0	0
Long Term Liabilities	(197)	(197)	(18,597)	(18,597)
Long term borrowings	0	0	(18,400)	(18,400)
Other long term liabilities	(197)	(197)	(197)	(197)
Net Assets	22,881	15,650	14,154	5,370
CASH FLOW				
Operating Cash Flow	(8,808)	(1,078)	(6,795)	(8,296)
Net Interest	329	231	(391)	(814)
Tax	(0)	(1)	0	0
Capex	(1,357)	(115)	(425)	(1,287)
Acquisitions/disposals	0	0	0	0
Financing	0	0	5,000*	0
Dividends	0	0	0	0
Net Cash Flow	(9,837)	(963)	(2,611)	(10,397)
Opening net debt/(cash)	(11,153)	(1,393)	(614)	1,540
HP finance leases initiated	0	0	0	0
Other	77	184	458	(0)
Closing net debt/(cash)	(1,393)	(614)	1,540	11,937

Source: MagForce Accounts, Edison Investment Research. Note: Historical and forecast cash flow numbers are Edison estimates as Magforce does not publish a statement of cash flows. All financial data is on an unconsolidated basis and does not include MagForce USA. *Gross equity proceeds.

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