

MagForce

Coming out in Force

Initiation of coverage

Pharma & biotech

27 November 2013

Price €4.6

Market cap €110m

Net cash (€m) as at end June 2013 13.5

Shares in issue 23.9m

Free float 51%

Code MF6

Primary exchange Frankfurt

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 23.9 62.7 146.4

Rel (local) 19.9 47.8 93.4

52-week high/low €5.3 €1.8

Business description

MagForce is a German firm with a 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

Additional NanoActivator installations in Germany Q413

Start of new GBM study Q413

US action plan Q413

First commercial sales 2014

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MagForce is well positioned to execute on its strategy to increase uptake of its novel NanoTherm therapy, which is already approved in Europe for brain cancer. A new glioblastoma study due to start imminently should help increase awareness and acceptance of this treatment. MagForce is also intending to enter the US market and to develop NanoTherm therapy for prostate cancer. Our risk-adjusted valuation is €197m or €8.2/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/11	0.0	(7.6)	(2.1)	0.0	N/A	N/A
12/12	0.0	(5.7)	(1.2)	0.0	N/A	N/A
12/13e	0.0	(6.7)	(0.5)	0.0	N/A	N/A
12/14e	1.6	(5.6)	(0.2)	0.0	N/A	N/A

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

Expanding Europe

MagForce's NanoTherm therapy is already approved in Europe for the treatment of brain cancer. In order to increase physician acceptance and awareness of the therapy, MagForce has worked closely with a number of key opinion leaders to design a new glioblastoma (GBM) study. The trial is due to start imminently and multiple centres have been established at which new NanoActivators will be installed. With two NanoActivators in place, this will bring the installed base to eight in Germany alone, with expansion into additional centres in Europe anticipated in the next few years. We estimate peak EU sales of €100m in GBM.

Looking to the US

MagForce is planning to introduce NanoTherm therapy to the US market. GBM is initially being targeted, with plans to also develop prostate cancer. With a purely physical 'thermal' mechanism of action, development risk in other indications is lower than for a drug acting on biological pathways. If medical device status is awarded, this would reduce the development and regulatory burden. In addition, the CEO's US network should facilitate US market entry, where sales could be around \$300m in prostate cancer alone.

A new approach for the treatment of cancer

MagForce's unique NanoTherm therapy has been designed to directly impact tumours from within, while sparing surrounding healthy tissue. Nanoparticles are injected into a tumour and heated by an external magnetic field. This can destroy or sensitise the tumour for additional treatment such as chemotherapy or radiotherapy.

Valuation: Risk-adjusted NPV of €197m

We value MagForce at €197m or €8.2/share based on a risk-adjusted NPV analysis, which includes €13.5m net cash and NanoTherm in Germany, in addition to risk-adjusted contributions from broader EU uptake, US market entry and new indications. MagForce will likely need additional funds to pursue the US opportunity.

MagForce is a research client of Edison Investment Research Limited

Investment summary

Company description: Entering a new phase

MagForce is uniquely positioned in Europe, with a novel approved nanotechnology-based treatment for brain cancer and the potential to expand this to other regions and indications. Magnetic nanoparticles are directly injected into a tumour, which are then heated with an external magnetic field. MagForce's NanoTherm therapy can thermally destroy or sensitise a solid tumour and can be used with existing treatment options including radio- and chemotherapy. Management is now working to drive uptake and acceptance of this therapy in Europe, introduce this treatment to the US market and develop it in other indications such as prostate cancer.

MagForce was founded in 1997 and is based in Berlin, with 18 employees, in addition to eight employees at its wholly owned subsidiary production company.

Exhibit 1: NanoTherm pipeline

Geography	Status	Comments
Germany	Approved in brain cancer	Two NanoActivators installed with an additional six planned; new GBM study about to start.
EU27 ex-Germany	Approved in brain cancer	Working with key opinion leaders and aiming to install NanoActivators in the next few years in countries including Switzerland, the UK, Italy, France, Sweden and the Netherlands.
Broader EU	Partnered with Tek Grup (Turkey and surrounding regions) and DELRUS (Russia and surrounding)	Each distributor is responsible for obtaining marketing authorisation.
US	Actively pursuing GBM and prostate cancer	Plans to initially introduce NanoTherm for GBM, with plans to expand into prostate cancer. A preclinical research agreement is already in place with the Mayo Clinic.

Source: MagForce, Edison Investment Research

Valuation: Risk-adjusted NPV of €197m or €8.2/share

We value MagForce at €197m or €8.2/share, based on a risk-adjusted NPV analysis using a 12.5% discount rate. Our rNPV includes €13.5m cash and NanoTherm therapy in Germany based on the existing and planned NanoActivators. In addition, we include risk-adjusted contributions for NanoTherm from broader EU penetration, both alone and with existing partners, and from the US market. The European GBM opportunity could generate around €100m in sales. The US could be at least \$300m, based on prostate cancer alone. If MagForce can successfully deliver on its NanoTherm strategy, our estimates suggest a potential valuation of nearly €400m.

Sensitivities: Strategy execution

With NanoTherm already approved in Europe in brain cancer, delivering on the strategy to increase uptake, drive installations and penetrate the US market will all be important to realise value from the technology. The new GBM study should help increase physician acceptance as part of the European strategy. Any delays to this study or installation of the NanoActivators could affect initial commercial sales in Europe. In the US, an experienced US CEO should facilitate entry into this market. With efficacy already demonstrated in Europe in GBM, this should reduce development risk in the US. Furthermore, a physical, rather than biological mechanism of action minimises development and regulatory risks in additional indications. However, any delays to trials in the US, or lack of physician buy-in, could prolong the launch or lead to lower sales than anticipated.

Financials: Sufficient cash to deliver on European strategy

MagForce has sufficient cash to fund the new GBM study, a prostate proof-of-concept study and to install the planned NanoActivators in Germany. Developing the broader EU market, US market entry, in addition to prostate cancer plans including development of smaller NanoActivators, will all require additional funding.

Outlook: A new approach to cancer therapy

NanoTherm therapy is MagForce's novel cancer treatment, designed to directly impact the tumour from within, while sparing surrounding healthy tissue. Nanoparticles are heated in the presence of an external magnetic field generated by specialist equipment (NanoActivator), which either destroys or sensitises the tumour for additional treatment such as chemotherapy or radiotherapy. The product is approved in Europe for the treatment of brain tumours, and installation of additional NanoActivators is expected in the near term as part of a new glioblastoma study, which should help increase uptake. In addition, new CEO Ben Lipps' (previously CEO at Fresenius Medical Care) knowledge and experience of the US market should facilitate introduction of this novel technology to this key region. We value MagForce at €8.2/share, of which €7.7/share is for the NanoTherm therapy, based on the existing and planned NanoActivators in Germany, in addition to risk-adjusted contributions from broader EU penetration (both alone and with existing partners), and from the US market.

Approved in Europe for brain cancer

European approval was granted for NanoTherm therapy for the treatment of brain cancer in June 2010, based on a pivotal clinical study in 59 patients using the NanoActivator installed in Berlin. An additional NanoActivator has recently been installed in Munster, Germany, and a further six are planned across Germany in the near term. NanoTherm therapy is regulated as a medical device in Europe, rather than as a drug, which typically requires less cumbersome clinical development, with fewer clinical trials and fewer patients needed to secure approval. Despite approval there has been limited uptake to date owing to a lack of key opinion leader acceptance and awareness.

New glioblastoma study to drive uptake

A new glioblastoma (GBM) trial has been planned and designed with collaboration from a number of German and European key opinion leaders (KOLs). The study should generate additional information about the mechanism of action and efficacy of the technology and help in raising awareness, increasing clinical experience and growing the NanoActivator installed base. All of these should help drive uptake and acceptance of NanoTherm therapy.

Expanding to the US

MagForce plans to introduce NanoTherm therapy to the US for glioblastoma and prostate cancer. We expect clarity around the US development path to market in coming months. The appointment of Ben Lipps as CEO, who has significant knowledge and experience in the US market, should facilitate US market entry and reduce execution risk. MagForce already has a preclinical research agreement in place with the Mayo Clinic, which has helped to raise early awareness of NanoTherm.

Exhibit 2: Anticipated newsflow

News	Period	Comment
Additional NanoActivators in Germany	Q413	Two already installed; an additional installation is expected by year end 2013 and a fourth in early 2014
US market plans	Q413	Clarity and strategy around entering the US market
Prostate cancer development plans	Q413	Clarity on the path to market; start of proof-of-concept prostate cancer study
New GBM study FPI	Q413	Treatment of the first patient in the new GBM study
New GBM study main study start	Mid 2014	Start of the main study phase (after monotherapy run-in phase) of the new GBM trial
New GBM study run-in phase data	H214	First monotherapy data
Commercial revenues	2014	MagForce could start treating patients not eligible for the new GBM study
NanoActivators in Europe	2015	We anticipate first European installations in 2015
New GBM study initial data	2015	Data from the first patients could be available during H115 (O/L trial)
New GBM study data	2017	Full data from the new GBM study

Source: Edison Investment Research

Thermal treatment of solid tumours

Exhibit 3: All about NanoTherm therapy

Why was NanoTherm therapy developed?	In order to try and overcome some of the issues associated with conventional solid tumour treatment (chemotherapy, radiotherapy, surgery, or a combination of these), and to offer a new alternative that can potentially be used alone or in combination with existing treatment.
What are the principles behind NanoTherm?	NanoTherm therapy is a novel treatment that combines nanotechnology and thermal therapy. Magnetic nanoparticles are directly injected into the tumour and heated up with an external magnetic field. The heat either kills the tumour cells (thermal ablation) or sensitises them (hyperthermia) for additional treatment such as chemotherapy or radiotherapy. There are three components of the treatment: (1) NanoTherm particles; (2) NanoPlan software; and (3) NanoActivator machine.
NanoTherm particles	These tiny iron oxide particles are directly injected into a tumour and convert energy from an external magnetic field into heat energy within the tumour. The particles have been designed so they can be injected via syringe and then remain within the tumour after treatment to allow for multiple/repeated treatment.
NanoPlan software	The planning software is used to determine the magnetic field strength to be applied. The software predicts the temperature distribution within and around the tumour based on the nanoparticle dispersion. This allows tailor-made treatment depending on physician/patient requirements, for example thermal ablation or hyperthermia.
NanoActivator machine	This specialist machine (Exhibit 5) supplies the external magnetic field that can be used to treat tumours anywhere in the body. The alternating magnetic field causes the iron oxide nanoparticles to oscillate and heat up. The strength of the magnetic field can be adjusted to reach the desired temperature within the tumour and to surrounding tissue. The NanoActivators are built by MT MedTech, a wholly owned subsidiary of MagForce.

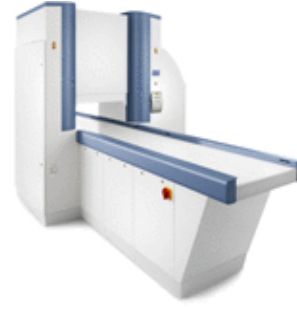
Source: Edison Investment Research

Exhibit 4: NanoTherm nanoparticles



Source: MagForce

Exhibit 5: NanoActivator



Source: MagForce

Survival benefits demonstrated in pivotal study...

The pivotal study was conducted in Germany in 59 patients with recurrent glioblastoma (66 patients were recruited, but seven did not meet the full inclusion criteria and were not included in the survival analysis). The primary endpoint was survival following a diagnosis of tumour recurrence or progression (OS-2). The secondary endpoint was overall survival from the point of glioblastoma diagnosis (OS-1). There was no comparator arm in the trial. Median OS-2 was 13.4 months, which compares favourably with reference data from a 2009 trial¹ of 6.2 months. Median OS-1 was 23.2 months, compared to reference data of 14.6 months. Although not directly comparable the study authors² concluded that the NanoTherapy data were clinically relevant.

In terms of safety and side effects, unsurprisingly, given the heat-based nature of the treatment, 50% of patients experienced grade 1 sweating, and 47% reported warmth in the treatment area. 22.7% of patients had convulsions with the study authors concluding that prophylactic anti-epileptic drug use should be considered in the future. Other side effects included body temperature in excess of 38°C (9.1%), grade 1 tachycardia (abnormally fast resting heart rate, 18.2%), blood pressure fluctuations (15.1%), headaches (13.6%) and motor disturbances (2.1%). Importantly, 19 patients were tested before and after nanoparticle injection for iron metabolism, and there was no indication of iron being released from within the tumour.

¹ Stupp R, Hegi ME, Mason WP et al (2009) Effects of radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy alone on survival in glioblastoma in a randomised Phase III study: five-year analysis of the EORTC-NCIC trial. *Lancet Oncol* 10:459–466.

² Maier-Hauff K, Ulrich F et al (2011) Efficacy and safety of intratumoral thermotherapy using magnetic iron-oxide nanoparticles combined with external beam radiotherapy on patients with recurrent glioblastoma multiforme. *J Neurooncol* (2011) 103:317–324.

NanoTherm nanoparticles were injected into the brain tumour under general anaesthetic in a procedure similar to a brain needle biopsy. The median dose was 0.28mL of magnetic fluid per cm³ of tumour volume, ie around 28% by volume. Once the magnetic nanoparticles were in place, six sessions in the NanoActivator were conducted semi-weekly, with radiotherapy performed immediately before or after. During this trial, the aim of the thermotherapy was hyperthermia, rather than thermal ablation, owing to the sensitivity of surrounding brain tissue; the median temperature recorded within the tumour was 51.2°C.

But approval has not led to sales

Despite EU approval in June 2010, commercial sales have been limited, with €41k of revenue from two patients in 2011. There are a number of reasons for the slow uptake, which include:

- **Lack of key opinion leader (KOL) awareness:** The pivotal clinical trial was carried out in two centres, using the NanoActivator installed in Berlin. The trial was primarily designed to fulfil regulatory requirements, and there was limited involvement by KOLs, either in the trial design or execution. This lack of KOL input led to reduced familiarity and awareness of the treatment, which has hampered uptake to date.
- **Lack of ‘real life’ data:** The single-arm trial, while sufficient to satisfy regulators for approval, did not contain any comparator arms. This makes it hard to put the data into context, with ‘real life’ data needed to drive physician uptake and patient understanding.

Multi-pronged strategy to drive commercial success

New management has put in place a comprehensive multi-pronged strategy to drive uptake of NanoTherm therapy in Europe, and to expand the geographical reach by entering the US market. Successfully executing this strategy should help crystallise value from NanoTherm therapy. A summary of the key elements of the strategy is shown in Exhibit 6.

Exhibit 6: Multi-pronged strategy to crystallise NanoTherm value

NanoTherm commercialisation			
Establishing EU <ul style="list-style-type: none"> ▪ New GBM study ▪ Total NPV: €130m ▪ Probability: 100% Germany; 65% ex-Germany ▪ rNPV: €4.1/share 	Global reach <ul style="list-style-type: none"> ▪ US market entry ▪ Total NPV: €90m ▪ Probability: 40% ▪ rNPV: €1.4/share 	New Indications <ul style="list-style-type: none"> ▪ Prostate cancer ▪ Total NPV: €140 ▪ Probability: 40% ▪ rNPV: €2.1/share 	Innovation <ul style="list-style-type: none"> ▪ Next generation NanoActivators ▪ Next generation particles

Source: Edison Investment Research. Note: GBM – glioblastoma.

Establishing Europe: New glioblastoma study

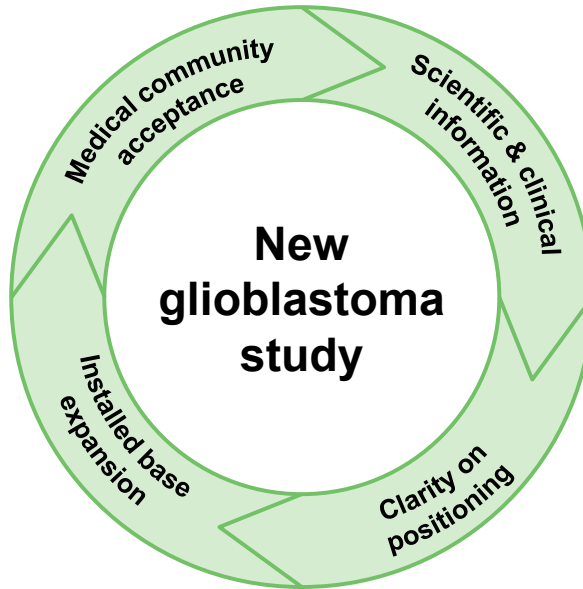
MagForce is aiming to address and overcome the hurdles that have prevented wider uptake with a new glioblastoma (GBM) study. This trial has been carefully designed with significant input and involvement from a number of German and European KOLs, which has been crucial in designing a trial with clinically relevant outcomes. The trial is strategically important for a number of reasons, outlined in Exhibit 7.

The study consists of two parts: (1) a run-in phase assessing the effectiveness of NanoTherm monotherapy, and (2) the main study, which will compare NanoTherm therapy alone and/or in combination with radiotherapy, with radiotherapy alone. The main study will be dependent on the outcome of the run-in phase: if the run-in phase demonstrates that NanoTherm monotherapy is effective (as determined by the proportion of patients with stable disease at three months), a NanoTherm monotherapy arm will be included in the main study. If NanoTherm monotherapy is not effective in the run-in phase, then a monotherapy arm will be excluded from the main study.

Exhibit 7: The new GBM study aims to establish NanoTherm therapy in Europe

Increasing physician experience and awareness: The trial will be run at up to 15 centres, including 8 in Germany alone. Each trial centre will provide the principal investigators with experience of using NanoTherm therapy. If this is positive, it seems likely that awareness of the technology will spread more broadly within the medical community.

Increases the NanoActivator installed base: Two NanoActivators are currently installed in Germany. An additional six NanoActivators are planned over the next 18 months in Germany as part of the new GBM study, with potential to expand into additional countries in the future.



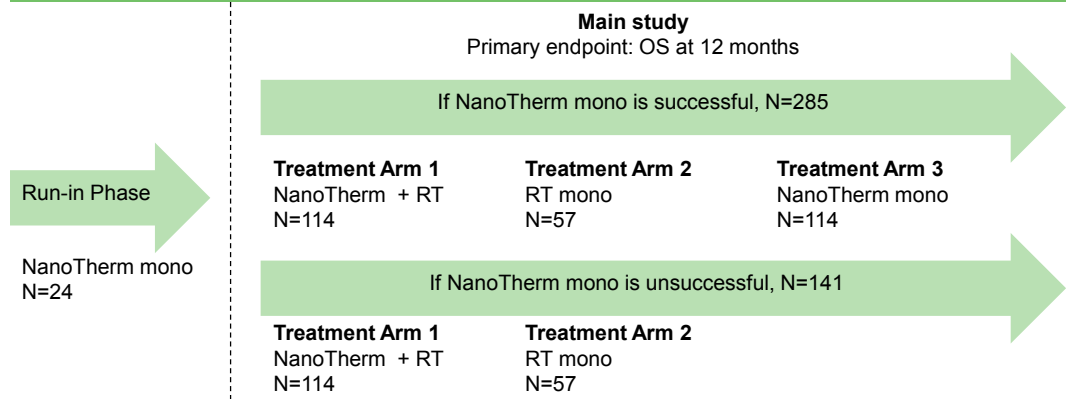
First insights into NanoTherm as a monotherapy: The potential utility of NanoTherm therapy as a standalone option has not been investigated, hence data from the new GBM study will provide insights into its potential in this setting. If the run-in phase is successful, the longer-term data will be important in determining potential positioning as a monotherapy.

Comparator data: The new GBM study will compare NanoTherm therapy in combination with radiotherapy, with radiotherapy alone. This will allow direct comparison of available treatment options, enabling physicians and patients to better understand where and when NanoTherm therapy could play a role.

Source: Edison Investment Research

Allowing time for the run-in phase, we expect the main study to commence in 2014. Given the open-label nature of the trial, it is therefore possible that data from the first patients could be available during H115. These data, in addition to KOL experience with the product as the trial is ongoing, could drive initial commercial revenues. We do not expect full data from the study to be available until around 2017, allowing around two years for complete recruitment.

Exhibit 8: New glioblastoma study design



Source: Edison Investment Research, MagForce. Note: RT = radiotherapy, mono = monotherapy, N = number of patients, OS = overall survival.

Expanding the global footprint: Entering the US

MagForce plans to initially introduce NanoTherm therapy to the US as a treatment option for glioblastoma (GBM), with plans to expand into other indications, discussed below. Upcoming meetings with the FDA should clarify the precise regulatory requirements to enable product registration and approval in the US. Management believes that similar to Europe, NanoTherm therapy will be designated as a medical device, which should confer shorter clinical development than a typical drug candidate. Depending on the outcome of these discussions, it is possible that the new glioblastoma study could be expanded to the US.

MagForce already has a preclinical research agreement in place with the Mayo Clinic, which has helped to raise early awareness of NanoTherm. In addition, new CEO Ben Lipps' extensive experience and knowledge of the US market, including KOLs, should help with this effort.

New indications: Broadening potential with prostate cancer

NanoTherm's ability to thermally destroy tumours could be especially relevant in localised solid tumours. Hence, MagForce intends to conduct a proof-of-concept study in prostate cancer, which is scheduled to start this year. The study will likely investigate monotherapy treatment with NanoTherm, in early to intermediate prostate cancer patients. Given the size of the prostate cancer market, this could represent a sizeable indication. If this is successful, in the longer term additional indications, including pancreatic and liver cancer, could also be pursued.

Innovating for the future: Next-generation NanoTherm therapy

MagForce is exploring the next generation of NanoActivators, which could include lower frequency machines, in addition to smaller machines. These could be particularly relevant in indications such as prostate cancer. In addition, in collaboration with the University of Bremen, MagForce is also developing next-generation nanoparticles, which can be activated by a lower frequency magnetic field. This could retain efficacy, while reducing side effects, particularly heat-related. Development in prostate cancer is not dependent on either the next generation particles or activators.

MagForce is also exploring the potential to combine NanoTherm nanoparticles with chemotherapeutic agents, such as doxorubicin and methotrexate, which would therefore combine NanoTherm therapy with locally released chemotherapy.

GBM could be a €200m opportunity

In glioblastoma, patients receive six sessions of treatment in the NanoActivator (two times per week for three weeks), with each session lasting an hour. Hence, we estimate that each NanoActivator can treat around 150 patients at peak per year. This assumes that each machine is operated Monday to Friday, for 50 weeks per year (allowing for servicing) and there is some downtime between sessions to allow for equipment and patient preparation. Each vial of NanoTherm costs €20k, hence this would lead to annual revenues of around €3m per NanoActivator.

As part of the new glioblastoma study, a total of eight NanoActivators are expected to be installed in Germany. Two are already in place (Berlin and Munster) and the next two should be installed in the next few months. Hence, future revenues from Germany alone could reach around €25m.

We assume MagForce will be able to install additional NanoActivators across Europe as physicians gain more experience of the therapy and data become available. With eight machines planned for Germany alone, installing a further 25-30 NanoActivators across Europe over the next five to 10 years seems achievable. This would either require one NanoActivator for each of the 27 member states where NanoTherm is approved, or an average of eight machines in the EU5 (Germany, UK, France, Italy and Spain). Hence, penetration of the broader European market could generate revenues of around €75-90m. MagForce also has partnerships in the broader European market, which could drive additional sales.

In the US, we believe it is realistic that MagForce could install at least one NanoActivator in each state. With conservative NanoTherm particle pricing assumptions of around \$20-25k per vial, we estimate the US could generate sales of around €100m.

These estimates suggest NanoTherm therapy would be treating fewer than 10k GBM patients in the US and EU per year. In the US alone, it is estimated there around 23k new cases of brain cancer diagnosed every year, of which GBM is the most common and most aggressive, with a five-year survival rate of <5%.

US prostate potential of \$300m

MagForce is actively working to develop NanoTherm therapy as a treatment option for localised prostate cancer, with an aim to define the path to market by year end 2013. With NanoTherm's mechanism already validated in brain cancer, development risk in other indications is reduced, owing to the purely physical "heating" mechanism of action, rather than a biological effect. Despite this, we believe regulators will at the very least require confirmatory studies prior to product approval. The current NanoActivators can be used to treat a tumour anywhere in the body and hence installation of these will allow any required trials to be conducted. In the mid-term, we expect MagForce will develop smaller NanoActivators, which could be used in prostate cancer. A smaller, cheaper machine should be easier to place and install within treatment centres.

Assuming MagForce can successfully develop a smaller, prostate-specific NanoActivator, we estimate it should be possible to install five to six per state in the US. Without yet knowing the duration or number of sessions that might be needed in prostate cancer, we conservatively assume each prostate NanoActivator could treat around 150 patients per year, in line with GBM. A smaller quantity of nanoparticles will likely be required in prostate cancer, hence we assume a lower vial price of around a quarter of GBM, ie around \$6k per vial. This price would position NanoTherm competitively with brachytherapy, a form of internal radiotherapy via the implantation of radioactive seeds, which is used to treat between 30-50% of localised prostate cancer patients in the US.

Each prostate NanoActivator could therefore generate revenues of almost \$1m per year, leading to a potential opportunity of \$300m, based on treating 40-50k patients per year versus around 240k newly diagnosed prostate cancer patients per year in the US alone.

A unique, approved product with barriers to entry

We are not aware of any other magnetic nanoparticles for thermal treatment that have reached clinical development. However, there are a number of other products that could be considered close/related competitors, described below. NanoTherm is already approved in Europe and hence is much further ahead than any of the closest competitors. In addition, the requirement for specialist NanoActivators will mean that any direct competitors will need to displace any installed base. If MagForce is unable to grow the installed base, it seems unlikely that any competitors with similar specialist equipment will be able to penetrate the market, either. However, if a competitor can develop an alternative activator, be it smaller, cheaper, etc, this could drive uptake. We note MagForce is already working to develop the next generation of activators.

Exhibit 9: Products with similarities to NanoTherm therapy

Therapy	Description
Nanoparticle radiotherapy enhancers	The most advanced that we are aware of is NanoBiotix's NBTXR3 for direct injection into a tumour, with specially designed nanoparticles to enhance existing radiotherapy without increasing damage to surrounding healthy tissue. NBTXR3 is currently in Phase I clinical development in Europe. Other similar approaches include gold and bismuth-based nanoparticles, but these are at an earlier stage of development.
Light activated nanoparticles	This includes products such as Nanospectra's AuroShell particles, which are currently in clinical trials in the US for head & neck, and lung cancer. These nanoparticles absorb and convert laser light into heat to destroy the tumour.
Other magnet-based approaches	Sirtex has patents relating to microparticles containing iron based nanomagnetic particles for selectively targeted hyperthermia. However, we note these refer to particles that are significantly larger (100-200nm) than MagForce's NanoTherm nanoparticles. The development status of these microparticles is unknown.

Source: Edison Investment Research

Valuation

We value MagForce at €197m or €8.2/share, based on a risk-adjusted NPV analysis, which includes €13.5m net cash at end June 2013. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 10. Our valuation is centred on NanoTherm therapy in various regions and indications, risk-adjusted to reflect the current status.

Within our valuation we include our revenue forecasts and estimates for costs, including R&D and S&M. In GBM we assume that MagForce will place, rather than sell the NanoActivators, recouping the c €400k cost of each in future years via a pay-per-use fee. Within prostate cancer we assume MagForce will sell the smaller and therefore cheaper prostate NanoActivators.

Exhibit 10: MagForce risk-adjusted NPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (€m)	Probability	rNPV (€m)	NPV/share (€/share)
NanoTherm EU – Germany	GBM	2014	25	36.7	100%	36.7	1.5
NanoTherm EU – Broader use	GBM	2015	80	92.6	65%	59.9	2.5
NanoTherm US	GBM	2016	100	91.3	40%	34.6	1.4
	Prostate cancer	2017	300	141.7	40%	50.4	2.1
NanoTherm EU – Partners	Solid tumours	2015	20	16.1	10%	1.6	0.1
Net cash/(debt)				13.5	100%	13.5	0.6
Valuation				391.9		196.7	8.2

Source: Edison Investment Research

We include Germany with a 100% probability, reflecting the approved status of the product in addition to concrete plans as part of the new GBM study to install a total of eight NanoActivators, with two already installed. Although approved, other countries and centres outside of Germany have not yet been established and hence installation of NanoActivators more broadly across Europe is not guaranteed. Hence we apply a more conservative 65% probability.

In the US, we apply a 40% probability of success, reflecting the product's lack of approval in this region. Efficacy has already been demonstrated in Europe in GBM, which we believe can be replicated in the US, although a number of uncertainties remain, including regulatory and execution risk. We believe development in prostate cancer presents similar risks, hence our equivalent probability of success.

Outside of the immediate EU, MagForce has distribution deals with DELRUS Inc, a Russian medical device distributor, and with Tek Grup, a Turkish distributor. DELRUS is responsible for marketing NanoTherm in the Russian Federation, Belarus Republic, Republic of Kyrgyzstan, Republic of Kazakhstan, Ukraine, Republic of Tajikistan and Republic of Uzbekistan. Tek Grup will distribute NanoTherm in Turkey, Albania, Iraq and Azerbaijan. Each distributor is responsible for obtaining marketing authorisation in these regions. We include a small contribution in our valuation, but heavily risk-adjust this opportunity as the commitment from these partners in installing NanoActivators and promoting the product remains to be seen.

Upside potential and downside risks: NanoActivator installation and utilisation

A key driver of future revenues will be the number of NanoActivators MagForce can install, and the number of patients that each machine can treat. Installation of the first NanoActivator outside of Germany could increase our probability in Europe. Likewise, clarity on the US development path could lead to a reduced risk-adjustment in our valuation. However, limited installations and utilisation could lead us to reassess our future revenue forecasts.

Sensitivities

MagForce is subject to the usual risks associated with product development in healthcare, including clinical trial delays or failures, regulatory risks, competitor successes, partnering setbacks, financing and commercial risks.

More specifically, NanoActivator placement and usage will be important in broadening the reach of this technology. In addition, driving physician uptake and acceptance of the technology will be crucial to realise value. Both of these are being addressed with the new GBM study. Any delays to the new GBM study or installation of the NanoActivators could affect initial commercial sales. In

addition, within Europe reimbursement has only been agreed in Germany, to our knowledge. If reimbursement cannot be successfully negotiated in other countries, this could potentially hinder more broad European uptake.

Additional trials will be needed to expand use beyond the initial indication. MagForce currently has enough resources to fund the new GBM study and an initial proof-of-concept trial in prostate cancer. However, further funds will be needed both to execute the US strategy and to complete trials to secure regulatory approval in additional indications.

In the US, the exact regulatory requirements have not been defined. We currently assume US launch in 2016, which should be sufficient time to perform a clinical trial similar in scope to the current EU post-marketing trial. Any requirement for additional trials would delay launch beyond our current forecast.

MagForce has sufficient cash to fund the new GBM study (c €8-9m), a prostate proof-of-concept study (<€1m) and to install the planned NanoActivators in Germany at a cost of around €400k per NanoActivator. Developing the broader EU market and US market entry, in addition to prostate cancer plans including development of smaller NanoActivators, will all require additional funding. A capital raise could be a dilutive financing event.

Financials

MagForce reported €13.5m net cash at end-June 2013, which we believe should be sufficient to fund the planned new GBM study in Germany and Europe, to install the planned NanoActivators in Germany, and to conduct a proof-of-concept trial in prostate cancer. US market entry will likely need additional funds. In addition, significantly broadening European uptake could require sales and marketing spend that current cash could not fund.

Our revenue forecasts include sales from NanoTherm therapy, primarily from Germany in the near term. With the product already approved in brain cancer, these revenues could originate from patients not eligible for the new GBM study but who could benefit from the treatment. As more NanoActivators are placed and physicians gain more experience with the treatment, sales should continue to expand. MagForce has recently announced its aim to generate sales of €100-150m in five years, which will likely need successful execution of the US strategy.

MagForce's expenses are classified according to nature (personnel and other) rather than by function (R&D, SG&A), hence we have had to make estimates for R&D spend in previous years. We expect R&D spend to increase in the next few years with the planned new GBM study, in addition to the proof-of-concept prostate cancer. Our R&D forecasts currently only include spend on these trials, and do not include any spend associated with entering the US market.

We capitalise the €400k cost of each NanoActivator as a tangible fixed asset, depreciating the cost over 10 years. We assume MagForce is able to recoup this initial outlay via an arrangement with the hospital, either potentially through a pay-per use fee or a standard leasing agreement over around five years, the former included within our revenue forecasts.

Our forecasts include illustrative financing in 2015 of nearly €7m, which we class as a long-term liability for the purposes of our model. This cash would not be sufficient for the US opportunity, but is potentially required to grow and broaden the European market.

MagForce completed a €33.5m capital increase in March, issuing 18.6m new shares at €1.8/share. 8.85m shares were used to convert €15.9m of shareholder loans into equity, leaving MagForce debt free and with €17.6m in cash in March. The shareholder loans originated from Nanostart AG, a nanotechnology VC firm, which were sold to Avalon Capital One at the end of 2012, which now holds a 37% stake in MagForce.

Exhibit 11: Financial summary

	€'000s	2008	2009	2010	2011	2012	2013e	2014e	2015e
Year end 31 December									
PROFIT & LOSS									
Revenue		0	0	0	41	0	0	1,610	3,634
Cost of Sales		(559)	(370)	(315)	(292)	(193)	(212)	(255)	(571)
Gross Profit		(559)	(370)	(315)	(251)	(193)	(212)	1,355	3,063
Research and development			(1,661)	(3,451)	(3,876)	(3,221)	(4,255)	(4,627)	(5,515)
EBITDA		(3,417)	(2,754)	(5,901)	(6,498)	(4,606)	(5,891)	(4,856)	(7,089)
Operating Profit (before amort. and except.)		(3,669)	(3,043)	(6,291)	(6,750)	(4,873)	(6,485)	(5,656)	(8,169)
Intangible Amortisation		(6)	(5)	(7)	(18)	(19)	(3)	(5)	(6)
Exceptionals		0	0	0	0	0	0	0	0
Other		(172)	(349)	(369)	(947)	0	0	0	0
Operating Profit		(3,847)	(3,398)	(6,666)	(7,714)	(4,891)	(6,488)	(5,660)	(8,175)
Net Interest		(346)	(670)	(863)	(872)	(826)	(241)	101	0
Profit Before Tax (norm)		(4,014)	(3,714)	(7,154)	(7,621)	(5,698)	(6,726)	(5,555)	(8,169)
Profit Before Tax (FRS 3)		(4,192)	(4,068)	(7,530)	(8,586)	(5,717)	(6,729)	(5,560)	(8,175)
Tax		(5)	(5)	83	(2)	(1)	0	0	0
Profit After Tax (norm)		(4,191)	(4,068)	(7,440)	(8,570)	(5,699)	(6,726)	(5,555)	(8,169)
Profit After Tax (FRS 3)		(4,197)	(4,073)	(7,447)	(8,588)	(5,718)	(6,729)	(5,560)	(8,175)
Average Number of Shares Outstanding (m)		3.8	3.8	3.8	4.0	4.9	14.6	23.9	23.9
EPS - normalised (€)		(1.1)	(1.1)	(1.9)	(2.1)	(1.2)	(0.5)	(0.2)	(0.3)
EPS - normalised and fully diluted (€)		(1.1)	(1.1)	(1.9)	(2.1)	(1.2)	(0.5)	(0.2)	(0.3)
EPS - (IFRS) (€)		(1.1)	(1.1)	(1.9)	(2.1)	(1.2)	(0.5)	(0.2)	(0.3)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	-611.2	N/A	N/A	84.2	84.3
EBITDA Margin (%)		N/A	N/A	N/A	-15848.8	N/A	N/A	-301.6	-195.1
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	-16462.7	N/A	N/A	-351.3	-224.8
BALANCE SHEET									
Fixed Assets		1,557	1,853	2,032	2,190	1,610	1,837	2,687	3,316
Intangible Assets		10	7	14	36	4	6	7	7
Tangible Assets		1,519	1,819	1,990	2,126	1,579	1,803	2,651	3,281
Investments		28	28	28	28	28	28	28	28
Current Assets		843	1,416	1,650	694	1,353	10,725	4,907	3,702
Stocks		0	0	39	0	0	0	21	47
Debtors		0	0	0	25	0	0	882	1,991
Cash		461	836	993	14	689	10,061	3,339	1,000
Other		382	580	618	654	664	664	664	664
Current Liabilities		(680)	(639)	(1,129)	(3,090)	(19,393)	(2,229)	(2,670)	(3,225)
Creditors		(680)	(639)	(1,129)	(3,090)	(3,312)	(2,229)	(2,670)	(3,225)
Short term borrowings		0	0	0	0	(16,081)	0	0	0
Long Term Liabilities		(7,185)	(12,169)	(14,490)	(16,158)	(198)	(198)	(198)	(7,094)
Long term borrowings		(6,976)	(11,850)	(14,229)	(15,930)	0	0	0	(6,896)
Other long term liabilities		(209)	(320)	(261)	(228)	(198)	(198)	(198)	(198)
Net Assets		(5,465)	(9,538)	(11,937)	(16,365)	(16,628)	10,134	4,724	(3,301)
CASH FLOW									
Operating Cash Flow		(3,322)	(2,935)	(5,454)	(4,537)	(5,473)	(6,823)	(5,168)	(7,520)
Net Interest		0	0	0	0	0	(241)	101	0
Tax		0	0	0	0	0	0	0	0
Capex		(650)	(589)	(562)	(392)	(39)	(818)	(1,648)	(1,709)
Acquisitions/disposals		0	0	0	0	0	0	0	0
Financing		(516)	0	4,903	3,951	4,266	33,342	0	0
Dividends		0	0	0	0	0	0	0	0
Net Cash Flow		(4,488)	(3,523)	(1,114)	(978)	(1,246)	25,459	(6,716)	(9,229)
Opening net debt/(cash)		2,027	6,515	11,014	13,236	15,916	15,392	(10,061)	(3,339)
HP finance leases initiated		0	0	0	0	0	0	0	0
Other		0	(976)	(1,108)	(1,701)	1,770	(6)	(6)	(6)
Closing net debt/(cash)		6,515	11,014	13,236	15,916	15,392	(10,061)	(3,339)	5,896

Source: MagForce accounts, Edison Investment Research. Note: MagForce reports according to German statutory accounting (HBG, Handelsgesetzbuch) in accordance with the provisions of the HGB for small corporations.

Contact details	Revenue by geography
Max-Planck-Strasse 3 12489 Berlin Germany +49 (0)30 3083 800 www.magforce.de	N/A

CAGR metrics	Profitability metrics	Balance sheet metrics	Sensitivities evaluation
EPS 2010-14e	N/A ROCE 2013e	N/A Gearing 2013e	N/A Litigation/regulatory
EPS 2012-14e	N/A Avg ROCE 2010-14e	N/A Interest cover 2013e	N/A Pensions
EBITDA 2010-14e	N/A ROE 2013e	N/A CA/CL 2013e	N/A Currency
EBITDA 2012-14e	N/A Gross margin 2013e	N/A Stock days 2013e	N/A Stock overhang
Sales 2010-14e	N/A Operating margin 2013e	N/A Debtor days 2013e	N/A Interest rates
Sales 2012-14e	N/A Gr mgn / Op mgn 2013e	N/A Creditor days 2013e	N/A Oil/commodity prices

Management team
Chairman and CEO: Ben Lipps Dr Lipps joined MagForce in September 2013, having previously been chairman and CEO of Fresenius Medical Care since 1999. Dr Lipps led the research team that developed the first commercial hollow fibre artificial kidney at the end of the 1960s. Before joining Fresenius Group in 1985, Dr Lipps held several research management positions in various companies, among them Dow Chemical. He earned his master's and doctoral degrees at the Massachusetts Institute of Technology in chemical engineering.
CFO: Christian von Volkmann Christian von Volkmann joined MagForce as CFO in May 2012. He was previously CFO at Jerini, successfully completing the IPO in 2005 and subsequent acquisition by Shire in 2008. Mr von Volkmann has more than 14 years of corporate finance and capital market transaction experience. He studied business administration at the Julius Maximilian University and is also a licensed certified public accountant in the US.

COO: Hoda Tawfik
 Prof Dr Hoda Tawfik has been at MagForce since May 2011. She has over 20 years' experience in the field of clinical development and medical affairs within the pharma/biotech industry. Before joining MagForce she worked at Medigene AG as head of global clinical operations department and medical affairs for nine years. Dr Tawfik completed her pharmacy studies at the University of Cairo, and obtained a PhD in pharmacology and toxicology from the University of Düsseldorf.

Principal shareholders	(%)
Avalon Capital One GmbH	37.0
Nanostart AG	10.8
Management	0.7

Companies named in this report
Nanobiotix (NANO FP); Nanospectra (private); Sirtex (SRX AU)

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