MagForce

Healthcare Equipment & Services
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Steady progress

MagForce is moving forward with its strategy to drive uptake and acceptance (in the US and Europe) of its NanoTherm nanoparticle-based therapy for cancer. In Germany, Magforce has six centres commercially capable (three utilised, c50 patients to date) of treating glioblastoma (GBM) patients. To accelerate uptake of NanoTherm treatment in Europe, we expect Magforce to look to expand from Germany into other countries over six to 18 months. In the US, its subsidiary Magforce USA is in talks with the FDA to initiate a planned clinical trial in prostate cancer patients (potential launch in 2018). Data is expected in 2018 (potential launch soon after).

First NanoActivators installed in the US

MagForce has installed the first NanoActivators (two out of four installed) in the US ahead of the planned prostate cancer trial. This machine is similar to those currently installed in Germany for GBM, with specific modifications for both the US market and treatment of prostate cancer. MagForce USA is in possession of four NanoActivators; we expect at least another one to be installed within the next six months for use in the forthcoming clinical trial.

Prostate IDE approval expected shortly

MagForce filed an investigational device exemption (IDE) in May 2015, which, if approved, would allow the planned pivotal prostate clinical trial to start in the US (the trial plans to assess NanoTherm therapy as focal treatment for prostate cancer). With investigators and two NanoActivators already in place, we believe the trial will start promptly on IDE approval; MagForce is in active dialogue with the FDA.

Expansion in Europe to drive uptake

In Europe, six NanoActivators are now installed in Germany and commercial GBM patients have received therapy at four centres to date. Cross-border travel for these patients has proven impractical, and as such Magforce plans to rapidly install more NanoActivators across Europe to allow patient treatment within their own countries.

Valuation: Expansion into new markets to drive value

Expansion into the broader EU outside of Germany starting late 2017 and continued progress towards a US launch in 2018 should help to realise value in the near term. However, sufficient patient recruitment will be vital to success in both markets (assuming approval in the US).

Historical financials

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/12	0.0	(5.7)	(1.16)	0.0	N/A	N/A
12/13	0.0	(6.7)	(0.34)	0.0	N/A	N/A
12/14	0.0	(7.9)	(0.33)	0.0	N/A	N/A
12/15	2.6	(4.5)	(0.18)	0.0	N/A	N/A

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

Price	€7.86
Market cap	€201m

Share price graph

Share details

Code	MF6
Listing	Deutsche Börse Scale
Shares in issue	25.6m
Last reported net (debt)/cash as at end March	€3.4m

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.

Bull

- Proven CEO.
- Validated technology.
- US and broader EU sales on near term horizon.

Bear

- Uptake in Germany of the device has been slow.
- Approval in the US needed before launch.
- Low current cash position.

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Company description: Advancing on all fronts

MagForce has an approved nanotechnology-based medical device treatment for brain cancer. MagForce's NanoTherm therapy is designed to directly affect the tumour from within, while sparing surrounding healthy tissue. Magnetic nanoparticles are directly injected into a tumour and are then heated in the presence of an external magnetic field generated by specialist equipment (NanoActivator). This can either sensitise a solid tumour for additional treatment, such as chemotherapy or radiotherapy, or thermally destroy it. The product is approved in Europe for the treatment of brain tumours, where management is working to drive uptake and acceptance of this therapy. NanoTherm therapy has the European CE mark (in 27 countries), so commercial patients can be treated at any of the centres. In addition, management is actively pursuing development in the US, with a clear path to market now established for prostate cancer, which could launch in 2018 and be a significant contributor to revenues in the longer term.

First NanoActivators installed in the US

MagForce installed the first NanoActivator in the US in Washington and a second NanoActivator in Texas in readiness for the planned start of the registration clinical trial in prostate cancer. Prostate cancer in the US presents a significant market opportunity, more so than GBM, and strategically makes sense as a first US indication, in our view. The start of the prostate cancer clinical trial (the focal thermal ablation study) with MagForce's NanoTherm therapy will be dependent on securing IDE approval, which is anticipated in mid-2017 following filing in May 2015. Once approval is granted, we believe the trial should be able to start shortly thereafter. If the IDE approval is granted and the trial starts in a timely manner, we believe first prostate cancer sales are possible from 2018. On this basis, we expect at least one further installation in the near term and further installations of both the large and small NanoActivators in the future.

First installations in readiness for prostate cancer trial

In November 2015, MagForce announced that the first NanoActivator had been installed in the US ahead of the start of the planned prostate cancer clinical trial. This NanoActivator is one of four machines that MagForce AG sold to its affiliate MagForce USA. The first machine has been installed in Seattle, Washington, and a second machine was recently installed at CHRISTUS Santa Rosa Hospital in San Antonio, Texas where Ian M Thompson Jr, MD, the co-principal investigator, is based. The clinical site incorporates a clinical office and the NanoActivator treatment centre. We anticipate at least one further machine will be installed in the US in the near term, taking the installed base to three for the purposes of running clinical trials.

These NanoActivators are similar in size and design to the machines currently installed in Germany for the treatment of brain cancer, but have been modified to conform to US market standards. More importantly, the machines can also be used for the treatment of prostate cancer, to prove the concept of NanoTherm therapy in treating this disease. We assume that the treatment of brain tumours will not be pursued in the US until NanoTherm for prostate cancer is commercially launched.

MagForce USA is continuing to develop pNanoActivators (ambulatory for outpatient care) for prostate cancer. The prototype design is similar to a dentist's chair in appearance. We believe that MagForce will aim to sell, rather than place, these machines into clinics in future. The importance of these machines lies in their ability to be placed within smaller clinics, thus potentially widening outreach to the US patient pool in the longer term. MagForce AG will manufacture core components of the machine, while production of non-core components and assembly will be undertaken by MagForce USA.

Exhibit 1: Prototype concept design of the pNanoActivators

MagForce is developing significantly smaller pNanoActivators (ambulatory, for outpatient care), which it will aim to sell (rather than place) in the future. At the 2016 AGM, a concept design was presented, with these machines essentially equivalent in size to a dentist's chair. This design could then be later approved via the 510k route (with the original NanoActivator for the pre-market approval as the predicate device).

Source: Edison Investment Research, MagForce

IDE approval for prostate cancer trial expected mid-2017

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. If approved, this will allow the first pivotal clinical trial with NanoTherm therapy to start in the US in prostate cancer. MagForce is currently working with the FDA and has updated preclinical study data conducted a decade ago to current FDA standards. In the last year, the company has already had a number of discussions with the FDA and obtained informal feedback on the submission.

Once approved, given two NanoActivators are already in place, the proposed focal thermal ablation registration trial could start shortly thereafter. MagForce anticipates the study to initiate by mid-2017. MagForce expects the trial to recruit up to 120 prostate cancer patients and to assess NanoTherm therapy as focal treatment for prostate cancer. 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 surgery and other treatment modalities which are associated with side effects such as impairment in urinary and sexual functions.

Assuming the trial takes around 12-18 months to complete, data could become available in 2018. This should be sufficient to support a pre-market approval application for the device (based on the larger NanoActivators), with the smaller ambulatory machines approved towards the end of the clinical trial via the 510k route (using the original NanoActivator as the predicate device). We assume approval and first sales from 2018 of the pNanoActivators, allowing time for filing and regulatory review following data in 2018. We assume that after the installation of the four larger NanoActivators (by the end of 2017) all future device sales will be the smaller pNanoActivators.

Europe moves forward with first sales

First commercial treatments

In Europe, where NanoTherm therapy is already approved via a CE mark to treat brain cancers, MagForce has six NanoActivators installed in Germany (in Berlin, Münster, Kiel, Cologne, Frankfurt, and Göttingen). With these installations, MagForce now has the capacity to continue with commercial treatments and the ongoing post-marketing GBM study. During 2015, MagForce initiated the first commercial treatment of GBM patients in Germany. Commercial therapy is currently available at three centres (in Münster, Berlin and Cologne), with all three having already treated patients. Although only a handful of patients were treated during 2015 and 2016, MagForce

is investing in its commercial development team to drive the near-term commercial treatment rate through increasing its reach out to the medical community, patients and patient advocacy groups as well as working to streamline the reimbursement process. Additionally, the slow progress in Germany highlighted the reluctance of many of these seriously ill patients to travel to other countries for treatment; as such, MagForce now plans to roll out additional devices across Europe in order to improve patient access.

The current CE mark in Europe is for 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 who could benefit from this treatment.

Post-marketing GBM study ongoing

The post-marketing GBM study is still ongoing (the first patient was enrolled in March 2014). Although NanoTherm is already approved in Europe, the study was planned to drive wider acceptance, awareness and uptake of NanoTherm. Installation of the current NanoActivators in Germany, in addition to familiarisation with their operation, has been facilitated by this study. Although the study has yet to yield any data, the benefits are already being realised through commercial treatment of patients (around 50 patients to date). We do not expect any data in the near term from the study and as it is not required for any regulatory purposes we do not expect the data to have a significant impact on the uptake and use of NanoTherm therapy. Instead, we believe this will be realised through ongoing commercial efforts; however, lack of granularity with regards to future commercial strategy make this difficult to assess.

Broader European expansion in the future

We expect that MagForce will look to accelerate installations of NanoActivators outside of Germany this year, as physicians gain more experience of the therapy and more data become available. We believe that installing a further 20-25 NanoActivators across the major European countries over the next five to 10 years seems achievable. Each NanoActivator costs around €400k, which we capitalise 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 where each large NanoActivator is placed through a pay per use fee. It could also adopt a standard leasing agreement over five years. This should be seen in the context of around 25k new cases of brain cancer in the EU5 (the United Kingdom, France, Germany, Italy and Spain) per year.

Glioblastoma: Treatment paradigm

GBMs arise from astrocytes and are usually highly malignant due to the speed at which they grow. At any time a large number of cancer cells are dividing and expanding; this growth is driven by a substantial blood supply, which nourishes the tumour cells. GBMs can be divided into two types: the more common faster growing primary tumours and slower but still aggressive secondary tumours. Primary tumours make up about 90% of all GBMs and are the focus of MagForce's NanoTherm therapy.

Standard GBM treatment involves tumour resection followed by postoperative radiotherapy combined with temozolomide. GBM tumours consist of about 15% of all primary brain cancers. The WHO reported approximately 250,000 new cases of brain or nervous system cancer worldwide in 2012, while mortality was around 190,000. Survival rates are some of the lowest among all cancers (three-year survival of c 10%).

Prostate cancer development is a distinct possibility

With NanoTherm nanoparticle-based therapy for cancer prostate cancer now advancing in the US, this indication could also be developed in Europe, utilising data from the US to help secure approval. The smaller NanoActivators (pNanoActivators) currently under development by MagForce USA could potentially be sold in Europe in the future, helping to drive this market. 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 with regards to the indication.

After lung cancer, prostate cancer is the most common cancer among men. In 2012, worldwide there were 1.1m reported new cases of prostate cancer with 307.5 thousand deaths. Treatment of prostate cancer depends on the progression of the disease; for localised cancer, surgery is commonly utilised, with chemo, radiation, hormone and biologic therapy combinations also utilised 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.

MagForce's upcoming prostate cancer study in the US plans to enrol 120 patients who have grade 7 (Gleason score) prostate cancer and are under active surveillance. Grade 7 defines a moderate growing tumour, one that can be readily operated on. The NanoTherm therapy will be used to ablate cancer lesions.

NanoTherm therapy

The destruction or treatment of cancerous cells with heat is well established, commonly through laser or microwave irradiation. Current techniques can often be intrusive and can suffer from unfocused heat distribution. Cancer cells are more susceptible to heat then healthy cells; while it is dependent on cell type it is generally believed healthy cells can survive at temperatures around 42°C, temperatures at which cancerous cells undergo necrosis (cell death). Temperature increases 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.

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 gets converted to heat by the hysteresis of the magnetic nanoparticles. Magnetic hysteresis produces heat, which is undesirable in most applications; however, for the treatment of tumours this effect can be taken advantage of.

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 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 (radio therapy/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 free-standing, 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, which 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.

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.

Management and shareholders

Management board

Consistent with the board organisation of German companies, MagForce has a two-tier board in which executive directors are in the executive board and non-executive directors are in a separate supervisory board. The composition of MagForce's management board is as follows:

- CEO, Dr Ben Lipps joined MagForce in September 2013, having previously been chair 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 joined MagForce as CFO in May 2012. He was previously at Jerini, successfully contributing to the IPO in 2005, and was promoted to CFO in 2008 during

the subsequent acquisition by Shire. 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.

- CMO Professor 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 the 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.

Shareholders

Exhibit 2: Principal shareholders

	(%)
Avalon Capital One GMBH	37.00
Nanostart	9.80
Skagen funds	1.74
SW Mitchell Capital Ltd	1.63
Baring Fund Managers Ltd	1.27
M&G Securities Ltd	0.68
Forwards management LLC	0.68

Source: MagForce

Financials

MagForce reports financial results according to Handelsgesetzbuch (HGB), the German Commercial Code, as a small company; under these provisions majority or fully owned subsidiaries and affiliates are not consolidated. Additionally no cash flow statement is published. Hence the accounts represent MagForce AG alone and do not include any contribution from MagForce USA, which is majority owned (76.9%) by MagForce AG.

In 2015 MagForce commenced initial commercial treatment with NanoTherm therapy in a handful of patients (number not disclosed), leading to small sales to the tune of €0.16m, which at a ~€20,000 cost per patient implies eight patients received treatment. Utilising the same assumptions, we estimate that up to 30 patients were treated in H116; however, due to uncertainty with regards to the breakdown of the revenues in H116, the number of patients treated could be lower. NanoTherm sales also include those on a cash basis and by reimbursement; as such the sale price will vary. In addition, during FY15 MagForce AG sold four NanoActivators to MagForce USA, which we estimate at around €600k each. FY15 revenues were €2.576m, with the bulk from the sale of these four machines (two of which were held on the balance sheet in inventories at the end of 2014). No sale of NanoActivators was booked in H116.

With 2015 results, MagForce also recorded a €3m accounting income (non-cash) in operating income to reflect an expansion of MagForce USA's rights to NanoTherm therapy to now include Mexico and Canada. €6.9m was recorded in 2014 and €5.1m in 2013 related to the same out-licensing deal. We include these as exceptional items in our financial forecasts (hence they do not appear in normalised numbers). There was no income accounted for from the rights in Mexico and Canada in H116.

Operating expenses (which are classified according to nature rather than by function) have remained tightly controlled, with only €6.6m spent in 2015 (including €3.0m personnel expenses and €3.2m other operating expenses). H116 operating expenses were €4.1m, a small decrease from H115 (€4.5m).

MagForce had reported cash and equivalents of €3.4m at end June 2016 versus €1.4m at end 2015. In addition, the company had no short-term loan receivables in H116 (disclosed in the notes to the financial statements) compared with €3.1m at end-2015. In the recent shareholder letter (March 2017), MagForce announced the issuance of a three-year €5m convertible bond with a 5% interest rate and a €5.0/share conversion price.

Cash and equivalents held in MagForce USA are not disclosed in the financial statements; we estimate these are currently c €10m (c $11m) as we assume only minimal use of the proceeds from the $15m fund-raise in August 2014, with spend only on purchasing the four NanoActivators and minimal operating expenses in the absence of any ongoing clinical trials in the US. We believe MagForce USA has sufficient funds in place to conduct the planned prostate trial once IDE approval is granted.

Exhibit 3: Financial summary

€'000s	2012	2013	2014	2015
December	HGB	HGB	HGB	HGB
Income statement				
Revenue	0	0	0	2,576
Profit Before Tax (reported)	(5,717)	(1,626)	(1,007)	(1,547)
Net income as reported	(5,718)	(1,628)	(1,008)	(1,547)
EPS - (reported) (€)	(1.16)	(0.08)	(0.04)	(0.06)
Dividend per share (c)	0.0	0.0	0.0	0.0
Balance sheet				
Total non-current assets	1,610	7,443	15,707	19,533
Total current assets	1,353	10,284	12,999	5,325
Total assets	**2,963**	**17,727**	**28,707**	**24,858**
Total current liabilities	(19,393)	(2,253)	(4,081)	(1,779)
Total non-current liabilities	(198)	(237)	(197)	(197)
Total liabilities	**(19,591)**	**(2,491)**	**(4,279)**	**(1,977)**
Net Assets	(16,628)	15,236	24,428	22,882
Shareholders' equity	(16,628)	15,236	24,428	22,882

Source: MagForce accounts

Valuation

In the next 12-18 months we expect MagForce to launch into the broader EU (outside of Germany) and the US. In the EU, difficulty in attracting cross border patients has led to slower than anticipated uptake. GBM is an aggressive disease and patients are often unwilling to travel to other countries to receive treatment, as such MagForce plan to place machines in other European countries, starting late 2017. A combination of increased awareness and access to treatment could drive revenues in 2018 and beyond. In the US, MagForce USA are close to potentially being granted an IDE which would allow them to start the planned pivotal prostate trial. Assuming approval and the prompt start of the trial, MagForce USA could be approved for treatment of prostate cancer patients by the end of 2018. Prostate cancer represents a major opportunity and will be a key value driver over the mid-term. For our detailed valuation methodology, please see our previously published note.

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. In the near term, defining the exact scope of the trials in the US, obtaining FDA approval for the trial design and starting trials will be critical. We expect updates on this process in coming months, with the pivotal prostate cancer trial expected to start by mid-2017. In addition, progress with the ongoing post-marketing GBM study in Europe and delivering on initial commercial revenues will help to increase confidence in management's targets. Any delays could affect expected revenue generation and this could translate to further funding requirements.

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