MagForce

Healthcare equipment & services
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The land of opportunity awaits NanoTherm

MagForce is making progress in its strategy to drive the uptake of its thermal ablation treatment, NanoTherm. It is approved in Europe for brain tumours and in a registrational US study for prostate cancer. Sales in Europe have been slow to date, but MagForce's realigned commercial strategy in Europe could be the catalyst for meaningful growth in the top line and enable sustainable profitability from 2022. In the pivotal US study, enrolment of the first phase has completed, with approval and launch expected in Q420. Long-term growth depends on commercial treatments in the US.

European roll-out installs first device ex Germany

Revenues from NanoTherm have not grown materially since commercial treatments (late 2015), primarily due to ongoing issues with reimbursement in Germany. The first tranche from its EIB loan has been utilised (in part) to establish a new treatment centre in Poland, where management believes there is significant demand from private patients for NanoTherm, which should enable growth in sales.

US prostate cancer study progressing

MagForce has completed treatment of the first 10-patient cohort in its pivotal prostate cancer study required by the US FDA for approval. Importantly, it has reported that the procedure for instilling its NanoTherm particles has now been standardised and the study can enrol up to 110 additional patients to establish efficacy in thermally ablating prostate cancer lesions; positive results would provide a key value inflection (Q420) for the company.

Financials: EIB extends cash reach until profitability

MagForce reported net debt of €15.1m at end June 2019, primarily from the draw-down of the first tranche (€10m) of the loan from its facility with the EIB in January 2018 (€25m remaining). Following a private placement of 1.2m shares (in June 2019), MagForce raised gross proceeds of €5m. We believe an additional €15m will be required to fund operations until profitability, which we forecast in 2022.

Valuation: EU roll-out & US launch

We expect MagForce to launch its NanoTherm treatment into the broader EU and the US by end 2020, which should help to realise value in the near term. Sufficient patient recruitment and securing reimbursement are vital to success.

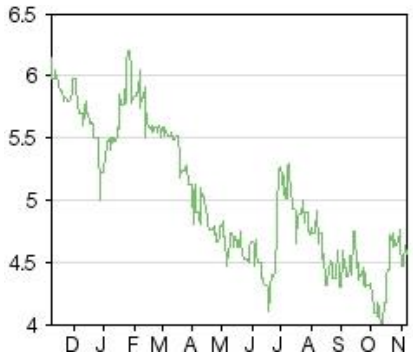
Edison estimates

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (€)	P/E (x)	Yield (%)
12/17	0.7	(9.5)	(36.0)	0.0	N/A	N/A
12/18	0.1	(8.7)	(32.8)	0.0	N/A	N/A
12/19e	0.7	(10.5)	(38.7)	0.0	N/A	N/A
12/20e	2.9	(6.6)	(23.7)	0.0	N/A	N/A

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

Price	€4.57
Market cap	€126m

Share price graph



Share details

Code	MF6
Listing	Deutsche Börse Scale
Shares in issue	27.6m
Net debt at 30 June 2019 (excluding €1.8m remaining proceeds from the capital raise received 2 July 2019)	€15.1m

Business description

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

Bull

- US and broader EU sales on near-term horizon.
- Technology is clinically validated.
- CEO track record.

Bear

- Cross-border reimbursement is difficult in the EU.
- Approval in the US is needed before launch.
- Uptake of treatment has been slow to date.

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Polish treatment centre established; next up Spain and Italy

During H119, MagForce announced the establishment of its first treatment centre outside Germany in Lubin, Poland. This marked an important moment for the company, as it is a clear signal that MagForce is progressing with its plans to broaden its geographical coverage, and enables it to provide patients, who were previously unable to travel across the border into Germany, to access NanoTherm. Management has highlighted that there has been significant demand (c 280 patient enquires) from Poland and this first treatment centre could prove to be the much-needed catalyst to drive near-term uptake in revenues; we expect that c 20 patients will be treated by year end. A small investigator-led trial will also be conducted before NanoTherm is included on local reimbursement lists, until which time patients will pay out of pocket for NanoTherm. However, unlike patients having to travel cross-border, all other treatment costs are covered.

In June 2019, an agreement was made with the Paracelsus Clinic in Zwickau, Germany, to establish a new treatment centre, which will broaden MagForce's geographical coverage further, although treatments are still likely to consist of private paying patients until reimbursement in Germany is attained. This new centre will use the same portable solution (which resembles a shipping container) to quickly install the device and will be fully operational in Q319. As MagForce has now established the ability to quickly install devices in a more cost-effective manner, and is making progress in its European roll-out, we expect it will continue to install two NanoActivator devices a year in new markets. We estimate that c 4,000 deaths a year were attributed to GBM in Spain and Italy during 2018 (source: Global Cancer Observatory), markets into which management has highlighted it is looking to expand next and is in negotiations with neurosurgical units to establish new treatment centres.

US prostate cancer launch delayed; trial is progressing

NanoTherm therapy is regulated as a device rather than a drug in the US, and therefore follows a medical device regulatory route to approval. Following receipt of an IDE from the US FDA, in July 2018 MagForce initiated its pivotal prostate cancer trial across two clinical sites where NanoActivators are installed (University of Washington in Seattle, Washington, and CHRISTUS Santa Rosa Hospital in San Antonio, Texas). Unexpected delays in standardising the procedure have affected the timeframe to complete the first stage of the study, but we now expect completion by year end. An additional site will be established in Sarasota, Florida, which will aid in recruitment of the second stage, and both completion and submission for FDA review are now expected in 2020.

The single-arm trial aims to recruit up to 120 patients with prostate cancer (Gleason score of 7) under active surveillance and will assess NanoTherm as focal treatment for prostate lesions. The study is structured such that 10 patients will be treated initially and preliminary data (H219) assessed to demonstrate that NanoTherm is safe and there is no systemic translocation of the nanoparticles from the prostate. Enrolment of the subsequent 110 patients will then be used to demonstrate efficacy as defined by no recurrence of tumour in a follow-up biopsy. In lieu of a control arm in the study, we assume that it will be compared to historical standard-of-care treatment outcomes to determine its benefit (similar to the GBM trial). Although this might be sufficient to achieve regulatory approval, payers might require a clearer measure of patient benefit before agreeing reimbursement. Management has guided that, in its initial engagement with the Centres for Medicare & Medicaid Services (CMS), it has indicated that efficacy in line with brachytherapy and tolerability in line with a biopsy could warrant similar reimbursement (c $7k). The therapy aims to destroy localised tumours in the prostate of patients by focal ablation. By ablating the prostate cancer focally, MagForce anticipates that patients will be able to maintain active surveillance and

avoid definitive treatments such as surgery or whole gland radiotherapy, which is associated with side effects such as impairment in urinary functions (incontinence) and sexual functions (impotence).

With a relatively quick turnaround time in determining whether the primary endpoint has been met (biopsy to confirm reduction of prostate cancer lesions), a six- to nine-month timeframe to complete the second stage of the trials after the preliminary safety results (H219) is conceivable, provided that trial recruitment proceeds as planned, and a regulatory application for the treatment could be filed in 2020. The smaller pNanoActivators that MagForce intends to roll out into urology centres prior to launch could be approved towards the end of the clinical trial, either by being included in the clinical data package or via the 510k route using the original NanoActivator as the predicate device. While the GBM indication is reliant on the larger NanoActivators for activation of the NanoTherm nanoparticles, more localised prostate cancer can be treated by the pNanoActivators (smaller ambulatory machines that resemble a dentist's chair), thereby widening outreach to the US patient pool in the longer term.

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