03/06/2015 - GBC Research Comment - MagForce AG

Company: MagForce AG[*5a,5b,11]
ISIN: DE000A0HGQF5
Analysts: Cosmin Filker, Felix Gode
Current price: 6.65 € (XETRA 03/06/2015; 10:20 am)
Target price: 13.20 €
Rating: BUY
Date of completion/Date of first Publication: 03/06/2015
* catalogue of potential conflicts of interests on page 4

Important milestone reached in the approval process in the USA; Investigational Device Exemption submitted as planned; market approval for the treatment of prostate cancer in the USA expected from mid-2017

According to company reports dated 21/05/2015, MagForce AG announced that it had submitted an Investigational Device Exemption (IDE) to the US American regulatory authority FDA. This completes the next significant step for the approval of NanoTherm® therapy for the treatment of prostate cancer patients in the USA.

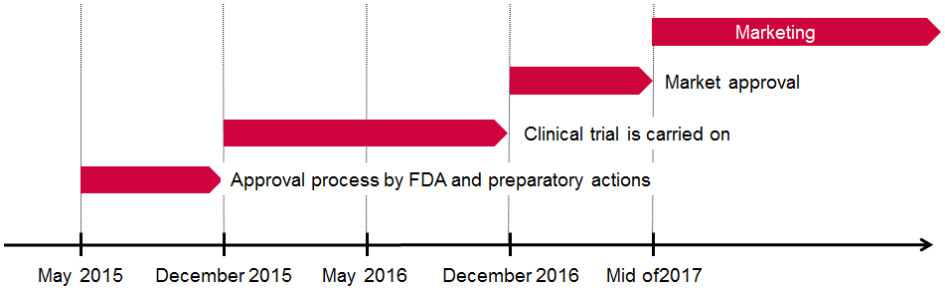
The planned single-arm study is designed to proof the ablation of prostate cancer lesions (cancer-related tissue damage) is to be provided in up to 120 patients, whereby patient selection is based on the internationally recognized Gleason Score (values between 2 and 10), used to classify the extent and growth of the prostate tumor. The registration study in the USA will recruit patients with a Gleason Score of 7, i.e. patients diagnosed with an aggressive and malignant prostate tumor. Today, the treatment of this patient group encompasses the application of current standard methods such as surgery, radiation or chemotherapy with the associated side effects (impaired urological and sexual functions). When applying NanoTherm® therapy, a super-paramagnetic liquid is inserted during a minimally invasive procedure, then activated via a magnetic field and heated to up to 80°C, whereby the injected tissue is destroyed without the necessity of surgery or radiation, meaning that typical side effects fail to appear.

This treatment developed by MagForce AG is a medical device, which means that the approval process is less time-consuming and cost-intensive than that for pharmaceutical drugs. The approval of medical products merely requires proof of a sufficient safety profile as well as sufficient efficacy. Due to the associated simple study design with a good verifiability of the primary endpoint, only a comparatively low number of patients (120 patients) will be included in the registration study. The company also plans to involve important US-American urological and oncological opinion leaders in the clinical trial at an early stage.

With the submission of the IDE to the FDA, MagForce AG entered the approval process according to plan. According to the FDA, the review process of application documents as well as the study approval for the medical device will take up to 180 days. In parallel, MagForce AG will take the necessary preparatory actions for the clinical trial phase. We can therefore assume that start of the registration study of NanoTherm® therapy will probably follow directly upon FDA approval of the IDE submission, i.e. shortly before the end of 2015. A period of approximately twelve months must be considered for the actual clinical trial with the primary endpoint of "ablation of prostate cancer lesions". Within this period, the patients will be treated at the study centres. We assume that, following a six-month period, additional biopsies could be taken to confirm the final study endpoint, so that the application for market approval could be submitted at the end of the upcoming

financial year 2016. In our opinion, the following schedule could form the basis of NanoTherm® therapy's market approval:

Forecast marketing schedule for NanoTherm® in the USA



Source: GBC AG

As part of our research study (Initial Coverage) dated 19/05/2015, we have, as an important basis of our forecasts, assumed that marketing in the indication prostate cancer will commence from mid-2017. In this respect, the most recent corporate news confirms our prior assumptions and the filing of IDE submission to the FDA as planned has resulted in the reduction of the timing risk. Due to the confirmed basis for our estimates, our revenue and earnings forecasts remain unchanged as well as the fair company value determined as part of the DCF.

in €m	2014e	2015e	2016e	2017e	2018e	2019e	2020e	2021e
Total output	7.08	1.88	5.20	19.23	53.27	84.42	117.07	140.74
Gross profit	7.04	1.50	4.16	13.54	42.47	67.39	94.04	113.01
EBITDA	-1.06	-9.25	-8.26	3.84	24.47	40.71	57.04	68.54
EBIT	-1.30	-9.37	-8.40	3.68	24.30	40.54	56.87	68.37
Net income before minorities	-1.00	-9.37	-8.40	3.68	24.30	28.38	39.81	47.86

Source: GBC AG

Market approval is critical for the significant sales increases we have assumed as from the financial year 2017 for the indication "prostate cancer" and its extremely sustainable potential. MagForce AG forecasts a market potential of approximately 100,000 male patients currently in active surveillance programs. Even if market penetration were to be lower, this large population is associated with considerable market potential. For our forecasts, we have assumed the treatment of only 5,500 patients per annum in the 2019 financial year.

Based on our unchanged forecasts, we expect an EBIT break-even in the 2017 financial year and therefore confirm the fair value per-share of €13.20 determined in the DCF model and a "BUY" rating.

ANNEX

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