MagForce AG Publishes Financial Results for the First Half of 2019 and Operative Highlights

- Further German cooperation with the Paracelsus Clinic in Zwickau and first NanoTherm treatment center outside of Germany opened at the Independent Public Clinical Hospital No. 4 (SPKS4) in Lublin, Poland
- Successful completion of the first stage of pivotal clinical US study for the focal ablation of intermediate risk prostate cancer; preparations for next study stage initiated
- Successful completion of a capital increase of the registered share capital of MagForce AG, with gross proceeds of EUR 5 million

Berlin, Germany and Nevada, USA, October 31, 2019 - MagForce AG (Frankfurt, Scale, XETRA: MF6, ISIN: DE000A0HGQF5), a leading medical device company in the field of nanomedicine focused on oncology, published today its financial results for the first half of 2019, ending on June 30, 2019, and operative highlights.

“During the first half of 2019 we have continued to pass several major milestones and have made significant progress both in the EU with our roll-out strategy and the US with the completion of the first stage in our pivotal clinical US study for the focal ablation of intermediate risk prostate cancer,” commented Ben Lipps, CEO of MagForce AG and MagForce USA, Inc. “I am steadfast in my belief that by pursuing a strategy of expansion with sustainable partnerships in Europe and providing NanoTherm therapy in the US to patients suffering from prostate cancer, MagForce is well positioned for the future.”

Operative Highlights:

Driving forward European roll-out strategy with two additional hospitals offering MagForce’s NanoTherm therapy for the treatment of brain tumors

In April of 2019, the first hospital outside of Germany, the Independent Public Clinical Hospital No. 4 (SPKS4) in Lublin, Poland, inaugurated its NanoTherm treatment center and is now offering the innovative therapy as an additional treatment option for brain tumor patients from Poland and
surrounding countries. The SPSK4 team, led by Prof. Dr. hab. n. med. Tomasz Trojanowski and Prof. Dr. hab. n. med. Radoslaw Rola, have initiated patient treatments for a small Investigator Initiated Trial (IIT) to apply to the Agency for Health Technology Assessment and Tariff System for patient reimbursement of NanoTherm therapy as a supplementary treatment. In addition, private pay treatments with NanoTherm therapy financed by crowd or personal funding are now available. Furthermore, in June, MagForce entered into a cooperation agreement with a further German hospital, the Paracelsus Clinic in Zwickau, where a mobile treatment center has been installed. In the meantime, construction has been completed and, subject to a standard final approval of the competent authority in Germany, the NanoActivator is ready-for-use in the clinic with its renowned neurosurgical team around Prof. Dr. med. habil. Jan-Peter Warnke.

These new cooperations in Germany and Poland cover geographically important regions, and therefore represent another crucial step in MagForce’s European roll-out strategy. Additionally, the Company continues to see great interest in its therapy from further European countries. In Spain, negotiations with a potential new clinical partner are in an advanced stage, and MagForce is confident to be able to update the market once a cooperation agreement has been successfully concluded. Also, in Italy the Company continues to pursue early stage discussions with specialist clinics.

While a broad geographic coverage to provide greater availability for NanoTherm therapy is at the center of MagForce’s roll-out strategy, the Company also constantly works to further optimize the therapy and educate medical professionals in its use to provide patients with the best care possible. To this day, 5-years survival rates for patients treated with standard of care have not significantly improved over the last decades and remain very poor at 5 percent. Currently, the best that can be offered applying conventional treatment methods is a modest 14-months overall median survival in patients undergoing maximum safe resection plus adjuvant chemoradiotherapy. Longer survival times are furthermore often limited by a decreased quality of life and to highly selected patient sub-groups with certain favorable prognostic factors. Local tumor ablative treatment modalities, such as NanoTherm therapy, have therefore received increasing interest, as NanoTherm therapy has demonstrated to increase overall median survival to 23.2 months.

In their quest to improve patient care, the neurosurgeons applying NanoTherm therapy for the treatment of brain tumors, continue to find additional strategies to improve efficacy. Prof. Dr. Stummer and his team at the University Hospital of Münster (UKM) for example, who have been treating brain tumor patients with MagForce’s NanoTherm therapy since early 2015, introduced a new nanoparticles application technique called ‘NanoPaste’ in the clinic in 2016. The method itself and variations thereof are protected by MagForce’s international patent applications. In previous clinical research, the UKM team demonstrated that a better applicability of heat-focusing nanoparticles around the resection wall
after surgical removal of a brain tumor could boost the thermotherapy treatment outcome. In a recent study published in January of 2019 in the Journal of Neuro-Oncology, the team was able to extend the previous findings demonstrating that NanoTherm therapy combined with radiotherapy may result in potent antitumor immune responses leading to long-term stabilization of recurrent GBM patients. The team now plans to further investigate their findings in a prospective study.

MagForce remains committed to providing the highest quality of treatment through ongoing support for physicians. Therefore, the Company announced its newly launched ‘NanoTherm Therapy School’ in January. ‘NanoTherm Therapy School’ offers a comprehensive application training series, developed in close collaboration with leading experts in the application of the MagForce’s therapy and consists of three consecutive modules to certify surgeons in the use of its innovative NanoTherm technology: Module A – The Basics; Module B – Advanced Course – Stereotactic Instillation; and Module C – Interaction with New Neurosurgical Techniques. The first session, Module A, took place at the end of January 2019, and was met with great excitement from participants. Building on this success, Module B will be held in Berlin on November 14 and 15. On the Company’s website, you will find the program and registration details for the next module in November.

**Pivotal US study for a unique focal prostate cancer treatment option completed stage 1; preparations for next study stage initiated**

In the US, prostate cancer, is one of the most frequently diagnosed forms of cancer. Fortunately, prostate cancer is treatable, if detected early. Still, there remains an important unmet need for patients who have progressed to the medium-risk stage and for whom the benefits of treatment with current methods come with a significant risk of related side effects. NanoTherm therapy has the potential to significantly change the way prostate cancer is treated, as it allows for a less invasive, less aggressive treatment modality that could cure the cancer or, at a minimum, reduce a patient’s chances of needing a more aggressive treatment in the future.

The MagForce US pivotal clinical study in the indication of prostate cancer continues to progress well and the Company announced the completion of enrollment, treatment, and the analysis of the results of this first stage. During Stage 1, MagForce USA worked diligently with study investigators, medical technicians and patients, to not only successfully develop a standardized clinical procedure but also demonstrated a favorable safety and tolerability profile.

In summary, Stage 1 of the study has shown the following important successes: Firstly, validation of standardized clinical procedure; secondly, initial findings in this cohort show only minimal treatment-related side effects, which were tolerable and similar to those commonly associated with biopsies; and
thirdly, the ablation analysis showed very well defined ablation and cell death in the region of the nanoparticle deposit as we observed with the previous pre-clinical results.

The Stage 1 ablation results also confirm the observations of Knavel and Brace in 2013 that “from 42°C to 46°C, irreversible damage occurs, and after 10 minutes, significant necrosis occurs. From 46°C to 52°C, the time to cell death decreases owing to a combination of microvascular thrombosis, ischemia, and hypoxia”. By heating from the inside out, as done with focal ablation using the NanoTherm therapy system, minimization of side effects can be achieved. With the encouraging results from Stage 1, MagForce is optimistic that the Company will also be able to successfully manage the treatments in the next stage of the clinical trial. With the high interest in enrollment received from prostate cancer patients and their attending physicians, MagForce is confident to be able to successfully enroll the required number of prostate cancer patients for the last stage of the study.

Results of operations, net assets and financial position

Revenues for the reporting period amounted to EUR 26 thousand compared to EUR 24 thousand in the previous year and resulted mainly from commercial treatments of patients with NanoTherm therapy.

Other operating income amounted to EUR 329 thousand (previous year: EUR 9,199 thousand). The high other operating income in the previous year is attributable to the transfer of shares in MagForce USA, Inc., between group companies, realizing hidden reserves in the amount of EUR 8,769 thousand.

The cost of materials decreased from EUR 364 thousand to EUR 194 thousand which was due in particular to the reduction in expenses for purchased services for the NanoActivators.

Personnel expenses increased to EUR 1,846 thousand (previous year: EUR 1,729 thousand) primarily resulting from the addition of employees in the second half of 2018. Other operating expenses remained at the level of the previous year at EUR 1,608 thousand (previous year: EUR 1,527 thousand).

Consequently, the operating result for the first half of 2019 was negative at EUR 3,610 thousand, whereas the previous year ended with a positive operating result of EUR 5,305 thousand due to the transfer of the shares in MagForce USA, Inc., within the group.

In total, the Company generated a net loss for the period of EUR 4,912 thousand (previous year: net profit of EUR 4,106 thousand)

Cash flows from operating activities amounted to EUR -2,856 thousand (previous year: EUR - 4,009 thousand). The cash outflow from operating activities was derived indirectly from the net loss for the period.
The cash outflows from investing activities amounted to EUR -785 thousand (previous year: EUR -516 thousand) and related primarily to the contributions made in the reporting period to provide financial support for the subsidiary MT MedTech Engineering GmbH and the completion of the mobile NanoActivator therapy center in Lublin, Poland, as well as the construction of a new mobile NanoActivator therapy center in Zwickau, Germany.

The cash flows from financing activities amounted to EUR 3,325 thousand (previous year: EUR 9,189 thousand) and is mainly attributable to the proceeds from the capital increase from Authorized Capital.

At the end of the reporting period, cash and cash equivalents amounted to EUR 1,178 thousand (December 31, 2018: EUR 1,494 thousand).

Financing transactions of the Company

To improve liquidity and to accelerate the on-going international expansion, the Company executed the following financing measure during the first half of the year.

In June, MagForce AG successfully resolved and completed a capital increase from authorized capital. By issuing 1,176,472 new no-par value bearer shares at a price of EUR 4.25 per share under exclusion of the shareholders' statutory subscription rights, the financing measure has a total volume of EUR 5 million, of which the Company received EUR 1.8 million after the reporting date on July 2, 2019.

The additional capital will primarily be used to accelerate the on-going international expansion of MagForce, in particular in Europe. Based on the highly satisfying treatment results, MagForce expects the European roll-out, combined with reimbursement approval in relevant countries, will significantly speed up revenue generation and profitability of the European business.

Outlook and financial prognosis 2019 and beyond

The outlook for the year 2019, as reported in the 2018 annual report, published on June 20, 2019 was reaffirmed by management.
About MagForce AG and MagForce USA, Inc.
MagForce AG, listed in the Scale segment of the Frankfurt Stock Exchange (MF6, ISIN: DE000A0HGQF5), together with its subsidiary MagForce USA, Inc. is a leading medical device company in the field of nanomedicine focused on oncology. The Group’s proprietary NanoTherm® therapy enables the targeted treatment of solid tumors through the intratumoral generation of heat via activation of superparamagnetic nanoparticles.

NanoTherm®, NanoPlan®, and NanoActivator® are components of the therapy and have received EU-wide regulatory approval as medical devices for the treatment of brain tumors. MagForce, NanoTherm, NanoPlan, and NanoActivator are trademarks of MagForce AG in selected countries.

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