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EDAP TMS SA
Form 6-K
April 04, 2007

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6 K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

EDAP TMS S.A. Files

Press release on U.S. Clinical Study

April 4, 2007

EDAP TMS S.A.
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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

This report on Form 6-K with respect to the Company's 2006 annual results, is hereby incorporated by reference in the registration statement of EDAP TMS S.A. on Form F-3, file number 333-136811.

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EDAP TO RESUME US CLINICAL STUDY OF ABLATHERM-HIFU

Company Restarts US Trials for Localized Prostate Cancer HIFU

Management Shifts Reflect Dual European Acceleration, US Launch Strategy

LYON, France, April 3 /PRNewswire/ -- EDAP TMS S.A. (Nasdaq: EDAP), the global leader in High Intensity Focused Ultrasound (HIFU) treatment of prostate cancer and the international leader in the development, production, and distribution of a wide portfolio of minimally invasive medical devices primarily for the treatment of urological diseases, announced the transfer of US clinical study responsibilities and conclusion of its management succession plan announced December 2006. EDAP now has full rights to future US market sales and profit following its elimination of the prior partnership arrangement. Ablatherm-HIFU must complete an already begun FDA clinical study and receive FDA clearance in order to be marketed in the US.

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"We have completed a full review of the FDA program in the US over the past three months and have made the decisions necessary to move forward with this important clinical program," said Hugues de Bantel, in charge of the US FDA programs for EDAP. "The IDE has been fully transferred to EDAP with clinical screening and patient enrollment proceeding immediately at centers including Duke, Georgetown, the Cleveland Clinic, Thomas Jefferson and Vanderbilt among many others. We are evaluating numerous requests from additional highly qualified medical centers to join the study. We are examining patient awareness options to speed up study subject enrollment. Our study centers are very enthusiastic about the Ablatherm trial as are our FDA support team including M Squared Associates, Inc., as the clinical study management and regulatory support group and Hogan and Hartson, as the group supporting FDA communications and submissions. In the process of this review, we spoke with numerous medical device and clinical study organizations, all of whom agreed that the clinical study protocol defines a very well designed study. Clearly Ablatherm's proven history and global leadership position are attracting strong interest from potential partners in this clinical study."

The company intends to begin treatments at participating clinical centers by the end of April. Patients interested in learning more about participating in the trial can locate centers and examine the inclusion criteria online at <http://www.edap-tms.com> .

Management Succession Plan Complete

Reflecting the full approval and broad support of Ablatherm-HIFU in Europe where the company primarily markets its products today, the company promoted former Chief Operating Officer Marc Oczachowski to the role of CEO with focus on European growth and making Ablatherm-HIFU a new standard of care in treatment of localized prostate cancer. Outgoing CEO Hugues de Bantel joins the Company Board of Directors with active leadership responsibilities for the US FDA program and securing additional reimbursement approvals for the company's global leading Ablatherm-HIFU device.

Philippe Chauveau, Chairman of EDAP, stated, "This succession clearly confirms the evolution of EDAP to a full marketing and growth business rapidly advancing HIFU therapy in the field of prostate cancer from its position as the unparalleled leader in both technology and clinical outcomes. This structure focuses the company on its strategy to accelerate European HIFU growth through successful execution of its education and Revenue-Per-Procedure programs. Additionally, the company will now have dedicated resources focused exclusively on reimbursement and approval programs, especially relating to the United States where EDAP owns full rights to this important global market. EDAP is the only company capable of making HIFU a new standard of care in localized prostate cancer on both continents, and we intend to do so."

"EDAP and Ablatherm-HIFU are the undisputed leaders in clinical success for localized prostate cancer HIFU with the only clinical outcomes that rival traditional therapies with proven long term repeatability and sustainability," said Oczachowski. "In Europe, EDAP is the clear leader based on our clinical results showing the best efficiency of treatment, repeatability of outcomes and consistent successful use of HIFU for localized prostate cancer. We are now moving to build a strong US focus to secure approval based on our clinical excellence; then take the same leadership role based on Ablatherm-HIFU's cost efficiency to the hospital and quality of care to the patient desiring effective treatment from his urologist with low side effects."

About EDAP TMS S.A.

EDAP TMS S.A. develops and markets Ablatherm, the most advanced and

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clinically proven choice for High Intensity Focused Ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. The company is also developing this technology for the potential treatment of certain other types of tumors. EDAP TMS S.A. also produces and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL).

For more information on the Company, contact Magnolia Investor Relations at (972) 801-4900, the Corporate Investor Relations Dept at +33 (0)4 78 26 40 46 or see the Company's Web sites at <http://www.edap-tms.com> and <http://www.hifu-planet.com>.

To sign up for alerts please visit:
<http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0>

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission. Ablatherm-HIFU treatment is in clinical trials but not yet FDA approved or marketed in the United States.

SOURCE EDAP TMS S.A.

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/Web site: <http://www.edap-tms.com>

<http://www.clinicaltrials.gov>

<http://www.hifu-planet.com>

<http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0> /

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 4, 2007

EDAP TMS S.A.

/s/ MARC OCZACHOWSKI

MARC OCZACHOWSKI
CHIEF EXECUTIVE OFFICER