

EDAP TMS SA
Form 6-K/A
November 06, 2007

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K/A

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 EDAP TMS S.A. Closes \$20 Million Placement to Fully Fund Its US Clinical Studies

November 6, 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-FX..... 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 NoX....

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.

EDAP TMS S.A. Closes \$20 Million Placement to Fully Fund Its U.S. Clinical Studies

Company Now in Position to Roll-Out Its U.S. Strategy

LYON, France, Nov. 5, 2007 (PRIME NEWSWIRE) -- EDAP TMS S.A. (Nasdaq:EDAP), the global leader in High Intensity Focused Ultrasound treatment of prostate cancer, announces that it has closed its capital raise with selected U.S. based qualified institutional buyers, pursuant to which the investors purchased US \$20 million in Unsecured Convertible Debentures, convertible into EDAP's ordinary shares, to be delivered in the form of American Depositary Receipts ("ADRs"). The Company expects this investment to fully fund EDAP's ongoing Phase II/III clinical studies

of Ablatherm-HIFU at selected leading cancer treatment centers across the U.S. Eligibility criteria and center information can be found online at www.clinicaltrials.gov or at participating centers.

"We are extremely happy with this financing because it provides EDAP with all the necessary funds to make HIFU a standard of care in the U.S., the most important market in the world for treatment of prostate disease," said EDAP CEO Marc Oczachowski. "Our European program, based on aggressive marketing and sales activity, is well on track, supported by last year's PIPE, and we are experiencing high growth in our Revenue-Per-Procedure business model, as reported. We believe EDAP now has all the resources we need to complete our ongoing U.S. clinical trials, which will allow us to seek FDA approval of Ablatherm HIFU within our expected timeframe, conforming our approved study protocol. In addition, we believe we have the right team in place to successfully conclude these trials, with our new North American-based Medical Director leading our group of investigators that are, without any doubt, among the best prostate cancer treatment centers in the U.S. and in the world. Thanks to this financing, we believe all of our strategic programs are now fully funded and well on track towards full success of Ablatherm HIFU as the real robotic option to treat localized Prostate Cancer."

EDAP's U.S. Phase II/III clinical study of the Ablatherm-HIFU system in the treatment of localized prostate cancer has already successfully treated patients at leading U.S. cancer treatment centers nationwide, with additional centers slated to join in the months to come. HIFU has been approved for use in the European Union and other countries worldwide. Current peer-reviewed clinical studies documenting efficacy and side effects using Ablatherm-HIFU over the past 10 years are available from the company or online at www.hifu-planet.com and www.edap-tms.com.

Dr. John Rewcastle, EDAP's Medical Director, commented: "The entire U.S. clinical team is very excited by the additional funding. We will now accelerate EDAP's FDA approval program building upon the strong forward momentum created in the past few months. Sites have been selected, several of which have received their local ethics committee approval allowing them to treat patients, and the logistical frame work to execute the trials is in place and is working well. In mid-October, we held an investigators meeting in Chicago with over 35 participants representing some of the most prestigious medical centers in the U.S. The trial is already benefiting from the leadership of Dr. Cary Robertson, from Duke University, who is now the principle investigator. We already have patients being treated on trial almost weekly in the U.S. and intend to deploy an education and recruitment program in the months ahead to raise awareness of the trial to quicken patient recruitment. The timing of this funding is excellent as we expect several high profile sites to receive ethics approval to participate in the clinical trials by the end of the year. In addition, centers not in the study are continuously inquiring about the FDA program. I believe this is reflective of the urologic community's optimism towards the role of HIFU as a prostate cancer treatment."

Eric Soyer, CFO, added: "The U.S. clinical study is now fully funded and can be carried out within the defined timeframe. The choice of this unsecured convertible debt instrument provided favorable terms without highly restrictive financial covenants. We thank our lead placement agent Cowen and Company, LLC and its team for helping us succeed in this transaction. Management will now be able to focus on delivering operating results in established and developing markets, now including the U.S."

The securities issued in connection with the private placement referenced herein have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the U.S. absent registration or an applicable exemption from registration requirements.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be, absent any exemption therefrom, any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About EDAP TMS S.A.

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

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.

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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 : November 6, 2007

EDAP TMS S.A.

S/ MARC OCZACHOWSKI
MARC OCZACHOWSKI
CHIEF EXECUTIVE OFFICER