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

February 1, 2013

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
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69120 Vaulx-en-Velin - France

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

Form 20-F [x] Form 40-F [ ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ___

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ___

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

This report on Form 6-K is hereby incorporated by reference in the following registration statements of EDAP TMS S.A. on Form F-3: file number 333-136811, 333-169793, 333-177224 and 333-179689.

SIGNATURES

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

Date: February 1, 2013
EDAP TMS S.A.

/s/ ERIC SOYER
ERIC SOYER
CHIEF FINANCIAL OFFICER

EDAP Submits U.S. FDA Pre-Market Approval Application for Ablatherm(R)-HIFU for Treatment of Low Risk, Localized Prostate Cancer

LYON, France, Feb. 1, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today the submission of its Pre-Market Approval (PMA) application to the U.S. Food and Drug Administration (FDA) on January 31, 2013 for the Company's Ablatherm-HIFU (High Intensity Focused Ultrasound) for treatment of low risk, localized prostate cancer. EDAP's PMA submission includes data from the ENLIGHT study, a multi-center U.S. Phase II/III clinical trial that completed the two year follow-up needed to evaluate its primary endpoint in August 2012, as well as data from the Company's extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer.

Prostate cancer is currently the most common form of cancer among men in the United States with approximately 238,000 new cases for 2013. In addition, men are being diagnosed at an earlier age and at earlier stages of the disease.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, remarked, "We have clearly seen a paradigm shift in prostate cancer, as patients are diagnosed earlier than ever before. Low risk patients need a middle ground between radical treatment, which is often overly-aggressive, and the anxiety of 'watchful waiting.' Ablatherm-HIFU is well-positioned to address this unmet medical need by providing a unique non-invasive and fully robotic treatment option."

Marc Oczachowski concluded, "The PMA submission to the FDA represents a significant milestone in the U.S. regulatory process for Ablatherm-HIFU. The EDAP team, together with its clinical, regulatory and legal advisors, has devoted six years to conducting the U.S. clinical trial that studied Ablatherm-HIFU as a treatment for localized prostate cancer. I am very proud of the team, and we will continue to work closely with the agency during the final stages of the process."

About Ablatherm-HIFU

Ablatherm-HIFU is an ultrasound guided HIFU device for the treatment of organ-confined prostate cancer. The device consists of a treatment module, a control table with a computer and a computer screen, and a diagnostic ultrasound device connected to the treatment module. After insertion of an endorectal probe, the physician visualizes the prostate and defines the area to be treated. The computer automatically calculates the optimum treatment distribution of lesions. During the treatment, the transducer automatically moves and fires at each predefined lesion until the entire area has been treated, while controlling and imaging the treatment in real time due to its integrated imaging system. Cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound. The procedure is performed under general or spinal anesthesia.

Ablatherm-HIFU is cleared for distribution in the European Union, South Korea, Canada, Australia, South Africa, New Zealand, the Philippines, Taiwan, Mexico, Argentina, Brazil and Russia. As of December 31, 2012, more than 32,000 prostate cancer treatments successfully performed clinical outside the U.S. with Ablatherm-HIFU and results have been published in 60 peer-reviewed scientific publications.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm(R), 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA, the ENLIGHT U.S. clinical study. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith(R) range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit http://www.edap-tms.com, and http://www.hifu-planet.com.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements that involve risks and uncertainties. Such statements are based on management's current expectations and are subject to a number of uncertainties, including the uncertainties of the regulatory process, 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 and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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