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

March 28, 2013

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
4/6 Rue du Dauphine
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: March 28, 2013
EDAP TMS S.A.

/s/ ERIC SOYER
ERIC SOYER
CHIEF FINANCIAL OFFICER

EDAP Receives U.S. FDA Filing Acceptance of Pre-Market Approval Application

Ablatherm(R)-HIFU PMA Application Proceeds to Substantive Review

LYON, France, March 28, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration has provided a positive Filing Review Notification on the Company's Pre-Market Approval (PMA) application for its Ablatherm Integrated Imaging HIFU (High Intensity Focused Ultrasound) device for the treatment of low-risk, localized prostate cancer. The FDA conducted a filing review of EDAP's PMA, and found it to contain all of the information needed to proceed with the substantive review, in which the FDA will evaluate the safety and effectiveness of Ablatherm Integrated Imaging HIFU device, as well as EDAP's engineering, manufacturing and quality systems.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "Receiving FDA filing acceptance for our PMA in less than two months is both very timely and a major milestone. We are moving forward in the PMA Review Process as the agency commences its substantive review. We will continue to work closely with the FDA review team."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® 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. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer, and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial conducted under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® 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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