UNITED STATES
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

For the month of **March 2015**.

Commission File Number: 000-29374

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): ___

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): ___

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 9, 2015
EDAP TMS S.A.

/s/ ERIC SOYER
ERIC SOYER
CHIEF FINANCIAL OFFICER

EDAP Announces Plans to Pursue Direct De Novo 510(k) Petition in Lieu of PMA for Its Ablatherm HIFU

FDA Meeting Held to Confirm Planned Approach

LYON, France, March 9, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that, based on a recent meeting with the U.S. Food and Drug Administration ("FDA"), the Company plans to seek clearance of Ablatherm HIFU by way of a Direct De Novo 510(k) application as opposed to the Pre-Market Approval ("PMA") application amendment EDAP had been pursuing.

The Agency indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a Direct De Novo 510(k) application. The De Novo process was introduced by FDA for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the De Novo pathway, the new device must also present no more than moderate risk. Therefore, the Company plans to pursue a De Novo pathway based on the discussions with FDA.

Marc Oczachowski, Chief Executive Officer of EDAP TMS SA, commented: "We are pleased with the outcome of our most recent meeting with FDA and the ongoing, open dialogue we have maintained with the Agency throughout the regulatory process. We believe pursuing a Direct De Novo 510(k) Petition is an opportunity for more expeditious clearance of Ablatherm HIFU technology in the United States. Our team is now diligently focused on preparing the De Novo application."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer outside the U.S. 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 for commercial distribution in Europe and some other countries including Mexico and Canada. EDAP TMS is currently pursuing a Direct De Novo 510(k) petition in lieu of a PMA for Ablatherm clearance by the U.S. FDA. The Company also markets an innovative robot-assisted HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. 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. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. Factors that may cause such a difference also may 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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