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

October 15, 2015

Commission File Number: 000-29374

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): ___

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: October 15, 2015
EDAP TMS S.A.

/s/ MARC OCZACHOWSKI
MARC OCZACHOWSKI
CHIEF EXECUTIVE OFFICER

EDAP Direct De Novo for Ablatherm HIFU Replaced by 510(k)

Clearance of Predicate HIFU Technology for Ablation of Prostatic Tissue Permits Streamlined 510(k) Pathway

LYON, France, Oct. 15, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that it has withdrawn its De Novo application for clearance of Ablatherm® HIFU and has submitted a 510(k) notice, in accordance with the U.S Food and Drug Administration ("FDA") guidelines, following the FDA clearance of another HIFU technology for prostatic tissue ablation.

Marc Oczachowski, Chief Executive Officer of EDAP TMS SA, commented: "This development is a significant step forward for HIFU technology and the U.S. urology community as a whole. EDAP, being the world leader in HIFU in Urology, believes that the FDA's approval of HIFU technology for prostatic tissue ablation with a predicate device is a crucial milestone in the recognition and establishment of HIFU as a standard of care tool in prostate tissue ablation in the US and Worldwide. Our path to market in the U.S. is now clearer than ever, as we can now obtain clearance via a more straightforward 510(k) pathway by demonstrating that Ablatherm is substantially equivalent to the predicate device, without the need to pursue a *de novo* pathway."

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 option for prostatic tissue ablation 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 has submitted a 510(k) notice 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 clearance 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 is not FDA-cleared or marketed in the United States.

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