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

April 6, 2016

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

Date: April 6, 2016
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EXHIBIT 99.1

EDAP Submits 510(k) Application for FDA Clearance of Focal One HIFU

LYON, France, April 06, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that it has submitted a 510(k) application to the U.S. Food and Drug Administration (FDA) for the clearance of its next generation HIFU device: the Focal One®. This submission follows the November 2015 FDA clearance of Ablatherm® Robotic HIFU for the ablation of prostate tissue.

“We are pleased to submit our Focal One HIFU device file to the FDA to further our goal of making EDAP’s full range of HIFU products available to both urologists and patients in the U.S. There is a clear, growing demand from the worldwide urology community for non-invasive options for the ablation of prostatic tissue, and we are well positioned to address this market with our complementary Ablatherm and Focal One devices,” said Marc Oczachowski, Chief Executive Officer of EDAP TMS SA. “We believe that HIFU has the potential to become a standard of care tool for prostate ablation. We are extremely excited by the progress of the U.S. commercial launch of Ablatherm Robotic HIFU and look forward to working with the FDA on the clearance process for Focal One.”

About EDAP TMS SA
EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. 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, and has received 510(k) 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 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.

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