

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

January 9, 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): \_\_\_\_

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**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: January 9, 2015  
EDAP TMS S.A.

/s/ ERIC SOYER  
ERIC SOYER  
CHIEF FINANCIAL OFFICER

## EDAP's Focal One HIFU Device Approved by Health Canada

LYON, France, Jan. 9, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that its Focal One HIFU device has been approved by Health Canada. With this approval, the Company is able to market the Focal One device for the treatment of prostate cancer in Canada.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "Health Canada approval of Focal One, our revolutionary tool for the focal treatment of prostate cancer, represents an important milestone for EDAP. Moreover, this is the first regulatory approval for our Focal One device in the Americas, and a key step forward in our overall regulatory strategy as we work to expand Focal One's global footprint and bring our innovative cancer therapies to a growing number of patients worldwide."

Oczachowski continued: "In the 18 months since we received EU marketing approval, the enthusiastic response from the European urology community has validated our belief in the potential of focal therapy for prostate cancer and, more specifically, our Focal One system. In a relatively short time, the technology has been adopted by some of Europe's leading prostate cancer Hospitals. We look forward to a similar reception as we establish our North American presence via the Canadian market."

### About EDAP TMS SA

EDAP TMS SA markets today Ablatherm<sup>®</sup> 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 under an Investigational Device Exemption (IDE) granted by the FDA. In March 2013, the Company introduced a new innovative HIFU device, the Focal One<sup>®</sup> dedicated to focal therapy of prostate cancer. Focal One<sup>®</sup> 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 commercializes medical equipment (the Sonolith<sup>®</sup> 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. 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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