18UNITED 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

June 7, 2018

Commission File Number: 0-29374

EDAP TMS S.A.
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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: June 7, 2018
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

Exhibit 99.1

EDAP Announces FDA Clearance for Focal One®

AUSTIN, TX, LYON, FRANCE -- JUNE 7, 2018 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in therapeutic ultrasound, today announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for its Focal One device for the ablation of prostate tissue.

The Focal One high intensity focused ultrasound (HIFU) device is the first medical apparatus designed specifically for focal treatment of the prostate. Focal One fuses MR and 3D biopsy data with real-time ultrasound imaging, which allows urologists to view integrated, detailed 3D images of the prostate on a large monitor and direct high intensity ultrasound waves to ablate the targeted area.

With Focal One, urology surgeons can establish precise contours around the diseased tissue and ablate an even smaller portion of the prostate. This lessens the damage to healthy tissue, and minimizes side effects of incontinence and impotence for patients. Using Focal One, surgeons can customize the HIFU procedure for each patient and each clinical condition.

"Focal One is a great step forward in using this new and important ultrasound technology for prostate tissue ablation," said Dr. Brian Miles, Urologist, Professor of Urology, Houston Methodist Hospital – Weill Cornell Medical College. "Focal One's ability to merge MRI images, ultrasound images and biopsy data in order to precisely outline and treat just the diseased tissue area of the prostate is truly remarkable."

"We are thrilled that this innovative technology will now be available to patients and physicians in the United States," said Marc Oczachowski, Chief Executive Officer of EDAP. "The FDA's clearance of Focal One validates not only the power of our technology but also the years of hard work and dedication by our clinical trial investigators and EDAP's outstanding employees. Focal One's real-time imaging and 3D robotic features allow for greater precision, leading to improved targeting and treatment planning, and we are excited to be able to expand access to Focal One to the most important healthcare market in the world."

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. For more information on the Company, please visit http://www.edap-tms.com, and us.hifu-prostate.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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