

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

July 25, 2019

Commission File Number: 0-29374

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 [] 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: July 25, 2019
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP TMS Pre-Announces Strong 98% Growth in HIFU sales in the Second Quarter 2019

- **45% growth in total Q2 2019 revenue year-over-year**
- **78% growth in HIFU sales year-to-date through June 30, 2019**
- **Company to Report Second Quarter 2019 Financial Results on Wednesday, August 28, 2019 and to host conference call and webcast on Thursday August 29, at 8:30 am EDT**

LYON, France, July 25, 2019 - EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, today announced preliminary unaudited revenues for the second quarter ended June 30, 2019.

Preliminary total revenue for the second quarter 2019 totaled EUR 12.5 million, a 45% year-over-year increase. Growth in total revenue includes strong 98% growth in HIFU sales, which totaled EUR 4.6 million for the second quarter.

Year-to-date through June 30, 2019, the Company reported 27% growth in total revenue over the comparable period in 2018, driven primarily by a strong 78% increase in HIFU sales.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are very happy to report preliminary second quarter revenue showing continued momentum and traction in HIFU sales. We reported 98% growth in HIFU sales for the second quarter 2019 compared to second quarter 2018, driven by the sale of five HIFU devices, including three in the U.S. Our revenue performance was also driven by strong growth in HIFU treatment revenue, which increased 51% in the quarter. We look forward to reporting our full second quarter financial and operating results during our earnings call on Thursday, August 29."

EDAP TMS will release its financial results for the second quarter ended June 30, 2019 after the financial markets close on Wednesday, August 28, 2019.

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30am EDT on Thursday, August 29, 2019. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday August 29th @ 8:30am Eastern Time

Domestic:	877-451-6152
International:	201-389-0879
Passcode:	13693076
Webcast:	http://public.viavid.com/index.php?id=135590

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.

Company Contact

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Investor Contact

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