

EDAP TMS SA  
Form 6-K  
February 03, 2009

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

EDAP TMS S.A. Files on

February 3, 2009

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 Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

This report on Form 6-K is hereby incorporated by reference in the registration statement of EDAP TMS S.A. on Forms F-3, file number 333-136811 and 333-147762.

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PRESS RELEASE – FOR IMMEDIATE RELEASE

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EDAP Reports Record 2008 Fourth Quarter and Full Year Preliminary Unaudited Revenues

Fourth Quarter 2008 Highlights:

- Record revenue of EUR 9.0 million, up 29% year-over-year
- Ablatherm-HIFU RPP treatments increased 32% year-over-year
- Strong EUR 15.0 million (USD 20.8 million) cash position
- Robust backlog of Ablatherm-HIFU and lithotripsy devices entering 2009

LYON, France, February 3, 2009 – EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today preliminary top-line financial revenues for the fourth quarter and full year ended December 31, 2008.

For the fourth quarter 2008, the Company reported record total revenue of approximately EUR 9.0 million up 29% compared to the same period in 2007. Full year revenues were approximately EUR 23.0 million, compared to EUR 22.2 million in the same period last year. The Company has reported record revenue growth for the past two consecutive years.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are pleased with record revenue achieved during the fourth quarter. Our top line growth reflected the positive trend we had anticipated for Ablatherm-HIFU sales as well as the majority of our third quarter 2008 backlog successfully converting into revenue. We continue to experience an increase in order flow, which is further supported by our robust fourth quarter HIFU and lithotripsy backlog. We expect this backlog to support our revenues into the first half of 2009."

Mr. Oczachowski continued, "Given the current economic uncertainty, we continue to prudently manage our financial resources and preserve our strong cash position, enabling us to move forward aggressively with our long-term growth strategy."

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm, the most advanced and clinically proven choice 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multicenter U.S. Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment 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>, <http://www.hifu-planet.com> and <http://www.pcaresearch.com>.

#### Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those described in the company's filings with the Securities and Exchange Commission. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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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 : February 3, 2009  
EDAP TMS S.A.

/S/ MARC OCZACHOWSKI  
MARC OCZACHOWSKI  
CHIEF EXECUTIVE OFFICER