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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 19, 2024

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 [ ]

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 19, 2024

EDAP TMS S.A.

/s/ KEN MOBECK
KEN MOBECK
CHIEF FINANCIAL OFFICER

EDAP Announces Interim Results from Phase 3 Study Evaluating Robotic HIFU for the Treatment of Deep Infiltrating Endometriosis

- Robotic HIFU therapy continues to maintain an excellent safety profile, confirming positive safety data from prior Phase 1 and 2 studies in patients with deep infiltrating endometriosis

- At three months post procedure, the study's primary endpoint of reduced acute pelvic pain in the HIFU treatment arm compared to the Sham treatment arm was not met

- Significant improvements were observed across primary and secondary outcome measures (endometriosis and digestive symptoms) across the entire study population at three months

- The Phase 3 study continues as planned per protocol, with patients from the Sham treatment arm electing HIFU therapy

LYON, France, July 19, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced interim results from its Phase 3 study evaluating robotic High-Intensity Focused Ultrasound (HIFU) therapy for the treatment of deep infiltrating endometriosis. The Phase 3 study is a 60-patient comparative, randomized, double blind trial, with the primary objective of evaluating acute pelvic pain levels. All patients were initially followed for three months after either the HIFU treatment or the Sham treatment.

Interim results:

· Robotic HIFU therapy continues to maintain an excellent safety profile in patients with deep infiltrating endometriosis, confirming results from earlier Phase 1 and Phase 2 studies

· While both arms of the study showed significant reduction in pelvic pain scores at three months from baseline as measured by Visual Analog Scale (VAS), the primary endpoint of reduced acute pelvic pain in the HIFU treatment arm compared to the Sham treatment arm was not met; the Company and the Principal Investigator of the study believe the three-month post-procedure follow-up period was likely too short of a time period to show clinically meaningful differences in pain scores between the two arms of the study

· As measured by MRI, patients receiving robotic HIFU therapy experienced higher volume reductions in the endometriosis nodule as compared to patients in the Sham treatment arm

· The Phase 3 study continues per protocol, with several patients initially in the Sham treatment arm having elected and already received HIFU therapy after their pelvic pain returned to baseline levels

"The interim results from the ongoing Phase 3 study demonstrate that robotic HIFU therapy continues to maintain an excellent safety profile in patients with deep infiltrating endometriosis. Additionally, the reduction in the volume of the nodules observed in the HIFU arm confirms the therapeutic effect of the HIFU treatment," said Professor Gil Dubernard, Head of Gynecology Department at Croix-Rousse Academic Hospital, Lyon, France, and Principal Investigator of the Study. "This data is consistent with the prior results from the Phase 2 study that was recently published in the Journal of Human Reproduction[1] on the safety and the potential benefit of HIFU treatment for well-selected patients with deep infiltrating endometriosis."

“Although this initial data shows similar levels of improvement in pelvic pain scores between the two arms, we believe that a therapeutic benefit favoring robotic HIFU is more likely to be confirmed over a longer period of time post-procedure, as suggested by the stabilization of pain scores at six and twelve months observed in the Phase 2 study,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “Moreover, the cumulative safety and efficacy data from the Phase 1, 2 and 3 studies, suggests that robotic HIFU is a safe, non-invasive treatment and has significant potential to reduce pain for women suffering from this debilitating condition. We are encouraged to see additional patients from the Sham treatment arm elect to be treated with HIFU therapy in accordance with the study protocol, and we look forward to providing another update on the program later this year.”

About Endometriosis

Endometriosis is a chronic, progressive disease affecting nearly 10-12% of women of reproductive age. The disease is characterized by tissue resembling the lining of the uterus growing outside the uterine cavity. This extraneous endometrial tissue may commonly occur in the peritoneum or in pelvic and extra-pelvic organs such as the bowels, appendix, bladder, diaphragm muscle and thoracic cavity. The space between the uterus and the rectum, known as the Douglas pouch, is one of the most frequent and symptomatic sites of endometriosis leading to (deep infiltrating) rectal endometriosis.[2]

[1] G Dubernard, E Maissiat, G Legendre, T Dennis, P Capmas, S Warembourg, P Descamps, F Chavrier, H Roman, H Fernandez, E Nguyen-Ba, B Merlot, P Rousset, C Lafon, Charles-André Philip, Evaluating the safety of high-intensity focused ultrasound treatment for rectal endometriosis: results from a French prospective multicentre study including 60 patients, *Human Reproduction*, 2024;, deae127, https://doi.org/10.1093/humrep/deae127

[2] Source: https://drseckin.com/rectal-endometriosis/

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies 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 Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit http://www.edap-tms.com, us.hifu-prostate.com and www.focalone.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as “believe,” “can,” “contemplate,” “could,” “plan,” “intend,” “is designed to,” “may,” “might,” “potential,” “objective,” “target,” “project,” “predict,” “forecast,” “ambition,” “guideline,” “should,” “will,” “estimate,” “expect” and “anticipate,” or the negative of these and similar expressions, which reflect our views about future events and financial performance. 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 and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Other factors that may cause such a difference may also 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.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

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