

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 13, 2025

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

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 13, 2025

EDAP TMS S.A.

/s/ KEN MOBECK
KEN MOBECK
CHIEF FINANCIAL OFFICER

EDAP Announces Preliminary Record Fourth Quarter Focal One[®] System Sales and Record U.S. Procedures

Company Reports Preliminary Worldwide Record Fourth Quarter Sales of 11 Focal One Systems

Record U.S. Fourth Quarter Focal One System Sales

Record Number of U.S. Focal One Procedures, with Year-Over-Year Growth of 30%

AUSTIN, Texas, January 13, 2025 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company” or “EDAP”), the global leader in robotic energy-based therapies, today announced preliminary record Focal One[®] System sales for the fourth quarter of calendar year 2024. The Company experienced robust demand for its Focal One Robotic HIFU technology, reporting preliminary record fourth quarter of 11 Focal One Systems.

“Our strong fourth quarter performance reflects the growing adoption of our industry-leading Focal One Robotic HIFU technology platform, which is fundamentally transforming how urologists manage prostate cancer,” said Ryan Rhodes, Chief Executive Officer of EDAP. “The number of Focal One procedures also continues to grow rapidly, underscoring the practice changing dynamics taking place as Focal One Robotic HIFU becomes a mainstream treatment option for patients with prostate cancer. As Focal One continues to grow, we also expect the recent publication of the groundbreaking HIFI study in the prestigious scientific journal, *European Urology*, will further drive awareness and adoption.”

“Entering 2025, our Focal One pipeline remains robust and strong, and we continue to expect a growing number of urology practices to adopt Focal One for men diagnosed with prostate cancer.”

The above information is preliminary and subject to completion of quarter-end financial reporting processes and reviews. EDAP expects to release final fourth quarter financial results in March.

About EDAP TMS SA

A recognized leader in the robotic energy-based therapies, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various conditions using ultrasound technology. By combining the latest technologies in imaging, robotics and precise non-invasive energy delivery, EDAP TMS introduced the Focal One[®] in Europe and in the U.S. as the leading prostate focal therapy controlled by urologists with the potential to expand to multiple indications beyond prostate cancer. 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.

Company Contact

Blandine Confort
Investor Relations / Legal Affairs
EDAP TMS SA
+33 4 72 15 31 50
bconfort@edap-tms.com

Investor Contact

John Fraunces
LifeSci Advisors, LLC
(917) 355-2395
jfraunces@lifesciadvisors.com
