

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

December 4, 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 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: December 4, 2024

EDAP TMS S.A.

/s/ KEN MOBECK

KEN MOBECK

CHIEF FINANCIAL OFFICER

Landmark HIFI Study Publication Demonstrates Positive Outcomes with Focal One® Robotic HIFU Versus Surgery in the Management of Prostate Cancer

- *HIFI Study is the largest (N = 3,328) prospective, comparative, multi-center clinical study ever conducted comparing prostate cancer treatments*
- *Positive study results are expected to drive further adoption of Focal One as a first line treatment option for the management of localized prostate cancer*
- *Study shows Focal One Robotic HIFU is non-inferior to surgery, meeting primary endpoint of non-inferiority for Salvage Treatment-free Survival (STFS) after High Intensity Focused Ultrasounds (HIFU) compared to Radical Prostatectomy (RP) at 30 months*
- *Study shows that patients receiving HIFU had better outcomes with respect to urinary continence and erectile function compared to patients receiving RP*

LYON, France, December 4, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced the publication of the full results from the HIFI study in the prestigious, peer-reviewed journal, *European Urology*, which has the highest impact factor amongst scientific journals focused in urology. The study evaluated HIFU versus radical prostatectomy (RP) as a first line treatment of localized prostate cancer. The paper is entitled “Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized, HIFI Trial” and is authored by Dr. Guillaume Ploussard from Department of Urology, UROSUD, Clinique La Croix du Sud, France. A link to the publication can be found [here](#).

“The publication of the HIFI study in *European Urology* will importantly serve to increase awareness amongst the global urology and patient community on how robotic HIFU technology is rapidly changing the treatment paradigm for patients with localized, early-stage prostate cancer,” said Professor Pascal Rischmann, Principal Investigator of the HIFI trial and senior author of the publication. “It is clear that a growing number of men with localized prostate cancer are seeking less invasive, tissue-sparing treatment options that will help preserve their sexual function and urinary continence. The data from the HIFI Study not only underscores HIFU’s excellent oncologic control, but also highlights its significantly better functional outcomes when compared to radical prostatectomy.”

“We are pleased to announce the publication of the HIFI study results in the prestigious medical journal, *European Urology*,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “As the single largest and most rigorous clinical study ever conducted comparing oncologic and functional outcomes between Focal One robotic HIFU and radical prostatectomy, the publication of this data highlights the substantial clinical benefits of Focal One as an important, first line treatment option for the management of localized prostate cancer. We believe the publication of such important, positive results will provide additional momentum to growing Focal One adoption, while further advancing treatment decision guidelines.”

HIFI is the first prospective, multi-center, non-inferiority comparative study evaluating HIFU and RP in the management of localized prostate cancer. This seven-year study (April 2015 - March 2022) enrolled a total of 3,328 patients from 46 treatment centers: 1,967 consecutive patients were treated with EDAP’s robotic HIFU technologies, where Focal One was used for 90% of the patients, and 1,361 patients underwent radical prostatectomy surgery. All patients were followed for 30 months.

Clinical Data Highlights:

- At 30 months, the adjusted STFS was higher in the HIFU arm (90%) compared with RP arm (86%)
- The propensity score-adjusted result is similar to the univariate result (HR=0.71 [95%CI, 0.52-0.97], p=0.008). After adjustment on different variables (Age, BMI, ASA score, Grade Group, prostate volume, PSA): the risk of salvage treatment is lower in the HIFU arm compared to RP. This result remains true when analyzing the subgroup with intermediate risk (HR=0.66 [95%CI, 0.50-0.86], p=0.001).
- International Continence Society (ICS) score, a measure of stress urinary incontinence was significantly less deteriorated for HIFU (29%) vs, RP (44%) (RR=0.66 [95%CI, 0.59-0.74], p<0.001) for all ages combined.
- International Index of Erectile Function-5 (IIEF-5), a well validated measurement of erectile function, decreased significantly less after HIFU than after RP with a drop in difference in medians from -9 (-10;-7.7) to -3.0 (-3.9; -2.1) between both groups, for all ages included.
- Post-procedural benefits of HIFU on both erectile function and urinary continence were demonstrated despite patients in the HIFU-treated group being an average of 9.6 years older (median age was 74.7 years for HIFU vs 65.1 years for RP, p<0.001)

About *European Urology*

European Urology is the official journal of the European Association of Urology (EAU). *European Urology* publishes peer-reviewed original articles and topical reviews on a wide range of urological problems. Topics such as oncology, impotence, infertility, pediatrics, lithiasis and endourology, as well as recent advances in techniques, instrumentation, surgery and pediatric urology provide readers with a complete guide to international developments in urology. Published monthly, *European Urology* is an important journal for all clinicians and researchers in this field. The 2023 Impact Factor of *European Urology* is 25.3, the highest impact factor of all urology-focused scientific journals.

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.

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