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Â Form 20-F [x] Â Â Â Form 40-F [Â] Â Â Â Â SIGNATURES Â 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. Â Date: January 13, 2025 Â EDAP TMS S.A. Â Â Â /s/ KEN MOBECK KEN MOBECK CHIEF FINANCIAL OFFICER Â Â Â Â EDAP Announces Preliminary Record Fourth Quarter Focal OneÂ® System Sales and Record U.S. Procedures Â Company Reports Preliminary Worldwide Record Fourth Quarter Sales of 11 Focal One Systems Â Record U.S. Fourth Quarter Focal One System Sales Â Record Number of U.S. Focal One Procedures, with Year-Over-Year Growth of 30% Â AUSTIN, Texas, January 13, 2025 -- EDAP TMS SA (Nasdaq: EDAP) (â€œthe Companyâ€ or â€œEDAPâ€), the global leader in robotic energy-based therapies, today announced preliminary record Focal OneÂ 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. Â â€œOur 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,â€ said Ryan Rhodes, Chief Executive Officer of EDAP. â€œThe 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.â€ Â â€œEntering 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.â€ Â 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. Â AboutÂ EDAP TMS SA Â A recognized leader in the robotic energy-based therapies,Â EDAP TMSÂ 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,Â EDAP TMSÂ introduced the FocalÂ OneÂ®Â inÂ EuropeÂ and in theÂ U.S.Â 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 visitÂ http://www.edap-tms.com,Â us.hifu-prostate.comÂ andÂ www.focalone.com. Â Forward-Looking Statements Â In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of theÂ U.S.Â Securities Act of 1933 (the â€œSecurities Actâ€) or Section 21E of theÂ U.S.Â Securities Exchange Act of 1934, which may be identified by words such as â€œbelieve,â€ â€œcan,â€ â€œcontemplate,â€ â€œcould,â€ â€œplan,â€ â€œintend,â€ â€œis designed to,â€ â€œmay,â€ â€œmight,â€ â€œpotential,â€ â€œobjective,â€ â€œtarget,â€ â€œproject,â€ â€œpredict,â€ â€œforecast,â€ â€œambition,â€ â€œguideline,â€ â€œshould,â€ â€œwill,â€ â€œestimate,â€ â€œexpectâ€ and â€œanticipate,â€ 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. Â Â Â Â Other factors that may cause such a difference may also include, but are not limited to, those described in the Company's filings with theÂ Securities and Exchange CommissionÂ 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. Â 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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