



EDAP Announces Preliminary Record Fourth Quarter and Full Year 2025 HIFU Revenue; Issues 2026 Revenue Guidance

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- *36% to 38% Annual YoY HIFU Revenue Growth Record Performance Driven by Increased Focal One® System Sales and Growth in Number of U.S. Focal One Procedures*
- *69% Annual YoY Growth in Focal One System Placements*
- *28% Q4 YoY Growth in U.S. Procedures Highlights Accelerating Quarterly Procedure Growth*

AUSTIN, Texas, January 12, 2026 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company” or “EDAP”), the global leader in robotic energy-based therapies, today announced select preliminary unaudited financial and operational results highlighting record fourth quarter and full-year 2025 HIFU revenue, driven by strong system placements and accelerating procedure growth. The Company also issued initial worldwide revenue guidance for 2026.

For the fourth quarter ended December 31, 2025, the Company’s worldwide HIFU revenue is expected to range between \$12.9 million and \$13.3 million (€11.2 million and €11.6 million), which would represent the highest quarterly HIFU revenue in its history. Annual 2025 worldwide HIFU revenue is expected to range between \$36.7 million and \$37.2 million (€32.5 million and €32.9 million), which would represent the highest annual HIFU revenue in the Company’s history. Performance was driven by a record 15 Focal One system placements during the fourth quarter, reflecting strong global demand from hospitals and urology centers. In the United States, the number of Focal One HIFU procedures increased approximately 28% year over year in the fourth quarter, demonstrating growing utilization across both newly placed and existing systems.

EDAP’s non-core (Distribution and ESWL) preliminary unaudited fourth quarter revenue is expected to range between \$7.9 million and \$8.3 million (€6.8 million and €7.1 million) and annual 2025 non-core revenue is expected to range between \$32.7 million to \$33.1 million (€29.0 million and €29.3 million).

“Our preliminary results reflect a strong finish to 2025 and accelerating demand for Focal One across global markets,” said Ryan Rhodes, Chief Executive Officer. “System placements reached a quarterly record, and procedure growth in the U.S. continues to scale, which we believe reinforces the strength and durability of our recurring revenue model. For the first time in the Company’s history, the expected growth in HIFU revenue represents more than half of our expected annual revenue, validating our execution strategy.”

Mr. Rhodes added, “We believe increasing clinical validation, including data from key trials such as the landmark HIFI study and FARP Randomized Controlled Trial, is driving broader clinical adoption of focal therapy for prostate cancer. As a result, more large hospital networks are recognizing Focal One as both a strategic and necessary investment in a comprehensive prostate cancer management program.”

“Entering 2026, our global pipeline is expanding, customer engagement remains strong, and procedure utilization continues to grow. Based on this momentum, we are confident in our ability to deliver continued revenue growth and shareholder value creation in the year ahead.”

2026 Financial Guidance

The Company is issuing its initial 2026 financial guidance. In 2026, the Company’s core HIFU business revenue is expected to be in the range of \$50.0 million to \$54.0 million (€43.0 million to €46.0 million) and combined non-core (Distribution and ESWL) business revenue is expected to be in the range of \$22.0 million to \$26.0 million (€19.0 million to €22.0 million).

The above information is preliminary and subject to completion of quarter-end financial reporting processes and reviews. The preliminary financial and operational results and 2026 financial guidance included in this press release have been prepared by, and are the responsibility of, our management. During the course of the preparation of our financial statements and related notes as of for the fiscal year ended December 31, 2025, we may identify items that would require us to make material adjustments to the preliminary financial and operational results presented herein. As a result, investors should exercise caution in relying on this information and should not draw any inferences from this information. Our independent registered public accounting firm has not audited, reviewed, examined, compiled, or performed any procedures with respect to these preliminary unaudited financial and operational results and 2026 financial guidance, nor has our independent registered public accounting firm expressed any opinion or any other form of assurance on these preliminary unaudited financial and operational results and 2026 financial guidance. This preliminary financial and operational information should not be viewed as a substitute for full financial statements prepared in

accordance with U.S. GAAP and reviewed by our independent registered public accounting firm. EDAP expects to release completed 2025 annual financial results in March 2026.

Currency Translation

Euro-denominated amounts have been translated into U.S. dollars for convenience using an average exchange rate of \$1.15 = €1.00 for the fourth quarter of 2025, \$1.13 = €1.00 for the full year 2025, and \$1.17 = €1.00 for 2026 financial guidance for illustrative purposes.

About EDAP TMS SA

A recognized leader in 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 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 <https://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 include those related to the demand and growing adoption of our products, the drivers thereof, and our future financial results. 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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