



EDAP Announces Record Preliminary Fourth Quarter and Full-Year 2023 Revenues

Feb 29, 2024

- Record full-year 2023 preliminary unaudited revenue of EUR 60.4 million (\$65.4 million USD), an increase of 9.6% over full-year 2022, driven by 31.7% HIFU growth
- Record Q4 2023 preliminary unaudited revenue of EUR 19.6 million (\$21.3 million USD), an increase of 24.8% over for Q4 2022, driven by 38.8% HIFU growth
- Strong Q4 2023 U.S. Focal One® HIFU procedure growth of 136% year-over-year

LYON, France, February 29, 2024 - EDAP TMS SA (Nasdaq: EDAP), a global leader in robotic energy-based therapies, today announced preliminary unaudited fourth quarter and full-year 2023 revenues.

"Our fourth quarter and full-year 2023 revenues each hit record levels driven by increased demand for Focal One Robotic HIFU and solid execution from our capital sales and regional clinical teams," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "During the fourth quarter, we saw growing demand for Focal One from both leading academic and community hospitals across global markets. Of particular significance was the increasing number of Focal One HIFU procedures in the U.S. which grew by 136% year-over-year."

"Entering 2024, our pipeline remains strong, and we anticipate sustained business momentum as Focal One Robotic HIFU becomes a necessary treatment option in the management of prostate cancer. As the number of Focal One HIFU procedures continue to grow, we also anticipate greater patient awareness to help drive further demand as men seek out less invasive treatment options with the potential for preserving both sexual function and urinary control. While we are still in the early stages of growth for this market, it is becoming increasingly clear that urologists are adopting the Focal One platform, and we are excited about the opportunities that lie ahead for our technology and our company throughout 2024."

This information is preliminary and subject to completion of quarter-end and annual financial reporting processes and reviews. EDAP expects to release final Fourth quarter and Full-year financial results in March.

This announcement assumes the following EUR-to-USD exchange rates:

EUR-to-USD Exchange Rate	2023	2022
Fourth quarter	1.0846	1.0302
Full-year	1.0827	1.0519
December 31 st	1.1062	1.0698

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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