

EDAP Reports First Quarter 2025 Financial Results

- Achieved a Record Number of Focal One® Robotic HIFU System Placements for a First Quarter Period
- Received CE Mark Designation for Focal One for the Treatment of Deep Infiltrating Endometriosis
- Positive Final Results of FARP Randomized Controlled Trial Presented at American Urology Association Annual Meeting (AUA 2025)
- Launched the New Focal One i Robotic HIFU System
- Performed World's First Remote Transcontinental Focal One Robotic HIFU Procedure Successfully

AUSTIN, Texas, May 15, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the first quarter of 2025.

"Demand for Focal One remains on a solid growth trajectory, as demonstrated by our strong first quarter system placements. We placed a record number of nine Focal One systems, which is the highest number of placements for any first quarter in our company's history," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "As the adoption of Focal One continues to strengthen, we are also seeing a growing number of large U.S. healthcare systems selecting the Focal One platform, which we believe serves as a positive indicator for future adoption and utilization. Consistent with these positive market trends and through our voice of customer activities, we proudly launched our new Focal One i Robotic HIFU System. Focal One i incorporates a number of important new features and enhanced capabilities, enabling us to further grow our leadership position in focal therapy.

"There is also a growing body of new clinical data supporting the use of HIFU for the treatment of early-stage prostate cancer. Most significantly, the final results from the much-anticipated positive FARP randomized controlled trial were presented at this year's AUA meeting, which demonstrated non-inferiority between patients receiving focal ablation therapy and those undergoing robotic radical prostatectomy for the treatment of early-stage prostate cancer. The FARP Study is the first randomized controlled trial completed providing Level 1 evidence supporting the use of ultrasound-based focal ablation as a first-line treatment option for prostate cancer. Together, with the groundbreaking HIFI study, we believe the impact from these two rigorously designed positive clinical trials will further accelerate Focal One adoption across the global urology community."

Business Update

- On April 29, 2025, the Company announced that the final 3-year outcome of Focal Ablation versus Radical Prostatectomy (FARP) Randomized Controlled Trial (RCT) were presented at the 120th AUA Annual Meeting on Sunday, April 27, 2025. The study achieved its primary endpoint and demonstrated that the rate of treatment failure in the Focal Ablation (FA) group was non-inferior to that in the Radical Prostatectomy (RP) group at the final 36-month follow-up.
- On April 24, 2025, the Company announced the launch of the new Focal One i Robotic HIFU System at this year's AUA Annual Meeting. The Focal One i system incorporates important new features and enhanced capabilities including:
 - New expanded HIFUson® compatibility including Prostate-Specific Membrane Antigen (PSMA) PET scans, ExactVu™ Micro-Ultrasound, Unfold AI® and OnQ Prostate®, as well as extended capabilities for Koelis 3D biopsy maps and DynaCAD Urology datasets

- Streamlined HIFusion and treatment workflows with guided, step-by-step procedures designed to improve efficiency
 - Onboard video libraries to facilitate sharing standard techniques and clinical best practices
 - Integrated ability to stream and record Focal One i treatments, as well as enabling remote proctoring and remote collaborative procedures
- On April 22, 2025, the Company announced a significant presence at AUA 2025, which included the following:
 - Expert-led physician demonstrations, semi-live Focal One procedures, and hands-on simulations
 - Presentation of the final results from the randomized clinical trial (FARP Study) comparing ultrasound-based focal ablation versus robotic radical prostatectomy as a first-line treatment for prostate cancer
 - Presentation on the first ever remote transatlantic Focal One Robotic HIFU procedure by Ruben Olivares, MD, Urologic Surgeon at the Cleveland Clinic, at the AUA session of the Engineering & Urology Society
 - Launch of the new Focal One i Robotic HIFU System
 - Notable increase in the number of scientific presentations on focal therapy and ablation in the management of prostate cancer
 - Robotic HIFU Masterclass was held at the Keck School of Medicine of the University of Southern California (USC) on April 24-25th, prior to AUA Annual Meeting
 - The Company recently attended the European Association of Urology (EAU) Meeting, which took place in Madrid, Spain from March 21-24, 2025. During the conference, the Company offered numerous hands-on simulations with Focal One while also discussing the treatment implications from the recently published landmark HIFI Study (hifistudy.com).
 - On March 3, 2025, the Company announced the appointment of Glen French to its Board of Directors. Mr. French is a highly accomplished executive with extensive business and clinical expertise in the development of innovative new medical devices and technology. For nearly a decade, Glen was the CEO and Director of Pulmonx Corporation, which develops minimally invasive technologies for the diagnosis and treatment for patients with severe emphysema. Under his leadership, Pulmonx experienced more than 20% annual compound revenue growth rate. Over the course of his career, he has co-founded, built and sold three medical device companies and took a fourth company public.
 - On February 6, 2025, the Company announced the successful completion of the world's first OnQ Prostate-assisted Focal One Robotic HIFU procedure at the University of California, San Francisco (UCSF) Prostate Center. This milestone marks the first clinical application of OnQ Prostate's patented Restriction Spectrum Imaging (RSI) technology to guide focal therapy, demonstrating how advanced MR-imaging can improve lesion localization and targeting for urologists performing focal therapy.
 - On January 10, 2026, the Company announced the appointment of Joshua H. Levine to its Board of Directors. Mr. Levine is a strategic business leader with decades of diverse global board and executive management experience within the medical technology industry. He possesses a deep expertise in portfolio transformation, strategic business development and driving shareholder value. From 2012 to 2022, Mr. Levine served as President, Chief Executive Officer, and Director of Accuray Incorporated, where he led a transformative turnaround that involved all strategic, operational, and financial activities that restored the business to consistent top line growth, positive operating profit, free cash flow (EBITDA), and expanded the company's global footprint.

Clinical Pipeline Update

Endometriosis Program

- On March 26, 2025, the Company's Focal One Robotic HIFU System received CE Mark designation from GMED, EDAP's notified body, for the treatment of posterior deep endometriosis infiltrating the rectum and surrounding structures.

Upcoming Meetings and Event

- EDAP management will attend and present at the upcoming Jefferies Global Healthcare Conference, which is taking place in New York City from June 3-5, 2025. The Company is scheduled to present on Thursday, June 5th from 4:20 - 4:50 pm ET. Click [here](#) to register for the EDAP webcast.

2025 Financial Guidance

The Company is reiterating its previously issued 2025 financial guidance. EDAP expects year-over-year revenue growth of 16 and 25% in its core HIFU business, and revenue declines between 20 and 25% in its non-core businesses (ESWL and Distribution).

First Quarter 2025 Results

Total HIFU revenue for the first quarter of 2025 was EUR 6.2 million (USD 6.5 million), an increase of 6.8% as compared to EUR 5.8 million (USD 6.3 million) for the first quarter of 2024. The increase in revenue was driven by six Focal One systems sold in the first quarter of 2025 versus five systems sold in the first quarter of 2024 as well as increases in service related revenue.

Total revenue in the Company's Non-core business (LITHO and Distribution) for the first quarter of 2025 was EUR 7.4 million (USD 7.8 million), as compared to EUR 9.1 million (USD 9.9 million) for the first quarter of 2024. The decline in non-core business revenue was expected based on the Company's strategic decision to focus exclusively on the high growth opportunity in focal therapy with the Focal One Robotic HIFU platform.

Total worldwide revenue for the first quarter of 2025 was EUR 13.6 million (USD 14.3 million), a decrease of 9.1% as compared to worldwide revenue of EUR 14.9 million (USD 16.1 million) for the same period in 2024.

Gross profit for the first quarter of 2025 was EUR 5.7 million (USD 6.0 million), compared to EUR 6.4 million (USD 6.9 million) for the same period in 2024. Gross profit margin on net sales was 42.0% in the first quarter of 2025, compared to 42.8% for the comparable period in 2024. The decrease in gross profit margin year-over-year was primarily due to the mix changes within our product portfolio.

Operating expenses were 11.7 million euros (USD 12.3 million) for the first quarter, compared to 11.2 million euros (USD 12.1 million) for the same period in 2024. The increase in operating expenses was primarily due to focused investments in our HIFU business segment.

Operating loss for the first quarter of 2025 was EUR 6.0 million (USD 6.3 million), compared to an operating loss of EUR 4.8 million (USD 5.2 million) in the first quarter of 2024.

Net loss for the first quarter of 2025 was EUR 7.1 million (USD 7.5 million), or EUR (0.19) per share, as compared to net loss of EUR 4.5 million (USD 4.9 million), or EUR (0.12) per share in the first quarter of 2024.

As of March 31, 2025, the Company held cash and cash equivalents of EUR 22.8 million (USD 24.6 million) as compared to EUR 29.8 million (USD 30.9 million) as of December 31, 2024.

Conference Call Information

A conference call and webcast to discuss the first quarter 2025 financial results will be hosted by Ryan Rhodes, Chief Executive Officer, Ken Mobeck, Chief Financial Officer, and François Dietsch, Chief Accounting Officer. Please refer to the information below for conference call dial-in information and webcast registration.

Date: Thursday, May 15th @ 8:30am Eastern Time
Domestic: 1-800-267-6316
International: 1-203-518-9783
Passcode (Conf ID): EDAP

Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1714475&tp_key=2c6b64f895

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 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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EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Three Months Ended:		Three Months Ended:	
	March 31,	March 31,	March 31,	March 31,
	2025	2024	2025	2024
	Euros	Euros	\$US	\$US
Sales of medical equipment	8,963	9,967	9,440	10,782
Net sales of RPP and leases	2,160	1,775	2,275	1,921
Sales of spare parts, supplies and services	2,435	3,165	2,565	3,424
TOTAL REVENUES	13,558	14,908	14,281	16,127
Cost of sales	(7,863)	(8,523)	(8,282)	(9,220)
GROSS PROFIT	5,695	6,385	5,999	6,907
Research & development expenses	(2,455)	(2,069)	(2,586)	(2,238)
Selling, general & administrative expenses	(9,236)	(9,132)	(9,728)	(9,879)
Total operating expenses	(11,691)	(11,201)	(12,314)	(12,117)
OPERATING LOSS	(5,996)	(4,816)	(6,315)	(5,210)
Interest (expense) income, net	14	145	15	157
Currency exchange gains (loss), net	(956)	236	(1,007)	255
LOSS BEFORE INCOME TAXES	(6,937)	(4,435)	(7,307)	(4,798)
Income tax (expense) credit, net	(137)	(111)	(144)	(120)
NET LOSS	(7,074)	(4,546)	(7,451)	(4,918)
Earning per share – Basic and diluted	(0.19)	(0.12)	(0.20)	(0.13)
Average number of shares used in computation of basic and diluted EPS	37,392,086	36,996,722	37,392,086	36,996,722

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average three months exchange rate of 1 Euro = 1.0533 USD, and 2024 average three months exchange rate of 1 Euro = 1.0818 USD

EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of Euros and U.S. Dollars)

	March 31, 2025 Euros	December 31, 2024 Euros	March 31, 2025 \$US	December 31, 2024 \$US
Cash, cash equivalents and short-term investments	22,825	29,836	24,641	30,883
Accounts receivable, net	16,200	20,288	17,489	21,000
Inventory	18,024	18,495	19,458	19,143
Other current assets	1,421	1,258	1,534	1,302
TOTAL CURRENT ASSETS	58,470	69,876	63,122	72,328
Property, plant and equipment, net	9,989	10,336	10,784	10,699
Goodwill	2,412	2,412	2,604	2,496
Other non-current assets	4,105	3,439	4,432	3,560
TOTAL ASSETS	74,976	86,063	80,942	89,083
Accounts payable & other accrued liabilities	17,340	21,350	18,720	22,099
Deferred revenues, current portion	7,121	6,641	7,688	6,874
Short term borrowing	5,687	6,243	6,139	6,462
Other current liabilities	3,405	3,577	3,675	3,702
TOTAL CURRENT LIABILITIES	33,553	37,811	36,223	39,138
Obligations under operating and finance leases non-current	1,773	1,939	1,914	2,007
Long-term debt, non-current	1,618	2,162	1,747	2,238
Deferred revenues, non-current	625	358	674	370
Other long-term liabilities	2,949	2,897	3,184	2,999
TOTAL LIABILITIES	40,518	45,167	43,742	46,752
TOTAL SHAREHOLDERS'EQUITY	34,458	40,896	37,200	42,331
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	74,976	86,063	80,942	89,083

NOTE: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.0796 USD, on March 31, 2025 and at the exchange rate of 1 Euro = 1.0351 USD, on December 31, 2024.

EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of Euros and U.S. Dollars)

	Three Months Ended March 31, 2025 (Euros)	Twelve Months Ended December 31, 2024 (Euros)	Three Months Ended March 31, 2025 (\$US)	Twelve Months Ended December 31, 2024 (\$US)
NET INCOME (LOSS)	(7,074)	(19,018)	(7,451)	(20,520)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	1,173	7,395	1,236	7,979
OPERATING CASH FLOW	(5,901)	(11,623)	(6,215)	(12,541)
Increase/Decrease in operating assets and liabilities	824	(1,961)	868	(2,116)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(5,076)	(13,584)	(5,347)	(14,657)
Additions to capitalized assets produced by the company and other capital expenditures	(1,239)	(4,120)	(1,305)	(4,445)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(1,239)	(4,120)	(1,305)	(4,445)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(1,191)	4,635	(1,255)	5,001
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	496	(566)	1,665	(3,103)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(7,011)	(13,635)	(6,242)	(17,204)

⁽¹⁾ including share based compensation expenses for 322 thousand of Euros for the three months ended March 31, 2025 and 3,283 thousand of Euros for the full year ended December 31, 2024.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average three months' exchange rate of 1 Euro = 1.0533 USD, and 2024 average twelve months exchange rate of 1 Euro = 1.0790 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended March 31, 2025
(Amounts in thousands of Euros)

	<u>HIFU Division</u>		<u>ESWL Division</u>		<u>Distribution Division</u>		<u>Reconciling Items</u>		<u>Total After Consolidation</u>	
Sales of medical equipment	3,611		416		4,936		—		8,963	
Net sales of RPP and leases	1,848		261		51		—		2,160	
Sales of spare parts, supplies and services	718		1,054		663		—		2,435	
TOTAL REVENUES	6,177		1,731		5,650		—		13,558	
GROSS PROFIT (% of Net Sales)	3,001	48.6 %	824	47.6 %	1,870	33.1 %	—		5,695	42.0 %
Research & development expenses	(2,241)		(41)		(173)		—		(2,455)	
Selling, general & administrative expenses	(6,121)		(270)		(1,918)		(927)		(9,236)	
OPERATING PROFIT (LOSS)	(5,361)		513		(221)		(927)		(5,996)	