

EDAP Reports Third Quarter 2025 Financial Results

- 49% YoY HIFU Revenue Growth, Driven by Increased Focal One® Sales and U.S. Procedure Volumes
- 167% YoY Growth in Focal One System Placements
- 15% YoY Growth in U.S. Focal One HIFU Procedures
- Company to Host Conference Call and Webcast on November 6 at 8:30 a.m. ET

AUSTIN, Texas, November 6, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the third quarter of 2025.

“Our record-breaking third-quarter revenue performance reflects the continued strong demand for our leading Focal One Robotic HIFU platform, with system placements increasing 167% year over year. Even in a seasonally softer period, we achieved our second consecutive quarter of record HIFU revenue for the respective period, underscoring the consistent and positive growth of our business. It is becoming increasingly clear that more urologists want to offer their patients both an effective and non-invasive treatment option for early-stage prostate cancer. These factors are driving demand as seen over the last two quarters, which reflects this important growing paradigm shift in prostate cancer management. During the quarter we also saw a return to double-digit Focal One procedure growth in the U.S. as we continue to see broader hospital adoption, increased patient demand and expanded insurance provider coverage.” said Ryan Rhodes, Chief Executive Officer of EDAP.

“We have also made notable progress strengthening our balance sheet. As announced last month, we finalized an agreement with the European Investment Bank for a €36 million credit facility to be made available in three tranches, with €11 million from the first tranche deposited earlier this week. Looking ahead, our Focal One pipeline continues to expand, reflecting both growing demand and continued execution by our commercial and clinical teams.”

Business Update

- On October 20, 2025, the Company announced the closing of a €36 million credit facility with the European Investment Bank (EIB). Proceeds from this financing will support the continued expansion of the Company’s Focal One® Robotic HIFU platform in Focal Therapy, the fastest-growing treatment category for early-stage prostate cancer and accelerate the development of new clinical indications.
- On September 30, 2025, the Company highlighted its Focal One Prostate Cancer Awareness Month campaign, featuring national television coverage on Friday, September 26, which reached millions of viewers nationwide. The segment, which included an interview with a patient treated with Focal One, aired during Health Uncensored with Dr. Drew on the Lifetime Network, providing unprecedented exposure and allowing audiences across the United States to learn about Focal One. In addition, the Company conducted multiple patient-education events and partnered with hospitals and practices nationwide to raise awareness through a range of local outreach activities.
- On September 16, 2025, the Company announced that it was honored with the 2025 Industry Award for Innovations in Endourological Instrumentation by the Endourological Society, recognizing its groundbreaking work with the Focal One High-Intensity Focused Ultrasound (HIFU) platform. Focal One is the first Focal Therapy technology to receive this distinguished award. Presented annually to an individual or organization that has made outstanding contributions to the field of urology, the award was conferred during the 42nd World Congress of Endourology and Uro-Technology (WCET).

Upcoming Meetings and Events

- UBS Global Healthcare Conference – November 10–13, 2025, in Palm Beach Gardens, Florida. EDAP management will participate in one-on-one meetings with investors.
- Jefferies London Healthcare Conference – November 18–20, 2025, in London, U.K. EDAP management will present on Tuesday, November 18, from 4:30–4:55 p.m. GMT.
- Piper Sandler 37th Annual Healthcare Conference – December 2–4, 2025, in New York, New York. EDAP management will present on Tuesday, December 2, at 10:30–10:55 a.m. ET.

2025 Financial Guidance

The Company is reiterating its 2025 financial guidance. Core HIFU business revenue is expected to grow within the range of 26% to 34% year over year, and combined non-core ESWL and Distribution business revenue is expected to decline within the range of 25% to 30% year over year.

Third Quarter 2025 Results

High-Intensity Focused Ultrasound (HIFU) Business

Total revenue in the HIFU business for the third quarter of 2025 was €6.7 million (US \$7.7 million), compared to €4.5 million (US \$4.9 million) for the same period in 2024, representing an increase of 49% year over year. The Company sold six Focal One systems during the quarter, versus three system sales in the same period in 2024. Worldwide disposables revenue grew 9% year over year, driven primarily by 15% growth in Focal One procedures in the U.S.

Non-Core Businesses (ESWL and Distribution)

Total revenue from the Company's non-core businesses for the third quarter of 2025 was €7.2 million (US \$8.4 million), compared to €8.6 million (US \$9.8 million) for the same period in 2024. The expected decline reflects the Company's strategic decision to focus on the high-growth opportunity in Focal Therapy through its Focal One Robotic HIFU platform.

Company

Total worldwide revenue for the third quarter of 2025 was €13.9 million (US \$16.1 million), an increase of 6% compared to €13.1 million (US \$14.4 million) for the same period in 2024.

Gross profit for the third quarter of 2025 was €6.0 million (US \$6.9 million), compared to €5.2 million (US \$5.7 million) for the same period in 2024. Gross profit margin on net sales was 43%, up from 39% for the same period in 2024. The margin improvement was primarily due to a favorable product-mix shift and better absorption of fixed costs, largely attributable to the growth of HIFU revenue.

Operating expenses for the third quarter of 2025 were stable at €10.9 million (US \$12.7 million), compared to €11.0 million (US \$12.1 million) for the same period in 2024.

Operating loss for the third quarter of 2025 was €4.9 million (US \$5.7 million), compared to €5.8 million (US \$6.4 million) for the same period in 2024.

Net loss for the third quarter of 2025 was €5.0 million (US \$5.8 million), or (€0.13) per share, compared to €6.4 million (US \$7.0 million), or (€0.17) per share, for the same period in 2024.

Year-to-Date Results

High-Intensity Focused Ultrasound (HIFU) Business

Total revenue in the HIFU business for the nine months ended September 30, 2025, was €21.3 million (US \$23.9 million), an increase of 42% compared to €15.1 million (US \$16.3 million) for the same period in 2024.

Non-Core Businesses (ESWL and Distribution)

Total revenue from the Company's non-core businesses for the nine months ended September 30, 2025, was €22.2 million (US \$24.9 million), a 23% decrease compared to €28.7 million (US \$31.2 million) for the same period in 2024.

Company

Total worldwide revenue for the nine months ended September 30, 2025, was €43.5 million (US \$48.8 million), a decrease of 0.7% compared to €43.8 million (US \$47.6 million) for the same period in 2024.

Gross profit for the nine months ended September 30, 2025, was €18.5 million (US \$20.7 million), compared to €17.5 million (US \$19.0 million) for the same period in 2024. Gross profit margin on net sales improved to 42.5% for the nine-month period ended September 30, 2025, up from 39.9% for the same period in 2024.

Operating expenses for the nine months ended September 30, 2025, totaled €35.2 million (US \$39.4 million), compared to €34.3 million (US \$37.2 million) for the same period in 2024.

Operating loss for the nine months ended September 30, 2025, was €16.7 million (US \$18.7 million), compared to €16.8 million (US \$18.2 million) for the same period in 2024.

Net loss for the nine months ended September 30, 2025, was €17.7 million (US \$19.8 million), or (€0.47) per share, compared to €17.1 million (US \$18.5 million), or (€0.46) per share, for the same period in 2024.

As of September 30, 2025, the Company held cash and cash equivalents of €10.6 million (US \$12.4 million), compared to €16.3 million (US \$19.1 million) as of June 30, 2025.

Conference Call Information

A conference call and webcast to discuss the third 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, November 6th @ 8:30am Eastern Time
Domestic: 1-800-274-8461
International: 1-203-518-9814
Passcode (Conf ID): EDAP

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1738018&tp_key=c91765d4a0

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:	
	September 30, 2025 Euros	September 30, 2024 Euros	September 30, 2025 \$US	September 30, 2024 \$US
Sales of medical equipment	9,430	8,393	10,958	9,240
Net sales of RPP and leases	2,194	1,586	2,550	1,746
Sales of spare parts, supplies and services	2,255	3,120	2,621	3,435
TOTAL REVENUES	13,879	13,098	16,128	14,420
Cost of sales	(7,908)	(7,944)	(9,189)	(8,746)
GROSS PROFIT	5,972	5,154	6,939	5,675
Research & development expenses	(2,086)	(1,716)	(2,424)	(1,889)
Selling, general & administrative expenses	(8,811)	(9,271)	(10,239)	(10,207)
Total operating expenses	(10,898)	(10,987)	(12,663)	(12,096)
OPERATING LOSS	(4,926)	(5,833)	(5,724)	(6,422)
Interest (expense) income, net	(49)	102	(57)	113
Currency exchange gains (loss), net	64	(606)	75	(667)
LOSS BEFORE INCOME TAXES	(4,911)	(6,337)	(5,707)	(6,976)
Income tax (expense) credit, net	(103)	(62)	(120)	(69)
NET LOSS	(5,014)	(6,399)	(5,827)	(7,045)
Earning per share – basic and diluted	(0.13)	(0.17)	(0.16)	(0.19)
Average number of shares used in computation of basic and diluted EPS	37,438,630	37,233,406	37,438,630	37,233,406

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average three months' exchange rate of 1 Euro = 1.1620 USD, and 2024 average three months' exchange rate of 1 Euro = 1.1010 USD

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

	Nine Months Ended:		Nine Months Ended:	
	September 30, 2025 Euros	September 30, 2024 Euros	September 30, 2025 \$US	September 30, 2024 \$US
Sales of medical equipment	29,614	29,478	33,207	32,006
Net sales of RPP and leases	6,600	5,247	7,401	5,697
Sales of spare parts, supplies and services	7,267	9,072	8,148	9,850
TOTAL REVENUES	43,480	43,797	48,755	47,553
Cost of sales	(24,992)	(26,338)	(28,024)	(28,597)
GROSS PROFIT	18,488	17,458	20,732	18,956
Research & development expenses	(6,749)	(5,862)	(7,568)	(6,364)
Selling, general & administrative expenses	(28,430)	(28,393)	(31,879)	(30,828)
Total operating expenses	(35,179)	(34,254)	(39,448)	(37,192)
OPERATING LOSS	(16,691)	(16,796)	(18,716)	(18,236)
Interest (expense) income, net	(92)	438	(104)	475
Currency exchange gains (loss), net	(572)	(419)	(642)	(455)
LOSS BEFORE INCOME TAXES	(17,355)	(16,777)	(19,461)	(18,216)
Income tax (expense) credit, net	(333)	(300)	(374)	(326)
NET LOSS	(17,689)	(17,077)	(19,835)	(18,542)
Earning per share – basic and diluted	(0.47)	(0.46)	(0.53)	(0.50)
Average number of shares used in computation of basic and diluted EPS	37,417,439	37,149,121	37,417,439	37,149,121

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average nine months' exchange rate of 1 Euro = 1.1213 USD, and 2024 average nine months' exchange rate of 1 Euro = 1.0858 USD

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

	September 30, 2025 Euros	December 31, 2024 Euros	September 30, 2025 \$US	December 31, 2024 \$US
Cash, cash equivalents and short-term investments	10,567	29,836	12,400	30,883
Accounts receivable, net	19,025	20,288	22,325	21,000
Inventory	13,799	18,495	16,193	19,143
Other current assets	960	1,258	1,127	1,302
TOTAL CURRENT ASSETS	44,352	69,876	52,044	72,328
Property, plant and equipment, net	10,016	10,336	11,753	10,699
Goodwill	2,412	2,412	2,830	2,496
Other non-current assets	4,685	3,439	5,498	3,560
TOTAL ASSETS	61,464	86,063	72,124	89,083
Accounts payable & other accrued liabilities	16,844	21,350	19,765	22,099
Deferred revenues, current portion	6,372	6,641	7,477	6,874
Short term borrowing	5,048	6,243	5,924	6,462
Other current liabilities	3,140	3,577	3,685	3,702
TOTAL CURRENT LIABILITIES	31,404	37,811	36,851	39,138
Obligations under operating and finance leases non-current	1,495	1,939	1,754	2,007
Long-term debt, non-current	1,009	2,162	1,183	2,238
Deferred revenues, non-current	1,202	358	1,411	370
Other long-term liabilities	3,034	2,897	3,560	2,999
TOTAL LIABILITIES	38,144	45,167	44,759	46,752
TOTAL SHAREHOLDERS' EQUITY	23,321	40,896	27,365	42,331
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	61,464	86,063	72,124	89,083

NOTE: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.1734 USD, on September 30, 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)

	Nine Months Ended September 30, 2025 (Euros)	Twelve Months Ended December 31, 2024 (Euros)	Nine Months Ended September 30, 2025 (\$US)	Twelve Months Ended December 31, 2024 (\$US)
NET INCOME (LOSS)	(17,689)	(19,018)	(19,835)	(20,520)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	4,591	7,395	5,148	7,979
OPERATING CASH FLOW	(13,098)	(11,623)	(14,687)	(12,541)
Increase/Decrease in operating assets and liabilities	625	(1,961)	701	(2,116)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(12,473)	(13,584)	(13,986)	(14,657)
Additions to capitalized assets produced by the company and other capital expenditures	(3,577)	(4,120)	(4,011)	(4,445)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(3,577)	(4,120)	(4,011)	(4,445)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(2,545)	4,635	(2,854)	5,001
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(673)	(566)	2,369	(3,103)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(19,268)	(13,635)	(18,483)	(17,204)

⁽¹⁾ including share based compensation expenses for 1,560 thousand of Euros for the nine months ended September 30, 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 nine months' exchange rate of 1 Euro = 1.1213 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
nine months ended September 30, 2025
(Amounts in thousands of Euros)

	<u>HIFU</u> <u>Division</u>		<u>ESWL</u> <u>Division</u>		<u>Distribution</u> <u>Division</u>		<u>Reconciling</u> <u>Items</u>	<u>Total After</u> <u>Consolidation</u>	
Sales of medical equipment	13,479		1,299		14,835		—	29,614	
Net sales of RPP and leases	5,645		749		206		—	6,600	
Sales of spare parts, supplies and services	2,182		3,058		2,027		—	7,267	
TOTAL REVENUES	21,306		5,106		17,068		—	43,480	
GROSS PROFIT (% of Net Sales)	10,428	48.9 %	2,253	44.1 %	5,807	34.0 %	—	18,488	42.5 %
Research & development expenses	(6,213)		(118)		(419)		—	(6,749)	
Selling, general & administrative expenses	(18,979)		(777)		(5,889)		(2,786)	(28,430)	
OPERATING PROFIT (LOSS)	(14,763)		1,358		(500)		(2,786)	(16,691)	