

EDAP Reports Strong Second Quarter 2025 HIFU Results

Aug 28, 2025

- +140% Focal One® Net Placement Growth Year over Year
- +76.8% HIFU Revenue Growth Year over Year
- 36 million Euro Credit Facility Letter of Intent Executed with European Investment Bank (EIB) to further accelerate HIFU Growth and Strategic Expansion
- Company raises 2025 HIFU Year over Year Revenue Growth Guidance range to 26% to 34%, up from the prior range of 16% to 25%

Company to Host Conference Call and Webcast Today, August 28th, at 8:30 a.m. EDT

AUSTIN, Texas, August 28, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the second quarter of 2025.

"We experienced our strongest second quarter performance in our company's history, placing a net total of 12 Focal One Robotic HIFU Systems with increased customer demand coming from both U.S. and international markets," said Ryan Rhodes, Chief Executive Officer. "The strong year over year growth in the second quarter underscores the accelerating momentum of our leading Focal One platform and its increased adoption amongst urologists. To continue to advance the expansion of Focal One, including new indications and further development of focused ultrasound technologies, we executed a letter of intent with the European Investment Bank that will provide a significant source of low interest rate capital. As we enter the second half of 2025, our Focal One pipeline continues to strengthen, and we anticipate demand for Focal One continuing to grow as more prostate cancer patients recognize the advantages of the Focal One treatment. This momentum is further supported by the groundbreaking publication from the large multicenter prospective comparative HIFI study and the compelling Level 1 clinical evidence from the FARP Randomized Controlled Trial, both of which are gaining wider dissemination within the global urology community."

Business Update

- On August 26, 2025, the Company announced a letter of intent for credit facility with the European Investment Bank (EIB) for 36 million Euros
- On July 1, 2025, the Company announced that, effective January 1, 2026, EDAP will become a U.S. domestic filer and will begin complying with corresponding U.S. SEC reporting rules and Nasdaq listing requirements
- On April 29, 2025, the Company announced that the positive final 3-year outcomes of Focal Ablation versus Radical Prostatectomy (FARP) Randomized Controlled Trial (RCT) were presented at the 120th AUA Annual Meeting
- On April 24, 2025, the Company announced the launch of the new Focal One i Robotic HIFU System

Upcoming Meetings and Events

EDAP management will attend and present at the upcoming H.C. Wainwright 27th Annual Global Investment Conference, in New York City from September 8-10, 2025. The Company is scheduled to present on September 9th from 8:30AM - 9:00AM ET and will also conduct 1x1 investor meetings. Click <https://journey.ct.events/view/ede7e5df-b6f5-4ffb-a947-50a936dfb93b> to register for the EDAP webcast.

2025 Financial Guidance

The Company is updating its 2025 financial guidance. Core HIFU business revenue is now 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. This compares to previous revenue guidance issued at the beginning of the calendar year 2025 of year over year revenue growth between 16% and 25% in core HIFU business, and year over year revenue decline between 20% and 25% in non-core ESWL and Distribution business.

Second Quarter 2025 Results

Total revenue in the HIFU business for the second quarter of 2025 was EUR 8.5 million (USD 9.7 million), as compared to EUR

4.8 million (USD 5.2 million) for the second quarter of 2024, representing growth of +76.8% on a year over year basis. The increase in year over year growth of the HIFU division was driven by nine Focal One capital sales in the second quarter of 2025 versus three systems sales in the second quarter of 2024. The Company recorded a 23.9% year over year growth in worldwide disposable revenue. Focal One procedures grew 4.8% in the U.S. on a year over year basis.

Total revenue in the Company's non-core business (ESWL and Distribution) for the second quarter of 2025 was EUR 7.6 million (USD 8.7 million), as compared to EUR 11.0 (USD 11.8 million) for the second 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 second quarter of 2025 was EUR 16.0 million (USD 18.4 million), an increase of 1.6% as compared to worldwide revenue of EUR 15.8 million (USD 17.0 million) for the same period in 2024.

Gross profit for the second quarter of 2025 was EUR 6.8 million (USD 7.8 million), compared to gross profit of EUR 5.9 million (USD 6.4 million) for the year-ago period. Gross profit margin on net sales was 42.5% in the second quarter of 2025, compared to 37.5% for the comparable period in Q2 2024. The increase in gross profit margin on a year over year basis was primarily due to Company's strategic focus on its core HIFU business segment, which drives higher gross margins.

Operating expenses were EUR 12.6 million (USD 14.5 million) for the second quarter, compared to EUR 12.1 million (USD 13.0 million) for the same period in 2024. The increase in operating expenses was primarily due to focused investments in our HIFU business.

Operating loss for the second quarter of 2025 was EUR 5.8 million (USD 6.6 million), compared to an operating loss of EUR 6.1 million (USD 6.6 million) in the second quarter of 2024.

Net loss for the second quarter of 2025 was EUR 5.6 million (USD 6.4 million), or EUR (0.15) per share, as compared to net loss of EUR 6.1 million (USD 6.6 million), or EUR (0.16) per share in the second quarter of 2024.

First Half 2025 Results

Total revenue in the HIFU business for the six months ended June 30, 2025, was EUR 14.7 million (USD 16.1 million), an increase of 38.5% as compared to EUR 10.6 million (USD 11.4 million) for the six months ended June 30, 2024.

Total revenue in the Company's non-core business (ESWL and Distribution) business for the six months ended June 30, 2025, was EUR 15.0 million (USD 16.5 million), a 25.7% decrease compared to EUR 20.1 million (USD 21.7 million) for the six months ended June 30, 2024.

Total worldwide revenue for the six months ended June 30, 2025, was EUR 29.6 million (USD 32.6 million), a decrease of 3.6% from total worldwide revenue of EUR 30.7 million (USD 33.1 million) for the same period in 2024.

Gross profit for the six months ended June 30, 2025, was EUR 12.5 million (USD 13.8 million), compared to EUR 12.3 million (USD 13.3 million), for the six months ended June 30, 2024. Gross profit margin on net sales was 42.3% for the six months ended June 30, 2025, compared to 40.1% for the comparable period in 2024.

Operating expenses were EUR 24.3 million (USD 26.7 million) for the six months ended June 30, 2025, compared to EUR 23.3 million (USD 25.1 million) for the same period in 2024.

Operating loss for the six months ended June 30, 2025, was EUR 11.8 million (USD 13.0 million), compared to an operating loss of EUR 11.0 million (USD 11.8 million) for the six months ended June 30, 2024.

Net loss for the six months ended June 30, 2025, was EUR 12.7 million (USD 14.0 million), or EUR (0.34) per share, as compared to a net loss of EUR 10.7 million (USD 11.5 million), or EUR (0.29) per share for the six months ended June 30, 2024.

As of June 30, 2025, the Company held cash and cash equivalents of EUR 16.3 million (USD 19.1 million) as compared to EUR 22.8 million (USD 24.6 million) as of March 31, 2025.

Conference Call Information

A conference call and webcast to discuss the second 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, August 28th @ 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=1726716&tp_key=220919ac3d

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 our expectations to enter into a credit facility with EIB, the size thereof, the timing thereof and the use of proceeds from such credit facility. 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:	
	June 30,	June 30,	June 30,	June 30,
	2025	2024	2025	2024
	Euros	Euros	\$US	\$US
Sales of medical equipment	11,221	11,118	12,891	11,948
Net sales of RPP and leases	2,246	1,886	2,580	2,027
Sales of spare parts, supplies and services	2,576	2,787	2,960	2,995
TOTAL REVENUES	16,043	15,791	18,431	16,970
Cost of sales	(9,221)	(9,872)	(10,594)	(10,609)

GROSS PROFIT	6,822	5,919	7,838	6,361
Research & development expenses	(2,208)	(2,077)	(2,537)	(2,232)
Selling, general & administrative expenses	(10,382)	(9,989)	(11,928)	(10,736)
Total operating expenses	(12,591)	(12,066)	(14,465)	(12,967)
OPERATING LOSS	(5,769)	(6,147)	(6,628)	(6,606)
Interest (expense) income, net	(57)	190	(66)	204
Currency exchange gains (loss), net	319	(49)	367	(52)
LOSS BEFORE INCOME TAXES	(5,507)	(6,005)	(6,327)	(6,454)
Income tax (expense) credit, net	(93)	(127)	(107)	(136)
NET LOSS	(5,600)	(6,132)	(6,434)	(6,590)
Earning per share – basic and diluted	(0.15)	(0.16)	(0.17)	(0.18)
Average number of shares used in computation of basic and diluted EPS	37,420,318	37,205,307	37,420,318	37,205,307

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average three months' exchange rate of 1 Euro = 1.1489 USD, and 2024 average three months' exchange rate of 1 Euro = 1.0747 USD

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

	Six Months Ended:		Six Months Ended:	
	June 30,	June 30,	June 30,	June 30,
	2025	2024	2025	2024
	Euros	Euros	\$US	\$US
Sales of medical equipment	20,184	21,085	22,224	22,735
Net sales of RPP and leases	4,406	3,661	4,851	3,948
Sales of spare parts, supplies and services	5,011	5,952	5,518	6,418
TOTAL REVENUES	29,601	30,698	32,593	33,102
Cost of sales	(17,084)	(18,394)	(18,811)	(19,834)
GROSS PROFIT	12,517	12,304	13,782	13,267
Research & development expenses	(4,663)	(4,146)	(5,134)	(4,470)
Selling, general & administrative expenses	(19,619)	(19,121)	(21,602)	(20,618)
Total operating expenses	(24,282)	(23,267)	(26,736)	(25,088)
OPERATING LOSS	(11,765)	(10,963)	(12,954)	(11,821)
Interest (expense) income, net	(43)	335	(47)	361
Currency exchange gains (loss), net	(637)	187	(701)	202
LOSS BEFORE INCOME TAXES	(12,444)	(10,440)	(13,702)	(11,258)
Income tax (expense) credit, net	(230)	(238)	(253)	(257)
NET LOSS	(12,674)	(10,678)	(13,955)	(11,514)
Earning per share – basic and diluted	(0.34)	(0.29)	(0.37)	(0.31)
Average number of shares used in computation of basic and diluted EPS	37,406,202	37,104,348	37,406,202	37,104,348

NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average six months' exchange rate of 1 Euro = 1.1011 USD, and 2024 average six months' exchange rate of 1 Euro = 1.0783 USD

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

June 30, December 31, June 30, December 31,

	2025	2024	2025	2024
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short-term investments	16,265	29,836	19,144	30,883
Accounts receivable, net	18,527	20,288	21,806	21,000
Inventory	15,531	18,495	18,281	19,143
Other current assets	1,157	1,258	1,362	1,302
TOTAL CURRENT ASSETS	51,480	69,876	60,593	72,328
Property, plant and equipment, net	10,202	10,336	12,009	10,699
Goodwill	2,412	2,412	2,839	2,496
Other non-current assets	4,248	3,439	5,000	3,560
TOTAL ASSETS	68,343	86,063	80,441	89,083
Accounts payable & other accrued liabilities	18,549	21,350	21,833	22,099
Deferred revenues, current portion	5,898	6,641	6,942	6,874
Short term borrowing	6,276	6,243	7,387	6,462
Other current liabilities	3,392	3,577	3,993	3,702
TOTAL CURRENT LIABILITIES	34,115	37,811	40,154	39,138
Obligations under operating and finance leases non-current	1,660	1,939	1,954	2,007
Long-term debt, non-current	1,022	2,162	1,203	2,238
Deferred revenues, non-current	718	358	845	370
Other long-term liabilities	3,006	2,897	3,538	2,999
TOTAL LIABILITIES	40,521	45,167	47,694	46,752
TOTAL SHAREHOLDERS' EQUITY	27,822	40,896	32,747	42,331
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	68,343	86,063	80,441	89,083

NOTE: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.1770 USD, on June 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)

	Six Months Ended	Twelve Months Ended	Six Months Ended	Twelve Months Ended
	June 30,	December 31,	June 30,	December 31,
	2025	2024	2025	2024
	(Euros)	(Euros)	(\$US)	(\$US)
NET INCOME (LOSS)	(12,674)	(19,018)	(13,955)	(20,520)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	2,767	7,395	3,046	7,979
OPERATING CASH FLOW	(9,907)	(11,623)	(10,909)	(12,541)
Increase/Decrease in operating assets and liabilities	713	(1,961)	785	(2,116)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(9,194)	(13,584)	(10,123)	(14,657)
Additions to capitalized assets produced by the company and other capital expenditures	(2,669)	(4,120)	(2,939)	(4,445)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(2,669)	(4,120)	(2,939)	(4,445)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(1,096)	4,635	(1,207)	5,001
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(611)	(566)	2,531	(3,103)

**NET INCREASE (DECREASE) IN CASH AND
CASH EQUIVALENTS**

(13,571)

(13,635)

(11,738)

(17,204)

⁽¹⁾ including share based compensation expenses for 775 thousand of Euros for the six months ended June 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 six months' exchange rate of 1 Euro = 1.1011 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
six months ended June 30, 2025
(Amounts in thousands of Euros)

	<u>HIFU</u>		<u>ESWL</u>		<u>Distribution</u>		<u>Reconciling</u>		<u>Total After</u>	
	<u>Division</u>		<u>Division</u>		<u>Division</u>		<u>Items</u>		<u>Consolidation</u>	
Sales of medical equipment	9,321		681		10,181		—		20,184	
Net sales of RPP and leases	3,752		538		117		—		4,406	
Sales of spare parts, supplies and services	<u>1,578</u>		<u>2,069</u>		<u>1,365</u>		<u>—</u>		5,011	
TOTAL REVENUES	<u>14,650</u>		<u>3,288</u>		<u>11,663</u>		<u>—</u>		<u>29,601</u>	
GROSS PROFIT (% of Net Sales)	7,339	50.1 %	1,468	44.6 %	3,710	31.8 %	—		12,517	42.3 %
Research & development expenses	(4,254)		(84)		(325)		—		(4,663)	
Selling, general & administrative expenses	<u>(13,248)</u>		<u>(507)</u>		<u>(4,035)</u>		<u>(1,828)</u>		<u>(19,619)</u>	
OPERATING PROFIT (LOSS)	(10,163)		876		(650)		(1,828)		(11,765)	

Attachment

- [EDAP Q2 2025 Financial Results](#)