

EDAP Reports Strong Financial Results with Record First Quarter HIFU Revenue

May 07, 2026

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Seventh Consecutive Quarter of Year-Over-Year HIFU Revenue Growth

- 78% Growth in First Quarter HIFU Revenue Year-Over-Year
- 53% Growth in First Quarter U.S. HIFU Procedures Year-Over-Year
- 83% Growth in First Quarter Focal One Shipments Year-Over-Year Demonstrating Strong Momentum
- Landmark HIFI-2 Study Results Further Strengthen Focal One Robotic HIFU Market Position

AUSTIN, Texas, May 7, 2026 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today reported financial results for the first quarter of 2026.

"We delivered our strongest HIFU quarter to date, with revenue of \$11.6 million, representing 78% year over year growth. U.S. Focal One procedure volumes reached a record high for the company with 53% year over year growth. We are executing well against our 2026 priorities and our results reflect a growing HIFU business. This includes expanded capital sales in key markets along with notable increased utilization across our global installed base," said Ryan Rhodes, Chief Executive Officer. "Internationally, we secured capital sales in the United Kingdom, France, and Hungary where, for the first time, hospitals are investing in Focal One Robotic HIFU to treat both prostate cancer and deep infiltrating endometriosis."

As previously announced, the landmark HIFI-2 study, published in European Urology Oncology, represents the largest prospective study to date evaluating salvage HIFU treatment following recurrence after failed radiation therapy. The positive study results show promise for use of Focal One HIFU as a breakthrough treatment for this important population of men who have previously been left with limited options that result in long-lasting, debilitating side effects. The publication of the HIFI-2 study further reinforces Focal One's unique position as a non-invasive, organ-sparing, and function-preserving treatment option for a patient population that has historically faced limited therapeutic alternatives beyond palliative care.

First Quarter 2026 Results

High-Intensity Focused Ultrasound (HIFU) Business

Total revenue in the HIFU business for the first quarter of 2026 was \$11.6 million, compared to \$6.5 million for the same period in 2025, representing an increase of 78% year over year. The Company sold eleven Focal One systems during the quarter, versus six system sales in the same period in 2025, representing a year-over-year growth of 83%. Worldwide disposables revenue grew 54% year over year, driven primarily by 53% 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 first quarter of 2026 was \$6.2 million, compared to \$7.8 million for the same period in 2025. The year over year decline reflects the Company's strategic decision to focus on the high-growth, high margin opportunity in focal therapy through its Focal One Robotic HIFU platform.

Company

Total worldwide revenue for the first quarter of 2026 was \$17.8 million, compared to \$14.3 million for the same period in 2025. Gross profit margin on net sales was 45.7%, up from 42.0% for the same period in 2025. 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 first quarter of 2026 were \$15.5 million, compared to \$12.3 million for the same period in 2025.

Operating loss for the first quarter of 2026 was \$7.4 million, compared to \$6.3 million for the same period in 2025.

Net loss for the first quarter of 2026 was \$9.1 million, or (\$0.24) per share, compared to \$7.4 million, or (\$0.20) per share, for the same period in 2025.

2026 Financial Guidance

The Company is reiterating its previously issued revenue guidance. The Company's core HIFU business revenue is expected to

be in the range of \$50.0 million to \$54.0 million, representing 34% to 45% year-over-year growth. Revenue for the Company's combined non-core ESWL and Distribution business is expected to be in the range of \$22.0 million to \$26.0 million.

Upcoming Meetings and Events

- American Urological Association (AUA) Annual Meeting: May 15-18 in Washington D.C.
- **Investor Day:** Monday, June 1, 2026 from 8:00-10:00am ET at Nasdaq MarketSite in New York City
- Jefferies Global Healthcare Conference: Marriott Marquis, June 4th in New York City. EDAP management will present at 2:00pm ET and will participate in one-on-one meetings with investors

Conference Call Information

A conference call and webcast to discuss the first quarter 2026 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 7, 2026, at 8:30 a.m. Eastern Time
Domestic: 1-800-343-4136
International: 1-203-518-9843
Passcode (Conf ID): EDAP

Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1759064&tp_key=77ec2128dc

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 the United States as a leading prostate focal therapy platform 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, 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 10-K.

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.

Investor Contact

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(Amounts in thousands of U.S. Dollars)

Three months ended March 31, 2026	HIFU Division	ESWL Division	Distribution Division	Reconciling Items	Total After Consolidation				
Sales of medical equipment	\$8,256	\$277	\$3,846	—	\$12,379				
Net sales of RPP and leases	2,492	224	91	—	2,808				
Sales of spare parts, supplies and services	845	1,031	749	—	2,626				
TOTAL REVENUES	\$11,593	\$1,533	\$4,686	—	\$17,812				
GROSS PROFIT (% of Net Sales)	\$5,962	51.4 %	\$586	38.2 %	\$1,597	34.1 %	—	\$8,146	45.7 %
Research & development expenses	(2,467)	(46)	(84)	—	(2,597)				
Selling, general & administrative expenses	(9,439)	(218)	(1,282)	(1,976)	(12,915)				
OPERATING PROFIT (LOSS)	(\$5,944)	\$322	\$231	(\$1,976)	(\$7,366)				

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

	Three Months Ended:	
	March 31, 2026 \$US	March 31, 2025 \$US
Sales of medical equipment	\$12,379	\$9,432
Net sales of RPP and leases	2,808	2,273
Sales of spare parts, supplies and services	2,626	2,563
TOTAL NET SALES	17,812	14,267
Other revenues	—	—
TOTAL REVENUES	17,812	14,267
Cost of sales	(9,666)	(8,274)
GROSS PROFIT	8,146	5,993
Research & development expenses	(2,597)	(2,583)
Selling, general & administrative expenses	(12,915)	(9,719)
Total operating expenses	(15,512)	(12,302)
OPERATING LOSS	(7,366)	(6,309)
Interest (expense) income, net	(1,714)	15
Currency exchange gains (loss), net	142	(1,006)
LOSS BEFORE INCOME TAXES	(8,938)	(7,300)
Income tax (expense) credit, net	(145)	(144)
NET LOSS	(\$9,083)	(\$7,444)
Earnings per share – Basic & diluted	(\$0.24)	(\$0.20)
Average number of shares used in computation of basic & diluted EPS	37,481,986	37,392,086

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UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of U.S. Dollars)

	March 31, 2026 \$US	December 31, 2025 \$US
Cash, cash equivalents and short-term investments	\$15,012	\$20,452
Accounts receivable, net	20,328	22,583
Inventory	13,332	12,830
Other current assets	1,691	1,299
TOTAL CURRENT ASSETS	\$50,364	\$57,164
Property, plant and equipment, net	13,007	13,505
Goodwill	2,773	2,834
Other non-current assets	5,915	5,495
TOTAL ASSETS	\$72,059	\$78,997
Accounts payable & other accrued liabilities	21,846	20,692
Deferred revenues, current portion	7,819	7,098
Short term borrowing	5,248	5,986
Other current liabilities	2,595	3,365
TOTAL CURRENT LIABILITIES	\$37,508	\$37,141
Operating and finance lease liabilities, non-current	2,345	2,429
Long-term debt, non-current	17,604	15,903
Deferred revenues, non-current	1,063	966
Other long-term liabilities	3,439	3,145
TOTAL LIABILITIES	\$61,959	\$59,584
TOTAL SHAREHOLDERS' EQUITY	\$10,101	\$19,413
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	\$72,059	\$78,997

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UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of U.S. Dollars)

	Three Months Ended March 31, 2026 \$US	Three Months Ended March 31, 2025 \$US
NET INCOME (LOSS)	(\$9,083)	(\$7,444)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	3,368	1,235
OPERATING CASH FLOW	(5,715)	(6,209)
Increase/Decrease in operating assets and liabilities	2,743	867
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(2,972)	(5,342)
Additions to capitalized assets produced by the company and other capital expenditures	(754)	(1,304)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(754)	(1,304)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(1,372)	(1,254)
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(341)	1,591
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(\$5,440)	(\$6,309)

⁽¹⁾ including share based compensation expenses for \$302 thousand for the three months ended March 31, 2026 and \$339 thousand for the three months ended March 31, 2025.