

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 25, 2026

EDAP TMS SA
(Exact name of registrant as specified in its charter)

France
(State or Other Jurisdiction of Incorporation)

000-29374
(Commission File Number)

98-1644844
(I.R.S. Employer Identification No.)

Parc d'Activites la Poudrette-Lamartine
4/6, rue du Dauphiné
Vaulx-en-Velin, France 69120
(Address of Principal Executive Offices) (Zip Code)

(+33) 47-215-3150
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| American Depositary Shares, each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share) | EDAP | NASDAQ Global Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On March 25, 2026, EDAP TMS S.A. issued a press release and will hold a conference call regarding its financial results for the quarter ended December 31, 2025. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information furnished with this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) [Press Release dated March 25, 2026](#)

104 Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EDAP TMS S.A

Date: March 25, 2026

By: /s/ Sanket Shah
Sanket Shah
General Counsel and Corporate Secretary

EDAP Reports Record Fourth Quarter and Full-Year 2025 HIFU Revenue

- 39% Full-Year YoY HIFU Revenue Growth, Record Performance Driven by Increased Focal One® System Sales and Growth in the Number of U.S. Focal One Procedures
- 69% Full-Year YoY Growth in Focal One System Placements
- 28% Q4 YoY Growth in U.S. Procedures, Marking the Second Consecutive Quarter of Double-Digit Procedure Growth
- Demand for Focal One Systems Remains Strong with System Placements in Academic Cancer Centers, Community Hospitals, and Large Integrated Healthcare Networks
- Company Reiterates its Previously Issued 2026 Revenue Guidance; HIFU Revenue Expected to Grow Between 34% and 45% YoY

AUSTIN, Texas, March 25, 2026 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today financial results for the fourth quarter and full-year 2025.

“We experienced strong global demand for Focal One Robotic HIFU as demonstrated by our 2025 results,” said Ryan Rhodes, Chief Executive Officer. “In the fourth quarter, we achieved a quarterly record of net system placements of 15, of which 14 were cash sales and one was an operating lease. We also experienced robust Focal One procedure growth in the U.S., which reflects a growing number of urologists utilizing focal therapy to manage early-stage prostate cancer. We believe demand for Focal One is being driven by growing clinical data, the versatility and adaptability of the Focal One platform, and increasing patient demand for a non-invasive treatment option designed to help preserve urinary and sexual function.”

Mr. Rhodes added, “Entering 2026, our pipeline continues to build, and demand for Focal One remains well balanced across both academic and community treatment centers. Importantly, we are also beginning to see large, integrated healthcare networks purchase multiple Focal One systems, signifying that Focal One is increasingly being adopted as an important technology platform for addressing early-stage prostate cancer. Looking ahead, we believe the adoption of focal therapy will continue to expand globally, and we remain well positioned to meet this growing demand from urologists and their patients.”

2026 Financial Guidance

The Company reiterates its previously issued 2026 revenue guidance of \$72.0 million to \$80.0 million. The Company’s core HIFU business revenue is expected to be in the range of \$50.0 million to \$54.0 million, which represents 34% to 45% year-over-year growth in the Company’s core HIFU business revenue.

Fourth Quarter 2025 Results

High-Intensity Focused Ultrasound (HIFU) Business

Total revenue in the HIFU business for the fourth quarter of 2025 was €11.7 million (\$13.5 million), compared to €8.8 million (\$9.4 million) for the same period in 2024, representing an increase of 34% year-over-year. The Company sold fourteen Focal One systems during the quarter, compared to eleven system sales in the same period in 2024. Worldwide disposables revenue grew 43% year-over-year, driven primarily by 28% growth in Focal One procedures in the U.S.

Non-Core Businesses (ESWL and Distribution)

Total revenue from the Company's non-core businesses (ESWL and Distribution) for the fourth quarter of 2025 was €7.2 million (\$8.4 million), compared to €11.5 million (\$12.3 million) for the same period in 2024. The decline primarily reflects lower revenue in the Company's non-core businesses as the Company continues to prioritize growth in its HIFU business.

Company

Total worldwide revenue for the fourth quarter of 2025 was €18.9 million (\$21.9 million), compared to €20.3 million (\$21.8 million) for the same period in 2024, representing a 7% decrease year-over-year.

Gross margin for the fourth quarter of 2025 was €8.1 million (\$9.3 million), compared to €9.1 million (\$9.8 million) for the same period in 2024. Gross margin on net sales was 42.6%, down from 44.8% for the same period in 2024. The decline in gross margin was primarily due to the impact of tariffs on imports of finished goods from France and an inventory reserve related to legacy parts. Excluding these items, gross margin would have been approximately 46.9%.

Operating expenses for the fourth quarter of 2025 were €13.2 million (\$15.3 million), compared to €12.8 million (\$13.7 million) for the same period in 2024.

Operating loss for the fourth quarter of 2025 was €5.2 million (\$6.0 million), compared to €3.7 million (\$4.0 million) for the same period in 2024.

Net loss for the fourth quarter of 2025 was €8.2 million (\$9.5 million), or (€0.22) per share, compared to €1.9 million (\$2.0 million), or (€0.05) per share, for the same period in 2024.

Full-Year 2025 Results

High-Intensity Focused Ultrasound (HIFU) Business

Total revenue in the HIFU business for the twelve months ended December 31, 2025, was €33.1 million (\$37.4 million), an increase of 39% as compared to €23.8 million (\$25.8 million) for the twelve months ended December 31, 2024.

Non-Core Businesses (ESWL and Distribution)

Total revenue in the Company's non-core businesses (ESWL and Distribution) for the twelve months ended December 31, 2025, was €29.4 million (\$33.2 million), a 27% decrease compared to €40.3 million (\$43.6 million) for the twelve months ended December 31, 2024.

Company

Total worldwide revenue for the twelve months ended December 31, 2025, was €62.4 million (\$70.5 million), a decrease of 3% compared to €64.1 million (\$69.4 million) for the same period in 2024.

Gross profit for the twelve months ended December 31, 2025, was €26.6 million (\$30.0 million), compared to €26.6 million (\$28.7 million), for the twelve months ended December 31, 2024. Gross profit margin on net sales was 42.5% for the twelve months ended December 31, 2025, compared to 41.4% for the comparable period in 2024.

Operating expenses were €48.4 million (\$54.7 million) for the twelve months ended December 31, 2025, compared to €47.1 million (\$51.0 million) for the same period in 2024.

Operating loss for the twelve months ended December 31, 2025, was €21.9 million (\$24.7 million), compared to an operating loss of €20.5 million (\$22.2 million) for the twelve months ended December 31, 2024.

Net loss for the twelve months ended December 31, 2025, was €25.9 million (\$29.2 million), or (€0.69) per share, as compared to a net loss of €19.0 million (\$20.6 million), or (€0.51) per share for the twelve months ended December 31, 2024.

As of December 31, 2025, the Company held cash and cash equivalents of €17.4 million (\$20.5 million) as compared to €29.8 million (\$31.0 million) as of December 31, 2024.

Upcoming Meetings and Events

- American Urological Association (AUA) Annual Meeting, which will take place from May 15-18, 2026, in Washington, D.C.
- Investor Day Meeting – June 1, 2026, Nasdaq MarketSite, in New York City
- Jefferies Global Healthcare Conference – June 2–4, 2026, in New York City

Conference Call Information

A conference call and webcast to discuss the fourth quarter and full-year 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: Wednesday, March 25, 2026, at 8:30 a.m. Eastern Time
Domestic: 1-800-579-2543
International: 1-785-424-1789
Passcode (Conf ID): EDAP

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1751611&tp_key=27ba007fb5

Currency Translation

Euro-denominated amounts have been translated into U.S. dollars for convenience using an average exchange rate of \$1.15 = €1.00 for the fourth quarter of 2025, \$1.13 = €1.00 for the full year 2025, and \$1.17 = €1.00 for 2026 financial guidance for illustrative purposes.

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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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: | |
|---|----------------------------|---------------------|----------------------------|---------------------|
| | December 31, | December 31, | December 31, | December 31, |
| | 2025 | 2024 | 2025 | 2024 |
| | Euros | Euros | U.S. Dollars | U.S. Dollars |
| Sales of medical equipment | 13,659 | 14,559 | 15,764 | 15,619 |
| Net sales of RPP and leases | 2,506 | 2,363 | 2,905 | 2,533 |
| Sales of spare parts, supplies and services | 2,771 | 3,395 | 3,212 | 3,632 |
| TOTAL REVENUES | 18,936 | 20,318 | 21,880 | 21,785 |
| Cost of sales | (10,874) | (11,220) | (12,564) | (12,020) |
| GROSS PROFIT | 8,063 | 9,098 | 9,316 | 9,765 |
| Research & development expenses | (1,800) | (1,865) | (2,109) | (1,991) |
| Selling, general & administrative expenses | (11,426) | (10,971) | (13,227) | (11,741) |
| Total operating expenses | (13,226) | (12,836) | (15,336) | (13,732) |
| OPERATING LOSS | (5,164) | (3,738) | (6,020) | (3,967) |
| Financial (expense) income, net | (2,660) | 122 | (3,007) | 130 |
| Currency exchange gains (loss), net | (316) | 1,664 | (363) | 1,803 |
| LOSS BEFORE INCOME TAXES | (8,140) | (1,952) | (9,391) | (2,034) |
| Income tax (expense) credit, net | (55) | 11 | (65) | 14 |
| NET LOSS | (8,194) | (1,940) | (9,456) | (2,020) |
| Earnings per share – Basic and diluted | (0.22) | (0.05) | (0.25) | (0.05) |
| Average number of shares used in computation of basic and diluted EPS | 37,447,486 | 37,371,992 | 37,447,486 | 37,371,992 |

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

| | Year Ended: | | Year Ended: | |
|---|-----------------|-----------------|-----------------|-----------------|
| | December 31, | December 31, | December 31, | December 31, |
| | 2025 | 2024 | 2025 | 2024 |
| | Euros | Euros | U.S. Dollars | U.S. Dollars |
| Sales of medical equipment | 43,273 | 44,037 | 48,896 | 47,664 |
| Net sales of RPP and leases | 9,106 | 7,610 | 10,289 | 8,237 |
| Sales of spare parts, supplies and services | 10,037 | 12,468 | 11,342 | 13,495 |
| TOTAL REVENUES | 62,416 | 64,114 | 70,527 | 69,395 |
| Cost of sales | (35,865) | (37,558) | (40,526) | (40,652) |
| GROSS PROFIT | 26,551 | 26,556 | 30,001 | 28,744 |
| Research & development expenses | (8,550) | (7,726) | (9,661) | (8,363) |
| Selling, general & administrative expenses | (39,856) | (39,364) | (45,035) | (42,606) |
| Total operating expenses | (48,406) | (47,090) | (54,695) | (50,969) |
| OPERATING LOSS | (21,854) | (20,534) | (24,694) | (22,225) |
| Financial (expense) income, net | (2,753) | 560 | (3,110) | 606 |
| Currency exchange gains (loss), net | (888) | 1,245 | (1,003) | 1,348 |
| LOSS BEFORE INCOME TAXES | (25,495) | (18,729) | (28,808) | (20,271) |
| Income tax (expense) credit, net | (388) | (289) | (438) | (313) |
| NET LOSS | (25,883) | (19,018) | (29,246) | (20,584) |
| Earnings per share – Basic and diluted | (0.69) | (0.51) | (0.78) | (0.55) |
| Average number of shares used in computation of basic and diluted EPS | 37,442,155 | 37,286,446 | 37,442,155 | 37,286,446 |

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

| | December 31, | December 31, | December 31, | December 31, |
|--|---------------|---------------|---------------|---------------|
| | 2025 | 2024 | 2025 | 2024 |
| | Euros | Euros | U.S. Dollars | U.S. Dollars |
| Cash, cash equivalents and short-term investments | 17,407 | 29,836 | 20,452 | 30,995 |
| Accounts receivable, net | 19,220 | 20,288 | 22,583 | 21,077 |
| Inventory | 10,919 | 18,495 | 12,830 | 19,213 |
| Other current assets | 1,105 | 1,258 | 1,299 | 1,307 |
| TOTAL CURRENT ASSETS | 48,652 | 69,876 | 57,164 | 72,591 |
| Property, plant and equipment, net | 11,494 | 10,336 | 13,505 | 10,738 |
| Goodwill | 2,412 | 2,412 | 2,834 | 2,505 |
| Other non-current assets | 4,677 | 3,439 | 5,495 | 3,573 |
| TOTAL ASSETS | 67,235 | 86,063 | 78,997 | 89,407 |
| Accounts payable and other accrued liabilities | 17,611 | 21,350 | 20,692 | 22,180 |
| Deferred revenues, current portion | 6,041 | 6,641 | 7,098 | 6,899 |
| Short-term borrowing | 5,095 | 6,243 | 5,986 | 6,485 |
| Other current liabilities | 2,864 | 3,577 | 3,365 | 3,716 |
| TOTAL CURRENT LIABILITIES | 31,610 | 37,811 | 37,141 | 39,280 |
| Obligations under operating and finance leases non-current | 2,067 | 1,939 | 2,429 | 2,014 |
| Long-term debt, non-current | 13,535 | 2,162 | 15,903 | 2,246 |
| Deferred revenues, non-current | 822 | 358 | 966 | 372 |
| Other long-term liabilities | 2,677 | 2,897 | 3,145 | 3,010 |
| TOTAL LIABILITIES | 50,712 | 45,167 | 59,584 | 46,922 |
| TOTAL SHAREHOLDERS' EQUITY | 16,523 | 40,896 | 19,413 | 42,485 |
| TOTAL LIABILITIES & SHAREHOLDERS' EQUITY | 67,235 | 86,063 | 78,997 | 89,407 |

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

| | Year Ended December 31, 2025 (Euros) | Twelve Months Ended December 31, 2024 (Euros) | Year Ended December 31, 2025 (U.S. Dollars) | Twelve Months Ended December 31, 2024 (U.S. Dollars) |
|---|---|--|--|---|
| NET INCOME (LOSS) | (25,883) | (19,018) | (29,246) | (20,584) |
| Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾ | 8,769 | 7,395 | 9,908 | 8,004 |
| OPERATING CASH FLOW | (17,114) | (11,623) | (19,338) | (12,580) |
| Increase/Decrease in operating assets and liabilities | 2,592 | (1,961) | 2,929 | (2,123) |
| NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES | (14,522) | (13,584) | (16,409) | (14,703) |
| Additions to capitalized assets produced by the company and other capital expenditures | (5,058) | (4,120) | (5,715) | (4,459) |
| NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES | (5,058) | (4,120) | (5,715) | (4,459) |
| NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES | 7,620 | 4,635 | 8,610 | 5,016 |
| NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS | (469) | (566) | 2,972 | (2,893) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (12,429) | (13,635) | (10,543) | (17,039) |

⁽¹⁾ including share-based compensation expenses for 2,265 thousand of Euros for the year ended December 31, 2025 and 3,283 thousand of Euros for the year ended December 31, 2024.

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

| | HIFU | | ESWL | | Distribution | | Reconciling | Total After | |
|---|-----------------|--------------|-----------------|--------------|---------------------|--------------|--------------------|----------------------|--------------|
| | Division | | Division | | Division | | Items | Consolidation | |
| Sales of medical equipment | 21,998 | | 1,515 | | 19,760 | | — | 43,273 | |
| Net sales of RPP and leases | 7,780 | | 1,025 | | 300 | | — | 9,106 | |
| Sales of spare parts, supplies and services | 3,277 | | 4,065 | | 2,695 | | — | 10,037 | |
| TOTAL REVENUES | 33,056 | | 6,605 | | 22,756 | | — | 62,416 | |
| GROSS PROFIT (% of Net Sales) | 15,911 | 48.1% | 3,050 | 46.2% | 7,591 | 33.4% | — | 26,551 | 42.5% |
| Research & development expenses | (7,884) | | (169) | | (496) | | — | (8,550) | |
| Selling, general & administrative expenses | (26,327) | | (1,023) | | (7,810) | | (4,695) | (39,856) | |
| OPERATING PROFIT (LOSS) | (18,301) | | 1,857 | | (716) | | (4,695) | (21,854) | |