

**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): May 29, 2026

EDAP TMS SA

(Exact name of Registrant as specified in its charter)

France
(State or other jurisdiction of incorporation)

000-29374
(Commission File No.)

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)

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

Not Applicable
(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

Indicated 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 8.01 Other Events.

On May 29, 2026, EDAP TMS S.A. (the “Company”) issued a press release announcing that it will begin operating under the new corporate name “FocalTherics” and that its American Depositary Shares (“ADS”), each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share), will begin trading under the new ticker symbol “FOCL” on the Nasdaq Global Market at the market open on June 1, 2026. The Company’s legal name will remain EDAP TMS S.A., and the Company intends to seek shareholder approval for a corresponding legal name change at a future general meeting of shareholders. The CUSIP number for the ADSs will remain unchanged, and shareholders are not required to take any action in connection with the corporate name or ticker symbol change.

In addition, the Company announced its intention to report and classify its Extracorporeal Shock Wave Lithotripsy (“ESWL”) and Distribution operating segments as discontinued operations in the Company’s financial statements beginning with the Company’s second quarter 2026 financial results.

The Company will discuss its new corporate identity, growth strategy, and business outlook at its Investor Day on June 1, 2026 at 8:00 a.m. ET and invites participants to join the event via the Events and Presentations section of the Company’s Investor Relations website. A replay of the webcast and associated slide presentation will be available on the Company’s website.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Exhibit No.	Description
99.1	Press Release dated May 29, 2026
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

EDAP Announces Corporate Name Change to FocalTherics™ to Reflect Exclusive Focus on High-Growth Robotic Focal Therapy

- *Company will Begin Trading Under New Ticker Symbol “FOCL” at Market Open on June 1, 2026*
- *Company Intends to Report and Classify its Legacy Non-Core ESWL and Distribution Operating Segments as Discontinued Operations Beginning with Second Quarter 2026 Financial Results*
- *Investor Day to be Held on June 1, 2026 to Highlight Company Vision and Long-Term Strategy under New FocalTherics Corporate Identity*

AUSTIN, Texas, May 29, 2026 - EDAP TMS S.A. (Nasdaq: EDAP) (the “Company”), the global leader in robotic energy-based therapies, today announced that it will operate under the new corporate name “FocalTherics” to reflect its exclusive and strategic focus on high-growth robotic focal therapy. The Company also announced its intention to report and classify its Extracorporeal Shock Wave Lithotripsy (“ESWL”) and Distribution operating segments as discontinued operations in the Company’s financial statements beginning with second quarter 2026 financial results. In conjunction with this defined focus, the Company is changing its ticker symbol on Nasdaq from “EDAP” to “FOCL”, effective at market open on June 1, 2026.

“FocalTherics is derived from the words ‘Focal Therapy’ and ‘Therapeutics’.” said Ryan Rhodes, Chief Executive Officer. “This new name and identity reflects and reinforces the Company’s emerging leadership in defining, building and driving the growing category of robotic focal therapy. Additionally, our new corporate identity aligns directly with our flagship market leading product brand, Focal One®.”

Rhodes added, “Together, the new corporate name and ticker symbol will create a stronger connection between our company identity, our strategic product brand and the significant opportunity ahead. These combined updates are designed to strengthen how investors, analysts, and stakeholders understand our vision, recognize the momentum of our HIFU business, and appreciate our growing leadership position in Robotic Focal Therapy.”

The ticker symbol change will apply to the Company’s American Depositary Shares, each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share). The Company’s legal name will remain EDAP TMS S.A., and the Company intends to submit a corresponding change of legal name for shareholder approval at a future general meeting of the Company’s shareholders. No action is required by shareholders with respect to the name change or ticker symbol change announced today, and these changes will not affect the existing rights of shareholders. Following the ticker symbol change, the American Depositary Shares will continue to be listed on Nasdaq and the CUSIP number will remain unchanged.

The Company will discuss its new corporate identity, growth strategy, and business outlook at the Investor Day scheduled on June 1, 2026 at 8:00 am ET and invites participants to join the event via the Events and Presentations section of the Investor Relations website. A replay of the webcast and associated slide presentation will be available on the Company’s website.

About FocalTherics

A recognized global leader in Robotic Focal Therapy, FocalTherics develops, manufactures, and markets minimally invasive medical devices worldwide to treat various conditions using proprietary focused ultrasound technology. The Company’s flagship platform, Focal One Robotic HIFU, combines advanced imaging, real-time treatment planning, robotic precision, and HIFU technology to deliver personalized focal therapy designed to optimize clinical outcomes while preserving quality of life. FocalTherics is committed to expanding the clinical adoption of its patented focused ultrasound-based robotic therapy platforms through continued innovation, clinical evidence generation, physician education, and global market development initiatives. For more information about FocalTherics, visit [FocalTherics.com](https://www.FocalTherics.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 High Intensity Focused Ultrasound ("HIFU") devices, risks associated with the intended discontinuation of the Company's ESWL and Distribution operating segments, including that the discontinuation may take longer or cost more than expected, may result in disputes with customers, distributors, employees or other counterparties, and may not produce the strategic benefits anticipated 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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