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): August 14, 2026

EDAP TMS S.A.

(Exact name of Registrant as specified in its charter)

France	000-29374	98-1644844
(State or other jurisdiction of incorporation)	(Commission File No.)	(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)	FOCL	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.

As previously disclosed, on August 11, 2026, EDAP TMS S.A. (the “Company”) entered into an underwriting agreement (the “Underwriting Agreement”) with TD Securities (USA) LLC and Mizuho Securities USA LLC, as representatives of the underwriters named therein (the “Underwriters”), relating to an underwritten public offering (the “Offering”) of 8,425,000 American Depositary Shares (“ADSs”), each representing one ordinary share of the Company, €0.13 nominal value per share (the “Ordinary Shares”), at a price of $4.75 per ADS, before underwriting discounts and commissions. The Offering closed on August 14, 2026. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option, exercisable in whole or in part, to purchase up to an additional 1,263,750 ADSs sold in the Offering (the “Option”). The Underwriting Agreement was previously filed as Exhibit 1.1 to the Company’s Current Report on Form 8-K filed on August 14, 2026.

On August 14, 2026, the Underwriters fully exercised the Option, electing to purchase an additional 1,263,750 ADSs (the “Additional ADSs”). The issuance of the Additional ADSs pursuant to the Option is expected to close on August 19, 2026, and is expected to result in net proceeds to the Company of approximately $5.6 million, after deducting underwriting discounts and commissions and before estimated offering expenses.

A copy of the opinion of Jones Day, counsel to the Company, relating to the validity of the Ordinary Shares and Additional ADSs in the Option is filed as Exhibit 5.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
5.1	Opinion of Jones Day
23.1	Consent of Jones Day (included in Exhibit 5.1)
104	Cover Page Interactive Data File-the cover page XBRL (embedded within the Inline XBRL document)

SIGNATURES

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: August 19, 2026

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

Exhibit 5.1

JONES DAY

PARTNERSHIP CONSTITUEE SELON LE DROIT DE L'OHIO, USA

AVOCATS AU BARREAU DE PARIS

2, RUE SAINT-FLORENTIN • 75001 PARIS

TELEPHONE: (0)1.56.59.39.39 • FACSIMILE: (0)1.56.59.38.38 • TOQUE J 001

WWW.JONESDAY.COM

August 19, 2026

EDAP TMS S.A.
Parc d'Activités la Poudrette-Lamartine
4/6, rue du Dauphiné
69120 Vaulx-en-Velin
France

Re: 1,263,750 ordinary shares in the form of American depositary shares issued by EDAP TMS

Ladies and Gentlemen:

We are acting as special French counsel for EDAP TMS, a French *société anonyme* (the "Company"), in connection with the issuance and sale by the Company of 1,263,750 ordinary shares, nominal value €0.13 per share (the "New Shares"), to be delivered in the form of an aggregate of 1,263,750 American depositary shares (the "ADSs"), each ADS representing one New Share, pursuant to the underwriting agreement, dated August 11, 2026 (the "Underwriting Agreement"), by and among the Company, TD Securities (USA) LLC and Mizuho Securities USA LLC, acting as the representatives of the several underwriters named therein.

In connection with the opinions expressed herein, we have examined such documents, records and matters of law as we have deemed relevant or necessary for purposes of such opinions. Based on the foregoing, and subject to the further limitations, qualifications and assumptions set forth herein, we are of the opinion that, as of the date hereof:

1. The issuance of the New Shares has been duly authorized;

2. The New Shares, when issued and delivered pursuant to the Underwriting Agreement against full payment of their subscription price as provided in the Underwriting Agreement, as shall be acknowledged by the certificate of the depository (*certificat du dépositaire*) to be delivered by BNP Paribas, will be validly issued, fully paid and non-assessable.

The term "non-assessable," which has no recognized meaning in French law, for the purposes of this opinion means that no present or future holder of New Shares will be subject to personal liability, by reason of being such a holder, for additional payments or calls for further funds by the Company or any other person after the issuance of the New Shares.

In rendering the foregoing opinions, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals and the conformity to originals of all documents submitted to us as certified or reproduced copies. We have also assumed that (i) the resolutions authorizing the Company to issue, offer and sell the New Shares as adopted by the extraordinary shareholders' meeting and/or the board of directors of the Company, as applicable, are accurately reflected in the minutes of such meetings provided to us, and remain in full force and effect and (ii) all New Shares will be issued in compliance with applicable securities and corporate law.

As to facts material to the opinions and assumptions expressed herein, we have relied upon written statements and representations of officers and other representatives of the Company and others. We are members of the Paris bar and this opinion is limited to the laws of the Republic of France as currently in effect. This opinion is subject to the sovereign power of the French courts to interpret agreements and assess the facts and circumstances of any adjudication. This opinion is given on the basis that it is to be governed by, and construed in accordance with, the laws of the Republic of France.

We hereby consent to the filing of this opinion as Exhibit 5.1 to the Current Report on Form 8-K filed on the date hereof by the Company and incorporated by reference into the registration statement on Form S-3 (File No. 333-294597) (the "Registration Statement") filed by the Company to effect the registration of the New Shares under the Securities Act of 1933 (the "Securities Act") and to the reference to Jones Day under the caption "Legal Matters" in the prospectus constituting a part of such Registration Statement and the final prospectus supplement, dated August 11, 2026 filed by the Company pursuant to Rule 424(b) under the Securities Act on August 12, 2026 relating to the New Shares. In giving such consent, we do not thereby admit that we are included in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Securities and Exchange Commission promulgated thereunder.

Very truly yours,

/s/ Jones Day