

EDAP TMS SA
Form 6-K
June 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

June 9, 2016

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
4/6 Rue du Dauphine
69120 Vaulx-en-Velin - France

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F [x] Form 40-F []

Edgar Filing: EDAP TMS SA - Form 6-K

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

SIGNATURES

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

Date: June 9, 2016
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EXHIBITS :

- Letter to shareholders
- Notice of 2016 June 30th, shareholders Meeting
- Board Report to the shareholders
- Draft of resolutions to be submitted to shareholders' approval

May 26, 2016

Dear EDAP Shareholders,

In 2015, we have achieved tremendous regulatory milestones including FDA clearance of Ablatherm-HIFU in the U.S. allowing EDAP to now market the device in the American territory, but we also achieved profitable financial results and performance.

Our 2015 net sales reached a record EUR 32.3 million, which was a 20.4% increase over full year 2014 results. In the fourth quarter particularly, we tripled our HIFU sales as compared to fourth quarter of 2014, which included the sale of two Ablatherm units in the U.S. immediately after receiving the FDA clearance in November. In the UDS-Lithotripsy division, we recorded a strong full year 2015 net sales, with growth of over 32% year-over-year, confirming EDAP's ability to expand its market share in lithotripsy and urology distribution.

Based on our strong, record, top-line performance, we recorded a full-year operating profit and positive cash flow for the year 2015. Still, as we intend to actively develop our marketing and commercial initiatives for HIFU in the U.S., we strengthened our financial position last April with the completion of a \$11.5 million registered direct offering. We believe that the investments we are making in our U.S. sales and marketing infrastructure will not only drive the continued growth of Ablatherm-HIFU but will support a successful commercial launch of Focal One following potential FDA clearance. We will also utilize a portion of the capital to expand our Ablatherm-HIFU and Focal One manufacturing capacity, to support R&D and the development of early-stage products, and to advance regulatory projects in other key markets, such as Japan, the second largest medical device market in the world.

This is an exciting business building time for EDAP that we have all been waiting for. EDAP has now reached the next level and is poised for success in 2016 and well into the future.

In this context, we are pleased to convene our shareholders in an Ordinary General Meeting on June 30, 2016 to approve EDAP's 2015 results.

We would like to thank our shareholders and investors for your continued support and confidence in EDAP's long-term success.

Sincerely,

S/P Chauveau

Philippe Chauveau

Chairman of the Board

EDAP TMS S.A.

This letter may contain forward-looking statements. 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 device. Factors that may cause such a difference also may 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.

Non binding, unofficial English translation for information purposes only. Original in French.

EDAP TMS

A corporation with a share capital of 3,348,018.57 euros

Registered office: Parc d'activité La Poudrette Lamartine

4, rue du Dauphiné - 69120 Vaulx en Velin, France

Lyon Registry of Commerce 316 488 204

Vaulx-en-Velin, May 26, 2016

NOTICE

On Thursday June 30, 2016, the shareholders are convened to attend an Ordinary General Meeting of the shareholders of EDAP TMS S.A., to be held:

at 10:30 am,

at EDAP TMS's headquarters

4, rue du Dauphiné,

69120 Vaulx-en-Velin, France

to consider the following agenda:

1. Reading and approval of the special report of the Statutory Auditor on the agreements referred to in article L. 225-38 of the French Commercial Code; approval of the agreements as mentioned in the report;

Reading of the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015; reading of the Board of Directors' special report pursuant to Article L. 225-184, paragraph 1 of the French Commercial Code; reading of the Statutory Auditor's report relating to the annual accounts for the fiscal year ended December 31, 2015; reading of the Statutory Auditor's report relating to the consolidated financial statements (US GAAP); approval of the statutory accounts and of the consolidated financial statements (US GAAP) for the fiscal year ended December 31, 2015; granting of a release to the members of the Board of Directors for their management;

3. Allocation of net income for the fiscal year ended December 31, 2015.

Yours sincerely,

The Board of Directors

Note: As per Depositary Agreement dated July 31, 1997 and amendment dated April 7, 2008, signed between Bank of New York Mellon (the "Depositary") and the Company, if no voting Instruction Form is received by the Depositary from a Holder with respect to any of the Securities represented by American Depositary Shares ("ADSs") on or before the Receipt Date (Record Date), or if the voting Instruction Form is improperly completed or blank, or if the voting instructions included in the voting Instruction Form are illegible or unclear, such Holder of ADSs shall be deemed to have instructed the Depositary to vote such ADSs and the Depositary shall vote such ADSs in favor of any resolution proposed or approved by the Board of Directors of the Company and against any resolution not so proposed or approved.

Non-binding, unofficial English translation for information purposes only. Only the original version in French has legal force.

EDAP TMS

A corporation with a share capital of 3,348,018.57 euros

Registered office : 4, rue du Dauphiné - Parc d'activité la Poudrette Lamartine

69120 Vaulx-en-Velin (France)

Lyon Trade and Companies Register Number 316 488 204

Report of the Board of Directors to the Ordinary Shareholders' Meeting of June 30, 2016

Ladies and Gentlemen,

We have called this Ordinary and Extraordinary Shareholders' Meeting to vote on the following agenda:

1. Reading and approval of the special report of the Statutory Auditor on the agreements referred to in article L. 225-38 of the French Commercial Code; approval of the agreements as mentioned in the report;

2. Reading of the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015; reading of the Board of Directors' special report pursuant to Article L. 225-184, paragraph 1 of the French Commercial Code; reading of the Statutory Auditor's report relating to the annual accounts for the fiscal year ended December 31, 2015; reading of the Statutory Auditor's report relating to the consolidated financial statements (US GAAP); approval of the statutory accounts and of the consolidated financial statements (US GAAP) for the fiscal year ended December 31, 2015; granting of a release to the members of the Board of Directors for their management;

3. Allocation of net income for the fiscal year ended December 31, 2015.

Management report on the Company's activity for the fiscal year ended December 31, 2015:

We invite you to read the Board of Directors' management report available pursuant to French laws and regulations and the Company's 2015 Annual Report on the 2015 consolidated accounts, which is available on the Company's website www.edap-tms.com, in the "Investor Relations" section.

We draw your attention on Resolution No 3 related to allocation of a record net income for EDAP TMS SA Holding, amounting for FY 2015 to a profit of 14,528,771 euros. This net profit is directly linked to the FDA approval of Ablatherm-HIFU in 2015, allowing EDAP to now market the device in U.S. During the past 10 years, various advances in cash totaling USD 17,350,000 were granted by EDAP TMS SA Holding to its U.S. subsidiary EDAP Technomed Inc, in charge of advancing on the FDA clearance of Ablatherm-HIFU. Upon FDA approval in 2015, it was decided, in the best interest of the Company, to incorporate these cash advances into the capital of EDAP Technomed Inc., its capital was then increased to USD 17,350,001. As these cash advances were depreciated along the years, their incorporation in capital generated a global reversal of the depreciation hence the recording of a Euros 14,5 million profit for EDAP TMS Holding. We suggest to allocate this profit to the cumulated losses account. As the depreciation was related to an intra-group cash advance, the reversal had no impact on the consolidated accounts.

In this context, we ask you to vote on the aforementioned resolutions submitted to you by your Board of Directors.

The Board of Directors

This is a free translation from the French language and is supplied solely for information purposes. Only the original version in French language has legal force.

EDAP - TMS

A corporation with a share capital of 3,348,018.57 euros

Registered office: Parc d'activité La Poudrette Lamartine

4, rue du Dauphiné - 69120 Vaulx-en-Velin, France

Lyon Registry of Commerce 316 488 204

DRAFT RESOLUTIONS TO BE SUBMITTED

TO THE ORDINARY SHAREHOLDERS' MEETING HELD

ON JUNE 30, 2016

Shareholders are invited to attend the Ordinary Shareholders' Meeting of EDAP-TMS S.A. (the "Company") on June 30, 2016, at 10.30 am., at the Company's offices, 4 Rue du Dauphiné, 69120, Vaulx-en-Velin, France. The shareholders will deliberate on the following agenda:

1. Reading and approval of the special report of the Statutory Auditor on the agreements referred to in article L. 225-38 of the French Commercial Code; approval of the agreements as mentioned in the report;
2. Reading of the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015; reading of the Board of Directors' special report pursuant to Article L. 225-184, paragraph 1 of the French Commercial Code; reading of the Statutory Auditor's report relating to the annual accounts for the fiscal year ended December 31, 2015; reading of the Statutory Auditor's report relating to the consolidated financial statements (US GAAP); approval of the statutory accounts and of the consolidated

financial statements (US GAAP) for the fiscal year ended December 31, 2015; granting of a release to the members of the Board of Directors for their management;

3. Allocation of net income for the fiscal year ended December 31, 2015.

* * *

FIRST RESOLUTION *(Reading and approval of the special report of the Statutory Auditor on the agreements referred to in Article L. 225-38 of the French Commercial Code; approval of the said report)*

After hearing the Statutory Auditor's special report relating to the agreements referred to in article L.225-38 of the French Commercial Code (related party transactions), the Shareholders' Meeting approves the terms of the report, mentioning that there is no such agreements.

1/2

SECOND RESOLUTION *(Reading of the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015; reading of the Board of Directors' special report pursuant to Article L. 225-184, paragraph 1 of the French Commercial Code; reading of the Statutory Auditor's report relating to the annual accounts for the fiscal year ended December 31, 2015; reading of the Statutory Auditor's report relating to the consolidated financial statements (US GAAP); approval of the statutory accounts and of the consolidated financial statements (US GAAP) for the fiscal year ended December 31, 2015; granting of a release to the members of the Board of Directors for their management)*

The Shareholders' Meeting, acting in accordance with the quorum and majority criteria required for Ordinary Shareholders' Meetings, and after having been read:

- the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015,

- the Board of Directors' special report on stock-options pursuant to Article L. 225-184 paragraph 1 of the French Commercial Code,

- the Statutory Auditor's report relating to the annual accounts relating to the fiscal year ended December 31, 2015,

- the Statutory Auditor's report relating to the consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles (US GAAP) applying to companies listed on the Nasdaq.

Approves the annual accounts, i.e., the balance sheet, income statement and the related note as of and for the period ended December 31, 2015 as they have been presented, together with the transactions transcribed in the aforesaid financial statements and summarized in such reports.

Approves the consolidated financial statements relating to the fiscal year ended December 31, 2015 established in accordance with US GAAP as applied to companies listed on the Nasdaq market, as they have been presented in the 20-F Report filed with SEC on April 4, 2016, together with the transactions transcribed in the aforesaid financial statements and summarized in such report.

The Shareholders' Meeting therefore grants a release to all members of the Board of Directors for their management during the fiscal year 2015.

THIRD RESOLUTION *(Allocation of net income for the fiscal year ended December 31, 2015)*

The Shareholders' Meeting, in accordance with the quorum and majority criteria required for Ordinary Shareholders' Meetings, acknowledges that the Company has recorded a net income (not consolidated) of €14,528,771 during fiscal year ended December 31, 2015.

The Shareholders' Meeting, after reading the Board of Directors report, decides to allocate the total net income €14,528,771 amount to the cumulated losses account, reducing this account from €27,888,266 to €13,359,495.

Pursuant to Article 243 bis of the French Tax Code, the Shareholders' Meeting takes note that no dividend has been paid during the last three fiscal years.

The Shareholders' Meeting, pursuant to the Board of Directors' report, in accordance with article 223 quarter of the French Tax Code, takes note that no expenses, nor charges concerned by article 39-4 of this Code, nor theoretical tax amount, will be recorded by the Company.

The Shareholders' Meeting grants all powers to the holder of an original, a copy or an extract of these meeting minutes in order to carry out all required or necessary filing publicity and other formalities.

EDAP TMS S.A.

IMPORTANT ANNUAL MEETING INFORMATION

Using a **black ink** pen, mark your votes with an X as shown in this example. Please do not write outside the designated areas.

X

Annual Meeting Proxy Card

PLEASE FOLD ALONG THE PERFORATION, DETACH AND RETURN THE BOTTOM PORTION IN THE ENCLOSED ENVELOPE.

A Proposals — The Board recommends a vote in favor of all resolutions.

ORDINARY SHAREHOLDERS' MEETING:

For Against Abstain

- 1.
- 2.
- 3.

B Non-Voting Items

Change of Address — Please print new address below. **Comments** — Please print your comments below.

C Authorized Signatures — This section must be completed for your vote to be counted. — Date and Sign Below

NOTE: Please sign as name appears hereon. Joint owners should each sign. When signing as attorney, executor, administrator, trustee or guardian, please give full title as such.

Date (mm/dd/yyyy) — Please print date below. Signature 1 — Please keep signature within the box. Signature 2 — Please
/ /

AGENDA OF THE ORDINARY SHAREHOLDERS' MEETING:

1. Reading and approval of the special report of the Statutory Auditor on the agreements referred to in article L. 225-38 of the French Commercial Code; approval of the agreements as mentioned in the report;
Reading of the Board of Directors' report on the activity, the situation and the financial statements of the Company relating to the fiscal year ended December 31, 2015; reading of the Board of Directors' special report pursuant to Article L. 225-184, paragraph 1 of the French Commercial Code; reading of the Statutory Auditor's report relating to the annual accounts for the fiscal year ended December 31, 2015; reading of the Statutory Auditor's report relating to the consolidated financial statements (US GAAP); approval of the statutory accounts and of the consolidated financial statements (US GAAP) for the fiscal year ended December 31, 2015; granting of a release to the members of the Board of Directors for their management;
- 2.
3. Allocation of net income for the fiscal year ended December 31, 2015.

PLEASE FOLD ALONG THE PERFORATION, DETACH AND RETURN THE BOTTOM PORTION IN THE ENCLOSED ENVELOPE.

Proxy - EDAP TMS S.A.

Instructions to the BANK OF NEW YORK MELLON, as Depositary
Must be received prior to 5:00 PM (New York City Time) on June 22, 2016 @ 5PM

The undersigned Holder of American Depositary Receipts hereby requests and instructs The Bank of New York Mellon, as Depositary, to endeavor, insofar as practicable, to vote or cause to be voted the Deposited EDAP TMS S.A. Shares represented by such Receipts registered in the name of the undersigned on the books of the Depositary as of the close of business on May 23, 2016 at the Ordinary General Meeting of EDAP TMS S.A. to be held in France, on June 30, 2016 at 10:30 am in respect of the resolutions specified in the enclosed Notice of Meeting.

NOTES:

Instructions as to voting on the specified resolutions should be indicated by an "X" in the appropriate box. If no Voting Instruction Card is received by the Depositary from an Owner with respect to any of the Shares represented by American Depositary Shares on or before the Receipt Date, or if the Voting Instruction Card is improperly completed or blank, or if the voting instructions included in the Voting Instruction Card are illegible or unclear, such Owner shall be deemed to have instructed the Depositary to vote such Shares and the Depositary shall vote such Shares in favor of any resolution proposed or approved by the Board of Directors of the Company and against any resolution not so proposed or approved.

(Continued and to be marked, dated and signed, on the other side)