

EDAP TMS SA
Form 6-K
June 05, 2018

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 5, 2018

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 5, 2018
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

Dear EDAP Shareholders,

In 2017, we continued to expand our business worldwide and to record accomplishments in our global activities. Our 2017 consolidated revenue amounted 35.7 million Euros, stable with 2016's. While we recorded weaker HIFU device sales over the year, we are encouraged by our increasing HIFU treatment driven revenues. Adoption of HIFU continues to grow as more physicians gain comfort and experience with this minimally invasive treatment option.

In the U.S., 2017 CMS's issuance of a C-Code to reimburse HIFU for prostate tissue ablation and Cigna's recent decision to reimburse HIFU as a salvage therapy also provide important validation for our technology. While today June 1st, we are still expecting an FDA decision on the clearance of our Focal One device, we did have our Ablatherm Fusion device approved by the FDA in October 2017. Ablatherm Fusion complements our HIFU device offering as it provides better treatment accuracy in merging MRI and ultrasound images. We do believe that focal therapy is the future of prostate cancer treatment and we very much look forward to FDA clearance to expand HIFU offering in the U.S.

Internationally, we also pursued the promotion of our Focal One HIFU device and initiated the process to roll out a clinical study in Japan in view of its Japanese clearance.

Turning to our lithotripsy business, we continued to see solid growth in 2017 driven primarily by strong device sales. Lithotripsy remains a relatively mature market but it is dynamic and subject to a burgeoning replacement cycle. Internationally, we also continued to see solid growth in our distribution business. This activity is primarily in France and Japan, although we are looking at opportunities to expand further by reaching new partnerships and agreements with companies offering products bringing clear synergies with our manufactured ranges of products and our expansion strategies.

2018 will prove to be an important year for EDAP with multiple pending milestones including a conclusion to the FDA review of Focal One, the expansion of our HIFU product offering and increase in HIFU reimbursement coverage. We will also pursue our clinical development programs beyond urology with a long-term objective of making HIFU a standard of care procedure for minimally invasive ablation of soft tissue available in each operating room.

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

Sincerely,

/s/ Philippe Chauveau

Chairman of the Board

EDAP TMS S.A.

June 1st, 2018

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

EDAP TMS

A corporation with a share capital of 3,817,891.22 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, June 1st, 2018

NOTICE

On Friday June 29, 2018, 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;

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, 2017; reading of the Board of Directors' report on Corporate Governance, 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, 2017; 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, 2017; granting of a release to the members of the Board of Directors for their management;

3. Allocation of net loss for the fiscal year ended December 31, 2017;

4. Determination of attendance fees to be allocated to the Board of Directors;

5. Appointment of a new Statutory Auditor and a new Alternate Statutory Auditor.

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 3,817,891.22 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 29, 2018

Ladies and Gentlemen,

We have called this Ordinary 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;

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, 2017; reading of the Board of Directors' report on Corporate Governance, 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, 2017; 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, 2017; granting of a release to the members of the Board of Directors for their management;

3. Allocation of net loss for the fiscal year ended December 31, 2017;
4. Determination of attendance fees to be allocated to the Board of Directors;
5. Appointment of a new Statutory Auditor and a new Alternate Statutory Auditor.

Management report on the Company's activity for the fiscal year ended December 31, 2017:

We invite you to read the Board of Directors' management report available pursuant to French laws and regulations and the Company's 2017 Annual Report on the 2017 consolidated accounts, which is available on the Company's website www.edap-tms.com, in the "Investor Relations" – "Financial Information" section.

Please note that the mandate of the Company's Statutory Auditor PriceWaterhouseCoopers Audit and its Alternate Statutory Auditor terminates on the date of the present General Meeting. Upon the Company's Audit Committee recommendation, the Board of Directors recommends not to renew the mandate of PriceWaterhouseCoopers Audit and to appoint KPMG audit, as Statutory Auditor of the Company, for a period of six fiscal years.

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

The Board of Directors

EDAP TMS – Board report to AGM – June 29, 20181

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 3,817,891.22 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 29, 2018

Shareholders are invited to attend the Ordinary Shareholders' Meeting of EDAP-TMS S.A. (the "Company") on June 29, 2018, 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;

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, 2017; reading of the Board of Directors' report on Corporate Governance, 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, 2017; 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, 2017; granting of a release to the members of the Board of Directors for their management;

2. Allocation of net loss for the fiscal year ended December 31, 2017;
3. Determination of attendance fees to be allocated to the Board of Directors;
4. Appointment of a new Statutory Auditor and a new Alternate Statutory Auditor.

* * *

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)*

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.

Draft of resolutions EDAP TMS AGO – 1/3
June 29, 2018

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, 2017; reading of the Board of Directors' report on Corporate Governance, 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, 2017; 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, 2017; 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, 2017,
the Board of Directors' special report on stock-options pursuant to Article L. 225-37, a16 and L.225-68 a16 of the French Commercial Code,
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, 2017,
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, 2017 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, 2017 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 30, 2018, 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 2017.

THIRD RESOLUTION (*Allocation of net loss for the fiscal year ended December 31, 2017*)

The Shareholders' Meeting, in accordance with the quorum and majority criteria required for Ordinary Shareholders' Meetings, acknowledges that the Company has recorded a net loss (not consolidated) of €783,715 during fiscal year ended December 31, 2017.

The Shareholders' Meeting, after reading the Board of Directors report, decides to allocate the total net loss €783,715 amount to the cumulated losses account, increasing this account from (€13,807,060) to (€14,590,775).

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.

Draft of resolutions EDAP TMS AGO – 2/3
June 29, 2018

FOURTH RESOLUTION *(Determination of attendance fees to be allocated to the Board of Directors)*

The General Meeting, in accordance with the quorum and majority criteria required for Ordinary Shareholders Meetings, sets the attendance fees to be allocated to the Board of Directors for the fiscal year ended December 31st, 2017 at a total amount of €108,000.00.

FIFTH RESOLUTION *(Appointment of a new Statutory Auditor and a new Alternate Statutory Auditor)*

The General Meeting, in accordance with the quorum and majority criteria required for Ordinary Shareholders Meetings and after hearing the Board of Directors' management report, acknowledges that the mandate of the Company's Statutory Auditor and Alternate Statutory Auditor terminates on the date of the present General Meeting.

Consequently, and after hearing the Board of Directors' management report, the General Meeting decides:

not to renew the mandates of PriceWaterhouseCoopers Audit and of Mme Anik Chaumartin, respectively Statutory Auditor and Alternate Statutory Auditor of the Company;

-

to appoint:

- (i) KPMG, with its registered office at 2, Avenue Gambetta, Tour Eqho, 92066 Paris la Défense CEDEX, registered with the Commercial Registry of Nanterre under number 775726417, as Statutory Auditor of the Company;
Salustro Reydel, with its registered office at 2, Avenue Gambetta, Tour Eqho, 92066 Paris la Défense CEDEX
- (ii) registered with the Commercial Registry of Nanterre under number 652044371, as Alternate Statutory Auditor of the Company.

for a period of six fiscal years to be terminated at the end of the General Meeting to be called in the course of year 2024 in order to approve the financial statements of the Company for the fiscal year ended December 31, 2023.

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.

Draft of resolutions EDAP TMS AGO – 3/3
June 29, 2018

