

EDAP TMS SA

FORM 6-K (Report of Foreign Issuer)

Filed 11/15/17 for the Period Ending 11/15/17

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| CIK | 0001041934 |
| Symbol | EDAP |
| SIC Code | 3845 - Electromedical and Electrotherapeutic Apparatus |
| Industry | Advanced Medical Equipment & Technology |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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

November 15, 2017

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 []

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: November 15, 2017
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP TMS Reports Third Quarter 2017 Results

- EDAP's HIFU patient treatment revenues grew 29% compared to third quarter 2016.
- EDAP received FDA clearance for its Ablatherm Fusion[®] late in the quarter.
- EDAP's cash position remains strong at US \$21.3 million on September 30, 2017

LYON, France, November 15, 2017 -- EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, today announced financial results for the third quarter ended September 30, 2017 and an update on strategic and operational accomplishments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "Our team has executed another successful quarter. Physicians and patients are clearly responding to the advantages of HIFU for prostate cancer as evidenced by our 29% growth in treatment driven revenues compared to the third quarter of 2016."

"EDAP received clearance for the Ablatherm Fusion late in the quarter. Our current Ablatherm users are initiating the upgrade process, excited for the increased accuracy provided by Ablatherm Fusion's proprietary imaging software. In the meantime, we continue to work with the FDA for the clearance of Focal One[®]."

Third Quarter 2017 Results

Total revenue for the third quarter of 2017 was EUR 7.1 million (USD 8.4 million), compared to EUR 8.0 million (USD 8.9 million) for the third quarter of 2016.

For the three months ended September 30, 2017, total revenue for the Lithotripsy division was EUR 5.3 million (USD 6.3 million), compared to EUR 5.4 million (USD 6.1 million) during the year-ago period. During the third quarter of 2017, EDAP sold 6 lithotripsy devices compared to 11 lithotripsy devices sold during the third quarter of 2016.

Total revenue in the HIFU business for the third quarter was EUR 1.8 million (USD 2.2 million) compared to EUR 2.5 million (USD 2.8 million) for the third quarter of 2016. During the third quarter of 2017, EDAP sold no HIFU devices compared to 2 Focal One devices during the third quarter of 2016.

Gross profit for the third quarter of 2017 was EUR 2.8 million (USD 3.3 million), compared to EUR 3.5 million (USD 3.9 million) for the year-ago period. Gross profit margin on net sales was 39.4% in the third quarter of 2017, compared to 43.2% in the prior year period, primarily due to a lower revenue.

Operating expenses for the third quarter of 2017 totaled EUR 3.8 million (USD 4.5 million) for the third quarter of 2017, compared to EUR 3.8 million (USD 4.2 million) for the same period in 2016.

Operating loss for the third quarter of 2017 was EUR 1.0 million (USD 1.2 million), compared to an operating loss of EUR 0.3 million (USD 0.4 million) in the third quarter of 2016.

Net loss for the third quarter of 2017 was EUR 0.5 million (USD 0.6 million), or loss of EUR 0.02 per diluted share, as compared to net income of EUR 1.3 million (USD 1.4 million), or earnings of EUR 0.04 per diluted share in the year-ago period. Net loss during the third quarter of 2017 included a non-cash interest income of EUR 0.8 million to adjust the accounting fair value of the outstanding warrants

First Nine Months 2017 Results

Total revenue for the first nine months of 2017 was EUR 25.1 million (USD 28.2 million) up 1% compared to 24.9 million (USD 27.8 million) during the first nine months of 2016.

For the nine months ended September 30, 2017, total revenue for the Lithotripsy division was EUR 18.1 million (USD 20.3 million), a growth of 15% compared to EUR 15.7 million (USD 17.5 million). During the first nine months of 2017 EDAP sold 21 Lithotripsy devices compared to 27 Lithotripsy devices during the year ago period.

HIFU revenue for the nine months ended September 30, 2017 was EUR 7.1 (USD 7.9 million) compared to EUR 9.2 million (USD 10.3 million) during the first nine months of 2016. During the first nine months of 2017, EDAP sold 4 HIFU devices, compared to 10 HIFU devices sold during the first nine months of 2016.

Gross profit for the first nine months of 2017 was EUR 10.4 million (USD 11.7 million) and gross profit margin on net sales was 41.4% compared to EUR 11.2 million (USD 12.5 million) and gross profit margin of 45.0% during the first nine months of 2016.

Operating loss for the first nine months of 2017 was EUR 1.8 million (USD 2.1 million) compared to an operating profit of EUR 0.1 million (USD 0.1 million) during the same period of 2016.

Net loss for the first nine months of 2017 was EUR 0.6 million (USD 0.7 million), or loss of EUR 0.02 per share (USD 0.02), compared to net income of EUR 5.1 million (USD 5.7 million), or earnings of EUR 0.18 (USD 0.20) per share during the first nine months of 2016. Net loss for the first nine months of 2017 included non-cash interest income of EUR 2.2 million to adjust the accounting fair value of the outstanding warrants.

As of September 30, 2017, cash and cash equivalents, including short-term treasury investments, were EUR 18.0 million (USD 21.3 million).

Conference Call

An accompanying conference call will be conducted by Philippe Chauveau, Chairman of the Board, Marc Oczachowski, Chief Executive Officer; and Francois Dietsch, Chief Financial Officer, to review the results. The call will be held at 8:30 AM ET, on Thursday, November 16, 2017. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Date: Thursday, November 16, 2017, 8:30 AM ET

Conference dial-in: 877-269-7756

International dial-in: 201-689-7817

Conference Call Name: EDAP-TMS Third Quarter 2017 Results Conference Call

Webcast Registration: [Click Here](#)

Following the live call, a replay will be available on the Company's website, www.edap-tms.com under "Investors Information."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved for commercial distribution in Europe and some other countries including Mexico and Canada, and has received 510(k) clearance by the U.S. FDA. Ablatherm Fusion, next generation of Ablatherm device is now FDA cleared. The Company also markets an innovative robot-assisted HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. In addition, the Company develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. For more information on the Company, please visit <http://www.edap-tms.com>, and <http://www.hifu-prostate.com>.

Forward-Looking Statements

In addition to historical information, this press release 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.

Company Contact

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

| | Three Months Ended: | | Three Months Ended : | |
|---|---|---|--|--|
| | September 30, 2017 Euros | September 30, 2016 Euros | September 30, 2017 \$US | September 30, 2016 \$US |
| Net sales of goods | 3,889 | 5,218 | 4,606 | 5,836 |
| Net sales of RPP and Leases | 1,277 | 1,098 | 1,512 | 1,228 |
| Net sales of spare parts and Services | 1,955 | 1,674 | 2,316 | 1,873 |
| TOTAL NET SALES | 7,121 | 7,990 | 8,434 | 8,936 |
| Other revenues | 4 | 2 | 4 | 2 |
| TOTAL REVENUES | 7,124 | 7,992 | 8,438 | 8,938 |
| Cost of sales | (4,317) | (4,537) | (5,114) | (5,075) |
| GROSS PROFIT | 2,807 | 3,454 | 3,324 | 3,864 |
| Research & development expenses | (918) | (1,032) | (1,087) | (1,154) |
| S, G & A expenses | (2,889) | (2,754) | (3,422) | (3,080) |
| Total operating expenses | (3,807) | (3,786) | (4,510) | (4,234) |
| OPERATING PROFIT (LOSS) | (1,001) | (332) | (1,185) | (371) |
| Interest (expense) income, net | 821 | 1,502 | 972 | 1,680 |
| Currency exchange gains (loss), net | (325) | 130 | (385) | 145 |
| Other income (loss), net | - | - | - | - |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (504) | 1,301 | (597) | 1,455 |
| Income tax (expense) credit | (21) | (40) | (25) | (44) |
| NET INCOME (LOSS) | (525) | 1,261 | (622) | 1,411 |
| Basic income (loss) per share | (0.02) | 0.04 | (0.02) | 0.05 |
| Basic weighted average shares outstanding | 28,997,866 | 28,727,616 | 28,997,866 | 28,727,616 |
| Diluted income (loss) per share | (0.02) | 0.04 | (0.02) | 0.05 |
| Diluted weighted average shares outstanding | 28,997,866 | 30,251,966 | 28,997,866 | 30,251,966 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2017 average three months' noon buying rate of 1 Euro = 1.1844USD, and 2016 average three months' noon buying rate of 1 Euro = 1.1184 USD.

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

| | <u>Nine Months Ended:</u> | | <u>Nine Months Ended:</u> | |
|---|--------------------------------|--------------------------------|-------------------------------|-------------------------------|
| | September 30, 2017 Euros | September 30, 2016 Euros | September 30, 2017 \$US | September 30, 2016 \$US |
| Net sales of goods | 15,367 | 16,480 | 17,276 | 18,356 |
| Net sales of RPP and leases | 3,876 | 3,675 | 4,357 | 4,094 |
| Net sales of spare parts and Services | 5,834 | 4,752 | 6,559 | 5,293 |
| TOTAL NET SALES | 25,076 | 24,907 | 28,192 | 27,742 |
| Other revenues | 43 | 10 | 48 | 11 |
| TOTAL REVENUES | 25,119 | 24,917 | 28,240 | 27,753 |
| Cost of sales | (14,745) | (13,709) | (16,576) | (15,269) |
| GROSS PROFIT | 10,375 | 11,208 | 11,663 | 12,484 |
| Research & development expenses | (2,783) | (2,733) | (3,129) | (3,044) |
| S, G & A expenses | (9,441) | (8,418) | (10,614) | (9,376) |
| Total operating expenses | (12,224) | (11,151) | (13,742) | (12,420) |
| OPERATING PROFIT (LOSS) | (1,849) | 57 | (2,079) | 63 |
| Interest (expense) income, net | 2,229 | 4,393 | 2,506 | 4,893 |
| Currency exchange gains (loss), net | (775) | 801 | (871) | 892 |
| Other income (loss), net | - | - | - | (1) |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (394) | 5,250 | (443) | 5,848 |
| Income tax (expense) credit | (196) | (130) | (220) | (145) |
| NET INCOME (LOSS) | (590) | 5,120 | (663) | 5,703 |
| Basic income (loss) per share | (0.02) | 0.19 | (0.02) | 0.21 |
| Basic weighted average shares outstanding | 28,947,947 | 27,497,107 | 28,947,947 | 27,497,107 |
| Diluted income (loss) per share | (0.02) | 0.18 | (0.02) | 0.20 |
| Diluted weighted average shares outstanding | 28,947,947 | 29,045,939 | 28,947,947 | 29,045,939 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2017 average six months' noon buying rate of 1 Euro = 1.1242USD, and 2016 average six months' noon buying rate of 1 Euro = 1.1138 USD.

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

| | Sept. 30, 2017 Euros | June 30, 2017 Euros | Sept. 30, 2017 \$US | June 30, 2017 \$US |
|---|----------------------------|---------------------------|---------------------------|--------------------------|
| Cash, cash equivalents and short term investments | 18,036 | 18,554 | 21,306 | 21,173 |
| Total current assets | 37,172 | 39,583 | 43,912 | 45,171 |
| Total current liabilities | 12,676 | 13,372 | 14,975 | 15,260 |
| Shareholders' Equity | 24,947 | 25,383 | 29,471 | 28,966 |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1813 USD, on September 30, 2017 and at the noon buying rate of 1 Euro = 1.1412 USD, on June 30, 2017.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2017
(Amounts in thousands of Euros)

| | HIFU Division | | UDS Division | | Corporate | Total After Consolidation |
|---------------------------------|----------------|------------|---------------|------------|----------------|------------------------------|
| Sales of goods | 3,109 | | 12,258 | | | 15,367 |
| Sales of RPPs & leases | 2,891 | | 984 | | | 3,876 |
| Sales of spare parts & services | 1,050 | | 4,784 | | | 5,834 |
| TOTAL NET SALES | 7,050 | | 18,026 | | | 25,076 |
| Other revenues | 8 | | 35 | | | 43 |
| TOTAL REVENUES | 7,058 | | 18,062 | | | 25,119 |
| GROSS PROFIT | | | | | | |
| (% of Total Revenues) | 3,621 | 51% | 6,754 | 37% | | 10,375 41% |
| Research & Development | (1,814) | | (969) | | | (2,783) |
| Total SG&A plus depreciation | (3,627) | | (4,711) | | (1,103) | (9,441) |
| OPERATING PROFIT (LOSS) | (1,820) | | 1,074 | | (1,103) | (1,849) |