

EDAP TMS SA

FORM 6-K (Report of Foreign Issuer)

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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

August 23, 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 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: August 23, 2017
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP-TMS Reports Record Second Quarter and First Half 2017 Results

- Revenue increased 13.7% to a record €9.3 million for the second quarter of 2017 compared to €8.2 million in 2016
- HIFU revenue grew 25% when compared to first quarter of 2017
- Ablatherm Fusion 510(k) submission completed
- C-Code reimbursement for HIFU treatments active as of July 1st, 2017

LYON, France, August 23, 2017 -- EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter ended June 30, 2017, and provided an update on strategic and operational accomplishments.

"We are incredibly pleased to announce record second quarter revenue of €9.3 million", said Marc Oczachowski, EDAP's Chief Executive Officer. "Additionally, the 25% growth in HIFU revenues compared to the first quarter of 2017 shows a significant return from our increased sales and marketing efforts. We also submitted our 510(k) filing to the FDA for our novel Ablatherm Fusion device recently, and are working to file a new 510(k) application with the FDA for the Focal One device in the U.S. The addition of these HIFU devices to our U.S. marketing efforts, coupled with the active C-Code, should serve to help our customers service the widest possible range of patients".

Second Quarter 2017 Results

Total revenue for the second quarter 2017 was EUR 9.3 million (USD 10.4 million), compared to EUR 8.2 million (USD 9.2 million) for the second quarter of 2016, a 13.7% increase and the highest second quarter revenue in EDAP's history.

For the three months ended June 30, 2017, total revenue for the Lithotripsy division was EUR 6.4 million (USD 7.2 million), a 33.9% increase compared to EUR 4.8 million (USD 5.4 million) during the year-ago period. During the second quarter of 2017, EDAP sold 7 lithotripsy devices compared to 6 lithotripsy devices sold during the second quarter of 2016.

Total revenue in the HIFU business for the second quarter was EUR 2.9 million (USD 3.2 million) compared to EUR 3.4 million (USD 3.8 million) for the second quarter of 2016. During the second quarter of 2017, EDAP sold 1 Focal One and 2 Ablatherm HIFU devices compared to 1 Focal One and 3 Ablatherm devices during the second quarter of 2016.

Gross profit for the second quarter 2017 was EUR 4.0 million (USD 4.5 million), compared to EUR 3.5 million (USD 3.9 million) for the year-ago period. Gross profit margin on net sales expanded to 43.2% in the second quarter of 2017, compared to 42.2% in the prior year period, primarily due to increase in revenues.

Operating expenses for the second quarter of 2017 totaled EUR 4.4 million (USD 5.0 million) for the second quarter of 2017, compared to EUR 3.8 million (USD 4.3 million) for the same period in 2016. The increase reflects increased sales and marketing efforts associated with the expansion of the HIFU and UDS businesses.

Operating loss for the second quarter of 2017 was EUR 0.4 million (USD 0.5 million), compared to an operating loss of EUR 0.3 million (USD 0.4 million) in the second quarter of 2016.

Net loss for the second quarter of 2017 was EUR 1.7 million (USD 2.0 million), or loss of EUR 0.06 per diluted share, as compared to net income of EUR 2.5 million (USD 2.8 million), or earnings of EUR 0.09 per diluted share in the year-ago period. Net loss during the second quarter of 2017 included a non-cash interest expense of EUR 0.6 million (USD \$0.6 million) to adjust the accounting fair value of the outstanding warrants.

First Six Months 2017 Results

Total revenue for the first half of 2017 was EUR 18.0 million (USD 19.7 million) - a new record level for the period, up 6.3% compared to EUR 16.9 million (USD 18.8 million) for the first half of 2016.

For the six months ended June 30, 2017, total revenue for the Lithotripsy division was EUR 12.8 million (USD 14.0 million), an increase of 24.6% when compared to EUR 10.2 million (USD 11.4 million), during the year ago period. This increase was driven by growth in both the distribution business and lithotripsy device sales.

Total revenue in the HIFU division for the first six months 2017 was EUR 5.2 million (USD 5.7 million) compared to EUR 6.7 million (USD 7.4 million) for the six months ended June 30, 2016. This decrease was primarily due to slow U.S. sales of HIFU devices during the first half of the year, tempered by an increase in HIFU treatment driven revenues.

Gross profit for the first half of 2017 was EUR 7.6 million (USD 8.3 million) and gross profit margin was 42.1%, compared to 45.8% in the year ago period. The contraction in gross profit margin was primarily due to an unfavorable mix of HIFU and UDS segment revenues.

The Company recorded an operating loss for the first half of 2017 of EUR 0.8 million (USD 0.9 million), compared with an operating profit of EUR 0.4 million (USD 0.4 million) in the first six months of 2016.

Net loss for the first half of 2017 was EUR 0.1 million (USD 0.1 million), or EUR 0.00 per diluted share, as compared to a net income of EUR 3.9 million (USD 4.3 million), or EUR 0.14 per diluted share, in the first half of 2016. Net income for the first six months of 2017 included non-cash interest income of EUR 1.4 million (USD 1.5 million) to adjust the accounting fair value of the outstanding warrants.

At June 30, 2017, cash and cash equivalents, including short-term treasury investments, were EUR 18.6 million (USD 21.2 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 go over the results. The call will be held at 9:00 AM ET, on Thursday, August 24, 2017. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Date: **Thursday, August 24, 2017, 9:00 AM ET**

Conference dial-in: 877-269-7756

International dial-in: 201-689-7817

Conference Call Name: EDAP-TMS Second 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 is not FDA cleared yet. 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. The Company also 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-planet.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 .

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:	
	June 30, 2017 Euros	June 30, 2016 Euros	June 30, 2017 \$US	June 30, 2016 \$US
Net sales of goods	5,966	5,262	6,670	5,896
Net sales of RPP & Leases	1,304	1,316	1,458	1,474
Net sales of spare parts and services	2,037	1,611	2,277	1,805
TOTAL NET SALES	9,307	8,189	10,405	9,175
Other revenues	13	8	15	9
TOTAL REVENUES	9,320	8,197	10,420	9,184
Cost of sales	(5,304)	(4,736)	(5,931)	(5,305)
GROSS PROFIT	4,016	3,461	4,489	3,879
Research & development expenses	(969)	(887)	(1,083)	(993)
S, G & A expenses	(3,477)	(2,919)	(3,887)	(3,271)
Total operating expenses	(4,446)	(3,806)	(4,970)	(4,264)
OPERATING PROFIT (LOSS)	(430)	(345)	(481)	(385)
Interest (expense) income, net	(575)	2,412	(643)	2,702
Currency exchange gains (loss), net	(625)	483	(699)	541
Other income (loss), net	-	-	-	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,630)	2,550	(1,823)	2,858
Income tax (expense) credit	(117)	(52)	(130)	(58)
NET INCOME (LOSS)	(1,747)	2,498	(1,953)	2,800
Basic income (loss) per share	(0.06)	0.09	(0.07)	0.09
Basic weighted average shares outstanding	28,997,866	28,288,307	28,997,866	28,288,307
Diluted income (loss) per share	(0.06)	0.08	(0.07)	0.08
Diluted weighted average shares outstanding	28,997,866	29,826,117	28,997,866	29,826,117

NOTE: Translated for convenience of the reader to U.S. dollars at the 2017 average three months' noon buying rate of 1 Euro = 1.1181USD, and 2016 average three months' noon buying rate of 1 Euro = 1.1203 USD.

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

	Six Months Ended:		Six Months Ended:	
	June 30, 2017 Euros	June 30, 2016 Euros	June 30, 2017 \$US	June 30, 2016 \$US
Net sales of goods	11,478	11,261	12,559	12,518
Net sales of RPPs & leases	2,599	2,578	2,844	2,865
Net sales of spare parts, supplies and services	3,879	3,078	4,244	3,421
TOTAL NET SALES	17,956	16,917	19,647	18,804
Other revenues	40	8	43	9
TOTAL REVENUES	17,996	16,925	19,690	18,813
Cost of sales	(10,427)	(9,171)	(11,410)	(10,195)
GROSS PROFIT	7,569	7,754	8,280	8,618
Research and development expenses	(1,865)	(1,701)	(2,040)	(1,890)
S, G&A expenses	(6,551)	(5,665)	(7,169)	(6,296)
Total operating expenses	(8,416)	(7,366)	(9,209)	(8,186)
OPERATING PROFIT (LOSS)	(847)	388	(929)	432
Interest (expense) income, net	1,408	2,891	1,541	3,213
Currency exchange gains (loss), net	(450)	671	(492)	746
Other income, net	-	-	-	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	111	3,950	120	4,391
Income tax (expense) credit	(175)	(91)	(191)	(101)
NET INCOME (LOSS)	(64)	3,859	(71)	4,290
Basic income (loss) per share	(0.00)	0.14	(0.00)	0.16
Basic weighted average shares outstanding	28,919,984	26,844,696	28,919,984	26,844,696
Diluted income (loss) per share	(0.00)	0.13	(0.00)	0.15
Diluted weighted average shares outstanding	28,919,984	28,615,172	28,919,984	28,615,172

NOTE: Translated for convenience of the reader to U.S. dollars at the 2017 average six months' noon buying rate of 1 Euro = 1.0942USD, and 2016 average six months' noon buying rate of 1 Euro = 1.1116 USD.

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

	June 30, 2017 Euros	March 31, 2017 Euros	June 30, 2017 \$US	March 31, 2017 \$US
Cash, cash equivalents and short term investments	18,554	20,321	21,173	21,739
Total current assets	39,583	40,542	45,171	43,370
Total current liabilities	13,372	14,052	15,260	15,032
Shareholders' Equity	25,383	26,904	28,966	28,780

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1412 USD, on June 30, 2017 and at the noon buying rate of 1 Euro = 1.0697 USD, on March 31, 2017.

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

	HIFU Division		UDS Division		Corporate	Total After Consolidation
Sales of goods	2,626		8,852			11,478
Sales of RPPs & leases	1,898		700			2,599
Sales of spare parts & services	696		3,183			3,879
TOTAL NET SALES	5,220		12,735			17,956
Other revenues	8		32			40
TOTAL REVENUES	5,228		12,767			17,996
GROSS PROFIT	2,794	53%	4,774	37%		7,569
(% of Total revenues)						42%
Research and development	(1,211)		(653)			(1,865)
Total SG&A plus depreciation	(2,467)		(3,315)		(768)	(6,551)
OPERATING PROFIT (LOSS)	(884)		804		(768)	(847)