

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

April 3, 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: April 3, 2017
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Achieves 63% Growth in HIFU Revenue in 2016

2016 Highlights

- Total revenue for 2016 reached double-digit growth, increasing to EUR 35.6 million (USD 39.3 million)
- Gross margin for 2016 expanded to 46.1% compared to 42.8% during the prior year period
- Strong cash position of EUR 22.0 million (USD 23.2 million) as of December 31, 2016

LYON, France, April 3, 2017 -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and twelve months ended December 31, 2016, and provided an update on strategic and operational accomplishments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "I am thrilled with the performance of our team in 2016. We successfully grew our HIFU revenue more than 63% to EUR 13.8 million, resulting in total 2016 revenue of EUR 35.6 million. EDAP strengthened its HIFU presence in the U.S. during 2016, adding key academic centers to its HIFU user base while significantly expanding operations globally. Ablatherm® and the Focal One® continued to enjoy a warm reception from the global medical community supported by strong, positive clinical data. Notably, Focal One's innovative prostate treatment received clear recognition from the global scientific community when awarded the prestigious Prix Galien Award this past December."

Mr. Oczachowski concluded, "2016 was rich in positive events; please join us Tuesday, April 4, 2017, for a detailed discussion of our continued success and expansion."

Fourth Quarter 2016 Results

Total revenue for the fourth quarter 2016 was EUR 10.7 million (USD 11.4 million), a 9.3% decrease compared to EUR 11.8 million (USD 12.8 million) for the fourth quarter of 2015.

Total revenue in the HIFU business for the fourth quarter was EUR 4.6 million (USD 4.9 million), a 38.3% increase compared to EUR 3.3 million (USD 3.6 million) for the fourth quarter of 2015.

For the three months ended December 31, 2016, total revenue for the Lithotripsy division was EUR 6.1 (USD 6.5 million), a 27.9% decrease compared to EUR 8.5 million (USD 9.2 million) during the year-ago period.

Gross profit for the fourth quarter 2016 was EUR 5.2 million (USD 5.6 million), compared to EUR 5.3 million (USD 5.7 million) for the year-ago period. Gross profit margin on net sales was 48.8% in the fourth quarter of 2016, compared to 45.0% in the year-ago period.

Operating expenses were EUR 4.9 million (USD 5.2 million) for the fourth quarter of 2016, compared to EUR 3.7 million (USD 4.0 million) for the same period in 2015.

Operating profit for the fourth quarter 2016 was EUR 0.3 million (USD 0.4 million), compared to EUR 1.6 million (USD 1.7 million) in the fourth quarter of 2015.

Net loss for the fourth quarter 2016 was EUR 1.3 (USD 1.4 million), or a loss of EUR 0.04 per diluted share, as compared to net income of EUR 5.1 million (USD 5.5 million), or EUR 0.18 per diluted share in the year-ago period. Net income in the fourth quarter of 2016 included non-cash interest expense of EUR 0.4 million (USD 0.5 million) to adjust the accounting fair value of the outstanding warrants.

Year Ended 2016 Results

Total revenue for 2016 was EUR 35.6 million (USD 39.3 million), an increase of 10.4% compared to EUR 32.3 million (USD 35.6) for the year ended December 31, 2015.

Total revenue in the HIFU business for 2016 was EUR 13.8 million (USD 15.2 million), an increase of 63.0% compared to EUR 8.5 million (USD 9.4 million) for the year ended December 31, 2015.

Total revenue in the Lithotripsy business for 2016 was EUR 21.8 million (USD 24.0 million), a decrease of 8.3% compared to EUR 23.8 million (USD 26.2 million) for the year ended December 31, 2015.

Gross profit for 2016 was EUR 16.4 million (USD 18.1 million), with gross profit margin on net sales of 46.1%, compared to 42.8% during the prior year period.

The Company recorded operating profit for 2016 of EUR 0.4 million (USD 0.4 million), compared to an operating profit of EUR 0.5 million (USD 0.5 million) during the prior year period.

Full-year net income was EUR 3.8 million (USD 4.2 million), or EUR 0.13 per diluted share, as compared to a net loss of EUR 1.7 million (USD 1.8 million), or a loss of EUR 0.07 per diluted share in 2015. Full-year net income included non-cash interest income of EUR 4.0 million to adjust the accounting fair value of the outstanding warrants.

At December 31, 2016, cash and cash equivalents were EUR 22.0 million (USD 23.2 million).

Conference Call

An accompanying conference call will be conducted by Marc Oczachowski, Chief Executive Officer, and Francois Dietsch, Chief Financial Officer, to go over the results. The call will be held at 8:30 AM ET, on Tuesday, April 4, 2017. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Date: Tuesday, April 4, 2017 8:30 AM ET

Conference dial-in: 877-269-7756

International dial-in: 201-689-7817

Conference Call Name: EDAP-TMS Fourth Quarter and Full Year 2016 Results 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. 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 (Amounts in thousands of Euros and U.S. Dollars,
except per share data)

	Three Months Ended:		Three Months Ended:	
	December 31, 2016 Euros	December 31, 2015 Euros	December 31, 2016 \$US	December 31, 2015 \$US
Sales of medical equipment	7,566	9,049	8,093	9,792
Net Sales of RPP and Leases	1,231	1,151	1,317	1,245
Sales of spare parts, supplies and Services	1,875	1,560	2,006	1,688
TOTAL NET SALES	10,672	11,760	11,417	12,726
Other revenues	22	32	24	35
TOTAL REVENUES	10,695	11,792	11,441	12,760
Cost of sales	(5,492)	(6,495)	(5,875)	(7,029)
GROSS PROFIT	5,203	5,297	5,566	5,732
Research & development expenses	(1,135)	(565)	(1,214)	(612)
S, G & A expenses	(3,733)	(3,147)	(3,994)	(3,406)
Total operating expenses	(4,868)	(3,713)	(5,208)	(4,018)
OPERATING PROFIT (LOSS)	335	1,584	358	1,714
Interest (expense) income, net	(444)	3,710	(475)	4,015
Currency exchange gains (loss), net	(698)	476	(746)	516
Other income (loss), net	-	5	-	5
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(807)	5,775	(863)	6,249
Income tax (expense) credit	(471)	(659)	(504)	(713)
NET INCOME (LOSS)	(1,278)	5,116	(1,367)	5,536
Earning per share – Basic	(0.04)	0.20	(0.05)	0.22
Average number of shares used in computation of EPS	28,727,616	25,254,618	28,727,616	25,254,618
Earning per share – Diluted	(0.04)	0.18	(0.05)	0.19
Average number of shares used in computation of EPS for positive net income	28,727,616	28,846,270	28,727,616	28,846,270

NOTE: Translated for convenience of the reader to U.S. dollars at the 2016 average three months' noon buying rate of 1 Euro = 1.0697 USD, and 2015 average three months' noon buying rate of 1 Euro = 1.0821 USD.

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

	Twelve Months Ended:		Twelve Months Ended:	
	December 31,	December 31,	December 31,	December 31,
	2016 Euros	2015 Euros	2016 \$US	2015 \$US
Sales of medical equipment	24,045	21,906	26,520	24,168
Net Sales of RPP and Leases	4,906	4,408	5,411	4,864
Sales of spare parts, supplies and Services	6,628	5,904	7,310	6,513
TOTAL NET SALES	35,579	32,218	39,240	35,545
Other revenues	32	35	35	39
TOTAL REVENUES	35,611	32,253	39,276	35,584
Cost of sales	(19,200)	(18,468)	(21,176)	(20,375)
GROSS PROFIT	16,411	13,785	18,100	15,209
Research & development expenses	(3,868)	(2,690)	(4,266)	(2,968)
S, G & A expenses	(12,152)	(10,608)	(13,402)	(11,703)
Total operating expenses	(16,019)	(13,298)	(17,668)	(14,671)
OPERATING PROFIT (LOSS)	392	488	432	538
Interest (expense) income, net	3,949	(2,094)	4,355	(2,310)
Currency exchange gains (loss), net	103	699	114	771
Other income (loss), net	-	-	-	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	4,444	(907)	4,901	(1,001)
Income tax (expense) credit	(602)	(759)	(663)	(838)
NET INCOME (LOSS)	3,842	(1,667)	4,238	(1,839)
Earning per share – Basic	0.14	(0.07)	0.15	(0.07)
Average number of shares used in computation of EPS	27,823,313	25,021,966	27,823,313	25,021,966
Earning per share – Diluted	0.13	(0.07)	0.14	(0.07)
Average number of shares used in computation of EPS for positive net income	29,365,583	25,021,966	29,365,583	25,021,966

NOTE: Translated for convenience of the reader to U.S. dollars at the 2016 average twelve months noon buying rate of 1 Euro = 1.1029 USD, and 2015 average twelve months noon buying rate of 1 Euro = 1.1033 USD.

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

	Dec. 31, 2016 Euros	Sept. 30, 2016 Euros	Dec. 31, 2016 \$US	Sept. 30, 2016 \$US
Cash, cash equivalents and short term investments	21,989	18,837	23,202	21,170
Total current assets	40,514	40,694	42,750	45,734
Total current liabilities	15,010	14,547	15,838	16,349
Shareholders' Equity	24,451	25,739	25,800	28,926

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0552 USD, on December 31, 2016 and at the noon buying rate of 1 Euro = 1.1238 USD, on September 30, 2016.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2016
(Amounts in thousands of Euros)

	HIFU Division		UDS Division		Corporate		Total After Consolidation	
Sales of goods	9,382		14,664				24,045	
Sales of RPPs & Leases	3,547		1,359				4,906	
Sales of spare parts & services	862		5,766				6,628	
TOTAL NET SALES	13,791		21,789				35,579	
Other revenues	28		4				32	
TOTAL REVENUES	13,819		21,792				35,611	
GROSS PROFIT (% of Total Revenues)	8,109	58.7%	8,302	38.1%			16,411	46.1%
Research & Development	(2,452)		(1,416)				(3,868)	
Total SG&A plus depreciation	(4,692)		(6,145)		(1,315)		(12,152)	
OPERATING PROFIT (LOSS)	964		742		(1,315)		392	