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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

May 18, 2016

Commission File Number: 0-29374

EDAP TMS S.A.  
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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):

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## SIGNATURES

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

Date: May 18, 2016  
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH  
FRANCOIS DIETSCH  
CHIEF FINANCIAL OFFICER

## EDAP First Quarter 2016 Revenue Increases 40% Year-over-Year to €8.7 Million

- First quarter 2016 HIFU Division revenue increased 102% year-over-year
- 37% growth in HIFU treatment driven revenues in Q1 2016 compared to Q1 2015
- €0.7 million operating profit, €1.4 million net income in first quarter 2016
- 510(k) application for Focal One submitted to FDA

LYON, France, May 18, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the first quarter ended March 31, 2016, and provided an update on strategic and operational achievements.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "2016 is off to an excellent start, as we delivered the strongest first quarter financial performance in the Company's history. We continue to build momentum following the FDA clearance of Ablatherm Robotic HIFU, with revenue from our HIFU division doubling over the first quarter of 2015 on strong system sales and treatment-driven revenues.

"In addition to the strong HIFU sales growth, we recently achieved an important regulatory milestone with the submission of our 510(k) application for the potential FDA clearance of Focal One<sup>®</sup>. We believe that the investments we are currently making in the expansion of our U.S. sales and marketing infrastructure for Ablatherm will play a key role in supporting the potential U.S. commercialization of Focal One as well. We generated significant interest in Ablatherm at last week's AUA Annual Meeting in San Diego, and are in the process of rolling out a series of direct marketing initiatives aimed at both urologists and patients. HIFU has only been available in the U.S. for several months and the market is still in its infancy. Nevertheless, we are thrilled with the adoption thus far and look forward to building a solid foundation for long-term growth.

"Our UDS / Lithotripsy business also continued to perform well, achieving 18.5% year-over-year growth in the first quarter. Our ability to grow this segment of the business in a crowded and highly competitive market speaks to the breadth of our lithotripter and urinary stone laser product portfolio as well as the quality of our technology."

Mr. Oczachowski added, "Overall, we believe that EDAP is positioned for further near-term growth and significant longer-term success. We have a strong, global pipeline of HIFU projects in our core urology market and continue to advance our R&D efforts aimed at expanding the application of our world-class technology into other indications. With the proceeds of our recently completed registered direct offering, we are well funded to support the Company's future growth, extend our leadership position in the markets we serve, enter new markets and create value for physicians, patients and our shareholders."

Total revenue for the first quarter 2016 was EUR 8.7 million (USD 9.6 million), compared to EUR 6.2 million (USD 6.9 million) for the first quarter 2015.

Total revenue for the HIFU division was EUR 3.3 million (USD 3.6 million) for the first quarter 2016, compared to EUR 1.6 million (USD 1.8 million) for the same period last year. During the first quarter of 2016, the Company recorded sales of four HIFU machines, comprised of three U.S. Ablatherm devices and one Focal One device which compares to one Focal One sold in the first quarter 2015.

For the three months ended March 31, 2016, total revenue for the lithotripsy division was EUR 5.5 million (USD 6.0 million), compared to EUR 4.6 million (USD 5.1 million), during the year ago period. During the first quarter 2016, the Company recorded sales of 10 lithotripsy machines, which compares to a total of 7 devices sold in the first quarter of 2015.

Gross profit for the first quarter 2016 was EUR 4.3 million (USD 4.7 million), compared to EUR 2.6 million (USD 2.9 million) for the year ago period. Gross profit margin on net sales was 49.2% in the first quarter of 2016, compared to 41.5% in the year ago period.

Operating expenses were EUR 3.6 million (USD 3.9 million) for the first quarter 2016, compared to EUR 3.2 million (USD 3.5 million) for the same period in 2015.

Operating profit for the first quarter 2016 was EUR 0.7 million (USD 0.8 million), compared with an operating loss in the first quarter of 2015 of EUR 0.6 million (USD 0.7 million).

Net income for the first quarter 2016 was EUR 1.4 million (USD 1.5 million), or EUR 0.05 per diluted share, as compared to a net loss of EUR 2.4 million (USD 2.7 million), or EUR 0.10 per diluted share, in the year ago period. Net income in the first quarter 2016 included non-cash interest income of EUR 0.5 million to adjust the accounting fair value of the outstanding warrants.

At March 31, 2016, cash and cash equivalents, including short-term treasury investments, were EUR 14.5 million (USD 16.6 million).

### Conference Call

EDAP will hold a conference call on Wednesday, May 18, 2016 at 8:30 a.m. EDT to discuss the results and provide an update on recent business developments. The dial-in numbers are 1-888-348-6419 in the U.S., and 1-412-902-4235 for international callers.

The conference ID number for both is 10085854. A live webcast of the conference call will be available online from the investor relations page of the Company's corporate website at [www.edap-tms.com](http://www.edap-tms.com).

After the live event, the webcast will remain available on EDAP's website, [www.edap-tms.com](http://www.edap-tms.com), through June 12, 2016. In addition, a dial-in replay of the call will be available. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 10085854.

## 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)

	<u>Three Months Ended:</u>		<u>Three Months Ended:</u>	
	<u>Mar. 31,</u> <u>2016</u> <u>Euros</u>	<u>Mar. 31,</u> <u>2015</u> <u>Euros</u>	<u>Mar. 31,</u> <u>2016</u> <u>\$US</u>	<u>Mar. 31,</u> <u>2015</u> <u>\$US</u>
Sales of medical equipment	5,999	3,746	6,617	4,149
Net Sales of RPP and Leases	1,262	1,029	1,392	1,140
Sales of spare parts, supplies and Services	1,467	1,442	1,618	1,597
<b>TOTAL NET SALES</b>	<b>8,728</b>	<b>6,217</b>	<b>9,627</b>	<b>6,886</b>
Other revenues	-	-	-	-
<b>TOTAL REVENUES</b>	<b>8,728</b>	<b>6,217</b>	<b>9,627</b>	<b>6,886</b>
Cost of sales	(4,436)	(3,637)	(4,893)	(4,028)
<b>GROSS PROFIT</b>	<b>4,292</b>	<b>2,580</b>	<b>4,734</b>	<b>2,858</b>
Research & development expenses	(814)	(773)	(898)	(857)
S, G & A expenses	(2,745)	(2,429)	(3,028)	(2,690)
Total operating expenses	(3,559)	(3,202)	(3,926)	(3,547)
<b>OPERATING PROFIT (LOSS)</b>	<b>733</b>	<b>(622)</b>	<b>808</b>	<b>(689)</b>
Interest (expense) income, net	479	(2,350)	528	(2,602)
Currency exchange gains (loss), net	188	565	207	626
Other income (loss), net	-	(3)	-	(3)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>1,400</b>	<b>(2,410)</b>	<b>1,544</b>	<b>(2,669)</b>
Income tax (expense) credit	(39)	(30)	(43)	(34)

<b>NET INCOME (LOSS)</b>	<b>1,360</b>	<b>(2,440)</b>	<b>1,501</b>	<b>(2,703)</b>
Earning per share – Basic	0.05	(0.10)	0.06	(0.11)
Average number of shares used in computation of EPS	25,400,445	24,894,049	25,400,445	24,894,049
Earning per share – Diluted	0.05	(0.10)	0.06	(0.11)
Average number of shares used in computation of EPS for positive net income	26,987,182	24,894,049	26,987,182	24,894,049

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2016 average three months' noon buying rate of 1 Euro = 1.1030 USD, and 2015 average three months' noon buying rate of 1 Euro = 1.1075 USD.

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

	<b>Mar. 31, 2016 Euros</b>	<b>Dec. 31, 2015 Euros</b>	<b>Mar. 31, 2016 \$US</b>	<b>Dec. 31, 2015 \$US</b>
Cash, cash equivalents and short term investments	14,533	14,578	16,552	15,831
Total current assets	33,019	33,039	37,607	35,877
Total current liabilities	16,529	16,271	18,826	17,668
Shareholders' Equity	15,901	14,430	18,111	15,669

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1390 USD, on March 31, 2016 and at the noon buying rate of 1 Euro = 1.0859 USD, on December 31, 2015.

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

	<b>HIFU Division</b>		<b>UDS Division</b>		<b>Total After Corporate Consolidation</b>
Sales of goods	2,265		3,734		5,999
Sales of RPPs & Leases	878		383		1,262
Sales of spare parts & services	131		1,336		1,467
<b>TOTAL NET SALES</b>	<b>3,275</b>		<b>5,453</b>		<b>8,728</b>
Other revenues	-		-		-
<b>TOTAL REVENUES</b>	<b>3,275</b>		<b>5,453</b>		<b>8,728</b>
<b>GROSS PROFIT</b>	<b>2,033</b>	<b>62.1%</b>	<b>2,259</b>	<b>41.4%</b>	<b>4,292</b>
<b>(% of Total Revenues)</b>					<b>49.2%</b>
Research & Development	(518)		(296)		(814)
Total SG&A plus depreciation	(871)		(1,533)		(2,745)
<b>OPERATING PROFIT (LOSS)</b>	<b>644</b>		<b>430</b>		<b>(341)</b>
					<b>733</b>

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