

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 21, 2013

Commission File Number: 000-29374

EDAP TMS S.A.  
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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): \_\_\_\_

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**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: October 21, 2013  
EDAP TMS S.A.

/s/ ERIC SOYER  
ERIC SOYER  
CHIEF FINANCIAL OFFICER

## EDAP Reports Third Quarter 2013 Results

LYON, France, Nov. 21, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter ended September 30, 2013.

### Recent Highlights

- Total third quarter 2013 revenue of EUR 5.6 million, sequential quarterly growth of 24%
- Strong device backlog entering fourth quarter 2013
- Focal One<sup>®</sup> delivered in October 2013 and first treatments performed in Europe
- Ablatherm-HIFU highlighted in presentations at the 31<sup>st</sup> World Congress of Endourology

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "During the third quarter, we continued to execute our business plan by generating revenue from sales of our commercialized devices. As expected, we closed several orders that were secured during the second quarter. Entering the fourth quarter, we have a strong device backlog of 14 Lithotripters and the entire EDAP team worldwide is focusing on closing deals before year end as this is the most active time of our seasonal business.

"Importantly, we recently delivered our first Focal One<sup>®</sup> device to a customer in Europe. The delivery and installation was completed as scheduled and the first treatments were successfully performed. We are pleased with the reception of this device in the early stages of our marketing efforts and we are excited about the potential opportunity of Focal One<sup>®</sup>."

### **Third Quarter 2013 Results**

Total revenue for the third quarter 2013 was EUR 5.6 million (USD 7.4 million), compared to EUR 5.7 million (USD 7.1 million) for the third quarter 2012.

Total revenue for the lithotripsy division was EUR 4.3 million (USD 5.8 million) for the three months ended September 30, 2013, as compared to EUR 4.8 million (USD 6.0 million) for the year ago period. During the third quarter 2013, the Company recorded sales of nine lithotripsy machines, compared to a total of 12 devices sold in the third quarter of 2012.

Total revenue for the HIFU division was EUR 1.2 million (USD 1.7 million) for the third quarter 2013, compared to EUR 0.9 million (USD 1.1 million) for the same period last year. The Company recorded the sale of one Ablatherm-HIFU device during the third quarter of 2013.

Gross profit for the third quarter 2013 was EUR 2.2 million (USD 3.0 million), compared to EUR 2.2 million (USD 2.8 million) for the year ago period. Gross profit margin was 40.3% in the third quarter 2013, compared to 39.6% in the year ago period.

Operating expenses were EUR 2.6 million (USD 3.4 million) for the third quarter 2013, compared to EUR 2.6 million (USD 3.3 million) for the same period in 2012. Operating loss was EUR 333,000 (USD 444,000) for the third quarter 2013, compared to EUR 341,000 (USD 429,000) in the third quarter of 2012.

Net loss for the third quarter 2013 was EUR 373,000 (USD 497,000), or EUR 0.02 per diluted share (USD 0.02 per diluted share), as compared to net loss for the third quarter 2012 of EUR 496,000 (USD 624,000), or EUR 0.03 per diluted share (USD 0.03 per diluted share).

### **First Nine Months 2013 Results**

Total revenue for the first nine months of 2013 was EUR 16.0 million (USD 21.1 million), and EUR 17.1 million on a constant currency basis compared to EUR 16.6 million (USD 21.4 million) in the first nine months of 2012.

Gross profit for the first nine months of 2013 was EUR 6.1 million (USD 8.0 million), compared to EUR 6.5 million (USD 8.4 million) for the first nine months of 2012. Gross profit margin was 37.9% in the first nine months of 2013, and 40.6% on a constant currency basis compared to 39.3% in the first nine months of 2012.

Operating loss for the first nine months of 2013 was EUR 3.0 million (USD 3.9 million), compared to EUR 2.3 million (USD 2.9 million) for the same period of 2012.

Net loss for the first nine months of 2013 was EUR 4.5 million (USD 5.9 million), or EUR 0.22 per diluted share (USD 0.29 per diluted share), as compared to net loss of EUR 6.4 million (USD 8.2 million), or EUR 0.37 per diluted share (USD 0.48 per diluted share), in the first nine months of 2012. Net loss for the first nine months of 2013 included a EUR 1.1 million (USD 1.5 million) currency exchange loss.

At September 30, 2013, cash and cash equivalents, including short-term treasury investments, were EUR 6.4 million (USD 8.7 million). The Company's net cash utilization was EUR 0.9 million in the third quarter 2013 and included EUR 1.4 million of inventory replenishment in preparation for the fourth quarter 2013 sales activity.

### **Conference Call**

EDAP will hold a conference call today, Thursday, November 21, 2013, at 8:30 a.m. EDT to discuss the results. The dial-in numbers are 1-877-300-8521 for domestic callers and 1-412-317-6026 for international callers. The conference ID number for both is 10035894. 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 webcast, the call will remain available on EDAP's website, [www.edap-tms.com](http://www.edap-tms.com), through December 19, 2013. In addition, a telephonic replay of the call will be available until November 28, 2013. 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 10035894.

## About EDAP TMS SA

EDAP TMS SA markets today Ablatherm<sup>®</sup> for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option 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 and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. In February 2013, the Company introduced a new innovative HIFU device, the Focal One<sup>®</sup> dedicated to focal therapy of prostate cancer. Focal One<sup>®</sup> 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 commercializes medical equipment (the Sonolith<sup>®</sup> range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). 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 uncertainties of the U.S. FDA approval process, 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

**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, 2013 Euros	September 30, 2012 Euros	September 30, 2013 \$US	September 30, 2012 \$US
Sales of goods	3,271	3,597	4,363	4,527
Net Sales of RPP and Leases	920	729	1,226	917
Sales of spare parts and Services	1,371	1,350	1,829	1,699
<b>TOTAL NET SALES</b>	<b>5,562</b>	<b>5,676</b>	<b>7,418</b>	<b>7,143</b>
Other revenues	1	2	2	3
<b>TOTAL REVENUES</b>	<b>5,563</b>	<b>5,678</b>	<b>7,420</b>	<b>7,145</b>
Cost of goods	(1,938)	(2,083)	(2,584)	(2,621)
Cost of RPP and Leases	(514)	(533)	(686)	(670)
Cost of spare parts & services	(870)	(816)	(1,161)	(1,026)
Cost of sales	(3,322)	(3,431)	(4,431)	(4,317)
<b>GROSS PROFIT</b>	<b>2,241</b>	<b>2,248</b>	<b>2,989</b>	<b>2,828</b>
Research & development expenses	(447)	(423)	(596)	(532)
Marketing & Sales expenses	(1,302)	(1,296)	(1,737)	(1,631)
G & A expenses	(825)	(869)	(1,100)	(1,094)
Total operating expenses	(2,574)	(2,588)	(3,432)	(3,257)
<b>OPERATING PROFIT (LOSS)</b>	<b>(333)</b>	<b>(341)</b>	<b>(444)</b>	<b>(429)</b>

Interest (expense) income, net	373	(63)	498	(79)
Currency exchange gains (loss), net	(385)	12	(514)	16
Other income (loss), net	3	(37)	3	(48)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(343)</b>	<b>(429)</b>	<b>(457)</b>	<b>(540)</b>
Income tax (expense) credit	(30)	(67)	(40)	(84)
<b>NET INCOME (LOSS)</b>	<b>(373)</b>	<b>(496)</b>	<b>(497)</b>	<b>(624)</b>
Earning per share – Basic	(0.02)	(0.03)	(0.02)	(0.03)
Average number of shares used in computation of EPS	21,789,670	18,257,273	21,789,670	18,257,273
Earning per share – Diluted	(0.02)	(0.03)	(0.02)	(0.03)
Average number of shares used in computation of EPS for positive net income	21,789,670	18,257,273	21,789,670	18,257,273

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2013 average three months noon buying rate of 1 Euro = 1.3337 USD, and 2012 average three months noon buying rate of 1 Euro = 1.2583 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, 2013 Euros	September 30, 2012 Euros	September 30, 2013 \$US	September 30, 2012 \$US
Sales of goods	9,216	9,809	12,150	12,616
Net Sales of RPP and Leases	2,889	2,930	3,809	3,769
Sales of spare parts and Services	3,883	3,901	5,120	5,017
<b>TOTAL NET SALES</b>	<b>15,988</b>	<b>16,640</b>	<b>21,079</b>	<b>21,402</b>
Other revenues	4	2	5	3
<b>TOTAL REVENUES</b>	<b>15,993</b>	<b>16,642</b>	<b>21,085</b>	<b>21,404</b>
Cost of goods	(5,550)	(5,678)	(7,317)	(7,302)
Cost of RPP and Leases	(1,636)	(1,775)	(2,157)	(2,283)
Cost of spare parts & services	(2,740)	(2,645)	(3,613)	(3,402)
Cost of sales	(9,926)	(10,098)	(13,087)	(12,988)
<b>GROSS PROFIT</b>	<b>6,066</b>	<b>6,544</b>	<b>7,998</b>	<b>8,416</b>
Research & development expenses	(2,025)	(1,986)	(2,670)	(2,554)
Marketing & Sales expenses	(4,396)	(4,255)	(5,795)	(5,472)
G & A expenses	(2,627)	(2,587)	(3,463)	(3,327)
Total operating expenses	(9,048)	(8,828)	(11,929)	(11,354)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,982)</b>	<b>(2,284)</b>	<b>(3,931)</b>	<b>(2,938)</b>
Interest (expense) income, net	(239)	(4,004)	(315)	(5,150)
Currency exchange gains (loss), net	(1,142)	2	(1,506)	2
Other income (loss), net	3	2	4	2
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(4,360)</b>	<b>(6,285)</b>	<b>(5,748)</b>	<b>(8,084)</b>
Income tax (expense) credit	(91)	(92)	(120)	(118)
<b>NET INCOME (LOSS)</b>	<b>(4,451)</b>	<b>(6,377)</b>	<b>(5,869)</b>	<b>(8,202)</b>
Earning per share – Basic	(0.22)	(0.37)	(0.29)	(0.48)
Average number of shares used in computation of EPS	20,169,756	17,248,329	20,169,756	17,248,329
Earning per share – Diluted	(0.22)	(0.37)	(0.29)	(0.48)

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2013 average nine months noon buying rate of 1 Euro = 1.3184 USD, and 2012 average nine months noon buying rate of 1 Euro = 1.2862 USD.

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

	Sept. 30, 2013	June 30, 2013	Sept. 30, 2013	June 30, 2013
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short term investments	6,439	7,373	8,716	9,592
Total current assets	20,873	21,470	28,252	27,933
Total current liabilities	10,596	10,902	14,342	14,184
Shareholders' Equity	10,011	9,907	13,550	12,890

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3535 USD, on September 30, 2013 and at the noon buying rate of 1 Euro = 1.3011USD, on June 30, 2013.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**NINE MONTHS ENDED SEPTEMBER 30, 2013**  
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	1,103	8,112			9,216
Sales of RPPs & Leases	1,737	1,152			2,889
Sales of spare parts & services	<u>748</u>	<u>3,136</u>			<u>3,883</u>
<b>TOTAL NET SALES</b>	<b>3,588</b>	<b>12,400</b>			<b>15,988</b>
Other revenues	<u>4</u>	<u>--</u>			<u>4</u>
<b>TOTAL REVENUES</b>	<b>3,592</b>	<b>12,400</b>			<b>15,993</b>
<b>GROSS PROFIT</b>	<b>1,893 52.7%</b>	<b>4,173 33.7%</b>			<b>6,066 37.9%</b>
Research & Development	(696)	(493)	(836)		(2,025)
Total SG&A plus depreciation	<u>(1,647)</u>	<u>(4,113)</u>	<u>(116)</u>	<u>(1,146)</u>	<u>(7,023)</u>
<b>OPERATING PROFIT (LOSS)</b>	<b>(450)</b>	<b>(433)</b>	<b>(952)</b>	<b>(1,146)</b>	<b>(2,982)</b>

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