

May 12, 2015

# **EDAP Reports First Quarter 2015 Results**

# 1Q 2015 and Recent Operational Highlights

- Direct De Novo petition for Ablatherm HIFU submitted to the FDA in April 2015;
- Treatment-driven revenue from the HIFU division increased 17% year-over-year;
- Revenue for first quarter 2015 totaled EUR 6.2 million (USD 6.9 million);
- Canadian regulatory approval of Focal One; first device sold and initial patients successfully treated
- Cash position remains strong at EUR 11.3 million (USD 12.1 million) as of March 31, 2015;

LYON, France, May 12, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced financial results for the first quarter ended March 31, 2015 and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "This quarter is in line with our normal business cycle, while Q1 2014 was an exceptional one for the Company with five HIFU systems sold. More specifically, our results in the first quarter of 2015 reflect the continued momentum in HIFU treatments, as we achieved a 17% year-over-year increase in procedure-driven revenue from the HIFU division. This positive trend confirms the increasing adoption of HIFU among urologists and a growing appreciation of the technology as a safe and effective therapeutic option for prostate cancer patients."

Mr. Oczachowski added, "We are pleased to announce that, as planned, we submitted our Direct De Novo 510(k) petition for Ablatherm HIFU to the FDA after the close of the first quarter, and look forward to moving ahead with the review process."

Total revenue in the HIFU business for the quarter was EUR 1.6 million (USD 1.8 million). HIFU revenue included the sale of one Focal One system in Canada.

For the three months ended March 31, 2015, total revenue for the Lithotripsy division was EUR 4.6 million (USD 5.1 million), compared to EUR 4.5 million (USD 6.1 million), during the year ago period.

Gross profit for the first quarter 2015 was EUR 2.6 million (USD 2.9 million), compared to EUR 3.6 million (USD 4.9 million) for the year ago period. Gross profit margin on net sales was 41.5% in the first quarter of 2015, compared to 45.9% in the year ago period.

Operating expenses were EUR 3.2 million (USD 3.5 million) for the first quarter 2015, compared to EUR 3.0 million (USD 4.1 million) for the same period in 2014.

Operating loss for the first quarter was EUR 622,000 (USD 689,000), compared with operating income in the first quarter of 2014 of EUR 558,000 (USD 765,000).

Net loss for the first quarter 2015 was EUR 2.4 million (USD 2.7 million), or EUR 0.10 per diluted share, as compared to net income of EUR 840,000 (USD 1.1 million), or EUR 0.04 per diluted share, in the year ago period. Net loss in the first quarter 2015 included a non-cash interest expense of EUR 2.4 million to adjust the accounting fair value of the outstanding warrants.

# **Conference Call**

EDAP will hold a conference call on Wednesday, May 13, 2015 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 10065516. A live webcast of the conference call will be available online from the investor relations page of the Company's corporate website at <a href="https://www.edap-tms.com">www.edap-tms.com</a>.

After the live event, the webcast will remain available on EDAP's website, <u>www.edap-tms.com</u>, through June 13, 2015. In addition, a dial-in replay of the call will be available until May 20, 2015. 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 10065516.

### **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer outside the U.S. 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 for commercial distribution in Europe and some other countries including Mexico and Canada. EDAP TMS is currently pursuing a Direct De Novo 510(K) petition in parallel to a PMA for Ablatherm 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 <a href="http://www.edap-tms.com">http://www.hifu-planet.com</a>.

## 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 clearance 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-cleared 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 :	
	March 31,	March 31,	March 31,	March 31,	
	2015	2014	2015	2014	
	Euros	Euros	\$US	\$US	
Sales of goods	3,746	5,414	4,149	7,415	
Net Sales of RPP and Leases	1,029	998	1,140	1,367	
Sales of spare parts and					
Services	1,442	1,349	1,597	1,848	
TOTAL NET SALES	6,217	7,762	6,886	10,630	
Other revenues		3		4	
TOTAL REVENUES	6,217	7,765	6,886	10,634	
Cost of goods	(2,045)	(2,815)	(2,265)	(3,855)	
Cost of RPP and Leases	(644)	(505)	(713)	(692)	
Cost of spare parts & services	(948)	(881)	(1,050)	(1,206)	
Cost of sales	(3,637)	(4,201)	(4,028)	(5,753)	
GROSS PROFIT	2,580	3,564	2,858	4,881	
Research & development expenses	(773)	(686)	(857)	(939)	
Marketing & Sales expenses	(1,549)	(1,441)	(1,716)	(1,973)	
G & A expenses	(880)	(879)	(974)	(1,204)	
Total operating expenses	(3,202)	(3,006)	(3,547)	(4,116)	
OPERATING PROFIT (LOSS)	(622)	558	(689)	765	
Interest (expense) income, net	(2,350)	259	(2,602)	355	

Currency exchange gains (loss), net	565	55	626	76
Other income (loss), net	(3)	(3)	(3)	(4)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(2,410)	870	(2,669)	1,192
Income tax (expense) credit	(30)	(30)	(34)	(41)
NET INCOME (LOSS)	(2,440)	840	(2,703)	1,151
Earnings per share - Basic	(0.10)	0.04	(0.11)	0.05
Larinings per chare Dadie	(0.10)	0.04	(0.11)	0.03
Average number of shares used in computation of EPS	24,894,049	21,789,670	24,894,049	21,789,670
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**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2015 average three months noon buying rate of 1 Euro = 1.1075 USD, and 2014 average three months noon buying rate of 1 Euro = 1.3695 USD.

EDAP TMS S.A.

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

	Mar. 31, 2015 Euros	Dec. 31, 2014 Euros	Mar. 31, 2015 \$US	Dec. 31, 2014 \$US	
Cash, cash equivalents and short term investments	11,285	12,142	12,121	14,693	
Total current assets	26,792	26,552	28,778	32,130	
Total current liabilities	12,021	12,158	12,912	14,711	
Shareholders' Equity	12,829	15,141	13,780	18,322	

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0741 USD, on March 31, 2015 and at the noon buying rate of 1 Euro = 1.2101 USD, on December 31, 2014.

# EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION THREE MONTHS ENDED MARCH 31, 2015 (Amounts in thousands of Euros)

					Total After	
	HIFU Division	ı	UDS Division		FDA Trials Corporate Consolidation	
Sales of goods	861		2,885		3,746	
Sales of RPPs & Leases	608		422		1,029	
Sales of spare parts & services	146		1,296			
TOTAL NET SALES	1,615		4,603		6,217	
Other revenues		•				
TOTAL REVENUES	1,615		4,603		6,217	
GROSS PROFIT (% of Total Revenues)	866	54%	1,714	37%	2,580 429	%
(70 Or Total Nevellues)						

OPERATING PROFIT (LOSS)	(204)	102	(153)	(367)	(622)
Total SG&A plus depreciation	(675)	(1,387)		(367)	(2,429)
Research & Development	(395)	(225)	(153)		(773)

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