

# **EDAP Reports First Quarter 2011 Financial Results**

### First Quarter 2011 Highlights

- Lithotripsy division revenues increased 28.9% year-over-year to EUR 3.5 million (USD 4.9 million), fueled by innovative
  product line
- Gross profit increased 15.2% to EUR 2.0 million (USD 2.7 million)
- Total operating expenses declined 14.6% year-over-year to EUR 2.6 million (USD 3.7 million) as a result of implementation of operating cost reduction initiatives
- Ablatherm-HIFU data and innovative Sonolith range of lithotripters featured and highlighted in global medical meetings including European Urology Association (EAU), Japanese Urology Association (JUA) and American Urology Association (AUA).

LYON, France, May 24, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the first quarter ended March 31, 2011.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "Our innovative lithotripsy product line continues to be well received by the global urology community as exemplified by the strong reception received at the recent EAU, JUA and AUA meetings. During the first quarter, we sold seven lithotripsy devices as we continue to increase market share. At the beginning of the second quarter 2011, we have a strong pipeline of projects and continue to promote and penetrate new markets with our innovative and unique range of lithotripters."

Mr. Oczachowski concluded, "The clinical arsenal supporting Ablatherm-HIFU for the treatment of localized prostate cancer is continuing to expand as illustrated by the strong interest demonstrated at both the EAU in March and the AUA in May. The interest in Ablatherm-HIFU as the preferred focal therapy treatment option is continuing to build."

#### **First Quarter 2011 Results**

Total revenue for the first quarter 2011 increased by 12.1% to EUR 4.9 million (USD 6.8 million), as compared to EUR 4.3 million (USD 5.9 million) for the first quarter 2010. The first quarter 2011 revenue reflected the strong lithotripsy device sales.

Total revenue for the HIFU division was EUR 1.3 million (USD 1.8 million) for the first quarter 2010, compared to 1.6 million (USD 2.2 million) for the same period last year. Results for the first quarter 2011 reflected the sale of zero Ablatherm-HIFU devices, as compared to the sale in the first quarter of 2010 of one previously owned Ablatherm-HIFU machine.

For the three months ended March 31, 2011, total revenue for the lithotripsy division increased by 28.9% to EUR 3.5 million (USD 4.9 million), compared to EUR 2.7 million (USD 3.8 million) during the year ago period. During the first quarter 2011, the Company recorded sales of seven lithotripsy machines, including two Sonolith i-sys devices and four Sonolith i-move devices, up from a total of six devices sold in the first quarter of 2010.

Gross profit for the first quarter 2011 increased by 15.2% to EUR 2.0 million (USD 2.7 million), compared to EUR 1.7 million (USD 2.3 million) for the year ago period. Gross profit margin was 40.7% in the first quarter 2011, compared to 39.6% in the year ago period. The change in the gross profit margin was mostly attributed to higher sales volumes.

Operating expenses were EUR 2.6 million (USD 3.7 million) for the first quarter 2011, down 14.6% from EUR 3.1 million (USD 4.2 million) for the same period 2010. Operating loss was EUR 670,000 (USD 932,000) for the first quarter 2011, compared to EUR 1.4 million (USD 1.9 million) in the first quarter of 2010.

Net income for the first quarter 2011 was EUR 213,000 (USD 295,000), or EUR 0.02 per diluted share, as compared to net loss of EUR 2.6 million (USD 3.5 million), or EUR 0.24 per diluted share, in the first quarter of 2010. The first quarter 2011 net income included non-cash interest income of EUR 1.6 million (USD 2.2 million) to adjust the Company's convertible debt and outstanding warrants to fair value.

At March 31, 2011, cash and cash equivalents, including short-term treasury investments, were EUR 6.0 million (USD 8.6 million).

#### **Conference Call**

EDAP will hold a conference call on Tuesday, May 24, 2011 at 8:30 a.m. EDT to discuss the results. The dial-in numbers are (877) 407-4134 for domestic callers and (201) 689-8430 for international. The conference ID number for both is 372206. A live Webcast of the conference call will be available online from the investor relations page of the Company's corporate Website at <u>www.edap-tms.com</u>.

After the live Webcast, the call will remain available on EDAP's Website, <u>www.edap-tms.com</u>, through June 24, 2011. In addition, a telephonic replay of the call will be available until May 31 5, 2011. The replay dial-in numbers are 877-660-6853 for domestic callers and 201-612-7415 for international callers. Please use account number 356 and event ID number 372206.

#### About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm, the most advanced and clinically proven choice 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA, the ENLIGHT U.S. clinical study. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <u>http://www.edap-tms.com</u>, and <u>http://www.hifu-planet.com</u>.

#### **Forward-Looking Statements**

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials and expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device. Such statements are based on management's current expectations and are subject to a number of uncertainties, including the uncertainties of the regulatory process, and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference 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 Mont	Three Months Ended:		
	March 31, 2011 Euros	March 31, 2010 Euros	March 31, 2011 \$US	March 31, 2010 \$US
Sales of goods	2,424	1,760	3,368	2,408
Net Sales of RPP and Leases	1,192	1,239	1,656	1,695
Sales of spare parts and Services	1,222	1,334	1,698	1,826
TOTAL NET SALES	4,837	4,333	6,722	5,929
Other revenues	22	2	31	3
TOTAL REVENUES	4,860	4,335	6,753	5,932
Cost of goods	(1,453)	(987)	(2,019)	(1,351)
Cost of RPP and Leases	(634)	(660)	(880)	(903)
Cost of spare parts & services	(797)	(972)	(1,108)	(1,330)
Cost of sales	(2,884)	(2,619)	(4,007)	(3,585)
GROSS PROFIT	1,976	1,715	2,746	2,347
Research & development expenses	(536)	(753)	(745)	(1,031)
Marketing & Sales expenses	(1,340)	(1,446)	(1,862)	(1,979)

G & A expenses	(770)	(900)	(1,070)	(1,232)
Total operating expenses	(2,646)	(3,100)	(3,678)	(4,242)
OPERATING PROFIT (LOSS)	(670)	(1,384)	(932)	(1,895)
Interest (expense) income, net	1,367	(1,598)	1,900	(2,187)
Currency exchange gains (loss), net	(440)	462	(611)	632
Other income (loss), net	2		3	
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	259	(2,521)	361	(3,450)
Income tax (expense) credit	(47)	(69)	(65)	(94)
NET INCOME (LOSS)	213	(2,589)	295	(3,544)
Earning per share — Basic	0.02	(0.24)	0.02	(0.32)
Average number of shares used in computation of EPS	13,081,778	10,944,958	13,081,778	10,944,958
Earning per share — Diluted	0.02	(0.24)	0.02	(0.32)
Average number of shares used in computation of EPS for positive net income	13,350,304	10,980,385	13,350,304	10,980,385

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2011 average three months noon buying rate of 1 Euro = 1.3897 USD, and 2010 average three months noon buying rate of 1 Euro = 1.3686 USD.

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

	Mar. 31, 2011 Euros	Dec. 31, 2010 Euros	Mar. 31, 2011 \$US	Dec. 31 2010 \$US
Cash, cash equivalents and short term investments	6,038	8,888	8,564	11,794
Total current assets	27,590	29,868	39,129	39,634
Total current liabilities	13,814	14,658	19,592	19,451
Shareholders' Equity	9,753	8,900	13,832	11,809
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**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.4182 USD, on March 31, 2011 and at the noon buying rate of 1 Euro = 1.3270 USD, on December 31, 2010.

# EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION THREE MONTHS ENDED MARCH 31, 2011 (Amounts in thousands of Euros)

	HIFU Division		UDS Division		FDA Trials	Corporate	Total After Consolidation	
Sales of goods	139		2,285				2,424	
Sales of RPPs & Leases	868		324				1,192	
Sales of spare parts & services	288		934				1,222	
TOTAL NET SALES	1,295		3,542				4,837	
Other revenues	22		0				22	
TOTAL REVENUES	1,317		3,542				4,860	
GROSS PROFIT	665	51%	1,310	37%			1,976	41%
Research & Development	(211)		(184)		(141)		(536)	
Total SG&A plus depreciation	(654)		(1,118)		(13)	(325)	(2,110)	
OPERATING PROFIT (LOSS)	(200)		8		(154)	(325)	(670)	

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