

### **EDAP Reports Third Quarter 2010 Financial Results**

#### **Third Quarter Highlights**

- Revenues increased 15.5% year-over-year to EUR 5.3 million (USD 7.0 million)
- Gross margin rose 500 basis points over last year to 41.6%
- Operating loss, excluding lower FDA clinical trial expense, improved by EUR 576,000 to EUR 404,000
- Net loss improved by EUR 3.9 million to EUR 1.9 million
- Inventory expanded for year-end sales opportunities; strong, growing machine backlog
- Initiated robust cost initiatives to drive timely financial breakeven

LYON, France, Nov. 17, 2010 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter ended September 30, 2010.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are optimistic about the continuing development and traction of our Ablatherm-HIFU treatment for localized prostate cancer and other new oncology indications. A tremendous opportunity exists to position HIFU as the optimum treatment option for focal therapy. We are pleased with the advancement of the focal therapy trials underway in France and the high level of interest that urologists are expressing in this therapy.

"During the third quarter, we invested in augmenting our device inventory to be positioned to take advantage of fourth quarter sales opportunities in both Ablatherm-HIFU and lithotripsy. We currently have thirteen lithotripsy and two Ablatherm machines in our backlog and a strong pipeline that we expect to convert to backlog by the end of the year. This sales activity is in line with the medical device sales seasonality as hospitals deploy capital expenditures budgets late in the year."

Mr. Oczachowski continued, "We achieved several major milestones across both of our product lines. We expect to aggressively pursue all of these opportunities as we expand our sales and advance our clinical programs. At the same time, we understand the necessity of bringing the Company to financial breakeven and have implemented some initiatives to accelerate the alignment of operational costs to meet this important metric.

"The long-term data for localized prostate cancer that was published in September further validated the clinical experience that has been achieved across Europe over the past fifteen years. At the same time, we are pursuing earlier stage opportunities to expand the oncology applications of our HIFU technology through the research collaborations for HIFU ablating metastatic liver cancer and for combining HIFU with ultrasound sensitive liposomes to activate the targeted delivery of cancer drugs."

#### **Recent Strategic Milestones and Initiatives**

- HIFU for potential treatment of metastatic liver cancer: The first phase of the clinical protocol aimed at evaluating High Intensity Focused Ultrasound (HIFU) technology in patients with metastatic liver cancer was successfully completed. Clinical results observed fully conformed with those obtained in pre-clinical studies and validated HIFU as being an additional potential option to address liver cancer.
- Expansion of sales force to address large Japanese market for lithotripsy: EDAP strengthened its lithotripsy sales force in Japan to address one of the largest markets for the treatment of urinary stones. Earlier this year, EDAP received Japanese marketing approval for its fully integrated and robotized Sonolith i-sys lithotripsy device.
- HIFU for potential improvement of cancer drug delivery: Feasibility studies aimed at improving delivery of cancer drugs using a combination of ultrasound sensitive liposomes and High Intensity Focused Ultrasound (HIFU) were successfully completed.
- Favorable long-term HIFU data for treatment of localized prostate cancer: In September 2010, EDAP reported on a study of 803 patients with localized prostate cancer, treated with Ablatherm-HIFU from 1993 until 2007. This study, carried out by Dr. Sebastien Crouzet, Urologist at Edouard Herriot Hospital in Lyon, France, demonstrated the durability of efficacy outcomes of robotic Ablatherm-HIFU in the treatment of localized prostate cancer.

• Entry into fast growing China market: EDAP entered into an exclusive distribution agreement with Shaw Han Biomedical Co. Ltd to obtain approval of EDAP's Ablatherm-HIFU device for the treatment of prostate cancer and distribute the devices in China.

#### **Third Quarter Results**

Total revenue for the third quarter 2010 were EUR 5.3 million (USD 7.0 million), an increase of 15.5% as compared to EUR 4.6 million (USD 6.7 million) for the third quarter 2009.

Total revenue for the HIFU division was EUR 1.4 million (USD 1.9 million) for the third quarter 2010, compared to EUR 2.1 million (USD 3.0 million) for the same period last year. Results for the third quarter 2010 reflected increased net sales of spare parts and services.

For the three months ended September 30, 2010, total revenue for the lithotripsy division was EUR 3.9 million (USD 5.2 million), compared to EUR 2.5 million (USD 3.6 million) during the year ago period. During the third quarter 2010, the Company recorded sales of ten lithotripsy machines, including three Sonolith i-sys devices and four Sonolith i-move devices.

Gross profit for the third quarter 2010 was EUR 2.2 million (USD 2.9 million), compared to EUR 1.7 million (USD 2.4 million) for the year ago period. Gross profit margin was 41.6% in the third quarter 2010, compared to 36.7% in the year ago period.

Operating expenses were EUR 3.0 million (USD 4.0 million) for the third quarter 2010, compared to EUR 3.2 million (USD 4.6 million) for the same period 2009. Third quarter 2010 operating expenses included EUR 393,000 related to the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU, down by 42% on a sequential quarter basis from EUR 674,000 in the second quarter 2010.

Operating loss was EUR 797,000 (USD 1.0 million) for the third quarter 2010, compared to EUR 1.5 million (USD 2.2 million) for the year ago period. Excluding U.S. FDA trial expenses, third quarter 2010 operating loss was EUR 404,000.

Net loss for the third quarter 2010 was EUR 1.9 million (USD 2.5 million), or EUR 0.17 per diluted share, compared to a net loss of EUR 5.8 million (USD 8.3 million), or EUR 0.55 per diluted share, in the year ago period. The third quarter 2010 net loss included a non-cash interest expense of EUR 0.2 million (USD 0.3 million) to adjust the Company's convertible debt and outstanding warrants to fair value, compared to a EUR 4.0 million (USD 5.7 million) non-cash expense during the prior year period.

At September 30, 2010, cash and cash equivalents, including short-term treasury investments, were EUR 8.0 million (USD 10.9 million). The Company deployed its cash during the third quarter 2010 to replenish its device inventories.

#### **Conference Call**

EDAP will hold a conference call on Wednesday, November 17, 2010 at 8:30 a.m. EST 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 359599. 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 Webcast, the call will remain available on EDAP's Website, <a href="www.edap-tms.com">www.edap-tms.com</a>, through December 17, 2010. In addition, a telephonic replay of the call will be available until November 24, 2010. 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 359599.

#### **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 <a href="http://www.edap-tms.com">http://www.edap-tms.com</a>, and <a href="http://www.hifu-planet.com">http://www.hifu-planet.com</a>.

#### **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 Months Ended:

Three Months Ended:

	Inree Mont	ns Ended:	Three Months Ended.	
	September 30,	September 30,	September 30,	September 30,
	2010	2009	2010	2009
	Euros	Euros	\$US	\$US
Sales of goods	2,823	2,100	3,706	3,030
Net Sales of RPP and Leases	1,090	1,160	1,431	1,675
Sales of spare parts and services	1,432	1,365	1,879	1,970
TOTAL NET SALES	5,345	4,625	7,015	6,674
Other revenues	3	3	3	4
TOTAL REVENUES	5,348	4,628	7,019	6,678
Cost of goods	(1,502)	(1,420)	(1,971)	(2,049)
Cost of RPP and Leases	(583)	(558)	(765)	(805)
Cost of spare parts and services	(1,036)	(953)	(1,360)	(1,376)
Cost of sales	(3,121)	(2,931)	(4,096)	(4,230)
GROSS PROFIT	2,227	1,697	2,923	2,448
Research & development expenses	(692)	(964)	(909)	(1,392)
Marketing & Sales expenses	(1,500)	(1,304)	(1,969)	(1,882)
G & A expenses	(832)	(939)	(1,091)	(1,355)
Total operating expenses	(3,024)	(3,208)	(3,969)	(4,629)
OPERATING PROFIT (LOSS)	(797)	(1,511)	(1,046)	(2,181)
Interest (expense) income, net	(569)	(4,362)	(747)	(6,295)
Currency exchange gains (loss), net	(491)	57	(644)	82
Other income (loss), net		1		1
INCOME (LOSS) BEFORE TAXES				
AND MINORITY INTEREST	(1,857)	(5,816)	(2,438)	(8,395)
Income tax (expense) credit	(29)	48	(38)	69
NET INCOME (LOSS)	(1,886)	(5,768)	(2,476)	(8,326)
Earning per share — Basic	(0.17)	(0.55)	(0.22)	(0.80)
Average number of shares used in computation of EPS	11,284,837	10,413,985	11,284,837	10,413,985
Earning per share — Diluted	(0.17)	(0.55)	(0.22)	(0.80)
Average number of shares used in computation of EPS for				
positive net income	11,320,262	10,467,966	11,320,262	10,467,966

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2010 average three months noon buying rate of 1 Euro = 1.3125 USD, and 2009 average three months noon buying rate of 1 Euro = 1.4430 USD.

# EDAP TMS S.A. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Nine Month	ns Ended: Nine Month		ıs Ended:	
	September 30,	September 30,	September 30,	September 30,	
	2010	2009	2010	2009	
	Euros	Euros	\$US	\$US	
Sales of goods	7,464	8,638	9,818	11,834	
Net Sales of RPP and Leases	3,625	4,008	4,768	5,490	
Sales of spare parts and services	4,076	4,177	5,361	5,640	
TOTAL NET SALES	15,165	16,763	19,948	22,963	
Other revenues	506	42	665	58	
TOTAL REVENUES	15,670	16,805	20,614	23,021	
Cost of goods	(4,277)	(5,079)	(5,627)	(6,958)	
Cost of RPP and Leases	(1,931)	(2,008)	(2,540)	(2,751)	
Cost of spare parts and services	(3,032)	(2,721)	(3,989)	(3,727)	
Cost of sales	(9,241)	(9,808)	(12,156)	(13,436)	
GROSS PROFIT	6,430	6,997	8,458	9,586	
Research & development expenses	(2,593)	(2,963)	(3,411)	(4,059)	
Marketing & Sales expenses	(4,709)	(4,391)	(6,194)	(6,015)	
G & A expenses	(2,575)	(2,944)	(3,387)	(4,033)	
Total operating expenses	(9,877)	(10,298)	(12,992)	(14,107)	
OPERATING PROFIT (LOSS)	(3,447)	(3,300)	(4,534)	(4,521)	
Interest (expense) income, net	(1,993)	(5,823)	(2,622)	(7,976)	
Currency exchange gains (loss), net	803	(256)	1,056	(351)	
Other income (loss), net	(2)		(2)		
INCOME (LOSS) BEFORE TAXES					
AND MINORITY INTEREST	(4,639)	(9,379)	(6,103)	(12,852)	
Income tax (expense) credit	(854)	(15)	(1,123)	(21)	
NET INCOME (LOSS)	(5,493)	(9,395)	(7,226)	(12,872)	
Earning per share — Basic	(0.49)	(0.90)	(0.64)	(1.24)	
Average number of shares used in computation of EPS	11,284,837	10,413,985	11,284,837	10,413,985	
Earning per share — Diluted	(0.49)	(0.90)	(0.64)	(1.24)	
Average number of shares used in computation of EPS for positive					
net income	11,355,075	10,422,816	11,355,075	10,422,816	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2010 average nine months noon buying rate of 1 Euro = 1.3154 USD, and

# EDAP TMS S.A. CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

(Amounts in thousands of Euros and U.S. Dollars)

	Sept. 30, 2010 Euros	June 30, 2010 Euros	Sept. 30, 2010 \$US	June 30, 2010 \$US
Cash, cash equivalents and short term investments	8,012	11,380	10,898	13,987
Total current assets	29,085	32,564	38,922	39,447
Total current liabilities	13,730	15,244	18,675	18,737
Shareholders' Equity	9,540	10,431	12,976	12,821

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3602 USD, on September 30, 2010 and at the noon buying rate of 1 Euro = 1.2291 USD, on June 30, 2010.

**Total After** 

## EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION

NINE MONTHS ENDED SEPTEMBER 30, 2010 (Amounts in thousands of Euros)

					Total After
	HIFU Division	UDS Division	FDA Trials	Corporate	Consolidation
Sales of goods	1,104	6,360			7,464
Sales of RPPs and Leases	2,728	897			3,625
Sales of spare parts and services	1,080	2,995			4,076
TOTAL NET SALES	4,912	10,253			15,165
Other revenues	5	500			506
TOTAL REVENUES	4,917	10,753			15,670
GROSS PROFIT	2,672	3,758			6,430
(as a % of Net Sales)	54.4%	36.6%			42.4%
Research & Development	(461)	(619)	(1,512)		(2,593)
Total SG&A plus depreciation	(2,586)	(3,498)	(149)	(1,051)	(7,284)
OPERATING PROFIT (LOSS)	(375)	(359)	(1,661)	(1,051)	(3,447)

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