

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

### **Outlines Strategic Initiatives to Counter Weak Global Economic Environment**

LYON, France, Aug 24, 2010 (GlobeNewswire via COMTEX News Network) --

- -- Maintained robust cash position of EUR 11.4 million (USD 14.0 million) at June 30, 2010
- -- Raised visibility for positive long-term European experience of Ablatherm(R)-HIFU with four abstracts presented at American Urological Association (AUA)
- -- Entering patient follow-up phase after completing enrollment in U.S. ENLIGHT Ablatherm-HIFU clinical trial
- -- Increasing global sales opportunities with receipt of European approval for Sonolith i-move and Japanese approval for Sonolith i-sys
- -- Enhancing U.S. lithotripsy market potential with submission of 510(k) marketing clearance application to U.S. FDA for Sonolith i-move
- -- Strengthening third quarter lithotripsy machine backlog with nine machines in pipeline to date
- -- Entered exclusive agreement with Lumenis to distribute state-of-the-art urological lasers in France

LYON, France, Aug. 24, 2010 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter ended June 30, 2010. The Company outlines strategic initiatives to counter the continuing weak global economic climate.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "Our second quarter results reflected the overall weak global economic environment and the resulting slowdown in hospital capital expenditures. In the face of these trends, we are undertaking several initiatives to broaden the market opportunities for our medical device portfolio. We are actively pursuing efforts for the clinical recognition of Ablatherm-HIFU for the treatment of localized prostate cancer. During the second quarter, four abstracts that outlined the long-term positive European experience were presented at the American Urological Association (AUA) 2010 Annual Meeting. The data confirmed that EDAP's lifestyle preserving Ablatherm treatment is on par with other more invasive treatment options, such as surgery or radiotherapy. Simultaneously, we are undertaking marketing initiatives to position HIFU as an alternative treatment for prostate cancer patients that did not respond to radiation treatments."

Mr. Oczachowski continued, "Prostate cancer treatment is currently going through a re-definition as the treatment approach transitions from a radical approach to a focal therapy approach that features focused treatment at the identified prostate cancer location. Due to its precision, accuracy and repeatability, EDAP's Ablatherm-HIFU is most advantageously positioned to address the focal therapy approach as it is being defined by the International Urology Community. We believe that the focal therapy approach represents a unique opportunity for Ablatherm HIFU to become the gold standard of treatment for prostate cancer. We at EDAP want to seize this tipping point opportunity and are now putting in place actions and plans to achieve this goal."

Mr. Oczachowski concluded, "Turning to our established lithotripsy franchise, EDAP continues to move forward with the rollout of its expanded product portfolio. In April 2010 at the European Associate Urology Congress, EDAP launched the Sonolith i-move, a compact, stand-alone lithotripter with a revolutionary infrared stereo-vision system for real-time, three-dimensional ultrasound localization of urinary stones. Following European approval, we sold two Sonolith i-move devices during the quarter. Our high-end Sonolith i-Sys lithotripsy device received Japanese approval in March 2010. We received our first sale in Japan in the weeks following approval and continue to cultivate positive sales leads that we should be able to convert in the coming months. Since the end of the second quarter 2010, the Company has built a strong promising backlog of nine lithotripsy systems, including four recently launched Sonolith i-move systems."

## Other Recent Developments

In June 2010, EDAP entered an exclusive agreement with Lumenis to distribute its high-technology urological lasers in France. Lumenis markets leading lasers that enable precise minimally invasive treatment for a wide array of urologic conditions such as benign prostatic hyperplasia (BPH) and bladder, urethral and kidney stones. These products are a natural, synergistic expansion of EDAP's product portfolio.

In July 2010, patient enrollment was completed in the Company's U.S. ENLIGHT Ablatherm-HIFU clinical trial, a multi-center Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA, and the Company entered the required two-year follow-up phase. In aggregate, 134 patients participated in the U.S. study.

In August 2010, EDAP filed its application for 510(k) marketing clearance with the U.S. FDA for its compact, multi-configurations Sonolith i-move lithotripsy device. Following receipt of FDA marketing clearance, EDAP should be well positioned to address all segments of the U.S. lithotripsy market offering the widest product range spanning compact to fully integrated devices.

#### Quarterly Results

Revenue for the second quarter 2010 was EUR 6.0 million (USD 7.6 million), compared to EUR 6.8 million (USD 9.4 million) for the second quarter 2009.

Total revenue for the HIFU division was EUR 1.9 million (USD 2.4 million) for the second quarter 2010, compared to EUR 2.2 million (USD 3.0 million) for the

same period last year. Results for the second quarter 2010 reflected the sale of one Ablatherm-HIFU machine.

For the three months ended June 30, 2010, total revenue for the lithotripsy division was EUR 4.1 million (USD 5.2 million), compared to EUR 4.6 million (USD 6.4 million) during the year ago period. During the second quarter 2010, the Company recorded sales of nine lithotripsy machines, including four Sonolith i-sys devices and two Sonolith i-move devices.

Gross profit for the second quarter 2010 was EUR 2.5 million (USD 3.1 million), compared to EUR 3.2 million (USD 4.4 million) for the year ago period. Gross profit margin was 41.5% in the second quarter 2010, compared to 46.6% in the year ago period.

Operating expenses were EUR 3.8 million (USD 4.7 million) for the second quarter 2010, compared to EUR 3.7 million (USD 5.1 million) for the same period 2009. Second quarter 2010 operating expenses included EUR 0.7 million related to the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU.

Operating loss was EUR 1.3 million (USD 1.6 million) for the second quarter 2010, compared to EUR 0.5 million (USD 0.7 million) for the year ago period. Excluding U.S. FDA trial expenses, second quarter 2010 operating loss was EUR 0.6 million.

Net loss for the second quarter 2010 was EUR 1.0 million (USD 1.3 million), or EUR 0.09 per diluted share, compared to a net loss of EUR 0.5 million (USD 0.7 million), or EUR 0.05 per diluted share, in the year ago period. The second quarter 2010 net loss included a non-cash interest income of EUR 0.6 million (USD 0.8 million) to adjust the Company's convertible debt and outstanding warrants to fair value, compared to a EUR 0.7 million (USD 0.9 million) non-cash income during the prior year period.

At June 30, 2010, cash and cash equivalents, including short-term treasury investments, were EUR 11.4 million (USD 14.0 million). With its current cash position, the Company continues to be well funded to pursue its strategic development projects, both in the U.S. and Europe.

#### **Conference Call**

EDAP will hold a conference call on Tuesday, August 24, 2010 at 8:30 a.m. ET 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 354299. 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 September 24, 2010. In addition, a telephonic replay of the call will be available until August 31, 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 354299.

# 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 Month	s Ended :	Three Months Ended :		
Sales of goods Net Sales of RPP and Leases	June 30, 2010 Euros 2,881 1,296	June 30, 2009 Euros 3,957 1,434	June 30, 2010 \$US 3,646 1,640	June 30, 2009 \$US 5,459 1,979	
Sales of spare parts and Services	1,310	1,387	1,658	1,913	
TOTAL NET SALES	5,487	6,678	6,943	9,351	
Other revenues	501	31	634	43	

TOTAL REVENUES	5,988	6,809	7,577	9,394
Cost of goods	(1,788)	(1,916)	(2,263)	(2,644)
Cost of RPP and Leases	(688)	(745)	(870)	(1,027)
Cost of spare parts & services	(1,024)	(974)	(1,296)	(1,344)
Cost of sales	(3,500)	(3,635)	(4,429)	(5,015)
GROSS PROFIT	2,488	3,174	3,148	4,379
Research & development expenses	(1, 147)	(1,067)	(1,452)	(1, 472)
	(1,763)			
G & A expenses	(843)	(1,023)	(1,067)	(1,411)
Total operating expenses	(3,753)	(3,694)	(4,749)	(5,097)
OPERATING PROFIT (LOSS)	(1,265)	(520)	(1,601)	(717)
Interest (expense) income, net Currency exchange gains (loss),	174	199	221	275
net	832	(192)	1,052	(264)
Other income (loss), net	(2)	(7)	(2)	(9)
INCOME (LOSS) BEFORE TAXES AND				
MINORITY INTEREST	(261)	(519)	(331)	(716)
Income tax (expense) credit	(756)	(20)	(957)	(28)
NET INCOME (LOSS)	(1,017)	(539)	(1,287)	(744)
Earning per share Basic Average number of shares used	(0.09)	(0.05)	(0.12)	(0.07)
in computation of EPS	11,124.274	9,937,816	11,124,274	9,937,816
Earning per share Diluted Average number of shares used in computation of EPS for	(0.09)			
positive net income	11,166,193	9,949,591	11,166,193	9,949,591

NOTE: Translated for convenience of the reader to U.S. dollars at the 2010 average three months noon buying rate of 1 Euro = 1.2653USD, and 2009 average three months noon buying rate of 1 Euro = 1.3797 USD.

# EDAP TMS S.A. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED) (Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Six Months Ended :		Six Months	Ended :	
	2010	June 30, 2009 Euros	June 30, 2010 \$US	2009	
Sales of goods Net Sales of RPP and Leases	4,641	6,539	6,112 3,339	8,731	
Sales of spare parts and Services	2,644	2,752	3,482	3,675	
TOTAL NET SALES	9,820	12,138	12,933	16,207	
Other revenues	503	39	662	53	
TOTAL REVENUES	10,323	12,177	13,595	16,260	
Cost of goods Cost of RPP and Leases			(3,655) (1,775)		
Cost of spare parts & services	(1,996)	(1,767)	(2,629)	(2,360)	

Cost of sales	(6,120)	(6,877)	(8,060)	(9,182)
GROSS PROFIT Research & development expenses Marketing & Sales expenses G & A expenses		5,301 (1,998) (3,087)	5,535 (2,503) (4,226)	(2,669) (4,122)
Total operating expenses	(6,853)	(7,090)	(9,025)	(9,467)
OPERATING PROFIT (LOSS) Interest (expense) income, net Currency exchange gains (loss), net	(1,424)	(1,789) (1,461) (313)	(1,875)	(1,950)
Other income (loss), net	(2)	(1)	(3)	(1)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(2,782)	(3,564)	(3,664)	(4,758)
Income tax (expense) credit	(825)	(63)	(1,086)	(84)
NET INCOME (LOSS)	(3,607)	(3,627)		
Earning per share Basic Average number of shares used	(0.32)	(0.36)		(0.49)
in computation of EPS Earning per share Diluted Average number of shares used in computation of EPS for	11,124,374 (0.32)	9,937,816 (0.36)		
positive net income	11,162,996	9,949,591	11,162,996	9,949,591

NOTE: Translated for convenience of the reader to U.S. dollars at the 2010 average six months noon buying rate of 1 Euro = 1.3170 USD, and 2009 average six months noon buying rate of 1 Euro = 1.3353 USD.

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

	June	Mar	June	Mar.
	30,	31,	30,	31,
	2010	2010	2010	2010
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short term investments Total current assets Total current liabilities Shareholders' Equity	32,564 15,244	11,342 31,875 13,341 11,287	39,447 18,737	

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2291 USD, on June 30, 2010 and at the noon buying rate of 1 Euro = 1.3526 USD, on March 31, 2010.

#### EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION THREE MONTHS ENDED JUNE 30, 2010 (Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods Sales of	929	3,712			4,641
RPPs & Leases	1,900	635			2,535

Sales of spare parts & services	662	1,983				2,644	
TOTAL NET SALES	3,491	6,329				9,820	
Other revenues	3	500				503	
TOTAL REVENUES	3,493	6,829				10,323	
GROSS PROFIT	1,913	54.8% 2,290	36.2%			4,203	42.8%
Research & Developm ent Total SG&A plus	(291)	(443)		(1,166)		(1,901)	
deprecia tion	(1,798)	(2,336)		(102)	(716)	(4,952)	
OPERATING PROFIT (LOSS)	(176)	(490)		(1,268)	(716)	(2,650)	

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