EDAP Reports First Quarter 2009 Financial Results

May 13, 2009 (GlobeNewswire via COMTEX News Network) --

First Quarter 2009 Highlights:

* FDA agreed changes to HIFU clinical trial protocol to accelerate enrollment
* Continuing dialogue with FDA for further changes to ensure timely completion of HIFU trials for treatment of prostate cancer
* Total revenue of EUR 5.4 million, up 19.4% year-over-year
* Ablatherm-HIFU RPP treatments increased 40% year-over-year
* Total Lithotripsy revenue of EUR 3.3 million, up 47.8% year-over-year
* Strong cash position of EUR 14.7 million (USD 19.5 million)

LYON, France, May 13, 2009 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the first quarter ended March 31, 2009.

For the first quarter 2009, the Company reported total revenue of EUR 5.4 million (USD 6.9 million), a 19.4% increase from EUR 4.5 million (USD 6.9 million) for the same period in 2008. Total revenue for the first quarter 2009 was driven by strong lithotripsy sales partially offset by the anticipated seasonality for HIFU device sales.

Total revenue for the Company's high intensity focused ultrasound (HIFU) division was EUR 2.0 million (USD 2.6 million) in the first quarter 2009, compared to EUR 2.2 million (USD 3.4 million) for the same period last year. Total revenue reflected the sale of one Ablatherm-HIFU machine during the first quarter 2009, compared with two in the first quarter of 2008.

Total revenue for the Company's lithotripsy division was EUR 3.3 million (USD 4.3 million) in the first quarter 2009, a 47.8% increase from EUR 2.3 million (USD 3.4 million) for the same period last year. The increase resulted from higher machine sales, as seven devices, including three Sonolith I-Sys systems were sold during the first quarter 2009, compared to five machines with no Sonolith I-Sys devices sold during the year ago period.

Gross profit for first quarter 2009 was EUR 2.1 million (USD 2.7 million), compared to EUR 2.0 million (USD 3.0 million) for the first quarter 2008. Gross profit margin was 39.7% in the first quarter of 2009 compared to 44.1% in the first quarter of 2008 primarily based on a year-over-year increase in sales of lower margin lithotripsy equipment.

Operating expenses decreased to EUR 3.4 million (USD 4.4 million) in the first quarter 2009, compared to EUR 3.5 million (USD 5.3 million) for the same period of 2008. First quarter 2009 operating expenses included EUR 0.4 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 first quarter 2009, compared to EUR 1.5 million (USD 2.4 million) for the year ago period. The year-over-year decrease in operating loss reflected higher lithotripsy machine sales in the first quarter of 2009.

The net loss for the first quarter 2009 was EUR 3.1 million (USD 4.0 million), or EUR 0.32 per diluted share, compared to net income of EUR 1.1 million (USD 1.6 million), or EUR 0.11 per diluted share in the year ago period. The first quarter 2009 net loss included a non-cash financial charge of EUR 1.2 million reflecting the adjustment of the Company's convertible debt and outstanding warrants to fair value, as opposed to a EUR 2.7 million non-cash gain the prior year first quarter.

Cash and cash equivalents, including short-term treasury investments, were EUR 14.7 million (USD 19.5 million) at March 31, 2009.

The Company recently worked successfully with the FDA and secured significant changes to its ENLIGHT clinical trial protocol for the treatment of prostate cancer. These changes include reduced minimum patient age, removal of some exclusion criteria,

decreased patient follow-up burden and the addition of three more treatment sites in the HIFU arm of the trial. These changes are now being implemented at most participating sites resulting in strong expectations for a major increase in patient enrollment.

The Company also indicates that discussions with the FDA are continuing regarding an alternative study control to the present cryo-ablation arm which has become an enrollment rate limiting factor for the completion of the trials.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We remain totally committed and focused on moving our HIFU prostate cancer treatment to commercialization in the U.S. We are very pleased that our discussions with the FDA have led to significant protocol changes for the trials which we believe will have a major impact to accelerate enrollment. As I have indicated in the past, we have been disappointed with the pace of trial enrollment which was below our expectation and believe these changes are an important step to rectify this situation. We remain in discussions with the FDA to advance the cryo arm of the study. Our major overall goal is to complete the trials within the targeted time. We are also strengthening our U.S. clinical team to better assist investigators and coordinators in their duties in order to achieve this goal."

Mr. Oczachowski continued, "We are quite pleased as well with the continued progress of our European business operations. Particularly we are encouraged by continued progress across our HIFU business as well as the strength of our lithotripsy division, driven by the continued penetration of our next generation Sonolith I-sys device."

Mr. Oczachowski concluded, "Given the current economic environment, we remain focused on conservatively managing our business, maintaining our cash and reducing costs while improving efficiencies. We are confident that our ample cash position and strong market position will continue to allow EDAP to weather the current volatility."

Separately, EDAP announced that Karim Fizazi has resigned from the Company's Board of Directors to pursue other interests. The Company thanks Karim for his dedication and support to EDAP over his seven year tenure. The Company is currently in the process of reviewing prospective board replacements in order to recruit a candidate that is in the best interest of all EDAP stakeholders.

Conference Call

EDAP will hold a conference call on Wednesday, May 13, 2009 at 8:30 a.m. ET to discuss first quarter 2009 financial results. The dial-in numbers are 1-888-241-0558 for domestic callers and 1-647-427-3417 for international. The conference ID number for both is 98142358. 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.

After the live Webcast, the call will remain available on EDAP's Website, www.edap-tms.com, through August 13, 2009. In addition, a telephonic replay of the call will be available until May 20, 2009. The replay dial-in numbers are 1-800-395-0363 for domestic callers and 1-402-220-2888 for international callers. Please use event ID number 98142358.

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 multicenter U.S. Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA. 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 http://www.edap-tms.com, http://www.hifu-planet.com and http://www.pcaresearch.com.

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. Such statements are based on management's current expectations and are subject to a number of uncertainties 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. 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:	
	March 31, 2009 Euros	March 31, 2008 Euros	March 31, 2009 $US	March 31, 2008 $US
Sales of goods	2,582	1,940	3,333	2,963
Net Sales of RPP and Leases	1,413	1,123	1,824	1,715
Sales of spare parts and Services	1,365	1,369	1,762	2,092
TOTAL NET SALES	5,360	4,432	6,919	6,770
Other revenues	8	64	11	98
TOTAL REVENUES	5,369	4,496	6,930	6,869
Cost of goods	(1,743)	(1,198)	(2,250)	(1,830)
Cost of RPP and Leases	(706)	(570)	(911)	(871)
Cost of spare parts & services	(793)	(772)	(1,024)	(1,180)
Cost of sales	(3,242)	(2,540)	(4,185)	(3,880)
GROSS PROFIT	2,127	1,956	2,745	2,988
Research & development expenses	(932)	(983)	(1,203)	(1,502)
Marketing & Sales expenses	(1,482)	(1,398)	(1,913)	(2,136)
G & A expenses	(981)	(1,114)	(1,267)	(1,702)
Total operating expenses	(3,396)	(3,496)	(4,384)	(5,340)
OPERATING PROFIT (LOSS)	(1,269)	(1,540)	(1,638)	(2,352)
Interest (expense) income, net	(1,660)	2,279	(2,143)	3,482
Currency exchange gains (loss), net	(122)	340	(157)	519
Other income (loss), net	6	7	8	11
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(3,045)	1,086	(3,930)	1,660

Income tax (expense) credit	(43)	(21)	(55)	(32)
NET INCOME (LOSS)	(3,088)	1,066	(3,986)	1,628
Earning per share - Basic	(0.32)	0.12	(0.42)	0.18
Average number of shares used in computation of EPS	9,582,593	9,200,757	9,582,593	9,200,757
Earning per share - Diluted	(0.32)	0.11	(0.42)	0.17
Average number of shares used in computation of EPS for positive net income	9,594,368	9,444,126	9,594,368	9,444,126

NOTE: Translated for convenience of the reader to U.S. dollars at the 2009 average three months noon buying rate of 1 Euro = 1.2909 USD, and 2008 average three months noon buying rate of 1 Euro = 1.5278 USD.

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

	March 31, 2009 Euros	Dec. 31, 2008 Euros	March 31, 2009 $US	Dec. 31, 2008 $US
Cash, cash equivalents and short term investments	14,699	14,970	19,492	20,837
Total current assets	35,392	35,786	46,311	49,158
Total current liabilities	14,506	14,457	19,237	20,123
Shareholders' Equity	14,133	17,191	18,742	23,929

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3261 USD, on March 31, 2009 and at the noon buying rate of 1 Euro = 1.3919 USD, on December 31, 2008.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2009
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	565	2,017			2,582
Sales of RPPs & Leases	1,125	287			1,412
Sales of					

spare parts & services	343		1,022					1,365	
TOTAL NET SALES	2,033		3,327					5,360	
Other revenues	1		7					8	
TOTAL REVENUES	2,235		3,334					5,369	
GROSS PROFIT	1,116	55%	1,010	30%				2,127	40%
Research & Development	(309)		(259)		(364)			(932)	
Total SG&A plus depreciation	(943)		(1,091)		(54)		(376)	(2,464)	
OPERATING PROFIT (LOSS)	(135)		(340)		(418)		(376)	(1,269)	

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