

EDAP Reports Third Quarter 2009 Financial Results

Highlights: , Nov 17, 2009 (GlobeNewswire via COMTEX News Network) -- Total revenues increased 19.8% for the first nine months of 2009 -- Ablatherm- HIFU revenue per procedure (RPP) treatments increased 36.7% for the first nine months of 2009 -- Sonolith I-Sys Lithotripter received U.S. FDA market clearance and first equipment sale signed -- Top U.S. urologist appointed to lead FDA HIFU clinical trial -- Robust cash position of EUR 12.8 million (USD 18.7 million) -- Strong pipeline of Ablatherm and lithotripsy machine sales entering the fourth quarter 2009

LYON, France, Nov. 17, 2009 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the nine months and third quarter ended September 30, 2009.

For the nine months ended September 30, 2009 total revenue increased 19.8% to EUR 16.8 million (USD 23.0 million), up from EUR 14.0 million (USD 21.3 million) during the year ago period. Total revenue for the first nine months of 2009 reflected strong HIFU revenue per procedure (RPP) volume and a more favorable product mix in lithotripsy machine sales.

For the third quarter 2009, the Company reported total revenue of EUR 4.6 million (USD 6.7 million). Total revenue for the third quarter 2009 reflected strong HIFU revenue per procedure (RPP) sales, somewhat offset by third quarter seasonality in lithotripsy sales.

Total revenue for the HIFU division increased to EUR 6.3 million (USD 8.7 million) for the first nine months of 2009, up 9.5% from EUR 5.8 million (USD 8.8 million) for the same period last year. During the first nine months of 2009, the Company sold three Ablatherm-HIFU machines compared to three HIFU device sold in the same period in the prior year. For the third quarter 2009, total revenue for the HIFU division increased to EUR 2.1 million (USD 3.0 million), up 10.4% from EUR 1.9 million (USD 2.8 million) for the same period last year. The increase was driven by 22.7% growth in revenue per procedure (RPP) sales compared to the year ago period.

For the nine months ended September 30, 2009, total revenue for the lithotripsy division was EUR 10.5 million (USD 14.4 million), an increase of 26.9% from EUR 8.3 million (USD 12.6 million) during the year ago period. Lithotripsy growth was driven by higher machine sales and a more favorable product mix of the Company's high-end Sonolith I-Sys device. During the first nine months of 2009, the Company recorded sales of 23 lithotripsy machines, including ten Sonolith I-Sys devices, compared to 23 machines, including four Sonolith I-Sys devices, sold during the first nine months of 2008. Total revenue for the lithotripsy division was EUR 2.5 million (USD 3.6 million) in the third quarter 2009. During the third quarter 2009, the Company sold five lithotripsy machines, including two high-range Sonolith I-Sys devices.

Gross profit for the first nine months of 2009 increased to EUR 7.0 million (USD 9.6 million), up 20.4% compared to EUR 5.8 million (USD 8.9 million) in the year ago period. Gross profit margin was 41.7% for the first nine months of 2009 compared to 41.8% in the prior year. Gross profit for the third quarter 2009 was EUR 1.7 million (USD 2.4 million), and gross profit margin was 36.7%.

For the nine months ended September 30, 2009, operating loss narrowed to EUR 3.3 million (USD 4.5 million) from EUR 4.3 million (USD 6.5 million) during the first nine months of 2008. Operating loss was EUR 1.5 million (USD 2.2 million) for the third quarter 2009. The year-over-year decrease in operating loss reflected a more favorable product mix of lithotripsy machine sales and higher HIFU-RPP sales in the nine months ended September 30, 2009 compared to the same period last year.

The net loss for the third quarter 2009 was EUR 5.8 million (USD 8.3 million), or EUR 0.55 per diluted share, compared to a net loss of EUR 4.0 million (USD 5.9 million), or EUR 0.43 per diluted share in the year ago period. The third quarter 2009 net loss included a non-cash interest expense of EUR 4.0 million (USD 5.7 million) to reflect adjustment of the Company's convertible debt and outstanding warrants to fair value and the USD 2.9 million conversion of debt into equity, compared to a EUR 2.5 million (USD 3.7 million) non-cash expense during the prior year period.

Cash and cash equivalents, including short-term treasury investments, were EUR 12.8 million at September 30, 2009. For the nine months ended September 30, 2009 the Company's cash burn was EUR 2.2 million, compared to EUR 4.5 million in the first nine months of 2008.

Most of the 2009 cash burn to date was attributable to the U.S. FDA clinical trials and related financing disbursements, totaling EUR 2.2 million, while operations outside the U.S. were cash flow break even. The robust EUR 12.8 million or USD 18.7 million

cash position leaves the Company well funded to pursue its strategic development projects, both in the U.S. and in Europe.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "The FDA 510k clearance of our new and innovative Sonolith I-Sys Lithotripter was a significant milestone for the Company. We have our first U.S. sales contract in less than two months following the FDA clearance. The FDA clearance and initial U.S. sale validate Sonolith I-Sys as a versatile device positioned to succeed in both European and American markets. While revenues in the third quarter reflected historical seasonality, we are encouraged by business flow at the beginning of the fourth quarter with increasing order flow and a pipeline of two Ablatherm units and ten lithotripsy devices in addition to a strong pipeline of projects as we move toward the end of the year."

Mr. Oczachowski concluded, "In addition to developments and sales achievements during the third quarter, we remain focused on advancing our U.S. ENLIGHT clinical trial to support FDA approval of HIFU. At the end of September 2009, we organized a dedicated investigators meeting in New York. The strong attendance of all of our prestigious HIFU sites, with more than 40 investigators and coordinators participating, confirmed their commitment to successfully complete the trial. The team of investigators, strengthened by the active role of Dr. Gill, is clearly motivated to provide patients with a non-invasive treatment option that preserves quality of life. We are actively leveraging this enthusiasm to increase awareness and drive additional patient recruitment."

Conference Call

EDAP will hold a conference call on Tuesday, November 17, 2009 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 337006. 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 December 17, 2009. In addition, a telephonic replay of the call will be available until November 24, 2009. 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 337006.

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.hifu-planet.com and 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)

	Euros	Euros	\$US	\$US
Sales of goods	2,100	2,218	3,030	3,279
Net Sales of RPP and Leases	1,160	1,003	1,675	1,482
Sales of spare parts and Services	1,365	1,309		
TOTAL NET SALES	4,625	4,530		
Other revenues	3	38	4	56
TOTAL REVENUES	4,628	4,568		
Cost of goods	(1,420)	(1,369)	(2,049)	(2,023)
Cost of RPP and Leases	(558)	(556)	(805)	(822)
Cost of spare parts & services		(660)		
Cost of sales	(2,931)	(2,585)	(4,230)	
GROSS PROFIT	1,697	1,984	2,448	2,932
Research & development expenses	(964)	(1,012)	(1,392)	(1,496)
Marketing & Sales expenses	(1,304)	(1,317)	(1,882)	(1,947)
G & A expenses		(988)		
Total operating expenses	(3,208)	(3,318)	(4,629)	(4,903)
OPERATING PROFIT (LOSS)	(1,511)	(1,334)	(2,181)	(1,971)
<pre>Interest (expense) income, net</pre>	(4,362)	(2,871)	(6,295)	(4,243)
Currency exchange gains (loss), net		305	82	451
Other income (loss), net	1	(4)	1	(6)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(5,816)	(3,904)	(8,395)	(5,770)

<pre>Income tax (expense) credit</pre>	48		69	(129)
NET INCOME (LOSS)	(5,768)		(8,326)	
Earning per share - Basic	(0.55)	(0.43)	(0.80)	(0.63)
Average number of shares used in computation of EPS	10,413,985	9,356,372	10,413,985	9,356,372
Earning per share - Diluted	(0.55)	(0.43)	(0.80)	(0.63)
Average number of shares used in computation of EPS for positive net income	10,467,966	9,432,074	10,467,966	9,432,074

NOTE: Translated for convenience of the reader to U.S. dollars at the 2009 average three months noon buying rate of 1 Euro = 1.4430 USD, and 2008 average three months noon buying rate of 1 Euro = 1.4780 USD.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

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

except per share data)

	Nine Months Ended:		Nine Months Ended:	
	Sept. 30, 2009	Sept. 30, 2008	Sept. 30, 2009 \$US	Sept. 30, 2008
Sales of goods	8,638	6,461	11,834	9,839
Net Sales of RPP and Leases Sales of spare parts and Services	·	•	5,490 5,640	·
TOTAL NET SALES	16,763	13,904	22,963	21,172
Other revenues	42	130	58	197
TOTAL REVENUES	16,805	14,033	23,021	21,369
Cost of goods	(5,079)	(4,216)	(6,958)	(6,419)
Cost of RPP and Leases	(2,008)	(1,759)	(2,751)	(2,679)

Cost of spare parts & services			(3,727)	
Cost of sales	(9,808)	(8,220)	(13,436)	(12,516)
GROSS PROFIT	6,997	5,814	9,586	8,853
Research & development expenses		(3,099)	(4,059)	(4,720)
Marketing & Sales expenses	(4,391)	(3,997)	(6,015)	(6,086)
G & A expenses	(2,944)	(2,991)	(4,033)	
Total operating expenses	(10,298)	(10,087)	(14,107)	(15,361)
OPERATING PROFIT (LOSS) (3,300)	(4,274)	(4,521)	(6,508)
<pre>Interest (expense) income, net</pre>	(5,823)	1,941	(7,976)	2,955
Currency exchange gain (loss), net		239	(351)	364
Other income (loss),				
net		4		6
net INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST				
INCOME (LOSS) BEFORE TAXES AND MINORITY	(9,379)	(2,090)	(12,852)	(3,183)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST Income tax (expense) credit	(9,379) (15) 	(2,090) 97 	(12,852)	(3,183)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST Income tax (expense) credit	(9,379) (15) (9,395) ========	(2,090) 97 (1,994) ========	(12,852) (21) 	(3,183)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST Income tax (expense) credit NET INCOME (LOSS) Earning per	(9,379) (15) (9,395) ======== (0.90)	(2,090) 97 (1,994) ======== (0.21)	(12,852) (21) (12,872) ======= (1.24)	(3,183) 147 (3,036) ======== (0.32)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST Income tax (expense) credit NET INCOME (LOSS) Earning per share - Basic Average number of shares used in	(9,379) (15) (9,395) ======== (0.90) 10,413,985	(2,090) 97 (1,994) ======= (0.21) 9,356,372	(12,852) (21) (12,872) ======= (1.24)	(3,183) 147 (3,036) ======== (0.32) 9,356,372

for positive net

NOTE: Translated for convenience of the reader to U.S. dollars at the 2009 average nine months noon buying rate of 1 Euro = 1.3699 USD, and 2008 average nine months noon buying rate of 1 Euro = 1.5228 USD.

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CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

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

	Sept. 30, 2009 Euros	June 30, 2009 Euros	Sept. 30, 2009 \$US	June 30, 2009 \$US
Cash, cash equivalents and short term				
investments	12,767	13,606	18,678	19,076
Total current assets	29,881	32,471	43,031	44,866
Total current liabilities	12,285	12,975	17,974	18,191
Shareholders' Equity	10,682	14,135	15,629	19,818

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.4631 USD, on September 30, 2009 and at the noon buying rate of 1 Euro = 1.4020 USD, on June 30, 2009.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION (UNAUDITED)

NINE MONTHS ENDED SEPTEMBER 30, 2009

(Amounts in thousands of Euros)

	HIFU Division	Lithotripsy Division	Corporate	Total After Consolidation
Sales of goods	2,002	6,636		8,638
Sales of RPPs & Leases	3,154	854		4,008
Sales of spare parts & services	1,170	2,947		4,117
TOTAL NET	6,325	10,438	 	16,763
Other			 	
revenues	4	38		42

TOTAL					
REVENUES	5 6,330	10,476			16,805
GROSS					
PROFIT	3,646 57.6%	3,352 32.1%			6,997 41.7%
Research					
& Devel-		()			(0.050)
opment	(875)	(774)	(1,314)		(2,963)
Total SG8	- 7				
	XΑ				
plus deprecia	2				
-	₄ - (2,783)	(2 201)	(161)	(1 106)	/7 22E\
CIOII	(2,703)	(3,201)	(104)	(1,100)	(7,333)
OPERATING	Ţ				
PROFIT					
_	(12)	(624)	(1.478)	(1,186)	(3,300)
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CONTACT: EDAP TMS SA

Investor Relations / Legal Affairs

Blandine Confort +33 4 72 15 31 72 bconfort@edap-tms.com The Ruth Group

Investors:
R.J. Pellegrino
646-536-7009

rpellegrino@theruthgroup.com

Nick Laudico 646-536-7030

nlaudico@theruthgroup.com

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