EDAP Reports Third Quarter 2011 Financial Results

- Record Third Quarter Revenues -

- Sonolith i-move FDA Marketing Clearance Leads to First U.S. Sale in Fourth Quarter -

Third Quarter 2011 Highlights

- Reported 61% sequential quarter revenue increase to EUR 6.1 million (USD 8.6 million)
- Generated strong devices sales with fourteen lithotripsy devices and one Ablatherm-HIFU device
- Recorded 85% sequential operating loss reduction supported by top-line growth and continuation of cost reduction initiatives
- Garnered continuing robust market demand for innovative lithotripsy device portfolio with replenished backlog of twelve lithotripsy devices
- Stabilized cash position supported by record quarterly sales activity

LYON, France, Nov. 16, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter ended September 30, 2011 and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "The major milestone in the third quarter was the U.S. FDA marketing clearance for our latest lithotripter, the Sonolith i-move. This was rapidly confirmed by the first U.S. sale of Sonolith i-move to a partnership in the New York Metro area comprised of prestigious and well respected urologists. This is a significant achievement as it exemplifies both our sales team capabilities and the strong interest in the Sonolith i-move's unique features and innovation from the American urologists."

Mr. Oczachowski continued, "The strong third quarter 2011 device sales fueled our top-line growth and narrowed our operating loss. Market acceptance for our best-in-class product lines is continuing to build as we advance our strong and solid device backlog that includes twelve lithotripsy machines and two Ablatherm-HIFU machines now that we have reached the midpoint of the fourth quarter 2011."

Mr. Oczachowski concluded, "Recognition of the focal therapy approach for treating prostate cancer is building acceptance around the world, which clearly represents a strong opportunity for Ablatherm-HIFU adoption and positions our device as a 'must-have' complement to radical surgery. At such recent medical meetings as the European Robotic Urology Symposium and 31st Congress of the Société Internationale d'Urologie, we showcased our device to international urologists. Our clinical validation was augmented by poster presentations including the first results from our U.S. FDA ENLIGHT trials that showed low morbidity at 1, 6, 12 and 24 months post treatment."

Recent Developments

In November 2011, EDAP sold its first Sonolith i-move lithotripter in the United States to Empire Litho, a mobile urological and orthopedic equipment provider that services physicians at six New York City area hospitals. The sale was recorded three months following the receipt of U.S. FDA 510(k) marketing clearance in August 2011.

In October 2011, EDAP received marketing clearance from the Russian Federal Healthcare Department for its Sonolith i-move device. EDAP's revolutionary compact lithotripter received European (CE) approval in April 2010, Japanese approval in September 2011 and U.S. marketing clearance in August 2011.

Third Quarter 2011 Results

Total revenue for the third quarter 2011 was EUR 6.1 million (USD 8.6 million), a 14% increase compared to EUR 5.3 million (USD 7.0 million) for the third quarter 2010 and a 61% increase compared to EUR 3.8 million (USD 5.5 million) for the third quarter 2011.

Total revenue for the HIFU division was EUR 1.4 million (USD 1.9 million) for the third quarter 2011, compared to 1.9 million

(USD 2.4 million) for the same period last year. Results for the third quarter 2011 reflected the sale of one Ablatherm-HIFU device.

For the three months ended September 30, 2011, total revenue for the lithotripsy division was EUR 4.7 million (USD 6.7 million), compared to EUR 3.9 million (USD 5.2 million) during the year ago period. During the third quarter 2011, the Company recorded sales of fourteen lithotripsy machines, comprised of nine Sonolith i-move devices, three Sonolith i-sys devices and two Sonolith Praktis devices, compared to a total of ten devices sold in the third quarter of 2010.

Gross profit for the third quarter 2011 was EUR 2.6 million (USD 3.6 million), compared to EUR 2.2 million (USD 2.9 million) for the year ago period. Gross profit margin was 41.8% in the third quarter 2011, compared to 41.6% in the year ago period.

Operating expenses were EUR 2.8 million (USD 3.9 million) for the third quarter 2011, down 9% from EUR 3.0 million (USD 4.0 million) for the same period 2010. Operating loss was EUR 195,000 (USD 275,000) for the third quarter 2011, compared to EUR 797,000 (USD 1.0 million) in the third quarter of 2010. Excluding operating expenses of EUR 247,000 (USD 348,000) associated with the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU, third quarter 2011 operating income was EUR 52,000 (USD 73,000).

Net income for the third quarter 2011 was EUR 871,000 (USD 1.2 million), or EUR 0.07 per diluted share (USD 0.09 per diluted share), as compared to net loss for the third quarter of 2010 of EUR 1.9 million (USD 2.5 million), or EUR 0.17 per diluted share (USD 0.22 per diluted share). Net income for the third quarter included a non-cash interest income of EUR 779,000 to adjust the Company's outstanding convertible debt and warrants to fair market value.

At September 30, 2011, cash and cash equivalents, including short-term treasury investments, were EUR 5.5 million (USD 7.4 million), which reflected the stabilization of Company's cash position. The cash utilization during the third quarter 2011 was reduced to EUR 52,000 as a result of strong cash management.

Conference Call

EDAP will hold a conference call on Wednesday, November 16, 2011 at 8:30 a.m. EST to discuss the results. The dial-in numbers are (877) 317-6789 for domestic callers and (412) 317-6789 for international. The conference ID number for both is 10005020. 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 16, 2011. In addition, a telephonic replay of the call will be available until November 30, 2011. The replay dial-in numbers are 877-344-7529 for domestic callers and 412-317-0088 for international callers. Please use event passcode10005020.

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 (IDE) 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 (the Sonolith® range) 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, and http://www.hifu-planet.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, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials, expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device and the market potential for the Sonolith i-move 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.

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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:	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
	Euros	Euros	$US	$US
Sales of goods	3,740	2,823	5,265	3,706
Net Sales of RPP and Leases	944	1,090	1,329	1,431
Sales of spare parts and Services	1,433	1,432	2,017	1,879
TOTAL NET SALES	**6,116**	**5,345**	**8,612**	**7,015**
Other revenues	2	3	3	3
TOTAL REVENUES	**6,188**	**5,348**	**8,614**	**7,019**
Cost of goods	(1,981)	(1,502)	(2,789)	(1,971)
Cost of RPP and Leases	(521)	(583)	(733)	(765)
Cost of spare parts & services	(1,058)	(1,036)	(1,490)	(1,360)
Cost of sales	(3,560)	(3,121)	(5,012)	(4,096)
GROSS PROFIT	**2,558**	**2,227**	**3,602**	**2,923**
Research & development expenses	(663)	(692)	(934)	(909)
Marketing & Sales expenses	(1,320)	(1,500)	(1,859)	(1,969)
G & A expenses	(771)	(832)	(1,085)	(1,091)
Total operating expenses	(2,754)	(3,024)	(3,878)	(3,969)
OPERATING PROFIT (LOSS)	**(195)**	**(797)**	**(275)**	**(1,046)**
Interest (expense) income, net	560	(569)	789	(747)
Currency exchange gains (loss), net	596	(491)	839	(644)
Other income (loss), net	(54)	--	(76)	--
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**906**	**(1,857)**	**1,276**	**(2,438)**
Income tax (expense) credit	(35)	(29)	(50)	(38)
NET INCOME (LOSS)	**871**	**(1,886)**	**1,226**	**(2,476)**
Earning per share — Basic	0.07	(0.17)	0.09	(0.22)
Average number of shares used in computation of EPS	13,227,043	11,284,837	13,227,043	11,284,837
Earning per share — Diluted	0.07	(0.17)	0.09	(0.22)
Average number of shares used in computation of EPS for positive net income	13,340,380	11,320,262	13,340,380	11,320,262

NOTE: Translated for convenience of the reader to U.S. dollars at the 2011 average three months noon buying rate of 1 Euro = 1.4081 USD, and 2010 average three months noon buying rate of 1 Euro = 1.3125 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:	
	September 30,	**September 30,**	**September 30,**	**September 30,**
	2011	**2010**	**2011**	**2010**
	Euros	**Euros**	**$US**	**$US**
Sales of goods	7,475	7,464	10,603	9,818
Net Sales of RPP and Leases	3,296	3,625	4,675	4,768
Sales of spare parts and Services	3,970	4,076	5,631	5,361
TOTAL NET SALES	**14,741**	**15,165**	**20,909**	**19,948**
Other revenues	27	506	39	665
TOTAL REVENUES	**14,768**	**15,670**	**20,948**	**20,614**
Cost of goods	(4,240)	(4,277)	(6,014)	(5,627)
Cost of RPP and Leases	(1,731)	(1,931)	(2,455)	(2,540)
Cost of spare parts & services	(2,740)	(3,032)	(3,886)	(3,989)
Cost of sales	(8,710)	(9,241)	(12,355)	(12,156)
GROSS PROFIT	**6,058**	**6,430**	**8,593**	**8,458**
Research & development expenses	(1,845)	(2,593)	(2,618)	(3,411)
Marketing & Sales expenses	(4,083)	(4,709)	(5,792)	(6,194)
G & A expenses	(2,255)	(2,575)	(3,199)	(3,387)
Total operating expenses	(8,184)	(9,877)	(11,608)	(12,992)
OPERATING PROFIT (LOSS)	**(2,126)**	**(3,447)**	**(3,015)**	**(4,534)**
Interest (expense) income, net	1,754	(1,993)	2,489	(2,622)
Currency exchange gains (loss), net	195	803	277	1,056
Other income (loss), net	(54)	(2)	(76)	(2)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(230)**	**(4,639)**	**(326)**	**(6,103)**
Income tax (expense) credit	(130)	(854)	(184)	(1,123)
NET INCOME (LOSS)	**(359)**	**(5,493)**	**(510)**	**(7,226)**
Earning per share — Basic	(0.03)	(0.49)	(0.04)	(0.64)
Average number of shares used in computation of EPS	13,227,043	11,284,837	13,227,043	11,284,837
Earning per share — Diluted	(0.03)	(0.49)	(0.04)	(0.64)
Average number of shares used in computation of EPS for positive net income	13,543,436	11,355,075	13,543,436	11,355,075

NOTE: Translated for convenience of the reader to U.S. dollars at the 2011 average nine months noon buying rate of 1 Euro = 1.4184 USD, and 2010 average nine months noon buying rate of 1 Euro = 1.3154 USD.

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CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

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

	Sept. 30, 2011	June 30, 2011	Sept. 30, 2011	June 30, 2011
	Euros	Euros	$US	$US
Cash, cash equivalents and short term investments	5,482	5,533	7,373	8,036
Total current assets	25,915	24,990	34,855	36,291
Total current liabilities	12,530	12,236	16,853	17,769
Shareholders' Equity	9,347	8,670	12,572	12,591

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3450 USD, on September 30, 2011 and at the noon buying rate of 1 Euro = 1.4522 USD, on June 30, 2011.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION

NINE MONTHS ENDED SEPTEMBER 30, 2011

(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	814	6,661			7,475
Sales of RPPs & Leases	2,387	908			3,296
Sales of spare parts & services	893	3,077			3,970
TOTAL NET SALES	**4,094**	**10,646**			**14,741**
Other revenues	27	--			27
TOTAL REVENUES	**4,122**	**10,646**			**14,768**
GROSS PROFIT	**2,271**	**3,787**			**6,058**
(as a % of Net Sales)	**55.5%**	**35.6%**			**41.1%**
Research & Development	(728)	(556)	(561)		(1,845)
Total SG&A plus depreciation	(1,889)	(3,449)	(58)	(943)	(6,338)
OPERATING PROFIT (LOSS)	**(347)**	**(217)**	**(619)**	**(943)**	**(2,126)**

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Source: EDAP TMS SA