EDAP Reports Second Quarter 2011 Financial Results

Sonolith i-move Approved by U.S. FDA

Second Quarter 2011 Highlights

- Received U.S. FDA 510(k) marketing clearance in August 2011 for Sonolith i-move device, a technologically advanced compact mobile lithotripter
- Obtained marketing approval in Japan in June 2011 for Sonolith i-move
- Drove market demand for renewed lithotripsy product range with significant lithotripsy backlog with up to fifteen devices
- Advancing Ablatherm-HIFU research initiatives in line with focal therapy strategy to treat localized prostate cancer
- Cost reduction initiatives progressing well with a 26% year-over-year operating expense decrease that supports cash management program

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

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "The U.S. FDA 510(k) marketing clearance for our Sonolith® i-move clearly demonstrates EDAP's successful track record of obtaining FDA approvals. This is very encouraging as we move forward with our Ablatherm-HIFU clinical trial in the U.S., as we have completed more than half of the two-year follow-up phase. Our lithotripsy business is now fully commercialized in the U.S. and EDAP is well positioned to become a U.S. market leader based on our status as the only lithotripsy manufacturer with a renewed range of innovative devices. We showcased our Sonolith i-move at the American Urological Association medical meeting in May 2011 and generated several sales leads. With the approval behind us, we are focused on advancing the sales process that includes holding upcoming product demonstrations and generating greater awareness across the U.S. urology community."

Mr. Oczachowski continued, "The second quarter reflected an unusually low level of activity during the period, as a number of sales projects shifted into the third quarter. Consequently as we reach the end of August, we have a very significant device backlog totaling fifteen lithotripsy devices and one Ablatherm-HIFU device. We are very excited that a portion of these confirmed purchase orders are coming from countries where we recently received marketing approvals for the Sonolith i-move, such as South Korea and Japan."

Recent Developments

In August 2011, EDAP secured U.S. FDA 510(k) marketing clearance for its Sonolith i-move device for the fragmentation of kidney stones, extracorporeal shock wave lithotripsy procedures and endourology applications. EDAP's established sales force is cultivating sales leads in the U.S., the second largest lithotripsy market worldwide.

In August 2011, EDAP's development partnership won a €2.4 million grant for further development of Ablatherm-HIFU technology to incorporate improved imaging and diagnostic techniques in line with the focal therapy approach for treating localized prostate cancer. The development partnership, comprised of EDAP, Edouard Herriot Hospital, and SuperSonic Imagine, received the highly competitive French government grant.

In June 2011, EDAP received marketing approval of its Sonolith i-move lithotripter in Japan. EDAP's experienced direct sales force, equipped with a full range of innovative devices, is taking market share in Japan, the largest global lithotripsy market.

Second Quarter 2011 Results

Total revenue for the second quarter 2011 was EUR 3.8 million (USD 5.5 million), as compared to EUR 6.0 million (USD 7.6 million) for the second quarter 2010.

Total revenue for the HIFU division was EUR 1.4 million (USD 2.1 million) for the second quarter 2011, compared to 1.9 million (USD 2.4 million) for the same period last year. Results for the second quarter 2011 reflected the sale of one Ablatherm-HIFU device, as compared to the sale in the second quarter of 2010 of one Ablatherm-HIFU machine.

For the three months ended June 30, 2011, total revenue for the lithotripsy division was EUR 2.4 million (USD 3.4 million), compared to EUR 4.1 million (USD 5.2 million) during the year ago period. During the second quarter 2011, the Company recorded sales of three lithotripsy machines, comprised of three Sonolith i-move devices, compared to a total of nine devices sold in the second quarter of 2010.

Gross profit for the second quarter 2011 was EUR 1.5 million (USD 2.2 million), compared to EUR 2.5 million (USD 3.2 million) for the year ago period. Gross profit margin was 40.2% in the second quarter 2011, compared to 41.5% in the year ago period. The second quarter 2010 gross profit margin was favorably impacted by a one-time French government grant of EUR 500,000.

Operating expenses were EUR 2.8 million (USD 4.1 million) for the second quarter 2011, down 26% from EUR 3.8 million (USD 4.7 million) for the same period 2010. Operating loss was EUR 1.3 million (USD 1.8 million) for the second quarter 2011, compared to EUR 1.3 million (USD 1.6 million) in the second quarter of 2010.

Net loss for the second quarter 2011 was EUR 1.4 million (USD 2.1 million), or EUR 0.11 per diluted share, as compared to net loss of EUR 1.0 million (USD 1.3 million), or EUR 0.09 per diluted share, for the second quarter of 2010.

At June 30, 2011, cash and cash equivalents, including short-term treasury investments, were EUR 5.5 million (USD 8.0 million), which reflected the Company's continued investment in sales and marketing in support of its robust device pipeline. The cash utilization during the second quarter 2011 was reduced to EUR 0.5 million as a result of strong cash management.

Conference Call

EDAP will hold a conference call on Tuesday, August 30, 2011 at 8:30 a.m. EDT 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 10002440. 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 September 30, 2011. In addition, a telephonic replay of the call will be available until September 7, 2011. The replay dial-in numbers are 877-344-7529 for domestic callers and 412-317-0088 for international callers. Please use event passcode 10002440.

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 :	
	June 30, 2011 Euros	June 30, 2010 Euros	June 30, 2011 $US	June 30, 2010 $US
Sales of goods	1,312	2,881	1,912	3,646
Net Sales of RPP and Leases	1,160	1,296	1,691	1,640
Sales of spare parts and Services	1,316	1,310	1,917	1,658
TOTAL NET SALES	**3,788**	**5,487**	**5,520**	**6,943**
Other revenues	3	501	4	634
TOTAL REVENUES	**3,791**	**5,988**	**5,524**	**7,577**
Cost of goods	(806)	(1,788)	(1,175)	(2,263)
Cost of RPP and Leases	(577)	(688)	(841)	(870)
Cost of spare parts & services	(884)	(1,024)	(1,288)	(1,296)
Cost of sales	(2,267)	(3,500)	(3,304)	(4,429)
GROSS PROFIT	**1,524**	**2,488**	**2,220**	**3,148**
Research & development expenses	(646)	(1,147)	(941)	(1,452)
Marketing & Sales expenses	(1,423)	(1,763)	(2,074)	(2,231)
G & A expenses	(715)	(843)	(1,041)	(1,067)
Total operating expenses	(2,784)	(3,753)	(4,056)	(4,749)
OPERATING PROFIT (LOSS)	**(1,260)**	**(1,265)**	**(1,836)**	**(1,601)**
Interest (expense) income, net	(173)	174	(253)	221
Currency exchange gains (loss), net	39	832	57	1,052
Other income (loss), net	(2)	(2)	(2)	(2)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(1,396)**	**(261)**	**(2,034)**	**(331)**
Income tax (expense) credit	(47)	(756)	(69)	(957)
NET INCOME (LOSS)	**(1,443)**	**(1,017)**	**(2,103)**	**(1,287)**
Earning per share — Basic	(0.11)	(0.09)	(0.16)	(0.12)
Average number of shares used in computation of EPS	13,148,421	11,124,274	13,148,421	11,124,274
Earning per share — Diluted	(0.11)	(0.09)	(0.16)	(0.12)
Average number of shares used in computation of EPS for positive net income	13,465,858	11,166,193	13,465,858	11,166,193

NOTE: Translated for convenience of the reader to U.S. dollars at the 2011 average three months noon buying rate of 1 Euro =
1.4573 USD, and 2010 average three months noon buying rate of 1 Euro = 1.2653 USD.

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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 :	
	June 30, 2011	June 30, 2010	June 30, 2011	June 30, 2010

	Euros	Euros	$US	$US
Sales of goods	3,736	4,641	5,318	6,112
Net Sales of RPP and Leases	2,352	2,535	3,348	3,339
Sales of spare parts and Services	2,537	2,644	3,612	3,482
TOTAL NET SALES	**8,625**	**9,820**	**12,278**	**12,933**
Other revenues	25	503	36	662
TOTAL REVENUES	**8,650**	**10,323**	**12,313**	**13,595**
Cost of goods	(2,259)	(2,776)	(3,215)	(3,655)
Cost of RPP and Leases	(1,210)	(1,348)	(1,723)	(1,775)
Cost of spare parts & services	(1,681)	(1,996)	(2,394)	(2,629)
Cost of sales	(5,151)	(6,120)	(7,332)	(8,060)
GROSS PROFIT	**3,500**	**4,203**	**4,982**	**5,535**
Research & development expenses	(1,182)	(1,901)	(1,683)	(2,503)
Marketing & Sales expenses	(2,763)	(3,209)	(3,933)	(4,226)
G & A expenses	(1,485)	(1,743)	(2,113)	(2,296)
Total operating expenses	(5,430)	(6,853)	(7,729)	(9,025)
OPERATING PROFIT (LOSS)	**(1,930)**	**(2,650)**	**(2,748)**	**(3,490)**
Interest (expense) income, net	1,194	(1,424)	1,700	(1,875)
Currency exchange gains (loss), net	(400)	1,293	(570)	1,703
Other income (loss), net	--	(2)	--	(3)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(1,136)**	**(2,782)**	**(1,618)**	**(3,664)**
Income tax (expense) credit	(94)	(825)	(134)	(1,086)
NET INCOME (LOSS)	**(1,230)**	**(3,607)**	**(1,751)**	**(4,750)**
Earning per share — Basic	(0.09)	(0.32)	(0.13)	(0.43)
Average number of shares used in computation of EPS	13,148,421	11,124,374	13,148,421	11,124,374
Earning per share — Diluted	(0.09)	(0.32)	(0.13)	(0.43)
Average number of shares used in computation of EPS for positive net income	13,591,364	11,162,996	13,591,364	11,162,996

NOTE: Translated for convenience of the reader to U.S. dollars at the 2011 average six months noon buying rate of 1 Euro = 1.4235 USD, and 2010 average six months noon buying rate of 1 Euro = 1.3170 USD.

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CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

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

	June 30, 2011 Euros	March 31, 2011 Euros	June 30, 2011 $US	March 31, 2011 $US
Cash, cash equivalents and short term investments	5,533	6,038	8,036	8,564

Total current assets	24,990	27,590	36,291	39,129
Total current liabilities	12,236	13,814	17,769	19,592
Shareholders' Equity	8,670	9,753	12,591	13,832

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.4522 USD, on June 30, 2011
and at the noon buying rate of 1 Euro = 1.4182 USD, on March 31, 2011.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION

SIX MONTHS ENDED JUNE 30, 2011

(Amounts in thousands of Euros)

	HIFU Division		**UDS Division**		**FDA Trials**	**Corporate**	**Total After Consolidation**	
Sales of goods	423		3,312				3,736	
Sales of RPPs & Leases	1,700		652				2,352	
Sales of spare parts & services	596		1,942				2,537	
TOTAL NET SALES	**2,719**		**5,906**				**8,625**	
Other revenues	25		--				25	
TOTAL REVENUES	**2,744**		**5,906**				**8,650**	
GROSS PROFIT	**1,470**	**53.6%**	**2,029**	**34.4%**			**3,500**	**40.5%**
Research & Development	(446)		(401)		(336)		(1,182)	
Total SG&A plus depreciation	(1,310)		(2,271)		(35)	(631)	(4,248)	
OPERATING PROFIT (LOSS)	**(285)**		**(643)**		**(372)**	**(631)**	**(1,930)**	

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