August 30, 2012

EDAP Reports Second Quarter 2012 Revenues Up 61%

Second Quarter 2012 Highlights

- Revenues increased 61% year-over-year to EUR 6.1 million (USD 7.8 million)
- Strong lithotripsy sales with fourteen devices sold globally
- Strengthened third quarter device backlog to sixteen lithotripsy devices at the end of August 2012
- Completed U.S. FDA HIFU trial two year follow-up phase in June 2012
- On track to file PMA submission for Ablatherm-HIFU Phase II/III clinical trial in fourth quarter 2012
- Retained Greenleaf Health as strategic advisor on U.S. FDA submission

LYON, France, Aug. 30, 2012 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter ended June 30, 2012.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "Market acceptance of our renewed lithotripsy device platform continues to grow and contributed to our strong second quarter results. Our quarterly revenues rose 61% year-over-year reflecting the sale of fourteen lithotripsy devices. Our strengthened global sales team is continuing to transform sales leads into confirmed purchase orders as our replenished device backlog now stands at sixteen lithotripsy machines."

Mr. Oczachowski continued, "The two year anniversary of the last patient treated in the ENLIGHT trial was in June 2012 and the subsequent patient follow-up visits and data collection were completed in the second half of August in line with our IDE approved clinical protocol. The EDAP teams in the U.S. and France are compiling the PMA submission file, inclusive of both clinical and manufacturing data, for a projected filing in the fourth quarter of 2012.

Recent Developments

In August, EDAP retained Greenleaf Health LLC, a full service regulatory consulting firm, to provide high-level strategic guidance regarding the final stages of its Ablatherm-HIFU (High Intensity Focused Ultrasound) ENLIGHT U.S. Phase II/III clinical trial for the indication of low risk, localized prostate cancer. Greenleaf Health joins the established EDAP team of experts, both internal and external, inclusive of specialized legal, regulatory, and Clinical Research Organization advisors.

In August, EDAP confirmed the completion of all follow-up visits in connection with its Ablatherm-HIFU ENLIGHT U.S. clinical trial for the indication of low risk, localized prostate cancer. The Company is on track to file its Premarket Approval (PMA) with the U.S. FDA in the fourth quarter of 2012.

In June, EDAP's experts in HIFU technology presented their recent advances in the development of therapeutic focused ultrasound at the 12th International Symposium of Therapeutic Ultrasound (ISTU 2012) held in Germany. Top level technical presentations from the Company's partner INSERM, a French public research laboratory, addressed the successful evaluation of HIFU technology in targeting liver cancer. Other presentations related to HIFU as a therapy for prostate cancer, and included a poster that examined data from large cohorts of prostate cancer patients treated with the Ablatherm-HIFU over more than ten years, computed from a comprehensive clinical registry. The long-term results confirm EDAP as the most advanced player in the use of HIFU to address prostate cancer.

During the second quarter, the United Kingdom's National Institute for Health and Clinical Excellence (NICE), an independent organization that advises the National Health Service (NHS) on treatment and care, published guidance regarding focal therapy using HIFU to treat localized prostate cancer. In its International Procedure Guidance 424 on focal HIFU, NICE highlighted the 'potential for focal HIFU to avoid many of the complications of more radical treatment procedures' for localized prostate cancer in properly selected patients.

During the second quarter, EDAP's Ablatherm-HIFU was successfully utilized by leading urology surgeons at the St-Augustin Urology Clinic in Bordeaux, France to eradicate prostate cancer tumors via a focal approach. This highly regarded urology practice is now positioning the focal therapy procedure using EDAP's device as a 'must have complement' to robotic surgery.

In May, EDAP showcased its Ablatherm-HIFU and its Sonolith i-move at the American Urological Association (AUA) 2012 Annual Meeting. Prostate cancer data generated using Ablatherm-HIFU was featured in two scientific sessions at AUA and in three

poster presentations at the 27th Annual Meeting of the Engineering and Urology Society that was held concurrently with the AUA. EDAP experienced record attendance from U.S. urologists at its AUA booth.

Second Quarter 2012 Results

Total revenue for the second quarter 2012 was EUR 6.1 million (USD 7.8 million), up 61% as compared to EUR 3.8 million (USD 5.5 million) for the second quarter 2011.

Total revenue for the lithotripsy division was EUR 5.0 million (USD 6.4 million) for the three months ended June 30, 2012, up 112% as compared to EUR 2.4 million (USD 3.4 million) for the year ago period. During the second quarter 2012, the Company recorded sales of fourteen lithotripsy machines, comprised of six Sonolith i-move devices, four Sonolith i-sys devices and four Sonolith Praktis devices, compared to a total of three devices sold in the second quarter of 2011.

Total revenue for the HIFU division was EUR 1.1 million (USD 1.4 million) for the second quarter 2012, compared to EUR 1.4 million (USD 2.1 million) for the same period last year. The Company did not record any Ablatherm-HIFU machine sale in the second quarter 2012, while, results for the second quarter 2011 reflected the sale of one Ablatherm machine.

Gross profit for the second quarter 2012 was EUR 2.4 million (USD 3.1 million), compared to EUR 1.5 million (USD 2.2 million) for the year ago period. Gross profit margin was 39.1% in the second quarter 2012, compared to 40.2% in the year ago period. The change in the gross profit margin was attributed to the evolution in product mix.

Operating expenses were EUR 3.3 million (USD 4.2 million) for the second quarter 2012, compared to EUR 2.8 million (USD 4.1 million) for the same period in 2011. Operating loss was EUR 937,000 (USD 1.2 million) for the second quarter 2012, compared to EUR 1.3 million (USD 1.8 million) in the second quarter of 2011.

First Six Months 2012 Results

Total revenue for the first half of 2012 was EUR 11.0 million (USD 14.3 million), up 27% as compared to EUR 8.6 million (USD 12.3 million) for the first half of 2011.

Gross profit for the first half of 2012 was EUR 4.3 million (USD 5.6 million), up 23% from EUR 3.5 million (USD 5.0 million) for the first half of 2011. Gross profit margin was 39.2% in the first half of 2012, compared to 40.5% in the first half of 2011.

Operating loss for the first half of 2012 was stable at EUR 1.9 million (USD 2.5 million) and net loss for the first half of 2012 was EUR 5.6 million (USD 7.2 million), or EUR 0.30 per diluted share, as compared to net income of EUR 1.2 million (USD 1.8 million), or EUR 0.13 per diluted share, in the first half of 2011. Net loss in 2012 included a non-cash interest expense of EUR 3.3 million (USD 4.2 million) to reflect the accounting fair value impact of the January 2012 exchange offering on its convertible debentures and related warrants.

At June 30, 2012, cash and cash equivalents, including short-term treasury investments, were EUR 8.1 million (USD 10.2 million) and reflected the payment in the second quarter 2012 of USD 2.0 million to the debt holders following the $5.625 million registered direct placement in March 2012.

Conference Call

EDAP will hold a conference call today, Thursday, August 30, 2012, at 8:30 a.m. EDT to discuss the results. The dial-in numbers are 1-877-317-6789 for domestic callers and 1-412-317-6789 for international. The conference ID number for both is 10016762. 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, 2012. In addition, a telephonic replay of the call will be available until September 11, 2012. The replay dial-in numbers are 1-877-344-7529 for domestic callers and 1-412-317-0088 for international callers. Please use event passcode 10016762.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm(R), 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(R) 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 may contain forward-looking statements.. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device.,. Factors that may cause such a difference also may 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, 2012 Euros	June 30, 2011 Euros	June 30, 2012 $US	June 30, 2011 $US
Sales of goods	3,747	1,312	4,779	1,912
Net Sales of RPP and Leases	1,088	1,160	1,388	1,691
Sales of spare parts and Services	1,290	1,316	1,646	1,917
TOTAL NET SALES	**6,126**	**3,788**	**7,813**	**5,520**
Other revenues	--	3	--	4
TOTAL REVENUES	**6,126**	**3,791**	**7,813**	**5,524**
Cost of goods	(2,200)	(806)	(2,806)	(1,175)
Cost of RPP and Leases	(608)	(577)	(775)	(841)
Cost of spare parts & services	(925)	(884)	(1,179)	(1,288)
Cost of sales	(3,732)	(2,267)	(4,760)	(3,304)
GROSS PROFIT	**2,394**	**1,524**	**3,053**	**2,220**
Research & development expenses	(854)	(646)	(1,090)	(941)
Marketing & Sales expenses	(1,536)	(1,423)	(1,959)	(2,074)
G & A expenses	(940)	(715)	(1,199)	(1,041)
Total operating expenses	(3,331)	(2,784)	(4,248)	(4,056)
OPERATING PROFIT (LOSS)	**(937)**	**(1,260)**	**(1,195)**	**(1,836)**
Interest (expense) income, net	(2,109)	(173)	(2,690)	(253)
Currency exchange gains (loss), net	296	39	377	57
Other income (loss), net	33	(2)	42	(2)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(2,717)**	**(1,396)**	**(3,465)**	**(2,034)**
Income tax (expense) credit	49	(47)	62	(69)
NET INCOME (LOSS)	**(2,669)**	**(1,443)**	**(3,403)**	**(2,103)**

Earning per share — Basic	(0.15)	(0.11)	(0.19)	(0.16)
Average number of shares used in computation of EPS	18,257,273	13,148,421	18,257,273	13,148,421
Earning per share — Diluted	(0.15)	(0.11)	(0.19)	(0.16)
Average number of shares used in computation of EPS for positive net income	18,249,273	13,465,858	18,249,273	13,465,858

NOTE: Translated for convenience of the reader to U.S. dollars at the 2012 average three months noon buying rate of 1 Euro = 1.2753 USD, and 2011 average three months noon buying rate of 1 Euro = 1.4573 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, 2012 Euros	**June 30, 2011 Euros**	**June 30, 2012 $US**	**June 30, 2011 $US**
Sales of goods	6,212	3,736	8,076	5,318
Net Sales of RPP and Leases	2,201	2,352	2,862	3,348
Sales of spare parts and Services	2,550	2,537	3,316	3,612
TOTAL NET SALES	**10,963**	**8,625**	**14,253**	**12,278**
Other revenues	--	25	--	36
TOTAL REVENUES	**10,963**	**8,650**	**14,253**	**12,313**
Cost of goods	(3,575)	(2,259)	(4,648)	(3,215)
Cost of RPP and Leases	(1,243)	(1,210)	(1,615)	(1,723)
Cost of spare parts & services	(1,850)	(1,681)	(2,404)	(2,394)
Cost of sales	(6,667)	(5,151)	(8,668)	(7,332)
GROSS PROFIT	**4,296**	**3,500**	**5,585**	**4,982**
Research & development expenses	(1,563)	(1,182)	(2,032)	(1,683)
Marketing & Sales expenses	(2,959)	(2,763)	(3,846)	(3,933)
G & A expenses	(1,718)	(1,485)	(2,233)	(2,113)
Total operating expenses	(6,239)	(5,430)	(8,111)	(7,729)
OPERATING PROFIT (LOSS)	**(1,943)**	**(1,930)**	**(2,526)**	**(2,748)**
Interest (expense) income, net	(3,665)	1,194	(4,764)	1,700
Currency exchange gains (loss), net	28	(400)	36	(570)
Other income (loss), net	40	--	51	--
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(5,540)**	**(1,136)**	**(7,203)**	**(1,618)**
Income tax (expense) credit	(25)	(94)	(33)	(134)
NET INCOME (LOSS)	**(5,565)**	**(1,230)**	**(7,236)**	**(1,751)**
Earning per share — Basic	(0.30)	(0.09)	(0.40)	(0.13)
Average number of shares used in computation of EPS	18,257,273	13,148,421	18,257,273	13,148,421
Earning per share — Diluted	(0.30)	(0.09)	(0.40)	(0.13)
Average number of shares used in computation of EPS for positive net income	18,277,698	13,591,364	18,277,698	13,591,364

NOTE: Translated for convenience of the reader to U.S. dollars at the 2012 average six months noon buying rate of 1 Euro = 1.3001 USD, and 2011 average six months noon buying rate of 1 Euro = 1. 4235 USD.

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CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

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

	June 30, 2012 Euros	March 31, 2012 Euros	June 30, 2012 $US	March 31, 2012 $US
Cash, cash equivalents and short term investments	8,068	10,714	10,221	14,311
Total current assets	25,834	26,754	32,726	35,734
Total current liabilities	13,075	13,744	16,563	18,357
Shareholders' Equity	11,682	13,618	14,799	18,189

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2668 USD, on June 30, 2012 and at the noon buying rate of 1 Euro = 1.3356 USD, on March 31, 2012.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION

SIX MONTHS ENDED JUNE 30, 2012

(Amounts in thousands of Euros)

	HIFU Division		UDS Division		FDA Trials	Corporate	Total After Consolidation	
Sales of goods	466		5,746				6,212	
Sales of RPPs & Leases	1,505		696				2,201	
Sales of spare parts & services	454		2,096				2,550	
TOTAL NET SALES	**2,426**		**8,538**				**10,963**	
Other revenues	(3)		3				--	
TOTAL REVENUES	**2,422**		**8,541**				**10,963**	
GROSS PROFIT	**1,103**	**45.5%**	**3,193**	**37.4%**			**4,296**	**39.2%**
Research & Development	(717)		(451)		(395)		(1,563)	
Total SG&A plus depreciation	(1,349)		(2,697)		(42)	(589)	(4,676)	
OPERATING PROFIT (LOSS)	**(964)**		**46**		**(437)**	**(589)**	**(1,943)**	

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