



November 21, 2012

## EDAP Reports Third Quarter 2012 Results

### Recent Highlights

- Recorded robust 13% sales growth over the nine-month period
- Strong lithotripsy sales in third quarter and replenished fourth quarter device backlog in lithotripsy and Ablatherm-HIFU
- Generated positive cash flow during third quarter 2012
- Held productive pre-PMA meeting with U.S. FDA for Ablatherm-HIFU Phase II/III clinical trial

LYON, France, Nov. 21, 2012 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter ended September 30, 2012.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "Our revenues for the first nine months of 2012 reflected the robust sales growth of our renewed lithotripsy device platform. We continue to pursue sales and marketing initiatives around the globe and recently strengthened our U.S. sales team with the appointment of a Senior Sales Manager experienced in lithotripsy. The Company showed 13% revenue growth at the end of the third quarter of 2012, as compared to last year, and we foresee additional positive momentum for the remainder of this year. As we approach the last week of November, our replenished device backlog is comprised of 19 lithotripsy devices and three Ablatherm-HIFU devices."

### Recent Developments

In October 2012, EDAP appointed Bill Brown as U.S. based Senior Sales Manager. With more than two decades in the medical field and over ten years in lithotripsy device sales, Mr. Brown joins EDAP's U.S. team to enhance and strengthen the EDAP U.S. expansion program.

Also in October, urologists with long-term Ablatherm-HIFU (High Intensity Focused Ultrasound) experience participated in a panel discussions at Third International Symposium on Focused Ultrasound, in Washington, D.C. On two separate panels, they outlined their experience using ultrasound guided Ablatherm-HIFU to treat prostate cancer and highlighted Ablatherm-HIFU's substantial clinical track record, with more than 32,000 prostate cancer treatments successfully performed. Video from Professor Christian Chaussy's presentation regarding his 15 years of experience using ultrasound guided Ablatherm-HIFU to treat prostate cancer will be available shortly on the Symposium's website at <http://www.fusfoundation.org/Symposium-2012/focused-ultrasound-2012>.

In early November, EDAP held a productive pre-PMA meeting with the U.S. FDA to discuss the PMA submission for the Company's Ablatherm-HIFU Phase II/III clinical trial for the indication of low risk, localized prostate cancer. Based on the guidance received in this FDA interaction, EDAP is finalizing its PMA file for submission in January 2013.

### Third Quarter 2012 Results

Total revenue for the third quarter 2012 was EUR 5.7 million (USD 7.1 million), compared to EUR 6.1 million (USD 8.6 million) for the third quarter 2011.

Total revenue for the lithotripsy division was EUR 4.8 million (USD 6.0 million) for the three months ended September 30, 2012, up 1% as compared to EUR 4.7 million (USD 6.7 million) for the year ago period. During the third quarter 2012, the Company recorded sales of 12 lithotripsy machines, comprised of six Sonolith i-move devices, three Sonolith i-sys devices, and three Sonolith Praktis devices, compared to a total of 14 devices sold in the third quarter of 2011.

Total revenue for the HIFU division was EUR 0.9 million (USD 1.1 million) for the third quarter 2012, compared to EUR 1.4 million (USD 1.9 million) for the same period last year.

Gross profit for the third quarter 2012 was EUR 2.2 million (USD 2.8 million), compared to EUR 2.6 million (USD 3.6 million) for the year ago period. Gross profit margin was 39.6% in the third quarter 2012, compared to 41.8% in the year ago period. The change in the gross profit margin was attributed to the evolution in product mix.

Operating expenses were EUR 2.6 million (USD 3.3 million) for the third quarter 2012, compared to EUR 2.8 million (USD 3.9 million) for the same period in 2011. Operating loss was EUR 341,000 (USD 429,000) for the third quarter 2012, compared to EUR 195,000 (USD 275,000) in the third quarter of 2011.

Net loss for the third quarter 2012 was EUR 496,000 (USD 624,000), or EUR 0.03 per diluted share (USD 0.03 per diluted share), as compared to net income for the third quarter of 2011 of EUR 871,000 (USD 1.2 million), or EUR 0.07 per diluted share (USD 0.09 per diluted share).

At September 30, 2012, cash and cash equivalents, including short-term treasury investments, were EUR 8.1 million (USD 10.5 million). Net cash of EUR 74,000 was generated during the third quarter 2012 as a result of strong cash management.

### **First Nine Months 2012 Results**

Total revenue for the first nine months of 2012 was EUR 16.6 million (USD 21.4 million), up 12.7% as compared to EUR 14.8 million (USD 20.9 million) in the first nine months of 2011.

Gross profit for the first nine months of 2012 was EUR 6.6 million (USD 8.4 million), up 8.0% from EUR 6.1 million (USD 8.6 million) for the first nine months of 2011. Gross profit margin was 39.3% in the first nine months of 2012, compared to 41.0% in the first nine months of 2011.

Operating loss for the first nine months of 2012 was EUR 2.3 million (USD 2.9 million), compared to EUR 2.1 million (USD 3.0 million) for the same period of 2011.

Net loss for the first nine months of 2012 was EUR 6.4 million (USD 8.2 million), or EUR 0.37 per diluted share (USD 0.48 per diluted share), as compared to net loss of EUR 359,000 (USD 510,000), or EUR 0.03 per diluted share (USD 0.04 per diluted share), in the first nine months of 2011. Net loss for the first nine months of 2012 included a non-cash interest expense of EUR 3.5 million to reflect the accounting fair value impact of the January 2012 exchange offering on its convertible debentures and related warrants.

### **Conference Call**

EDAP will hold a conference call today, Wednesday, November 21, 2012 at 8:30 a.m. EST to discuss the results. The dial-in numbers are 1-877-317-6789 for domestic callers and 1-412-317-6789 for international callers. The conference ID number for both is 10020283. 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](http://www.edap-tms.com).

After the live webcast, the call will remain available on EDAP's website, [www.edap-tms.com](http://www.edap-tms.com), through December 21, 2012. In addition, a telephonic replay of the call will be available until December 6, 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 10020283.

### **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.

**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 :	
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011
	Euros	Euros	\$US	\$US
Sales of goods	3,597	3,740	4,527	5,265
Net Sales of RPP and Leases	729	944	917	1,329
Sales of spare parts and Services	1,350	1,433	1,699	2,017
<b>TOTAL NET SALES</b>	<b>5,676</b>	<b>6,116</b>	<b>7,143</b>	<b>8,612</b>
Other revenues	2	2	3	3
<b>TOTAL REVENUES</b>	<b>5,678</b>	<b>6,118</b>	<b>7,145</b>	<b>8,614</b>
Cost of goods	(2,083)	(1,981)	(2,621)	(2,789)
Cost of RPP and Leases	(533)	(521)	(670)	(733)
Cost of spare parts & services	(816)	(1,058)	(1,026)	(1,490)
Cost of sales	(3,431)	(3,560)	(4,317)	(5,012)
<b>GROSS PROFIT</b>	<b>2,248</b>	<b>2,558</b>	<b>2,828</b>	<b>3,602</b>
Research & development expenses	(423)	(663)	(532)	(934)
Marketing & Sales expenses	(1,296)	(1,320)	(1,631)	(1,859)
G & A expenses	(869)	(771)	(1,094)	(1,085)
Total operating expenses	(2,588)	(2,754)	(3,257)	(3,878)
<b>OPERATING PROFIT (LOSS)</b>	<b>(341)</b>	<b>(195)</b>	<b>(429)</b>	<b>(275)</b>
Interest (expense) income, net	(63)	560	(79)	789
Currency exchange gains (loss), net	12	596	16	839
Other income (loss), net	(37)	(54)	(48)	(76)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(429)</b>	<b>906</b>	<b>(540)</b>	<b>1,276</b>
Income tax (expense) credit	(67)	(35)	(84)	(50)
<b>NET INCOME (LOSS)</b>	<b>(496)</b>	<b>871</b>	<b>(624)</b>	<b>1,226</b>
Earning per share — Basic	(0.03)	0.07	(0.03)	0.09
Average number of shares used in computation of EPS	18,257,273	13,227,043	18,257,273	13,227,043
Earning per share — Diluted	(0.03)	0.07	(0.03)	0.09
Average number of shares used in computation of EPS for positive net income	18,665,964	13,340,380	18,665,964	13,340,380

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2012 average three months noon buying rate of 1 Euro = 1.2583 USD, and 2011 average three months noon buying rate of 1 Euro = 1.4081 USD.

**EDAP TMS S.A.**  
**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,
	2012	2011	2012	2011
	Euros	Euros	\$US	\$US
Sales of goods	9,809	7,475	12,616	10,603
Net Sales of RPP and Leases	2,930	3,296	3,769	4,675
Sales of spare parts and Services	3,901	3,970	5,017	5,631
<b>TOTAL NET SALES</b>	<b>16,640</b>	<b>14,741</b>	<b>21,402</b>	<b>20,909</b>
Other revenues	2	27	3	39
<b>TOTAL REVENUES</b>	<b>16,642</b>	<b>14,768</b>	<b>21,404</b>	<b>20,948</b>
Cost of goods	(5,678)	(4,240)	(7,302)	(6,014)
Cost of RPP and Leases	(1,775)	(1,731)	(2,283)	(2,455)
Cost of spare parts & services	(2,645)	(2,740)	(3,402)	(3,886)
Cost of sales	(10,098)	(8,710)	(12,988)	(12,355)
<b>GROSS PROFIT</b>	<b>6,544</b>	<b>6,058</b>	<b>8,416</b>	<b>8,593</b>
Research & development expenses	(1,986)	(1,845)	(2,554)	(2,618)
Marketing & Sales expenses	(4,255)	(4,083)	(5,472)	(5,792)
G & A expenses	(2,587)	(2,255)	(3,327)	(3,199)
Total operating expenses	(8,828)	(8,184)	(11,354)	(11,608)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,284)</b>	<b>(2,126)</b>	<b>(2,938)</b>	<b>(3,015)</b>
Interest (expense) income, net	(4,004)	1,754	(5,150)	2,489
Currency exchange gains (loss), net	2	195	2	277
Other income (loss), net	2	(54)	2	(76)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(6,285)</b>	<b>(230)</b>	<b>(8,084)</b>	<b>(326)</b>
Income tax (expense) credit	(92)	(130)	(118)	(184)
<b>NET INCOME (LOSS)</b>	<b>(6,377)</b>	<b>(359)</b>	<b>(8,202)</b>	<b>(510)</b>
Earning per share — Basic	(0.37)	(0.03)	(0.48)	(0.04)
Average number of shares used in computation of EPS	17,248,329	13,227,043	17,248,329	13,227,043
Earning per share — Diluted	(0.37)	(0.03)	(0.48)	(0.04)
Average number of shares used in computation of EPS for positive net income	17,628,840	13,543,436	17,628,840	13,543,436

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2012 average nine months noon buying rate of 1 Euro = 1.2862 USD, and 2011 average nine months noon buying rate of 1 Euro = 1.4184 USD.

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

	Sept. 30, 2012 Euros	June 30, 2012 Euros	Sept. 30, 2012 \$US	June 30, 2012 \$US
Cash, cash equivalents and short term investments	8,145	8,068	10,472	10,221
Total current assets	24,831	25,834	31,924	32,726
Total current liabilities	12,968	13,075	16,672	16,563
Shareholders' Equity	8,847	11,682	11,374	14,799

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2857 USD, on September 30, 2012 and at the noon buying rate of 1 Euro = 1.2668USD, on June 30, 2012.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**NINE MONTHS ENDED SEPTEMBER 30, 2012**  
**(Amounts in thousands of Euros)**

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	623	9,186			9,809
Sales of RPPs & Leases	1,983	947			2,930
Sales of spare parts & services	<u>726</u>	<u>3,175</u>	<u>          </u>	<u>          </u>	<u>3,901</u>
<b>TOTAL NET SALES</b>	<b>3,332</b>	<b>13,308</b>			<b>16,640</b>
Other revenues	<u>2</u>	<u>--</u>	<u>          </u>	<u>          </u>	<u>2</u>
<b>TOTAL REVENUES</b>	<b>3,334</b>	<b>13,308</b>			<b>16,642</b>
<b>GROSS PROFIT</b>	<b>1,470 44.1%</b>	<b>5,074 38.1%</b>			<b>6,544 39.3%</b>
Research & Development	(699)	(654)	(633)		(1,986)
Total SG&A plus depreciation	<u>(1,994)</u>	<u>(3,860)</u>	<u>(59)</u>	<u>(929)</u>	<u>(6,842)</u>
<b>OPERATING PROFIT (LOSS)</b>	<b>(1,223)</b>	<b>560</b>	<b>(692)</b>	<b>(929)</b>	<b>(2,284)</b>

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