



## EDAP Reports Fourth Quarter Revenue Up 23% Sequentially

### Highlights

- Reported revenue of EUR 7.5 million (USD 10.1 million), up 23% sequentially
- Sold sixteen lithotripsy devices and one Ablatherm-HIFU device
- Recorded year-end cash position of EUR 6.5 million following positive cash flow of EUR 1.0 million
- Streamlined capital structure by issuing 9% USD 10.0 million non-convertible notes due in June 2014

LYON, France, March 21, 2012 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and year ended December 31, 2011 and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "The sales and demand traction for our innovative lithotripsy machines continued in the fourth quarter. The sixteen devices sold during the quarter exceeded the previously reported global market backlog and our robust pipeline underscores the continuing interest. Following FDA clearance of our Sonolith i-move lithotripter in August 2011, we focused on expanding our presence in the U.S. market where we are building a strong pipeline of devices following successful product demonstrations. We sold in the fourth quarter two lithotripsy devices to prestigious U.S. urology groups on both the East and West coasts. We believe these sales demonstrate the growing interest from the community in our advanced technology and provide us with a high level of confidence regarding the ability to take significant share of the U.S. lithotripsy market in the near term."

Mr. Oczachowski continued, "Over the past year, we continued to operate in a very challenging economic environment that impacted medical device purchasing activity globally. Our cost reduction strategy resulted in a significant decrease in our global expenses, allowing us to improve our operating result. These initiatives continue to bring our breakeven point to a level that is more aligned with our sales and therefore provides us with the confidence that we will continue to closely control our expenses and investments."

### Recent Developments

In January 2012, EDAP streamlined its capital structure by exchanging its outstanding convertible debt and warrants for USD 10.0 million 9% non-convertible term notes due June 30, 2014.

In December 2011, EDAP installed its second Sonolith i-move lithotripter at USC Medical Center in Los Angeles and UC San Diego following the receipt of the US 510 clearance in August 2011 and expanded its U.S. sales pipeline to include a third device in its backlog that is on track to be delivered and installed in the first half of 2012.

In February 2012, EDAP's Ablatherm-HIFU was featured in seven poster presentations supporting its efficacy for the treatment of localized prostate cancer at the 27th Annual European Association of Urology (EAU) Congress held in Paris, France. The comprehensive data validates the international urology community's support for Ablatherm-HIFU as a complement to surgery in addressing prostate cancer and EDAP's proven ability to bring minimally invasive treatment to younger patients seeking effective treatments that afford quality of life preservation.

### Fourth Quarter 2011 Results

EDAP's total consolidated revenue for the fourth quarter 2011 was EUR 7.5 million (USD 10.1 million), a 6% decrease compared to EUR 8.0 million (USD 10.8 million) for the fourth quarter 2010 and a 23% increase compared to EUR 6.1 million (USD 8.6 million) for the third quarter 2011.

Total revenue for the HIFU division was EUR 1.8 million (USD 2.4 million) for the fourth quarter 2011, compared to EUR 2.0 million (USD 2.6 million) for the same period last year. Results for the fourth quarter 2011 reflected the sale of one Ablatherm-HIFU device, as compared to two devices sold in the same period last year.

For the three months ended December 31, 2011, total revenue for the lithotripsy division was EUR 5.8 million (USD 7.8 million), compared to EUR 6.1 million (USD 8.1 million) during the year ago period. During the fourth quarter 2011, the Company recorded sales of sixteen lithotripsy machines, comprised of seven Sonolith i-move devices, five Sonolith i-sys devices and four

Sonolith Praktis devices, compared to a total of twenty devices sold in the fourth quarter of 2010.

Gross profit for the fourth quarter 2011 was EUR 2.8 million (USD 3.8 million), compared to EUR 3.0 million (USD 4.0 million) for the year ago period. Gross profit margin was 37.2% in the fourth quarter 2011, stable from 37.6% in the year ago period.

Operating expenses were EUR 3.2 million (USD 4.3 million) for the fourth quarter 2011, down 7% from EUR 3.4 million (USD 4.6 million) for the same period 2010. Operating loss was EUR 371,000 (USD 499,000) for the fourth quarter 2011, compared to EUR 371,000 (USD 496,000 million) in the fourth quarter of 2010. Excluding operating expenses of EUR 154,000 (USD 207,000) associated with the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU, fourth quarter 2011 operating loss was EUR 217,000 (USD 292,000).

Net loss for the fourth quarter 2011 was EUR 579,000 (USD 779,000), or EUR 0.04 per diluted share (USD 0.06 per diluted share), as compared to net loss for the fourth quarter of 2010 of EUR 7.2 million (USD 9.7 million), or EUR 0.56 per diluted share (USD 0.74 per diluted share). Net income for the fourth quarter 2011 included a non-cash interest expense of EUR 23,000 to adjust the Company's outstanding convertible debt and warrants to fair market value.

At December 31, 2011, cash and cash equivalents, including short-term treasury investments, were EUR 6.5 million (USD 8.4 million), which reflected the stabilization of Company's cash position. The Company was cash flow positive during the fourth quarter 2011 and generated EUR 1.0 million as a result of strong cash management.

Eric Soyer, Chief Financial Officer, commented, "Following the end of our reporting year for 2011, we achieved a major milestone by restructuring our capital structure that removes the short term debt burden for the Company. The transaction exchanged the outstanding convertible debt and warrants for term notes with extended maturity and also eliminated the potential dilution connected with our 2007 convertible bond. We believe the transaction strengthens our financial profile and therefore is in the best interests of all EDAP shareholders."

## **Full Year 2011 Results**

EDAP's total consolidated revenue for the full year ended December 31, 2011 was EUR 22.3 million (USD 31.2 million), as compared to EUR 23.7 million (USD 31.3 million) for the full year 2010. The 2011 revenue included the sale of 40 lithotripsy devices that featured a higher average selling price due to product innovation.

Gross profit for the full year 2011 was EUR 8.9 million (USD 12.4 million) and operating loss was EUR 2.5 million (USD 3.5 million), compared to EUR 9.5 million (USD 12.5 million) and EUR 3.8 million (USD 5.0 million), respectively, for the same period 2010. The revenue shift was reflected in the lower gross profit, but was more than offset by reductions in operating expenses, which were EUR 11.4 million (USD 15.9 million) for the full year 2011, compared to EUR 13.3 million (USD 17.5 million) for the same period 2010.

Net loss for the full year 2011 was EUR 939,000 (USD 1.3 million), or EUR 0.07 per diluted share. The full year 2011 net loss included a non-cash interest income of EUR 2.4 million (USD 3.4 million) to adjust the Company's convertible debt and outstanding warrants to fair value, and to reduce the outstanding convertible debt.

## **Conference Call**

EDAP will hold a conference call today Wednesday, March 21, 2012 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 10010520. 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 April 18, 2012. In addition, a telephonic replay of the call will be available until April 4, 2012. The replay dial-in numbers are 877-344-7529 for domestic callers and 412-317-0088 for international callers. Please use event passcode: 10010520.

## **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. 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.

### 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:	
	December 31, 2011 Euros	December 31, 2010 Euros	December 31, 2011 \$US	December 31, 2010 \$US
Sales of medical equipment	4,924	5,671	6,626	7,599
Net Sales of RPP and Leases	1,213	1,064	1,632	1,426
Sales of spare parts, supplies and Services	1,394	1,302	1,877	1,745
<b>TOTAL NET SALES</b>	<b>7,531</b>	<b>8,037</b>	<b>10,134</b>	<b>10,769</b>
Other revenues	(7)	1	(10)	1
<b>TOTAL REVENUES</b>	<b>7,523</b>	<b>8,038</b>	<b>10,124</b>	<b>10,770</b>
Cost of sales	(4,725)	(5,013)	(6,358)	(6,717)
<b>GROSS PROFIT</b>	<b>2,798</b>	<b>3,025</b>	<b>3,766</b>	<b>4,053</b>
Research & development expenses	(591)	(675)	(795)	(904)
S, G & A expenses	(2,579)	(2,721)	(3,470)	(3,646)
Total operating expenses	(3,170)	(3,396)	(4,265)	(4,550)
<b>OPERATING PROFIT (LOSS)</b>	<b>(371)</b>	<b>(371)</b>	<b>(499)</b>	<b>(496)</b>
Interest (expense) income, net	(233)	(6,851)	(313)	(9,180)
Currency exchange gains (loss), net	287	81	386	109
Other income (loss), net	3	2	5	3
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(313)</b>	<b>(7,138)</b>	<b>(422)</b>	<b>(9,565)</b>
Income tax (expense) credit	(266)	(86)	(357)	(115)
<b>NET INCOME (LOSS)</b>	<b>(579)</b>	<b>(7,224)</b>	<b>(779)</b>	<b>(9,680)</b>
Earning per share — Basic	(0.04)	(0.56)	(0.06)	(0.74)
Average number of shares used in computation of EPS	13,345,004	13,008,401	13,345,004	13,008,401
Earning per share — Diluted	(0.04)	(0.56)	(0.06)	(0.74)

Average number of shares used in computation of EPS for positive net income	13,317,115	13,496,394	13,317,115	13,496,394
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**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2011 average three months noon buying rate of 1 Euro = 1.3457USD, and 2010 average three months noon buying rate of 1 Euro = 1.3399 USD.

**EDAP TMS S.A.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Twelve Months Ended:		Twelve Months Ended:	
	December 31, 2011 Euros	December 31, 2010 Euros	December 31, 2011 \$US	December 31, 2010 \$US
Sales of medical equipment	12,399	13,135	17,361	17,358
Net Sales of RPP and Leases	4,508	4,689	6,312	6,197
Sales of spare parts, supplies and Services	5,365	5,378	7,511	7,107
<b>TOTAL NET SALES</b>	<b>22,272</b>	<b>23,202</b>	<b>31,184</b>	<b>30,662</b>
Other revenues	20	506	28	669
<b>TOTAL REVENUES</b>	<b>22,292</b>	<b>23,708</b>	<b>31,212</b>	<b>31,331</b>
Cost of sales	(13,435)	(14,253)	(18,811)	(18,836)
<b>GROSS PROFIT</b>	<b>8,857</b>	<b>9,455</b>	<b>12,401</b>	<b>12,495</b>
Research & development expenses	(2,436)	(3,268)	(3,411)	(4,318)
S, G & A expenses	(8,917)	(10,005)	(12,486)	(13,222)
Total operating expenses	(11,353)	(13,272)	(15,897)	(17,540)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,497)</b>	<b>(3,818)</b>	<b>(3,496)</b>	<b>(5,045)</b>
Interest (expense) income, net	1,522	(8,844)	2,131	(11,688)
Currency exchange gains (loss), net	482	884	675	1,168
Other income (loss), net	(50)	--	(70)	--
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(543)</b>	<b>(11,778)</b>	<b>(761)</b>	<b>(15,565)</b>
Income tax (expense) credit	(395)	(939)	(553)	(1,241)
<b>NET INCOME (LOSS)</b>	<b>(938)</b>	<b>(12,717)</b>	<b>(1,314)</b>	<b>(16,806)</b>
Earning per share — Basic	(0.07)	(0.98)	(1.10)	(1.29)
Average number of shares used in computation of EPS	13,345,004	13,008,401	13,345,004	13,008,401
Earning per share — Diluted	(0.07)	(0.98)	(1.10)	(1.29)
Average number of shares used in computation of EPS for positive net income	13,353,985	13,094,235	13,353,985	13,094,235

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2011 average twelve months noon buying rate of 1 Euro = 1.4002 USD, and 2010 average twelve months noon buying rate of 1 Euro = 1.3215 USD.

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

	Dec. 31, 2011 Euros	Sept. 30, 2011 Euros	Dec. 31, 2011 \$US	Sept. 30, 2011 \$US
Cash, cash equivalents and short term investments	6,472	5,482	8,396	7,373
Total current assets	26,740	25,915	34,691	34,855
Total current liabilities	20,757	12,530	26,930	16,853
Shareholders' Equity	8,713	9,347	11,303	12,572

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2974 USD, on December 31, 2011 and at the noon buying rate of 1 Euro = 1.3450 USD, on September 30, 2011.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2011**  
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	1,442	10,957			12,399
Sales of RPPs & Leases	3,270	1,238			4,508
Sales of spare parts & services	1,153	4,212			5,365
<b>TOTAL NET SALES</b>	<b>5,865</b>	<b>16,407</b>			<b>22,272</b>
Other revenues	20	--			20
<b>TOTAL REVENUES</b>	<b>5,885</b>	<b>16,407</b>			<b>22,292</b>
<b>GROSS PROFIT</b>	<b>3,264 56%</b>	<b>5,592 34%</b>			<b>8,857 40%</b>
Research & Development	(950)	(792)	(694)		(2,436)
Total SG&A plus depreciation	<u>(2,571)</u>	<u>(4,679)</u>	<u>(79)</u>	<u>(1,588)</u>	<u>(8,917)</u>
<b>OPERATING PROFIT (LOSS)</b>	<b>(257)</b>	<b>122</b>	<b>(773)</b>	<b>(1,588)</b>	<b>(2,497)</b>

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