



April 2, 2013

## EDAP Reports Fourth Quarter 2012 and Full Year Results

### Highlights

- Record fourth quarter 2012 revenue of EUR 9.5 million (USD 12.3 million), up 25.3% year-over-year
- Record full year revenue of EUR 26.1 million (USD 33.6 million), up 16.9% year-over-year
- Record lithotripsy sales in 2012
- PMA for Ablatherm®-HIFU for treatment of low risk, localized prostate cancer accepted by the FDA for filing on March 26, 2013

LYON, France, April 2, 2013 (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, 2012, and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are very pleased with our record revenues in the fourth quarter, and for the full year 2012. Our sales growth can be attributed to the robust sales of our innovative Sonolith lithotripters around the globe. Customers continue to respond to our innovative products and improving offerings. We continue to aggressively pursue market penetration, and strengthen our sales operations across key markets, including Europe, Asia, and the U.S."

Mr. Oczachowski continued, "Our PMA application for Ablatherm-HIFU is steadily moving forward through the U.S. FDA review process. Last week we received notification that our PMA had been accepted for Filing Review, less than two months after we submitted the complete application to the FDA. With this significant milestone completed, we have now entered the substantive review phase, and we are looking forward to a continuing dialog with the agency as the review process advances."

### Recent Developments

In March 2013, the U.S. Food and Drug Administration (FDA) provided a positive Filing Review Notification for the EDAP's Pre-Market Approval (PMA) application for its Ablatherm Integrated Imaging HIFU (High Intensity Focused Ultrasound) device for treatment of low risk, localized prostate cancer. The PMA was received by the FDA on February 5, 2013, and was given a filing date of February 28, 2013. The PMA submission included data from the Company's ENLIGHT study, a multi-center U.S. Phase II/III clinical trial that completed the two year follow-up needed to evaluate its primary endpoint in August 2012, as well as data from the Company's extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer.

In March 2013, EDAP introduced Focal.One®, the Company's new robotic HIFU device for focal therapy of prostate cancer at the European Association of Urology Annual Congress in Milan, Italy. Focal.One is the first device fully dedicated to the focal approach for prostate cancer therapy. It combines three essential components to efficiently perform a focal treatment: (i) state-of-the-art imaging to localize tumors with the use of magnetic resonance imaging combined with real-time ultrasound, (ii) utmost precision of HIFU treatment focused on identified targeted cancer areas only and (iii) immediate feedback on treatment efficacy utilizing Contrast-Enhanced Ultrasound Imaging.

In February 2013, the Journal of Urology, the Official Journal of the American Urological Association published results from a study in Munich on 704 patients over fifteen years. The study demonstrated high rates of both cancer-specific survival, and freedom from salvage therapy for patients treated with HIFU therapy. Investigators concluded that the 15 year outcome data may warrant closing of investigational phase for HIFU.

In January 2013, the British Journal of Urology, International, published a landmark study of over 538 patients demonstrating the safety and long-term efficacy of EDAP's Ablatherm-HIFU for the treatment of localized prostate cancer with ten year biochemical outcomes and follow-up extending to fourteen years. Data from this long-term year retrospective study, the longest study of HIFU patients to date published, confirmed benefits of the treatment.

### Fourth Quarter 2012 Results

Total revenue for the fourth quarter 2012 was EUR 9.4 million (USD 12.3 million), a 25.3% year over year increase compared to EUR 7.5 million (USD 10.1 million) for the fourth quarter 2011 and a 66% sequential increase compared to EUR 5.7 million (USD 7.1 million) for the third quarter 2012.

Total revenue for the HIFU division was EUR 2.3 million (USD 3.0 million) for the fourth quarter 2012, compared to EUR 1.8 million (USD 2.4 million) for the same period last year. Results for the fourth quarter 2012 reflected the sale of three Ablatherm-HIFU devices, as compared to one device sold in the same period last year.

For the three months ended December 31, 2012, total revenue for the Lithotripsy division was EUR 7.1 million (USD 9.3 million), compared to EUR 5.8 million (USD 7.8 million), during the year ago period. During the fourth quarter 2012, the Company recorded sales of 21 lithotripsy machines, comprised of 11 Sonolith i-move devices, seven Sonolith i-sys devices and three Sonolith Praktis devices, compared to a total of sixteen devices sold in the fourth quarter of 2011.

Gross profit for the fourth quarter 2012 was EUR 3.9 million (USD 5.1 million), compared to EUR 2.8 million (USD 3.8 million) for the year ago period. Gross profit margin was 41.3% in the fourth quarter 2012, compared to 37.2% in the year ago period. The change in the gross profit margin was mostly attributed to sales volumes.

Operating expenses were EUR 3.6 million (USD 4.7 million) for the fourth quarter 2012, compared to EUR 3.2 million (USD 4.3 million) for the same period 2011. Operating profit was EUR 254,000 (USD 331,000) for the fourth quarter 2012, compared to an operating loss of EUR 371,000 (USD 499,000 million) in the fourth quarter of 2011.

Net loss for the fourth quarter 2012 was EUR 1.1 million (USD 1.4 million), or EUR 0.06 per diluted share, as compared to net loss for the fourth quarter of 2011 of EUR 579,000 (USD 779,000), or EUR 0.04 per diluted share. Net income for the fourth quarter 2012 included a non-cash interest expense of EUR 439,000 to adjust the Company's outstanding convertible debt and warrants to fair market value.

At December 31, 2012, cash and cash equivalents, including short-term treasury investments, were EUR 8.1 million (USD 10.7 million). The Company's cash flow was stable in the fourth quarter.

## **Full Year 2012 Results**

Total revenue for the full year ended December 31, 2012 was EUR 26.1 million (USD 33.7 million), a 16.9% growth year-over-year as compared to EUR 22.3 million (USD 31.2 million) for the full year 2011. 2012 revenue included the sale of 52 lithotripsy devices and 4 Ablatherm-HIFU devices..

Gross profit for the full year 2012 was EUR 10.4 million (USD 13.5 million) and operating loss was EUR 2.0 million (USD 2.6 million), compared to EUR 8.9 million (USD 12.4 million) and EUR 2.5 million (USD 3.5 million), respectively, for the same period 2011.

Net loss for the full year 2012 was EUR 7.5 (USD 9.7 million), or EUR 0.43 per diluted share. The full year 2012 net loss included a non-cash interest expense of EUR 4.0 million (USD 5.1 million) to reflect the accounting fair value impact of the January 2012 exchange offering on its convertible debentures and related warrants, the reduction of the outstanding non-convertible debt and fair-value adjustments of outstanding warrants.

## **Conference Call**

EDAP will hold a conference call today Tuesday, April 2, 2013 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 10026204. 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 May 2, 2013. In addition, a telephonic replay of the call will be available until April 12, 2013. The replay dial-in numbers are (877) 344-7529 for domestic callers and (412) 317-0088 for international callers. Please use event passcode: 10026204.

## **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm® 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., Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III

clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU 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 may contain 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, 2012 Euros	December 31, 2011 Euros	December 31, 2012 \$US	December 31, 2011 \$US
Sales of medical equipment	7,200	4,924	9,397	6,626
Net Sales of RPP and Leases	1,058	1,213	1,380	1,632
Sales of spare parts, supplies and Services	1,121	1,394	1,463	1,877
<b>TOTAL NET SALES</b>	<b>9,378</b>	<b>7,531</b>	<b>12,240</b>	<b>10,134</b>
Other revenues	45	(7)	59	(10)
<b>TOTAL REVENUES</b>	<b>9,423</b>	<b>7,523</b>	<b>12,299</b>	<b>10,124</b>
Cost of sales	(5,534)	(4,725)	(7,222)	(6,358)
<b>GROSS PROFIT</b>	<b>3,889</b>	<b>2,798</b>	<b>5,076</b>	<b>3,766</b>
Research & development expenses	(673)	(591)	(878)	(795)
S, G & A expenses	(2,963)	(2,579)	(3,867)	(3,470)
Total operating expenses	(3,636)	(3,170)	(4,745)	(4,265)
<b>OPERATING PROFIT (LOSS)</b>	<b>254</b>	<b>(371)</b>	<b>331</b>	<b>(499)</b>
Interest (expense) income, net	(591)	(233)	(772)	(313)
Currency exchange gains (loss), net	(735)	287	(959)	386
Other income (loss), net	--	3	--	5
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(1,073)</b>	<b>(313)</b>	<b>(1,400)</b>	<b>(422)</b>
Income tax (expense) credit	(26)	(266)	(34)	(357)
<b>NET INCOME (LOSS)</b>	<b>(1,099)</b>	<b>(579)</b>	<b>(1,434)</b>	<b>(779)</b>
Earning per share — Basic	(0.06)	(0.04)	(0.08)	(0.06)
Average number of shares used in computation of EPS	18,372,229	13,227,043	18,372,229	13,227,043
Earning per share — Diluted	(0.06)	(0.04)	(0.08)	(0.06)
Average number of shares used in computation of EPS for positive net income	18,780,920	13,317,115	18,780,920	13,317,115

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2012 average three months noon buying rate of 1 Euro = 1.3051 USD, and 2011 average three months noon buying rate of 1 Euro = 1.3457 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, 2012 Euros	December 31, 2011 Euros	December 31, 2012 \$US	December 31, 2011 \$US
Sales of medical equipment	17,900	12,399	21,959	17,361
Net Sales of RPP and Leases	3,988	4,508	5,148	6,312
Sales of spare parts, supplies and Services	5,021	5,365	6,482	7,511
<b>TOTAL NET SALES</b>	<b>26,018</b>	<b>22,272</b>	<b>33,589</b>	<b>31,184</b>
Other revenues	47	20	61	28
<b>TOTAL REVENUES</b>	<b>26,065</b>	<b>22,292</b>	<b>33,650</b>	<b>31,212</b>
Cost of sales	(15,632)	(13,435)	(20,181)	(18,811)
<b>GROSS PROFIT</b>	<b>10,433</b>	<b>8,857</b>	<b>13,469</b>	<b>12,401</b>
Research & development expenses	(2,659)	(2,436)	(3,432)	(3,411)
S, G & A expenses	(9,805)	(8,917)	(12,658)	(12,486)
Total operating expenses	(12,463)	(11,353)	(16,090)	(15,897)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,030)</b>	<b>(2,497)</b>	<b>(2,621)</b>	<b>(3,496)</b>
Interest (expense) income, net	(4,594)	1,522	(5,931)	2,131
Currency exchange gains (loss), net	(733)	482	(947)	675
Other income (loss), net	--	(50)	--	(70)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(7,358)</b>	<b>(543)</b>	<b>(9,499)</b>	<b>(761)</b>
Income tax (expense) credit	(118)	(395)	(152)	(553)
<b>NET INCOME (LOSS)</b>	<b>(7,475)</b>	<b>(938)</b>	<b>(9,651)</b>	<b>(1,314)</b>
Earning per share — Basic	(0.43)	(0.07)	(0.55)	(0.10)
Average number of shares used in computation of EPS	17,556,395	13,345,004	17,556,395	13,345,004
Earning per share — Diluted	(0.43)	(0.07)	(0.55)	(0.10)
Average number of shares used in computation of EPS for positive net income	17,944,651	13,353,985	17,944,651	13,353,985

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2012 average twelve months noon buying rate of 1 Euro = 1.2910 USD, and 2011 average twelve months noon buying rate of 1 Euro = 1.4002 USD.

**EDAP TMS S.A.**

**CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)**

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

	Dec. 31, 2012 Euros	Sept. 30, 2012 Euros	Dec. 31, 2012 \$US	Sept. 30, 2012 \$US
Cash, cash equivalents and short term investments	8,077	8,145	10,650	10,472
Total current assets	24,729	24,831	32,607	31,924
Total current liabilities	13,124	12,968	17,305	16,672
Shareholders' Equity	8,161	8,847	10,761	11,374

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3186USD, on December 31, 2012 and at the noon buying rate of 1 Euro = 1.2857 USD, on September 30, 2012.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2012**  
**(Amounts in thousands of Euros)**

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	1,884	15,125			17,009
Sales of RPPs & Leases	2,695	1,293			3,988
Sales of spare parts & services	1,006	4,015			5,021
<b>TOTAL NET SALES</b>	<b>5,585</b>	<b>20,433</b>			<b>26,018</b>
Other revenues	47	--			47
<b>TOTAL REVENUES</b>	<b>5,632</b>	<b>20,433</b>			<b>26,065</b>
<b>GROSS PROFIT</b>	<b>2,723 48%</b>	<b>7,710 38%</b>			<b>10,433 40%</b>
Research & Development	(920)	(746)	(992)		(2,659)
Total SG&A plus depreciation	(2,548)	(5,809)	(97)	(1,352)	(9,805)
<b>OPERATING PROFIT (LOSS)</b>	<b>(746)</b>	<b>1,156</b>	<b>(1,089)</b>	<b>(1,352)</b>	<b>(2,030)</b>

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