



May 16, 2013

EDAP Reports 23% Increase in First Quarter 2013 Revenues

- First quarter 2013 revenue rose 23% to EUR 5.9 million (USD 7.8 million)
- Continuing US investments in both FDA regulatory process and US operations
- Great momentum and success achieved at two of the world major urology congresses for EDAP's advanced technologies
- Publication of two independent studies both reporting 10 year outcomes of men undergoing Ablatherm HIFU for localized prostate cancer

LYON, France, May 16, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the first quarter ended March 31, 2013, and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "With total revenues up 23% year-over-year, we are continuing to see strong demand for our innovative lithotripsy product range in key global markets. In parallel, we increased our investments in both our FDA regulatory program and our U.S. sales and marketing efforts to further penetrate the U.S. market with both our technologies, which in combination contributed to the 16.5% increase in our first quarter operating expenses. Our device backlog is comprised of ten lithotripters at the midpoint of the second quarter and our team is continuing to cultivate customer leads around the world. Leveraging our aggressive marketing strategy, we anticipate seeing continuous traction in our sales across targeted geographic markets."

"As reported, we had significant attendance at our booths and recorded strong interest in both our HIFU and ESWL technologies during the two most important urology congresses in the world, the European Annual Urology (EAU) meeting in Milan, Italy, and the American Urology Association (AUA) annual meeting in San Diego, California. We have increasing momentum on both our HIFU range of devices, fueled by the launch of our innovative Focal.One® device at the EAU, and on our lithotripsy technologies propelled by a high number of live demonstrations to physicians during the AUA."

Mr. Oczachowski continued, "The FDA process for our Ablatherm-HIFU is on track as we submitted our Pre-Market Approval (PMA) application that was reviewed and approved for filing in late March. We continue working and communicating smoothly with the agency and we have a 100-day meeting scheduled with the FDA for early June to discuss our file."

First Quarter Highlights and Recent Developments

EDAP received positive reception at the American Urological Association (AUA) 2013 Annual Meeting, held in San Diego on May 4-8, 2013. Sonolith i-move treatment demonstrations at the booth were very well attended by urologists. At the meeting, four scientific abstracts presented clinical outcomes for HIFU treatment of prostate cancer and two regarding the exclusive ultrasound Visio Track® localization system of Sonolith lithotripter. Two of the HIFU presentations were awarded "Best Posters" from the AUA.

EDAP received a positive Filing Review Notification from the FDA in March for its PMA application for its Ablatherm-HIFU device for the treatment of low risk, localized prostate cancer. The PMA submission included clinical 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.

EDAP introduced Focal.One®, the first robotic HIFU device fully dedicated to the focal therapy of prostate cancer, at the European Association of Urology Annual Congress in Milan, Italy in March 2013. Focal.One® combines three essential components to efficiently perform a focal treatment: (i) state-of-the-art imaging to visualize tumors with elastic image fusion of magnetic resonance imaging and real-time ultrasound, (ii) high resolution HIFU treatment with smaller elementary lesions allowing for unprecedented treatment precision within the prostate and (iii) immediate feedback on treatment efficacy utilizing Contrast-Enhanced Ultrasound Imaging. Not only is Focal.One® the only device to have all three of these features - no other HIFU device has any of these features.

In January 2013, the British Journal of Urology, International, published a landmark study from the University of Regensburg in Germany. The study included 538 patients and demonstrated 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.

This publication was quickly followed by a second paper reporting 10 year outcomes. In February 2013, the Official Journal of the American Urological Association, the Journal of Urology, published results from a study in Munich of 704 patients followed over a period of 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.

First Quarter 2013 Results

Total revenue for the first quarter 2013 was EUR 5.9 million (USD 7.8 million), a 23% year over year increase compared to EUR 4.8 million (USD 6.8 million) for the first quarter 2012.

Total revenue for the HIFU division was EUR 1.4 million (USD 1.8 million) for the first quarter 2013, compared to EUR 1.3 million (USD 1.9 million) for the same period last year. Results for the first quarter 2013 included the sale of one Ablatherm-HIFU device.

For the three months ended March 31, 2013, total revenue for the lithotripsy division was EUR 4.5 million (USD 6.0 million), compared to EUR 3.5 million (USD 4.9 million), during the year ago period. During the first quarter 2013, the Company recorded sales of ten lithotripsy machines, comprised of eight Sonolith i-move devices and two Sonolith i-sys devices, compared to a total of five devices sold in the first quarter of 2012.

Gross profit for the first quarter 2013 was EUR 2.2 million (USD 2.9 million), compared to EUR 1.9 million (USD 2.7 million) for the year ago period. Gross profit margin was 37.1% in the first quarter 2013, compared to 39.3% in the year ago period. The change in the gross profit margin was mostly attributed to the negative impact of the Japanese Yen exchange rate to the Euro.

Operating expenses were EUR 3.4 million (USD 4.5 million) for the first quarter 2013, compared to EUR 2.9 million (USD 4.1 million) for the same period 2012. The sizeable increase in operating expenses was mostly attributable to continued regulatory expenses associated with the PMA filing for Ablatherm-HIFU, as well as sales and marketing investments in the U.S.. As a result of such investments, operating loss was EUR 1.2 million (USD 1.6 million) for the first quarter 2013, compared to an operating loss of EUR 1.0 million (USD 1.4 million) in the first quarter of 2012.

Net loss for the first quarter 2013 was EUR 3.9 million (USD 5.1 million), or EUR 0.21 per share, as compared to net loss for the first quarter 2012 of EUR 2.9 million (USD 4.1 million), or EUR 0.22 per share. Net loss for the first quarter 2013 included a non-cash interest expense of EUR 2.3 million related to fair value adjustments in the accounting of the Company's outstanding debt and warrants, mostly driven by the increase in the stock price during the first quarter 2013.

At March 31, 2013, cash and cash equivalents, including short-term treasury investments, were EUR 7.3 million (USD 9.3 million).

Conference Call

EDAP will hold a conference call today Thursday, May 16, 2013, at 8:30 am EDT to discuss the results. The dial-in numbers are 1-877-300-8521 for domestic callers and 1-412-317-6026 for international callers. The conference ID number for both is 10029077. 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 June 13, 2013. In addition, a telephonic replay of the call will be available until May 26, 2013. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 10029077.

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 January 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)

	<u>Three Months Ended :</u>		<u>Three Months Ended :</u>	
	<u>March 31,</u>	<u>March 31,</u>	<u>March 31,</u>	<u>March 31,</u>
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
	<u>Euros</u>	<u>Euros</u>	<u>\$US</u>	<u>\$US</u>
Sales of goods	3,693	2,465	4,860	3,451
Net Sales of RPP and Leases	933	1,113	1,228	1,558
Sales of spare parts and Services	<u>1,301</u>	<u>1,260</u>	<u>1,712</u>	<u>1,764</u>
TOTAL NET SALES	5,927	4,838	7,800	6,773
Other revenues	<u>(0)</u>	<u>(0)</u>	<u>(0)</u>	<u>(0)</u>
TOTAL REVENUES	5,927	4,837	7,800	6,773
Cost of goods	(2,243)	(1,375)	(2,951)	(1,925)
Cost of RPP and Leases	(523)	(635)	(688)	(889)
Cost of spare parts & services	<u>(964)</u>	<u>(925)</u>	<u>(1,268)</u>	<u>(1,295)</u>
Cost of sales	<u>(3,729)</u>	<u>(2,935)</u>	<u>(4,908)</u>	<u>(4,109)</u>
GROSS PROFIT	2,198	1,902	2,892	2,664
Research & development expenses	(932)	(708)	(1,227)	(992)
Marketing & Sales expenses	(1,534)	(1,422)	(2,019)	(1,992)
G & A expenses	<u>(922)</u>	<u>(778)</u>	<u>(1,213)</u>	<u>(1,089)</u>
Total operating expenses	(3,389)	(2,909)	(4,459)	(4,072)
OPERATING PROFIT (LOSS)	(1,191)	(1,006)	(1,567)	(1,409)
Interest (expense) income, net	(2,429)	(1,556)	(3,197)	(2,178)
Currency exchange gains (loss), net	(212)	(268)	(279)	(376)
Other income (loss), net	<u>(2)</u>	<u>7</u>	<u>(2)</u>	<u>9</u>
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(3,833)	(2,823)	(5,045)	(3,953)
Income tax (expense) credit	<u>(50)</u>	<u>(74)</u>	<u>(65)</u>	<u>(103)</u>
NET INCOME (LOSS)	<u>(3,883)</u>	<u>(2,897)</u>	<u>(5,110)</u>	<u>(4,056)</u>
Earning per share — Basic	(0.21)	(0.16)	(0.27)	(0.22)
Average number of shares used in computation of EPS	18,716,013	18,257,273	18,716,013	18,257,273
Earning per share — Diluted	(0.18)	(0.16)	(0.27)	(0.22)
Average number of shares used in computation of EPS for positive net income	21,155,488	18,283,909	21,155,488	18,283,909

NOTE: Translated for convenience of the reader to U.S. dollars at the 2013 average three months noon buying rate of 1 Euro = 1.3160 USD, and 2012 average three 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)

	Mar. 31, 2013 Euros	Dec. 31, 2012 Euros	Mar. 31, 2013 \$US	Dec. 31, 2012 \$US
Cash, cash equivalents and short term investments	7,288	8,077	9,340	10,650
Total current assets	22,249	24,729	28,513	32,607
Total current liabilities	12,292	13,124	15,753	17,305
Shareholders' Equity	4,190	8,161	5,369	10,761

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2816 USD, on March 31, 2013 and at the noon buying rate of 1 Euro = 1.3186 USD, on December 31, 2012.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2013
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	571	3,123			3,693
Sales of RPPs & Leases	571	362			933
Sales of spare parts & services	244	1,057			1,301
TOTAL NET SALES	1,385	4,542			5,927
Other revenues	(0)	0			(0)
TOTAL REVENUES	1,385	4,542			5,927
GROSS PROFIT	740	1,458			2,198
Research & Development	(319)	(175)	(439)		(932)
Total SG&A plus depreciation	(598)	(1,446)	(34)	(377)	(2,456)
OPERATING PROFIT (LOSS)	(177)	(163)	(473)	(377)	(1,191)

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