



EDAP Reports Fourth Quarter and Full Year 2010 Financial Results

2010 Highlights

- U.S. ENLIGHT Ablatherm-HIFU clinical trial completed enrollment in June 2010 and entered two year follow-up phase
- Lithotripsy division revenues increased 10.2% year-over-year to EUR 16.8 million (USD 22.2 million), fueled by innovative lithotripter product line
- Outstanding convertible debt further reduced by USD 6.6 million to USD 10.5 million at 12/31/10, down from USD 17.1 million at 12/31/09

LYON, France, March 29, 2011 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and full year ended December 31, 2010.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "During 2010, EDAP achieved a major strategic milestone by completing patient enrollment in its ENLIGHT Ablatherm-HIFU U.S. FDA trial. Preliminary patients' follow-up shows satisfactory outcomes with very low side effects comparable to the European clinical results obtained over the past fifteen years, and facilitating the preservation of patients' quality of life. The final data is yet to be submitted to the U.S. FDA for PMA review.

"Over the past year, the economic environment has impacted our HIFU division as hospitals are delaying some capital equipment expenditures. We remain very encouraged by the growing signals on the prominent role HIFU is expected to play in the therapeutic arsenal against prostate cancer. As exemplified by the significant interest at our booth at the European Association of Urology's Annual Congress held last week in Vienna, we are seeing an increasing interest in Ablatherm-HIFU as we position it as the preferred focal therapy treatment option in line with the prostate cancer treatment paradigm shift. The international urological community and patients are demanding a best-in-class device that combines accurate ablative treatment and quality of life preservation, and this is the optimal positioning of our Ablatherm-HIFU solution.

"We are pleased to see return on our investment over the past few years in our lithotripsy innovation. Our continued growth in lithotripsy revenues is a clear demonstration that this market remains very dynamic and in need of technological innovation. EDAP is the only company in this field to have completely renewed its range of products and, more importantly to have implemented new features, concepts and innovation that specifically address the needs of both patients and urologists. We continue to actively pursue opportunities to take market share across the global lithotripsy market and see significant growth potential as we pursue our regulatory filing strategy in both Japan and the US, the two largest markets worldwide."

Mr. Oczachowski continued, "Turning to our balance sheet, we are taking steps to closely manage our cash position. We reduced the convertible debt outstanding by USD 6.6 million over the past year and initiated company-wide cost initiatives to position us to reach timely financial breakeven."

Fourth Quarter 2010 Results

Total revenue for the fourth quarter 2010 was EUR 8.0 million (USD 10.8 million), as compared to EUR 8.1 million (USD 11.9 million) for the fourth quarter 2009.

Total revenue for the HIFU division was EUR 2.0 million (USD 2.6 million) for the fourth quarter 2010, compared to EUR 3.3 million (USD 4.8 million) for the same period last year. Results for the fourth quarter 2010 reflected the sale of two Ablatherm-HIFU devices, as compared to four Ablatherm-HIFU systems sold in the fourth quarter of 2009.

For the three months ended December 31, 2010, total revenue for the lithotripsy division was EUR 6.1 million (USD 8.1 million), compared to EUR 4.8 million (USD 7.0 million) during the year ago period. During the fourth quarter 2010, the Company recorded sales of twenty lithotripsy machines, including seven Sonolith i-sys devices and five Sonolith i-move devices, up from a total of fifteen devices sold in the fourth quarter of 2009.

Gross profit for the fourth quarter 2010 was EUR 3.0 million (USD 4.1 million), compared to EUR 3.7 million (USD 5.4 million) for the year ago period. Gross profit margin was 37.6% in the fourth quarter 2010, compared to 45.5% in the year ago period. The change in the gross profit margin was attributed to shift in the product mix sold in the fourth quarter of 2010 to a lower percentage of Ablatherm-HIFU devices.

Operating expenses were EUR 3.4 million (USD 4.6 million) for the fourth quarter 2010, compared to EUR 3.6 million (USD 5.3 million) for the same period 2009. Fourth quarter 2010 operating expenses included EUR 265,000 related to the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU, down by 33% on a sequential quarter basis from EUR 393,000 in the third quarter 2010.

Operating loss was EUR 371,000 (USD 496,000) for the fourth quarter 2010, and net loss for the fourth quarter 2010 was EUR 7.2 million (USD 9.7 million), or EUR 0.56 per diluted share. The fourth quarter 2010 net loss included a non-cash interest expense of EUR 5.5 million (USD 7.3 million) to adjust the Company's convertible debt and outstanding warrants to fair value, and to reduce the outstanding convertible debt. Excluding the non-cash interest expense, the net loss for the fourth quarter 2010 was EUR 1.8 million (USD 2.4 million), or EUR 0.14 per diluted share.

At December 31, 2010, cash and cash equivalents, including short-term treasury investments, remained strong at EUR 8.9 million (USD 11.8 million).

Full Year 2010 Results

Total revenue for the full year ended December 31, 2010 was EUR 23.7 million (USD 31.3 million), as compared to EUR 24.9 million (USD 34.7 million) for full year 2009. Full Year revenues were mostly impacted by the lower Ablatherm-HIFU machines sales in 2010 with four devices sold, as compared to seven systems sold in 2009, a revenue shift that could not be fully offset by the 10.2% increase in lithotripsy revenues.

For the full year 2010, gross profit was EUR 9.5 million (USD 12.5 million) and operating loss was EUR 3.9 million (USD 5.0 million), compared to EUR 10.7 million (USD 14.9 million) and EUR 3.2 million (USD 4.5 million), respectively, for the same period 2009. The revenue shift was reflected in the lower gross profit, but was partially offset by reductions in operating expenses, which were EUR 13.3 million (USD 17.5 million) for the full year 2010, compared to EUR 13.9 million (USD 19.4 million) for the same period 2009.

Net loss for the full year 2010 was EUR 12.7 million (USD 16.8 million), or EUR 0.98 per diluted share. The full year 2010 net loss included a non-cash interest expense of EUR 6.1 million (USD 8.0 million) to adjust the Company's convertible debt and outstanding warrants to fair value, and to reduce the outstanding convertible debt. Excluding the non-cash interest expense, the net loss for the full year 2010 was EUR 6.7 million (USD 8.8 million), or EUR 0.51 per diluted share.

Mr. Oczachowski concluded, "We continue to advance our strategic initiatives to expand our market penetration. Recent milestones achieved include implementing cost reductions, receiving temporary reimbursement in France, entering new markets with our state-of-the-art lithotripsy product range, expanding our HIFU business in key regions and moving forward our approval processes in various major countries."

Conference Call

EDAP will hold a conference call on Tuesday, March 29, 2011 at 8:30 a.m. EDT to discuss the results. The dial-in numbers are (877) 407-4134 for domestic callers and (201) 689-8430 for international. The conference ID number for both is 368595. 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 April 29, 2011. In addition, a telephonic replay of the call will be available until April 5, 2011. The replay dial-in numbers are 877-660-6853 for domestic callers and 201-612-7415 for international callers. Please use account number 356 and event ID number 368595.

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 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 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. These include statements regarding the Company's growth and expansion plans, the conclusiveness of the results of and success of its Ablatherm-HIFU clinical trials and expectations regarding the IDE submission to and approval by the FDA of the Ablatherm-HIFU device. 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, 2010 Euros	December 31, 2009 Euros	December 31, 2010 \$US	December 31, 2009 \$US
Sales of medical equipment	5,671	5,137	7,599	7,547
Net Sales of RPP and Leases	1,064	1,436	1,426	2,110
Sales of spare parts, supplies and Services	1,302	1,503	1,745	2,209
TOTAL NET SALES	8,037	8,076	10,769	11,866
Other revenues	1	3	1	5
TOTAL REVENUES	8,038	8,080	10,770	11,871
Cost of sales	(5,013)	(4,405)	(6,717)	(6,472)
GROSS PROFIT	3,025	3,675	4,053	5,399
Research & development expenses ⁽¹⁾	(675)	(688)	(904)	(1,012)
S, G & A expenses	(2,721)	(2,888)	(3,646)	(4,243)
Total operating expenses	(3,396)	(3,576)	(4,550)	(5,254)
OPERATING PROFIT (LOSS)⁽¹⁾	(371)	98	(496)	145
Interest (expense) income, net	(6,851)	1,433	(9,180)	2,105
Currency exchange gains (loss), net	81	155	109	228
Other income (loss), net	2	--	3	--
INCOME (LOSS) BEFORE TAXES⁽¹⁾ AND MINORITY INTEREST	(7,139)	1,686	(9,565)	2,477
Income tax (expense) credit ⁽¹⁾	(86)	(57)	(115)	(84)
NET INCOME (LOSS)	(7,224)	1,629	(9,680)	2,393
Earning per share — Basic	(0.56)	0.15	(0.74)	0.23
Average number of shares used in computation of EPS	13,008,401	10,510,305	13,008,401	10,510,305
Earning per share — Diluted	(0.56)	0.15	(0.74)	0.23
Average number of shares used in computation of EPS for positive net income	13,496,394	10,545,730	13,496,394	10,545,730

NOTE: Translated for convenience of the reader to U.S. dollars at the 2010 average three months noon buying rate of 1 Euro = 1.3399 USD, and 2009 average three months noon buying rate of 1 Euro = 1.4693 USD.

⁽¹⁾ Certain prior year amounts have been reclassified to conform to the current year's presentation

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, 2010 Euros	December 31, 2009 Euros	December 31, 2010 \$US	December 31, 2009 \$US
Sales of medical equipment	13,135	13,775	17,358	19,223
Net Sales of RPP and Leases	4,689	5,444	6,197	7,597
Sales of spare parts, supplies and Services	5,378	5,620	7,107	7,843
TOTAL NET SALES	23,202	24,839	30,662	34,663
Other revenues	506	46	669	64
TOTAL REVENUES	23,708	24,885	31,331	34,727
Cost of sales	(14,253)	(14,213)	(18,836)	(19,834)
GROSS PROFIT	9,455	10,672	12,495	14,893
Research & development expenses ⁽¹⁾	(3,268)	(3,651)	(4,318)	(5,095)
S, G & A expenses	(10,005)	(10,223)	(13,222)	(14,265)
Total operating expenses	(13,272)	(13,874)	(17,540)	(19,361)
OPERATING PROFIT (LOSS)⁽¹⁾	(3,818)	(3,202)	(5,045)	(4,468)
Interest (expense) income, net	(8,844)	(4,390)	(11,688)	(6,127)
Currency exchange gains (loss), net	884	(101)	1,168	(142)
Other income (loss), net	--	--	--	--
INCOME (LOSS) BEFORE TAXES⁽¹⁾ AND MINORITY INTEREST	(11,778)	(7,694)	(15,565)	(10,736)
Income tax (expense) credit ⁽¹⁾	(939)	(72)	(1,241)	(101)
NET INCOME (LOSS)	(12,717)	(7,766)	(16,806)	(10,837)
Earning per share — Basic	(0.98)	(0.74)	(1.29)	(1.03)
Average number of shares used in computation of EPS	13,008,401	10,510,305	13,008,401	10,510,305
Earning per share — Diluted	(0.98)	(0.74)	(1.29)	(1.03)
Average number of shares used in computation of EPS for positive net income	13,094,235	10,567,563	13,094,235	10,567,563

NOTE: Translated for convenience of the reader to U.S. dollars at the 2010 average twelve months noon buying rate of 1 Euro = 1.3215 USD, and 2009 average twelve months noon buying rate of 1 Euro = 1.3955 USD.

⁽¹⁾ Certain prior year amounts have been reclassified to conform to the current year's presentation.

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

	Dec. 31, 2010 Euros	Sept. 30, 2010 Euros	Dec. 31, 2010 \$US	Sept. 30, 2010 \$US
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Cash, cash equivalents and short term investments	8,888	8,012	11,794	10,898
Total current assets	29,868	29,085	39,634	38,922
Total current liabilities	14,658	13,730	19,451	18,675
Shareholders' Equity	8,900	9,540	11,809	12,976

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3270 USD, on December 31, 2010 and at the noon buying rate of 1 Euro = 1.3602 USD, on September 30, 2010.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2010
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	1,940	11,196			
Sales of RPPs & Leases	3,505	1,184			4,689
Sales of spare parts & services	<u>1,438</u>	<u>3,940</u>			<u>5,378</u>
TOTAL NET SALES	6,882	16,319			23,202
Other revenues	<u>6</u>	<u>500</u>			<u>506</u>
TOTAL REVENUES	6,888	16,820			23,708
GROSS PROFIT	3,604 52%	5,851 35%			9,455 40%
Research & Development	(741)	(793)	(1,734)		(3,268)
Total SG&A plus depreciation	<u>(3,506)</u>	<u>(4,968)</u>	<u>(193)</u>	<u>(1,338)</u>	<u>(10,005)</u>
OPERATING PROFIT (LOSS)	(644)	91	(1,927)	(1,338)	(3,818)

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