

April 4, 2016

EDAP Reports 20% Revenue Growth to EUR 32.3 Million and EUR 0.5 Million Operating Profit for Full-year 2015

- Obtained FDA clearance in November 2015 for Ablatherm Robotic HIFU;
- Fourth guarter 2015 HIFU Division revenues tripled over fourth guarter 2014;
- Overall fourth quarter 2015 revenues increased 82% over 2014 to EUR 11.8 million (USD 12.8 million);
- Solid cash position of EUR 14.6 million (USD 15.8 million) as of December 31, 2015;
- Strong momentum in U.S. for adoption of HIFU.

LYON, France, April 04, 2016 (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, 2015, and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "2015 was a pivotal year for EDAP with significant regulatory and financial achievements. Foremost was the decision by the FDA to clear our Ablatherm[®] Robotic HIFU for prostate tissue ablation, enabling us to sell the device in the U.S. market. We are currently expanding our US operations to grow Ablatherm unit sales and initiating direct marketing programs targeting urologists and patients. Our team is totally focused on reinforcing the Company's foundation for future growth."

"We are delighted by our 2015 global revenue performance and its 20% growth over 2014. This resulted from a 41% increase in treatment-driven revenues from the HIFU division reflecting increased global acceptance of our technology to ablate prostate tissue non-invasively. In the fourth quarter of 2015, we tripled our HIFU sales as compared to fourth quarter of 2014, which included the sale of two Ablatherm units in the U.S. after receiving the FDA clearance in November. In the UDS/lithotripsy division, we are thrilled to report growth of 32% year-over-year in 12-month revenues, and a highly successful fourth quarter, in which revenues grew 55% vs Q4 2014, exhibiting EDAP's ability to expand its market share in a very competitive field."

Mr. Oczachowski added, "In addition to delivering record revenues and our full-year operating profit, we are establishing a strong pipeline of HIFU projects in the U.S. and the rest of the world as we build upon the momentum that began with November's FDA clearance of Ablatherm.

Fourth Quarter 2015 Results

Total revenue for the fourth quarter 2015 was EUR 11.8 million (USD 12.8 million), compared to EUR 6.5 million (USD 8.0 million) for the fourth quarter 2014.

Total revenue for the HIFU division was EUR 3.3 million (USD 3.6 million) for the fourth quarter 2015, compared to EUR 1.0 million (USD 1.3 million) for the same period last year. During the fourth quarter of 2015, the Company recorded sales of four HIFU machines, comprised of two Ablatherm devices and two Focal One devices.

For the three months ended December 31, 2015, total revenue for the lithotripsy division was EUR 8.5 million (USD 9.2 million), compared to EUR 5.5 million (USD 6.7 million), during the year ago period. During the fourth quarter 2015, the Company recorded sales of 25 lithotripsy machines, which compares to a total of 14 devices sold in the fourth quarter of 2014.

Gross profit for the fourth quarter 2015 was EUR 5.3 million (USD 5.7 million), compared to EUR 2.4 million (USD 3.0 million) for the year ago period. Gross profit margin on net sales was 45.0% in the fourth quarter of 2015, compared to 37.6% in the year ago period.

Operating expenses were EUR 3.7 million (USD 4.0 million) for the fourth quarter 2015, compared to EUR 3.5 million (USD 4.3 million) for the same period in 2014.

Operating profit for the fourth quarter was EUR 1.6 million (USD 1.7 million), compared with an operating loss in the fourth quarter of 2014 of EUR 1.0 million (USD 1.3 million).

Net income for the fourth quarter 2015 was EUR 5.1 million (USD 5.5 million), or EUR 0.18 per diluted share, as compared to a net loss of EUR 2.6 million (USD 3.3 million), or EUR 0.11 per diluted share, in the year ago period. Net income in the fourth quarter 2015 included non-cash interest income of EUR 3.7 million to adjust the accounting fair value of the outstanding warrants.

Full-year 2015 Financial Results

Total revenue for the twelve months ended December 31, 2015 was EUR 32.3 million (USD 35.6 million), up 20.4% compared to EUR 26.8 million (USD 35.4 million) in 2014.

Total revenue for the HIFU division was EUR 8.5 million (USD 9.4 million) for 2015, compared to EUR 8.7 million (USD 11.5 million) in 2014.

Lithotripsy division revenue was EUR 23.8 million (USD 26.2 million), compared to EUR 18.1 million (USD 23.9 million) in 2014.

Gross profit for the year was EUR 13.8 million (USD 15.2 million), with gross profit margin on net sales of 42.8%, compared to 42.7% a year ago.

Operating income was EUR 0.5 million (USD 0.5 million) as compared to an operating loss of EUR 1.7 million (USD 2.3 million) in 2014.

Full-year net loss was EUR 1.7 million (USD 1.8 million), or EUR 0.07 per diluted share, as compared to net loss of EUR 0.5 million (USD 0.7 million), or EUR 0.02 per diluted share, in 2014. Full-year 2015 net loss included non-cash interest expense of EUR 2.0 million to adjust the accounting fair value of the outstanding warrants.

At December 31, 2015, cash and cash equivalents, including short-term treasury investments, were EUR 14.6 million (USD 15.8 million).

Conference Call

EDAP will hold a conference call on Monday, April 4, 2016 at 8:30 a.m. EDT to discuss the results and provide an update on recent business developments. The dial-in numbers are 1-888-348-6419 in the U.S., and 1-412-902-4235 for international callers. The conference ID number for both is 10083055. 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 event, the webcast will remain available on EDAP's website, <u>www.edap-tms.com</u>, through May 6, 2016. In addition, a dial-in replay of the call will be available. 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 10083055.

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation 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 for commercial distribution in Europe and some other countries including Mexico and Canada, and has received 510(k) clearance by the U.S. FDA. The Company also markets an innovative robot-assisted HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. For more information on the Company, please visit http://www.edap-tms.com, and 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 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.

EDAP TMS S.A.

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

	Three Mont	hs Ended:	Three Months Ended:		
	December 31,	ber 31, December 31, Dece		December 31,	
	2015	2014	2015	2014	
	Euros	Euros	\$US	\$US	
Sales of medical equipment	9,049	3,947	9,792	4,877	
Net Sales of RPP and Leases	1,151	1,111	1,245	1,372	
Sales of spare parts, supplies and					
Services	1,560	1,398	1,688	1,727	
TOTAL NET SALES	11,760	6,455	12,726	7,976	
Other revenues	32	22	35	27	
TOTAL REVENUES	11,792	6,477	12,760	8,003	
Cost of sales	(6,495)	(4,049)	(7,029)	(5,003)	
GROSS PROFIT	5,297	2,428	5,732	3,000	
Research & development expenses	(565)	(600)	(612)	(741)	
S, G & A expenses	(3,147)	(2,857)	(3,406)	(3,531)	
Total operating expenses	(3,713)	(3,457)	(4,018)	(4,272)	
OPERATING PROFIT (LOSS)	1,584	(1,030)	1,714	(1,272)	
Interest (expense) income, net	3,710	(1,159)	4,015	(1,432)	
Currency exchange gains (loss), net	476	(402)	516	(497)	
Other income (loss), net	5	6	5	7	
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	5,775	(2,585)	6,249	(3,194)	
Income tax (expense) credit	(659)	(54)	(713)	(66)	
NET INCOME (LOSS)	5,116	(2,638)	5,536	(3,260)	
Earning per share - Basic	0.20	(0.11)	0.22	(0.13)	
Average number of shares used in computation of EPS	25,254,618	24,865,420	25,254,618	24,865,420	
Earning per share - Diluted	0.18	(0.11)	0.19	(0.13)	
Average number of shares used in computation of EPS for positive net income	28,846,270	24,865,420	28,846,270	24,865,420	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2015 average three months' noon buying rate of 1 Euro = 1.0821 USD, and 2014 average three months noon buying rate of 1 Euro = 1.2356 USD.

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

	Twelve Mor	nths Ended:	Twelve Months Ended:		
	December 31,	December 31,	December 31,	December 31,	
	2015	2014	2015	2014	
	Euros	Euros	\$US	\$US	
Sales of medical equipment	21,906	16,895	24,168	22,318	
Net Sales of RPP and Leases	4,408	3,957	4,864	5,227	
Sales of spare parts, supplies and					
Services	5,904	5,400	6,513	7,133	
TOTAL NET SALES	32,218	26,252	35,545	34,679	
Other revenues	35	533	39	704	
TOTAL REVENUES	32,253	26,785	35,584	35,383	
Cost of sales	(18,468)	(15,584)	(20,375)	(20,586)	

GROSS PROFIT	13,785	11,201	15,209	14,797
Research & development expenses	(2,690)	(2,932)	(2,968)	(3,873)
S, G & A expenses	(10,608)	(10,006)	(11,703)	(13,217)
Total operating expenses	(13,298)	(12,937)	(14,671)	(17,090)
OPERATING PROFIT (LOSS)	488	(1,736)	538	(2,294)
Interest (expense) income, net	(2,094)	1,771	(2,310)	2,338
Currency exchange gains (loss), net	699	(431)	771	(569)
Other income (loss), net	-	-	-	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(907)	(396)	(1,001)	(524)
Income tax (expense) credit	(759)	(116)	(838)	(153)
NET INCOME (LOSS)	(1,667)	(512)	(1,839)	(676)
Earning per share - Basic	(0.07)	(0.02)	(0.07)	(0.03)
Average number of shares used in computation of EPS	25,021,966	23,600,428	25,021,966	23,600,428
Earning per share - Diluted	(0.07)	(0.02)	(0.07)	(0.03)
Average number of shares used in computation of EPS for positive net income	25,021,966	23,600,428	25,021,966	23,600,428

NOTE: Translated for convenience of the reader to U.S. dollars at the 2015 average twelve months noon buying rate of 1 Euro = 1.1033 USD, and 2014 average twelve months noon buying rate of 1 Euro = 1.3210 USD.

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

	Dec. 31, 2015 Euros	Sept. 30, 2015 Euros	Dec. 31, 2015 \$US	Sept. 30, 2015 \$US
Cash, cash equivalents and short term investments	14,578	11,073	15,831	12,359
Total current assets	33,039	27,003	35,877	30,141
Total current liabilities	16,271	12,570	17,668	14,030
Shareholders' Equity	14,430	8,914	15,669	9,949

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0859 USD, on December 31, 2015 and at the noon buying rate of 1 Euro = 1.1162 USD, on September 30, 2015.

EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION TWELVE MONTHS ENDED DECEMBER 31, 2015 (Amounts in thousands of Euros)

	HIFU Division		UDS Division		FDA Trials	Corporate	Total After Consolidation	
Sales of goods	4,878		17,027				21,906	
Sales of RPPs & Leases	2,908		1,501				4,408	
Sales of spare parts & services	658		5,246				5,904	
TOTAL NET SALES	8,444	•	23,774	•			32,218	
Other revenues	32	-	3	-			35	
TOTAL REVENUES	8,476		23,777	-			32,253	
GROSS PROFIT	4,841	57.1%	8,945	37.6%			13,785	42.7%
(% of Total Revenues)								
Research & Development	(1,387)		(992)		(311)		(2,690)	
Total SG&A plus depreciation	(2,931)		(6,314)		(1)	(1,363)	(10,608)	

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Source: EDAP TMS SA

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