

EDAP TMS SA
Form 6-K
October 28, 2005

EDAP TMS S.A. Reports 2005 Third Quarter Results
UK Market Launch Begins Following Reimbursement Approval
Per Procedure Model Continues Rapid Growth Worldwide

Lyon, France, October 26, 2005 -- EDAP TMS S.A. (NASDAQ: EDAP) , today reported financial results for the 2005 third quarter ended September 30, 2005. For the third quarter of 2005, the company reported total revenues of EUR 4.5 million compared to EUR 5.5 million in the same quarter of 2004. Year to date revenue includes the sale of 24 lithotripsy and six Ablatherm-HIFU units. Revenues for the nine months ended September 30, 2005 were EUR 14.6 million compared to EUR 16.5 million in 2004.

Hugues de Bantel, CEO of EDAP TMS, commented: "The third quarter of 2005 certainly does not reflect the current business situation as of October 1. The third quarter is below our expectations due to our total mix in lithotripsy. Necessary actions have been taken during the course of the quarter and will enable us to resolve this issue before year-end. More importantly, we have already secured a backlog of two Ablatherm units since October 1, confirming our anticipation of a strong fourth quarter with two months still ahead. The shift from dependency on the purchase of equipment toward a business model providing Ablatherm-HIFU procedures on a mobile basis is clearly under way and will ensure predictable and recurring revenues in the future as we are accumulating a significant site base. We believe we are positioned for a fourth quarter demonstrating both our capability to continue increasing per procedure treatment interest and sell Ablatherm units to larger sites, including in new markets, which we are entering at present."

The company's gross margin as a percentage of total revenue increased from 38 percent in 2004 to 41 percent to date due to continued focus on efficiency, consistent average selling prices and increasing service contributions. The company's operating expenses increased by 1 percent compared to 2004, with a clear focus on the HIFU division sales and marketing, in line with the company's continued expansion of physician and patient education activities.

The company's net loss for the third quarter 2005 was EUR 572,000 compared to EUR 259,000 in the third quarter 2004. Net loss for the first nine months was EUR 1,111,000 compared to EUR 778,000 in 2004. The net loss level is largely attributable to the delay in booking expected sales to the later part of the year, and the shift to an expansion of mobile business and its ensuing near-term alteration of the revenue model and working capital.

As of September 30, 2005, the company had EUR 7.5 million in cash. During the third quarter, EDAP invested a portion of available cash in capitalized assets for increased new cost per procedure installations worldwide. The working capital will be returned through the sale of Ablatherm HIFU units and procedures in both new and existing markets.

EDAP: SUCCESSFUL UK LAUNCH GENERATING ADDITIVE ORDERS THROUGH YEAR END

For the first nine months of 2005, the HIFU division experienced a 30% growth in the mobile per-procedure business. Maintenance and service contract sales continued to increase due to the end of the warranty period for Ablatherm units already installed, fueling a 47% percent increase year to date. With two additional Ablatherm units sold during the quarter, revenues for the third quarter were EUR 1.4 million, amounting to EUR 5.0 million for the nine months ended September 30, 2005. Gross margins improved to 49 percent of sales at EUR 2.5 million as compared to 45 percent at EUR 2.3 million in the prior year period. Year-to-date margin improvement was driven by efficiencies within the manufacturing process, positive contribution from services and ongoing attention to average selling price.

For the nine months of 2005, sales and marketing expenses increased in the EDAP division in line with the company's planned expansion of education programs. R&D expenses also increased, as planned, in order to further strengthen the company's technological mastery and strong IP portfolio.

EDAP - HIFU Division:

Year

Gross Margin

Edgar Filing: EDAP TMS SA - Form 6-K

	Revenues <i>(Euros' millions)</i>		Operating Income (Loss) <i>(Euros '000)</i>
Q3 2004	1.5	47%	1
Q3 2005	1.4	51%	(146)
YTD 2004	5.0	45%	164
YTD 2005	5.0	49%	(333)

Total Ablatherm-HIFU treatments are now more than 8,400 to date, which is the most extensive body of experience on HIFU for localized prostate cancer in the world. Additionally, the company now reports more than 80 sites using Ablatherm-HIFU on a fixed or mobile basis, as compared to 55 sites at September 30, 2004, a 45 percent increase over the prior year.

Over the last four months, the Company reached significant milestones by establishing Ablatherm-HIFU in leading centers, worldwide.

In the United Kingdom , where more than 30,000 new prostate cancer cases are diagnosed every year, the Company's marketing efforts are bearing fruits. In addition, NICE positive guidance obtained earlier in the year recommending the use of HIFU for localized prostate cancer, together with the recent approval of HIFU treatment by BUPA, the UK 's largest private medical insurer, to fund such therapy for its members, led to the sale of two units in the UK in October. This brings to four the number of sites now using Ablatherm-HIFU in the UK .

After a thorough review of available HIFU technologies for prostate cancer, Guy's Hospital, in London , decided to purchase the Ablatherm because of its unique clinical outcomes and safety features. Guy's is a part of one of the largest UK Hospital Trusts. Additionally, this hospital represents one of the country's most well known teaching hospitals under a partnership with King's College London and one of the largest urology centers in the United Kingdom . Additionally, "Mobile-HIFU," a private UK company, purchased an Ablatherm unit to offer the treatment on a mobile cost-per-procedure basis. Treatments will begin in October in various hospitals and clinics around the UK . This fully complies with the company's strategy to expand the use of HIFU by offering the technology to a wider number of patients.

In October, the company also entered the Australian market, by placing an Ablatherm-HIFU at the highly regarded St Vincent's Clinic in Sydney . Pr. Stricker, Head of the Urology department, and in charge of the St Vincent 's Prostate Cancer Centre has already treated eight patients. Pr. Stricker's team has been fully trained on the use of Ablatherm-HIFU and is now ready to offer the treatment to Australian men with prostate cancer who are not candidates for surgery, failed prior radiotherapy or choose the treatment for its capacity to preserve the patient's quality of life.

The Ablatherm-HIFU Clinic opened in Toronto , Canada , in April 2005 by an affiliate of Maple Leaf HIFU Company continued to attract new patients during the third quarter. Patients have been treated with excellent outcomes at the Toronto clinic since it opened building a strong base of credibility based on local treatments for Canadian men. Whereas most of the patients treated at the Toronto clinic have been Canadian citizens, an increasing percentage of patients have come from the United States , and it is believed that this trend will continue.

In Germany , the third largest market in the world for medical devices, the mobile per-procedure business increased 78 percent compared to the same period last year. As of today, the company reports 25 Ablatherm user sites in Germany , 19 of which are served with the mobile model, a 108 percent increase compared to last year with only 12 sites served. The Company recently expanded its mobile services toward Austria and Switzerland based on its strength in user experience and clinical credibility.

The mobile Italian HIFU market continues to grow with a more than fourfold increase in the HIFU activity compared with the first nine months last year. The number of sites doubled to 12 compared to the same period last year. The Italian market is growing from a smaller base but confirms the acceleration of demand for both fixed and mobile sites as well as treatments provided. The Italian progress is similar to what the company has experienced in Germany following reimbursement approval further confirming the validity of the model.

The company plans to begin its first treatments in the United States through trials sponsored by its partner HealthTronics by the end of 2005. HealthTronics has identified the centers to conduct trial treatments and EDAP is providing Ablatherm units according to its existing agreement.

Hugues de Bantel commented: "We are particularly pleased with the ground work performed so far, which allowed us to enter new markets successfully including the UK market with two machines already sold in October and Australia with the installation of our

first Ablatherm-HIFU in that country. In both cases, as with prior market entries, we are engaging key opinion leaders who are widely respected within their respective urological communities. Progress in our mobile business in key markets confirms the validity of our strategic move toward offering payment on treatment performed models as a primary method of propagating Ablatherm treatment in new and existing markets. We are particularly pleased with the quality of the centers which recently joined the list of Ablatherm users. They continue to advance the credibility of Ablatherm-HIFU as the most advanced and refined HIFU treatment worldwide for localized prostate cancer."

TMS: STEADY SALES IN LITHOTRIPTERS

The UDS Division continued steady sales with 24 lithotripters sold in the first nine months of 2005. The company's mix of new unit sales year to date was weighted toward the mid-range product family. Revenues for the third quarter were EUR 4.0 million, amounting to EUR 11.7 million for the nine month ended September 30, 2005. Gross margins held steady at 30 percent for the division. The company continued to maintain strict controls on internal expenses, which decreased by 15 percent within the UDS division year to date. Consequently, the company's operating profit for the quarter increased 27 percent compared to last year. TMS finished the third quarter with a strong backlog of 6 lithotripters anticipating a solid fourth quarter.

TMS - UDS Division :

Year	Revenues (Euros' millions)	Gross Margin	Operating Income (Loss) (Euros '000)
Q3 2004	4,6	34%	61
Q3 2005	4,0	30%	120
YTD 2004	13,2	31%	164
YTD 2005	11,7	30%	209

Hugues de Bantel commented: "Year-to-date we had a slower cycle in one of our key markets. These cycles occur periodically within submarkets of our Lithotripsy base, especially following strong uptrends in unit sales which remove a certain amount of maintenance demand on older units. We saw more sales of our mid-range product as compared to prior periods which has affected the total revenues. We are now seeing a return in sales activity to more normalized levels and mix in the later part of the year as we had expected. TMS remains committed to Lithotripsy as we have a broad and established base providing strong support for the total company. Lithotripsy is a mature market, but TMS competes effectively and has an established leadership position. We continue to operate this division successfully with a focus on operating income strength regardless of the short-term up and down fluctuations within regional lithotripsy markets as demonstrated by the increase in operating income during a period of lower total revenues.

CORPORATE OUTLOOK

EDAP continues to make significant strides forward in advancing and accelerating our corporate model, said de Bantel. The second and third quarters represented a shift in our business that will further build our capability and global reach. We continue to launch Ablatherm treatment successfully into new markets and have high expectations from the activity we have undertaken so far this year. We have invested some of our capital position during this period of transition, and we expect to see positive effects on revenues while continuing our solid margins and corporate efficiency improvement. Our new market launches in the third quarter and October demonstrate the outcomes of that short-term investment. Our experience with continued growth and success in key countries also confirms the potential returns with the assistance of a strong mobile model and reimbursement approvals from key health plans. We look forward to reporting continued success and growth going forward.

Commenting on the position of the company, de Bantel stated, While our revenues have been down year to date, our model is clearly demonstrating its strength. The revenue fall-off has largely been in the lithotripsy market due to cycle and mix issues which are already correcting. However, we have been able to improve our absolute operating income even on these lower sales. The same is true in the HIFU division where we have sold one fewer Ablatherm unit year to date than in the prior year. Mobile procedure growth and increasing contributions from our installed base have made up the difference. Finally, we are already positioned very well to report a solid final quarter in HIFU due to new market launches.

Edgar Filing: EDAP TMS SA - Form 6-K

EDAP continues to operate with the future in mind, de Bantel continued. To that end, our primary focus is utilizing our capital position to grow our available base of users and potential patients through investment in expanding our market reach and educational efforts directed to both patients and physicians. The per procedure model clearly is successfully expanding our treatable population by making Ablatherm-HIFU available on a broader basis and growing treatment demand once centers are established. In short, we are very excited about our future growth opportunities.

CONFERENCE ACTIVITY

EDAP is participating in the 5th International Symposium on Therapeutic Ultrasound October 27 - 29, 2005, at Harvard Medical School , Boston . EDAP is one of the key sponsors of the ISTU meeting and will have scientific and clinical presentations made during the event related to its clinical results at seven years, the longest presented HIFU follow-up.

EDAP will be actively participating in the French Association of Urology (AFU) meeting to be held in Paris , from November 16-19, 2005 (Booth #B7). During that congress, the French HIFU Club will meet to discuss clinical results obtained with the new Ablatherm-HIFU integrated imaging system and a presentation will be made on selected criteria related to the HIFU treatment of patients who failed radiotherapy. The company will report on the proceedings following the event.

Additionally, the company plans to resume its market outreach efforts with investor meetings the week of November 7 in Germany and the UK . The company will also make visits in the United States during December. Details or appointments for these events can be arranged through the company's investor relations representation, Halliburton investor Relations, at +1 972-458-8000.

Conference Call and Webcast

The company will host a conference call to discuss the results and answer questions from investors on Thursday, October 27, 2005, at noon Eastern Time, 6:00 p.m. Paris Time. Representing the Company on the call will be Philippe Chauveau, Chairman of the Board, Hugues de Bantel, Chief Executive Officer, and Thierry Turbant, Chief Financial Officer. Interested investors may join the call live by dialing (888) 214-7592 from the United States or +1 (415) 537-1828 from international locations and requesting the EDAP TMS Third Quarter Conference Call.

Investors unable to join the call can access a playback of the conference call. To access the replay, please dial (800) 633-8284 or +1 (402) 977-9140 and using access code 21265876 beginning two hours after the end of the call until November 3, 2005.

About EDAP TMS S.A.

EDAP TMS S.A. develops and markets the 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. The company is also developing this technology for the treatment of certain other types of tumors. EDAP TMS S.A. also produces and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL).

For more information on the Company, contact the Investor Relations Dept by phone at +33 (0)4 78 26 40 46.

This press release contains, in addition to historical information, forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in the 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.

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

	Three Months Ended :		Three Months Ended :	
	September 30, 2005 Euros	September 30, 2004 Euros	September 30, 2005 \$US	September 30, 2004 \$US
Net sales of medical equipment	2,062	3,211	2,510	3,920
Net sales of spare parts, supplies and services	2,464	2,320	2,999	2,833
NET SALES	4,526	5,531	5,509	6,753
Other revenues	-	(13)	-	(15)
TOTAL REVENUES	4,526	5,518	5,509	6,738
Cost of sales	(2,681)	(3,256)	(3,263)	(3,976)
GROSS PROFIT	1,845	2,262	2,246	2,762
Research & development expenses	(255)	(360)	(510)	(439)
S, G & A expenses	(2,084)	(2,094)	(2,337)	(2,557)
Total operating expenses	(2,339)	(2,454)	(2,847)	(2,996)
OPERATING PROFIT (LOSS)	(494)	(192)	(601)	(234)
Interest (expense) income, net	8	60	9	73
Currency exchange gains (loss), net	(79)	(120)	(96)	(147)
Other income (loss), net	20	-	24	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(545)	(252)	(664)	(308)
Income tax (expense) credit	(28)	(7)	(33)	(9)
NET INCOME (LOSS)	(573)	(259)	(697)	(317)
Earning per share - Basic	(0.07)	(0.03)	(0.09)	(0.04)
Average number of shares used in computation of EPS	7,781,731	7,781,731	7,781,731	7,781,731
Earning per share - Diluted	(0.07)	(0.03)	(0.09)	(0.04)
	8,344,368	8,038,156	8,344,368	8,038,156

Edgar Filing: EDAP TMS SA - Form 6-K

Average number of shares used in computation of EPS

NOTE: Translated for convenience of the reader to U.S. dollars at the 2005 average three months noon buying rate of 1 Euro = 1.2172 USD, and 2004 average three months noon buying rate of 1 Euro = 1,2211 USD.

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

	Nine Months Ended :		Nine Months Ended :	
	September 30, 2005 Euros	September 30, 2004 Euros	September 30, 2005 \$US	September 30, 2004 \$US
Net sales of medical equipment	6,997	8,839	8,795	10,822
Net sales of spare parts, supplies and services	7,553	7,453	9,493	9,124
NET SALES	14,550	16,292	18,288	19,946
Other revenues	53	219	67	269
TOTAL REVENUES	14,603	16,511	18,355	20,215
Cost of sales	(8,688)	(10,158)	(10,920)	(12,437)
GROSS PROFIT	5,915	6,353	7,435	7,778
Research & development expenses	(788)	(613)	(1,696)	(1,392)
S, G & A expenses	(6,497)	(6,360)	(7,460)	(7,146)
Non recurring operating expenses	-	(208)	-	(254)
Total operating expenses	(7,285)	(7,181)	(9,156)	(8,792)
OPERATING PROFIT (LOSS)	(1,370)	(828)	(1,721)	(1,014)
Interest (expense) income, net	35	29	44	36
Currency exchange gains (loss), net	229	72	287	87
Other income (loss), net	22	4	28	5
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,084)	(723)	(1,362)	(886)
Income tax (expense) credit	(27)	(55)	(34)	(67)
NET INCOME (LOSS)	(1,111)	(778)	(1,396)	(953)

Edgar Filing: EDAP TMS SA - Form 6-K

Earning per share - Basic	(0.14)	(0.10)	(0.18)	(0.12)
Average number of shares used in computation of EPS	7,781,731	7,781,731	7,781,731	7,781,731
Earning per share - Diluted	(0.14)	(0.10)	(0.18)	(0.12)
Average number of shares used in computation of EPS	8,344,368	8,047,393	8,344,368	8,047,393

NOTE: Translated for convenience of the reader to U.S. dollars at the 2005 average nine months noon buying rate of 1 Euro = 1.2569 USD, and 2004 average nine months noon buying rate of 1 Euro = 1.2243 USD.

EDAP TMS S.A.
CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)
(Amounts in thousands of Euro's and U.S. Dollars)

	September 30, 2005 Euros	June 30, 2005 Euros	September 30, 2005 \$US	June 30, 2005 \$US
Cash, cash equivalents and short term investments	7,463	8,222	8,999	9,947
Total current assets	22,014	23,254	26,545	28,133
Total current liabilities	9,786	10,089	11,800	12,205
Shareholders' Equity	16,953	17,543	20,442	21,224

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2058 USD, on September 30, 2005 and at the noon buying rate of 1 Euro = 1.2098 USD, on June 30, 2005.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2005
(Amounts in thousands of Euro's)

	EDAP S.A. HIFU Division		TMS S.A. UDS Division		EDAP TMS HQ	Consolidation Impact	Total After Consolidation	
Net sales of medical devices	2,586		5,676		-	(1,265)	6,997	
Net sales of spare parts, supplies and services	2,376		5,963		-	(786)	7,553	
Other revenues	71		47		-	(65)	53	
TOTAL REVENUES	5,033		11,686		-	(2,116)	14,603	
GROSS PROFIT	2,460	50%	3,540	30%	-	(86)	5,914	41%
Research & Development	(794)		(555)		-	-	(1,349)	
Total SG&A plus depreciation	(1,999)		(2,776)		(1,160)	-	(5,935)	
Non recurring op. expenses	-		-		-	-	-	
OPERATING PROFIT (LOSS)	(333)		209		(1,160)	(86)	(1,370)	