

EDAP TMS SA  
Form 6-K  
May 16, 2005

**EDAP TMS S.A. REPORTS 2005 FIRST QUARTER PERFORMANCE**

Opening of Canadian and U.K. Markets for Ablatherm HIFU  
Strong Revenue Growth in Reimbursed Countries  
Strengthening of EDAP TMS Gross Margin

**Lyon, France, May 11, 2005 -- EDAP TMS S.A. (Nasdaq: EDAP)** , today reported financial results for the 2005 first quarter ended March 31, 2005. For the first quarter of 2005, the Company reported total revenues of EUR 5.1 million compared to EUR 5.8 million in the same quarter of 2004. First quarter revenue included the sale of nine lithotripsy and two Ablatherm-HIFU units compared to nine lithotripsy and three Ablatherm -HIFU units in 2004.

The Company's gross margin as a percentage of total revenue increased from 36 percent to 40 percent due to an increase in average product selling price for both lithotripsy and Ablatherm-HIFU units, and therefore remained stable in absolute value at EUR 2.1 million, level with same quarter of 2004.

The Company's operating expenses increased by 6 percent from the prior year, in line with the company's strategy to further increase education and awareness for Ablatherm-HIFU, to further enhance technological leadership in HIFU and to accelerate the reimbursement process in key countries, while continuing to control UDS division expenses.

Both EDAP TMS operating divisions reported a profitable quarter, confirming the repositioning of the Company executed in 2004. The Company's net loss was EUR 140,000 in Q1 2005 versus EUR 13,000 in Q1 2004.

As of March 31, 2005, the Company had EUR 8.2 million in cash and recorded a net book value of EUR 17.9 million, level with December 2004 shareholders' equity.

Hugues de Bantel, CEO of EDAP TMS, commented: "This quarter is in line with our corporate plan, particularly with regard to a sensible shift from equipment purchase to procedure purchase in countries where we are reimbursed for Ablatherm-HIFU, as well as continued and sustainable growth patterns in our total number of treatments performed. As awareness of Ablatherm-HIFU continues to grow, we will be addressing a broader geography of patients providing access to the procedure to our doctors and clinics through our mobile services. Once the treatment is established in the doctor and patient community, a permanent installation will become more attractive, leading to the equipment sale in many of the large locations. In the interim, both our machine sale and mobile procedure models remain healthy and are making meaningful contributions to operating income."

**EDAP: ABLATHERM-HIFU EXPANDS ITS RECOGNITION WORLDWIDE**

For the first quarter of 2005, the HIFU division recorded continued Ablatherm growth through the sale of two treatment units as well as continued growth in the mobile treatment business. Net sales amounted to EUR 1.7 million compared to EUR 1.8 million for the same quarter of 2004. While the company sold one fewer unit compared to the prior year quarter, continued market penetration and growth in the mobile and permanent treatment rates made significant contributions to the division's total revenues. Expenses increased from EUR 658,000 in Q1 2004 to EUR 871,000 in Q1 2005, in line with the Company's strategy to strengthen its marketing, sales and R&D and to further penetrate the market. Operating income remained positive at EUR 4,000 versus EUR 72,000 the prior year. Gross margin as a percentage of revenue strengthened from 40 percent up to 50 percent on a quarterly comparison, thanks to the implementation of major cost reduction programs on the device and an increase in the Company's average selling price for these two units.

EDAP - HIFU Division : Euros 000's

Year	Revenues	Gross Margin %	Operating Income (Loss)
Q1 2004	1,840	40%	72
Q1 2005	1,761	50%	4

Performance achieved in countries where Ablatherm-HIFU has already secured reimbursement demonstrates continued development in the company's operating model for both fixed and mobile treatment centers. In Germany and Italy, where the company has received approval for reimbursement of approximately half the total treatment cost, mobile HIFU-related revenues

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increased three-fold. This is in line with the Company's mobile strategy to provide access to HIFU treatment without initial investment from the hospital or clinic. The company is continuing to seek additional reimbursement approvals as well as increases to obtain appropriate levels in countries with partial reimbursement.

Additionally, the EDAP HIFU division launched its initial presence in the North American market and strengthened its distribution channel with the placement of EDAP's first Ablatherm-HIFU unit in Toronto. The company's Canadian partner Maple Leaf HIFU Company, now fully operational, treated its first patients in late April.

We are pleased to report that patient treatments at the Toronto clinic have started following the official launch this spring, said de Bantel. To date, our partner Maple Leaf HIFU has successfully treated a number of patients from North America and plans to continue doing so at an aggressive pace in the months to come. We see significant interest in and demand for an alternative prostate cancer treatment for men in North America who are not good candidates for more traditional, but potentially difficult, treatments such as surgery or radiation. HIFU offers these patients a proven, safe and effective treatment with lower side effects and faster recovery all critical elements in a successful treatment program.

The company also made significant progress in Great Britain. After reviewing all available data on HIFU, the U.K. National Institute of Clinical Excellence (NICE) issued guidance mentioning that current evidence on the safety and efficacy of HIFU, as measured by reduction in PSA levels and biopsy findings, appears adequate to support the use of HIFU for the treatment of prostate cancer, provided that normal arrangements are in place. Following that review and its recommendations, the largest U.K. private insurance company is now reviewing the company's application for reimbursement.

Our first U.K. center, Stepping Hill Hospital in Stockport, has now performed approximately 30 treatments and, based on this guidance, is now planning to increase the pace of its Ablatherm treatments in the future. Furthermore, over the last few months, we strengthened our presence in the U.K. with the selection of a local distributor with very strong credibility and network connections in Great Britain. We plan to rapidly increase the number of operating sites over the months to come, added de Bantel.

The company continues to work with its U.S. partner, HealthTronics, in pursuit of clinical trials for the Ablatherm device in the United States. American clinical trials are expected to begin in the second half of 2005.

On the clinical side, a recent review article published in the April edition of *Nature Clinical Practice* highlighted comparable results in four different Ablatherm-HIFU centers in Europe and outlined excellent outcome reports for patients with prostate cancer who chose Ablatherm-HIFU treatment. These results confirm that Ablatherm-HIFU, with its sustained outcomes at five years combined with a good preservation of quality of life, is now considered as a routine treatment for the management of prostate cancer.

### **TMS: CONTINUED DEMAND FOR OUR LITHOTRIPTERS**

The UDS division continued its predictable revenue and net income delivery with another quarter of operating income profit. The UDS division delivered another strong quarter with 9 lithotripsy units sold. Over the quarter, the company's mix of new unit sales was weighted toward the mid-range Sonolith Praktis, rather than the more advanced and higher priced Sonolith Vision, which accounts for the difference in revenue. Nevertheless, the division succeeded in increasing its gross margin through stronger pricing per unit in both equipment lines.

TMS - UDS Division : Euros 000's

Year	Revenues	Gross Margin %	Operating Income (Loss)
Q1 2004	4,556	29%	92
Q2 2005	3,920	30%	34

The company continued to maintain strict controls on internal expenses, which decreased by 6% within the UDS division.

The company also participated significantly in the 93 rd Annual Meeting of the Japanese Urological Association (JUA) in April. More than 6,000 doctors attended the proceedings in Tokyo, including Dr. Osamu Muraki of Fujita General Hospital and Dr. Kenichi Tajima of Tokyo Teishin Hospital, both of whom presented clinical results unique to the EDAP lithotripsy platforms.

TMS entered the second quarter with a strong backlog of five lithotripters.

## **CORPORATE OUTLOOK**

Hugues de Bantel concluded: This 2005 first quarter further demonstrates the importance for the HIFU division of accelerating the reimbursement process in key countries and securing a satisfactory level of reimbursement, as this is tied to significant increases in procedure utilization and acceptance by patients. Many of the patients rely on reimbursement to afford the total cost of their care. Results obtained in Q1 also confirm the stability of our lithotripsy business.

With the turnaround executed throughout 2004, we envisioned having enough resources to implement our strategy despite potential quarter-to-quarter changes in the total number and mix of treatment units sold. Our continued forward progress on total treatments and penetration of key markets remains steady on multiple fronts utilizing both the mobile pay-per-procedure and fixed installation models as the local population dictates. We continue to be well capitalized for growth, are investing in additional marketing and education initiatives to grow market demand, and gain strength as more urologists and patients are turning to Ablatherm-HIFU as a desirable alternative to the risks and uncertainties that can make more traditional treatments difficult for patients.

The company will participate in the upcoming American Urological Association Annual Meeting to be held in San Antonio, Texas, May 21-26, 2005.

## **Conference Call and Webcast**

The company will host a conference call to discuss the results and answer questions from investors on Thursday, May 12, 2005, at 12:00 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. Investors may join the call live by dialing 877-707-9628 within the United States or +1-785-832-0301 from international locations and requesting the EDAP TMS 2005 First Quarter Conference Call.

Investors unable to join the call can access a playback of the conference call. To access the replay, please dial 800-839-5490 or +1-402-220-2550 beginning two hours after the end of the call until Saturday, May 21, 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)**

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	Three Months Ended :		Three Months Ended :	
	March 31 , 2005 Euros	March 31 , 2004 Euros	March 31 , 2005 \$US	March 31 , 2004 \$US
Net sales of medical equipment	2,699	3,190	3,530	3,954
Net sales of spare parts, supplies and services	2,377	2,431	3,109	3,014
<b>TOTAL NET SALES</b>	<b>5,076</b>	<b>5,621</b>	<b>6,639</b>	<b>6,968</b>
Other revenues	50	152	65	188
<b>TOTAL REVENUES</b>	<b>5,126</b>	<b>5,773</b>	<b>6,704</b>	<b>7,156</b>
Cost of sales	(3,062)	(3,719)	(4,004)	(4,610)
<b>GROSS PROFIT</b>	<b>2,064</b>	<b>2,054</b>	<b>2,700</b>	<b>2,546</b>
Research & development expenses	(450)	(391)	(589)	(484)
S, G & A expenses	(1,936)	(1,854)	(2,533)	(2,299)
Total operating expenses	(2,386)	(2,245)	(3,122)	(2,783)
<b>OPERATING PROFIT (LOSS)</b>	<b>(323)</b>	<b>(191)</b>	<b>(422)</b>	<b>(237)</b>
Interest (expense) income, net	7	(28)	9	(34)
Currency exchange gains (loss), net	168	272	220	337
Other income (loss), net	9	(3)	12	(4)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(139)</b>	<b>50</b>	<b>(181)</b>	<b>62</b>
Income tax (expense) credit	(1)	(63)	(1)	(78)
<b>NET INCOME (LOSS)</b>	<b>(140)</b>	<b>(13)</b>	<b>(182)</b>	<b>(16)</b>
Earning per share - Basic	(0.02)	(0.00)	(0.02)	(0.00)
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	(0.02)	(0.00)	(0.02)	(0.00)
Average number of shares used in computation of EPS	8,344,368	7,822,842	3,344,368	7,822,368

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2005 average three months noon buying rate of 1 Euro = 1.3079 USD, and 2004 average three months noon buying rate of 1 Euro = 1.2395 USD.

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

	March 31, 2005 Euros	December 31, 2004 Euros	March 31, 2005 \$US	December 31, 2004 \$US
Cash, cash equivalents and short term investments	8,183	9,398	10,567	12,723
Total current assets	22,954	22,025	29,641	29,818
Total current liabilities	9,553	8,038	12,335	10,881
Shareholders' Equity	17,872	17,964	23,079	24,320

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2913 USD, on March 31, 2005 and at the noon buying rate of 1 Euro = 1.3538 USD, on December 31, 2004.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**THREE MONTHS ENDED MARCH 31, 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	1,010	2,002	-	(313)	2,699
Net sales of spare parts, supplies and services	703	1,871	-	(197)	2,377
<b>Total net sales</b>	<b>1,713</b>	<b>3,873</b>	<b>-</b>	<b>(510)</b>	<b>5,076</b>
Other revenues	48	47	-	(45)	50
<b>TOTAL REVENUES</b>	<b>1,761</b>	<b>3,920</b>	<b>-</b>	<b>(555)</b>	<b>5,126</b>
<b>GROSS PROFIT</b>	<b>875 50%</b>	<b>1,189 30%</b>	<b>-</b>	<b>-</b>	<b>2,064 40%</b>
Research & Development	(276)	(175)	-	-	(451)
Total SG&A plus depreciation	(595)	(980)	(361)	-	(1,936)
<b>OPERATING PROFIT (LOSS)</b>	<b>4</b>	<b>34</b>	<b>(361)</b>	<b>-</b>	<b>(323)</b>