

EDAP TMS SA  
Form 6-K  
May 13, 2004

**EDAP TMS S.A. REPORTS 2004 FIRST QUARTER FINANCIAL RESULTS**

**-- Both Operating Divisions Post Operating Profits for the First Time - -**

**-- Company Increases Revenues 30%; Decreases Expenses 21% --**

**Vaulx-en-Velin, France, May 12, 2004-- EDAP TMS S.A. (Nasdaq: EDAP)** , a global leader in the development, marketing and distribution of a portfolio of minimally-invasive medical devices for the treatment of urological diseases, today reported financial results for the first quarter ended March 31, 2004.

The Company's revenues for the first quarter of 2004 were EUR 5.8 million compared to EUR 4.4 million in the same quarter of 2003, a 30% increase from the prior year same period. This double-digit increase in revenues tracked to the Company's budgeted expectations for the quarter. Revenues included a higher total number of machines sold in the first quarter of 2004 versus the first quarter of 2003 in both of the Company's operating divisions.

The Company's gross margins were 37% for the first quarter of 2004 versus 36% for the first quarter of 2003 and 17% for the fourth quarter of 2003. The strong Euro continues to impact margins, but during the quarter the Euro remained constant and did not strengthen further. However, should the Euro continue to strengthen it would have an adverse affect on future gross margins.

The Company's operating expenses in the first quarter of 2004 were EUR 2.2 million versus EUR 2.8 million in 2003. The decrease of 21% reflects the savings generated as a result of the restructuring completed at the end of 2003.

While both divisions generated a cumulative operating profit of EUR 164 thousand in the first quarter, the Company's consolidated operating loss was EUR 0.2 million in the first quarter of 2004 compared to EUR 1.2 million loss in the first quarter of 2003. The EUR 1.0 million improvement in operating loss met the Company's budgeted expectations for the first quarter.

The Company was close to breakeven with a consolidated net loss of EUR 13 thousand in the first quarter of 2004 compared to EUR 1.4 million in the first quarter of 2003 and further shows that the Company is on track with its 2004 expectations.

**CONSOLIDATED COMPANY**

The overall performance of the Company in the first quarter 2004 shows that the restructuring plan put into place at the end of 2003 has begun to provide immediate results. The most tangible example of this is the 21% reduction in operating expenses as a direct result of the restructuring. Additionally, the increased focus by the Company in its core markets proved beneficial with the 30% increase in revenues. This however is only the beginning of the process and there are still challenges and risks that lay ahead. The Company is pleased with the progress thus far and is looking to improve upon the results in the future.

Cash management remains a high priority for the management of the Company and cash balances remain strong. The Company ended the quarter with EUR 9.3 million cash on hand; the decrease from the previous quarter is from cash used in operations and from the various severance payments made to former employees during the quarter. As the Company has previously announced, there are several severance payments still to be made with the following schedule: EUR 0.7 million in Q2 and EUR 0.3 million in the balance of the year. These future payments will affect the timing of the Company's turn to cash-flow positive, but the Company reiterates its belief that it will not drop below EUR 7.0 million cash on hand during 2004.

**UROLOGICAL DEVICES AND SERVICES ("UDS") DIVISION**

The UDS division returned to operating profitability during the quarter due, in large part, to the good start in the implementation of its strategy. Revenues increased significantly with nine lithotripsy units sold. This continued strength is indicative of the strong

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demand for the UDS division's products in each of its key markets and the first sale of a lithotripsy unit to HealthTronics in the United States. The UDS division ended the quarter with a backlog of five machines that are expected to be delivered over the course of the next quarter. Additionally, the UDS division's efforts in reducing manufacturing costs is beginning to bear fruit with a stabilized gross margin even in light of the continued strength of the Euro.

The first quarter for the UDS division further validated the strategy of aggressively taking market share, with competitive pricing, while exercising continued strong control over the division's cost structure.

### **HIGH INTENSITY FOCUSED ULTRASOUND ("HIFU") DIVISION**

The HIFU division reached a historical milestone in the first quarter of 2004 by achieving its first ever operating profit. Revenues grew significantly in the quarter with three units sold and the addition of eight new sites with access to HIFU technology, which brings the total number of sites with access to HIFU in Europe to 50. The quarter clearly confirmed the strong interest in HIFU with Ablatherm® from both patients and physicians in Europe.

The restructuring generated clear savings in SG&A thus bringing the costs of the HIFU division more in line with revenue expectations.

In February, the Company announced an agreement with HealthTronics Surgical Services, Inc. ("HealthTronics") granting HealthTronics the right to begin clinical trials with the Ablatherm in order to pursue marketing approval for the device, from the Food and Drug Administration ("FDA"), in the United States. HealthTronics informs the Company that they anticipate that the clinical trails and application process could take from three to five years. HealthTronics is currently in the early planning stages in advance of beginning clinical trails, which could begin by the end of the year.

Hugues de Bantel, President of the Company's two operating divisions, EDAP S.A. and TMS S.A., commented, "The performance of the Company during the first quarter clearly confirms that both operating divisions are on track with the commitments made at the end of 2003. Strong revenue growth and operating profit, in the operating divisions, in the first quarter post restructuring is very encouraging. The overall progress of the business, in the first quarter, met our expectations. This is the result of a combination of factors including the continuous implementation of the strategy to reduce the cost structure of the Company, increase and strengthen the acceptance of the Company's technologies and a huge commitment from our team.

EDAP TMS S.A. is the global leader in the development, production, marketing and distribution of a portfolio of minimally invasive medical devices primarily for the treatment of urological diseases. The Company currently develops and markets devices for the minimally invasive treatment of localized prostate cancer, using High Intensity Focused Ultrasound (HIFU), through its EDAP SA subsidiary; it 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), via its TMS SA subsidiary. In addition, the Company markets in Japan and Italy devices for the non-surgical treatment of benign Prostate Hyperplasia (BPH) using Microwave Thermotherapy (TUMT). For more information, in the U.S., contact EDAP Technomed Inc., the Company's U.S. subsidiary located in Atlanta, GA, by phone at (770) 446-9950.

*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 :**

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	March 31, 2004 Euros	March 31, 2003 Euros	March 31, 2004 \$US	March 31, 2003 \$US
Net sales of medical equipment	3,190	1,873	3,954	2,024
Net sales of spare parts, supplies and services	2,431	2,481	3,014	2,681
<b>NET SALES</b>	<b>5,621</b>	<b>4,354</b>	<b>6,968</b>	<b>4,705</b>
Other revenues	152	80	188	86
<b>TOTAL REVENUES</b>	<b>5,773</b>	<b>4,434</b>	<b>7,156</b>	<b>4,791</b>
Cost of sales	(3,719)	(2,849)	(4,610)	(3,079)
<b>GROSS PROFIT</b>	<b>2,054</b>	<b>1,585</b>	<b>2,546</b>	<b>1,712</b>
Research & development expenses	(391)	(732)	(484)	(791)
S, G & A expenses	(1,854)	(2,093)	(2,299)	(2,262)
Total operating expenses	(2,245)	(2,825)	(2,783)	(3,053)
<b>OPERATING PROFIT (LOSS)</b>	<b>(191)</b>	<b>(1,240)</b>	<b>(237)</b>	<b>(1,341)</b>
Interest (expense) income, net	(28)	12	(34)	13
Currency exchange gains (loss), net	272	(184)	337	(199)
Other income (loss), net	(3)	(57)	(4)	(62)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>50</b>	<b>(1,469)</b>	<b>62</b>	<b>(1,589)</b>
Income tax (expense) credit	(63)	36	(78)	39
<b>NET INCOME (LOSS)</b>	<b>(13)</b>	<b>(1,433)</b>	<b>(16)</b>	<b>(1,550)</b>
Earning per share - Basic	0.00	(0.18)	0.00	(0.20)
Average number of shares used in computation of EPS	7,782	7,782	7,782	7,782
Earning per share - Diluted	0.00	(0.18)	0.00	(0.20)
Average number of shares used in computation of EPS	7,823	7,821	7,823	7,821

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2004 average three months noon buying rate of 1 Euro = 1.2395 USD, and 2003 average three months noon buying rate of 1 Euro = 1.0806 USD.

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

	March 31, 2004 Euros	December 31, 2003 Euros	March 31, 2004 \$US	December 31, 2003 \$US
Cash, cash equivalents and short term investments	9,342	10,429	11,483	13,137
Total current assets	26,140	25,870	32,132	32,588
Total current liabilities	10,571	10,819	12,994	13,629
Shareholders' Equity	19,027	18,961	23,388	23,885

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2292 USD, on March 31, 2004 and at the noon buying rate of 1 Euro = 1.2597 USD, on December 31, 2003.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**THREE MONTHS ENDED MARCH 31, 2004**  
(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	1,191		2,448		-	(449)	3,190	
Net sales of spare parts, supplies and services	635		1,970		-	(174)	2,431	
Other revenues	14		138		-	-	152	
<b>TOTAL REVENUES</b>	<b>1,840</b>		<b>4,556</b>		<b>-</b>	<b>(623)</b>	<b>5,773</b>	
<b>GROSS PROFIT</b>	<b>730</b>	<b>40%</b>	<b>1,324</b>	<b>30%</b>	<b>0</b>	<b>0</b>	<b>2,054</b>	<b>37%</b>
Research & Development	(205)		(186)		-	-	(391)	
Total SG&A plus depreciation	(453)		(1,046)		(355)	-	(1,854)	
<b>OPERATING PROFIT (LOSS)</b>	<b>72</b>		<b>92</b>		<b>(355)</b>	<b>0</b>	<b>(191)</b>	

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