

EDAP TMS SA  
Form 6-K  
March 11, 2005

**EDAP TMS S.A. REPORTS STRONG PERFORMANCE FOR FISCAL 2004**

*Both Divisions Post Fourth Consecutive Profitable Quarter  
Continuing Strong Cash Resources for Growth*

**Lyon, France, March 9, 2005 - EDAP TMS S.A. (Nasdaq: EDAP)** , today reported strong financial results for the fourth quarter and year ended December 31, 2004.

For the full year 2004, the company reported total revenues of EUR 22.2 million, a 20 percent increase compared to EUR 18.5 million in 2003. The increase in revenues was primarily attributable to an almost 2.5 times revenue increase in the HIFU division. In 2004, the company also recorded a decrease in operating expenses reflecting the company's restructuring implemented since the end of 2003. Operating expenses declined 31 percent from EUR 13.5 million in 2003 to EUR 9.3 million in 2004.

In the fourth quarter of 2004 the company included a non-cash charge, booked in deduction of UDS division sales revenues, of EUR 174,000 in connection with warrants issued to HealthTronics Inc., its U.S. marketing partner, under its distribution agreement with HealthTronics. The non-cash charge recorded in 2004 related to a series of warrants that vested in 2004 upon the purchase of lithotripters by HealthTronics in accordance with the terms of the agreement. These warrants entitle HealthTronics to acquire 100,000 shares at an exercise price of USD 1.50 per share. The distribution agreement and the accounting treatment of the warrants issued under the agreement are discussed further below.

The company's revenues for the fourth quarter of 2004 were EUR 5.7 million compared with EUR 4.6 million in the same quarter of 2003, a 24 percent increase. Operating expenses in the fourth quarter of 2004 declined by 57 percent to EUR 2.1 million from EUR 4.9 million in the fourth quarter of 2003 (which included an exceptional non-recurring expense of EUR 2.1 million related to the restructuring in the fourth quarter of 2003).

The Company's gross margin, as a percentage of total revenues, increased from 17 percent in the fourth quarter of 2003 to 38 percent in the fourth quarter of 2004 and from 29 percent in the full year 2003 to 38 percent in the full year 2004, despite the continuing strengthening of the Euro against the U.S. dollar and the Japanese yen. However, should the Euro pursue its progression, our 2005 annual operating income will be impacted.

Both EDAP TMS divisions reported a fourth consecutive profitable quarter. The company's cash position remained strong at more than EUR 9 million . Corporate expenses continued to decline as a result of cost control initiatives from the restructuring at the end of 2003 as well as additional measures linked to the management succession plan implemented in June 2004.

**EDAP: HIFU DIVISION REPORTS SIGNIFICANT SALES INCREASE**

In 2004, EDAP, the HIFU Division, recorded a 136 percent increase in total net revenues to EUR 7.0 million in 2004 from EUR 3.0 million in 2003. Operating income improved to a profit of EUR 387,000 in 2004 compared to a loss of EUR 5.8 million in 2003. Gross margin as a percentage of total revenues in 2004 was 46 percent compared to 31 percent in 2003, and total gross margin increased from EUR 903,000 in 2003 to EUR 3.2 million in 2004, a more than three-fold increase. The increase in operating income was also driven by a 58 percent decrease in operating expenses.

EDAP - HIFU Division : Euros 000's

Year	Revenues	Gross Margin %	Operating Income (Loss)
2004	6,969	46%	387
2003	2,959	31%	(5,802)

Performance in the HIFU division was driven by a dramatic 248 percent increase in sales of its Ablatherm units and a 135 percent progression in its Ablatherm mobile revenues. In Europe, EDAP's HIFU presence continued to accelerate its growth rate through continued expansion of its marketplace and adoption as a solution for patients who are not candidates for surgery or who failed

radiotherapy treatment. With more than 63 centers using Ablatherm for the treatment of localized prostate cancer, and more than 6,600 treatments performed to date, with over 2,000 treatments in 2004, EDAP continues to build on its strong global leadership position in HIFU. In North America, the company is ready to expand its HIFU distribution network.

## **TMS: CONTINUED GROWTH IN MARKET SHARE FUELS CASH FLOW**

The UDS division continued its successful operations with its fourth consecutive quarter of operating profit. In the fourth quarter of 2004, the UDS division realized an operating profit of EUR 19,000 (or EUR 193,000 excluding the EUR 174,000 impact of the recognition of the expense associated with the warrants issued to HealthTronics). In 2004, the division recorded EUR 17.4 million in total revenues (EUR 17.6 million excluding the warrants impact) compared with EUR 17.5 million in 2003. But, the number of lithotripters sold increased by 15% over 2003, in line with our strategy to take market share, with a service revenue increase to follow on in 2005 and beyond.

In 2004, TMS operating expenses decreased by 8 percent and gross margin improved by 3 percent, in line with the company's planned careful control of expenses and cost reductions. The company continues to focus on its technology and service levels to gain additional share as the market replaces aging competitive machines. Added sales growth is also bringing additional long-term sales in service and consumable parts. The UDS division ended 2004 with a backlog of four lithotripters.

TMS - UDS Division : Euros 000's

Year	Revenues	Gross Margin %	Operating Income (Loss)
2004	17,385	30%	184 (*)
2003	17,482	27%	(687)

(\*) 358 excluding warrants impact.

## **EXECUTIVE COMMENTS**

Hugues de Bantel, Chief Executive Officer of EDAP TMS, commented: "We ended 2004 a much stronger and more focused company due to the restructuring we undertook in 2003 and executed during the past year. This effort has allowed the company to significantly reduce expenses while growing its market share in both divisions. Furthermore, sales of both technologies have continued to grow, creating a stronger installed base and demonstrating EDAP's continued success in establishing a reputation as an innovative and effective treatment provider."

Hugues de Bantel added: "Further gains in market share in the mature UDS division marketplace represents a source of stable operating profit that will keep expanding as we add to our installed base. In addition to the unit sales, each device in the marketplace represents a significant opportunity to continue serving our customers by providing parts, service and supplies consumed in use of the machine. The improvement in operating margin effected during 2004 represents the careful controls of this steady cash contributor in the business."

Hugues de Bantel concluded: "The HIFU with Ablatherm continues to make significant progress towards becoming a preferred treatment for localized prostate cancer. With more than 6,600 treatments performed through December 2004, EDAP is a clear global leader in this technology. During 2004 a broad number of clinical studies were presented at leading urological conferences confirming the success of HIFU with Ablatherm as a solution for patients who are not candidates for surgery or who failed radiotherapy treatment. Additionally, EDAP entered the U.K. market in 2004, the third largest in Europe. We are convinced of the growth opportunity this unique and well established therapy provides to EDAP."

## **WARRANT EXPENSE**

On February 25, 2004, the company entered into a distribution agreement with a subsidiary of HealthTronics granting HealthTronics, among other things, (i) the right to begin clinical trials in the U.S. with the Ablatherm (which utilizes HIFU to provide minimally invasive treatment of prostate cancer), (ii) the right to seek Pre-Market Approval ("PMA") from the FDA and (iii) exclusive distribution rights in the United States, when and if a PMA is granted. Under the terms of the distribution agreement, the company also agreed to grant HealthTronics 1 million warrants on January 28, 2005, each which will entitle HealthTronics to purchase a share of the Company at a price of U.S.\$1.50. The distribution agreement allows HealthTronics to exercise specified numbers of warrants as it meets various specified milestones, some of which relate to HealthTronics' commitment to purchase a specified number of lithotripter units and others to various stages of completion of clinical trials and the regulatory process leading to the

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approval of a PMA for the Ablatherm. (See the Company's annual report on Form 20-F for the year ended December 31, 2003 and its exhibits for more detail.) In accordance with EITF 96-18, the company accounts for the warrants issued to HealthTronics under the distribution agreement based upon the fair value of the warrants, measured at the date of milestone achievement. The amount related, which is a non-cash charge, is then recorded in operating expenses or in reduction of revenue. The non-cash charge recorded for 2004 related to a series of warrants linked to the purchase of four lithotripters by HealthTronics in 2004, in accordance with the terms of the agreement. As additional series of warrants vest upon the completion of the milestones set out in the distribution agreement, the amount of the non-cash charge, recorded by the company as a result in future financial periods, may significantly impact the Company's reported income statements and will be more than offset, of course, by significant EDAP business progress.

Thierry Turbant, Chief Financial Officer of EDAP TMS, commented: "While we are recording a non-cash charge to our financial operations, this charge reflects the success in meeting performance goals that will benefit shareholders in the long term by utilizing HealthTronics's expertise to assist EDAP in entering the North American market, a key region for long-term growth. Additionally, we expect that we will book future non-cash charges of the same nature as HealthTronics continues to meet and exceed key growth metrics necessary to ultimately bring EDAP into the market for the United States."

### INVESTOR COMMUNICATIONS

#### Road Shows

Management plans to begin an enhanced program of investor outreach with road show visits in major financial centers. Presently EDAP plans to conduct meetings on the East Coast in early April and on the West Coast in early May.

#### Participation in Congresses

EDAP will be participating in the next European Association of Urology (E.A.U.) meeting to be held in Istanbul, Turkey from March 16 to 19, 2005. The Company is pleased to welcome all interested parties to EDAP's booth C17 and meet with EDAP's representatives. EDAP will also present at the American Urology Association (A.U.A.) conference 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, March 10, 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 +1 (785) 832-2422 and requesting the EDAP TMS 2004 Year End Conference Call.

Investors unable to join the call can access a playback of the conference call, by dialing +1 (402) 220-2332 beginning two hours after the end of the call until Saturday, March 19, 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 :	
	December 31 , 2004 Euros	December 31 , 2003 Euros	December 31 , 2004 \$US	December 31 , 2003 \$US
Sales of medical equipment	3,083	1,995	4,063	2,408
Sales of spare parts, supplies and services	2,754	2,514	3,630	3,034
<b>TOTAL SALES</b>	<b>5,837</b>	<b>4,509</b>	<b>7,693</b>	<b>5,442</b>
Warrants granted	(174)	-	(229)	-
<b>TOTAL NET SALES</b>	<b>5,663</b>	<b>4,509</b>	<b>7,464</b>	<b>5,442</b>
Other revenues	(12)	106	(15)	127
<b>TOTAL REVENUES</b>	<b>5,651</b>	<b>4,615</b>	<b>7,449</b>	<b>5,569</b>
Cost of sales	(3,518)	(3,849)	(4,637)	(4,645)
<b>GROSS PROFIT</b>	<b>2,133</b>	<b>766</b>	<b>2,812</b>	<b>924</b>
Research & development expenses	(386)	(725)	(509)	(875)
S, G & A expenses	(1,639)	(2,127)	(2,161)	(2,567)
Non-recurring operating expenses	(110)	(2,097)	(144)	(2,531)
Total operating expenses	(2,135)	(4,949)	(2,814)	(5,973)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2)</b>	<b>(4,183)</b>	<b>(2)</b>	<b>(5,049)</b>
Interest (expense) income, net	42	136	56	164
Currency exchange gains (loss), net	(110)	(272)	(145)	(328)
Other income (loss), net	(78)	(54)	(104)	(65)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(148)</b>	<b>(4,373)</b>	<b>(195)</b>	<b>(5,278)</b>
Income tax (expense) credit	(223)	36	(294)	43
<b>NET INCOME (LOSS)</b>	<b>(371)</b>	<b>(4,337)</b>	<b>(489)</b>	<b>(5,235)</b>
Earning per share - Basic	(0.05)	(0.56)	(0.06)	(0.67)
Average number of shares used in computation of EPS	7,782	7,782	7,782	7,782
Earning per share - Diluted	(0.05)	(0.56)	(0.06)	(0.67)
	8,066	7,805	8,066	7,805

Average number of shares used in computation of EPS

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2004 average three months noon buying rate of 1 Euro = 1.3181 USD, and 2003 average three months noon buying rate of 1 Euro = 1.2067 USD.

**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 , 2004 Euros	December 31 , 2003 Euros	December 31 , 2004 \$US	December 31 , 2003 \$US
Sales of medical equipment	11,922	8,512	14,876	9,713
Sales of spare parts, supplies and services	10,207	9,518	12,736	10,861
<b>TOTAL SALES</b>	<b>22,129</b>	<b>18,030</b>	<b>27,612</b>	<b>20,574</b>
Warrants granted	(174)	-	(217)	-
<b>TOTAL NET SALES</b>	<b>21,955</b>	<b>18,030</b>	<b>27,395</b>	<b>20,574</b>
Other revenues	208	443	259	505
<b>TOTAL REVENUES</b>	<b>22,163</b>	<b>18,473</b>	<b>27,654</b>	<b>21,079</b>
Cost of sales	(13,676)	(13,094)	(17,065)	(14,942)
<b>GROSS PROFIT</b>	<b>8,487</b>	<b>5,379</b>	<b>10,589</b>	<b>6,137</b>
Research & development expenses	(1,523)	(3,069)	(1,900)	(3,502)
S, G & A expenses	(7,476)	(8,334)	(9,328)	(9,509)
Non-recurring operating expenses	(318)	(2,097)	(396)	(2,393)
Total operating expenses	(9,317)	(13,500)	(11,624)	(15,404)
<b>OPERATING PROFIT (LOSS)</b>	<b>(830)</b>	<b>(8,121)</b>	<b>(1,035)</b>	<b>(9,267)</b>
Interest (expense) income, net	71	177	89	202
Currency exchange gains (loss), net	(38)	(928)	(48)	(1,059)
Other income (loss), net	(74)	(218)	(93)	(249)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(871)</b>	<b>(9,090)</b>	<b>(1,087)</b>	<b>(10,373)</b>
Income tax (expense) credit	(278)	114	(346)	130

<b>NET INCOME (LOSS)</b>	<b>(1,149)</b>	<b>(8,976)</b>	<b>(1,433)</b>	<b>(10,243)</b>
Earning per share - Basic	(0.15)	(1.15)	(0.18)	(1.32)
Average number of shares used in computation of EPS	7,782	7,782	7,782	7,782
Earning per share - Diluted	(0.14)	(1.15)	(0.18)	(1.31)
Average number of shares used in computation of EPS	8,074	7,817	8,074	7,817

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2004 average twelve months noon buying rate of 1 Euro = 1.2478 USD, and 2003 average twelve months noon buying rate of 1 Euro = 1.1411 USD.

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

	<b>Dec. 30, 2004 Euros</b>	<b>Sept. 30, 2004 Euros</b>	<b>Dec. 30, 2004 \$US</b>	<b>Sept. 30, 2004 \$US</b>
Cash, cash equivalents and short term investments	9,398	9,075	12,723	11,269
Total current assets	22,025	23,128	29,818	28,718
Total current liabilities	8,038	8,829	10,881	10,963
Shareholders' Equity	17,964	18,168	24,320	22,560

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3538 USD, on December 31, 2004 and at the noon buying rate of 1 Euro = 1.2417 USD, on September 30, 2004.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2004**  
(Amounts in thousands of Euro's)

	<b>EDAP S.A. HIFU Division</b>	<b>TMS S.A. UDS Division</b>	<b>EDAP TMS HQ</b>	<b>Consolidation Impact</b>	<b>Total After Consolidation</b>
Sales of medical devices	3,993	9,384	-	(1,455)	11,922
Sales of spare parts, supplies and services	2,942	8,001	-	(737)	10,206
<b>Total sales</b>	<b>6,935</b>	<b>17,385</b>	<b>-</b>	<b>(2,192)</b>	<b>22,128</b>

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Warrants granted	0	(174)	-	0	(174)			
<b>Total net sales</b>	<b>6,935</b>	<b>17,211</b>	-	<b>(2,192)</b>	<b>21,954</b>			
Other revenues	34	174	-	0	208			
<b>TOTAL REVENUES</b>	<b>6,969</b>	<b>17,385</b>	<b>0</b>	<b>(2,192)</b>	<b>22,162</b>			
<b>GROSS PROFIT</b>	<b>3,220</b>	<b>46%</b>	<b>5,266</b>	<b>30%</b>	<b>0</b>	<b>0</b>	<b>8,486</b>	<b>38%</b>
Research & Development	(817)	(706)	-	-	(1,523)			
Total SG&A plus depreciation	(1,934)	(4,349)	(1,193)	-	(7,476)			
Non recurring op. expenses	(82)	(27)	(208)	-	(317)			
<b>OPERATING PROFIT (LOSS)</b>	<b>387</b>	<b>184</b>	<b>(1,401)</b>	<b>0</b>	<b>(830)</b>			