

EDAP TMS SA

Form 6-K

March 12, 2004

**EDAP TMS S.A. REPORTS 2003 FOURTH QUARTER & YEAR END FINANCIAL RESULTS**

**- Action Taken to Stop Sizeable Operating Losses - Cash Balances Remain Strong - USA HIFU Partner Agreement Finalized -**

Vaulx-en-Velin, France, March 10, 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 fourth quarter and year ended December 31, 2003.

Revenues for the fourth quarter 2003 were EUR 4.6 million compared to EUR 6.0 million in the same quarter of 2002. Total year 2003 revenues were EUR 18.5 million versus EUR 20.0 million in year 2002.

Gross margin, as a percent of sales, decreased to 16.6% in the fourth quarter of 2003, versus 46.1% in the same quarter of 2002. Full year 2003 gross margin, as a percent of sales, decreased to 29.8% in fiscal year 2003 versus 42.9% in fiscal year 2002.

Operating loss for the fourth quarter of 2003 was EUR 4.2 million versus EUR 1.4 million in the fourth quarter of 2002. Operating loss for the full year 2003 was EUR 8.1 million compared to full year 2002 operating loss of EUR 4.8 million.

Net loss for the fourth quarter of 2003 was EUR 4.3 million versus EUR 2.5 million in the same period of 2002. Net loss for the full year ended December 31, 2003 was EUR 9.0 versus EUR 4.0 million in the same period of 2002.

**CONSOLIDATED COMPANY**

The fourth quarter 2003 results were affected by several reserves against earnings that are exceptional and non-recurring. The first of these reserves was related to the previously announced restructuring charge of EUR 2.1 million. Additionally, the Company took an inventory write down in the fourth quarter of EUR 0.6 million related to the revaluation of inventories under U.S. GAAP. Furthermore, there were two fewer Ablatherm sales versus budget which, if sold, would have contributed an additional EUR 0.4 in gross margin. Altogether, this contributed to the 2003 operating loss of EUR 8.1 million. The two budgeted Ablatherm units have subsequently been sold in the first quarter of 2004.

However, one of the most significant impacts to the results of the Company was the strength of the Euro in 2003. The following table compares 2003 and 2002 exchange rates and illustrates the impact the exchange rates had on the results of 2003, which on its own, reduced gross profit by EUR 2.0 million in 2003.

In millions of Euro (Year End rate)	2003 at 2003 Rate (USD 1.26 / YEN 135)	2003 at 2002 Rate (USD 1.05 / YEN 124)	2002 at 2002 Rate (USD 1.05 / YEN 124)
Net Revenues	18.5	20.8	20.0
Cost of Sales / COGS	(13.1)	(13.4)	(11.5)

Gross Profit	5.4	7.4	8.5
Operating Exp.	(11.4)	(11.7)	(12.1)
Non-recurring Exp.	(2.1)	(2.1)	(1.2)
Operating Loss	(8.1)	(6.4)	(4.8)

Note: Today's rate : USD 1.22 / YEN 136 mid-day March 10, 2004

Cash management continues to remain a high priority and cash balances remain strong. The Company ended 2003 with EUR 10.4 million cash on hand and had EUR 10.7 million as of the end of February 2004. As planned, there are still payments to be made against the EUR 2.1 restructuring total reserve with the following schedule: EUR 0.2 million for the balance of Q1, EUR 0.7 million in Q2 and EUR 0.3 million for the balance of the year. At year-end 2003, the Company had EUR 1.33 per diluted share in cash on hand and a net book value of EUR 19.0 million or EUR 2.43 per diluted share.

Hugues de Bantel, President of the Company's two operating divisions, commented: "These operating losses for both divisions are totally unacceptable. Only three months into my new role as head of both divisions, I am forcibly driven to a five-point action plan, which I began executing on in December 2003. The plan is as follows:

Putting a stop to the multi-million operating losses with a total Company restructuring, which has now been completed, but this is only the first step;

Maintaining strong cash management. This is an on going and tough discipline that I am committed to ensure at all times. Currently the Company's cash balances are tracking reasonably;

Increasing Revenues, with double-digit growth, is a personal commitment that I am devoted to in every market segment of the business. This is a challenge, but one that I feel is attainable;

A major cost of sales reduction program is being implemented with all of our suppliers and partners; and

Disciplined control of all already reduced operating expenses is every Manager's commitment and is reviewed by me weekly.

As President of the operating divisions, my personal objective is operating income and positive cash flow for the Company and I look forward to reviewing this plan with everyone at tomorrow's conference call and reporting quarterly on the Company's results against these objectives going forward," concluded Mr. de Bantel.

#### UROLOGICAL DEVICES AND SERVICES (UDS) DIVISION

The UDS division experienced another record year in terms of the number of lithotripsy units sold. The total number of units sold in 2003 was 34 versus 30 in 2002, which increased the division's installed base by a net 23 units bringing the total installed base, at December 31, 2003, to 404 units worldwide. The UDS division saw a decrease in its average sales price (ASP) in 2003 primarily due to the strength of the Euro versus the local currencies in the division's strongest markets in Asia.

The division, even with the challenges impacting its ASP, was cash flow neutral during 2003 and produced an operating profit, exclusive of restructuring charges and inventory write-down. The division anticipates continued

growth in its revenue in 2004. The division is confident in its expectations, in part because, the backlog of machines at the end of 2003 was four units and the outlook for 2004 looks promising as the demand in the Asian market remains strong and sales will begin in the U.S. through the Company's relationship with HealthTronics Surgical Services (Nasdaq: HTRN) (HealthTronics).

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

The HIFU division clearly did not meet the Company's expectations in 2003. Hence the restructuring at the end of 2003 whereby the Company took extraordinary steps to ensure the strength of the division and to position it for success in 2004 by focusing the efforts of the organization on its key European markets. Additionally, to further focus the division's efforts on the European market, the Company finalized, in early 2004, an agreement with HealthTronics granting the Ablatherm's distribution rights to the U.S. market when and if HealthTronics is able to receive marketing clearance from the U.S. Food and Drug Administration (FDA). We believe that HIFU technology has a potential to play an important role in the United States, in the treatment of localized prostate cancer and can be a clinically effective and a very cost efficient alternative. Several prominent urologists in the United States have already expressed a strong interest in participating in the planned FDA clinical trials.

The acceptance of Ablatherm continues its progress in Europe, albeit at a slower pace than expected, due to a longer than expected process of securing reimbursement rates. Even with these challenges, as of today, over 4,500 patients have been treated and 42 sites have access to the Ablatherm and utilize it as part of their daily practice. In 2003, there were 1,477 Ablatherm treatments performed versus 1,104 in 2002, which is an increase of 34% year over year.

The division is optimistic that 2004 will be a breakout year for HIFU technology, with a cost structure now more in line with revenue expectations in 2004. Additionally, there have been a series of exciting subsequent events that have yet to positively impact the financials of the division. These events include:

The Company's finalization of an agreement with HealthTronics allowing HealthTronics to be the champion of HIFU in the U.S.A.;

The recent Scientific meeting of the American Association for the Advancement of Science ("AAAS"), held in Seattle last February, generated extensive interest and news releases on HIFU technology as a whole and for the treatment of prostate cancer specifically; and

Three Ablatherm orders have been received in the first quarter with two units already delivered.

Philippe Chauveau, Chairman and Chief Executive Officer of EDAP TMS S.A., commented, "2003 was a very bad year. The Company made significant changes to the cost structure of its operating divisions with the goal of stopping the sizeable operating losses that the Company has been sustaining over the years. The Board and the Management of the Company are committed to the statement that each of the operating divisions will be profitable and cash flow positive."

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 Thermoablation (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.

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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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Three Months Ended :

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December 31 , 2003  
Euros

December 31 , 2002  
Euros

December 31 , 2003  
\$US

December 31 , 2002  
\$US

Net sales of medical equipment

1,995

3,940

2,408

	3,979
Net sales of spare parts, supplies and services	
	2,514
	1,975
	3,034
	1,994
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NET SALES	
	4,509
	5,915
	5,442
	5,973
Other revenues	
	106
	87

127

88

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TOTAL REVENUES

**4,615**

**6,002**

**5,569**

**6,061**

Cost of sales

(3,849)

(3,272)

(4,645)

(3,305)

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GROSS PROFIT

	766
	2,730
	924
	2,756
Research & development expenses	(725)
	(1,010)
	(875)
	(1,020)
S, G & A expenses	(2,127)
	(2,643)
	(2,567)
	(2,668)
Non-recurring operating expenses	(2,097)
	(496)

(2,531)

(501)

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Total operating expenses

(4,949)

(4,149)

(5,973)

(4,189)

OPERATING PROFIT (LOSS)

(4,183)

(1,419)



	(5,049)
	(1,433)
Interest (expense) income, net	136
	(94)
	164
	(95)
Currency exchange gains (loss), net	(272)
	(426)
	(328)
	(430)
Other income (loss), net	(54)
	(535)
	(65)
	(540)

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INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST

(4,373)

(2,474)

(5,278)

(2,498)

Income tax (expense) credit

36

3

43

10

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NET INCOME (LOSS)

(4,337)

(2,471)

(5,235)

(2,495)

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Earning per share - Basic

	(0.56)
	(0.32)
	(0.67)
	(0.32)
Average number of shares used in computation of EPS	
	7,782
	7,782
	7,782
	7,782
Earning per share - Diluted	
	(0.56)
	(0.32)
	(0.67)
	(0.32)
Average number of shares used in computation of EPS	
	7,805
	7,782
	12

## NOTE:

Translated for convenience of the reader to U.S. dollars at the 2003 average three months noon buying rate of 1 Euro = 1.2067 USD, and 2002 average three months noon buying rate of 1 Euro = 1.0099 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 , 2003 Euros	December 31 , 2002 Euros	December 31 , 2003 \$US	December 31 , 2002 \$US
Net sales of medical equipment	8,512	10,527	9,713	9,995
Net sales of spare parts, supplies and services	9,518	9,198	10,861	8,734
<b>NET SALES</b>	<b>18,030</b>	<b>19,725</b>	<b>20,574</b>	<b>18,729</b>
Other revenues	443	236	505	224
<b>TOTAL REVENUES</b>	<b>18,473</b>	<b>19,961</b>	<b>21,079</b>	<b>18,953</b>
Cost of sales	(13,094)	(11,503)	(14,942)	(10,022)
<b>GROSS PROFIT</b>	<b>5,379</b>	<b>8,458</b>	<b>6,137</b>	<b>8,031</b>
Research & development expenses	(3,069)	(3,186)	(3,502)	(3,025)
S, G & A expenses	(8,334)	(8,807)	(9,509)	(8,363)
Non-recurring operating expenses	(2,097)	(1,241)	(2,393)	(1,178)
<b>Total operating expenses</b>	<b>(13,500)</b>	<b>(13,234)</b>	<b>(15,404)</b>	<b>(12,566)</b>
<b>OPERATING PROFIT (LOSS)</b>	<b>(8,121)</b>	<b>(4,776)</b>	<b>(9,267)</b>	<b>(4,535)</b>
Interest (expense) income, net	177	455	202	432
	(928)	(1,025)	(1,059)	(973)

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Currency exchange gains (loss), net				
Other income (loss), net	(218)	1,473	(249)	1,399
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INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(9,090)	(3,873)	(10,373)	(3,678)
Income tax (expense) credit	114	(167)	130	(159)
	<hr/>	<hr/>	<hr/>	<hr/>
NET INCOME (LOSS)	(8,976)	(4,040)	(10,243)	(3,836)
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Earning per share - Basic	(1.15)	(0.52)	(1.32)	(0.49)
Average number of shares used in computation of EPS	7,782	7,771	7,782	7,771
Earning per share - Diluted	(1.15)	(0.52)	(1.31)	(0.49)
Average number of shares used in computation of EPS	7,817	7,834	7,817	7,834

NOTE

: Translated for convenience of the reader to U.S. dollars at the 2003 average twelve months noon buying rate of 1 Euro = 1.1411 USD, and 2002 average twelve months noon buying rate of 1 Euro = 0.9495 USD.

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

	Dec. 30, 2003 Euros	Sept 30, 2003 Euros	Dec. 30, 2003 \$US	Sept 30, 2003 \$US
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Cash, cash equivalents and short term investments	10,429	11,963	13,137	13,937
Total current assets	25,870	28,551	32,588	33,262
Total current liabilities	10,819	9,363	13,629	10,908
Shareholders' Equity	18,961	23,663	23,885	27,567

NOTE

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: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2597 USD, on December 31, 2003 and at the noon buying rate of 1 Euro = 1.165 USD, on September 30, 2003.

EDAP TMS S.A.  
 CONDENSED STATEMENTS OF OPERATIONS BY DIVISION  
 TWELVE MONTHS ENDED DECEMBER 31, 2003  
 (Amounts in thousands of Euros)

	EDAP S.A. HIFU Division	TMS S.A. UDS Division	EDAP TMS HQ	Consolidation Impact	Total After Consolidation
Net sales of medical equipment	1,148	8,684	-	(1,320)	8,512
Net sales of spare parts, supplies and services	1,712	8,456	-	(650)	9,518
Other revenues	99	342	2	-	443
<b>TOTAL REVENUES</b>	<b>2,959</b>	<b>17,482</b>	<b>2</b>	<b>(1,970)</b>	<b>18,473</b>
<b>GROSS PROFIT</b>	<b>903 32%</b>	<b>4,711 27%</b>	<b>2</b>	<b>(237)</b>	<b>5,379</b>
Research & Development	(2,345)	(725)	-	-	(3,069)
Total SG&A plus depreciation	(2,770)	(4,210)	(1,353)	-	(8,334)
Non recurring operating expenses	(1,590)	(463)	(44)	-	(2,097)
<b>OPERATING PROFIT (LOSS)</b>	<b>(5,802)</b>	<b>(687)</b>	<b>(1,395)</b>	<b>(237)</b>	<b>(8,121)</b>