

EDAP TMS SA
Form 6-K
October 29, 2004

**EDAP TMS S.A. CONFIRMS SOLID PERFORMANCE
FOR THE FIRST NINE MONTHS OF 2004**

*- Both Divisions Post Third Consecutive Profitable Quarter -
- Strong Cash Position -*

Vaulx-en-Velin, France, October 27, 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 strong financial results for the third quarter and nine months ended September 30, 2004.

Both EDAP TMS divisions reported a third consecutive profitable quarter, improving group operating results by over EUR 3 million, as of September 2004, versus same period of 2003. Cash remained strong at over EUR 9 million. This dramatic improvement was achieved due to a significant increase in the Company's revenues and operating margins, together with a further decline in the expenses.

The Company's revenues for the third quarter of 2004 were EUR 5.5 million compared with EUR 4.7 million in the same quarter of 2003, a 17% increase from the prior year same period. Total revenues for the nine months ended September 30, 2004 were EUR 16.5 million compared with EUR 13.9 million in the same period of 2003, a 19% increase over year 2003 same period and a 21% increase at constant exchange rate.

The Company's gross margins, as a percent of sales, improved from 30% for the third quarter of 2003 up to 41% for the third quarter of 2004 and from 33% for the nine months ending September 30, 2003 up to 38% for the same period of 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 2004 annual operating income could be highly impacted.

The Company's operating expenses in the third quarter of 2004 were EUR 2.5 million versus EUR 2.6 million for the third quarter of 2003 and were EUR 7.2 million for the nine months ended September 30, 2004 compared with EUR 8.6 million in the same period of 2003. During the first nine months of 2004, the Company recorded a 16% decrease in its operating expenses from the prior year same period while still supporting non-recurring expenses directly related to the restructuring initiated in December, 2003.

The Company ended the quarter with EUR 9.1 million in cash on hand which confirms that cash remains the top priority for the management. Cash at end of each quarter of 2004 was EUR 9.3 million for Q1, EUR 9.3 million for Q2 and EUR 9.1 million for Q3.

EDAP: HIGH GROWTH PERFORMANCE FOR THE HIFU DIVISION

EDAP, the HIFU Division, recorded a 108% increase in its total revenue, for the first nine months of 2004, and over EUR 3 million improvement in its operating income, compared with the prior year same period.

EDAP - HIFU Division : Euros 000's

| First 9 Months | Revenue | Gross Margin % | Operating Income (Loss) |
|-----------------------|----------------|-----------------------|--------------------------------|
| Year 2004 | 5,064 | 44% | 164 |
| Year 2003 | 2,450 | 32% | (3,125) |

Performance was driven by a strong growth in sales of Ablatherm units, mobile business and consumables. EDAP recorded a dramatic 158% increase in the sales of its Ablatherm units and a 123% progression in its Ablatherm treatments sold on a mobile or leasing basis. The performance of EDAP was strong in key European markets, confirming its strategy to build up credibility for HIFU technology in Europe while securing long term growth by strengthening its distribution network in North America.

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With more than 55 centers using Ablatherm for the treatment of localized prostate cancer, and more than 6,000 patients treated in Europe, EDAP confirms its strong leadership in HIFU.

TMS: CONFIRMED RETURN TO BREAK-EVEN IN A COMPETITIVE MARKET FOR THE UDS DIVISION

The UDS division recorded a 2% increase in revenue for the first nine months of 2004. Performance was driven specifically by a remarkable 13% increase in the sales of lithotriptors on a mature market which validates its strategy to gain market shares. This confirmed again the attractiveness of its technology and the strength of its distribution channels. For 2005, the division anticipates, an increase in its service revenues directly related to this year's sales of lithotriptors. The UDS division enters the fourth quarter with a strong backlog of five machines.

TMS - UDS Division : Euros 000's

| Year 2004 | Revenue | Gross Margin % | Operating Income (Loss) |
|-----------|---------|----------------|-------------------------|
| Q1 | 4,556 | 27% | 87 |
| Q2 | 4,058 | 30% | 12 |
| Q3 | 4,600 | 34% | 61 |

The UDS division confirmed its return to break-even by recording a positive operating income for each of the three quarters of 2004, versus a loss of Euros 0,7 million for the total year of 2003.

OUTLOOK FOR QUARTER FOUR 2004

Hugues de Bantel, Chief Executive Officer of EDAP TMS commented: "Our performance during the first nine months of 2004 once again demonstrated the confirmed interest for our technologies and the effectiveness of our strategy with a tight control of our expenses and the systematic plan of COGS reduction put in place earlier this year. Thanks to a successful combination of these factors, we have been able to record both an increase in our revenue and a confirmed improvement in our operating margins.

Sales figures during the third quarter and the first nine months of 2004 confirmed the Group's previous growth trend. EDAP continues its strong progress in Europe and starts benefiting from the recognition of HIFU with Ablatherm as an alternative for the treatment of localized prostate cancer. TMS confirmed its return to profitability, despite unfavorable exchange rates and will pursue its aggressive approach of gaining market shares. All the above positive factors allow the Group to confirm its objective of a double digit growth for 2004. Our strong cash position places us in an ideal position to implement our growth development strategy."

INVESTOR COMMUNICATIONS

Conference Call and Webcast

We look forward to reporting this progress during our conference call tomorrow Thursday, October 28, 2004 at 12.00 noon Eastern Standard Time. To participate in the live call, please dial +1 (785) 832-1508. The conference call will also be broadcast live over the internet via the Investor Relations Section of the Company's web site. If you are unable to participate, a playback of the conference call will be available by dialing +1 (402) 220-1549 beginning two hours after the end of the call until Friday, November 5, 2004.

Road Shows in Early 2005

In quarter one of 2005, the Senior Management of EDAP TMS SA plans to meet with its investors in the USA and Europe, through a program of road shows to share the EDAP TMS story, in view of improving the Company's valuation and stock trading liquidity.

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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 devices for the non-surgical treatment of benign Prostate Hyperplasia (BPH) using Microwave Thermotherapy (TUMT). For more information, contact the Investor Relations Department 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.

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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, 2004 Euros | September 30, 2003 Euros | September 30, 2004 \$US | September 30, 2003 \$US |
| Net sales of medical equipment | 3,211 | 2,129 | 3,920 | 2,404 |
| Net sales of spare parts, supplies and services | 2,320 | 2,349 | 2,833 | 2,652 |
| NET SALES | 5,531 | 4,478 | 6,753 | 5,056 |
| Other revenues | (13) | 241 | (15) | 271 |
| TOTAL REVENUES | 5,518 | 4,719 | 6,738 | 5,327 |
| Cost of sales | (3,256) | (3,308) | (3,976) | (3,734) |
| GROSS PROFIT | 2,262 | 1,411 | 2,762 | 1,593 |
| Research & development expenses | (360) | (792) | (439) | (894) |
| S, G & A expenses | (2,094) | (1,846) | (2,557) | (2,084) |
| Total operating expenses | (2,454) | (2,638) | (2,996) | (2,978) |
| OPERATING PROFIT (LOSS) | (192) | (1,227) | (234) | (1,385) |
| Interest (expense) income, net | 60 | 35 | 73 | 40 |
| Currency exchange gains (loss), net | (120) | 60 | (147) | 67 |
| Other income (loss), net | - | (3) | - | (3) |

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| | | | | |
|---|--------------|----------------|--------------|----------------|
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (252) | (1,135) | (308) | (1,281) |
| Income tax (expense) credit | (7) | 14 | (9) | 16 |
| NET INCOME (LOSS) | (259) | (1,121) | (317) | (1,265) |
| Earning per share - Basic | (0.03) | (0.14) | (0.04) | (0.16) |
| 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 | (0.03) | (0.14) | (0.04) | (0.16) |
| Average number of shares used in computation of EPS | 8,038,156 | 7,821,195 | 8,038,156 | 7,821,195 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2004 average three months noon buying rate of 1 Euro = 1.2211 USD, and 2003 average three months noon buying rate of 1 Euro = 1,1289 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, 2004 Euros | September 30, 2003 Euros | September 30, 2004 \$US | September 30, 2003 \$US |
| Net sales of medical equipment | 8,839 | 6,516 | 10,822 | 7,294 |
| Net sales of spare parts, supplies and services | 7,453 | 7,004 | 9,124 | 7,839 |
| NET SALES | 16,292 | 13,520 | 19,946 | 15,133 |
| Other revenues | 219 | 338 | 269 | 378 |
| TOTAL REVENUES | 16,511 | 13,858 | 20,215 | 15,511 |
| Cost of sales | (10,158) | (9,245) | (12,437) | (10,348) |
| GROSS PROFIT | 6,353 | 4,613 | 7,778 | 5,163 |
| Research & development expenses | (1,137) | (2,344) | (1,392) | (2,623) |
| S, G & A expenses | (5,836) | (6,207) | (7,146) | (6,947) |
| Non recurring operating expenses | (208) | - | (254) | - |

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| | | | | |
|---|--------------|----------------|----------------|----------------|
| Total operating expenses | (7,181) | (8,551) | (8,792) | (9,570) |
| OPERATING PROFIT (LOSS) | (828) | (3,938) | (1,014) | (4,407) |
| Interest (expense) income, net | 29 | 42 | 36 | 47 |
| Currency exchange gains (loss), net | 72 | (656) | 87 | (734) |
| Other income (loss), net | 4 | (164) | 5 | (184) |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (723) | (4,716) | (886) | (5,278) |
| Income tax (expense) credit | (55) | 78 | (67) | 87 |
| NET INCOME (LOSS) | (778) | (4,638) | (953) | (5,191) |
| Earning per share - Basic | (0.10) | (0.60) | (0.12) | (0.67) |
| 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 | (0.10) | (0.59) | (0.12) | (0.66) |
| Average number of shares used in computation of EPS | 8,047,393 | 7,821,195 | 8,047,393 | 7,821,195 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2004 average nine months noon buying rate of 1 Euro = 1.2243 USD, and 2003 average nine months noon buying rate of 1 Euro = 1.1193 USD.

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

| | Sept. 30, 2004 Euros | June 30, 2004 Euros | Sept. 30, 2004 \$US | June 30, 2004 \$US |
|---|----------------------------|---------------------------|---------------------------|--------------------------|
| Cash, cash equivalents and short term investments | 9,075 | 9,282 | 11,269 | 11,305 |
| Total current assets | 23,128 | 24,703 | 28,718 | 30,085 |
| Total current liabilities | 8,829 | 9,884 | 10,963 | 12,038 |
| Shareholders' Equity | 18,168 | 18,476 | 22,560 | 22,502 |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2417 USD, on September 30, 2004 and at the noon buying rate of 1 Euro = 1.2179 USD, on June 30, 2004.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 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 | 2,990 | 7,113 | - | (1,264) | 8,839 |
| Net sales of spare parts, supplies and services | 2,029 | 5,927 | - | (503) | 7,453 |
| Other revenues | 45 | 174 | - | - | 219 |
| | <hr/> | <hr/> | <hr/> | <hr/> | <hr/> |
| TOTAL REVENUES | 5,064 | 13,214 | - | (1,767) | 16,511 |
| | <hr/> | <hr/> | <hr/> | <hr/> | <hr/> |
| GROSS PROFIT | 2,255 45% | 4,098 31% | - | - | 6,353 39% |
| Research & Development | (590) | (547) | - | - | (1,137) |
| Total SG&A plus depreciation | (1,501) | (3,387) | (948) | - | (5,836) |
| Non recurring op. expenses | - | - | (208) | - | (208) |
| | <hr/> | <hr/> | <hr/> | <hr/> | <hr/> |
| OPERATING PROFIT (LOSS) | 164 | 164 | (1,156) | - | (828) |