

EDAP TMS SA  
Form 6-K  
August 02, 2005

# EDAP TMS S.A. REPORTS 2005 SECOND QUARTER RESULTS

Continued Growth in Mobile Demand  
Increased Marketing in Preparation for Future Reimbursement

Lyon, France, July 27, 2005 -- EDAP TMS S.A. (NASDAQ: EDAP)

, today reported financial results for the 2005 second quarter ended June 30, 2005. For the second quarter of 2005, the company reported total revenues of EUR 5.0 million compared to EUR 5.2 million in the same quarter of 2004. Year to date revenue includes the sale of 16 lithotripsy and four Ablatherm-HIFU units. Revenues for the first six months of 2005 were EUR 10.1 million compared to EUR 11.0 million in 2004.

Year to date, the company's gross margin as a percentage of total revenue increased from 37 percent in 2004 to 40 percent presently due to continued focus on cost reductions. The company's operating expenses increased by 5 percent year to date compared to 2004, primarily in relation to the company's continued focus on marketing in the Ablatherm-HIFU division. Progress toward reimbursement is ongoing, and the company is advancing its marketing and pipeline development activities in anticipation of future approvals.

The company's net loss for the second quarter 2005 was EUR 398,000 compared to EUR 507,000 in the second quarter 2004. Net loss for the first six months was EUR 538,000 compared to EUR 519,000 in 2004. The net loss is largely attributable to the company's investment in sales and marketing expenses ahead of revenues, as previously planned and announced.

As of June 30, 2005, the company had EUR 8.2 million in cash, level with the first quarter of 2005. The company continues to invest operating cash flows into marketing, product enhancement and market expansion to grow the total eligible user base for its Ablatherm-HIFU product line. The company plans to continue using cash in the third quarter to advance the Ablatherm-HIFU business.

Hugues de Bantel, CEO of EDAP TMS, commented: "The second quarter results reflect the company's current strategic initiatives to continue a steady increase in our shift to mobile per-procedure treatment sales. This model benefits the growth of Ablatherm-HIFU availability in European markets while steadily investing in sales, marketing and education initiatives in countries where we believe reimbursement will open the market opportunity for both mobile and equipment sales."

## EDAP: GROWTH IN ABLATHERM-HIFU MOBILE BUSINESS, POSITIONED FOR REIMBURSEMENT APPROVALS

For the first half of 2005, the HIFU division continued to experience steady unit sales while the majority of growth was in the mobile per-procedure and service business. Revenues were up slightly for the first six months of 2005 to EUR 3.6 million, and gross margins improved to 48 percent of sales as compared to 43 percent in the prior year six months. Maintenance and service contract sales increased as older Ablatherm-HIFU machines exited their warranty

period, fueling a 44 percent increase year to date. Year-to-date margin improvement was driven by efficiencies within the manufacturing and production process.

Sales and marketing expenses increased in the EDAP division according to the company's planned expansion of education programs for doctors and patients and to grow the pipeline in anticipation of future reimbursement approvals. Additionally, research and development expenses were up associated with the launch of the company's integrated imaging system allowing physicians to image while treating and reduce total treatment time. During the quarter, the company added one additional sales position to support growth in the mobile business across Europe .

EDAP - HIFU Division : Euros 000's

| Year     | Revenues | Gross Margin | Operating Income (Loss) |
|----------|----------|--------------|-------------------------|
| Q2 2004  | 1,708    | 47%          | 91                      |
| Q2 2005  | 1,841    | 47%          | (192)                   |
| YTD 2004 | 3,548    | 43%          | 163                     |
| YTD 2005 | 3,601    | 48%          | (187)                   |

Ablatherm-HIFU continued to build on its strong clinical foundation with now up to 8 years of patient data and total treatments of more than 7,800 worldwide. Additionally, the company now reports 75 sites using Ablatherm-HIFU on a fixed or mobile basis, as compared to 67 sites at the end of the first quarter of 2005 and 53 sites at the end of the second quarter 2004, a 42% increase over the twelve months.

In Germany , where Ablatherm-HIFU is partially reimbursed, the mobile per-procedure business increased 71 percent compared to the same period last year. The company ended the quarter with 12 sites in Germany , nine of which are served with the mobile model. In June the company added an additional mobile Ablatherm-HIFU unit to meet continuing growth in treatment demand and inquiries from additional sites. The company is continuing to train new physicians regularly at its Centers of Excellence.

The Italian mobile market continues to grow, benefiting from strong enthusiasm from doctors, patients and key opinion leaders selecting the procedure as an alternative for patients not able to cope with the rigors or restrictions of current treatments. Additionally, the reduced side effects and long-term success rate of Ablatherm-HIFU treatment are increasing interest among the broader urological community.

The United Kingdom market continues to develop following the introduction of Ablatherm-HIFU in June 2004. The company is currently working to secure private reimbursement approvals following positive reviews and acceptance by the National Institute for Clinical Excellence announced in April 2005. The company has strong leads and expects to place additional Ablatherm units by year end in response to demand from local doctors to gain access to the Ablatherm-HIFU technology.

"Total Ablatherm-HIFU treatments are now more than 7,800 to date, which is the most extensive body of experience on HIFU for localized prostate cancer in the world," said de Bantel. "In addition to our strong existing clinical evidence, we continue to work with the urological community to refine and improve this procedure to further lower patient side effects beyond the success we have already enjoyed. We introduced our new imaging head allowing doctors to better visualize the prostate while treatment is occurring. This accelerates treatment efficiencies and allows for even finer application of the HIFU technology."

"The HIFU business continues its strong growth in the mobile model giving clinics easier access by lowering their initial expenses to begin treating patients with Ablatherm-HIFU," continued de Bantel. "Doctors are very pleased with

the successful patient outcomes while offering their patients a better quality of life and shorter recovery period following treatment of localized prostate cancer. We continue to receive new inquiries daily about Ablatherm-HIFU, and our experienced clinical practitioners are an excellent resource in demonstrating the benefits of Ablatherm-HIFU to new contacts as well as conducting training to grow our population of practicing physicians."

#### TMS: CONTINUED DEMAND FOR OUR LITHOTRIPTERS

The UDS Division continued steady sales with 16 lithotripters sold in the first half of 2005, stable with the prior year same period. The company's mix of new unit sales year to date 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. Cost of sales continued to decline as a result of manufacturing efficiencies while gross margins held steady at 30 percent for the division. Operating profit for the quarter declined 15 percent from the change in unit sales mix and corresponding change in service contract mix.

TMS - UDS Division : Euros 000's

| Year     | Revenues | Gross Margin % | Operating Income (Loss) |
|----------|----------|----------------|-------------------------|
| Q2 2004  | 4,058    | 30%            | 12                      |
| Q2 2005  | 3,802    | 30%            | 54                      |
| YTD 2004 | 8,614    | 30%            | 104                     |
| YTD 2005 | 7,722    | 30%            | 86                      |

The company continued to maintain strict controls on internal expenses, which decreased by 8% within the UDS division year to date. TMS ended the second quarter with a strong backlog of 5 lithotripters.

#### CONFERENCE ACTIVITY

During the second quarter the company actively participated in three worldwide conferences: the American Urological Association Conference held in San Antonio , Texas , the 6th International Consultation on New Developments in Prostate Cancer and Prostate Diseases, co-sponsored by the International Union Against Cancer, in Paris and the British Association of Urology Surgeons meeting held in Glasgow, Scotland.

On Sept 21-24, 2005, EDAP will participate in the Deutsche Gesellschaft für Urologie (Congress of the German Society for Urology), in Dusseldorf, with events for urologists to meet practitioners using Ablatherm-HIFU, as well as present a number of abstracts on successful Ablatherm studies and outcomes.

#### CORPORATE OUTLOOK

"EDAP management continues to see our move toward the mobile model as the larger and growing portion of the Ablatherm-HIFU business," said de Bantel. "We continue to gain strength in key markets such as Italy and Germany where we are seeing strong growth through the spread of enthusiastic support from many key opinion leaders in the urological community of both countries. Our commitment to making the Ablatherm unit available without a

substantial initial expense allows these doctors to offer care to their patients while working toward future approvals in the clinical budgets to purchase a unit or develop a robust per procedure business, whichever is most suitable to their needs. This commitment to supporting their needs has helped to forge strong cooperative relationships benefiting EDAP, the urologist and the patient. Additionally, our launch in the U.K. continues to offer a significant market with ever increasing interest among physicians following the positive recommendation from N.I.C.E. and expanding interest among the private insurance community toward the possibility of using Ablatherm-HIFU as a means to treat patients at moderate cost and without the expense and difficulty of side effects."

"We continue to focus on building the base of Ablatherm-HIFU users through a blend of fixed and mobile installations in multiple markets," de Bantel continued. "In the short term, our revenue mix can vary between unit sales and procedure sales, but the overall model continues to build our corporate strength by working closely with members of the urological community to strengthen our reputation as the leading provider of HIFU for localized prostate cancer. We are executing our plan to invest in sales and marketing efforts in proportion to the growing opportunity we see ahead. We are placing resources into the market to manage the increasing interest we are seeing as well as in anticipation of reimbursement approvals and opportunities to continue expanding the markets we are serving in Europe and around the world."

#### Conference Call and Webcast

The company will host a conference call to discuss the results and answer questions from investors on Thursday, July 28, 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 888-343-7144 within the United States or +1-415-537-1933 from international locations and requesting the EDAP TMS 2005 Second Quarter Conference Call. Investors may also listen to the live call online at [www.edap-tms.com](http://www.edap-tms.com).

Investors unable to join the call can access a playback of the conference call. To access the replay,

please dial 800-633-8284 or +1-402-977-9140 and using access code 21253116 beginning two hours after the end of the call until August 7, 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)

**Three Months Ended :**

**Three Months Ended :**

June 30,  
 2005  
 Euros

June 30,  
 2004  
 Euros

June 30,  
 2005  
 \$US

June 30,  
 2004  
 \$US

Net sales of medical equipment

2,236

2,439

2,786

2,957

Net sales of spare parts, supplies and services

2,712

2,701

3,377  
3,275

NET SALES

**4,948**  
**5,140**  
**6,193**  
**6,232**

Other revenues

4  
80  
5  
97

TOTAL REVENUES

**4,952**  
**5,220**  
**6,168**  
**6,329**

Cost of sales

(2,946)  
(3,183)  
(3,670)  
(3,859)

GROSS PROFIT

**2,006**  
**2,037**  
**2,498**  
**2,470**

Research & development expenses

|                                     |         |
|-------------------------------------|---------|
|                                     | (479)   |
|                                     | (386)   |
|                                     | (597)   |
| S, G & A expenses                   | (468)   |
|                                     | (2,079) |
|                                     | (1,889) |
|                                     | (2,589) |
| Non recurring operating expenses    | (2,290) |
|                                     | -       |
|                                     | (207)   |
|                                     | -       |
|                                     | (252)   |
| <hr/>                               |         |
| <hr/>                               |         |
| <hr/>                               |         |
| Total operating expenses            | (2,558) |
|                                     | (2,482) |
|                                     | (3,186) |
|                                     | (3,010) |
| <br>                                |         |
| OPERATING PROFIT (LOSS)             |         |
|                                     | (552)   |
|                                     | (445)   |
|                                     | (688)   |
| Interest (expense) income, net      | (540)   |
|                                     | 21      |
|                                     | (3)     |
|                                     | 26      |
|                                     | (4)     |
| Currency exchange gains (loss), net |         |
|                                     | 139     |
|                                     | (81)    |
|                                     | 174     |
|                                     | (98)    |
| Other income (loss), net            |         |
|                                     | (7)     |

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INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST

|                             |              |
|-----------------------------|--------------|
|                             | <b>(399)</b> |
|                             | <b>(522)</b> |
|                             | <b>(497)</b> |
| Income tax (expense) credit | <b>(633)</b> |
|                             | 1            |
|                             | 15           |
|                             | 2            |
|                             | 19           |

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NET INCOME (LOSS)

|  |              |
|--|--------------|
|  | <b>(398)</b> |
|  | <b>(507)</b> |
|  | <b>(495)</b> |
|  | <b>(614)</b> |

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Earning per share - Basic

|  |        |
|--|--------|
|  | (0.05) |
|  | (0.07) |
|  | (0.06) |
|  | (0.08) |

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



(0.05)

(0.07)

(0.06)

(0.08)

Average number of shares used in computation of EPS

8,344,368

8,102,979

8,344,368

8,102,979

## NOTE:

Translated for convenience of the reader to U.S. dollars at the 2005 average three months noon buying rate of 1 Euro = 1.2455 USD, and 2004 average three months noon buying rate of 1 Euro = 1.2124 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)

|  | Six Months Ended :        |                           | Six Months Ended :       |                          |
|--|---------------------------|---------------------------|--------------------------|--------------------------|
|  | June 30,<br>2005<br>Euros | June 30,<br>2004<br>Euros | June 30,<br>2005<br>\$US | June 30,<br>2004<br>\$US |
| Net sales of medical equipment                     | 4,935                     | 5,629                     | 6,301                    | 6,900                    |
| Net sales of spare parts, supplies<br>and services | 5,089                     | 5,132                     | 6,497                    | 6,292                    |
| <b>NET SALES</b>                                   | <b>10,024</b>             | <b>10,761</b>             | <b>12,798</b>            | <b>13,192</b>            |
| Other revenues                                     | 54                        | 232                       | 68                       | 284                      |
| <b>TOTAL REVENUES</b>                              | <b>10,078</b>             | <b>10,993</b>             | <b>12,866</b>            | <b>13,476</b>            |
| Cost of sales                                      | (6,008)                   | (6,902)                   | (7,670)                  | (8,461)                  |
| <b>GROSS PROFIT</b>                                | <b>4,070</b>              | <b>4,091</b>              | <b>5,196</b>             | <b>5,015</b>             |
| Research & development<br>expenses                 | (930)                     | (777)                     | (1,187)                  | (953)                    |
| S, G & A expenses                                  | (4,015)                   | (3,743)                   | (5,127)                  | (4,588)                  |
| Non recurring operating<br>expenses                | -                         | (207)                     | -                        | (255)                    |

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|   |              |              |                |              |
|---|--------------|--------------|----------------|--------------|
| Total operating expenses                                | (4,945)      | (4,727)      | (6,314)        | (5,796)      |
| <b>OPERATING PROFIT (LOSS)</b>                          | <b>(875)</b> | <b>(636)</b> | <b>(1,118)</b> | <b>(781)</b> |
| Interest (expense) income, net                          | 28           | (31)         | 36             | (37)         |
| Currency exchange gains (loss), net                     | 307          | 192          | 392            | 235          |
| Other income (loss), net                                | 2            | 4            | 3              | 5            |
| <b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b> | <b>(538)</b> | <b>(471)</b> | <b>(687)</b>   | <b>(578)</b> |
| Income tax (expense) credit                             | -            | (48)         | -              | (58)         |
| <b>NET INCOME (LOSS)</b>                                | <b>(538)</b> | <b>(519)</b> | <b>(687)</b>   | <b>(636)</b> |
| Earning per share - Basic                               | (0.07)       | (0.07)       | (0.09)         | (0.08)       |
| 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                             | (0.07)       | (0.07)       | (0.09)         | (0.08)       |
| Average number of shares used in computation of EPS     | 8,344,368    | 8,051,689    | 8,344,368      | 8,051,689    |

NOTE:

Translated for convenience of the reader to U.S. dollars at the 2005 average six months noon buying rate of 1 Euro = 1.2767 USD, and 2004 average six months noon buying rate of 1 Euro = 1.2259 USD.

EDAP TMS S.A.

CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

(Amounts in thousands of Euro's and U.S. Dollars)

|   | June 30,<br>2005<br>Euros | March 31,<br>2005<br>Euros | June 30,<br>2005<br>\$US | March 31,<br>2005<br>\$US |
|---|---------------------------|----------------------------|--------------------------|---------------------------|
| Cash, cash equivalents and short term investments | 8,222                     | 8,183                      | 9,947                    | 10,567                    |

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|                           |        |        |        |        |
|---------------------------|--------|--------|--------|--------|
| Total current assets      | 23,254 | 22,954 | 28,133 | 29,641 |
| Total current liabilities | 10,089 | 9,553  | 12,205 | 12,335 |
| Shareholders' Equity      | 17,543 | 17,872 | 21,224 | 23,079 |

NOTE:

Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2098 USD, on June 30, 2005 and at the noon buying rate of 1 Euro = 1.2913 USD, on March 31, 2005.

EDAP TMS S.A.  
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION  
SIX MONTHS ENDED JUNE 30, 2005

(Amounts in thousands of Euro's)

|  | EDAP S.A.<br>HIFU<br>Division | TMS S.A.<br>UDS<br>Division | EDAP<br>TMS<br>HQ | Consolidation<br>Impact | Total<br>After<br>Consolidation |
|--|-------------------------------|-----------------------------|-------------------|-------------------------|---------------------------------|
| Net sales of medical devices                       | 1,883                         | 3,837                       | -                 | (785)                   | 4,935                           |
| Net sales of spare parts,<br>supplies and services | 1,665                         | 3,838                       | -                 | (414)                   | 5,089                           |
| Other revenues                                     | 53                            | 47                          | -                 | (47)                    | 53                              |
|  | <hr/>                         | <hr/>                       | <hr/>             | <hr/>                   | <hr/>                           |
| TOTAL REVENUES                                     | 3,601                         | 7,722                       | -                 | (1,246)                 | 10,077                          |
|  | <hr/>                         | <hr/>                       | <hr/>             | <hr/>                   | <hr/>                           |
| GROSS PROFIT                                       | 1,740 48%                     | 2,330 30%                   | -                 | -                       | 4,070 40%                       |
| Research & Development                             | (556)                         | (374)                       | -                 | -                       | (930)                           |
| Total SG&A plus depreciation                       | (1,371)                       | (1,870)                     | (774)             | -                       | (4,015)                         |
| Non recurring op. expenses                         | -                             | -                           | -                 | -                       | -                               |
|  | <hr/>                         | <hr/>                       | <hr/>             | <hr/>                   | <hr/>                           |
| OPERATING PROFIT<br>(LOSS)                         | (187)                         | 86                          | (774)             | -                       | (875) >                         |

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