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EDAP TMS SA  
Form 6-K  
November 08, 2006

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 6 K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934

EDAP TMS S.A. Files  
EDAP TMS S.A. Reports 2006 Third Quarter Results

November 8, 2006

EDAP TMS S.A.  
Parc Activite La Poudrette Lamartine  
4/6 Rue du Dauphine  
69120 Vaulx-en-Velin - France

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

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EDAP TMS S.A. REPORTS 2006 THIRD QUARTER RESULTS;  
EDAP AND HEALTHTRONICS IN DISCUSSIONS REALIGNING US MARKET ENTRY;  
ABLATHERM RPP SUCCESS GROWING EUROPE;  
LITHOTRIPSY RETURNS TO PROFITABILITY - SOLID CASH POSITION FOR CONTINUED GROWTH

LYON, France, Nov. 7 /PRNewswire-FirstCall/ -- EDAP TMS S.A. (Nasdaq: EDAP), today reported results for the third quarter and first nine months ended September 30, 2006.

Hugues de Bantel announced, "We are reporting two very different kinds of news. In Europe, the major HIFU market today, EDAP continues to successfully lead the growth and adoption of HIFU. Centers, treatments and RPP activity are rising in response to our growth initiatives. Regarding additional markets for future years, we have recently been informed by HealthTronics that they intend to discontinue the partnership in the United States. This comes as a surprise to us and is disappointing to us and to our shareholders. The US is clearly an important future market in the coming years. EDAP will now aggressively take action to address this change."

The Company immediately implemented a US action plan to manage the transition process:

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- \* The Company will hire a US consultant to review the US market entry program and provide recommendations.
- \* EDAP is currently in discussions with HealthTronics regarding the ongoing Ablatherm clinical trials in the United States and the position of the parties under the Distribution Agreement dated February 2004 between the Company and HealthTronics, including the Company's legal remedies under that Agreement.
- \* Should the collaboration contemplated by the Distribution Agreement terminate, EDAP intends to actively seek another partner to continue toward the goal of obtaining regulatory approval for the Ablatherm in the United States. Both EDAP and HealthTronics have expressed their wish to create a smooth transition and clinical trials are expected to progress in the interim. The trials are currently suspended for software updates and are expected to resume shortly.
- \* While this represents a disruption to the anticipated schedule, EDAP's business plan does not contemplate revenue from the marketing of the Ablatherm in the United States in the immediate future as the trials are a multiyear enterprise. EDAP remains firmly committed to entering the U.S. market. In the event of a termination of the Distribution Agreement, EDAP retains all rights, data and trial related property associated with the program.
- \* The Company intends no change in the use of the proceeds obtained through the PIPE transaction as they are dedicated to the development of our Ablatherm RPP business in Europe.

"Today, EDAP is more committed than ever to focus its efforts on confirming the growing RPP Ablatherm HIFU business in Europe," stated de Bantel. "We will address the US program to ensure we enter this important market. In the interim, we continue, as previously planned, to grow HIFU in markets where it is already approved, most notably Europe where EDAP is achieving success."

The company's HIFU division continued to expand treatments in its Revenue-Per-Procedure (RPP) business as well as grow the number of sites offering therapy. Confirming the company's success transitioning to recurring revenues from RPP treatments and services, total revenues in the first 9 months increased in the HIFU division in spite of decreased revenues from device sales. EDAP's marketing program showed early success driving increased HIFU awareness and demand in European markets. Additional treatment growth is expected and already visible as the company continues to transition to treatment sales in its revenue focus. The company's lithotripsy business grew and returned to operating profitability on strong sales.

The company added six new Ablatherm sites in the third quarter bringing the total trained centers to 123 as compared to 80 a year ago. Since September 30, already an additional six sites have launched or are launching with more scheduled throughout the rest of 2006. In what is traditionally the company's slowest quarter due to European procedure scheduling trends, the company reported approximately 700 treatments, level to the second quarter as opposed to the typical seasonal drop seen in prior years. Total Ablatherm treatments now approach 11,000 as compared to the 10,000 mark passed in the spring of this year.

"The third quarter demonstrates EDAP's marketing program is growing HIFU demand and sustainable RPP revenue trends," said Hugues de Bantel, CEO of EDAP. "The company has a number of initiatives still to launch, including the hiring of several additional key sales and support positions, but we clearly see

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success as we continue to address the growing market for HIFU in Europe. Treatments in the third quarter were strong compared to prior years. This is an acceleration from the success of our marketing efforts -- patients are increasingly seeking Ablatherm-HIFU therapy. EDAP is the only major HIFU company with the clinical credibility, installation base, broad distribution networks and, most importantly, dedicated funds to rapidly build HIFU as a minimally invasive prostate cancer treatment, preserving quality of life, in Europe. We are taking full advantage of this opportunity as the market is ready for growth."

### EDAP: EUROPEAN HIFU GROWTH ADVANCING UNDER EDAP; RPP ACTIVITY RISES

For the first nine months of 2006, HIFU revenues increased 5% reflecting the shift from device sales to recurring service and RPP revenues as well as growth in total HIFU demand. Revenues related to RPP treatments were up 69% year to date to EUR 2.0 million. Services increased 72% to EUR 1.0 million due to a larger installed base of equipment, greater sales of disposable supplies at sold sites and upgrade sales. The revenue increase comes despite a 42% drop in equipment sales invoices, per the company's transition plan from equipment sales to RPP business that will ultimately reduce its dependence on straight device sales.

"We are pleased to report our RPP business is not only making up the difference in equipment sales, but could also in the mid-term provide for revenue growth according to the goals we shared in previous reports," said de Bantel. "We are also seeing a strong increase in services and disposables as many of our sold sites exit their initial warranty period. Together, this represents solid activity in HIFU as the market begins to grow in response to EDAP's marketing initiatives focused on Europe."

### EDAP - HIFU Division: Euros 000's

| Year     | Revenues | Gross Margin % | Operating Income (Loss) |
|----------|----------|----------------|-------------------------|
| Q3 2006  | 1,351    | 54%            | (326)                   |
| Q3 2005  | 1,432    | 51%            | (146)                   |
| YTD 2006 | 5,262    | 55%            | (540)                   |
| YTD 2005 | 5,033    | 49%            | (333)                   |

RPP activity increased for the quarterly comparison in Germany, France, Italy and treatments increased in the UK. The company launched its third German mobile Ablatherm in response to heightened market activity and demand. RPP treatments accounted for 188 sessions in the third quarter and 705 year to date compared to 128 and 437 respectively in the same periods of 2005. Gross margins improved to 55% compared to 49% for the year ago first nine months. The improvement included increased RPP and services revenues as well as ongoing cost efficiency gains.

Total HIFU revenues in the third quarter were down 4% compared to the prior year, related to the shift of selling one Ablatherm device as opposed to two, while revenues in RPP services and disposables grew substantially in the comparable periods as the company's mix shifted to favor these recurring revenue streams. Clinical expenses increased year over year as the company increased funding of clinical works and development programs to further establish HIFU as a primary treatment therapy for localized primary indication and post-radiation recurrent prostate cancers. This clearly correlates to increasing conversion of urologists to HIFU users based on its strong clinical results and appeal to patients concerned about lifestyle post treatment.

Year-to-date marketing expenses increased from EUR 432,000 to EUR 827,000

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related to the company's dedicated marketing programs to drive doctor and patient awareness as well as increased activity related to medical congresses and marketing as HIFU visibility has grown significantly in the past year causing a corresponding increase in medical community interest at these events.

"The shift in our financial reports clearly demonstrates the commitment to rapidly accelerate our marketing and scientific activities using dedicated funds in advance of expected market gains, especially in growth of RPP revenues," said de Bantel. "We see signs of success in key markets where we first activated these programs and expect more growth ahead. These early indications show we are definitely making full use of our opportunities today to build markets for the future."

### TMS: RETURNS TO OPERATING PROFITABILITY

The UDS division reported strong sales returning the division to profitability for both the quarter and first nine month periods. Year to date the company sold 30 pieces of equipment; service revenues remain steady. Gross margin increased slightly to 32% in line with the company's normal range. The division results include a slight increase in expenses related to marketing and research programs to ongoing development programs. Backlog entering the fourth quarter stands at 4 lithotripters.

### TMS - UDS Division : Euros 000's

| Year     | Revenues | Gross Margin % | Operating Income (Loss) |
|----------|----------|----------------|-------------------------|
| Q3 2006  | 4,335    | 35%            | 276                     |
| Q3 2005  | 3,964    | 30%            | 120                     |
| YTD 2006 | 12,178   | 32%            | 106                     |
| YTD 2005 | 11,686   | 30%            | 209                     |

### CORPORATE: CASH POSITION STRONG FOR CONTINUED GROWTH FUNDING

Consolidated group revenue increased 5% year to date to EUR 15.4 million reflecting the increases in RPP and services revenues and improved lithotripsy sales. Consolidated gross margins increased to 42% versus 41% in the prior year nine month period. Group expenses increased 17%, primarily related to growth in marketing program activity for HIFU. Total company losses increased to EUR 2.3 million year to date compared to EUR 1.1 million in the prior year period. Of the EUR 1.2 million increase in the year to date loss, EUR 559,000 is primarily related to a potential exchange loss in currency changes and the difference of EUR 647,000 is primarily related to investment in marketing and operations. Marketing expenses were up to EUR 1.2 million compared to EUR 653,000 with the primary increase related to HIFU activity building larger recurring revenue streams based on increased treatment activity. Cash balances stood at EUR 10.5 million at September 30, 2006. Total cash used in operations for the third quarter was EUR 360,000. Working capital in accounts payable net of receivables increased by EUR 890,000. Corporate expenses were up 16% to EUR 1.3 million related to increases in regulatory, legal, audit including Sarbanes Oxley fees and other expenses.

The company also reports Olivier Missoffe resigned from his position on the Board for personal reasons. The Board will announce a replacement member at a future date. The Company thanks Mr. Missoffe for his service and support of EDAP-TMS since 2002.

### OUTLOOK

Hugues de Bantel, CEO of EDAP TMS, commented: "EDAP made significant

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progress in Europe during the third quarter and continues to announce advances as they occur. EDAP is well funded to take advantage of this market opportunity to recruit the best and most progressive centers in major European markets as they seek to offer patients additional options with fewer side effects in treating prostate cancer. Our efforts to date in building the most comprehensive clinical background on HIFU and accelerating our marketing programs are having a positive effect, much of which relates to recurring revenue lines in the RPP business. We are excited to see these markets unfold creating growth opportunities ahead.

"The latest developments in our relationship with HealthTronics will likely result in a delay in the Ablatherm approval process, and we intend to take the opportunity to reclaim the US market as well as evaluate all strategic and partnership opportunities as HIFU is today more broadly regarded as an important and innovative choice for primary and radiation failure treatment of prostate cancer and beyond.

"This year already demonstrates significant advances in major European markets such as France, Germany, Italy and the U.K., all of which have a major EDAP presence as the global leader. Additionally, the appeal of HIFU is driving advances for EDAP in new markets, especially European countries like Norway, Spain, Portugal and others in the process of launching services. EDAP and the Ablatherm continue to advance on proven scientific results using documented and repeatable techniques at centers in each country prior to the formal launch. Our dedication to clinical and education programs showing the highly repeatable outcomes rivaling standard therapies with low side effects has been well received and continues to open doors for EDAP in current and future markets."

### Conference Call and Webcast

The company will host a conference call to discuss the results and answer questions from investors on Wednesday, November 8, 2006, at 12:00 noon Eastern Time, 6:00 p.m. Paris Time. Investors may join the call live by dialing (866) 200-5830 from the United States or +1 (212) 659-4210 from international locations and entering PIN code 241092#. Investors may also listen to the live call online at <http://www.edap-tms.com> .

A replay will be available by telephone or online. To access the replay, dial (866) 206-0173 or +1 (646) 216-7204 and enter access code 190287# beginning one hour after the end of the call until November 18, 2006, or visit the company's Web site at <http://www.edap-tms.com> .

### About EDAP TMS S.A.

EDAP TMS S.A. develops and markets 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. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. The company is also developing this technology for the potential 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 Halliburton Investor Relations at (972) 458-8000, the Corporate Investor Relations Dept at +33 (0)4 78 26 40 46 or see the Company's Web sites at <http://www.edap-tms.com> and <http://www.hifu-planet.com> .

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In addition to historical information, this press release contains 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 these 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. Ablatherm-HIFU treatment is in clinical trials but not yet FDA approved or marketed in the United States.

EDAP TMS S.A.  
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)  
 (Amounts in thousands of Euros and U.S. Dollars, except per share data)

|  | Three Months Ended: |               | Three Months Ended: |               |
|--|---------------------|---------------|---------------------|---------------|
|  | September 30,       | September 30, | September 30,       | September 30, |
|  | 2006                | 2005          | 2006                | 2005          |
|  | Euros               | Euros         | \$US                | \$US          |
| Net sales of medical equipment                   | 2,193               | 2,062         | 2,795               | 2,510         |
| Net sales of RPP                                 | 597                 | 355           | 761                 | 432           |
| Net sales of spare parts, supplies and Services  | 2,186               | 2,109         | 2,787               | 2,567         |
| NET SALES  | 4,976               | 4,526         | 6,343               | 5,509         |
| Other revenues                                   | 37                  | ---           | 47                  | ---           |
| TOTAL REVENUES                                   | 5,013               | 4,526         | 6,390               | 5,509         |
| Cost of sales                                    | (2,978)             | (2,681)       | (3,795)             | (3,263)       |
| GROSS PROFIT                                     | 2,035               | 1,845         | 2,595               | 2,246         |
| Research & development expenses                  | (646)               | (255)         | (823)               | (510)         |
| S, G & A expenses                                | (2,066)             | (2,084)       | (2,634)             | (2,337)       |
| Non recurring operating expenses                 | (72)                | (92)          |                     |               |
| Total operating expenses                         | (2,784)             | (2,339)       | (3,549)             | (2,847)       |
| OPERATING PROFIT (LOSS)                          | (749)               | (494)         | (954)               | (601)         |
| Interest (expense) income, net                   | 53                  | 8             | 67                  | 9             |
| Currency exchange gains (loss), net              | (154)               | (79)          | (196)               | (96)          |
| Other income (loss), net                         | (8)                 | 20            | (11)                | 24            |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (858)               | (545)         | (1,094)             | (664)         |
| Income tax (expense)                             |                     |               |                     |               |

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|  |           |           |           |           |
|--|-----------|-----------|-----------|-----------|
| credit   | 15        | (28)      | 19        | (33)      |
| NET INCOME (LOSS)  | (843)     | (573)     | (1,075)   | (697)     |
| Earning per share<br>- Basic                                 | (0.10)    | (0.07)    | (0.12)    | (0.09)    |
| Average number of<br>shares used in<br>computation of<br>EPS | 8,802,507 | 7,781,731 | 8,802,507 | 7,781,731 |
| Earning per share<br>- Diluted                               | (0.10)    | (0.07)    | (0.12)    | (0.09)    |
| Average number of<br>shares used in<br>computation of<br>EPS | 9,525,669 | 8,344,368 | 9,525,669 | 8,344,368 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2006 average three months noon buying rate of 1 Euro = 1.2748 USD, and 2005 average three months noon buying rate of 1 Euro = 1.2172 USD.

EDAP TMS S.A.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)  
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

|   | Nine Months Ended:    |                       | Nine Months Ended:    |                       |
|---|-----------------------|-----------------------|-----------------------|-----------------------|
|   | September 30,<br>2006 | September 30,<br>2005 | September 30,<br>2006 | September 30,<br>2005 |
|   | Euros                 | Euros                 | \$US                  | \$US                  |
| Net sales of medical<br>equipment                     | 6,651                 | 6,997                 | 8,329                 | 8,795                 |
| Net sales of RPPs                                     | 2,022                 | 1,197                 | 2,532                 | 1,505                 |
| Net sales of spare<br>parts, supplies<br>and Services | 6,590                 | 6,356                 | 8,252                 | 7,988                 |
| NET SALES   | 15,263                | 14,550                | 19,113                | 18,288                |
| Other revenues  | 116                   | 53                    | 145                   | 67                    |
| TOTAL REVENUES  | 15,379                | 14,603                | 19,258                | 18,355                |
| Cost of sales   | (8,846)               | (8,688)               | (11,077)              | (10,920)              |
| GROSS PROFIT  | 6,533                 | 5,915                 | 8,181                 | 7,435                 |
| Research &<br>development<br>expenses                 | (1,869)               | (788)                 | (2,340)               | (1,696)               |
| S, G & A expenses (6,616)                             | (6,497)               | (8,285)               | (7,460)               |                       |
| Non recurring<br>operating<br>expenses                | (72)                  | ---                   | (91)                  | ---                   |
| Total operating<br>expenses                           | (8,557)               | (7,285)               | (10,716)              | (9,156)               |
| OPERATING PROFIT<br>(LOSS)                            | (2,024)               | (1,370)               | (2,535)               | (1,721)               |

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|   |           |           |           |           |
|---|-----------|-----------|-----------|-----------|
| Interest (expense) income, net                      | 88        | 35        | 110       | 44        |
| Currency exchange gains (loss), net                 | (330)     | 229       | (414)     | 287       |
| Other income (loss), net                            | (8)       | 22        | (10)      | 28        |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST    | (2,274)   | (1,084)   | (2,849)   | (1,362)   |
| Income tax (expense) credit                         | (42)      | (27)      | (52)      | (34)      |
| NET INCOME (LOSS)                                   | (2,316)   | (1,111)   | (2,901)   | (1,396)   |
| Earning per share - Basic                           | (0.26)    | (0.14)    | (0.33)    | (0.18)    |
| Average number of shares used in computation of EPS | 8,802,507 | 7,781,731 | 8,802,507 | 7,781,731 |
| Earning per share - Diluted                         | (0.26)    | (0.14)    | (0.33)    | (0.18)    |
| Average number of shares used in computation of EPS | 9,550,740 | 8,344,368 | 9,550,740 | 8,344,368 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2006 average nine months noon buying rate of 1 Euro = 1.2522 USD, and 2005 average nine months noon buying rate of 1 Euro = 1.2569 USD.

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

|   | September 30,<br>2006 | June 30,<br>2006 | September 30,<br>2006 | June 30,<br>2006 |
|---|-----------------------|------------------|-----------------------|------------------|
|   | -----<br>Euros        | -----<br>Euros   | -----<br>\$US         | -----<br>\$US    |
| Cash, cash equivalents and short term investments | 10,540                | 6,635            | 13,372                | 8,479            |
| Total current assets                              | 27,542                | 22,216           | 34,942                | 28,390           |
| Total current liabilities                         | 11,828                | 10,822           | 15,007                | 13,829           |
| Shareholders' Equity                              | 20,463                | 16,057           | 25,961                | 20,519           |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2687 USD, on September 30, 2006 and at the noon buying rate of 1 Euro = 1.2779 USD, on June 30, 2006.



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EDAP TMS S.A.  
 CONDENSED STATEMENTS OF OPERATIONS BY DIVISION  
 NINE MONTHS ENDED SEPTEMBER 30, 2006  
 (Amounts in thousands of Euros)

|   | EDAP S.A.<br>HIFU<br>Division<br>----- | TMS S.A.<br>UDS<br>Division<br>----- | EDAP TMS<br>HQ<br>----- | Consolidation<br>Impact<br>----- | Total Aft<br>Consolidat<br>----- |
|---|--|--------------------------------------|-------------------------|----------------------------------|----------------------------------|
| Net sales of medical devices                  | 1,506                                  | 6,246                                | ---                     | (1,101)                          | 6,                               |
| Net sales of RPPs                             | 2,022                                  |                                      |                         |                                  | 2,                               |
| Net sales of spare parts, supplies & services | 1,679                                  | 5,871                                | ---                     | (960)                            | 6,                               |
| Other revenues                                | 55                                     | 61                                   | ---                     |                                  |                                  |
| TOTAL REVENUES                                | 5,262                                  | 12,178                               | ---                     | (2,061)                          | 15,                              |
| GROSS PROFIT                                  | 2,917 55%                              | 3,866 32%                            | ---                     | (250)                            | 6,533                            |
| Research & Development                        | (1,027)                                | (842)                                | ---                     | ---                              | (1,                              |
| Selling and Marketing                         | (1,905)                                | (1,628)                              |                         |                                  | (3,                              |
| Total G&A plus depreciation                   | (525)                                  | (1,290)                              | (1,268)                 | ---                              | (3,                              |
| Non recurring op. expenses                    | ---                                    | ---                                  | (72)                    | ---                              |                                  |
| OPERATING PROFIT (LOSS)                       | (540)                                  | 106                                  | (1,340)                 | (250)                            | (2,                              |

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/Web site: <http://www.edap-tms.com>  
<http://www.hifu-planet.com> /  
(EDAP)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date : November 8, 2006

EDAP TMS S.A.

/s/ HUGUES DE BANTEL  
-----  
HUGUES DE BANTEL  
CHIEF EXECUTIVE OFFICER