EDAP TMS SA
Form 6-K
September 30, 2010

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 on

September 30, 2010

EDAP TMS S.A.
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Commission File Number : 0-29374

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 .........X........ Form 40-F.................

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): .......

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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 .....X....

This report on Form 6-K is hereby incorporated by reference in the registration statement of EDAP TMS S.A. on Form F-3, file number 333-136811, 333-147762 and 333-152738.

Explanatory Note

Operating and Financial Review and Prospects and Unaudited Consolidated Interim Financial Statements for the six months ended and as of June 30, 2010

The following discussion of our results of operations and liquidity and capital resources for the six months ended June 30, 2010 is based on, and should be read in conjunction with the unaudited consolidated interim financial statements and the notes thereto included in this report on Form 6-K. The unaudited consolidated interim financial statements have been prepared in accordance with U.S. GAAP and refer to the new topic-based FASB Accounting Standards Codification (‘ASC’).

The unaudited consolidated interim financial statements furnished in this report on Form 6-K supplements the unaudited financial information furnished on Form 6-K on August 24, 2010. The unaudited financial information included herein does not amend or restate the information furnished on August 24, 2010.

Operating and Financial Review and Prospects for the six months ended and as of June 30, 2010

Operating Results

Six Months Ended June 30, 2010 Compared to Six Months Ended June 30, 2009

| (in millions of euros) | 6 months 2010 | | 6 months 2009 | |
|---|---|---|---|---|
| Total revenues | 10.3 | | 12.2 | |
| Total net sales | 9.8 | | 12.1 | |
| Of which HIFU | 3.5 | | 4.2 | |
| Of which UDS | 6.3 | | 7.9 | |
| Total cost of sales | (6.1 | ) | (6.9 | ) |
| Gross profit | 4.2 | | 5.3 | |
| Gross profit as a percentage of total net sales | 42.8 | % | 43.7 | % |
| Operating expenses before FDA PMA | (5.6 | ) | (6.1 | ) |
| FDA PMA expenses | (1.3 | ) | (0.9 | ) |
| Total operating expenses | (6.9 | ) | (7.1 | ) |
| Operating loss before FDA PMA | (1.4 | ) | (0.8 | ) |
| Loss from operations | (2.7 | ) | (1.8 | ) |
| Net income (loss) | (3.6 | ) | (3.6 | ) |

Total revenues.

Our total revenues decreased 15.2% from €12.2 million in the first half of 2009 to €10.3 million in the first half of 2010, principally due to decreased HIFU-RPP sales and the decrease in lithotripsy equipment sales. The decrease in revenues reflected the overall weak global economic environment in the first part of 2010 and the resulting slowdown in healthcare expenditures.

HIFU division. The HIFU division’s total revenues decreased 17.3% to €3.5 million in the first half of 2010 as compared to €4.2 million in the first half of 2009.

The HIFU division’s net sales of medical devices decreased 23.5% to €0.6 million in the first half of 2010, with two Ablatherm units sold, as compared €0.7 million in the first half of 2009. In the first half of 2009, we also sold two

Ablatherm units. The sale of one used unit in the first half of 2010 resulted in the decrease of the average unit sales price to €286 thousand in the first half of 2010 (down 23.5% from €374 thousand in the first half of 2009).

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Net sales of RPP treatments decreased 12.3% to €1.9 million in the first half of 2010, as a result of the 14.5% decrease in the number of treatments performed both on a mobile and fixed RPP basis.

Net sales of consumables decreased 21.1% at €0.4 million in the first half of 2010, and net sales of HIFU-related spare parts, supplies, leasing and services decreased 22.7 % from €0.9 million in the first half of 2009 to €0.7 million in the first half of 2010.

Other HIFU-related revenue were stable at €3 thousand in the first half of2010,  from €5 thousand in the first half of 2009.

UDS division. The UDS division’s total revenues decreased 14.1% from €8.0 million in the first half of 2009 to €6.8 million in the first half of 2010, mostly due to decreased sales volumes in medical devices.

The UDS division’s net sales of medical devices decreased 34.9% from €4.6 million in the first half of 2009 to €3.0 million in the first half of 2010 with 15 lithotripsy devices sold in the first half of 2010 compared to 18 lithotripsy devices sold in the first half of 2009. Equipement sales in the first half of 2010 reflected also a negative change in product mix, as a used LT02 machine and a lower proportion of high-end Sonolith Isys machines were sold, thus driving the 22.7% decrease in average sales price in the first half of 2010.

Net sales of UDS-related spare parts, supplies, leasing and services decreased 1.0% from €2.4 million in the first half of 2009 to €2.3 million in the first half of 2010.

Other UDS-related revenue increased from €34 thousand in the first half of 2009 to €500 thousand in the first half of 2010, and reflected a €500 thousand government subsidy that was granted to the Company as a public aid to small businesses in the difficult economic environment.

Cost of sales.

Cost of sales decreased 11.0% from €6.9 million in the first half of 2009 to €6.1 million in the first half of 2010, and represented 62.3% as a percentage of net sales in the first half of 2010, up from 56.7% as a percentage of net sales in the first half of 2009.

Operating expenses.

Operating expenses decreased 3.3%, or €0.2 million, from €7.1 million in the first half of 2009 to €6.9 million in the first half of 2010. Without the effect of the FDA PMA trials, operating expenses decreased €0.6 million or 9.1%.

The costs associated with the FDA PMA trial increased 33.8% at €1.3 million in the first half of 2010 compared to €0.9 million in the first half of 2009, as a result of the greater number of patients enrolled and treated in the PMA trials in the United States. The enrollment and treatment phase ended on June 30, 2010.

Excluding the FDA PMA trials, marketing and sales expenses increased €0.1 million, or 4.0%, mostly due to the inception of sales and marketing efforts in the United States to introduce the Sonolith Isys lithotripsy machine to the US market.

Excluding the FDA PMA trials, research and development expenses decreased 37.1% at €0.7 million in  the first half of 2010 from €1.2 million in the first half of 2009. Research and development expenses in the first half of 2010 included R&D tax credits of €409 thousand.

Excluding the FDA PMA trials, general and administrative expenses decreased 13.2% from €1.9 million in the first half of 2009 to €1.6 million in the first half of 2010.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €2.7 million in the first half of 2010, as compared to a consolidated operating loss of €1.8 million in the first half of 2009.

Excluding the expenses of the FDA PMA trials, the consolidated operating loss in the first half of 2010 was €1.4 million, compared to €0.8 million in the first half of 2009.

We realized an operating loss in the HIFU division of €0.2 million in the first half of 2010, stable from the first half of 2009, and an operating loss in the UDS division of €0.5 million in the first half of 2010, as compared to an operating profit of €0.1 million in the first half of 2009.

Financial (expense) income, net. Financial (expense) income net was an expense of €1.4 million in the first half of 2010, including a €0.4 million expense due to the adjustment of the convertible debt to fair value, compared with a loss of €1.4 million in the first half of 2009, including a €0.6 million expense due to the adjustment of the convertible debt to fair value.

Foreign currency exchange gains (loss), net. In the first half of 2010, we recorded a net foreign currency exchange gain of €1.3 million, compared to a loss of €0.3 million in the first half of 2009.

Other income (expense), net. An expense of €2 thousand in the first half of 2010, compared to an expense of €1 thousand in the first half of 2009.

Income taxes. Income tax was an expense of €825 thousand in the first half of 2010, compared to an expense of €63 thousand in the first half of 2009. Income tax in the first half of 2010 included the reimbursement of a state aid received by EDAP-TMS France in 1994 for the acquisition of the activities of Technomed International. This aid was finally considered as an illegal State Aid by European Court of Justice (C-214/07 "Commission of the European Communities vs French Republic"). The requested amount was €772,822, including €374,156 of late interest.

Net income (loss)

As a result of the above, we realized a consolidated net loss of €3.6 million in the first half of 2010 compared with a consolidated net loss of €3.6 million in the first half of 2009.

Liquidity and Capital Resources

| (in thousands of euros) | 6 months 2010 | 6 months 2009 |
|---|---|---|
| Net cash used in operating activities | (1,245) | (1,730) |
| Net cash used in investing activities | (5,670) | (7,924) |
| Net cash used in financing activities | 361 | (239) |
| Net effect of exchange rate changes | (92) | 733 |
| Net increase/(decrease) in cash and cash equivalents | (6,646) | (9,159) |
| Cash and cash equivalents at the beginning of the year | 11,590 | 13,827 |
| Cash and cash equivalents at the end of the year | 4,944 | 4,668 |
| | | |
| Total cash and cash equivalents, and short-term investments as of June 30 | 11,380 | 13,606 |

Our cash position as of June 30, 2010 and 2009 was €11.4 million (including €6.4 million of short-term treasury investments), and €13.6 million (including €8.9 million of short-term treasury investments), respectively. We experienced negative cash flows of €6.6 million and €9.2 million in the first half of 2010 and 2009, respectively.

In 2010, net cash used in operating activities was €1.2 million compared with net cash used in operating activities of €1.7 million in the first half of 2009.

In the first half of 2010, net cash used in operating activities reflected principally:

- a net loss of €3.6 million;
- elimination of €1.3 million of net expenses without effects on cash, including €0.7 million of depreciation and amortization, €0.1 million of change in long-term provisions and a loss of €0.5 million due to variation of the fair value of financial instruments (convertible debentures, investor warrants and placement agent warrants);

- a decrease in trade accounts receivable of €1.6 million;
- an increase in other receivables of €0.4 million;
- an increase in inventories of €0.8 million;
- a decrease in payables of €0.3 million;
- a decrease in prepaid expenses of €0.3 million; and
- an increase in accrued expenses of €0.6 million.

In the first half of 2009, net cash used in operating activities reflected principally:

- a net loss of €3.6 million;
- elimination of €1.4 million of net expenses without effects on cash, including €1.2 million of depreciation and amortization, and the €0.6 million profit due to changes in the fair value of financial instruments (convertible debentures, investor warrants and placement agent warrants);
- a decrease in trade accounts receivable of €1.2 million;
- a decrease in other receivables of €0.5 million
- an increase in inventories of €0.7 million;
- a decrease in payables of €1.0 million;
- a decrease in prepaid expenses of €0.4 million; and
- an increase in accrued expenses of €0.1 million.

In the first half of 2010, net cash used in investing activities was €5.6 million compared with net cash used of €7.9 million in investing activities in the first half of 2009.

Net cash used in investing activities of €5.6 million in the first half of 2010 reflected investments of €0.1 million in capitalized assets produced by the Company, mostly HIFU devices used on the RPP basis, an investment of €0.2 million in property and equipment, and acquisitions of short-term treasury investments of €5.3 million.

In the first half of 2009, net cash used in investing activities was €7.9 million, reflecting investments of €0.2 million in capitalized assets produced by the Company (mainly Ablatherm devices as a support of the RPP business model in HIFU), an investment of €0.1 million in property, plant and equipment, acquisitions of short-term treasury investments of €8.4 million, and net proceeds from sales of leased-back assets of €0.8 million.

In the first half of 2010, net cash provided by financing activities was €0.3 million compared with net cash used in financing activities of €0.2 million in the first half of 2009.

Net cash provided by financing activities of €0.3 million in the first half of 2010 reflected principally the €2.0 million increase in capital related to the issuance of new shares in payment of the interest coupons on the convertible debt and the US$1.5 million partial conversion of the convertible debt, a long-term debt increase of €0.6 million, repayment of long term borrowings for €1.3 million, repayment of capital lease obligations totaling €0.4 million, and a decrease of €0.4 million in bank overdrafts.

In the first half of 2009, net cash used in financing activities was €0.2 million, reflecting principally the €0.3 million increase in capital related to the issuance of new shares in payment of the interest coupons on the convertible debt, a long-term debt increase of €0.4 million, repayment of long term borrowings for €0.1 million, repayment of capital lease obligations totaling €0.5 million, and a decrease of €0.4 million in bank overdrafts.

Contractual Obligations and Commercial Commitments as of June 30, 2010 (in thousands of euro, excluding interest expenses)

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 1-3 years | 4-5 years | More than 5 years |
| Short-Term Debt | 2,231 | 2,231 | — | — | — |
| Long-Term Debt | 11,667 | 250 | 11,330 | 87 | — |
| Capital Lease Obligations | 1,804 | 762 | 1,042 | — | — |

Significant Developments

On April 13, 2010, one holder of convertible debentures elected to convert 250 debentures, representing a total value of $250,000. Under the terms of the convertible debentures and the December 3, 2009 Supplement, 53,332 new shares were issued including 38,052 Conversion Shares and 15,280 Accelerated Interest Shares (as defined in the 2009 Supplements). Following this conversion, the aggregate amount of our outstanding Convertible debenture was reduced to $15,558,000.

Following the December 11, 2009 FDA Gastroenterology and Urology Devices panel's recommendations and the Company's January 2010 meeting with the FDA concerning its recommendations for the U.S. ENLIGHT Ablatherm-HIFU clinical trial, we had thoroughly evaluated all options aiming at an IDE submission in a feasible timeframe and with acceptable economics. In July 2010, patient enrollment was completed and the Company entered the required two-year follow-up phase. In aggregate, 134 patients participated in the U.S. study.

On June 24, 2010, our shareholders adopted several resolutions extending the validity of certain delegations of authority already granted to the Board of Directors to allow renegotiation with the OCRABSA holders of the bond indebtedness of the Company and, if need be, to seize financing opportunities which would allow the Company to increase shareholder equity. Any increases in capital will be implemented within the existing authorized dilution parameters that have already received shareholder approval.

In June 2010, the Company entered an exclusive agreement with Lumenis to distribute its high-technology urological lasers in France. Lumenis' market leading lasers enable precise minimally invasive treatment for a wide array of urologic conditions such as benign prostatic hyperplasia (BPH) and bladder, urethral and kidney stones. These products are a natural, synergistic expansion of EDAP's product portfolio.

In August 2010, the Company filed its application for 510(k) marketing clearance with the U.S. FDA for its compact, multi-configurations Sonolith i-move lithotripsy device. Following receipt of FDA marketing clearance, EDAP expects to be well positioned to address all segments of the U.S. lithotripsy market offering the widest range of lithotripters from compact to fully integrated devices.

Interim Unaudited Financial Statements for the six months ended and as of June 30, 2010

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EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
As of June 30, 2010 (unaudited) and December 31, 2009
(in thousands of euros unless otherwise noted)

| ASSETS | Notes | 06-30-2010 | 12-31-2009 |
|---|---|---|---|
| Current assets | | | |
| Cash and cash equivalents | 2 | 4,944 | 11,590 |
| Net Trade accounts and notes receivable | | 14,207 | 14,802 |
| Other receivables | | 1,092 | 723 |
| Inventories | 3 | 4,766 | 3,794 |
| Deferred tax assets | | 314 | 355 |
| Other assets, current portion | | 805 | 870 |
| Short-term investment | 2 | 6,436 | 1,113 |
| Total current assets | | 32,564 | 33,248 |
| Other assets, non-current | | 626 | 861 |
| Property and equipment, net | | 3,150 | 3,288 |
| Intangible assets, net | | 90 | 103 |
| Goodwill | | 2,412 | 2,412 |
| Deposits and other non-current assets | | 518 | 466 |
| Total assets | | 39,360 | 40,378 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | | |
| Current liabilities | | | |
| Trade accounts and notes payable | | 5,466 | 5,734 |
| Deferred revenues, current portion | | 603 | 558 |
| Social security and other payroll withholdings taxes | | 749 | 823 |
| Income taxes payable | | 831 | 124 |
| Other accrued liabilities | | 4,352 | 4,250 |
| Short-term borrowings | 4 | 2,231 | 2,675 |
| Current portion of capital lease obligations | 5 | 762 | 837 |
| Current portion of long-term debt | 6 | 250 | 173 |
| Total current liabilities | | 15,244 | 15,175 |
| Deferred revenues, non current | | 349 | 330 |
| Capital lease obligations, non current | 5 | 1,042 | 1,372 |
| Convertible debentures carried at fair value | 6 | 9,840 | 8,934 |
| Financial instruments carried at fair value | 6 | 705 | 808 |
| Long-term debt, non current | 6 | 871 | 396 |
| Other long-term liabilities | | 876 | 784 |
| Total liabilities | | 28,928 | 27,799 |
| Shareholders' equity | | | |
| Common stock, €0.13 par value; | | | |
| 10,523,902 shares issued and 11,124,374 shares outstanding ; | | | |
| 10,909,833 shares issued and 10,510,305 shares outstanding | | | |
| at June 30, 2010 and at December 31, 2009, respectively | | 1,498 | 1,418 |
| Additional paid-in capital | | 31,940 | 29,961 |
| Retained earnings | | (18,043 ) | (14,436 ) |
| Cumulative other comprehensive loss | | (3,730 ) | (3,131 ) |
| Treasury stock, at cost; 399,528 shares at June 30, 2010 and at December 31, 2009 | | (1,233 ) | (1, 233 ) |

| | | |
|---|---|---|
| Total shareholders' equity | 10,431 | 12,579 |
| Total liabilities and shareholders' equity | 39,360 | 40,378 |

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME (UNAUDITED)
For the periods ended June 30, 2010 and 2009
(in thousands of euros unless otherwise noted)

| | Notes | 6 months 2010 | 6 months 2009 |
|---|---|---|---|
| Sales of goods | | 4,641 | 6,539 |
| Sales of RPPs & leases | | 2,535 | 2,847 |
| Sales of spare parts and services | | 2,644 | 2,752 |
| Total sales | | 9,820 | 12,138 |
| Warrants granted | | — | — |
| Total net sales | | 9,820 | 12,138 |
| Other revenues | | 503 | 39 |
| Total revenues | | 10,323 | 12,177 |
| | | | |
| Cost of goods | | (2,776) | (3,659) |
| Cost of RPPs & leases | | (1,348) | (1,450) |
| Cost of spare parts and services | | (1,996) | (1,767) |
| Total cost of sales | | (6,120) | (6,877) |
| | | | |
| Gross profit | | 4,203 | 5,301 |
| | | | |
| Research and development expenses | | (1,901) | (1,998) |
| Selling and marketing expenses | | (3,209) | (3,087 |