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

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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 month<br>2010 | ns | 6 montl<br>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  $\le$ 3.5 million in the first half of 2010 as compared to  $\le$ 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).

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

The costs associated with the FDA PMA trial increased 33.8% at  $\le 1.3$  million in the first half of 2010 compared to  $\le 0.9$  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  $\le 0.7$  million in the first half of 2010 from  $\le 1.2$  million in the first half of 2009. Research and development expenses in the first half of 2010 included R&D tax credits of  $\le 409$  thousand.

Excluding the FDA PMA trials, general and administrative expenses decreased 13.2% from  $\le$ 1.9 million in the first half of 2009 to  $\le$ 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  $\[ \in \]$ 2.7 million in the first half of 2010, as compared to a consolidated operating loss of  $\[ \in \]$ 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  $\[ \in \]$  1.4 million in the first half of 2010, including a  $\[ \in \]$  0.4 million expense due to the adjustment of the convertible debt to fair value, compared with a loss of  $\[ \in \]$  1.4 million in the first half of 2009, including a  $\[ \in \]$  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  $\[ \in \]$ 1.3 million, compared to a loss of  $\[ \in \]$ 0.3 million in the first half of 2009.

Other income (expense), net. An expense of  $\ell$ 2 thousand in the first half of 2010, compared to an expense of  $\ell$ 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  $\le 3.6$  million in the first half of 2010 compared with a consolidated net loss of  $\le 3.6$  million in the first half of 2009.

#### Liquidity and Capital Resources

| (in thousands of euros)                                     | 6 months<br>2010 | 6 months<br>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  $\in$ 11.4 million (including  $\in$ 6.4 million of short-term treasury investments), and  $\in$ 13.6 million (including  $\in$ 8.9 million of short-term treasury investments), respectively. We experienced negative cash flows of  $\in$ 6.6 million and  $\in$ 9.2 million in the first half of 2010 and 2009, respectively.

In 2010, net cash used in operating activities was  $\leq 1.2$  million compared with net cash used in operating activities of  $\leq 1.7$  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  $\le 5.6$  million compared with net cash used of  $\le 7.9$  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  $\[ \in \]$ 7.9 million, reflecting investments of  $\[ \in \]$ 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  $\[ \in \]$ 0.1 million in property, plant and equipment, acquisitions of short-term treasury investments of  $\[ \in \]$ 8.4 million, and net proceeds from sales of leased-back assets of  $\[ \in \]$ 0.8 million.

In the first half of 2010, net cash provided by financing activities was  $\le 0.3$  million compared with net cash used in financing activities of  $\le 0.2$  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  $\{0.2 \text{ million}\}$ , reflecting principally the  $\{0.3 \text{ million}\}$  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  $\{0.4 \text{ million}\}$ , repayment of long term borrowings for  $\{0.1 \text{ million}\}$ , repayment of capital lease obligations totaling  $\{0.5 \text{ million}\}$ , and a decrease of  $\{0.4 \text{ million}\}$  in bank overdrafts.

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

|                           | Payments Due by Period |        |           |           |           |
|---------------------------|------------------------|--------|-----------|-----------|-----------|
|                           | Less than              |        |           |           | More than |
|                           | Total                  | 1 year | 1-3 years | 4-5 years | 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   | 2     | 4.044      | 11.500      |
| Cash and cash equivalents  | 2     | 4,944      | 11,590      |
| Net Trade accounts and notes receivable                                      |       | 14,207     | 14,802      |
| Other receivables  | 2     | 1,092      | 723         |
| Inventories  | 3     | 4,766      | 3,794       |
| Deferred tax assets  |       | 314        | 355         |
| Other assets, current portion  | 2     | 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)       |
| General and administrative expenses             |       | (1,743        | ) | (2,004)       |
| Non-recurring operating expenses                |       | _             |   | _             |
| Loss from operations                            |       | (2,650        | ) | (1,789)       |
| Financial (expense) income, net                 | 8     | (1,424        | ) | (1,461)       |
| Foreign currency exchange gain (loss), net      |       | 1,293         |   | (313)         |
| Other income (expense), net                     |       | (2            | ) | (1)           |
| Income (loss) before taxes                      |       | (2,782        | ) | (3,564)       |
| Income tax (expense) benefit                    |       | (825          | ) | (63)          |
| Net income (loss)                               |       | (3,607        | ) | (3,627)       |
| Basic net earnings (loss) per share             |       | (0.32         | ) | (0.36)        |
| Basic weighted average shares outstanding       |       | 11,124,374    | 4 | 9,937,816     |
| Diluted net earnings (loss) per share (1)       |       | (             | ) | (0.36)        |
| Diluted weighted average shares outstanding (1) |       | 11,162,996    | 5 | 9,949,591     |

<sup>(1)</sup> Due to the net losses in 2009 and 2010, the assumed net exercise of stock options/warrants and stock relating to the convertible bonds in this year was excluded, as the effect would have been anti-dilutive.

# EDAP TMS S.A. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

For the period ended June 30, 2010 (unaudited) (in thousands of euros unless otherwise noted)

|                                    |            |        |            |          | Cumula- |          |         |
|------------------------------------|------------|--------|------------|----------|---------|----------|---------|
|                                    |            |        |            |          | tive    |          |         |
|                                    |            |        |            |          | Other   |          |         |
|                                    | Number of  | Common | Additional | Retained | Compre- | Treasury |         |
|                                    | Shares     | Stock  | paid-in    | Earnings | hensive | Stock    | Total   |
|                                    |            |        | Capital    | C        | Income  |          |         |
|                                    |            |        | •          |          | (loss)  |          |         |
| Balance as of December 31, 2009    | 10,510,305 | 1,418  | 29,961     | (14,436) | (3,131  | (1,233)  | 12,579  |
| Net income                         |            |        |            | (3,607)  |         |          | (3,607) |
| Translation adjustment             |            |        |            |          | (599    | )        | (599)   |
| Warrants and stock options granted |            |        | 99         |          |         |          | 99      |
| Capital increase                   | 614,069    | 80     | 1,880      |          |         |          | 1,960   |
| Provision for retirement           |            |        |            |          |         |          |         |
| indemnities                        |            |        |            |          |         |          |         |
| Balance as of June 30, 2010        | 11,124,374 | 1,498  | 31,940     | (18,043) | (3,730  | (1,233)  | 10,431  |

# EDAP TMS S.A. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

For the periods ended June 30, 2010 and June 30, 2009 (in thousands of euros unless otherwise noted).

| Cash flows from operating activities  | 6 months<br>2010 |   | 6 months<br>2009 |   |
|---|------------------|---|------------------|---|
| Net income (loss)   | (3,607           | ) | (3,627           | ) |
| Adjustments to reconcile net loss to net cash used in operating activities: | (3,007           | ) | (3,027           | ) |
| Depreciation and amortization   | 724              |   | 1,208            |   |
| Change in fair value on Convertible Debentures                              | 615              |   | 461              |   |
| Change in fair value on Investors Warrants and Placement Agent Warrants     | (243             | ) | 92               |   |
| Other Non-cash compensation   | 182              | , | 189              |   |
| Change in allowances for doubtful accounts & slow-moving inventories        | (94              | ) | (514             | ) |
| Change in long-term provisions  | (92              | ) | 11               | , |
| Net capital loss on disposals of assets                                     | 47               | , | 27               |   |
| Deferred tax expense/(benefit)  | 144              |   | (24              | ) |
| Operating cash flow   | (2,323           | ) | (2,177           | ) |
| Increase/Decrease in operating assets and liabilities:                      | (2,323           | , | (2,177           | , |
| Decrease/(Increase) in trade accounts and notes and other receivables       | 1,274            |   | 1,642            |   |
| Decrease/(Increase) in inventories  | (842             | ) | (725             | ) |
| Decrease/(Increase) in other assets   | 315              | , | 416              |   |
| (Decrease)/Increase in trade accounts and notes payable                     | (280             | ) | (976             | ) |
| (Decrease)/Increase in accrued expenses, other current liabilities          | 611              |   | 91               |   |
| Net increase/decrease in operating assets and liabilities                   | 1,078            |   | 448              |   |
| Net cash used in operating activities                                       | (1,245           | ) | (1,730           | ) |
| Cash flows from investing activities  | Ź                |   | ,                |   |
| Additions to capitalized assets produced by the Company                     | (146             | ) | (220             | ) |
| Net proceeds from sale of leased back assets                                | 29               |   | 789              |   |
| Acquisitions of property and equipment                                      | (226             | ) | (110             | ) |
| Acquisitions of intangible assets   | (3               | ) | (12              | ) |
| Acquisitions of short term investments                                      | (5,323           | ) | (8,358           | ) |
| Net proceeds from sale of assets  |                  |   | _                |   |
| Increase in deposits and guarantees   | (2               | ) | (13              | ) |
| Reimbursement of deposits and guarantees                                    |                  |   | _                |   |
| Net cash used in investing activities                                       | (5,670           | ) | (7,924           | ) |
| Cash flow from financing activities   |                  |   |                  |   |
| Proceeds from capital increase  | 1,960            |   | 338              |   |
| Proceeds from long term borrowings, net of financing costs                  | 569              |   | 393              |   |
| Repayment of long term borrowings   | (1,289           | ) | (65              | ) |
| Repayment of obligations under capital leases                               | (434             | ) | (459             | ) |
| Increase/(decrease) in bank overdrafts and short-term borrowings            | (444             | ) | (446             | ) |
| Net cash used in financing activities                                       | 361              |   | (239             | ) |
| Net effect of exchange rate changes on cash and cash equivalents            | (92              | ) | 733              |   |
| Net increase/(decrease) in cash and cash equivalents                        | (6,646           | ) | (9,159           | ) |
| Cash and cash equivalents at beginning of year                              | 11,590           |   | 13,827           |   |
| Cash and cash equivalents at end of period                                  | 4,944            |   | 4,668            |   |

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### 1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries (the "Company") are engaged in the development, production, marketing, distribution and maintenance of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. The Company currently produces devices for treating stones of the urinary tract and localized prostate cancer. Net sales consist primarily of direct sales to hospitals and clinics in France and Europe, export sales to third-party distributors and agents, and export sales through subsidiaries based in Germany, Italy and Asia.

The Company purchases the majority of the components used in its products from a number of suppliers but for some components, relies on a single source. Delay would be caused if the supply of these components or other components was interrupted and these delays could be extended in certain situations where a component substitution may require regulatory approval. Failure to obtain adequate supplies of these components in a timely manner could have a material adverse effect on the Company's business, financial position and results of operation.

#### 1-2 Management estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("US GAAP") requires management to make estimates and assumptions, such as business plans, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### 1-3 Consolidation

The accompanying consolidated financial statements include the accounts of EDAP TMS S.A. and all its domestic and foreign owned subsidiaries, which include EDAP TMS France SAS, EDAP Technomed Inc., Edap Technomed Sdn Bhd, Edap Technomed Italia S.R.L, EDAP Technomed Co. Ltd. and EDAP TMS Gmbh. Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP TMS Gmbh was created in July 2006. EDAP SA, a subsidiary incorporating HIFU activities merged all of its activity into EDAP TMS France SAS in 2008. All intercompany transactions and balances are eliminated in consolidation.

#### 1-4 Revenue recognition

#### Sales of goods:

For medical device sales with no significant remaining vendor obligation, payments contingent upon customer financing, acceptance criteria that can be subjectively interpreted by the customer, or tied to the use of the device, revenue is recognized when evidence of an arrangement exists, title to the device passes (depending on terms, either upon shipment or delivery), and the customer has the intent and ability to pay in accordance with contract payment terms that are fixed or determinable. For sales in which payment is contingent upon customer financing, acceptance criteria can be subjectively interpreted by the customer, or payment depends on use of the device, revenue is recognized when the contingency is resolved. The Company provides training and provides a minimum of one-year warranty upon installation. The Company accrues for the estimated training and warranty costs at the time of sale.

Revenues related to disposables are recognized when goods are delivered.

Sales of RPPs and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a "Revenue-Per-Procedure" ("RPP") basis are recognized when the treatment procedure has been completed. Revenues from devices leased to customers under operating leases are recognized on a straight-line basis.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

Sales of spare parts and services:

Revenues related to spare parts are recognized when goods are delivered. Maintenance contracts rarely exceed one year and are recognized on a linear basis. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

### 1-5 Shipping and handling costs

The Company recognizes revenue from the shipping and handling of its products as a component of revenue. Shipping and handling costs are recorded as a component of cost of sales.

#### 1-6 Cash equivalents and short term investments

Cash equivalents are cash investments which are highly liquid and have initial maturities of 90 days or less.

Cash investments with a maturity higher than 90 days are considered as short-term investments.

#### 1-7 Accounts Receivables

Accounts receivables are stated at cost net of allowances for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables when collection becomes doubtful. Provision is made based upon a specific review of all significant outstanding invoices. These estimates are based on our bad debt write-off experience, analysis of credit information, specific identification of probable bad debt based on our collection efforts, aging of accounts receivables and other known factors.

#### 1-8 Inventories

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow moving, first based on a detailed comparison between quantity in inventory and historical consumption and then based on case-by-case analysis of the difference between the cost of inventory and the related estimated market value.

#### 1-9 Property and equipment

Property and equipment is stated at historical cost. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful life of the related assets, as follows:

| Leasehold improvements                  | 10 years or lease term if shorter |
|---|-----------------------------------|
| Equipment                               | 3-10 years                        |
| Furniture, fixtures, fittings and other | •                                 |

Equipment includes industrial equipment and research equipment that has alternative future uses. Equipment also includes devices that are manufactured by the Company and leased to customers through operating leases related to

Revenue-Per-Procedure transactions and devices subject to sale and leaseback transactions. This equipment is depreciated over a period of seven years.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

### 1-10 Long-lived assets

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the assets (or the group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the assets, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on assumptions and are subject to risk and uncertainty.

### 1-11 Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, "Goodwill and other intangible assets", the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company's tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit's goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased trade name and a purchased trademark. The basis for valuation of these assets is their historical acquisition cost. Amortization of intangible assets is calculated by the straight-line method over the shorter of the contractual or estimated useful life of the assets, as follows:

| Patents                  | 5 years |
|--------------------------|---------|
| Licenses                 | 5 years |
| Trade name and trademark | 7 years |

#### 1-12 Treasury Stocks

Treasury stock purchases are accounted for at cost. The sale of treasury stocks is accounted for using the first in first out method. Gains on the sale or retirement of treasury stocks are accounted for as additional paid-in capital whereas losses on the sale or retirement of treasury stock are recorded as additional paid-in capital to the extent that previous

net gains from sale or retirement of treasury stocks are included therein; otherwise the losses shall be recorded to accumulated benefit (deficit) account. Gains or losses from the sale or retirement of treasury stock do not affect reported results of operations.

# 1-13 Warranty expenses

The Company generally provides customers with a warranty for each product sold and accrues warranty expense at time of sale based upon historical claims experience. Actual warranty costs incurred are charged against the accrual when paid and are classified in cost of sales in the statement of income.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 1-14 Income taxes

The Company accounts for income taxes in accordance with ASC 740, "Accounting for Income Taxes". Under ASC 740, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured by applying enacted tax rates and laws to taxable years in which such differences are expected to reverse. A valuation allowance is established if, based on the weight of available evidence, it is more likely than not that some portion, or all of the deferred tax assets, will not be realized. In accordance with ASC 740, no provision has been made for income or withholding taxes on undistributed earnings of foreign subsidiaries, such undistributed earnings being permanently reinvested.

As of January 1, 2007, the Company adopted FIN 48 "Accounting for uncertainty in income tax". Under FIN48, the measurement of a tax position that meets the more-likely-that-not recognition threshold must take into consideration the amounts and probabilities of the outcomes that could be realized upon ultimate settlement using the facts, circumstances and information available at the reporting date.

#### 1-15 Research and development costs

Research and development costs are recorded as an expense in the period in which they are incurred. The French government provides tax credits to companies for innovative research and development. This tax credit is calculated based on a percentage of eligible research and development costs and it can be refundable in cash.

In 2009, the Company reviewed the presentation of its research tax credit and elected to change for the preferred classification as permitted under ASC 250-10.

As such the company reclassified the research tax credit as a reduction of research and development expense instead of income tax.

#### 1-16 Advertising costs

Advertising costs are recorded as an expense in the period in which they are incurred

#### 1-17 Foreign currency translation and transactions

Translation of the financial statements of consolidated companies

The reporting currency of EDAP TMS S.A. for all years presented is the euro (€). The functional currency of each subsidiary is its local currency. In accordance with ASC 830, all accounts in the financial statements are translated into euro from the functional currency at exchange rate as follows:

- assets and liabilities are translated at year-end exchange rates;
- shareholders' equity is translated at historical exchange rates (as of the date of contribution);
  - statement of income items are translated at average exchange rates for the year; and
- translation gains and losses are recorded in a separate component of shareholders' equity.

Foreign currencies transactions

Transactions involving foreign currencies are translated into the functional currency using the exchange rate prevailing at the time of the transactions. Receivables and payables denominated in foreign currencies are translated at year-end exchange rates. The resulting unrealized exchange gains and losses are carried to the statement of income.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 1-18 Earnings per share

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period.

#### 1-19 Derivative instruments

ASC 815 requires the Company to recognize all of its derivative instruments as either assets or liabilities in the statement of financial position at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must classify the hedging instrument, based upon the exposure being hedged, as fair value hedge, cash flow hedge or a hedge of a net investment in a foreign operation.

Gains and losses from derivative instruments are recorded in the income statement.

#### 1-20 Employee stock option plans

At June 30, 2010, the Company had four stock-based employee compensation plans. The Company adopted ASC 718, "Share-Based Payment", effective January 1, 2006. ASC 718 requires the recognition of fair value of stock compensation as an expense in the calculation of net income (loss).

The fair value of each stock option granted during the year is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

|  | 06-30-201 | 0 | 12-31-2009(1) | 12-31-2008(1) |
|--|-----------|---|---------------|---------------|
| Weighted-average expected life (years)                             | 6.25      |   | _             | _             |
| Expected volatility rates  | 76        | % | _             | _             |
| Expected dividend yield  | <u>—</u>  |   | _             | _             |
| Risk-free interest rate  | 2.18      | % |               | _             |
| Weighted-average exercise price (€)                                | 2.23      |   | <del>_</del>  | _             |
| Weighted-average fair value of options granted during the year (€) | 1.62      |   | _             | _             |

(1) The Company did not make any grants during the years ended December 31, 2008 and 2009.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 1-21 Convertible debentures and detachable warrants

#### Convertible Debentures

On October 29, 2007, the Company issued \$20 million in aggregate principal amount of non-secured, convertible debentures with detachable warrants. See Note 14 of the 2009 Annual Report on Form 20-F for further discussion. At the inception date, the Company elected to measure the instrument and the embedded derivatives in their entirety at fair value, with changes in fair value reported in the income statement under financial income, in accordance with ASC 815. Thus, the convertible debentures together with their embedded derivatives are recorded as a liability, with subsequent changes in fair value recorded in financial income and expenses. The Company used a binomial valuation model to measure the fair value of the Investor Warrants as defined below and a binomial valuation model with a Company specific credit spread to measure the fair value of the convertible debentures, including the inducement option from the December 3, 2009 Supplement.

#### Warrants:

As part of the October 2007 \$20 million issuance of the 9% Senior Convertible Debentures, the Company issued warrants to both the investors in the convertible debentures and to the bank that assisted the Company as the Placement Agent. See Note 14 of the 2009 Annual Report on Form 20-F for further discussion.

In accordance with ASC 815, the warrants issued to the investors in the convertible debentures ("Investor Warrants") and the Placement Agent ("Placement Agent Warrants") are classified as a liability because the Company may be required to net-cash and settle them upon the occurrence of certain events outside the control of the Company. The Company accounted for the Investor Warrants based on their fair value at inception date, with subsequent changes in fair value recorded as financial earnings (or loss) as each balance sheet date. The Company used a binomial pricing model to determine the fair value of the Investor Warrants: the binomial model was developed to capture the specific nature of this instrument, and in particular the possibility the holder may exercise the call option at any time from the inception date. The application of the model to the warrants therefore requires the use of subjective assumptions, including historical share price volatility, the expected life of the warrants and our risk-free interest rate, and the liquidity discount factor. A change in one or more of these assumptions could result in a material change to the estimated fair value of the vested warrants.

The Placement Agent Warrants were issued as partial consideration for placing the convertible debentures recorded as a liability, with changes in fair value at each balance sheet date reflected in financial income. The Company used the Black-Scholes option-pricing model to determine the fair value of the Placement Agent Warrants. The application of the model to the warrants at inception date therefore required the use of subjective assumptions, including historical share price volatility, the expected life of the warrants and the Company's risk-free interest rate.

#### 1-22 Leases and Sales and leaseback transactions

In accordance with ASC 840, Accounting for Leases, the Company classifies all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;
  - The lease contains a bargain purchase option;

- The lease term is at least 75% of the property's estimated remaining economic life;
- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

The Company enters into sale and leaseback transactions from time to time. In accordance with ASC 840, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

# 2—CASH AND CASH EQUIVALENTS

Cash and cash equivalents are comprised of the following:

|                                       | 06-30-2010 | 12-31-2009 |
|---------------------------------------|------------|------------|
| Total cash and cash equivalents       | 4,944      | 11,590     |
| Short term investments                | 6,436      | 1,113      |
| Total cash and short term investments | 11,380     | 12,703     |

Short term investments are monetary investments in liquid cash mutual fund securities.

#### 3—INVENTORIES

Inventories consist of the following:

|   | 06-30-2010 | 12-31-2009 |
|---|------------|------------|
| Components, spare parts                   | 3,565      | 3,656      |
| Work-in-progress                          | 902        | 317        |
| Finished goods                            | 997        | 627        |
| Total gross inventories                   | 5,464      | 4,600      |
| Less: provision for slow-moving inventory | (699 )     | (805)      |
| Total                                     | 4,766      | 3,794      |

#### 4—SHORT-TERM BORROWINGS

As of June 30, 2010, short-term borrowings consist of €1,231 thousand of account receivables factored and for which the Company is supporting the risk of non-collection and loans in euros amounting to €1,000 thousand with the following conditions:

| '000 Euros          | Amount | Maturation       | Interest rate  |
|---------------------|--------|------------------|----------------|
| EDAP-TMS France SAS | 1,000  | January 20, 2011 | Euribor + 0,5% |

#### 5—CAPITAL LEASE OBLIGATIONS

The Company leases certain of its equipment under capital leases. At June 30, 2010, this equipment consists of medical devices for an amount of  $\{0,7,14\}$  thousand and vehicles for an amount of  $\{0,7,14\}$  thousand.

#### EDAP TMS S.A. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 6—LONG-TERM DEBT

Long-term debt consists of the following:

|  | 06-30-2010 | 12-31-2009 |
|--|------------|------------|
| Japanese yen term loan                       | 758        | 568        |
| Italian euro term loan                       | 364        | -          |
| Convertible debentures carried at fair value | 9,840      | 8,934      |
|  |            |            |
| Investor Warrants                            | 620        | 702        |
| Placement Agent Warrants                     | 85         | 106        |
| Financial instruments carried at fair value  | 705        | 808        |
|  |            |            |
| Total  | 11,667     | 10,310     |
| Less current portion                         | (250)      | (173)      |
| Total long-term portion                      | 11,417     | 10,137     |

Long-term debt at June 30, 2010 matures as follows:

| 2010         | 165    |
|--------------|--------|
| 2011         | 349    |
| 2012         | 10,184 |
| 2013<br>2014 | 881    |
| 2014         | 78     |
| 2015         | 9      |
| Total        | 11,667 |

As of June 30, 2010, long-term debt in Japan consists of 6 loans in Yen with the following conditions:

| '000 Yen | Amount | Maturation         | Interest rate |
|----------|--------|--------------------|---------------|
| Japan    | 30,000 | November 17, 2011  | 2.87 %        |
|          | 50,000 | February 27, 2014  | 2.00 %        |
|          | 10,000 | July 17, 2014      | 2.00 %        |
|          | 5,000  | September 30, 2014 | 1.60 %        |
|          | 10,000 | March 31, 2015     | 0.10 %        |
|          | 10,000 | April 30, 2015     | 1.60 %        |

As of June 30, 2010, long-term debt in Italy consists of one loan in Euro with the following conditions:

| '000 Euros | Amount | Maturation       | Interest rate |
|------------|--------|------------------|---------------|
| Italy      | 404    | January 31, 2014 | Euribor +1.9% |

As of June 30, 2010, long-term debt in USD consists of a \$20 million convertible debt with warrants, raised on October 29, 2007 through a Private Investment in Public Equity transaction with selected investors – see Note 1-21 on

the accounting treatment of the convertible debentures and the detachable warrants.

At inception date, the fair value of the convertible debentures and detachable warrants was \$20 million. The Company has allocated the proceeds to the fair value of the debt host and the warrants.

The \$20 million convertible debt is in the form of 20,000 debentures with a face value of \$1,000 and each bond is convertible into shares of common stock at any time at the election of the holder, using a conversion price of \$6.57, subject to standard anti-dilution adjustments.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

The debentures mature in five years (October 28, 2012) and bear an annual interest rate of 9% payable on a quarterly basis in cash or in common stock, at the option of the Company (decision made every quarter) with a 10% discount price over the average market price of common stock.

Investors in the convertible debentures also received an aggregate number of 1,680,000 detachable warrants to purchase one share of common stock for each warrant (the "Investor Warrants"). The Investor Warrants have a six-year term and an exercise price of \$6.87, subject to standard anti-dilutive adjustments.

The Company also granted to the bank acting as placement agent in the transaction warrants (the "Placement Agent Warrants") to purchase 188,965 shares of common stock, with a five-year term and the following exercise prices: 121,765 shares at \$6.57 and 67,200 shares at \$6.87.

Observable and unobservable inputs for fair value measurements:

Given the classification established by FAS#157, the following table indicates each input or assumption and the level it belongs to:

| Input              | FAS157 level | Comment  |
|--------------------|--------------|--|
| Share price        | Level 1      | Quoted price directly linked to the instrument |
| Risk free rate     | Level 2      | Observable input                               |
| Volatility         | Level 3      | Unobservable input                             |
| Credit Spread      | Level 3      | Unobservable input                             |
| Liquidity discount | Level 3      | Unobservable input                             |

Fair Value of Investor Warrants:

The valuation model of the Investor Warrants uses a binomial valuation model to capture the complexity of the instruments, and notably the possibility to exercise the call option at any time from the inception date.

As of December 31, 2009, the binomial valuation model uses the following main assumptions and parameters:

Share price at closing date: \$2.75Strike price of warrants: \$6.87

- Risk free interest rate at 6 years: 2.11%

- Share price volatility: 80%

- Liquidity discount factor: 42.66%

As of June 30, 2010, the binomial valuation model uses the following main assumptions and parameters:

- Share price at closing date: \$2.33

- Strike price of warrants: \$6.87

- Risk free interest rate at 6 years: 1.13%

- Share price volatility: 86%

- Liquidity discount factor: 42.66%

On that basis, the unit fair value of the Investor Warrants was \$0.60 per warrant as of December 31, 2009, and \$0.45 per warrant as of June 30, 2010. The total fair value for the 1,680,000 issued Investor warrants was \$1.011 million at December 31, 2009 and \$0.761 million at June 30, 2010.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

Fair Value of the Convertible Debt:

The total fair value of the convertible debt is the aggregate of the fair value of the underlying debt host instrument and the fair value of the embedded derivative (conversion option).

The estimate of the fair value of the underlying debt component is obtained by using the actual interest spread the Company would have had to pay if a straight, unsecured, debt had been raised, with no additional remuneration to lenders in the form of conversion options or warrants. Before and at inception date, the Company conducted an analysis of the terms on a non-convertible, unsecured, conventional debt. Based on this analysis, a rate of 30% has been used to assess the fair value of the debt host, which represents an interest spread of 26% over the risk-free interest rate at inception date. The present value of the debt host using an effective interest rate of 30% was \$10.330 million.

At December 31, 2009 the fair value has been measured considering any changes required in underlying assumptions, and mostly the risk free interest rate and the credit spread. With the support of third-party experts, the Company determined that the spread to be used over the risk-free rate was 28.51%, in line with the increase in risk-aversion on financial markets. The present value of the debt host at December 31, 2009 was \$11.217 million.

At June 30, 2010 the fair value has been measured again considering any changes required in underlying assumptions, and mostly the risk free interest rate and the credit spread. The Company considered unchanged at 28.51% the spread to be used over the risk-free rate. The present value of the debt host at June 30, 2010 was \$11.048 million.

The valuation model of the conversion option uses a binomial valuation model to capture the complexity of the instrument, and notably the continuous possibility of an arbitrage between holding common shares versus interest bearing bonds.

As of December 31, 2009, the binomial valuation model uses the following main assumptions and parameters:

- Share price at closing date: \$2.75
  - Strike price of warrants: \$6.57
- Risk free interest rate at 5 years: 1,56%
  - Share price volatility: 80%
  - Liquidity discount factor: 42.66%

As of June 30, 2010, the binomial valuation model uses the following main assumptions and parameters:

- Share price at closing date: \$2.33
  - Strike price of warrants: \$6.57
- Risk free interest rate at 5 years: 0.74%
  - Share price volatility: 86%
  - Liquidity discount factor: 42.66%

On that basis, the fair value of the conversion option was \$1.653 million (\$2.883 million before liquidity discount) as of December 31, 2009, and \$1.027 million (\$1.791 million before liquidity discount) as of June 30, 2010.

# Placement Agent Warrants:

As part of the transaction costs, the Company granted to the bank acting as placement agent in the transaction warrants to purchase 188,965 shares of common stock, with a five year term and the following exercise prices:

121,765 shares at \$6.57 per share and 67,200 shares at \$6.87 per share (the "Placement Agent Warrants"). The fair value of the Placement Agent Warrants has been valued using the Black-Scholes option valuation method, using a 1.56% risk free interest rate and a 80% stock volatility at December 31, 2009 and a 0.74% risk free interest rate and a 86% stock volatility at June 30, 2010.

#### EDAP TMS S.A. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

The following table summarizes the fair value of the entire indebtedness related to the convertible debentures, Investor Warrants and Placement Agent Warrants:

| In '000 US Dollars                 | Total Fair<br>Value<br>At<br>Inception | Total Fair<br>Value<br>At Dec<br>31,<br>2009 | Total Fair<br>Value<br>At June<br>30,<br>2010 | Conversion | Change in<br>Fair Value<br>in USD<br>2010 vs<br>2009 |
|------------------------------------|--|--|---|------------|--|
| Convertible debt                   | 16,110                                 | 12,870                                       | 12,075  | (2,094)    | 1,299  |
| Investor Warrants                  | 3,890                                  | 1,011  | 761   |            | (250)  |
| Total                              | 20,000                                 | 13,881                                       | 12,836  | (2,094)    | 1,049  |
| Placement Agent Warrants at \$6.57 | 448                                    | 100  | 68  |            | (32)   |
| Placement Agent Warrants at \$6.87 | 244                                    | 53   | 36  |            | (17)   |
| Total                              | 20,692                                 | 14,034                                       | 12,940  | (2,094)    | 1,000  |

The following table reflects the impact after translation in euros:

| In '000 Euros               | Total Fair<br>Value<br>At<br>Inception | Total Fair<br>Value<br>At Dec<br>31,<br>2009 | Total<br>Fair<br>Value<br>At June<br>30,<br>2010 | Conversion | Change in<br>Fair<br>Value in<br>EUR | Exchange<br>rate<br>impact |
|-----------------------------|--|--|--|------------|--------------------------------------|----------------------------|
| Exchange Rate (USD/EUR)     | 1.4548                                 | 1.4405                                       | 1.2271   |            |                                      |                            |
| Convertible debt            | 11,074                                 | 8,934  | 9,840  | (1,139)    | 615                                  | 1,430                      |
| Investor Warrants           | 2,674                                  | 702  | 620  |            | (204)                                | 122                        |
| Total                       | 13,748                                 | 9,636  | 10,460   | (1,139)    | 411                                  | 1,552                      |
| Placement Agent<br>Warrants | 476                                    | 106  | 85   |            | (39)                                 | 18                         |
| Total                       | 14,224                                 | 9,743  | 10,545   | (1,139)    | 371                                  | 1,570                      |

# 7—SHAREHOLDERS' EQUITY

#### 7-1 Common stock

As of June 30, 2010, EDAP TMS S.A.'s common stock consisted of 11,523,902 issued shares, fully paid, and with a par value of €0.13 each. 11,124,374 of the shares were outstanding.

#### 7-2 Pre-emptive subscription rights

Shareholders have preemptive rights to subscribe on a pro rata basis for additional shares issued by the Company for cash. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

#### 7-3 Dividend rights

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception.

### 7-4 Treasury stock

As of June 30, 2010, the 399,528 shares of treasury stock consisted of (i) 349,988 shares acquired between August and December 1998 for €1,008 thousand and (ii) 49,540 shares acquired in June and July 2001 for €150 thousand. All 399,528 shares of treasury stock have been acquired to cover outstanding stock options (see Note 7-5).

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 7-5 Stock-option plans

As of June 30, 2010, the 399,528 ordinary shares held as treasury stock were dedicated to serve stock purchase option plans as follows:

- 32,000 shares which may be purchased at a price of €2.08 per share and 3,425 shares which may be purchased at a price of €2.02 per share pursuant to the exercise of options that were granted in 2001 and in 2002 and are outstanding;
- 135,000 shares which may be purchased at a price of €2.60 per share pursuant to the exercise of options that were granted in 2004, and
- 299,100 shares which may be purchased at a price of €2.38 per share pursuant to the exercise of options that were granted on June 25, 2010.

As of June 30 2010, the Company sponsored four stock purchase and subscription option plans:

On June 12, 2001, the shareholders of the Company authorized the Board of Directors to grant up to 300,000 options to purchase pre-existing Shares, at a fixed exercise price to be set by the Supervisory Board. Under this plan, 35,425 options were still in force on June 30, 2010.

On January 29, 2004, the shareholders of the Company authorized the Board of Directors to grant up to 240,000 options to purchase pre-existing Shares at a fixed price to be set by the Board of Directors. All of the Shares that may be purchased through the exercise of stock options are currently held as treasury stock. Under this plan, 135,000 options were still in force on June 30, 2010.

On May 22, 2007, the shareholders of the Company authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new Shares. Conforming to this stock option plan, the Board of Directors granted 504,088 options to subscribe to new Shares to certain employees of EDAP TMS on October 29, 2007, and 95,912 options to subscribe to new Shares to certain employees of EDAP TMS on June 25, 2010. Under this plan, a total of 564,500 options to subscribe to new shares were still in force on June 30, 2010.

On June 25, 2010, the shareholders of the Company authorized the Board of Directors to grant up to 229,100 options to purchase up to 229,100 Shares. Conforming to this stock option plan, the Board of Directors granted 229,100 options to purchase Shares to certain employees of EDAP TMS on June 25, 2010. All those options were still in force on June 30, 2010.

#### EDAP TMS S.A. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

As of June 30, 2010, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

|  | June 30, | 2010                                | December 31, 2009 |                                     | December 31, 2008 |   |
|--|----------|-------------------------------------|-------------------|-------------------------------------|-------------------|---|
|  | Options  | Weighted average exercise price (€) | Options           | Weighted average exercise price (€) | Options           | Weighted<br>average<br>exercise<br>price<br>(€) |
| Outstanding on January 1,                              | 656,013  | 3.57                                | 706,725           | 3.51                                | 781,625           | 3.51  |
| Granted  | 325,012  | 2.23                                |                   |                                     |                   |   |
| Exercised  |          |                                     | (24,212)          | 2.07                                |                   |   |
| Forfeited  | (17,000) | 2.76                                | (26,500)          | 3.36                                | (34,000)          | 3.59  |
| Expired  |          |                                     |                   |                                     | (40,900)          | 3.37  |
| Outstanding at the end of the                          |          |                                     |                   |                                     |                   |   |
| period   | 964,025  | 3.13                                | 656,013           | 3.57                                | 706,725           | 3.51  |
| Exercisable at the end of the                          |          |                                     |                   |                                     |                   |   |
| period   | 404,719  | 3.36                                | 420,719           | 3.33                                | 342,929           | 3.00  |
| Shares purchase options available for grant on June 30 | 3        | _                                   | 105,328           |                                     | 105,328           |   |

The following table summarizes information about options to purchase Shares already held by the Company as treasury Shares, or to subscribe to new Shares, at June 30, 2010:

|                    |         |             |          | Exercisable |          |  |
|--------------------|---------|-------------|----------|-------------|----------|--|
|                    | Out     | standing op | tions    | options     |          |  |
|                    |         | Weighted    | Weighted | •           | Weighted |  |
|                    |         | average     | average  |             | average  |  |
|                    | Options | remaining   | exercise | Options     | exercise |  |
|                    |         | contractual | price    |             | price    |  |
| Exercise price (€) |         | life        | (€)      |             | (€)      |  |
|                    |         |             |          |             |          |  |
| 3.99               | 468,588 | 7.8         | 3.99     | 234.294     | 3.99     |  |
| 2.60               | 135,000 | 4.2         | 2.60     | 135,000     | 2.60     |  |
| 2.38               | 229,100 | 10.0        | 2.38     |             |          |  |
| 2.08(1)            | 32,000  | 1.8         | 2.08     | 32,000      | 2.08     |  |
| 2.02(2)            | 3,425   | 2.5         | 2.02     | 3,425       | 2.02     |  |
| 1.88               | 95,912  | 10.0        | 1.88     |             |          |  |
| 1.88 to 3.99       | 964,025 | 7.2         | 3.13     | 404,719     | 3.36     |  |

<sup>(1)</sup> All the 32,000 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on September 25, 2001 (\$1 = \$1.085).

(2) All the 3,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on June 18, 2002 (\$1 = \$1.0545).

The Company applies FAS 123R on Share Based Payments and its related interpretations in accounting for its employee stock options.

#### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

#### 8—FINANCIAL INCOME, NET

Interest (expense) income, net consists of the following:

|   | 6 months | 6 months |
|---|----------|----------|
|   | 2010     | 2009     |
| Interest income                                       | 106      | 70       |
| Interest expense                                      | (923)    | (743)    |
| Depreciation of prepaid expenses on debt grant        | (235)    | (235)    |
| Changes in fair value of the Convertible Debentures   | (615)    | (461)    |
| Changes in fair value of the Investor Warrants        | 204      | (75)     |
| Changes in fair value of the Placement Agent Warrants | 39       | (17)     |
| Total   | (1,424)  | (1,461)  |

Interest expense in 2010 comprises a €836 thousand expense for the payment of the 9% interest coupon on the convertible debentures and accelerated conversion.

Interest expense in 2009 comprises a €655 thousand expense for the payment of the 9% interest coupon on the convertible debentures.

See Note 6 for discussion on the accounting for the convertible debentures, Investor Warrants, and Placement Agent Warrants.

#### 9—SEGMENT INFORMATION

In July of fiscal year 2002, the Company announced an organizational realignment that created two operating divisions within the Company. For reporting purposes, this organizational realignment created three reporting segments: the holding company, EDAP TMS S.A., the High Intensity Focused Ultrasound division and the Urological Devices and Services division.

In January 2007, the Company announced that a fourth segment was created, named FDA, to report the on the clinical activity pursuing the FDA approval for the Ablatherm. In addition and for the purpose of a better understanding of the economic performance of each segment, all four segments were now reported in direct contribution method, thus taking out the Consolidation column that was previously needed to eliminate inter company flows.

Segment operating profit or loss are determined in accordance with the same policies as those described in the summary of significant accounting policies except that interest income and expense, current and deferred income taxes, are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net loss is as follows:

|   | 6 months | 6 months |
|---|----------|----------|
|   | 2010     | 2009     |
| Segment operating loss                        | (2,650)  | (1,789)  |
| Interest income, net                          | (1,424 ) | (1,461)  |
| Foreign Currency exchange (losses) gains, net | 1,293    | (313)    |

| Other income, net               | (2     | ) | (1     | ) |
|---------------------------------|--------|---|--------|---|
| Income tax (expense) credit net | (825   | ) | (63    | ) |
| Consolidated net loss           | (3,607 | ) | (3,627 | ) |
|                                 |        |   |        |   |
|                                 |        |   |        |   |
|                                 |        |   |        |   |
| 25                              |        |   |        |   |

# EDAP TMS S.A. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

A summary of the Company's operations by business unit is presented below for periods ending June 30, 2010 and 2009:

| 2007.                           | HIFU Division    | UDS<br>Division | EDAP<br>TMS<br>FDA | EDAP<br>TMS<br>Corporate | Total consolidated |
|---------------------------------|------------------|-----------------|--------------------|--------------------------|--------------------|
| 6 months 2010                   |                  |                 |                    |                          |                    |
| Sales of Goods                  |                  |                 |                    |                          |                    |
| (incl. consumables)             | 929              | 3,712           |                    |                          | 4,641              |
| Sales of RPPs & Leases          | 1,900            | 635             |                    |                          | 2,535              |
| Sales of Spare Parts & Services | 662              | 1,983           |                    |                          | 2,644              |
| Total Net Sales                 | 3,491            | 6,329           |                    |                          | 9,820              |
| Other Revenues                  | 3                | 500             |                    |                          | 503                |
| Total Revenues                  | 3,493            | 6,829           |                    |                          | 10,323             |
| Gross Profit                    | 1,913            | 2,290           |                    |                          | 4,203              |
| Research & Development          | (290 )           | (444 )          | (1,166)            |                          | (1,900)            |
| SG&A + Depreciation             | (1,799 )         | (2,336)         | (102)              | (716                     | (4,952)            |
| Non recurring profit/(expenses) |                  |                 |                    |                          |                    |
| Operating income (loss)         | (176)            | (490)           | (1,268)            | (716                     | (2,650)            |
|                                 | HIFU<br>Division | UDS<br>Division | EDAP<br>TMS<br>FDA | EDAP<br>TMS<br>Corporate | Total consolidated |
| 6 months 2009                   |                  |                 |                    |                          |                    |
| Sales of Goods                  |                  |                 |                    |                          |                    |
| (incl. consumables)             | 1,200            | 5,339           | _                  |                          | 6,539              |
| Sales of RPPs & Leases          | 2,239            | 608             |                    |                          | 2,847              |
| Sales of Spare Parts & Services | 782              | 1,970           |                    |                          | 2,752              |
| Total Net Sales                 | 4,221            | 7,917           |                    |                          | 12,138             |
| Other Revenues                  | 5                | 34              |                    |                          | 39                 |
| Total Revenues                  | 4,227            | 7,951           |                    |                          | 12,177             |
| Gross Profit                    | 2,426            | 2,875           |                    |                          | 5,301              |
| Research & Development          | (647)            | (519)           | (832)              |                          | (1,998)            |
| SG&A + Depreciation             | (1,952)          | (2,261)         | (116)              | (763                     | (5,091)            |
| Non recurring profit/(expenses) |                  |                 |                    |                          |                    |
| Operating income (loss)         | (173)            | 94              | (948)              | (763                     | (1,789)            |

# **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: September 30, 2010 EDAP TMS S.A.

/S/ MARC OCZACHOWSKI MARC OCZACHOWSKI CHIEF EXECUTIVE OFFICER