

Edgar Filing: EDAP TMS SA - Form 6-K

EDAP TMS SA
Form 6-K
May 15, 2008

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

May 15, 2008

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

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

Form 20-F Form 40-F

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

Yes No

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

PRESS RELEASE

Contact:

Blandine Confort
Investor Relations / Legal Affairs
EDAP TMS SA
+33 4 72 15 31 72
bconfort@edap-tms.com

Investors:

R.J. Pellegrino
The Ruth Group
646-536-7009
rpellegrino@theruthgroup.com

EDAP Reports First Quarter 2008 Financial Results

First Quarter 2008 Highlights:

- **Total HIFU revenue of EUR 2.2 million, up 39% year-over-year**
- **Gross margin increased to 44.1% compared to 43.1% in the first quarter of 2007**
- **Continued progress in U.S. ENLIGHT clinical study driven by IRB approval of 11 premiere Ablatherm and 8 Cryotherapy sites**
- **25% ENLIGHT enrollment growth in past six weeks**

LYON, France, May 15, 2008 - EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today financial results for the first quarter ended March 31, 2008.

For the first quarter 2008, the Company reported total revenue of EUR 4.5 million, compared to EUR 4.7 million for the same period in 2007. The first quarter 2008 total revenues were driven by strong growth in HIFU sales partially offset by lower lithotripsy sales.

Total Revenues for the Company's HIFU division increased 38.6% to EUR 2.2 million in the first quarter of 2008, compared to EUR 1.6 million in the same period of 2007. The increase was primarily driven by growth in Ablatherm-HIFU machine sales. During the first quarter 2008, the Company sold two machines, compared to zero in the first quarter of 2007.

Total Revenues for the Company's lithotripsy division were EUR 2.3 million in first quarter 2008, compared to EUR 3.0 million reported in the same period last year. The decrease reflected lower machine sales following a very strong fourth quarter in 2007. In the first quarter 2008, a total of five machines were sold. At the beginning of the second quarter 2008, the Company has a backlog of seven machines, including two Sonolith I-sys devices and is well positioned for a return to historical sales levels for the remainder of the year.

Gross profit for the first quarter 2008 was EUR 2.0 million, flat from the first quarter of 2007. Gross profit margin increased to 44.1% in the first quarter of 2008, compared to 43.1% in the first quarter of 2007. The increased margin was based on the sale of two HIFU machines partially offset by lower lithotripsy sales.

Operating expenses were EUR 3.5 million in the first quarter 2008, compared to EUR 3.1 million for the same period of 2007. This increase primarily reflected a EUR 0.5 million expense related to the U.S. FDA ENLIGHT clinical trial for Ablatherm.

Operating loss was EUR 1.5 million for the first quarter 2008, compared to operating loss of EUR 1.1 million for the first quarter 2007.

Net income for the first quarter 2008 was EUR 1.1 million, or EUR 0.11 per diluted share, compared to a net loss of EUR 1.2 million, or EUR 0.14 per diluted share, in 2007. First quarter 2008 net income included a EUR 2.7 million non-cash financial gain related to the adjustment of the Company's convertible preferred debt and outstanding warrants to fair value and a EUR 1.0 million currency exchange gain due to the weakening of the U.S. dollar against the Euro.

Cash and cash equivalents including short-term treasury investments were EUR 15.5 million (USD 24.6 million) at March 31, 2008.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are especially pleased with the Ablatherm-HIFU sales growth coupled with continued progress in our U.S. ENLIGHT clinical study evaluating the use of minimally invasive therapeutic ultrasound in patients with localized prostate cancer. As anticipated, RPP revenue was impacted by the transition of two large hospitals to direct ownership of our capital equipment and a slower start in January and February. We are experiencing a return to stronger RPP growth in March."

Mr. Oczachowski continued, "We have made substantial progress on our U.S. clinical development program during the first quarter, receiving IRB approval of additional participating sites, including the premier Memorial Sloan Kettering and University of Texas M.D. Anderson Cancer Centers. The continued evaluation of HIFU by such industry thought leaders, combined with our patient program has consistently raised the profile of our technology in the clinical community. They have been instrumental in driving our recruitment efforts and expediting access to this novel and minimally invasive treatment alternative.

HIFU technology continues to gain traction among the scientific and medical community as a safe and effective treatment option for various applications. We believe our strong IP portfolio and demonstrated experience leave EDAP well positioned to participate in the growth and development of future minimally invasive HIFU options that will benefit patients across multiple pathologies. We will continue to leverage our twenty years of HIFU expertise and experience aimed at achieving improved therapeutic solutions. As proof of our support and commitment towards HIFU innovation, we, together with INSERM and EpiTarget have recently announced our involvement with HIFU and its utilization in liposome drug delivery. Our ability to secure patent rights on our innovations and protect the strength of our intellectual property estate is of critical importance."

Conference Call

EDAP will hold a conference call on Thursday, May 15, 2008 at 8:30 a.m. ET to discuss the results. The dial-in numbers are 1-888-241-0558 for domestic callers and 1-647-427-3417 for international. The conference ID number for both is 46509351. A live Webcast of the conference call will be available online from the investor relations page of the Company's corporate Website at www.edap-tms.com.

After the live Webcast, the call will remain available on EDAP's Website, www.edap-tms.com, through July 15, 2008. In addition, a telephonic replay of the call will be available until May 20, 2008. The replay dial-in numbers are 1-800-839-4177 for domestic callers and 1-402-220-2901 for international callers. Please use event ID number 46509351.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm, the most advanced and clinically proven choice for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multicenter U.S. Phase II/III clinical trial under an Investigational Device Exemption granted by the FDA. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the company, please visit <http://www.edap-tms.com> and <http://www.hifu-planet.com> or <http://www.urotoday.com/HIFU>.

###

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

| | Three Months Ended : | | Three Months Ended : | |
|---|-----------------------------|------------------|-----------------------------|------------------|
| | March 31, | March 31, | March 31, | March 31, |
| | 2008 | 2007 | 2008 | 2007 |
| | Euros | Euros | \$US | \$US |
| Sales of goods | 1,940 | 1,902 | 2,963 | 2,508 |
| Net Sales of RPP and Leases | 1,123 | 1,308 | 1,715 | 1,725 |
| Sales of spare parts and Services | 1,369 | 1,420 | 2,092 | 1,872 |
| TOTAL NET SALES | 4,432 | 4,630 | 6,770 | 6,105 |
| Other revenues | 64 | 36 | 98 | 47 |
| TOTAL REVENUES | 4,496 | 4,666 | 6,869 | 6,152 |
| Cost of goods | (1,198) | (1,273) | (1,830) | (1,679) |
| Cost of RPP and Leases | (570) | (568) | (871) | (750) |
| Cost of spare parts & services | (772) | (831) | (1,180) | (1,095) |
| Cost of sales | (2,540) | (2,672) | (3,880) | (3,524) |
| GROSS PROFIT | 1,956 | 1,994 | 2,988 | 2,629 |
| Research & development expenses | (983) | (616) | (1,502) | (813) |
| Marketing & Sales expenses | (1,398) | (1,341) | (2,136) | (1,768) |
| G & A expenses | (1,114) | (1,183) | (1,702) | (1,560) |
| Total operating expenses | (3,496) | (3,140) | (5,340) | (4,141) |
| OPERATING PROFIT (LOSS) | (1,540) | (1,147) | (2,352) | (1,512) |
| Interest (expense) income, net | 2,279 | 3 | 3,482 | 4 |
| Currency exchange gains (loss), net | 340 | (48) | 519 | (63) |
| Other income (loss), net | 7 | 3 | 11 | 4 |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | 1,086 | (1,188) | 1,660 | (1,567) |
| Income tax (expense) credit | (21) | (21) | (32) | (27) |
| NET INCOME (LOSS) | 1,066 | (1,209) | 1,628 | (1,594) |
| Earning per share - Basic | 0.12 | (0.14) | 0.18 | (0.18) |
| Average number of shares used in computation of EPS | 9,200,757 | 8,942,007 | 9,200,757 | 8,942,007 |
| Earning per share - Diluted | 0.11 | (0.14) | 0.17 | (0.18) |
| | 9,444,126 | 9,606,863 | 9,444,126 | 9,606,863 |

Average number of shares used in
computation of EPS for positive net
income

NOTE: Translated for convenience of the reader to U.S. dollars at the 2008 average three months noon buying rate of 1 Euro = 1.5278 USD, and 2007 average three months noon buying rate of 1 Euro = 1.3186 USD.

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

| | Mar. 31, 2008 Euros | Dec. 31, 2007 Euros | Mar. 31, 2008 \$US | Dec. 31, 2007 \$US |
|---|------------------------------------|------------------------------------|-----------------------------------|-----------------------------------|
| Cash, cash equivalents and short term investments | 15,542 | 18,611 | 24,565 | 27,178 |
| Total current assets | 32,298 | 36,123 | 51,047 | 52,751 |
| Total current liabilities | 11,329 | 12,884 | 17,906 | 18,815 |
| Shareholders' Equity | 15,701 | 14,498 | 24,815 | 21,171 |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.5805 USD, on March 31, 2008 and at the noon buying rate of 1 Euro = 1.4603 USD, on December 31, 2007.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2008
(Amounts in thousands of Euros)

| | HIFU Division | | UDS Division | | FDA Trials | Corporate | Total After Consolidation | |
|---------------------------------|--------------------------|------------|-------------------------|------------|-----------------------|------------------|--------------------------------------|------------|
| Sales of goods | 945 | | 994 | | | | 1,940 | |
| Sales of RPPs & Leases | 872 | | 251 | | | | 1,123 | |
| Sales of spare parts & services | 374 | | 995 | | | | 1,369 | |
| TOTAL NET SALES | 2,192 | | 2,240 | | | | 4,432 | |
| Other revenues | 48 | | 16 | | | | 64 | |
| TOTAL REVENUES | 2,240 | | 2,256 | | | | 4,496 | |
| GROSS PROFIT | 1,401 | 65% | 555 | 24% | | | 1,956 | 44% |
| Research & Development | (247) | | (261) | | (475) | | (983) | |
| Total SG&A plus depreciation | (1,026) | | (895) | | (34) | (559) | (2,513) | |
| | 127 | | (600) | | (508) | (559) | (1,540) | |

**OPERATING
PROFIT
(LOSS)**

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 : May 15, 2008

EDAP TMS S.A.

/S/ MARC OCZACHOWSKI
MARC OCZACHOWSKI
CHIEF EXECUTIVE OFFICER
