

EDAP TMS SA
Form 6-K
March 26, 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

March 26, 2008

EDAP TMS S.A.
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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 - FOR IMMEDIATE RELEASE

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EDAP Reports Fourth Quarter and Full Year 2007 Financial Results

Highlights:

- **Record fourth quarter revenue of EUR 7.0 million, up 44% year-over-year**
 - **Full year revenue of EUR 22.3 million, up 10% year-over-year**
 - **Approximately 3,400 Ablatherm-HIFU treatments in 2007; 15,000 cumulative treatments at 176 clinical sites**
 - **Full year Ablatherm-HIFU RPP treatments increased 36% year-over-year**
 - **Full year gross profit of EUR 9.2 million, up 10% year-over-year; gross profit margin of 41.3%**
 - **Ablatherm-HIFU U.S. clinical trials continue to progress with successful launch of patient awareness program and fully funded by USD 20 million convertible debt raise**
 - **Launch of integrated Sonolith I-Sys for the disintegration of urinary tract stones**
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LYON, France, March 26, 2008 - EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and full year ended December 31, 2007.

Fourth Quarter 2007 Results

For the fourth quarter 2007, the Company reported total revenue of EUR 7.0 million, a 43.8% increase from EUR 4.9 million for the same period in 2006. The fourth quarter 2007 total revenues reflected the anticipated strong seasonality for hospital capital equipment sales.

Net sales for the Company's HIFU division increased 23.2% to EUR 3.0 million in the fourth quarter of 2007, compared to EUR 2.4 million in the same period of 2006. The increase was primarily driven by growth in Ablatherm-HIFU machine sales. During the fourth quarter 2007, three machines were sold, which was the strongest quarter of the year.

Net sales for the Company's lithotripsy division were EUR 4.0 million in fourth quarter 2007, a 61.3% increase from EUR 2.5 million reported for the same period last year. The increase in net sales for the lithotripsy division reflected the launch of the Sonolith I-sys machine, the Company's latest generation lithotripsy machine. In the fourth quarter 2007, the machines sold totaled thirteen, three of which were Sonolith I-sys devices.

Gross profit increased 68.9% to EUR 3.0 million for the fourth quarter 2007, compared to EUR 1.8 million for the same period of 2006. Gross profit margin increased to 43.1% in the fourth quarter of 2007.

Operating expenses were EUR 3.8 million in the fourth quarter 2007, compared to EUR 2.9 million for the same period of 2006. This increase primarily reflected expenses related to the U.S. FDA clinical trial for Ablatherm and our marketing and educational initiatives in Europe to build adoption of our HIFU technology.

Operating loss was EUR 741,000 for the fourth quarter 2007, compared to operating loss of EUR 1.1 million for the fourth quarter 2006.

The net loss for fourth quarter 2007 was EUR 2.0 million, or EUR 0.22 per diluted share, compared to a net loss of EUR 1.1 million, or EUR 0.13 per diluted share, in 2006. The fourth quarter 2007 net loss included a EUR 1.2 million non-cash financial charge related to the adjustment of the Company's convertible preferred debt and outstanding warrants to fair value.

Full Year 2007 Results

For the full year 2007, the Company reported total revenue of EUR 22.3 million, a 10.2% increase from EUR 20.3 million for the same period in 2006. The majority of the increase was due to the transition in the HIFU division to the new revenue per procedure (RPP) model and the increase in the number of HIFU treatments.

Net sales for the Company's HIFU division increased 22% to EUR 9.3 million in 2007, compared to EUR 7.6 million in 2006. The year-over-year change was primarily driven by a 36% increase in number of Ablatherm-HIFU RPP treatments to 1,273, as compared to 936 in the prior year. At the end of 2007, cumulative Ablatherm-HIFU treatments reached over 15,000 at 176 global sites.

Net sales for the Company's lithotripsy division were EUR 12.9 million in 2007, a 3% increase from EUR 12.6 million reported for the same period last year. The increase in net sales for the lithotripsy division was primarily attributable to an 8% increase in net sales of medical devices. The year-over-year increase was primarily due to sales of three Sonolith I-sys devices; the Company's recently launched next-generation lithotripter targeting the high-end market segment.

Gross profit increased 10.3% to EUR 9.2 million for 2007, compared to EUR 8.3 million for the same period of 2006. Gross profit margin for 2007 was stable at 41.3%.

Operating expenses increased 16.3% to EUR 13.3 million in 2007 from EUR 11.4 million in 2006. This increase primarily reflected expense related to the U.S. FDA clinical trial for Ablatherm and the sustained efforts in Europe to increase market awareness of the Company's HIFU technology.

Operating loss was EUR 4.1 million for 2007, compared to operating loss of EUR 3.1 million for 2006. The year-over-year change in the operating loss was primarily due to increased gross profit offset by increased operating expenses.

The net loss for 2007 was EUR 5.4 million, or EUR 0.59 per diluted share, compared to a net loss of EUR 3.4 million, or EUR 0.39 per diluted share, in 2006. The 2007 net loss included a EUR 1.2 million non-cash financial charge related to the adjustment of the Company's convertible preferred debt and outstanding warrants to fair value and a EUR 254,000 currency exchange loss mainly due to the continuous weakening of the Japanese Yen against the Euro.

Cash and cash equivalents including short-term treasury investments were EUR 18.6 million at December 31, 2007.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are pleased to report record revenue for the fourth quarter, which reflected the positive seasonality we had expected for hospital capital equipment sales and the continued execution of our sales and marketing strategy. Our Ablatherm-HIFU revenue per procedure model added to our positive performance. With over 15,000 Ablatherm treatments performed worldwide, our HIFU technology continues to emerge as a consistent, solid and clinically proven therapeutic option for the long-term treatment of prostate cancer. We also successfully launched our next-generation Sonolith I-Sys for the disintegration of urinary tract stones with already positive feedback from urologists.

We were extremely pleased with the U.S. \$20 million convertible debt raise and the reception U.S. investors had to the EDAP story. The funds mean that our U.S. clinical trials are fully funded and allow us to move these trials ahead with the most effective support and marketing to drive patients to the sites."

Mr. Oczachowski continued, "During 2008, we plan to achieve deeper product penetration and expand our market share across Europe. Our focus is to strengthen treatment growth at our leading centers, while driving demand and increasing awareness of our Ablatherm-HIFU as a treatment for prostate cancer at new centers. We continue to remain focused on advancing our Phase II/III Ablatherm-HIFU clinical trials as a major step toward U.S. commercialization. The ENLIGHT clinical trial for localized prostate cancer is currently enrolling patients at sites in the United States and Canada under an Investigational Device Exemption granted by the FDA. The launch of our patient awareness program in February 2008 was a major milestone for the Company. We are encouraged by the momentum that Ablatherm-HIFU is building in the United States and remain on track to increase enrollment driven by our nationwide patient awareness campaign."

Eric Soyer, EDAP's Chief Financial Officer, stated, "We believe our fourth quarter and full year financial results were in line with our expectations and reflect very strong revenue growth across both our HIFU and Lithotripsy businesses. Our 2007 operating loss was composed of EUR 2.7 million from our European operations and EUR 1.4 million related to our U.S. operations for the advancement of our Ablatherm-HIFU clinical trials. The 2006 operating loss of EUR 3.1 million was attributed entirely to operating expenses for Europe as EDAP expended no costs related to the U.S. PMA trials in 2006. Our net income was impacted by a non-cash charge of EUR 1.2 million related to the fair value adjustment of our convertible debt and warrants for the successful completion of a \$20 million private placement of unsecured convertible debentures. These funds should allow the Company to drive enrollment and fully complete our ENLIGHT FDA clinical trials."

Conference Call

EDAP will hold a conference call on Wednesday, March 26, 2008 at 8:30 a.m. ET to discuss the results. The dial-in numbers are 1-800-374-0113 for domestic callers and 1-706-758-9607 for international. The conference ID number for both is 39006506. 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 June 26, 2008. In addition, a telephonic replay of the call will be available until April 3, 2008. The replay dial-in numbers are 1-800-642-1687 for domestic callers and 1-706-645-9291 for international callers. Please use event ID number 39006506.

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>.

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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 :	
	December 31,	December 31,	December 31,	December 31,
	2007	2006	2007	2006
	Euros	Euros	\$US	\$US
Sales of medical equipment	4,321	2,529	6,303	3,307
Net Sales of RPP and Leases	1,238	1,014	1,806	1,326
Sales of spare parts, supplies and Services	1,437	1,368	2,096	1,789
TOTAL NET SALES	6,997	4,910	10,206	6,421
Other revenues	31	(25)	45	(32)
TOTAL REVENUES	7,028	4,885	10,251	6,389
Cost of sales	(4,012)	(3,100)	(5,852)	(4,054)
GROSS PROFIT	3,016	1,786	4,399	2,335
Research & development expenses	(874)	(573)	(1,275)	(750)
S, G & A expenses	(2,354)	(2,087)	(3,432)	(2,729)
Non-recurring operating expenses	(529)	(195)	(772)	(255)
Total operating expenses	(3,757)	(2,855)	(5,479)	(3,734)
OPERATING PROFIT (LOSS)	(741)	(1,070)	(1,081)	(1,399)
Interest (expense) income, net	(1,254)	66	(1,830)	86
Currency exchange gains (loss), net	(37)	(100)	(54)	(131)
Other income (loss), net	1	3	2	4
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(2,031)	(1,101)	(2,963)	(1,439)
Income tax (expense) credit	(8)	(14)	(12)	(18)
NET INCOME (LOSS)	(2,040)	(1,114)	(2,975)	(1,458)
Earning per share - Basic	(0.22)	(0.13)	(0.32)	(0.17)
Average number of shares used in computation of EPS	9,201	8,817	9,201	8,817
Earning per share - Diluted	(0.22)	(0.13)	(0.32)	(0.17)
Average number of shares used in computation of EPS for positive net income	9,201	9,536	9,201	9,536

NOTE: Translated for convenience of the reader to U.S. dollars at the 2007 average three months noon buying rate of 1 Euro = 1.4586 USD, and 2006 average three months noon buying rate of 1 Euro = 1.3077 USD.

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

	Twelve Months Ended :		Twelve Months Ended :	
	December 31, 2007 Euros	December 31, 2006 Euros	December 31, 2007 \$US	December 31, 2006 \$US
Sales of medical equipment	11,752	10,849	16,214	13,736
Net Sales of RPP and Leases	4,814	3,805	6,642	4,818
Sales of spare parts, supplies and Services	5,647	5,520	7,792	6,989
TOTAL NET SALES	22,213	20,174	30,648	25,542
Other revenues	113	91	156	115
TOTAL REVENUES	22,327	20,265	30,804	25,658
Cost of sales	(13,148)	(11,946)	(18,140)	(15,125)
GROSS PROFIT	9,179	8,319	12,664	10,533
Research & development expenses	(3,194)	(2,442)	(4,407)	(3,092)
S, G & A expenses	(9,850)	(8,703)	(13,590)	(11,019)
Non recurring operating expenses	(224)	(267)	(309)	(338)
Total operating expenses	(13,268)	(11,413)	(18,306)	(14,449)
OPERATING PROFIT (LOSS)	(4,089)	(3,094)	(5,642)	(3,917)
Interest (expense) income, net	(1,243)	153	(1,716)	194
Currency exchange gains (loss), net	(254)	(430)	(350)	(545)
Other income (loss), net	16	(5)	21	(6)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(5,571)	(3,375)	(7,686)	(4,274)
Income tax (expense) credit	140	(56)	193	(70)
NET INCOME (LOSS)	(5,430)	(3,431)	(7,492)	(4,344)
Earning per share - Basic	(0.59)	(0.39)	(0.81)	(0.49)
Average number of shares used in computation of EPS	9,201	8,817	9,201	8,817
Earning per share - Diluted	(0.59)	(0.39)	(0.81)	(0.49)
Average number of shares used in computation of EPS for positive net income	9,717	9,558	9,717	9,558

NOTE: Translated for convenience of the reader to U.S. dollars at the 2007 average twelve months noon buying rate of 1 Euro = 1.3797 USD, and 2006 average twelve months noon buying rate of 1 Euro = 1.2661 USD.

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

	Dec. 31, 2007 Euros	Sept. 30, 2007 Euros	Dec. 31, 2007 \$US	Sept. 30, 2007 \$US
Cash, cash equivalents and short term investments	18,611	7,584	27,178	10,783
Total current assets	36,123	24,730	52,065	35,164
Total current liabilities	12,884	12,690	18,815	18,044
Shareholders' Equity	14,498	16,298	21,171	23,174

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.4603 USD, on December 31, 2007 and at the noon buying rate of 1 Euro = 1.4219 USD, on September 30, 2007.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2007
(Amounts in thousands of Euros)

	EDAP S.A. HIFU Division	TMS S.A. UDS Division	EDAP TMS HQ	FDA Trials Division	Total
Sales of medical devices	2,661	6,496			9,157
Sales of spare parts, supplies & services	6,610	6,446			13,056
TOTAL NET SALES	9,271	12,943			22,213
Other revenues	60	53			113
TOTAL REVENUES	9,331	12,996			22,327
GROSS PROFIT	5,391	3,788			9,179
Research & Development	(1,216)	(1,060)		(918)	(3,194)
Total SG&A plus depreciation	(3,972)	(3,352)	(1,786)	(741)	(9,850)
Non-recurring expenses		(7)	(512)	295	(224)
OPERATING PROFIT (LOSS)	204	(631)	(2,298)	(1,363)	(4,089)

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 : March 26, 2008

EDAP TMS S.A.

/S/ MARC OCZACHOWSKI

MARC OCZACHOWSKI

CHIEF EXECUTIVE OFFICER
