

EDAP TMS SA
Form 6-K
September 05, 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

September 4, 2008

2008 Second Quarter Financial Results

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, 333-147762 and 333-152738.

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 Second Quarter 2008 Financial Results

LYON, France, August 21, 2008 – EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter ended June 30, 2008.

For the second quarter 2008, the Company reported total revenue of EUR 5.0 million (USD 7.8 million), compared to EUR 5.9 million (USD 8.0 million) for the same period in 2007. Total revenue for the second quarter 2008 reflected already experienced seasonal HIFU device sales fluctuations, partially offset by the anticipated return of strong lithotripsy sales over the period

Total revenue for the Company's HIFU division was EUR 1.6 million (USD 2.6 million) in the second quarter 2008, compared to EUR 2.8 million (USD 3.8 million) in the same period of 2007. The second quarter 2008 faced a challenging year-over-year revenue comparison due to no sales of the Ablatherm-HIFU system versus two in the second quarter of 2007, including one high-priced unit. As the Company has previously indicated, quarterly revenues may be impacted by fluctuating HIFU device sales. For the six months ended June 30, 2008, the Company sold a total of two Ablatherm-HIFU systems equivalent to the number of HIFU devices sold during the same period of last year.

Total revenue for the Company's lithotripsy division was EUR 3.3 million (USD 5.2 million) in the second quarter 2008, compared to EUR 3.1 million (USD 4.2 million) for the same period last year and up 47.9% sequentially. The increase was attributed to the sale of ten machines, including two Sonolith I-Sys devices, during the second quarter 2008. Higher machine sales were consistent with the Company's statement during the first quarter 2008, which indicated that seven machines were in backlog, including two Sonolith I-sys devices. As anticipated, the Company converted much of its first quarter 2008 backlog into revenue during the second quarter of 2008. At the beginning of the third quarter 2008, the Company has a backlog of eight machines, including five 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 second quarter 2008 was EUR 1.9 million (USD 2.9 million), compared to EUR 2.3 million (USD 3.1 million) from the second quarter of 2007. Gross profit margin was 37.9% in the second quarter of 2008, compared to 39.5% in the second quarter of 2007 based on lower HIFU capital equipment sales. For the six months ended June 30, 2008, gross profit margin remained flat at 41%. Gross profit margin for the Company's HIFU division increased to 62.3% in the first six months of 2008 compared to 59.9% in the same period of 2007.

Operating expenses were EUR 3.3 million (USD 5.1 million) in the second quarter 2008, compared to EUR 3.1 million (USD 4.1 million) for the same period of 2007. The increase primarily reflected an expense of EUR 0.5 million related to the U.S. FDA ENLIGHT clinical trial for Ablatherm. Operating loss was EUR 1.4 million for the

second quarter 2008, compared to operating loss of EUR 0.7 million for the second quarter 2007.

Net income for the second quarter 2008 was EUR 0.9 million, or EUR 0.10 per diluted share, compared to a net loss of EUR 0.7 million, or EUR 0.08 per diluted share, in 2007. Second quarter 2008 net income included a non-cash gain of EUR 3.0 million related to the adjustment to fair value of the Company's convertible preferred debt and outstanding warrants (shown on the interest line).

Cash and cash equivalents, including short-term treasury investments, were EUR 13.4 million (USD 21.1 million) at June 30, 2008, as planned.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are encouraged by lithotripsy sales growth, driven by the continued penetration of our next-generation Sonolith-I-sys device, which targets the high-end market. We have seen a return to machine sales growth in the second quarter 2008 and already have a strong backlog of machines going forward into the third quarter. We believe this positions us well for a return to historical sales levels in the second half of 2008. Our HIFU revenue was impacted by the typical quarterly fluctuations in our capital equipment sales. While it created a difficult comparison, we are encouraged, entering the third quarter, by the sale of one Ablatherm device to Russia which is expected to drive HIFU revenue in the second half of 2008 and assist in our efforts to increase penetration in Europe. Our RPP business remained flat over the quarter reaching a steady level of HIFU treatments performed each quarter. The Management, supported by the Board of Directors, convened all Sales & Marketing Managers of each key country and implemented an aggressive RPP action plan to increase RPP sales efforts. We look forward to seeing positive outcomes very soon."

Mr. Oczachowski added, "In the US, we continued to make progress on our U.S. ENLIGHT clinical trial during the quarter, as the world-renowned M.D. Anderson Cancer Center treated its first two localized prostate cancer patients with Ablatherm-HIFU. Attracting leading cancer centers while promoting the study to patients is part of our strategy to gain HIFU visibility and accelerate patient enrollment as we advance towards pre market approval submission to the FDA, with an anticipated approval in 2012. In addition, during the second quarter 2008, we were proud to announce validation of our HIFU treatment by a scientific independent society when the French Association of Urology acknowledged HIFU as a standard of care for select primary care patients with localized prostate cancer. This publication marked a clear milestone for our technology and further underscores Ablatherm-HIFU's clinical superiority and treatment potential across multiple pathologies."

Conference Call

EDAP will hold a conference call on Thursday, August 21, 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 59091975. A live Webcast of the conference call will be available online from the investor relations page of the Company's new 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 November 21, 2008. In addition, a telephonic replay of the call will be available until August 26, 2008. The replay dial-in numbers are 1-800-766-3146 for domestic callers and 1-402-220-7733 for international callers. Please use event ID number 59091975.

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

Edgar Filing: EDAP TMS SA - Form 6-K

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>, <http://www.hifu-planet.com> and <http://www.pcaresearch.com> or <http://www.urotoday.com/HIFU>.

#

Edgar Filing: EDAP TMS SA - Form 6-K

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:	
	June 30, 2008 Euros	June 30, 2007 Euros	June 30, 2008 \$US	June 30, 2007 \$US
Sales of goods	2,303	3,261	3,599	4,417
Net Sales of RPP and Leases	1,191	1,262	1,862	1,710
Sales of spare parts and Services	1,447	1,410	2,261	1,910
TOTAL NET SALES	4,942	5,933	7,721	8,036
Other revenues	27	14	43	19
TOTAL REVENUES	4,969	5,947	7,764	8,055
Cost of goods	(1,645)	(2,085)	(2,570)	(2,824)
Cost of RPP and Leases	(634)	(549)	(990)	(744)
Cost of spare parts & services	(817)	(967)	(1,276)	(1,309)
Cost of sales	(3,095)	(3,601)	(4,836)	(4,877)
GROSS PROFIT	1,874	2,346	2,928	3,178
Research & development expenses	(1,104)	(943)	(1,726)	(1,277)
Marketing & Sales expenses	(1,282)	(1,322)	(2,003)	(1,790)
G & A expenses	(888)	(1,235)	(1,388)	(1,673)
Non-recurring profit / (expenses)		441		598
Total operating expenses	(3,274)	(3,059)	(5,116)	(4,142)
OPERATING PROFIT (LOSS)	(1,400)	(712)	(2,188)	(965)
Interest (expense) income, net	2,533	3	3,957	4
Currency exchange gains (loss), net	(406)	(180)	(634)	(244)
Other income (loss), net	1	9	1	12
INCOME (LOSS) BEFORE TAXES	728	(880)	1,137	(1,192)

Edgar Filing: EDAP TMS SA - Form 6-K

AND MINORITY INTEREST

Income tax (expense) credit	205	144	320	195
	-----	-----	-----	-----
NET INCOME (LOSS)	932	(736)	1,457	(997)
	=====	=====	=====	=====
Earning per share - Basic	0.10	(0.08)	0.16	(0.11)
Average number of shares used in computation of EPS	9,200,757	9,163,007	9,200,757	9,163,007
Earning per share - Diluted	0.10	(0.08)	0.16	(0.11)
Average number of shares used in computation of EPS for positive net income	9,276,459	9,543,569	9,276,459	9,543,569

NOTE: Translated for convenience of the reader to U.S. dollars at the 2008 average three months noon buying rate of 1 Euro = 1.5625 USD, and 2007 average three months noon buying rate of 1 Euro = 1.3544 USD.

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

	Six Months Ended:		Six Months Ended:	
	June 30,	June 30,	June 30,	June 30,
	2008	2007	2008	2007
	Euros	Euros	\$US	\$US
Sales of goods	4,243	5,163	6,556	6,900
Net Sales of RPP and Leases	2,314	2,571	3,576	3,436
Sales of spare parts and Services	2,816	2,830	4,352	3,782
	-----	-----	-----	-----
TOTAL NET SALES	9,373	10,564	14,483	14,118
Other revenues	92	49	141	66
	-----	-----	-----	-----
TOTAL REVENUES	9,465	10,613	14,624	14,184
	-----	-----	-----	-----
Cost of goods	(2,847)	(3,358)	(4,398)	(4,488)
Cost of RPP and Leases	(1,203)	(1,117)	(1,860)	(1,493)
Cost of spare parts & services	(1,585)	(1,797)	(2,449)	(2,402)
	-----	-----	-----	-----

Edgar Filing: EDAP TMS SA - Form 6-K

Cost of sales	(5,635)	(6,273)	(8,707)	(8,384)
	-----	-----	-----	-----
GROSS PROFIT	3,830	4,340	5,918	5,800
Research & development expenses	(2,087)	(1,559)	(3,225)	(2,084)
Marketing & Sales expenses	(2,680)	(2,663)	(4,141)	(3,559)
G & A expenses	(2,003)	(2,418)	(3,095)	(3,232)
Non-recurring profit / (expenses)		441		590
	-----	-----	-----	-----
Total operating expenses	(6,770)	(6,199)	(10,460)	(8,285)
OPERATING PROFIT (LOSS)	(2,940)	(1,859)	(4,542)	(2,484)
Interest (expense) income, net	4,812	6	7,434	9
Currency exchange gains (loss), net	(66)	(228)	(102)	(305)
Other income (loss), net	8	12	12	16
	-----	-----	-----	-----
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	1,814	(2,069)	2,803	(2,765)
Income tax (expense) credit	184	124	285	165
	-----	-----	-----	-----
NET INCOME (LOSS)	1,998	(1,945)	3,087	(2,600)
	=====	=====	=====	=====
Earning per share - Basic	0.22	(0.21)	0.34	(0.28)
Average number of shares used in computation of EPS	9,200,757	9,163,007	9,200,757	9,163,007
Earning per share - Diluted	0.22	(0.21)	0.34	(0.28)
Average number of shares used in computation of EPS for positive net income	9,276,459	9,685,022	9,276,459	9,685,022

NOTE: Translated for convenience of the reader to U.S. dollars at the 2008 average six months noon buying rate of 1 Euro = 1.5452 USD, and 2007 average six months noon buying rate of 1 Euro = 1.3365 USD.

Edgar Filing: EDAP TMS SA - Form 6-K

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

	June 30, 2008 Euros	Mar. 31, 2008 Euros	June 30, 2008 \$US	Mar. 31, 2008 \$US
Cash, cash equivalents and short term investments	13,406	15,542	21,112	24,565
Total current assets	31,061	32,298	48,176	51,047
Total current liabilities	11,580	11,329	18,236	17,906
Shareholders' Equity	16,758	15,701	26,391	24,815

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.5748 USD, on June 30, 2008 and at the noon buying rate of 1 Euro = 1.5805 USD, on March 31, 2008.

EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION SIX MONTHS ENDED JUNE 30, 2008 (Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consoli- dation
Sales of goods	1,195	3,048			4,243
Sales of RPPs & Leases	1,785	529			2,314
Sales of spare parts & services	832	1,984			2,816
	-----	-----	-----	-----	-----
TOTAL NET SALES	3,811	5,562			9,373
	-----	-----	-----	-----	-----
Other revenues	62	29			92
	-----	-----	-----	-----	-----
TOTAL REVENUES	3,873	5,591			9,465
	-----	-----	-----	-----	-----
GROSS PROFIT	2,375 61%	1,456 26%			3,830 41%
Research & Development	(574)	(533)	(981)		(2,087)
Total SG&A plus depreciation	(1,828)	(1,764)	(40)	(1,051)	(4,682)
	-----	-----	-----	-----	-----

Edgar Filing: EDAP TMS SA - Form 6-K

OPERATING					
PROFIT (LOSS)	(27)	(841)	(1,021)	(1,051)	(2,940)

Contact:

EDAP TMS SA

Contact:

Blandine Confort, Investor Relations/Legal Affairs

+33 4 72 15 31 72

bconfort@edap-tms.com

The Ruth Group

Investors:

R.J. Pellegrino

646-536-7009

rpellegrino@theruthgroup.com

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 4, 2008

EDAP TMS S.A.

/S/ MARC OCZACHOWSKI

MARC OCZACHOWSKI

CHIEF EXECUTIVE OFFICER