EDAP Reports Second Quarter 2009 Financial Results

Sep 01, 2009

Second Quarter 2009 Highlights: * Year-over-year comparisons, Sep 1, 2009 (GlobeNewswire via COMTEX News Network) -- Total revenue of EUR 6.8 million, up 37.0% -- Total HIFU revenue of EUR 2.2 million, up 34.2% -- Ablatherm-HIFU revenue per procedure (RPP) treatments increased 34.9% -- Total Lithotripsy revenue of EUR 4.6 million, up 38.4% -- Gross profit of EUR 3.2 million, up 69.4% -- Gross margin increased to 46.8% compared to 37.9% * Achieved break even operating income in the second quarter 2009, excluding U.S. FDA trial expenses * Appointed key U.S. urologist and a U.S. industry veteran to Board of Directors * Strengthened U.S. ENLIGHT clinical trial team to accelerate patient enrollment

LYON, France, Sept. 1, 2009 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter ended June 30, 2009.

For the second quarter 2009, the Company reported total revenue of EUR 6.8 million (USD 9.4 million), a 37.0% increase from EUR 5.0 million (USD 7.8 million) for the same period in 2008. The increase was primarily driven by strong sales across both the HIFU and Lithotripsy divisions.

Total revenue for the HIFU division increased to EUR 2.2 million (USD 3.0 million) in the second quarter 2009, up 34.2% from EUR 1.6 million (USD 2.6 million) for the same period last year. The increase reflected the sale of one Ablatherm-HIFU machine and a 20.4% increase in revenue per procedure (RPP) sales compared to the year ago period during which no HIFU devices were sold.

Total revenue for the lithotripsy division increased to EUR 4.6 million (USD 6.4 million) in the second quarter 2009, up 38.4% from EUR 3.3 million (USD 5.2 million) for the same period last year. The increase was primarily attributable to higher machine sales and a more favorable product mix. During the second quarter 2009, 11 lithotripsy machines, including five high-range Sonolith I-Sys systems, were sold compared to 10 machines, including two Sonolith I-Sys devices, sold during the year ago period. For the six months ended June 30, 2009, lithotripsy revenue was EUR 8.0 million (USD 10.6 million), an increase of 42.2% from EUR 5.6 million (USD 8.6 million) during the year ago period. The increase was driven by higher machine sales, with 18 lithotripsy machines, including eight Sonolith I-Sys devices, sold during the first six months of 2009 compared to 15 machines, including two Sonolith I-Sys devices, sold during the first six months of 2008.

Gross profit increased to EUR 3.2 million (USD 4.4 million) in the second quarter 2009, up 69.4% compared to EUR 1.9 million (USD 2.9 million) for the second quarter 2008. Gross profit margin increased to 46.8% in the second quarter 2009, up from 37.9% in the second quarter 2008 due to higher HIFU and lithotripsy machine sales volume.

Operating expenses were EUR 3.7 million (USD 5.1 million) in the second quarter 2009, compared to EUR 3.3 million (USD 5.1 million) for the same period of 2008. Second quarter 2009 operating expenses included EUR 0.5 million related to the U.S. FDA ENLIGHT clinical trial for Ablatherm-HIFU.

Operating loss decreased to EUR 0.5 million (USD 0.7 million) for the second quarter 2009, compared to EUR 1.4 million (USD 2.2 million) for the year ago period. Excluding U.S. clinical trial expenses, the Company was break even in the second quarter 2009. The year-over-year decrease in operating loss reflected both higher HIFU and lithotripsy machine sales and higher HIFU-RPP sales in the second quarter of 2009 versus the year ago period.

The net loss for the second quarter 2009 was EUR 0.5 million (USD 0.7 million), or EUR 0.05 per diluted share, compared to net income of EUR 0.9 million (USD 1.5 million), or EUR 0.10 per diluted share in the year ago period. The second quarter 2009 net loss included a non-cash financial gain of EUR 0.7 million (USD 0.9 million) to reflect the adjustment of the Company's convertible debt and outstanding warrants to fair value, compared to a EUR 3.0 million (USD 4.6 million) non-cash gain during the prior year period.

Cash and cash equivalents, including short-term treasury investments, were EUR 13.6 million (USD 19.1 million) at June 30, 2009.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are very pleased to report robust revenue for the second quarter of 2009, driven by strong sales growth in both HIFU and lithotripsy machine sales. With the continued penetration of our next generation Sonolith I-sys device which recently received U.S. FDA approval, our lithotripsy division performed very well. We are also encouraged by the progress of our HIFU business and the RPP sales momentum and growth in existing European markets and the increased adoption in new geographical territories."

Mr. Oczachowski continued, "Since the recently implemented changes to the ENLIGHT clinical trial protocol, we have experienced an increase in patient flow and screening. In order to further support the execution of these positive enhancements to the protocol, we have strengthened our U.S. team dedicated to implementing these trials."

Mr. Oczachowski concluded, "During the quarter we also expanded our board of directors with two new U.S. based members, namely Dr. Argil Wheelock and Rob Michiels. We believe both of these highly knowledgeable individuals will be invaluable in contributing to the continuing growth in our HIFU European business and progressing toward FDA approval of the Ablatherm system in the U.S."

Conference Call

EDAP will hold a conference call on Tuesday, September 1, 2009 at 8:30 a.m. ET to discuss second quarter 2009 financial results. The dial-in numbers are (877) 407-4134 for domestic callers and (201)-689-8430 for international. The conference ID number for both is 330546. 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 December 1, 2009. In addition, a telephonic replay of the call will be available until September 8, 2009. The replay dial-in numbers are (877) 660-6853 for domestic callers and (201) 612-7415 for international callers. Please use account number 356 and event ID number 330546.

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, http://www.hifu-planet.com and http://www.pcaresearch.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those described in the company's filings with the Securities and Exchange Commission. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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, 2009 Euros	June 30, 2008 Euros	June 30, 2009 $US	June 30, 2008 $US
Sales of goods	3,957	2,303	5,459	3,599
Net Sales of RPP and Leases	1,434	1,191	1,979	1,862
Sales of spare parts and Services	1,387	1,447	1,913	2,261
TOTAL NET SALES	6,678	4,942	9,351	7,721
Other revenues	31	27	43	43
TOTAL REVENUES	6,809	4,969	9,394	7,764
Cost of goods	(1,916)	(1,645)	(2,644)	(2,570)
Cost of RPP and Leases	(745)	(634)	(1,027)	(990)
Cost of spare parts & services	(974)	(817)	(1,344)	(1,276)
Cost of sales	(3,635)	(3,095)	(5,015)	(4,836)

GROSS PROFIT	3,174	1,874	4,379	2,928
Research & development expenses	(1,067)	(1,104)	(1,472)	(1,726)
Marketing & Sales expenses	(1,605)	(1,282)	(2,214)	(2,003)
G & A expenses	(1,023)	(888)	(1,411)	(1,388)
Non-recurring profit / (expenses)				
Total operating expenses	(3,694)	(3,274)	(5,097)	(5,116)
OPERATING PROFIT (LOSS)	(520)	(1,400)	(717)	(2,188)
Interest (expense) income, net	199	2,533	275	3,957
Currency exchange gains (loss), net	(192)	(406)	(264)	(634)
Other income (loss), net	(7)	1	(9)	1
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(519)	728	(716)	1,137
Income tax (expense) credit	(20)	205	(28)	320
NET INCOME (LOSS)	(539)	932	(744)	1,457
Earning per share - Basic	(0.05)	0.10	(0.07)	0.16
Average number of shares used in computation of EPS	9,937,816	9,200,757	9,937,816	9,200,757
Earning per share - Diluted	(0.05)	0.10	(0.07)	0.16
Average number of shares used in computation of EPS for positive net income	9,949,591	9,276,459	9,949,591	9,276,459

NOTE: Translated for convenience of the reader to U.S. dollars at the 2009 average three months noon buying rate of 1 Euro = 1.3797 USD, and 2008 average three months noon buying rate of 1 Euro = 1.5625 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, 2009 Euros	June 30, 2008 Euros	June 30, 2009 $US	June 30, 2008 $US
Sales of goods	6,539	4,243	8,731	6,556
Net Sales of RPP and Leases	2,847	2,314	3,802	3,576
Sales of spare parts and Services	2,752	2,816	3,675	4,352
TOTAL NET SALES	12,138	9,373	16,207	14,483
Other revenues	39	92	53	141
TOTAL REVENUES	12,177	9,465	16,260	14,624

Cost of goods	(3,659)	(2,847)	(4,886)	(4,398)
Cost of RPP and Leases	(1,450)	(1,203)	(1,936)	(1,860)
Cost of spare parts & services	(1,767)	(1,585)	(2,360)	(2,449)
Cost of sales	(6,877)	(5,635)	(9,182)	(8,707)
GROSS PROFIT	5,301	3,830	7,078	5,918
Research & development expenses	(1,998)	(2,087)	(2,669)	(3,225)
Marketing & Sales expenses	(3,087)	(2,680)	(4,122)	(4,141)
G & A expenses	(2,004)	(2,003)	(2,676)	(3,095)
Non-recurring profit / (expenses)				
Total operating expenses	(7,090)	(6,770)	(9,467)	(10,460)
OPERATING PROFIT (LOSS)	(1,789)	(2,940)	(2,389)	(4,542)
Interest (expense) income, net	(1,461)	4,812	(1,950)	7,434
Currency exchange gains (loss), net	(313)	(66)	(418)	(102)
Other income (loss), net	(1)	8	(1)	12
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(3,564)	1,814	(4,758)	2,803
Income tax (expense) credit	(63)	184	(84)	285
NET INCOME (LOSS)	(3,627)	1,998	(4,843)	3,087
Earning per share - Basic	(0.36)	0.22	(0.49)	0.34
Average number of shares used in computation of EPS	9,937,816	9,200,757	9,937,816	9,200,757
Earning per share - Diluted	(0.36)	0.22	(0.49)	0.34
Average number of shares used in computation of EPS for positive net income	9,949,591	9,276,459	9,949,591	9,276,459

NOTE: Translated for convenience of the reader to U.S. dollars at the 2009 average six months noon buying rate of 1 Euro = 1.3353 USD, and 2008 average six months noon buying rate of 1 Euro = 1.5452 USD.

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

	June 30, 2009 Euros	Mar. 31, 2009 Euros	June 30, 2009 $US	Mar. 31, 2009 $US
Cash, cash equivalents and short term investments	13,606	14,699	19,076	19,492
Total current assets	32,471	35,392	44,866	46,311
Total current liabilities	12,975	14,506	18,191	19,237
Shareholders' Equity	14,135	14,133	19,818	18,742

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.4020 USD, on June 30, 2009 and at the noon buying rate of 1 Euro = 1.3261 USD, on March 31, 2009.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
SIX MONTHS ENDED JUNE 30, 2009
(Amounts in thousands of Euros)

	HIFU Division	Lithotripsy Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	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 58%	2,875 36%			5,301 44%
Research & Development	(647)	(519)	(832)		(1,998)
Total SG&A plus depreciation	(1,952)	(2,261)	(116)	(763)	(5,091)
OPERATING PROFIT (LOSS)	(173)	94	(948)	(763)	(1,789)

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CONTACT: EDAP TMS SA
Investor Relations / Legal Affairs
Blandine Confort
+33 4 72 15 31 72
bconfort@edap-tms.com
The Ruth Group
Investors:
R.J. Pellegrino
646-536-7009
rpellegrino@theruthgroup.com
Nick Laudico
646-536-7030
nlaudico@theruthgroup.com

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