

August 28, 2013

EDAP Reports Second Quarter 2013 Results

- Received CE mark for innovative robotic HIFU device Focal One[®]
- Eliminated all outstanding long-term debt and strengthened financial profile
- Publication of long-term study reporting 10 year cancer-specific survival and metastatic-free survival rates for prostate cancer patients treated with Ablatherm-HIFU

LYON, France, Aug. 28, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the second quarter and six months ended June 30, 2013, and provided an update on recent strategic developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "During the quarter, we continued to make strides in our business plan as we strengthened our balance sheet and reached a significant milestone with our innovative technology. In particular, we repaid the full \$8 million of our outstanding long-term debt. We also received CE mark in June for Focal One®, our additional and complementary robotic HIFU device, and we have subsequently commenced our commercialization efforts in Europe. In addition, device sales are progressing well as we reach the end of August, with several pending lithotripsy projects that we anticipated closing during the second quarter confirmed in early July due to customer related factors. We continue to strengthen our sales backlog and are working toward closing these in the coming weeks."

Recent Developments

In June 2013, EDAP received CE mark (European regulatory approval) for Focal One[®], its new and innovative robotic HIFU device fully dedicated to focal therapy of prostate cancer. The CE mark positions Focal One for commercialization in Europe and in many other countries.

In June 2013, EDAP completed the full redemption of its \$8.0 million outstanding long-term debt by using a portion of the net proceeds from the \$12.0 million private placement executed in May 2013.

In June 2013, the 100-day meeting with the FDA provided a discussion forum regarding the PMA application for EDAP's Ablatherm-HIFU device for the treatment of localized prostate cancer and confirmed that our submission process is ongoing.

In May 2013, new long-term data demonstrating high rates of both cancer-specific and overall survival of 1,002 patients treated with high-intensity focused ultrasound (HIFU) was electronically published in European Urology, the official journal of the European Association of Urology. The prospective, single-arm, single-institution cohort study, led by Drs. Sebastien Crouzet and Albert Gelet of Edouard Herriot Hospital, evaluated the morbidity and long-term oncologic outcomes of primary HIFU therapy for localized prostate cancer. The study is the Company's third peer reviewed publication this year reporting 10 year cancer-specific survival and metastatic-free survival rates following Ablatherm-HIFU treatment.

Second Quarter 2013 Results

Total revenue for the second quarter 2013 was EUR 4.5 million (USD 5.9 million), compared to EUR 6.1 million (USD 7.8 million) for the second quarter 2012.

Total revenue for the HIFU division was EUR 967,000 (USD 1.3 million) for the second quarter 2013, compared to EUR 1.1 million (USD 1.4 million) for the same period last year. Results for the second quarter 2013 included the sales of RPP's and sales of spare parts and services.

For the three months ended June 30, 2013, total revenue for the lithotripsy division was EUR 3.5 million (USD 4.6 million), compared to EUR 5.0 million (USD 6.4 million), during the year ago period. During the second quarter 2013, the Company recorded sales of eight lithotripsy machines, comprised of five Sonolith i-move devices and three Sonolith Praktis devices, compared to a total of fourteen devices sold in the second quarter of 2012.

Gross profit for the second quarter 2013 was EUR 1.6 million (USD 2.1 million), compared to EUR 2.4 million (USD 3.1 million) for the year ago period. Gross profit margin was 36.1% in the second quarter 2013, compared to 39.1% in the year ago period.

The change in the gross profit margin was mostly attributed to the negative impact of the Japanese Yen exchange rate variations against the Euro.

Operating expenses were EUR 3.1 million (USD 4.0 million) for the second quarter 2013, compared to EUR 3.3 million (USD 4.2 million) for the same period 2012. Operating loss was EUR 1.5 million (USD 1.9 million) for the second quarter 2013, compared to an operating loss of EUR 937,000 (USD 1.2 million) in the second quarter of 2012.

Net loss for the second quarter 2013 was EUR 195,000 (USD 255,000), or EUR 0.01 per diluted share, as compared to net loss for the second quarter 2012 of EUR 3.0 million (USD 3.8 million), or EUR 0.16 per diluted share. Net loss for the second quarter 2013 included interest income of EUR 1.9 million as a result of non-cash accounting adjustments related to the full redemption of the Company's long-term debt and to fair value variations of the Company's outstanding warrants.

First Six Months 2013 Results

Total revenue for the first half of 2013 was EUR 10.4 million (USD 13.7 million), including a negative impact of EUR 800,000 due to currency exchange rate variations, down 4.9% compared to EUR 11.0 million (USD 14.3 million) for the first half of 2012. Excluding the impact of exchange rate variations, total revenues would have experienced moderate growth of 2% for the period.

Gross profit for the first half of 2013 was EUR 3.8 million (USD 5.0 million) and gross profit margin was 36.7% and 39.5% on a like-for-like basis after adjusting for the currency exchange variations, compared to 39.2% in the year ago period.

Operating loss for the first half of 2013 was EUR 2.6 million (USD 3.5 million) and net loss for the first half of 2013 was EUR 4.1 million (USD 5.3 million), or EUR 0.21 per diluted share, as compared to net loss of EUR 5.9 million (USD 7.6 million), or EUR 0.32 per diluted share, in the first half of 2012. Net loss for the first six months of 2013 included a non-cash interest expense of EUR 0.4 million (USD 0.5 million) to reflect the full redemption of the Company's long-term financial debt and accounting fair value adjustments on its outstanding warrants.

At June 30, 2013, cash and cash equivalents, including short-term treasury investments, were EUR 7.4 million (USD 9.6 million). The Company's net cash position was stable in the second quarter 2013.

Conference Call

EDAP will hold a conference call on Wednesday, August 28, 2013 at 8:30 a.m. EDT to discuss the results. The dial-in numbers are 1-877-300-8521 for domestic callers and 1-412-317-6026 for international callers. The conference ID number for both is 10032218. 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, <u>www.edap-tms.com</u>, through September 25, 2013. In addition, a telephonic replay of the call will be available until September 4, 2013. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 10032218.

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® 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, Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® range) 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.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements that involve risks and uncertainties. Such statements are based on management's current expectations and are subject to a number of uncertainties, including the uncertainties of the regulatory process, 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 and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F. Ablatherm-

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, 2013 Euros	June 30, 2012 Euros	June 30, 2013 \$US	June 30, 2012 \$US
Sales of goods	2,251	3,747	2,939	4,779
Net Sales of RPP and Leases	1,037	1,088	1,353	1,388
Sales of spare parts and Services	1,211	1,290	1,581	1,646
TOTAL NET SALES	4,499	6,126	5,873	7,813
Other revenues	3		4	
TOTAL REVENUES	4,502	6,126	5,877	7,813
Cost of goods	(1,369)	(2,200)	(1,788)	(2,806)
Cost of RPP and Leases	(599)	(608)	(782)	(775)
Cost of spare parts & services	(906)	(925)	(1,183)	(1,179)
Cost of sales	(2,875)	(3,732)	(3,753)	(4,760)
GROSS PROFIT	1,627	2,394	2,124	3,053
Research & development expenses	(646)	(854)	(843)	(1,090)
Marketing & Sales expenses	(1,560)	(1,536)	(2,036)	(1,959)
G & A expenses	(880)	(940)	(1,149)	(1,199)
Total operating expenses	(3,086)	(3,331)	(4,028)	(4,248)
OPERATING PROFIT (LOSS)	(1,458)	(937)	(1,904)	(1,195)
Interest (expense) income, net	1,817	(2,386)	2,372	(3,043)
Currency exchange gains (loss), net	(545)	257	(712)	328
Other income (loss), net	2	33	3	42
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(184)	(3,032)	(240)	(3,868)
Income tax (expense) credit	(12)	49	(15)	62
NET INCOME (LOSS)	(195)	(2,984)	(255)	(3,806)
Earning per share — Basic	(0.01)	(0.16)	(0.01)	(0.21)
Average number of shares used in computation of Basic EPS	19,923,003	18,257,273	19,923,003	18,257,273
Earning per share — Diluted	(0.01)	(0.16)	(0.01)	(0.21)
Average number of shares used in computation of Diluted EPS	19,923,003	18,257,273	19,923,003	18,257,273

NOTE: Translated for convenience of the reader to U.S. dollars at the 2013 average three months noon buying rate of 1 Euro = 1.3055 USD, and 2012 average three months noon buying rate of 1 Euro = 1.2753 USD.

	Six Months Ended:		Six Months Ended :		
	June 30, 2013 Euros	June 30, 2012 Euros	June 30, 2013 \$US	June 30, 2012 \$US	
Sales of goods	5,944	6,212	7,792	8,076	
Net Sales of RPP and Leases	1,970	2,201	2,582	2,862	
Sales of spare parts and Services	2,512	2,550	3,293	3,316	
TOTAL NET SALES	10,426	10,963	13,667	14,253	
Other revenues	3		4		
TOTAL REVENUES	10,429	10,963	13,671	14,253	
Cost of goods	(3,612)	(3,575)	(4,735)	(4,648)	
Cost of RPP and Leases	(1,122)	(1,243)	(1,471)	(1,615)	
Cost of spare parts & services	(1,870)	(1,850)	(2,451)	(2,405)	
Cost of sales	(6,604)	(6,667)	(8,657)	(8,668)	
GROSS PROFIT	3,825	4,296	5,014	5,585	
Research & development expenses	(1,578)	(1,563)	(2,069)	(2,032)	
Marketing & Sales expenses	(3,094)	(2,959)	(4,055)	(3,846)	
G & A expenses	(1,802)	(1,718)	(2,362)	(2,233)	
Total operating expenses	(6,474)	(6,239)	(8,486)	(8,111)	
OPERATING PROFIT (LOSS)	(2,649)	(1,943)	(3,472)	(2,526)	
Interest (expense) income, net	(612)	(3,941)	(803)	(5,124)	
Currency exchange gains (loss), net	(757)	(11)	(992)	(14)	
Other income (loss), net	1	40	1	51	
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(4,017)	(5,855)	(5,266)	(7,613)	
Income tax (expense) credit	(61)	(25)	(80)	(33)	
NET INCOME (LOSS)	(4,078)	(5,880)	(5,346)	(7,645)	
Earning per share — Basic	(0.21)	(0.32)	(0.28)	(0.42)	
Average number of shares used in computation of Basic EPS	19,321,827	18,257,273	19,321,827	18,257,273	
Earning per share — Diluted	(0.21)	(0.32)	(0.28)	(0.42)	
Average number of shares used in computation of Diluted EPS	19,321,827	18,257,273	19,321,827	18,257,273	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2013 average six months noon buying rate of 1 Euro = 1.3108 USD, and 2012 average six months noon buying rate of 1 Euro = 1.3001 USD.

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

	June 30, 2013 Euros	March 31, 2013 Euros	June 30, 2013 \$US	March 31, 2013 \$US
Cash, cash equivalents and short term investments	7,373	7,288	9,592	9,340
Total current assets	21,470	22,249	27,933	28,513
Total current liabilities	10,902	12,292	14,184	15,753
Shareholders' Equity	9,907	4,190	12,890	5,369

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3011 USD, on June 30, 2013 and at the noon buying rate of 1 Euro = 1.2816 USD, on March 31, 2013.

EDAP TMS S.A. CONDENSED STATEMENTS OF OPERATIONS BY DIVISION SIX MONTHS ENDED JUNE 30, 2013 (Amounts in thousands of Euros)

HIFU Division UDS Division FDA Trials Corporate Total After Consolidation

Sales of goods	650	5,294			5,944
Sales of RPPs & Leases	1,203	766			1,970
Sales of spare parts & services _	495	2,017			2,512
TOTAL NET SALES	2,349	8,077			10,426
Other revenues	3				3
TOTAL REVENUES	2,352	8,077			10,429
GROSS PROFIT	1,203	2,623			3,825
Research & Development	(571)	(362)	(645)		(1,578)
Total SG&A plus depreciation _	(1,146)	(2,915)	(74)	(761)	(4,896)
OPERATING PROFIT (LOSS)	(514)	(654)	(719)	(761)	(2,649)

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