

November 20, 2014

EDAP Reports Continued Strong Growth in Third Quarter 2014

Highlights

- Revenues increased 27% year-over-year to EUR 20.3 million (USD 27.4 million) for the first nine months of 2014
- HIFU revenue increased 114% year-over-year during first nine months of 2014
- Positive operating income, excluding FDA-related costs, for three and nine months ended September 30, 2014
- Solid financial profile with cash position of EUR 11.1 million (USD 14.0 million)
- Three Focal One Systems sold during third quarter, demonstrates robust OUS demand for next-generation HIFU device
- Recent FDA guidance on Ablatherm HIFU PMA submission provides clear U.S. regulatory path and opportunity.

LYON, France, Nov. 20, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter and nine months ended September 30, 2014 and provided an update on recent strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We continue to make significant progress on several fronts in the second half of 2014. Of most note is the continued OUS adoption of our world class HIFU technology, which led revenue from this segment of our business to more than double in the first nine months of 2014 compared to the first nine months of 2013 with a total of ten systems sold, up from two in the year-ago period."

"The third quarter was particularly exciting, as we recognized revenue from three Focal One device sales. As reported in recent communication, these 3 devices were sold and installed in recognized and leading prostate cancer centers in France and Germany. This is a clear recognition of the high value of EDAP's broad range of HIFU devices and the increasing need of a complement to surgery, to address the changing prostate cancer patient population."

Mr. Oczachowski continued, "In the U.S., we recently reached an important milestone in our ongoing regulatory efforts with the receipt of a letter from the FDA. This letter provided specific recommendations for amendments to our Ablatherm-HIFU PMA that would make the application approvable. This comprehensive guidance reflects the extensive discussions we have had with the FDA since our Advisory Panel meeting. We are excited by the growth that our HIFU business has achieved to-date and the broader growth potential in the global urology market. In addition, we remain steadfastly committed to advancing the FDA approval process, and to bringing this therapeutic option to prostate cancer patients in the U.S."

Third Quarter 2014 Results

Total revenue for the third quarter 2014 was EUR 6.9 million (USD 9.0 million), a 24% year-over-year increase compared to EUR 5.6 million (USD 7.4 million) for the third quarter 2013. Total revenue included a EUR 0.5 million (USD 0.7 million) one-off revenue related to the licensing of a HIFU patent.

Total revenue for the HIFU division was EUR 2.9 million (USD 3.9 million) for the third quarter 2014, compared to EUR 1.2 (USD 1.7 million) for the same period last year. Results for the third quarter 2014 included the sale of three Focal One devices.

For the three months ended September 30, 2014, total revenue for the lithotripsy division was EUR 4.0 million (USD 5.4 million), compared to EUR 4.3 million (USD 5.8 million), during the year ago period. During the third quarter 2014, the Company recorded sales of seven lithotripsy machines, comprised of five Sonolith i-move devices, one Sonolith i-sys device, and one Sonolith Praktis. This compares to nine devices sold in the third quarter of 2013.

Gross profit for the third quarter 2014 was EUR 3.4 million (USD 4.4 million), compared to EUR 2.2 million (USD 3.0 million) for the year ago period. Gross profit margin on net sales was 45.2% in the third quarter of 2014, compared to 40.3% in the year ago period.

Operating expenses were EUR 3.1 million (USD 4.0 million) for the third quarter 2014, compared to EUR 2.6 million (USD 3.4 million) for the same period in 2013.

Operating income for the quarter was EUR 339,000 (USD 443,000), compared with an operating loss in the third quarter of 2013 of EUR 333,000 (USD 444,000).

Net income for the third quarter 2014 was EUR 6.6 million (USD 8.6 million), or EUR 0.26 per diluted share, as compared to a net loss for the third quarter 2013 of EUR 373,000 (USD 497,000), or EUR 0.02 per diluted share. Net income in the third quarter of 2014 included non-cash interest income of EUR 6.5 million to adjust the accounting fair value of outstanding warrants.

Results for the Nine Months Ended September 30, 2014

Total revenue for the first nine months of 2014 was EUR 20.3 million (USD 27.4 million), up 27.0% compared to EUR 16.0 million (USD 21.1 million) for the first nine months of 2013.

Gross profit for the period was EUR 8.8 million (USD 11.8 million), with gross profit margin on net sales of 41.7%, compared to 37.9% in the year ago period.

Operating loss for the first nine months of 2014 was EUR 707,000 (USD 954,000), an improvement of EUR 2.3 million over operating loss of EUR 3.0 million (USD 3.9 million) in the first nine months of 2013. Excluding FDA-related costs, operating income for the first nine months of 2014 was EUR 0.3 million (USD 0.4 million).

Net income for the nine months ended September 30, 2014 was EUR 2.1 million (USD 2.9 million), or EUR 0.09 per diluted share, as compared to net loss of EUR 4.5 million (USD 5.9 million), or EUR 0.22 per diluted share, in the same period in 2013. Net income in the 2014 period included non-cash interest income of EUR 3.0 million to adjust the accounting fair value of the outstanding warrants.

At September 30, 2014, cash and cash equivalents, including short-term treasury investments, were EUR 11.1 million (USD 14.0 million).

Conference Call

EDAP will hold a conference call on Thursday, November 20, 2014 at 8:30 a.m. EST 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 10055617. A live webcast of the conference call will be available online from the investor relations page of the Company's corporate website at <u>www.edap-tms.com</u>.

After the live event, the webcast will remain available on EDAP's website, <u>www.edap-tms.com</u>, through December 20, 2014. In addition, a dial-in replay of the call will be available until November 27, 2014. 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 10055617.

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. In March 2013, the Company introduced a new innovative HIFU device, the Focal One[®] dedicated to focal therapy of prostate cancer. Focal One[®] is CE marked but is not FDA approved. 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 <u>http://www.edap-tms.com</u>, and <u>http://www.hifu-planet.com</u>.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. Factors that may cause such a difference also may 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-HIFU treatment is in clinical trials, but not FDAapproved or marketed in the United States.

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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 :		
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013	
	Euros	Euros	\$US	\$US	
Sales of goods	4,192	3,271	5,474	4,363	
Net Sales of RPP and Leases	824	920	1,075	1,226	
Sales of spare parts and services	1,384	1,371	1,807	1,829	
TOTAL NET SALES	6,400	5,562	8,356	7,418	
Other revenues	511	1	667	2	
TOTAL REVENUES	6,911	5,563	9,023	7,420	
Cost of goods	(2,163)	(1,938)	(2,825)	(2,584)	
Cost of RPP and Leases	(442)	(514)	(577)	(686)	
Cost of spare parts & services	(899)	(870)	(1,174)	(1,161)	
Cost of sales	(3,505)	(3,322)	(4,576)	(4,431)	
GROSS PROFIT	3,406	2,241	4,447	2,989	
Research & development expenses	(714)	(447)	(932)	(596)	
Marketing & Sales expenses	(1,458)	(1,302)	(1,903)	(1,737)	
G & A expenses	(895)	(825)	(1,169)	(1,100)	
Total operating expenses	(3,067)	(2,574)	(4,004)	(3,432)	
OPERATING PROFIT (LOSS)	339	(333)	443	(444)	
Interest (expense) income, net	6,484	373	8,466	498	
Currency exchange gains (loss), net	(245)	(385)	(320)	(514)	
Other income (loss), net	(2)	3	(2)	3	
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	6,577	(343)	8,587	(457)	
Income tax (expense) credit	(26)	(30)	(34)	(40)	
NET INCOME (LOSS)	6,551	(373)	8,554	(497)	
Earning per share - Basic	0.26	(0.02)	0.34	(0.02)	
Average number of shares used in computation of Basic EPS	24,859,267	21,789,670	24,859,267	21,789,670	
Earning per share - Diluted	0.26	(0.02)	0.33	(0.02)	
Average number of shares used in computation of Diluted EPS	25,623,929	21,789,670	25,623,929	21,789,670	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2014 average three months noon buying rate of 1 Euro = 1.3057 USD, and 2013 average three months noon buying rate of 1 Euro = 1.3337 USD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Nine Months Ended :		Nine Months Ended :		
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013	
	Euros	Euros	\$US	\$US	
Sales of goods	12,948	9,216	17,474	12,150	
Net Sales of RPP and Leases	2,846	2,889	3,841	3,809	
Sales of spare parts and services	4,002	3,883	5,401	5,120	
TOTAL NET SALES	19,797	15,988	26,716	21,079	
Other revenues	511	4	690	5	
TOTAL REVENUES	20,308	15,993	27,406	21,085	
Cost of goods	(7,322)	(5,550)	(9,881)	(7,317)	
Cost of RPP and Leases	(1,583)	(1,636)	(2,137)	(2,157)	
Cost of spare parts & services	(2,629)	(2,740)	(3,548)	(3,613)	
Cost of sales	(11,535)	(9,926)	(15,566)	(13,087)	
GROSS PROFIT	8,773	6,066	11,840	7,998	
Research & development expenses	(2,332)	(2,025)	(3,147)	(2,670)	
Marketing & Sales expenses	(4,521)	(4,396)	(6,102)	(5,795)	
G & A expenses	(2,627)	(2,627)	(3,545)	(3,463)	
Total operating expenses	(9,480)	(9,048)	(12,793)	(11,929)	
OPERATING PROFIT (LOSS)	(707)	(2,982)	(954)	(3,931)	
Interest (expense) income, net	2,930	(239)	3,954	(315)	
Currency exchange gains (loss), net	(29)	(1,142)	(39)	(1,506)	
Other income (loss), net	(6)	3	(8)	4	
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	2,188	(4,360)	2,953	(5,748)	
Income tax (expense) credit	(62)	(91)	(84)	(120)	
NET INCOME (LOSS)	2,126	(4,451)	2,869	(5,869)	
Earning per share - Basic	0.09	(0.22)	0.12	(0.29)	
Average number of shares used in computation of Basic EPS	23,157,314	20,169,756	23,157,314	20,169,756	
Earning per share - Diluted	0.08	(0.22)	0.11	(0.29)	
Average number of shares used in computation of Diluted EPS	25,296,513	20,169,756	25,296,513	20,169,756	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2014 average nine months noon buying rate of 1 Euro = 1.3495 USD, and 2013 average nine months noon buying rate of 1 Euro = 1.3184 USD.

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CONSOLIDATED BALANCE SHEETS HIGHLIGHTS (UNAUDITED)

(Amounts in thousands of Euros and U.S. Dollars)

	2014	2014	2014	2014	
	Euros	Euros	\$US	\$US	
Cash, cash equivalents and short term investments	11,055	12,799	13,960	17,520	
Total current assets	27,578	27,473	34,825	37,608	
Total current liabilities	11,622	11,484	14,676	15,721	
Shareholders' Equity	17,778	11,283	22,450	15,445	

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2628 USD, on September 30, 2014 and at the noon buying rate of 1 Euro = 1.3689 USD, on June, 2014.

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CONDENSED STATEMENTS OF OPERATIONS BY DIVISION

NINE MONTHS ENDED SEPTEMBER 30, 2014

(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation	
Sales of goods	5,053	7,895			12,948	
Sales of RPPs & Leases	1,536	1,310			2,846	
Sales of spare parts & services	596	3,406			4,002	
TOTAL NET SALES	7,186	12,611			19,797	
Other revenues	511				511	
TOTAL REVENUES	7,697	12,611			20,308	
GROSS PROFIT	4,540 56%	4,233 34%			8,773	42%
Research & Development	(751)	(582)	(999)		(2,332)	
Total SG&A plus depreciation	(1,915)	(4,133)		(1,100)	(7,148)	
OPERATING PROFIT (LOSS)	1,875	(482)	(999)	(1,100)	(707)	

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