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Bringing New Horizons to Therapy

August 25, 2016

## **EDAP Reports 69% Growth in HIFU Revenues and Operating Profit for First Half 2016**

- | Total EDAP revenue up 20.4% year-over-year in the first six months of 2016
- | Continued growth in HIFU system sales and treatment-driven revenue with strong margins
- | Focal One® 510k under FDA review
- | Solid cash position at €21.9 million as of June 30, 2016

LYON, France, Aug. 25, 2016 (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, 2016, and provided an update on strategic and operational accomplishments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "EDAP has made steady progress in the first half of the year. The FDA clearance of Ablatherm Robotic HIFU in late 2015 has resulted in strong system sales, while the growth in treatment driven revenues continued as a result of the traction and momentum of HIFU globally."

"The solid performance of the HIFU division, in which revenues increased 69% over the first half of 2015, is clear evidence that our market penetration strategy is working and supports the expansion and growth of our global HIFU business. We continue penetrating the U.S. market with our strategy of targeting large and recognized institutions directly, while also providing access to the entire urology community by partnering with mobilizers and service providers.

In April, we submitted a 510(k) application for our next generation Focal One® HIFU system with the FDA. We are closely working on the file through direct interaction with the agency."

Mr. Oczachowski added, "We are pleased with our business development during the first half of 2016, and with the great traction we are achieving in our HIFU division with a significant increase in our project pipeline, particularly in the U.S. Thanks to this continued growth, the company generated an operating profit for the first half of the year and has a solid cash position that makes EDAP well-funded to further drive its growth and expansion initiatives."

### **Second Quarter 2016 Results**

Total revenue for the second quarter 2016 was EUR 8.2 million (USD 9.2 million), a 4.6% year-over-year increase compared to EUR 7.8 million (USD 8.7 million) for the second quarter 2015.

Total revenue in the HIFU business for this quarter was EUR 3.4 million (USD 3.8 million) compared to EUR 2.3 million (USD 2.6 million) for the second quarter 2015. HIFU revenue included the sale of three Ablatherm systems and one Focal One.

For the three months ended June 30, 2016, total revenue for the Lithotripsy division was EUR 4.8 million (USD 5.4 million), compared to EUR 5.5 million (USD 6.1 million), during the year ago period.

Gross profit for the second quarter 2016 was EUR 3.5 million (USD 3.9 million), compared to EUR 3.3 million (USD 3.7 million) for the year ago period. Gross profit margin on net sales was 42.3% in the second quarter of 2016, compared to 42.5% in the year ago period.

Operating expenses were EUR 3.8 million (USD 4.3 million) for the second quarter 2016, compared to EUR 3.6 million (USD 3.9 million) for the same period in 2015.

Operating loss for the second quarter 2016 was EUR 0.3 million (USD 0.4 million), compared with EUR 0.2 million (USD 0.2 million) in the second quarter of 2015.

Net income for the second quarter 2016 was EUR 2.5 million (USD 2.8 million), or EUR 0.08 per diluted share, as compared to net income of EUR 0.5 million (USD 0.5 million), or EUR 0.02 per diluted share, in the year ago period. Net income in the second quarter of 2016 included non-cash interest income of EUR 2.4 million to adjust the accounting fair value of the outstanding warrants.

### **First Six Months 2016 Results**

Total revenue for the first half of 2016 was EUR 16.9 million (USD 18.9 million), up 20.4% compared to EUR 14.1 million (USD 15.6 million) for the first half of 2015.

Total revenue in the HIFU division for the first six months 2016 was EUR 6.7 million (USD 7.4 million) compared to EUR 3.9 million (USD 4.4 million) for the six months ended June 30, 2015. HIFU revenue included the sale of six Ablatherm systems and two Focal One.

For the six months ended June 30, 2016, total revenue for the Lithotripsy division was EUR 10.2 million (USD 11.4 million), compared to EUR 10.1 million (USD 11.2 million), during the year ago period.

Gross profit for the first half of 2016 was EUR 7.8 million (USD 8.6 million) and gross profit margin was 45.8%, compared to 42.1% in the year ago period.

Operating expenses were EUR 7.4 million (USD 8.2 million) for the first six months of 2016, compared to EUR 6.8 million (USD 7.5 million) for the same period in 2015.

The Company recorded an operating profit the first half of 2016 of EUR 0.4 million (USD 0.4 million), compared with an operating loss of EUR 0.8 million (USD 0.9 million) in the first six months of 2015.

Net income for the first half of 2016 was EUR 3.9 million (USD 4.3 million), or EUR 0.13 per diluted share, as compared to a net loss of EUR 2.0 million (USD 2.2 million), or EUR 0.08 per diluted share, in the first half of 2015. Net income in the first half of 2016 included a non-cash interest income of EUR 2.9 million to adjust the accounting fair value of the outstanding warrants.

At June 30, 2016, cash and cash equivalents, including short-term treasury investments, were EUR 21.9 million (USD 24.2 million).

### **Conference Call**

EDAP will hold a conference call on Thursday, August 25<sup>th</sup>, 2016 at 8:30 a.m. EDT to discuss the results and provide an update on recent business developments. The dial-in numbers are 1-888-348-6419 in the U.S., and 1-412-902-4235 for international callers. The conference ID number for both is 10091258. 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](http://www.edap-tms.com).

After the live event, the webcast will remain available on EDAP's website, [www.edap-tms.com](http://www.edap-tms.com), through September 27, 2016. In addition, a dial-in replay of the call will be available. 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 10091258.

### **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation 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 for commercial distribution in Europe and some other countries including Mexico and Canada, and has received 510(k) clearance by the U.S. FDA. The Company also markets an innovative robot-assisted 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 distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. 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. 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 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.

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

	<u>Three Months Ended:</u>		<u>Three Months Ended:</u>	
	June 30, 2016 Euros	June 30, 2015 Euros	June 30, 2016 \$US	June 30, 2015 \$US
Sales of goods	5,262	5,357	5,896	5,948
Net Sales of RPP and Leases	1,316	1,090	1,474	1,210
Sales of spare parts and Services	1,611	1,388	1,805	1,541
<b>TOTAL NET SALES</b>	<b>8,189</b>	<b>7,834</b>	<b>9,174</b>	<b>8,699</b>
Other revenues	8	2	9	2
<b>TOTAL REVENUES</b>	<b>8,197</b>	<b>7,836</b>	<b>9,183</b>	<b>8,701</b>
Cost of goods	(2,768)	(2,996)	(3,101)	(3,327)
Cost of RPP and Leases	(805)	(648)	(902)	(720)
Cost of spare parts & services	(1,162)	(861)	(1,302)	(956)
Cost of sales	(4,736)	(4,505)	(5,305)	(5,002)
<b>GROSS PROFIT</b>	<b>3,461</b>	<b>3,331</b>	<b>3,878</b>	<b>3,699</b>
Research & development expenses	(887)	(739)	(993)	(820)
Marketing & Sales expenses	(2,147)	(1,859)	(2,406)	(2,064)
G & A expenses	(772)	(950)	(865)	(1,055)
Total operating expenses	(3,806)	(3,548)	(4,264)	(3,940)
<b>OPERATING PROFIT (LOSS)</b>	<b>(345)</b>	<b>(217)</b>	<b>(386)</b>	<b>(241)</b>
Interest (expense) income, net	2,412	1,005	2,702	1,116
Currency exchange gains (loss), net	483	(262)	541	(291)
Other income (loss), net	-	-	-	-
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>2,550</b>	<b>526</b>	<b>2,857</b>	<b>584</b>
Income tax (expense) credit	(52)	(39)	(58)	(43)
<b>NET INCOME (LOSS)</b>	<b>2,498</b>	<b>487</b>	<b>2,799</b>	<b>541</b>
Earning per share - Basic	0.09	0.02	0.109	0.02
Average number of shares used in computation of Basic EPS	28,288,307	24,958,174	28,288,307	24,958,174
Earning per share - Diluted	0.08	0.02	0.09	0.02
Average number of shares used in computation of Diluted EPS	29,826,117	27,016,460	29,826,117	27,016,460

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2016 average three months' noon buying rate of 1 Euro = 1.1203 USD, and 2015 average three months' noon buying rate of 1 Euro = 1.1104 USD.

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

	<u>Six Months Ended:</u>		<u>Six Months Ended:</u>	
	June 30, 2016 Euros	June 30, 2015 Euros	June 30, 2016 \$US	June 30, 2015 \$US

Sales of goods	11,261	9,103	12,518	10,095
Net Sales of RPP and Leases	2,578	2,119	2,865	2,350
Sales of spare parts and Services	3,078	2,830	3,421	3,138
<b>TOTAL NET SALES</b>	<b>16,917</b>	<b>14,052</b>	<b>18,805</b>	<b>15,584</b>
Other revenues	8	2	9	2
<b>TOTAL REVENUES</b>	<b>16,925</b>	<b>14,054</b>	<b>18,814</b>	<b>15,586</b>
Cost of goods	(5,561)	(5,042)	(6,182)	(5,591)
Cost of RPP and Leases	(1,513)	(1,292)	(1,681)	(1,433)
Cost of spare parts & services	(2,097)	(1,809)	(2,332)	(2,006)
Cost of sales	(9,171)	(8,143)	(10,195)	(9,030)
<b>GROSS PROFIT</b>	<b>7,753</b>	<b>5,911</b>	<b>8,619</b>	<b>6,556</b>
Research & development expenses	(1,701)	(1,512)	(1,890)	(1,677)
Marketing & Sales expenses	(4,013)	(3,408)	(4,460)	(3,780)
G & A expenses	(1,652)	(1,830)	(1,836)	(2,030)
Total operating expenses	(7,365)	(6,750)	(8,187)	(7,486)
<b>OPERATING PROFIT (LOSS)</b>	<b>388</b>	<b>(839)</b>	<b>432</b>	<b>(931)</b>
Interest (expense) income, net	2,891	(1,344)	3,213	(1,491)
Currency exchange gains (loss), net	671	303	746	336
Other income (loss), net	-	(3)	-	(3)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>3,950</b>	<b>(1,884)</b>	<b>4,391</b>	<b>(2,089)</b>
Income tax (expense) credit	(91)	(69)	(101)	(77)
<b>NET INCOME (LOSS)</b>	<b>3,859</b>	<b>(1,953)</b>	<b>4,289</b>	<b>(2,166)</b>
Earning per share - Basic	0.14	(0.08)	0.16	(0.09)
Average number of shares used in computation of Basic EPS	26,844,696	24,926,627	26,844,696	24,926,627
Earning per share - Diluted	0.13	(0.08)	0.15	(0.09)
Average number of shares used in computation of Diluted EPS	28,615,172	24,926,627	28,615,172	24,926,627

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2016 average six months' noon buying rate of 1 Euro = 1.1116 USD, and 2015 average six months' noon buying rate of 1 Euro = 1.1090 USD.

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

	<b>June 30, 2016 Euros</b>	<b>Mar. 31, 2016 Euros</b>	<b>June 30, 2016 \$US</b>	<b>Mar. 31, 2016 \$US</b>
Cash, cash equivalents and short term investments	21,940	14,533	24,203	16,552
Total current assets	40,963	33,019	45,188	37,607
Total current liabilities	14,817	16,529	16,345	18,826
Shareholders' Equity	24,358	15,901	26,870	18,111

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1031 USD, on June 30, 2016 and at the noon buying rate of 1 Euro = 1.1390 USD, on March 31, 2016.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**SIX MONTHS ENDED JUNE 30, 2016**  
**(Amounts in thousands of Euros)**

	HIFU Division	UDS Division	FDA Trials	Corporate	Total After Consolidation
Sales of goods	4,536	6,725			11,261
Sales of RPPs & Leases	1,811	766			2,578
Sales of spare parts & services	328	2,750			3,078
<b>TOTAL NET SALES</b>	<b>6,676</b>	<b>10,241</b>			<b>16,917</b>
Other revenues	6	2			8
<b>TOTAL REVENUES</b>	<b>6,682</b>	<b>10,243</b>			<b>16,925</b>
<b>GROSS PROFIT</b> (% of Total Revenues)	<b>4,081 61%</b>	<b>3,672 36%</b>			<b>7,753 46%</b>
Research & Development	(1,048)	(653)	-		(1,701)
Total SG&A plus depreciation	(1,979)	(2,996)		(689)	(5,664)
			-		
<b>OPERATING PROFIT (LOSS)</b>	<b>1,054</b>	<b>23</b>		<b>(689)</b>	<b>388</b>

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