



April 3, 2017

## EDAP Achieves 63% Growth in HIFU Revenue in 2016

### 2016 Highlights

- ┆ Total revenue for 2016 reached double-digit growth, increasing to EUR 35.6 million (USD 39.3 million)
- ┆ Gross margin for 2016 expanded to 46.1% compared to 42.8% during the prior year period
- ┆ Strong cash position of EUR 22.0 million (USD 23.2 million) as of December 31, 2016

LYON, France, April 3, 2017 -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and twelve months ended December 31, 2016, and provided an update on strategic and operational accomplishments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "I am thrilled with the performance of our team in 2016. We successfully grew our HIFU revenue more than 63% to EUR 13.8 million, resulting in total 2016 revenue of EUR 35.6 million. EDAP strengthened its HIFU presence in the U.S. during 2016, adding key academic centers to its HIFU user base while significantly expanding operations globally. Ablatherm® and the Focal One® continued to enjoy a warm reception from the global medical community supported by strong, positive clinical data. Notably, Focal One's innovative prostate treatment received clear recognition from the global scientific community when awarded the prestigious Prix Galien Award this past December."

Mr. Oczachowski concluded, "2016 was rich in positive events; please join us Tuesday, April 4, 2017, for a detailed discussion of our continued success and expansion."

### Fourth Quarter 2016 Results

Total revenue for the fourth quarter 2016 was EUR 10.7 million (USD 11.4 million), a 9.3% decrease compared to EUR 11.8 million (USD 12.8 million) for the fourth quarter of 2015.

Total revenue in the HIFU business for the fourth quarter was EUR 4.6 million (USD 4.9 million), a 38.3% increase compared to EUR 3.3 million (USD 3.6 million) for the fourth quarter of 2015.

For the three months ended December 31, 2016, total revenue for the Lithotripsy division was EUR 6.1 (USD 6.5 million), a 27.9% decrease compared to EUR 8.5 million (USD 9.2 million) during the year-ago period.

Gross profit for the fourth quarter 2016 was EUR 5.2 million (USD 5.6 million), compared to EUR 5.3 million (USD 5.7 million) for the year-ago period. Gross profit margin on net sales was 48.8% in the fourth quarter of 2016, compared to 45.0% in the year-ago period.

Operating expenses were EUR 4.9 million (USD 5.2 million) for the fourth quarter of 2016, compared to EUR 3.7 million (USD 4.0 million) for the same period in 2015.

Operating profit for the fourth quarter 2016 was EUR 0.3 million (USD 0.4 million), compared to EUR 1.6 million (USD 1.7 million) in the fourth quarter of 2015.

Net loss for the fourth quarter 2016 was EUR 1.3 (USD 1.4 million), or a loss of EUR 0.04 per diluted share, as compared to net income of EUR 5.1 million (USD 5.5 million), or EUR 0.18 per diluted share in the year-ago period. Net income in the fourth quarter of 2016 included non-cash interest expense of EUR 0.4 million (USD 0.5 million) to adjust the accounting fair value of the outstanding warrants.

### Year Ended 2016 Results

Total revenue for 2016 was EUR 35.6 million (USD 39.3 million), an increase of 10.4% compared to EUR 32.3 million (USD 35.6) for the year ended December 31, 2015.

Total revenue in the HIFU business for 2016 was EUR 13.8 million (USD 15.2 million), an increase of 63.0% compared to

EUR 8.5 million (USD 9.4 million) for the year ended December 31, 2015.

Total revenue in the Lithotripsy business for 2016 was EUR 21.8 million (USD 24.0 million), a decrease of 8.3% compared to EUR 23.8 million (USD 26.2 million) for the year ended December 31, 2015.

Gross profit for 2016 was EUR 16.4 million (USD 18.1 million), with gross profit margin on net sales of 46.1%, compared to 42.8% during the prior year period.

The Company recorded operating profit for 2016 of EUR 0.4 million (USD 0.4 million), compared to an operating profit of EUR 0.5 million (USD 0.5 million) during the prior year period.

Full-year net income was EUR 3.8 million (USD 4.2 million), or EUR 0.13 per diluted share, as compared to a net loss of EUR 1.7 million (USD 1.8 million), or a loss of EUR 0.07 per diluted share in 2015. Full-year net income included non-cash interest income of EUR 4.0 million to adjust the accounting fair value of the outstanding warrants.

At December 31, 2016, cash and cash equivalents were EUR 22.0 million (USD 23.2 million).

## Conference Call

An accompanying conference call will be conducted by Marc Oczachowski, Chief Executive Officer, and Francois Dietsch, Chief Financial Officer, to go over the results. The call will be held at 8:30 AM ET, on Tuesday, April 4, 2017. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Date: Tuesday, April 4, 2017 8:30 AM ET

Conference dial-in: 877-269-7756

International dial-in: 201-689-7817

Conference Call Name: EDAP-TMS Fourth Quarter and Full Year 2016 Results Call

Webcast Registration: [Click Here](#)

Following the live call, a replay will be available on the Company's website, [www.edap-tms.com](http://www.edap-tms.com) under "Investors Information."

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

|  | Three Months Ended: |              | Three Months Ended: |              |
|--|---------------------|--------------|---------------------|--------------|
|  | December 31,        | December 31, | December 31,        | December 31, |
|  | 2016                | 2015         | 2016                | 2015         |
|  | Euros               | Euros        | \$US                | \$US         |

|   |               |               |               |               |
|---|---------------|---------------|---------------|---------------|
| Sales of medical equipment  | 7,566         | 9,049         | 8,093         | 9,792         |
| Net Sales of RPP and Leases   | 1,231         | 1,151         | 1,317         | 1,245         |
| Sales of spare parts, supplies and Services                                 | 1,875         | 1,560         | 2,006         | 1,688         |
| <b>TOTAL NET SALES</b>  | <b>10,672</b> | <b>11,760</b> | <b>11,417</b> | <b>12,726</b> |
| Other revenues  | 22            | 32            | 24            | 35            |
| <b>TOTAL REVENUES</b>   | <b>10,695</b> | <b>11,792</b> | <b>11,441</b> | <b>12,760</b> |
| Cost of sales   | -5,492        | -6,495        | -5,875        | -7,029        |
| <b>GROSS PROFIT</b>   | <b>5,203</b>  | <b>5,297</b>  | <b>5,566</b>  | <b>5,732</b>  |
| Research & development expenses   | -1,135        | -565          | -1,214        | -612          |
| S, G & A expenses   | -3,733        | -3,147        | -3,994        | -3,406        |
| Total operating expenses  | -4,868        | -3,713        | -5,208        | -4,018        |
| <b>OPERATING PROFIT (LOSS)</b>  | <b>335</b>    | <b>1,584</b>  | <b>358</b>    | <b>1,714</b>  |
| Interest (expense) income, net  | -444          | 3,710         | -475          | 4,015         |
| Currency exchange gains (loss), net   | -698          | 476           | -746          | 516           |
| Other income (loss), net  | -             | 5             | -             | 5             |
| <b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>                     | <b>-807</b>   | <b>5,775</b>  | <b>-863</b>   | <b>6,249</b>  |
| Income tax (expense) credit   | -471          | -659          | -504          | -713          |
| <b>NET INCOME (LOSS)</b>  | <b>-1,278</b> | <b>5,116</b>  | <b>-1,367</b> | <b>5,536</b>  |
| Earning per share - Basic   | -0.04         | 0.2           | -0.05         | 0.22          |
| Average number of shares used in computation of EPS                         | 28,727,616    | 25,254,618    | 28,727,616    | 25,254,618    |
| Earning per share - Diluted   | -0.04         | 0.18          | -0.05         | 0.19          |
| Average number of shares used in computation of EPS for positive net income | 28,727,616    | 28,846,270    | 28,727,616    | 28,846,270    |

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2016 average three months' noon buying rate of 1 Euro = 1.0697 USD, and 2015 average three months noon buying rate of 1 Euro = 1.0821 USD.

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

|  | Twelve Months Ended: |              | Twelve Months Ended: |              |
|--|----------------------|--------------|----------------------|--------------|
|  | December 31,         | December 31, | December 31,         | December 31, |
|  | 2016                 | 2015         | 2016                 | 2015         |
|  | Euros                | Euros        | \$US                 | \$US         |

|   |               |               |               |               |
|---|---------------|---------------|---------------|---------------|
| Sales of medical equipment                              | 24,045        | 21,906        | 26,520        | 24,168        |
| Net Sales of RPP and Leases                             | 4,906         | 4,408         | 5,411         | 4,864         |
| Sales of spare parts, supplies and Services             | 6,628         | 5,904         | 7,310         | 6,513         |
| <b>TOTAL NET SALES</b>                                  | <b>35,579</b> | <b>32,218</b> | <b>39,240</b> | <b>35,545</b> |
| Other revenues  | 32            | 35            | 35            | 39            |
| <b>TOTAL REVENUES</b>                                   | <b>35,611</b> | <b>32,253</b> | <b>39,276</b> | <b>35,584</b> |
| Cost of sales   | -19,200       | -18,468       | -21,176       | -20,375       |
| <b>GROSS PROFIT</b>                                     | <b>16,411</b> | <b>13,785</b> | <b>18,100</b> | <b>15,209</b> |
| Research & development expenses                         | -3,868        | -2,690        | -4,266        | -2,968        |
| S, G & A expenses                                       | -12,152       | -10,608       | -13,402       | -11,703       |
| Total operating expenses                                | -16,019       | -13,298       | -17,668       | -14,671       |
| <b>OPERATING PROFIT (LOSS)</b>                          | <b>392</b>    | <b>488</b>    | <b>432</b>    | <b>538</b>    |
| Interest (expense) income, net                          | 3,949         | -2,094        | 4,355         | -2,310        |
| Currency exchange gains (loss), net                     | 103           | 699           | 114           | 771           |
| Other income (loss), net                                | -             | -             | -             | -             |
| <b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b> | <b>4,444</b>  | <b>-907</b>   | <b>4,901</b>  | <b>-1,001</b> |

|   |              |               |              |               |
|---|--------------|---------------|--------------|---------------|
| Income tax (expense) credit   | -602         | -759          | -663         | -838          |
| <b>NET INCOME (LOSS)</b>  | <b>3,842</b> | <b>-1,667</b> | <b>4,238</b> | <b>-1,839</b> |
| Earning per share - Basic   | 0.14         | -0.07         | 0.15         | -0.07         |
| Average number of shares used in computation of EPS                         | 27,823,313   | 25,021,966    | 27,823,313   | 25,021,966    |
| Earning per share - Diluted   | 0.13         | -0.07         | 0.14         | -0.07         |
| Average number of shares used in computation of EPS for positive net income | 29,365,583   | 25,021,966    | 29,365,583   | 25,021,966    |

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2016 average twelve months noon buying rate of 1 Euro = 1.1029 USD, and 2015 average twelve months noon buying rate of 1 Euro = 1.1033 USD.

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

|   | Dec. 31, 2016 | Sept. 30, 2016 | Dec. 31, 2016 | Sept. 30, 2016 |
|---|---------------|----------------|---------------|----------------|
|   | Euros         | Euros          | \$US          | \$US           |
| Cash, cash equivalents and short term investments | 21,989        | 18,837         | 23,202        | 21,170         |
| Total current assets                              | 40,514        | 40,694         | 42,750        | 45,734         |
| Total current liabilities                         | 15,010        | 14,547         | 15,838        | 16,349         |
| Shareholders' Equity                              | 24,451        | 25,739         | 25,800        | 28,926         |

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0552 USD, on December 31, 2016 and at the noon buying rate of 1 Euro = 1.1238 USD, on September 30, 2016.

**EDAP TMS S.A.**  
**CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2016**  
**(Amounts in thousands of Euros)**

|                                 | HIFU Division       | UDS Division        | Corporate     | Total After Consolidation |
|---------------------------------|---------------------|---------------------|---------------|---------------------------|
| Sales of goods                  | 9,382               | 14,664              |               | 24,045                    |
| Sales of RPPs & Leases          | 3,547               | 1,359               |               | 4,906                     |
| Sales of spare parts & services | 862                 | 5,766               |               | 6,628                     |
| <b>TOTAL NET SALES</b>          | <b>13,791</b>       | <b>21,789</b>       |               | <b>35,579</b>             |
| Other revenues                  | 28                  | 4                   |               | 32                        |
| <b>TOTAL REVENUES</b>           | <b>13,819</b>       | <b>21,792</b>       |               | <b>35,611</b>             |
| <b>GROSS PROFIT</b>             |                     |                     |               |                           |
| <b>(% of Total Revenues)</b>    | <b>8,109 58.70%</b> | <b>8,302 38.10%</b> |               | <b>16,411 46.10%</b>      |
| Research & Development          | -2,452              | -1,416              |               | -3,868                    |
| Total SG&A plus depreciation    | -4,692              | -6,145              | -1,315        | -12,152                   |
| <b>OPERATING PROFIT (LOSS)</b>  | <b>964</b>          | <b>742</b>          | <b>-1,315</b> | <b>392</b>                |

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