



## **EDAP TMS SA : EDAP Reports 2017 Annual Results**

March 27, 2018

### **2017 Highlights**

- 2017 revenue on par with 2016; lower HIFU capital equipment sales offset by double-digit HIFU treatment revenue growth
- CMS issued C-Code allocation for reimbursement of HIFU for prostate tissue ablation in July
- CIGNA to reimburse HIFU as salvage therapy for prostate cancer patients, at the start of 2018
- Meeting scheduled for April 4 with FDA to advance on Focal One clearance final steps
- 20% growth in our USD division, including lithotripsy, keeps EDAP among world urology leaders
- Solid liquidity position with cash balance of EUR 20.0 million as of December 31, 2017

LYON, France, March 27, 2018 -- EDAP TMS SA (Nasdaq:EDAP) ("the Company"), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and twelve months ended December 31, 2017, and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, commented: "While 2017 revenue did not meet our expectations due to weak HIFU device sales, we achieved several notable milestones and are encouraged by our commercial and clinical progress as we begin 2018. The decline in our HIFU sales was driven primarily by the decision by U.S. hospital customers to delay purchases of a HIFU system while waiting for Focal One clearance. However, adoption of HIFU continues to grow as more physicians gain comfort and experience with this minimally invasive treatment option. CMS's issuance of a C-Code to reimburse HIFU for prostate tissue ablation and Cigna's decision to reimburse HIFU as a salvage therapy also provide important validation for our technology."

Mr. Oczachowski continued, "We were also pleased to secure FDA clearance of our Ablatherm Fusion device and look forward to further discussion with the FDA regarding our 510(k) submission for Focal One. A meeting is scheduled with the FDA on April 4<sup>th</sup>, 2018 to clarify and reach a common understanding on the new clinical data submitted in our last application".

### **Fourth Quarter 2017 Results**

Total revenue for the fourth quarter 2017 was EUR 10.6 million (USD 12.6 million), stable as compared to EUR 10.7 million (USD 11.4 million) for the fourth quarter of 2016.

Total revenue in the HIFU business for the fourth quarter was EUR 2.5 million (USD 2.9 million), a 46.5% decrease compared to EUR 4.6 million (USD 4.9 million) for the fourth quarter of 2016. This decrease was caused in part by the decision of some hospital customers to delay purchasing a HIFU device until the FDA issues a verdict on the Company's 510(k) submission for its Focal One device.

For the three months ended December 31, 2017, total revenue for the Lithotripsy division was EUR 8.2 (USD 9.7 million), a 33.9% increase compared to EUR 6.1 million (USD 6.5 million) during the year-ago period.

Gross profit for the fourth quarter 2017 was EUR 4.4 million (USD 5.3 million), compared to EUR 5.2 million (USD 5.6 million) for the year-ago period. Gross profit margin on net sales was 41.8% in the fourth quarter of 2017, compared to 48.8% in the year-ago period.

Operating expenses were EUR 4.6 million (USD 5.5 million) for the fourth quarter of 2017, compared to EUR 4.9 million (USD 5.2 million) for the same period in 2016.

Operating loss for the fourth quarter 2017 was EUR 0.2 million (USD 0.2 million), compared to an operating profit of EUR 0.3 million (USD 0.4 million) in the fourth quarter of 2016.

Net loss for the fourth quarter 2017 was EUR 91 thousand (USD 108 thousand), or a loss of EUR 0.00 per diluted share, as compared to a net loss of EUR 1.3 million (USD 1.4 million), or a loss of EUR 0.04 per diluted share in the year-ago period. Net income in the fourth quarter of 2017 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 2017 Results**

Total revenue for 2017 was EUR 35.7 million (USD 40.7 million), stable compared to EUR 35.6 million (USD 39.3 million) for the year ended December 31, 2016.

Total revenue in the HIFU business for 2017 was EUR 9.5 million (USD 10.8 million), a decrease of 31.2% compared to EUR 13.8 million (USD 15.2 million) for the year ended December 31, 2016.

Total revenue in the Lithotripsy business for 2017 was EUR 26.2 million (USD 29.9 million), an increase of 20.4% compared to EUR 21.8 million (USD 24.0 million) for the year ended December 31, 2016.

Gross profit for 2017 was EUR 14.8 million (USD 16.9 million), with gross profit margin on net sales of 41.5%, compared to 46.1% during the prior year period.

The Company recorded an operating loss for 2017 of EUR 2.0 million (USD 2.3 million), compared to an operating profit of EUR 0.4 million (USD 0.4 million) during the prior year period.

Full-year net loss was EUR 0.7 million (USD 0.8 million), or a loss of EUR 0.02 per diluted share, as compared to a net profit of EUR 3.8 million (USD 4.2 million), or a profit of EUR 0.13 per diluted share in 2016. Full-year net income included non-cash interest income of EUR 2.7 million (USD 3.0 million) to adjust the accounting fair value of the outstanding warrants.

At December 31, 2017, cash and cash equivalents were EUR 20.0 million (USD 24.0 million).

### **Conference Call**

An accompanying conference call will be conducted by Philippe Chauveau, Chairman of the Board; Marc Oczachowski, Chief Executive Officer; and François Dietsch, Chief Financial Officer, to review the results. The call will be held at 8:30 AM ET, on Wednesday, March 28, 2018. Please refer to the information below for conference call dial-in information and webcast registration.

#### Conference Call & Webcast

Wednesday, March 28, 2018 @ 8:30am Eastern Time

Domestic: 800-263-0877

International: 323-794-2094

Passcode: 8625502

Webcast: <http://public.viavid.com/index.php?id=128794>

Or on Company's web site: <http://investor.edap-tms.com/events-and-presentations>

Replays, Available through April 11, 2018:

Domestic: 844-512-2921

International: 412-317-6671

Replay PIN: 8625502

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

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® (currently pending FDA clearance) in 2013 as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. For more information on the Company, please visit <https://www.edap-tms.com>, and [us.hifu-prostate.com](http://us.hifu-prostate.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.

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**EDAP TMS S.A.**  
**UNAUDITED 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, 2017 Euros	December 31, 2016 Euros	December 31, 2017 \$US	December 31, 2016 \$US
Sales of medical equipment	7,213	7,566	8,552	8,093
Net Sales of RPP and Leases	1,219	1,231	1,446	1,317
Sales of spare parts, supplies and Services	2,177	1,875	2,581	2,006
<b>TOTAL NET SALES</b>	<b>10,610</b>	<b>10,672</b>	<b>12,578</b>	<b>11,417</b>
Other revenues	16	22	20	24
<b>TOTAL REVENUES</b>	<b>10,626</b>	<b>10,695</b>	<b>12,598</b>	<b>11,441</b>
Cost of sales	(6,193)	(5,492)	(7,342)	(5,875)
<b>GROSS PROFIT</b>	<b>4,433</b>	<b>5,203</b>	<b>5,256</b>	<b>5,566</b>
Research & development expenses	(1,099)	(1,135)	(1,302)	(1,214)
S, G & A expenses	(3,513)	(3,733)	(4,164)	(3,994)
Total operating expenses	(4,611)	(4,868)	(5,467)	(5,208)
<b>OPERATING PROFIT (LOSS)</b>	<b>(178)</b>	<b>335</b>	<b>(211)</b>	<b>358</b>

Interest (expense) income, net	414	(444)	490	(475)
Currency exchange gains (loss), net	(134)	(698)	(159)	(746)
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>100</b>	<b>(807)</b>	<b>119</b>	<b>(863)</b>
Income tax (expense) credit	(192)	(471)	(227)	(504)
<b>NET INCOME (LOSS)</b>	<b>(91)</b>	<b>(1,278)</b>	<b>(108)</b>	<b>(1,367)</b>
Earning per share - Basic	(0.00)	(0.04)	(0.00)	(0.05)
Average number of shares used in computation of EPS	28,997,866	28,727,616	28,997,866	28,727,616
Earning per share - Diluted	(0.00)	(0.04)	(0.00)	(0.05)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,727,616	28,997,866	28,727,616

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2017 average three months' noon buying rate of 1 Euro = 1.1855 USD, and 2016 average three months noon buying rate of 1 Euro = 1.0697 USD.

**EDAP TMS S.A.**  
**UNAUDITED 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, 2017 Euros	December 31, 2016 Euros	December 31, 2017 \$US	December 31, 2016 \$US
Sales of medical equipment	22,580	24,045	25,732	26,520
Net Sales of RPP and Leases	5,095	4,906	5,806	5,411
Sales of spare parts, supplies and Services	8,011	6,628	9,130	7,310
<b>TOTAL NET SALES</b>	<b>35,686</b>	<b>35,579</b>	<b>40,668</b>	<b>39,240</b>
Other revenues	60	32	68	35
<b>TOTAL REVENUES</b>	<b>35,746</b>	<b>35,611</b>	<b>40,736</b>	<b>39,276</b>
Cost of sales	(20,938)	(19,200)	(23,861)	(21,176)
<b>GROSS PROFIT</b>	<b>14,808</b>	<b>16,411</b>	<b>16,875</b>	<b>18,100</b>
Research & development expenses	(3,881)	(3,868)	(4,423)	(4,266)
S, G & A expenses	(12,954)	(12,152)	(14,762)	(13,402)
Total operating expenses	(16,835)	(16,019)	(19,185)	(17,668)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,027)</b>	<b>392</b>	<b>(2,310)</b>	<b>432</b>
Interest (expense) income, net	2,643	3,949	3,011	4,355
Currency exchange gains (loss), net	(909)	103	(1,036)	114
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(294)</b>	<b>4,444</b>	<b>(335)</b>	<b>4,901</b>
Income tax (expense) credit	(388)	(602)	(442)	(663)
<b>NET INCOME (LOSS)</b>	<b>(681)</b>	<b>3,842</b>	<b>(776)</b>	<b>4,238</b>
Earning per share - Basic	(0.02)	0.14	(0.02)	0.15
Average number of shares used in computation of EPS	28,961,928	27,823,313	28,961,928	27,823,313
Earning per share - Diluted	(0.02)	0.13	(0.02)	0.14
Average number of shares used in computation of EPS for positive net income	28,961,928	29,365,583	28,961,928	29,365,583

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2017 average twelve months noon buying rate of 1 Euro = 1.1396 USD, and 2016 average twelve months noon buying rate of 1 Euro = 1.1029 USD.

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

Dec. 31, 2017 Euros	Sept. 30, 2017 Euros	Dec. 31, 2017 \$US	Sept. 30, 2017 \$US
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Cash, cash equivalents and short term investments	20,004	18,036	24,049	21,306
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Total current assets	39,738	37,172	47,774	43,912
Total current liabilities	16,134	12,676	19,397	14,975
Shareholders' Equity	25,158	24,947	30,246	29,471

**NOTE:** Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2022 USD, on December 31, 2017 and at the noon buying rate of 1 Euro = 1.1813 USD, on September 30, 2017.

**EDAP TMS S.A.**  
**UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**TWELVE MONTHS ENDED DECEMBER 31, 2017**  
**(Amounts in thousands of Euros)**

	HIFU Division		UDS Division		Corporate	Total After Consolidation	
Sales of goods	4,232		18,348			22,580	
Sales of RPPs & Leases	3,800		1,295			5,095	
Sales of spare parts & services	1,445		6,566			8,011	
<b>TOTAL NET SALES</b>	<b>9,477</b>		<b>26,210</b>			<b>35,686</b>	
Other revenues	36		23			60	
<b>TOTAL REVENUES</b>	<b>9,513</b>		<b>26,233</b>			<b>35,746</b>	
<b>GROSS PROFIT</b> <b>(% of Total Revenues)</b>	<b>4,782</b>	<b>50.3%</b>	<b>10,026</b>	<b>38.2%</b>		<b>14,808</b>	<b>41.4%</b>
Research & Development	(2,469)		(1,413)			(3,881)	
Total SG&A plus depreciation	(5,014)		(6,578)		(1,362)	(12,954)	
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,701)</b>		<b>2,035</b>		<b>(1,362)</b>	<b>(2,027)</b>	

[Primary Logo](#)

Source: EDAP TMS S.A.