

EDAP TMS SA : EDAP Reports 2018 Second Quarter Results

Aug 29, 2018

- Receives FDA clearance for novel Focal One device for prostate tissue ablation

LYON, France, August 29, 2018 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in therapeutic ultrasound, announced today financial results for the second quarter of 2018 and provided a strategic and operational update. Management will host a conference call on Thursday, August 30th at 8:30 ET.

Marc Oczachowski, EDAP's Chief Executive Officer, said: "During the second quarter, we achieved a significant milestone with the FDA clearance of our Focal One device for the targeted ablation of prostate tissue. With its exclusive Dynamic Focusing Technology, combined with unique imaging and diagnostic features, we believe Focal One is superior to currently available HIFU devices, and represents a leap forward in the minimally invasive management of prostate tissue ablation. We have already commenced marketing this novel HIFU technology to the urology community, and look forward to providing further updates on our sales momentum on future calls."

First Six Months 2018 Results

Total revenue for the first half of 2018 was EUR 17.8 million (USD 21.4 million), a 1.3% decrease compared to EUR 18.0 million (USD 19.7 million) for the first half of 2017.

Total revenue in the HIFU division for the first six months 2018 was EUR 4.8 million (USD 5.7 million) compared to EUR 5.2 million (USD 5.7 million) for the six months ended June 30, 2017.

For the six months ended June 30, 2018, total revenue for the Lithotripsy division was EUR 13.0 million (USD 15.7 million), a 1.9% increase compared to EUR 12.8 million (USD 14.0 million), during the year ago period.

Gross profit for the first half of 2018 was EUR 7.6 million (USD 9.1 million) and gross profit margin was 42.6%, compared to 42.1% in the year ago period.

Operating expenses were EUR 9.0 million (USD 10.9 million) for the first six months of 2018, compared to EUR 8.4 million (USD 9.2 million) for the same period in 2017.

The Company recorded an operating loss for the first half of 2018 of EUR 1.5 million (USD 1.8 million), compared with an operating loss of EUR 0.8 million (USD 0.9 million) in the first six months of 2017.

Net loss for the first half of 2018 was EUR 0.7 million (USD 0.8 million), or a loss of EUR 0.02 per diluted share, as compared to a net loss of EUR 0.1 million (USD 0.1 million), or EUR 0.00 per diluted share, in the first half of 2017. Net loss for the first six months of 2018 included non-cash interest income of EUR 0.5 million (USD 0.6 million) to adjust the accounting fair value of the outstanding warrants

Second Quarter 2018 Results

Total revenue for the second quarter 2018 was EUR 8.6 million (USD 10.2 million), a 7.7% decrease compared to EUR 9.3 million (USD 10.4 million) for the second quarter of 2017.

Total revenue in the HIFU business for the second quarter 2018 was EUR 2.3 million (USD 2.7 million), a 20.2% decline compared to EUR 2.9 million (USD 3.2 million) for the second quarter of 2017.

For the three months ended June 30, 2018, total revenue for the Lithotripsy division was EUR 6.3 (USD 7.4 million), a 2.0% decrease compared to EUR 6.4 million (USD 7.2 million) during the prior year period.

Gross profit for the second quarter 2018 was EUR 3.6 million (USD 4.2 million), compared to EUR 4.0 million (USD 4.5 million) for the year-ago period. Gross profit margin on net sales was 41.3% in the second quarter of 2018, compared to 43.2% in the second quarter of 2017.

Operating expenses were EUR 4.6 million (USD 5.5 million) for the second quarter of 2018, compared to EUR 4.4 million (USD 5.0 million) for the same period in 2017.

Operating loss for the second quarter 2018 was EUR 1.1 million (USD 1.3 million), compared to an operating loss of EUR 0.4 million (USD 0.5 million) in the second quarter of 2017.

Net loss for the second quarter 2018 was EUR 0.8 million (USD 0.9 million), or a loss of EUR 0.03 per diluted share, as compared to a net loss of EUR 1.7 million (USD 2.0 million), or a loss of EUR 0.06 per diluted share in the year-ago period.

At June 30, 2018, cash and cash equivalents, including short-term treasury investments, were EUR 17.2 million (USD 20.7 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 Thursday August 30, 2018. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, August 30, 2018 @ 8:30am Eastern Time

Domestic: 800-239-9838

International: 323-794-2551

Passcode: 9816635

Webcast: <http://public.viavid.com/index.php?id=130698>

Replays, Available through September 13, 2018:

Domestic: 844-512-2921

International: 412-317-6671

Replay PIN: 9816635

Following the live call, a replay will be available on the Company's website, 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® in 2013 in Europe and in 2018 in the U.S. 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 <http://www.edap-tms.com>, and 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:

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Months Ended:

	June 30, 2018 Euros	June 30, 2017 Euros	June 30, 2018 \$US	June 30, 2017 \$US
Sales of goods	5,178	5,966	6,114	6,670
Net Sales of RPP and Leases	1,270	1,304	1,500	1,458
Sales of spare parts, supplies and Services				2,277
	2,141	2,037	2,528	
TOTAL NET SALES	8,590	9,307	10,141	10,405
Other revenues	14	13	17	15
TOTAL REVENUES	8,604	9,320	10,158	10,420
Cost of sales	(5,053)	(5,304)	(5,966)	(5,931)
GROSS PROFIT	3,550	4,016	4,191	4,489
Research & development expenses	(1,199)	(969)	(1,416)	(1,083)
S, G & A expenses	(3,431)	(3,477)	(4,050)	(3,887)
Total operating expenses	(4,630)	(4,446)	(5,466)	(4,970)
OPERATING PROFIT (LOSS)	(1,080)	(430)	(1,275)	(481)
Interest (expense) income, net	(111)	(575)	(131)	(643)
Currency exchange gains (loss), net	470	(625)	555	(699)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(721)	(1,630)	(851)	(1,823)
Income tax (expense) credit	(46)	(117)	(55)	(130)
NET INCOME (LOSS)	(767)	(1,747)	(906)	(1,953)

Earning per share - Basic	(0.03)	(0.06)	(0.03)	(0.07)
Average number of shares used in computation of EPS	28,997,866	28,997,866	28,997,866	28,997,866
Earning per share - Diluted	(0.03)	(0.06)	(0.03)	(0.07)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,997,866	28,997,866	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2018 average three months' noon buying rate of 1 Euro = 1.1806 USD, and 2017 average three months noon buying rate of 1 Euro = 1.1181USD.

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

Months Ended:	Six Months Ended:		Six	
	June 30, 2018 Euros	June 30, 2017 Euros	June 30, 2018 \$US	June 30, 2017 \$US
Sales of goods	10,929	11,478	13,184	12,559
Net Sales of RPP and Leases	2,480	2,599	2,992	2,844
Sales of spare parts, supplies and Services				4,244
	4,338	3,879	5,233	
TOTAL NET SALES	17,748	17,956	21,409	19,647
Other revenues	14	40	17	43
TOTAL REVENUES	17,762	17,996	21,426	19,690
Cost of sales	(10,201)	(10,427)	(12,305)	(11,410)
GROSS PROFIT	7,561	7,569	9,121	8,280
Research & development expenses	(2,200)	(1,865)	(2,653)	(2,040)
S, G & A expenses	(6,843)	(6,551)	(8,255)	(7,169)

Total operating expenses	(9,043)	(8,416)	(10,908)	(9,209)
OPERATING PROFIT (LOSS)	(1,482)	(847)	(1,787)	(929)
Interest (expense) income, net	528	1,408	637	1,541
Currency exchange gains (loss), net	456	(450)	550	(492)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(498)	111	(601)	120
Income tax (expense) credit	(180)	(175)	(218)	(191)
NET INCOME (LOSS)	(679)	(64)	(819)	(71)

Earning per share - Basic	(0.02)	(0.00)	(0.03)	(0.00)
Average number of shares used in computation of EPS	28,997,866	28,919,984	28,997,866	28,919,984
Earning per share - Diluted	(0.02)	(0.00)	(0.03)	(0.00)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,919,984	28,997,866	28,919,984

NOTE: Translated for convenience of the reader to U.S. dollars at the 2018 average six months' noon buying rate of 1 Euro = 1.2063 USD, and 2017 average six months noon buying rate of 1 Euro = 1.0942 USD.

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

June 30,	Mar. 31,	June 31,	Mar. 31,
2018	2018	2018	2018
Euros	Euros	\$US	\$US

Cash, cash equivalents and short term investments	17,203	18,142	20,087	22,351
Total current assets	38,535	37,734	44,997	46,687
Total current liabilities	16,016	13,843	18,702	17,054
Shareholders' Equity	24,535	25,439	28,648	31,340

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1677 USD, on June 30, 2018 and at the noon buying rate of 1 Euro = 1.2320 USD, on March 31, 2018.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
SIX MONTHS ENDED JUNE 30, 2018
(Amounts in thousands of Euros)

Total After Consolidation

	HIFU Division	UDS Division	Corporate	
Sales of goods	2,082	8,848		10,929
Sales of RPPs & Leases	1,791	689		2,480
Sales of spare parts & services	870	3,469		4,338
TOTAL NET SALES	4,742	13,006		17,748
Other revenues	14	-		14
TOTAL REVENUES	4,756	13,006		17,762

GROSS PROFIT (% of Total Revenues)	2,326 48.9%	5,236 40.3%	7,561 42.6%
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Research & Development	(1,437)	(763)	(2,200)
Total SG&A plus depreciation	<u>(2,798)</u>	<u>(3,405)</u>	<u>(6,843)</u>

OPERATING PROFIT (LOSS)	(1,909)	1,068	(640)	(1,482)
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Source: EDAP TMS S.A.