EDAP Reports 2019 Second Quarter Results

Aug 28, 2019

- Third consecutive profitable quarter
- Positive reimbursement decision by the American Medical Association announced in June
- Significant improvement in gross profit margin from 41.3% in Q2 2018 to 50.7% in Q2 2019
- Q2 HIFU sales growth of 98% year-over-year
- Total Q2 revenues of EUR 12.5 million; +45% year-over-year, strongest Q2 to date

LYON, France, **August 28, 2019** -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in therapeutic ultrasound, announced today financial results for the second quarter of 2019 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, said: "We are very pleased with our second quarter results that demonstrated another period of robust HIFU revenue growth, significant gross margin expansion and profitability. We have now posted three consecutive profitable quarters, and we are confident that this type of growth and consistency in our results could be maintained going forward. We were very pleased with the American Medical Association's decision in June to accept our request for a Category 1 CPT code that will facilitate reimbursement for the ablation of malignant prostate tissue with HIFU technology. This is an important milestone for the adoption curve of HIFU technology, and, we believe will help our customers gain confidence in implementing next generation prostate cancer therapy programs. Importantly, we are still in the early stages of our Focal One marketing and sales development efforts, and as these activities continue, we expect to see continued robust expansion of our pipeline of sales prospects. We look forward to providing further updates on our progress in the coming months."

Second Quarter 2019 Results

Total revenue for the second quarter 2019 was EUR 12.5 million (USD 14.0 million), a 45.1% increase compared to EUR 8.6 million (USD 10.2 million) for the second quarter of 2018.

Total revenue in the HIFU business for the second quarter 2019 was EUR 4.6 million (USD 5.1 million), a 97.1% increase compared to EUR 2.3 million (USD 2.7 million) for the second quarter of 2018.

For the three months ended June 30, 2019, total revenue for the UDS division was EUR 7.9 million (USD 8.9 million), a 25.9% increase compared to EUR 6.3 million (USD 7.4 million) during the year-ago period.

Gross profit for the second quarter 2019 was EUR 6.3 million (USD 7.1 million), compared to EUR 3.6 million (USD 4.2 million) for the year-ago period. Gross profit margin on net sales was 50.7% in the second quarter of 2019, compared to 41.3% in the year-ago period.

Operating expenses were EUR 4.7 million (USD 5.3 million) for the second quarter of 2019, compared to EUR 4.6 million (USD 5.5 million) for the same period in 2018.

Operating profit for the second quarter 2019 was EUR 1.7 million (USD 1.9 million), compared to an operating loss of EUR 1.1 million (USD 1.3 million) in the second quarter of 2018.

Net income for the second quarter 2019 was EUR 1.4 million (USD 1.6 million), or earnings of EUR 0.05 per diluted share, as compared to a net loss of EUR 0.8 million (USD 0.9 million), or a loss of EUR 0.03 per diluted share in the year-ago period.

First six months 2019 Results

Total revenue for the first half of 2019 was EUR 22.6 million (USD 25.6 million), a 27.3% increase compared to EUR 17.8 million (USD 21.4 million) for the first half of 2018.

Total revenue in the HIFU business for the first six months of 2019 was EUR 8.4 million (USD 9.5 million), a 77.4% increase compared to EUR 4.8 million (USD 5.7 million) for the six months ended June 30, 2018.

For the six months ended June 30, 2019, total revenue for the UDS division was EUR 14.2 million (USD 16.0 million), a 9.0% increase compared to EUR 13.0million (USD 15.7 million) during the year-ago period.

Gross profit for the first half of 2019 was EUR 11.2 million (USD 12.6 million), compared to EUR 7.6 million (USD 9.1 million) for the year-ago period. Gross profit margin on net sales was 49.5% compared to 42.6% in the year-ago period.

Operating expenses were EUR 9.3 million (USD 10.5 million) for the first six months of 2019, compared to EUR 9.0 million (USD 10.9 million) for the same period in 2018.

Operating profit for the first half of 2019 was EUR 1.9 million (USD 2.1 million), compared to an operating loss of EUR 1.5 million (USD 1.8 million) in the first six months of 2018.

Net income for the first half of 2019 was EUR 1.7 million (USD 1.9 million), or earnings of EUR 0.06 per diluted share, as compared to a net loss of EUR 0.7 million (USD 0.8 million), or a loss of EUR 0.02 per diluted share in the year-ago period.

As of June 30, 2019, cash and cash equivalents, including short term investments, were EUR 16.3 million (USD 18.5 million).

Conference Call

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30am EDT on Thursday, August 29, 2019. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast
Thursday August 29th @ 8:30am Eastern Time
Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13693076
Webcast: http://public.viavid.com/index.php?id=135590

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 US 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:		Three Months Ended:	
	June 30, 2019 Euros	June 30, 2018 Euros	June 30, 2019 $US	June 30, 2018 $US

Sales of medical equipment	8,716	5,178	9,797	6,114
Net Sales of RPP and Leases	1,429	1,270	1,606	1,500
Sales of spare parts, supplies and Services	2,341	2,141	2,631	2,528
TOTAL NET SALES	**12,485**	**8,590**	**14,035**	**10,141**
Other revenues	-	14	-	17
TOTAL REVENUES	**12,485**	**8,604**	**14,035**	**10,158**
Cost of sales	(6,154)	(5,053)	(6,918)	(5,966)
GROSS PROFIT	**6,331**	**3,550**	**7,117**	**4,191**
Research & development expenses	(986)	(1,199)	(1,108)	(1,416)
S, G & A expenses	(3,691)	(3,431)	(4,149)	(4,050)
Total operating expenses	(4,677)	(4.630)	(5,257)	(5,466)
OPERATING PROFIT (LOSS)	**1,654**	**(1,080)**	**1,860**	**(1,275)**
Interest (expense) income, net	(32)	(111)	(36)	(131)
Currency exchange gains (loss), net	(161)	470	(181)	555
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**1,462**	**(721)**	**1,643**	**(851)**
Income tax (expense) credit	(82)	(46)	(92)	(55)
NET INCOME (LOSS)	**1,379**	**(767)**	**1,551**	**(906)**
Earning per share – Basic	0.05	(0.03)	0.05	(0.03)
Average number of shares used in computation of EPS	28,997,886	28,997,866	28,997,886	28,997,866
Earning per share – Diluted	0.05	(0.03)	0.05	(0.03)
Average number of shares used in computation of EPS for positive net income	29,604,779	28,997,866	29,604,779	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average three months' noon buying rate of 1 Euro = 1.1241 USD, and 2018 average three months noon buying rate of 1 Euro = 1.1806 USD.

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

	Six Months Ended:		**Six Months Ended:**	
	June 30, 2019 Euros	**June 30, 2018 Euros**	**June 30, 2019 $US**	**June 30, 2018 $US**
Sales of medical equipment	15,262	10,929	17,241	13,184
Net Sales of RPP and Leases	2,799	2,480	3,163	2,992
Sales of spare parts, supplies and Services	4,555	4,338	5,146	5,233
TOTAL NET SALES	**22,617**	**17,748**	**25,550**	**21,409**
Other revenues	-	14	-	17
TOTAL REVENUES	**22,617**	**17,762**	**25,550**	**21,426**
Cost of sales	(11,420)	(10,201)	(12,901)	(12,305)
GROSS PROFIT	**11,196**	**7,561**	**12,648**	**9,121**
Research & development expenses	(1,999)	(2,200)	(2,258)	(2,653)
S, G & A expenses	(7,335)	(6,843)	(8,286)	(8,255)
Total operating expenses	(9,334)	(9,043)	(10,544)	(10,908)
OPERATING PROFIT (LOSS)	**1,862**	**(1,482)**	**2,104**	**(1,787)**

Interest (expense) income, net	(63)	528	(71)	637
Currency exchange gains (loss), net	104	456	118	550
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**1,904**	**(498)**	**2,151**	**(601)**
Income tax (expense) credit	(197)	(180)	(223)	(218)
NET INCOME (LOSS)	**1,707**	**(679)**	**1,928**	**(819)**
Earning per share – Basic	0.06	(0.02)	0.07	(0.03)
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	0.06	(0.02)	0.07	(0.03)
Average number of shares used in computation of EPS for positive net income	29,630,567	28,997,866	29,630,567	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average six months' noon buying rate of 1 Euro = 1.1297 USD, and 2018 average six months noon buying rate of 1 Euro = 1.2063 USD.

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

	June 30, 2019 Euros	Mar. 31, 2019 Euros	June 30, 2019 $US	Mar. 31, 2019 $US
Cash, cash equivalents and short-term investments	16,257	18,555	18,491	20,834
Total current assets	40,749	39,904	46,348	44,806
Total current liabilities	16,357	16,837	18,604	18,905
Shareholders' Equity	26,780	25,266	30,460	28,370

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1374 USD, on June 30, 2019 and at the noon buying rate of 1 Euro = 1.1228 USD, on March 31, 2019.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
SIX MONTHS ENDED JUNE 30, 2019
(Amounts in thousands of Euros)

	HIFU Division		UDS Division		Reconciling Items	Total After Consolidation	
Sales of goods	5,602		9,659			15,262	
Sales of RPPs & Leases	1,973		827			2,799	
Sales of spare parts & services	862		3,694			4,555	
TOTAL NET SALES	**8,437**		**14,180**			**22,617**	
Other revenues	-		-			-	
TOTAL REVENUES	**8,437**		**14,180**			**22,617**	
GROSS PROFIT	**5,077**	**60.2%**	**6,119**	**43.2%**		**11,196**	**49.5%**
(% of Total Revenues)							
Research & Development	(1,068)		(931)			(1,999)	

Total SG&A plus depreciation	(2,668)	(3,971)	(696)	(7,335)
OPERATING PROFIT (LOSS)	**1,341**	**1,217**	**(696)**	**1,862**

Attachment

- EDAP Reports Q2 2019 - AUG 28 2019

Source: EDAP TMS S.A.