EDAP Reports Third Quarter 2020 Results and Provides Operational Update

Nov 18, 2020

- Generated strongest total revenue quarter of 2020
- Reported growth in HIFU procedure revenues year-over-year notwithstanding ongoing COVID-19 pandemic
- Completed sales to renowned healthcare institutions Mount Sinai Health System in New York and Keck Medical Center at the University of Southern California
- Announced first patients treated in Phase 2 clinical trial assessing Focal One® as a potential treatment for deep rectal endometriosis
- Increased strong cash position to EUR 19.9 million (USD 23.4 million) as of September 30, 2020
- Company to host a conference call tomorrow, November 19th, at 8:30 am ET

LYON, France, November 18, 2020 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), the global leader in robotic energy based therapies, announced today financial results for the third quarter of 2020 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "The third quarter of 2020 was our strongest of the year thus far, a clear signal that we are successfully navigating through the challenges posed by the ongoing COVID-19 pandemic. We closed several notable transactions during the quarter, including a bundled Focal One-ExactVu sale to Mount Sinai Health System in New York, and a Focal One sale to Keck Medical Center of University of Southern California, an early adopter of our first generation HIFU technology, Ablatherm®. At the same time, we continued to grow our sales pipeline, both in the U.S. and internationally.

"Also, during the quarter, we received regulatory approval to initiate a Phase 2 study assessing Focal One® as a potential treatment for deep rectal endometriosis and we initiated patient treatments quickly thereafter. Endometriosis represents an important expansion of our development pipeline as we work to maximize the clinical utility of HIFU across new indications beyond prostate.

"We ended the quarter with a strong cash position of $23.4 million, sufficient to continue to execute on our Focal One-ExactVu commercial plan while advancing HIFU in endometriosis and other soft tissue indications where we believe this non-invasive technology can be beneficial.

"With COVID cases again rising in many parts of the world, including most of the US, we are carefully monitoring the effect on our operations during the fourth quarter. While we are seeing some impact on procedure volumes as hospitals continue to focus on the pandemic, we are nonetheless optimistic that we will be able to announce additional sales by the end of the year," Mr. Oczachowski concluded.

Third Quarter 2020 Results

Total revenue for the third quarter 2020 was EUR 9.4 million (USD 11.2 million), a decrease of 8.5% compared to total revenue of EUR 10.3 million (USD 11.3 million) for the same period in 2019. Third quarter 2020 revenue reflects the impact of the ongoing COVID-19 pandemic on equipment sales.

Total revenue in the HIFU business for the third quarter 2020 was EUR 2.6 million (USD 3.0 million), a 7.9% decrease compared to EUR 2.8 million (USD 3.1 million) for the third quarter of 2019.

Total revenue in the LITHO business for the third quarter 2020 was EUR 2.4 million (USD 2.9 million), a 27.6% decrease compared to EUR 3.3 million (USD 3.7 million) for the third quarter of 2019

Total revenue in the Distribution business for the third quarter 2020 was EUR 4.4 million (USD 5.2 million), a 6.4% increase compared to EUR 4.2 million (USD 4.6 million) for the third quarter of 2019.

Gross profit for the third quarter 2020 was EUR 4.0 million (USD 4.7 million), compared to EUR 4.7 million (USD 5.1 million) for the year-ago period. Gross profit margin on net sales was 42.0% in the third quarter of 2020, compared to 45.3% in the year-ago period. The decline in gross profit year-over-year was due to in part to lower sales in HIFU business as compared to the year-ago period driven primary by COVID-19.

Operating expenses were EUR 4.3 million (USD 5.0 million) for the third quarter of 2020, compared to EUR 4.4 million (USD 4.9 million) for the same period in 2019.

Operating loss for the third quarter of 2020 was EUR 0.3 million (USD 0.3 million), compared to an operating profit of EUR 0.3 million (USD 0.3 million) in the third quarter of 2019.

Net loss for the third of 2020 was EUR 1.0 million (USD 1.2 million), or EUR (0.03) per diluted share, as compared to net income of EUR 0.8 million (USD 0.9 million), or EUR 0.03 per diluted share in the year-ago period.

For the first nine months 2020 Results

Total revenue for the first nine months of 2020 was EUR 26.3 million (USD 29.8 million), a decrease of 20.1% compared to total revenue of EUR 32.9 million (USD 36.9 million) for the same period in 2019. As mentioned, year-to-date revenue reflects the impact of the ongoing COVID-19 pandemic on the company's activities.

Total revenue in the HIFU business for the first nine months of 2020 was EUR 7.1 million (USD 8.0 million), a 37.2% decrease compared to EUR 11.2 million (USD 12.6 million) for the first nine months of 2019.

Total revenue in the LITHO business for the first nine months of 2020 was EUR 8.3 million (USD 9.4 million), a 17.8% decrease compared to EUR 10.1 million (USD 11.3 million) for the first nine months of 2019.

Total revenue in the Distribution business for the first nine months of 2020 was EUR 11.0 million (USD 12.4 million), a 5.6% decrease compared to EUR 11.6 million (USD 13.0 million) for the first nine month of 2019.

Gross profit for the first nine months of 2020 was EUR 11.4 million (USD 12.8 million), compared to EUR 15.9 million (USD 17.8 million) for the year-ago period. Gross profit margin on net sales was 43.2% for the first nine months of 2020, compared to 48.2% in the year-ago period. The decline in gross profit year-over-year was due in part to lower sales in the HIFU business driven by COVID-19.

Operating expenses were EUR 12.8 million (USD 14.5 million) for the first nine months of 2020, compared to EUR 13.7 million (USD 15.4 million) for the same period in 2019.

Operating loss for the first nine months of 2020 was EUR 1.5 million (USD 1.6 million), compared to an operating profit of EUR 2.1 million (USD 2.4 million) for the same period of 2019.

Net loss for the first nine months of 2020 was EUR 2.5 million (USD 2.8 million), or EUR (0.09) per diluted share, as compared to a net income of EUR 2.5 million (USD 2.8 million), or EUR 0.09 per diluted share in the year-ago period.

As of September 30, 2020, the Company recorded a strong cash position of EUR 19.9 million (USD 23.4 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 tomorrow, November 19, 2020. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast
Thursday, November 19, 2020 @ 8:30am Eastern Time

Domestic:	877-451-6152
International:	201-389-0879
Passcode:	13712293
Webcast:	http://public.viavid.com/index.php?id=142115

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, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies 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 Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device,EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). 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 contains 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 and distribution divisions, as well as the length and severity of the COVID-19 pandemic, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference may also 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:	
	Sept. 30, 2020 Euros	**Sept. 30, 2019 Euros**	**Sept. 30, 2020 $US**	**Sept. 30, 2019 $US**
Sales of medical equipment	5,984	6,877	7,080	7,571
Net Sales of RPP and Leases	1,207	1,228	1,428	1,352
Sales of spare parts, supplies and Services	2,255	2,187	2,668	2,407
TOTAL NET SALES	**9,446**	**10,292**	**11,176**	**11,330**
Other revenues	(13)	15	(16)	17
TOTAL REVENUES	**9,433**	**10,307**	**11,160**	**11,347**
Cost of sales	(5,469)	(5,641)	(6,470)	(6,209)
GROSS PROFIT	**3,964**	**4,667**	**4,690**	**5,137**
Research & development expenses	(1,090)	(886)	(1,289)	(975)
S, G & A expenses	(3,167)	(3,522)	(3,748)	(3,877)
Total operating expenses	(4,257)	(4,408)	(5,037)	(4,852)
OPERATING PROFIT (LOSS)	**(293)**	**259**	**(347)**	**285**
Interest (expense) income, net	(12)	(40)	(14)	(44)
Currency exchange gains (loss), net	(574)	684	(679)	753
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(879)**	**903**	**(1,040)**	**994**
Income tax (expense) credit	(122)	(120)	(145)	(132)
NET INCOME (LOSS)	**(1,001)**	**783**	**(1,185)**	**862**
Earning per share – Basic	(0.03)	0.03	(0.04)	0.03
Average number of shares used in computation of EPS	29,144,010	28,997,886	29,144,010	28,997,886
Earning per share – Diluted	(0.03)	0.03	(0.04)	0.03
Average number of shares used in computation of EPS for positive net income	29,144,010	29,622,866	29,144,010	29,622,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average three months' noon buying rate of 1 Euro = 1.1832 USD, and 2019 average three months noon buying rate of 1 Euro = 1.1008 USD

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

	Nine Months Ended:		Nine Months Ended:	
	Sept. 30, 2020 Euros	Sept. 30, 2019 Euros	Sept. 30, 2020 $US	Sept. 30, 2019 $US
Sales of medical equipment	16,083	22,139	18,204	24,797
Net Sales of RPP and Leases	3,409	4,028	3,858	4,512
Sales of spare parts, supplies and Services	6,795	6,742	7,691	7,551
TOTAL NET SALES	**26,287**	**32,909**	**29,753**	**36,860**
Other revenues	11	15	12	17
TOTAL REVENUES	**26,298**	**32,924**	**29,765**	**36,877**
Cost of sales	(14,948)	(17,061)	(16,919)	(19,110)
GROSS PROFIT	**11,350**	**15,863**	**12,846**	**17,768**
Research & development expenses	(3,058)	(2,884)	(3,461)	(3,231)
S, G & A expenses	(9,743)	(10,857)	(11,027)	(12,161)
Total operating expenses	(12,800)	(13,742)	(14,488)	(15,392)
OPERATING PROFIT (LOSS)	**(1,451)**	**2,121**	**(1,642)**	**2,376**
Interest (expense) income, net	(51)	(103)	(58)	(115)
Currency exchange gains (loss), net	(631)	788	(714)	883
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(2,133)**	**2,807**	**(2,415)**	**3,144**
Income tax (expense) credit	(351)	(317)	(397)	(356)
NET INCOME (LOSS)	**(2,484)**	**2,490**	**(2,812)**	**2,789**
Earning per share – Basic	(0.09)	0.09	(0.10)	0.10
Average number of shares used in computation of EPS	29,142,788	28,997,866	29,142,788	28,997,866
Earning per share – Diluted	(0.09)	0.08	(0.10)	0.09
Average number of shares used in computation of EPS for positive net income	29,142,788	29,623,683	29,142,788	29,623,683

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average nine months' noon buying rate of 1 Euro = 1.1319 USD, and 2019 average nine months noon buying rate of 1 Euro = 1.1201 USD

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

	Sept. 30, 2020 Euros	June. 30, 2020 Euros	Sept. 30, 2020 $US	June 30, 2020 $US
Cash, cash equivalents and short-term treasury investments	19,929	15,704	23,364	17,647
Account receivables, net	11,572	12,607	13,567	14,167
Inventory	9,455	9,365	11,084	10,523
Other current assets	604	631	708	709
TOTAL CURRENT ASSETS	**41,560**	**38,307**	**48,722**	**43,046**
Property, plant and equipment, net	5,928	6,072	6,950	6,823
Goodwill	2,412	2,412	2,827	2,710
Other non-current assets	1,739	1,794	2,039	2,016
TOTAL ASSETS	**51,639**	**48,585**	**60,538**	**54,596**
Accounts payable & other accrued liabilities	9,122	9,618	10,694	10,808
Deferred revenues, current portion	2,695	2,519	3,160	2,831
Short term borrowing	1,459	887	1,711	997
Other current liabilities	5,825	1,820	6,829	2,045
TOTAL CURRENT LIABILITIES	**19,102**	**14,845**	**22,394**	**16,681**
Obligations under operating and finance leases non-current	1,724	1,906	2,021	2,141

Long term debt, non-current	1,219	1,193	1,429	1,341
Deferred revenues, non-current	821	1,100	963	1,236
Other long term liabilities	3,626	3,673	4,251	4,128
TOTAL LIABILITIES	**26,493**	**22,717**	**31,059**	**25,528**
TOTAL SHAREHOLDERS'EQUITY	**25,146**	**25,867**	**29,480**	**29,068**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**51,639**	**48,585**	**60,538**	**54,596**

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1723 USD, on September 30, 2020 and at the noon buying rate of 1 Euro = 1.1237 USD, on June 30, 2020.

EDAP TMS S.A.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of Euros)

	Sept. 30, 2020 Euros	June 30, 2020 Euros	Sept. 30, 2020 $US	June 30 2020 $US
NET INCOME (LOSS)	**(2,484)**	**(1,483)**	**(2,812)**	**(1,640)**
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities	2,211	1,457	2,503	1,612
OPERATING CASH FLOW	**(273)**	**(25)**	**(309)**	**(28)**
Increase/Decrease in operating assets and liabilities	(1,735)	(1,774)	(1,964)	(1,963)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**(2,008)**	**(1,799)**	**(2,273)**	**(1,991)**
Short term investments[(1)]	(1,708)	(1,786)	(1,933)	(1,976)
Additions to capitalized assets produced by the company and other capital expenditures	(1,508)	(844)	(1,707)	(933)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(3,216)**	**(2,630)**	**(3,640)**	**(2,909)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**2,248**	**(2,444)**	**2,544**	**(2,704)**
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**312**	**(44)**	**1,281**	**(204)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(2,665)**	**(6,968)**	**(2,088)**	**(7,808)**

[(1)] *Short term investments are comprised of money market funds*

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average nine months' noon buying rate of 1 Euro = 1.1319 USD, and 2019 average nine months noon buying rate of 1 Euro = 1.1201 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2020
(Amounts in thousands of Euros)

	HIFU Division	ESWL Division	Distribution Division	Reconciling Items	Total After Consolidation
Sales of goods	3,095	3,408	9,580		16,083
Sales of RPPs & Leases	2,594	659	156		3,409

Sales of spare parts & services	1,351		4,217		1,226			6,795	
TOTAL NET SALES	**7,041**		**8,284**		**10,962**			**26,287**	
Other revenues	11		0		0			11	
TOTAL REVENUES	**7,052**		**8,284**		**10,962**			**26,298**	
GROSS PROFIT (% of Total Revenues)	**3,877**	**55.0 %**	**3,490**	**42.1%**	**3,982**	**36.3%**		**11,350**	**43.2%**
Research & Development	(1,763)		(1,006)		(289)			(3,058)	
Total SG&A plus depreciation	(2,870)		(2,154)		(3,599)		(1,119)	(9,743)	
OPERATING PROFIT (LOSS)	**(756)**		**331**		**94**		**(1,119)**	**(1,451)**	

Attachment

- 2020-11-18 -- EDAP 3Q 2020 Press Release Final

Source: EDAP TMS S.A.