EDAP Reports First Quarter 2021 Results and Provides Operational Update

May 11, 2021

- Generated record first quarter revenue of EUR 10.3 million (USD 12.4 million), an increase of 35.4% year-over-year
- Increased gross margin year-over-year to 42.4%, contributing to a profitable quarter
- Raised gross proceeds of approximately $28 million through an underwritten offering of American Depository Shares (ADSs)
- Strong cash position of EUR 24.4 million (USD 28.6 million) as of March 31, 2021, excluding $28 million of gross proceeds raised in April
- Company to host a conference call tomorrow, May 12, at 8:30 am ET

LYON, France, May 11, 2021 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the first quarter of 2021 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "We are thrilled to have completed a successful offering in April which, added to our existing strong cash position, provides funding to achieve potentially value-creating milestones across all aspects of our business. We are acutely focused on driving accelerating growth in the US by building market access and coverage now that our Category 1 CPT code is in place. We also continue to advance our Phase 2 endometriosis program and have now opened a second trial site in France where we commenced patient treatments last week.

"While we continue to experience some effect of COVID-19 on our operations, we are pleased with the global performance of our business as compared to the first quarter of last year. We grew revenue by 35.4%, expanded our gross margin to 42.4%, and generated a profitable quarter for the company. We also saw continued growth in our Focal One and HIFU treatments in the US, reflecting increasing awareness and adoption of our next generation HIFU technology."

"In summary, with our strong balance sheet and US growth initiatives continuing to gain traction, I believe we are well positioned to drive growing adoption of HIFU for the management of prostate cancer in 2021," Mr. Oczachowski concluded.

First Quarter 2021 Results

Total revenue for the first quarter 2021 was EUR 10.3 million (USD 12.4 million), an increase of 35.4% compared to total revenue of EUR 7.6 million (USD 8.4 million) for the same period in 2020.

Total revenue in the HIFU business for the first quarter 2021 was EUR 1.8 million (USD 2.2 million), a decline of 6.2% as compared to EUR 1.9 million (USD 2.1 million) for the first quarter of 2020.

Total revenue in the LITHO business for the first quarter 2021 was EUR 2.9 million (USD 3.5 million), roughly flat with EUR 2.9 million (USD 3.2 million) for the first quarter of 2020.

Total revenue in the Distribution business for the first quarter 2021 was EUR 5.6 million (USD 6.7 million), a 102.5 % increase compared to EUR 2.8 million (USD 3.1 million) for the first quarter of 2020.

Gross profit for the first quarter 2021 was EUR 4.4 million (USD 5.2 million), compared to EUR 3.1 million (USD 3.4 million) for the year-ago period. Gross profit margin on net sales was 42.4% in the first quarter of 2021, compared to 40.2% in the year-ago period. The increase in gross profit year-over-year was due to higher sales effect on fixed costs.

Operating expenses were EUR 4.1 million (USD 5.0 million) for the first quarter of 2021, compared to EUR 4.5 million (USD 5.0 million) for the same period in 2020.

Operating profit for the first quarter of 2021 was EUR 0.2 million (USD 0.3 million), compared to an operating loss of EUR 1.5 million (USD 1.6 million) in the first quarter of 2020.

Net income for the first quarter of 2021 was EUR 0.8 million (USD 0.9 million), or EUR 0.03 per diluted share, as compared to a net loss of EUR 1.3 million (USD 1.4 million), or EUR (0.04) per diluted share in the year-ago period.

As of March 31, 2021, the company held cash and cash equivalents of EUR 24.4 million (USD 28.6 million), as compared to EUR 24.7 million (USD 30.2 million) as of December 31, 2020. Subsequent to the end of the first quarter, the completed an underwritten public offering of its American Depository Shares that yielded gross proceeds of approximately $28 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, May 12, 2021. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast
Wednesday, May 12, 2021 @ 8:30am Eastern Time
Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13718852
Webcast: http://public.viavid.com/index.php?id=144433

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:	
	Mar. 31, 2021 Euros	Mar. 31, 2020 Euros	Mar. 31, 2021 $US	Mar. 31, 2020 $US
Sales of medical equipment	6,691	4,125	8,023	4,551
Net Sales of RPP and Leases	1,212	1,255	1,453	1,385
Sales of spare parts, supplies and Services	2,396	2,228	2,873	2,458
TOTAL NET SALES	**10,299**	**7,608**	**12,349**	**8,394**
Other revenues	3	2	3	2
TOTAL REVENUES	**10,302**	**7,610**	**12,353**	**8,395**
Cost of sales	(5,932)	(4,548)	(7,112)	(5,018)
GROSS PROFIT	**4,371**	**3,062**	**5,241**	**3,378**
Research & development expenses	(851)	(1,042)	(1,020)	(1,150)
S, G & A expenses	(3,281)	(3,480)	(3,934)	(3,839)
Total operating expenses	(4,132)	(4,522)	(4,954)	(4,989)
OPERATING PROFIT (LOSS)	**239**	**(1,460)**	**287**	**(1,611)**
Interest (expense) income, net	164	(20)	196	(22)

Currency exchange gains (loss), net	489	289	587	319
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**892**	**(1,191)**	**1,070**	**(1,315)**
Income tax (expense) credit	(119)	(116)	(143)	(128)
NET INCOME (LOSS)	**773**	**(1,308)**	**927**	**(1,443)**
Earning per share – Basic	0.03	(0.04)	0.03	(0.05)
Average number of shares used in computation of EPS	29,189,955	29,141,566	29,189,955	29,141,566
Earning per share – Diluted	0.03	(0.04)	0.03	(0.05)
Average number of shares used in computation of EPS for positive net income	30,352,216	29,141,566	30,352,216	29,141,566

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average three months' noon buying rate of 1 Euro = 1.1990 USD, and 2020 average three months noon buying rate of 1 Euro = 1.1033 USD

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

	Mar. 31, 2021 Euros	Dec. 31, 2020 Euros	Mar. 31, 2021 $US	Dec. 31, 2020 $US
Cash, cash equivalents and short-term treasury investments	24,382	24,696	28,630	30,201
Account receivables, net	10,264	12,339	12,053	15,090
Inventory	8,348	7,989	9,802	9,771
Other current assets	564	369	662	451
TOTAL CURRENT ASSETS	**43,557**	**45,393**	**51,147**	**55,513**
Property, plant and equipment, net	5,570	5,599	6,540	6,847
Goodwill	2,412	2,412	2,832	2,949
Other non-current assets	1,761	1,790	2,068	2,189
TOTAL ASSETS	**53,299**	**55,193**	**62,587**	**67,498**
Accounts payable & other accrued liabilities	9,374	10,485	11,008	12,823
Deferred revenues, current portion	3,011	2,701	3,535	3,304
Short term borrowing	1,391	2,638	1,634	3,227
Other current liabilities	5,492	5,679	6,449	6,945
TOTAL CURRENT LIABILITIES	**19,268**	**21,504**	**22,626**	**26,298**
Obligations under operating and finance leases non-current	1,679	1,653	1,972	2,022
Long term debt, non-current	1,157	1,143	1,359	1,397
Deferred revenues, non-current	837	926	983	1,132
Other long term liabilities	3,502	3,720	4,112	4,549
TOTAL LIABILITIES	**26,443**	**28,945**	**31,051**	**35,399**
TOTAL SHAREHOLDERS'EQUITY	**26,856**	**26,248**	**31,536**	**32,099**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**53,299**	**55,193**	**62,587**	**67,498**

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1743 USD on March 31, 2021 and at the noon buying rate of 1 Euro = 1.2229 USD, on December 31, 2020

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

	3-months ended Mar. 31, 2021 Euros	12-months ended Dec. 31, 2020 Euros	3-months ended Mar. 31, 2021 $US	12-months ended Dec. 31 2020 $US
NET INCOME (LOSS)	**773**	**(1,704)**	**927**	**(1,955)**

Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities[1]	167	3,790	201	4,349
OPERATING CASH FLOW	**940**	**2,087**	**1,128**	**2,394**
Increase/Decrease in operating assets and liabilities	539	(110)	646	(126)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**1,479**	**1,977**	**1,774**	**2,269**
Short term investments[2]	-	-	-	-
Additions to capitalized assets produced by the company and other capital expenditures	(294)	(2,011)	(353)	(2,307)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(294)**	**(2,011)**	**(353)**	**(2,307)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**(1,230)**	**3,201**	**(1,475)**	**3,673**
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**(269)**	**642**	**(1,517)**	**3,118**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(314)**	**3,810**	**(1,571)**	**6,752**

(1) *including Share based compensation expenses for 28 thousands of Euros at the end of March 2021, and 160 thousands of Euros at the end of December 2020*

(2) *Short term investments are comprised of money market funds*

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average three months' noon buying rate of 1 Euro = 1.1990 USD and at the 2020 average twelve months' noon buying rate of 1 Euro = 1.1474 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2021
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	487		1,212		4,992			6,691	
Sales of RPPs & Leases	888		262		62			1,212	
Sales of spare parts & services	427		1,420		549			2,396	
TOTAL NET SALES	**1,802**		**2,895**		**5,603**			**10,299**	
Other revenues	3		0		0			3	
TOTAL REVENUES	**1,805**		**2,895**		**5,603**			**10,302**	
GROSS PROFIT (% of Total Revenues)	**690**	**38.2 %**	**1,422**	**49.1%**	**2,259**	**40.3%**		**4,371**	**42.4%**
Research & Development	(582)		(196)		(73)			(851)	
Total SG&A plus depreciation	(918)		(657)		(1,344)		(362)	(3,281)	
OPERATING PROFIT (LOSS)	**(810)**		**570**		**841**		**(362)**	**239**	

Attachment

- 2021-05-11 -- EDAP Q1 2021 press release FINAL