EDAP Reports Fourth Quarter and Full Year 2021 Results

Mar 30, 2022

- Full year revenue of approximately EUR 44.1 million (USD 51.9 million) as compared to EUR 41.7 million (USD 47.8 million) for the full year 2020
- Full year US HIFU treatment volumes increased 65% over full year 2020; Strong cash position of EUR 47.2M€ (USD 53.4M) as of December 31, 2021
- Company to host a conference call tomorrow, Thursday, March 31, at 8:30 am ET

LYON, France, March 30, 2022 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the fourth quarter and full year 2021.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "We finished 2021 on a positive note, having reported several U.S. Focal One™ installations at renowned academic and community hospitals while growing our pipeline opportunities to their highest level since receiving regulatory approval of Focal One in mid-2018. At the same time, US HIFU treatment volumes, our most important leading indicator, were up 65% for the full year, reflecting ongoing growth in adoption of focal therapy by urologists. We continued to make measured investments in our US team, and with growing support for focal therapy as a necessary part of any comprehensive prostate oncology program, we entered 2022 with a right-sized, world class organization capable of capturing this significant untapped opportunity with our state-of-the-art HIFU technology."

Full Year 2021 Results

Total revenue for the full year 2021 was EUR 44.1 million (USD 51.9 million), an increase of 5.8% from total revenue of 41.7 million (USD 47.8 million) for the full year 2020.

Total revenue in the HIFU business for the full year 2021 were EUR 9.9 million (USD 11.7 million), as compared to EUR 11.4 million (USD 13.1 million) for the full year 2020.

Total revenue in the LITHO business for the full year 2021 was EUR 11.0 million (USD 13.0 million), as compared to EUR 12.9 million (USD 14.8 million) for the full year 2020.

Total revenue in the Distribution business for the full year 2021 was EUR 23.1 million (USD 27.3 million), as compared to EUR 17.3 million (USD 19.9 million) for the full year 2020.

Gross profit for the full year 2021 was EUR 18.4 million (USD 21.7 million), compared to EUR 18.4 million (USD 21.1 million) for the full year 2020. Gross profit margin on net sales was 41.8 % for the full year 2021, compared to 44.1% for the comparable period in 2020.

Operating expenses were EUR 20.0 million (USD 23.6 million) for the full year 2021 as compared to EUR 18.1 million (USD 20.8 million) for the full year 2020.

Operating loss for the full year 2021 was EUR 1.6 million (USD 1.9 million), compared to an operating profit of EUR 0.3 million (USD 0.3 million) for the full year 2020.

Net income for the full year 2021 was EUR 0.7 million (USD 0.8 million), or EUR 0.02 per diluted share, as compared to a net loss of EUR 1.7 million (USD 2.0 million), or EUR 0.06 per diluted share for the full year 2020.

Fourth Quarter 2021 Results

Total revenue for the fourth quarter 2021 was EUR 14.0 million (USD 15.9 million), as compared to total revenue of EUR 15.4 million (USD 18.3 million) for the same period in 2020.

Total revenue in the HIFU business for the fourth quarter 2021 was EUR 4.2 million (USD 4.8 million), as compared to EUR 4.4 million (USD 5.2 million) for the fourth quarter of 2020.

Total revenue in the LITHO business for the fourth quarter 2021 was EUR 3.3 million (USD 3.8 million), as compared to EUR 4.6 million (USD 5.5 million) for the fourth quarter of 2020.

Total revenue in the Distribution business for the fourth quarter 2021 was EUR 6.4 million (USD 7.3 million), as compared to EUR 6.4 million (USD 7.6 million) for the fourth quarter of 2020.

Gross profit for the fourth quarter 2021 was EUR 6.2 million (USD 7.1 million), compared to EUR 7.0 million (USD 8.4 million) for the year-ago period. Gross profit margin on net sales was 44.5 % in the fourth quarter of 2021, compared to 45.8% in the year-ago period. The decrease in gross profit year-over-year was due to lower sales effect on fixed costs.

Operating expenses were EUR 5.8 million (USD 6.5 million) for the fourth quarter of 2021, compared to EUR 5.3 million (USD 6.3 million) for the same period in 2020.

Operating profit for the fourth quarter of 2021 was EUR 0.5 million (USD 0.5 million), compared to an operating profit of EUR 1.7 million (USD 2.1 million) in the fourth quarter of 2020.

Net income for the fourth quarter of 2021 was EUR 1.4 million (USD 1.6 million), or EUR 0.04 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.

As of December 31, 2021, the company held cash and cash equivalents of EUR 47.2M (USD 53.4M) as compared to EUR 24.7 million (USD 30.2 million) as of December 31, 2020.

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, March 31, 2022. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast
Thursday, March 31, 2022 @ 8:30am Eastern Time
Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13727107
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1529371&tp_key=b54f335485

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.

Company Contact
Blandine Confort
Investor Relations / Legal Affairs
EDAP TMS SA
+33 4 72 15 31 50
bconfort@edap-tms.com

Investor Contact
John Fraunces
LifeSci Advisors, LLC
917-355-2395
jfraunces@lifesciadvisors.com

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:	
	Dec. 31, 2021 Euros	**Dec. 31, 2020 Euros**	**Dec. 31, 2021 $US**	**Dec. 31, 2020 $US**
Sales of medical equipment	9,864	11,439	11,231	13,661
Net Sales of RPP and Leases	1,387	1,336	1,579	1,596
Sales of spare parts, supplies and Services	2,720	2,587	3,097	3,089
TOTAL NET SALES	**13,971**	**15,363**	**15,907**	**18,346**
Other revenues	1	1	2	2
TOTAL REVENUES	**13,973**	**15,364**	**15,909**	**18,348**
Cost of sales	(7,762)	(8,335)	(8,837)	(9,953)
GROSS PROFIT	**6,211**	**7,029**	**7,072**	**8,394**
Research & development expenses	(562)	(1,439)	(640)	(1,718)
S, G & A expenses	(5,188)	(3,871)	(5,907)	(4,622)
Total operating expenses	(5,750)	(5,310)	(6,547)	(6,341)
OPERATING PROFIT (LOSS)	**461**	**1,720**	**525**	**2,053**
Interest (expense) income, net	23	(46)	26	(55)

Currency exchange gains (loss), net	786	(728)	895	(869)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**1,270**	**945**	**1,446**	**1,129**
Income tax (expense) credit	95	(165)	108	(197)
NET INCOME (LOSS)	**1,365**	**780**	**1,554**	**932**
Earning per share – Basic	0.04	0.03	0.05	0.03
Average number of shares used in computation of EPS	33,466,136	29,164,983	33,466,136	29,164,983
Earning per share – Diluted	0.04	0.03	0.04	0.03
Average number of shares used in computation of EPS for positive net income	34,555,716	30,222,258	33,555,716	30,222,258

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average three months' noon buying rate of 1 Euro = 1.1386 USD, and 2020 average three months noon buying rate of 1 Euro = 1.1942 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:	
	Dec. 31, 2021 Euros	**Dec. 31, 2020 Euros**	**Dec. 31, 2021 $US**	**Dec. 31, 2020 $US**
Sales of medical equipment	29,040	27,523	34,229	31,581
Net Sales of RPP and Leases	4,968	4,745	5,856	5,445
Sales of spare parts, supplies and Services	10,052	9,382	11,848	10,765
TOTAL NET SALES	**44,060**	**41,649**	**51,932**	**47,791**
Other revenues	6	12	7	14
TOTAL REVENUES	**44,065**	**41,662**	**51,939**	**47,805**
Cost of sales	(25,643)	(23,283)	(30,225)	(26,716)
GROSS PROFIT	**18,422**	**18,379**	**21,714**	**21,089**
Research & development expenses	(3,402)	(4,496)	(4,010)	(5,159)
S, G & A expenses	(16,633)	(13,614)	(19,605)	(15,621)
Total operating expenses	(20,034)	(18,110)	(23,614)	(20,780)
OPERATING PROFIT (LOSS)	**(1,612)**	**269**	**(1,900)**	**309**
Interest (expense) income, net	145	(98)	171	(112)
Currency exchange gains (loss), net	2,360	(1,359)	2,781	(1,559)
Other income, net	-	-	-	(1)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**893**	**(1,188)**	**1,052**	**(1,363)**
Income tax (expense) credit	(193)	(516)	(227)	(592)
NET INCOME (LOSS)	**700**	**(1,704)**	**825**	**(1,955)**
Earning per share – Basic	0.02	(0.06)	0.02	(0.07)
Average number of shares used in computation of EPS	33,457,469	29,148,108	33,457,469	29,148,108
Earning per share – Diluted	0.02	(0.06)	0.02	(0.07)
Average number of shares used in computation of EPS for positive net income	35,843,019	29,148,108	35,843,019	29,148,108

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average twelve months' noon buying rate of 1 Euro = 1.1787 USD, and 2020 average twelve months noon buying rate of 1 Euro = 1.1474 USD

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

Dec. 31, 2021 Euros	**Dec. 31, 2020 Euros**	**Dec. 31, 2021 $US**	**Dec. 31, 2020 $US**

Cash, cash equivalents and short-term treasury investments	47,183	24,696	53,405	30,201
Account receivables, net	12,118	12,339	13,716	15,090
Inventory	7,499	7,989	8,487	9,771
Other current assets	581	369	658	451
TOTAL CURRENT ASSETS	**67,382**	**45,393**	**76,267**	**55,513**
Property, plant and equipment, net	5,173	5,599	5,855	6,847
Goodwill	2,412	2,412	2,730	2,949
Other non-current assets	2,260	1,790	2,558	2,189
TOTAL ASSETS	**77,226**	**55,193**	**87,409**	**67,498**
Accounts payable & other accrued liabilities	10,786	10,485	12,208	12,823
Deferred revenues, current portion	3,408	2,701	3,857	3,304
Short term borrowing	1,914	2,638	2,167	3,227
Other current liabilities	1,843	5,679	2,086	6,945
TOTAL CURRENT LIABILITIES	**17,951**	**21,504**	**20,318**	**26,298**
Obligations under operating and finance leases non-current	1,318	1,653	1,492	2,022
Long term debt, non-current	4,930	1,143	5,580	1,397
Deferred revenues, non-current	440	926	498	1,132
Other long term liabilities	2,534	3,720	2,868	4,549
TOTAL LIABILITIES	**27,172**	**28,945**	**30,755**	**35,399**
TOTAL SHAREHOLDERS'EQUITY	**50,054**	**26,248**	**56,655**	**32,099**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**77,226**	**55,193**	**87,409**	**67,498**

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1319 USD on December 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)

	Dec. 31, 2021 Euros	Dec. 31, 2020 Euros	Dec. 31, 2021 $US	Dec. 31, 2020 $US
NET INCOME (LOSS)	**700**	**(1,704)**	**825**	**(1,955)**
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities[(1)]	3,225	3,790	3,801	4,349
OPERATING CASH FLOW	**3,925**	**2,087**	**4,626**	**2,394**
Increase/Decrease in operating assets and liabilities	520	(110)	613	(126)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**4,445**	**1,977**	**5,239**	**2,269**
Short term investments[(2)]	-	-	-	-
Additions to capitalized assets produced by the company and other capital expenditures	(1,638)	(2,011)	(1,931)	(2,307)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(1,638)**	**(2,011)**	**(1,931)**	**(2,307)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**20,266**	**3,201**	**23,887**	**3,673**
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**(585)**	**642**	**(3,992)**	**3,118**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**22,488**	**3,810**	**23,204**	**6,752**

(1) *including Share based compensation expenses for 1,900 thousand of Euros at the end of December 2021, and 160 thousand 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 twelve months' noon buying rate of 1 Euro = 1.1787 USD and 2020 average twelve months' noon buying rate of 1 Euro = 1.1474 USD.

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

	HIFU Division	ESWL Division	Distribution Division	Reconciling Items	Total After Consolidation
Sales of goods	4,515	4,236	20,289		29,040
Sales of RPPs & Leases	3,679	1,022	267		4,968
Sales of spare parts & services	1,715	5,758	2,578		10,052
TOTAL NET SALES	**9,910**	**11,016**	**23,134**		**44,060**
Other revenues	6	0	0		6
TOTAL REVENUES	**9,915**	**11,016**	**23,134**		**44,065**
GROSS PROFIT	**4,604**	**4,936**	**8,882**		**18,422**
(% of Total Revenues)	**46.4%**	**44.8%**	**38.4%**		**41.8%**
Research & Development	(2,238)	(835)	(329)		(3,402)
Total SG&A plus depreciation	(5,391)	(3,208)	(6,129)	(1,904)	(16,633)
OPERATING PROFIT (LOSS)	**(3,025)**	**893**	**2,424**	**(1,904)**	**(1,612)**

Attachment

- 2022-3-30 -- EDAP 4Q 2021 PR final