

EDAP Reports Third Quarter 2022 Results

- Generated Q3 2022 total revenue of approximately EUR 12.2 million (USD 12.3 million), an increase of 29.7 % as compared to EUR 9.4 million (USD 11.1 million) for Q3 2021; nine-month year-to-date revenue increased 30.9% compared to the same period in 2021
- Generated HIFU sales of EUR \$3.5 million (USD 3.5 million), representing growth of 81% over EUR 1.9 million (USD 2.3 million) for Q3 2021
- Reimbursement increase finalized: U.S. Centers for Medicare and Medicaid Services (CMS), in its final Outpatient Prospective Payment System (OPPS) rule for CY23, increased reimbursement for HIFU prostate ablation from APC Level 5 to Level 6 which increases hospital reimbursement by more than 90%
- Exited the quarter with a strong cash position of EUR 68.3 million (USD 66.8 million) as of September 30, 2022
- Conference call and webcast scheduled for tomorrow, Thursday, November 17, at 8:30 am ET

LYON, France, November 16, 2022 -- EDAP TMS SA (Nasdaq: EDAP) (the “Company”), a global leader in robotic energy-based therapies, announced today unaudited financial results for the third quarter 2022.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: “For the third quarter 2022, we generated robust year-over-year revenue growth of nearly 30%, driven by continued strength in our HIFU business, which contributed revenue growth of 81% over the prior year period. This was a record calendar third quarter for our company. Clearly, our recent efforts to bolster our U.S. commercial presence are having a significant positive impact, and I believe we are well positioned to complete the year with significant momentum.”

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, “We successfully executed in the third quarter to drive adoption of Focal One HIFU as the leading non-invasive focal therapy platform. Three new hospitals purchased Focal One systems in the quarter, and we continue to see increased adoption of Focal One amongst our growing installed base. We believe the increase in 2023 reimbursement for HIFU ablation will significantly improve access in the number of facilities that choose to invest in Focal One Robotic HIFU as part of a comprehensive approach to the management of prostate cancer.”

Year-to-Date Results

Total revenue for the nine months ended September 30, 2022, was EUR 39.4 million (USD 41.7 million), an increase of 30.9% from total revenue of was EUR 30.1 million (USD 35.9 million) for the same period in 2021.

Total revenue in the HIFU business for the nine months ended September 30, 2022, was EUR 10.3 million (USD 10.9 million), an increase of 79.7% as compared to EUR 5.7 million (USD 6.8 million) for the nine months ended September 30, 2021.

Total revenue in the LITHO business for the nine months ended September 30, 2022, was EUR 8.0 million (USD 8.4 million), an increase of 3.9% from EUR 7.7 million (USD 9.1 million) for the nine months ended September 30, 2021.

Total revenue in the Distribution business for the nine months ended September 30, 2022, was EUR 21.2 million (USD 22.4 million), a 26.6% increase compared to EUR 16.7 million (USD 19.9 million) for the nine months ended September 30, 2021.

Gross profit for the nine months ended September 30, 2022, was EUR 17.0 million (USD 18.0 million), compared to EUR 12.2 million (USD 14.6 million) for the year-ago period. Gross profit margin on net sales was 43.1% for the nine months ended September 30, 2022, compared to 40.6% for the comparable period in 2021. The increase in gross profit year-over-year was due to higher sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 19.7 million (USD 20.8 million) for the nine months ended September 30, 2022, compared to EUR 14.3 million (USD 17.0 million) for the same period in 2021.



Operating loss for the nine months ended September 30, 2022, was EUR 2.7 million (USD 2.8 million), compared to an operating loss of EUR 2.1 million (USD 2.5 million) for the nine months ended September 30, 2021.

Net income for the nine months ended September 30, 2022, was EUR 2.2 million (USD 2.3 million), or EUR 0.07 per diluted share, as compared to a net loss of EUR 0.7 million (USD 0.8 million), or EUR (0.02) per diluted share in the year-ago period.

As of September 30, 2022, the company held cash, cash equivalents and short term investments of EUR 68.3 million (USD 66.8 million), as compared to EUR 47.2 million (USD 53.4 million) as of December 31, 2021.

Third Quarter 2022 Results

Total revenue for the third quarter 2022 was EUR 12.2 million (USD 12.3 million), a 29.7% increase as compared to total revenue of EUR 9.4 million (USD 11.1 million) for the same period in 2021.

Total revenue in the HIFU business for the third quarter 2022 was EUR 3.5 million (USD 3.5 million), an increase of 80.9% as compared to EUR 1.9 million (USD 2.3 million) for the third quarter of 2021.

Total revenue in the LITHO business for the third quarter 2022 was EUR 2.2 million (USD 2.2 million), a decrease of 12.1% from was EUR 2.5 million (USD 2.9 million) for the third quarter of 2021.

Total revenue in the Distribution business for the third quarter 2022 was EUR 6.6 million (USD 6.6 million), a 30.9% increase compared to EUR 5.0 million (USD 5.9 million) for the third quarter of 2021.

Gross profit for the third quarter 2022 was EUR 5.0 million (USD 5.0 million), compared to EUR 3.6 million (USD 4.2 million) for the year-ago period. Gross profit margin on net sales was 41.0% in the third quarter of 2022, compared to 38.4% in the year-ago period. The increase in gross profit year-over-year was driven by the higher sales effect on fixed costs.

Operating expenses were EUR 7.2 million (USD 7.2 million) for the third quarter of 2022, compared to EUR 5.5 million (USD 6.5 million) for the same period in 2021.

Operating loss for the third quarter of 2022 was EUR 2.1 million (USD 2.2 million), compared to an operating loss of EUR 1.9 million (USD 2.2 million) in the third quarter of 2021.

Net income for the third quarter of 2022 was EUR 0.0 million (USD 0.0 million), or EUR 0.00 per diluted share, as compared to a net loss of EUR 1.0 million (USD 1.2 million), or EUR (0.03) per diluted share in the year-ago period.

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 17, 2022. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, November 17, 2022 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13733576

Webcast link: [Here](#)

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 and www.focalone.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:	
	September 30, 2022 Euros	September 30, 2021 Euros	September 30, 2022 \$US	September 30, 2021 \$US
Sales of medical equipment	8,319	5,788	8,333	6,799
Net Sales of RPP and Leases	1,214	1,104	1,216	1,297
Sales of spare parts, supplies and Services	2,710	2,548	2,714	2,993
TOTAL NET SALES	12,243	9,440	12,263	11,089
Other revenues	—	—	—	—
TOTAL REVENUES	12,243	9,440	12,263	11,089
Cost of sales	(7,226)	(5,815)	(7,238)	(6,831)
GROSS PROFIT	5,017	3,625	5,026	4,258
Research & development expenses	(1,361)	(1,064)	(1,363)	(1,250)
S, G & A expenses	(5,805)	(4,446)	(5,815)	(5,222)
Total operating expenses	(7,165)	(5,510)	(7,178)	(6,472)
OPERATING PROFIT (LOSS)	(2,148)	(1,885)	(2,152)	(2,215)
Interest (expense) income, net	(4)	(22)	(4)	(25)
Currency exchange gains (loss), net	3,020	1,003	3,025	1,178
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	867	(904)	869	(1,062)
Income tax (expense) credit	(854)	(111)	(856)	(130)
NET INCOME (LOSS)	13	(1,015)	13	(1,192)
Earning per share – Basic	0.00	(0.03)	0.00	(0.04)
Average number of shares used in computation of EPS	33,696,543	33,448,136	33,696,543	33,448,136
Earning per share – Diluted	0.00	(0.03)	0.00	(0.04)
Average number of shares used in computation of EPS for positive net income	34,612,773	33,448,136	34,612,773	33,448,136

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.0017 USD, and 2021 average three months noon buying rate of 1 Euro = 1.1747 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:	
	September 30, 2022 Euros	September 30, 2021 Euros	September 30, 2022 \$US	September 30, 2021 \$US
Sales of medical equipment	26,969	19,176	28,563	22,858
Net Sales of RPP and Leases	4,176	3,581	4,423	4,269
Sales of spare parts, supplies and Services	8,245	7,331	8,733	8,739
TOTAL NET SALES	39,391	30,088	41,719	35,866
Other revenues	—	4	—	5
TOTAL REVENUES	39,391	30,092	41,719	35,871
Cost of sales	(22,416)	(17,881)	(23,741)	(21,315)
GROSS PROFIT	16,975	12,211	17,978	14,556
Research & development expenses	(3,615)	(2,840)	(3,829)	(3,385)
S, G & A expenses	(16,047)	(11,444)	(16,995)	(13,642)
Total operating expenses	(19,662)	(14,284)	(20,824)	(17,027)
OPERATING PROFIT (LOSS)	(2,687)	(2,073)	(2,846)	(2,471)
Interest (expense) income, net	(62)	122	(66)	145
Currency exchange gains (loss), net	6,001	1,574	6,355	1,876
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	3,251	(378)	3,443	(450)
Income tax (expense) credit	(1,054)	(288)	(1,117)	(343)
NET INCOME (LOSS)	2,197	(665)	2,327	(793)
Earning per share – Basic	0.07	(0.02)	0.07	(0.02)
Average number of shares used in computation of EPS	33,544,003	32,881,747	33,544,003	32,881,747
Earning per share – Diluted	0.06	(0.02)	0.07	(0.02)
Average number of shares used in computation of EPS for positive net income	34,301,115	32,881,747	34,301,115	32,881,747

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average nine months' noon buying rate of 1 Euro = 1.0591 USD, and 2021 average nine months noon buying rate of 1 Euro = 1.1920 USD

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

	September 30, 2022 Euros	December 31, 2021 Euros	September 30, 2022 \$US	December 31, 2021 \$US
Cash, cash equivalents and short-term treasury investments	68,329	47,183	66,845	53,405
Account receivables, net	15,131	12,118	14,802	13,716
Inventory	9,561	7,499	9,353	8,487
Other current assets	1,007	581	985	658
TOTAL CURRENT ASSETS	94,027	67,382	91,985	76,267
Property, plant and equipment, net	6,133	5,173	6,000	5,855
Goodwill	2,412	2,412	2,359	2,730
Other non-current assets	2,230	2,260	2,181	2,558
TOTAL ASSETS	104,801	77,226	102,525	87,409
Accounts payable & other accrued liabilities	13,366	10,786	13,076	12,208
Deferred revenues, current portion	4,230	3,408	4,138	3,857
Short term borrowing	1,237	1,914	1,210	2,167
Other current liabilities	2,688	1,843	2,629	2,086
TOTAL CURRENT LIABILITIES	21,521	17,951	21,053	20,318
Obligations under operating and finance leases non-current	1,583	1,318	1,548	1,492
Long term debt, non-current	4,021	4,930	3,934	5,580
Deferred revenues, non-current	331	440	324	498
Other long term liabilities	3,104	2,534	3,037	2,868
TOTAL LIABILITIES	30,560	27,172	29,896	30,755
TOTAL SHAREHOLDERS' EQUITY	74,242	50,054	72,629	56,655
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	104,801	77,226	102,525	87,409

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 0.9783 USD, on September 30, 2022 and at the noon buying rate of 1 Euro = 1.1319 USD, on December 31, 2021.

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

	Nine Months Ended September 30, 2022 (Euros)	Twelve Months Ended December 31, 2021 (Euros)	Nine Months Ended September 30, 2022 (\$US)	Twelve Months Ended December 31, 2021 (\$US)
NET INCOME (LOSS)	2,197	700	2,327	825
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	2,931	3,225	3,104	3,801
OPERATING CASH FLOW	5,128	3,925	5,431	4,626
Increase/Decrease in operating assets and liabilities	(1,505)	520	(1,594)	613
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	3,623	4,445	3,837	5,239
Short term investments (2)	(17,952)	—	(19,013)	—
Additions to capitalized assets produced by the company and other capital expenditures	(1,786)	(1,638)	(1,892)	(1,931)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(19,739)	(1,638)	(20,905)	(1,931)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	21,399	20,266	22,663	23,887
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(2,089)	(585)	(9,717)	(3,992)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,193	22,488	(4,123)	23,204

⁽¹⁾ including share based compensation expenses for 1,345 thousand of Euros for the nine months ended September 30, and 1,900 thousand of Euros for the full year ended December 31, 2021.

⁽²⁾ short term investments are comprised of money market funds.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average nine months' noon buying rate of 1 Euro = 1.0591 USD, and 2021 average twelve months noon buying rate of 1 Euro = 1.1787 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
nine months ended September 30, 2022
(Amounts in thousands of Euros)

	<u>HIFU</u> <u>Division</u>		<u>ESWL</u> <u>Division</u>		<u>Distribution</u> <u>Division</u>		<u>Reconciling</u> <u>Items</u>	<u>Total After</u> <u>Consolidation</u>	
Sales of goods	5,657		2,914		18,398		—	26,969	
Sales of RPPs & Leases	3,166		792		218		—	4,176	
Sales of spare parts & services	1,441		4,261		2,543		—	8,245	
TOTAL NET SALES	10,264		7,967		21,159		—	39,391	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	10,264		7,967		21,159		—	39,391	
GROSS PROFIT (% of Net Sales)	5,587	54.4 %	3,319	41.7 %	8,069	38.1 %	—	16,975	43.1 %
Research & Development	(2,584)		(714)		(318)		—	(3,615)	
Total SG&A plus depreciation	(6,560)		(2,042)		(5,711)		(1,733)	(16,047)	
OPERATING PROFIT (LOSS)	(3,557)		563		2,040		(1,733)	(2,687)	