EDAP Reports Second Quarter 2021 Results and Provides Operational Update

Aug 25, 2021

- Total revenue for the first half 2021 of EUR 20.7 million (USD $24.8 million) increased 22.5% over the same period of the prior year
- Net income was EUR 0.4 million (USD 0.4 million), or EUR 0.01 per diluted share, for the first half of 2021
- Cash balance of EUR 45 million (USD $53.3 million) as of June 30, 2021
- Second quarter U.S. HIFU treatment volumes increased 79% over the comparable period in 2020; strong leading indicator of Focal One adoption
- CMS Advisory Panel on Hospital Outpatient Payment (HOP panel), at its summer meeting, unanimously recommended increasing reimbursement for HIFU prostate ablation to APC Level 6 in 2022 from Level 5 currently
- Company to host a conference call tomorrow, August 26, at 8:30 am ET

LYON, France, August 25, 2021 -- EDAP TMS SA (Nasdaq: EDAP) (the “Company”), a global leader in robotic energy-based therapies, announced today unaudited financial results for the second quarter of 2021 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: “We were very pleased during the second quarter to see continued strong growth in U.S. Focal One treatment volumes, a metric that we believe reflects accelerating HIFU adoption as a prostate cancer treatment alternative. While the ongoing COVID pandemic continues to weigh on hospital capital spending, we nonetheless continued to build a robust pipeline of Focal One and ExactVu pipeline opportunities, and we are optimistic that we will close additional high-profile sales this year."

“On the reimbursement front, just a few days ago, the CMS HOP panel voted unanimously in favor of increasing reimbursement for HIFU prostate ablation to APC Level 6 next year from Level 5 currently. Even if the HOP panel has only an advisory role to CMS, we believe this is a strong signal and further recognition of the value of HIFU in this indication. We hope this will be taken into account by CMS when building the final rule, which will be published in December of this year. If this is the case, reimbursement for Focal One HIFU would increase from an average of approximately $4,500 per procedure this year to an average of approximately $8,500 per procedure in 2022. This increase, if implemented, could be a significant catalyst to accelerating Focal One sales in 2022 and beyond."

“Importantly, our U.S. expansion plans, led by new U.S. subsidiary CEO Ryan Rhodes, are progressing and we are well financed with more than $53 million on our balance sheet. I believe we are poised for a strong back half of the year and accelerating HIFU momentum heading into 2022.”

For the first six months 2021 Results

Total revenue for the first half of 2021 was EUR 20.7 million (USD 24.8 million), an increase of 22.5% compared to total revenue of EUR 16.9 million (USD 18.7 million) for the same period in 2020.

Total revenue in the HIFU business for the first six months of 2021 was EUR 3.8 million (USD 4.6 million), a decline of 15.1% as compared to EUR 4.5 million (USD 4.9 million) for the first six months of 2020.

Total revenue in the LITHO business for the first six months of 2021 was EUR 5.2 million (USD 6.2 million), a decline of 11.8% from EUR 5.9 million (USD 6.5 million) for the first six months of 2020.

Total revenue in the Distribution business for the first six months of 2021 was EUR 11.7 million (USD 14.0 million), a 79.0% increase compared to EUR 6.5 million (USD 7.2 million) for the first six months of 2020.

Gross profit for the first six months of 2021 was EUR 8.6 million (USD 10.3 million), compared to EUR 7.4 million (USD 8.2 million) for the year-ago period. Gross profit margin on net sales was 41.6% in the first six months of 2021, compared to 43.9% in the year-ago period. The decrease in gross profit year-over-year was due to lower sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 8.8 million (USD 10.5 million) for the first six months of 2021, compared to EUR 8.5 million (USD 9.5 million) for the same period in 2020.

Operating loss for the first six months of 2021 was EUR 0.2 million (USD 0.2 million), compared to an operating loss of EUR 1.2 million (USD 1.3 million) for the same period in 2020.

Net income for the first six months of 2021 was EUR 0.4 million (USD 0.4 million), or EUR 0.01 per diluted share, as compared to a net loss of EUR 1.5 million (USD 1.6 million), or EUR (0.05) per diluted share in the year-ago period.

As of June 30, 2021, the company held cash and cash equivalents of EUR 45.0 million (USD 53.3 million), as compared to EUR 24.7 million (USD 30.2 million) as of December 31, 2020.

Second Quarter 2021 Results

Total revenue for the second quarter 2021 was EUR 10.4 million (USD 12.4 million), an increase of 11.8% compared to total revenue of EUR 9.3 million (USD 10.3 million) for the same period in 2020.

Total revenue in the HIFU business for the second quarter 2021 was EUR 2.0 million (USD 2.4 million), a decline of 21.8% as compared to EUR 2.6 million (USD 2.8 million) for the second quarter of 2020.

Total revenue in the LITHO business for the second quarter 2021 was EUR 2.3 million (USD 2.7 million), a decline of 22.6% from EUR 2.9 million (USD 3.2million) for the second quarter of 2020.

Total revenue in the Distribution business for the second quarter 2021 was EUR 6.1 million (USD 7.3 million), a 61.6% increase compared to EUR 3.8 million (USD 4.2 million) for the second quarter of 2020.

Gross profit for the second quarter 2021 was EUR 4.2 million (USD 5.1 million), compared to EUR 4.3 million (USD 4.8 million) for the year-ago period. Gross profit margin on net sales was 40.7% in the second quarter of 2021, compared to 46.8% in the year-ago period.

Operating expenses were EUR 4.6 million (USD 5.6 million) for the second quarter of 2021, compared to EUR 4.0 million (USD 4.5 million) for the same period in 2020.

Operating loss for the second quarter of 2021 was EUR 0.4 million (USD 0.5 million), compared to an operating profit of EUR 0.3 million (USD 0.3 million) in the second quarter of 2020.

Net loss for the second quarter of 2021 was EUR 0.4 million (USD 0.5 million), or EUR (0.01) per diluted share, as compared to a net loss of EUR 0.2 million (USD 0.2 million), or EUR (0.01) 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, August 26, 2021. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast
Thursday, August 26, 2021 @ 8:30am Eastern Time

Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13721942
Webcast: http://public.viavid.com/index.php?id=145982

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
Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@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:	
	June. 30, 2021 Euros	June. 30, 2020 Euros	June. 30, 2021 $US	June. 30, 2020 $US
Sales of medical equipment	6,696	5,975	8,051	6,628
Net Sales of RPP and Leases	1,265	947	1,521	1,050

Sales of spare parts, supplies and Services	2,387	2,311	2,870	2,564
TOTAL NET SALES	**10,349**	**9,233**	**12,443**	**10,242**
Other revenues	1	23	2	25
TOTAL REVENUES	**10,350**	**9,255**	**12,445**	**10,267**
Cost of sales	(6,134)	(4,931)	(7,376)	(5,470)
GROSS PROFIT	**4,216**	**4,324**	**5,069**	**4,797**
Research & development expenses	(925)	(926)	(1,112)	(1,027)
S, G & A expenses	(3,718)	(3,096)	(4,470)	(3,434)
Total operating expenses	(4,642)	(4,022)	(5,582)	(4,461)
OPERATING PROFIT (LOSS)	**(427)**	**303**	**(513)**	**336**
Interest (expense) income, net	(20)	(19)	(25)	(21)
Currency exchange gains (loss), net	82	(346)	98	(384)
Other income, net	-	(1)	-	(1)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(365)**	**(63)**	**(439)**	**(70)**
Income tax (expense) credit	(58)	(112)	(70)	(124)
NET INCOME (LOSS)	**(424)**	**(175)**	**(509)**	**(194)**
Earning per share – Basic	(0.01)	(0.01)	(0.02)	(0.01)
Average number of shares used in computation of EPS	32,220,414	29,141,566	32,220,414	29,141,566
Earning per share – Diluted	(0.01)	(0.01)	(0.02)	(0.01)
Average number of shares used in computation of EPS for positive net income	32,220,414	29,141,566	32,220,414	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 = 1.2024 USD, and 2020 average three months noon buying rate of 1 Euro = 1.1093 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, 2021 Euros	**June. 30, 2020 Euros**	**June. 30, 2021 $US**	**June. 30, 2020 $US**
Sales of medical equipment	13,387	10,099	16,075	11,173
Net Sales of RPP and Leases	2,477	2,202	2,975	2,436
Sales of spare parts, supplies and Services	4,784	4,539	5,744	5,022
TOTAL NET SALES	**20,648**	**16,841**	**24,794**	**18,631**
Other revenues	4	24	5	27
TOTAL REVENUES	**20,653**	**16,865**	**24,799**	**18,658**
Cost of sales	(12,066)	(9,479)	(14,488)	(10,487)
GROSS PROFIT	**8,587**	**7,386**	**10,311**	**8,171**
Research & development expenses	(1,776)	(1,968)	(2,132)	(2,177)
S, G & A expenses	(6,998)	(6,575)	(8,403)	(7,274)
Total operating expenses	(8,774)	(8,543)	(10,536)	(9,452)
OPERATING PROFIT (LOSS)	**(188)**	**(1,157)**	**(225)**	**(1,280)**
Interest (expense) income, net	143	(39)	172	(43)
Currency exchange gains (loss), net	571	(57)	685	(63)
Other income, net	-	0	-	(1)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**527**	**(1,254)**	**632**	**(1,388)**
Income tax (expense) credit	(177)	(228)	(213)	(252)
NET INCOME (LOSS)	**350**	**(1,483)**	**420**	**(1,640)**
Earning per share – Basic	0.01	(0.05)	0.01	(0.06)
Average number of shares used in computation of EPS	30,705,356	29,141,566	30,705,356	29,141,566
Earning per share – Diluted	0.01	(0.05)	0.01	(0.06)

Average number of shares used in computation of EPS for positive net income	31,994,402	29,141,566	31,994,402	29,141,566

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average six months' noon buying rate of 1 Euro = 1.2008 USD, and 2020 average six months noon buying rate of 1 Euro = 1.1063 USD

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

	June 30, 2021 Euros	Dec. 31, 2020 Euros	June 30, 2021 $US	Dec. 31, 2020 $US
Cash, cash equivalents and short-term treasury investments	44,961	24,696	53,272	30,201
Account receivables, net	11,183	12,339	13,249	15,090
Inventory	8,610	7,989	10,202	9,771
Other current assets	618	369	732	451
TOTAL CURRENT ASSETS	**65,372**	**45,393**	**77,455**	**55,513**
Property, plant and equipment, net	5,135	5,599	6,084	6,847
Goodwill	2,412	2,412	2,858	2,949
Other non-current assets	1,704	1,790	2,019	2,189
TOTAL ASSETS	**74,622**	**55,193**	**88,415**	**67,498**
Accounts payable & other accrued liabilities	9,297	10,256	11,016	12,543
Deferred revenues, current portion	3,264	2,701	3,867	3,304
Short term borrowing	1,447	2,638	1,714	3,227
Other current liabilities	1,340	5,679	1,588	6,945
TOTAL CURRENT LIABILITIES	**15,348**	**21,275**	**18,185**	**26,018**
Obligations under operating and finance leases non-current	1,415	1,653	1,677	2,022
Long term debt, non-current	5,215	1,143	6,179	1,397
Deferred revenues, non-current	826	926	979	1,132
Other long term liabilities	3,628	3,949	4,298	4,829
TOTAL LIABILITIES	**26,432**	**28,945**	**31,317**	**35,399**
TOTAL SHAREHOLDERS'EQUITY	**48,191**	**26,248**	**57,098**	**32,099**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**74,622**	**55,193**	**88,415**	**67,498**

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1848 USD on June 30, 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)

	6-months ended June 30, 2021 Euros	12-months ended Dec. 31, 2020 Euros	6-months ended June 30, 2021 $US	12-months ended Dec. 31 2020 $US
NET INCOME (LOSS)	**350**	**(1,704)**	**420**	**(1,955)**
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities[1]	976	3,790	1,172	4,349
OPERATING CASH FLOW	**1,326**	**2,087**	**1,592**	**2,394**
Increase/Decrease in operating assets and liabilities	(585)	(110)	(702)	(126)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**741**	**1,977**	**890**	**2,269**
Short term investments[2]	-	-	-	-
Additions to capitalized assets produced by the company and other capital expenditures	(644)	(2,011)	(773)	(2,307)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(644)**	**(2,011)**	**(773)**	**(2,307)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**20,368**	**3,201**	**24,457**	**3,673**

NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**(199)**	**642**	**(1,503)**	**3,118**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**20,266**	**3,810**	**23,071**	**6,752**

(1) *including Share based compensation expenses for 180 thousand of Euros at the end of June 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 six months' noon buying rate of 1 Euro = 1.2008 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
SIX MONTHS ENDED JUNE 30, 2021
(Amounts in thousands of Euros)

	HIFU Division		**ESWL Division**		**Distribution Division**		**Reconciling Items**	**Total After Consolidation**	
Sales of goods	1,151		1,881		10,356			13,387	
Sales of RPPs & Leases	1,798		540		139			2,477	
Sales of spare parts & services	846		2,755		1,182			4,784	
TOTAL NET SALES	**3,795**		**5,176**		**11,677**			**20,648**	
Other revenues	4		0		0			4	
TOTAL REVENUES	**3,799**		**5,176**		**11,677**			**20,653**	
GROSS PROFIT	**1,501**	**39.5%**	**2,472**	**47.8%**	**4,614**	**39.5%**		**8,587**	**41.6%**
(% of Total Revenues)									
Research & Development	(1,208)		(418)		(150)			(1,776)	
Total SG&A plus depreciation	(1,946)		(1,453)		(2,689)		(911)	(6,998)	
OPERATING PROFIT (LOSS)	**(1,652)**		**601**		**1,775**		**(911)**	**(188)**	

Attachment

- 2021-08-25 -- EDAP Q2 2021 press release - approved