EDAP Reports First Quarter 2024 Financial Results

May 16, 2024

- Strong Q1 2024 U.S. Focal One® HIFU procedure growth of +92% year-over-year
- Q1 2024 HIFU revenue of EUR 5.8 million ($6.3 million USD), an increase of 10.2% over Q1 2023
- Q1 2024 total revenue of EUR 14.9 million ($16.1 million USD) increased 0.8% over Q1 2023
- Company to host conference call and webcast today, May 16th, at 8:30 a.m. EDT

LYON, France, May 16, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited financial results for the first quarter of 2024.

“We are off to a strong start in 2024 driven by seven Focal One system placements in the quarter of 2024 and strong year over year procedure growth, reflecting the increasing acceptance of robotic HIFU for the management of prostate cancer,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “Important to note, the final results from the HIFI study, which is the single largest comparative study ever conducted evaluating robotic HIFU versus radical prostatectomy, were just presented at the119th Annual Meeting of the America Urology Association, held in San Antonio, Texas. The final results from the study were presented during the main plenary session of the AUA, which focused exclusively on evolving practices and changing treatment paradigms in urology. We believe the results from the HIFI Study clearly demonstrate that Focal One robotic HIFU delivers effective oncologic control as compared to surgery, but with the added potential benefit for improved functional outcomes with respect to maintaining both erectile function and urinary continence. Based on these definitive results, we expect to see both growing and continued adoption of our Focal One robotic HIFU technology in the management of localized prostate cancer.

“EDAP continues to make strategic investments to grow HIFU applications beyond prostate health. Last quarter, we received Breakthrough Device designation from the FDA for the application of Focal One robotic HIFU for treatment of deep infiltrating rectal endometriosis. As noted, our Phase 3 study completed patient enrollment in January, and we expect topline results from this study in the second half of 2024. Endometriosis represents a significant unmet medical need in women’s health, and we believe Focal One has the opportunity to become an important new treatment alternative to address this painful and debilitating condition which impacts thousands of women each year.

“Looking ahead in 2024, we believe Focal One will become an essential component to the urology suite, as an increasing number of patients seek out effective, less invasive treatment options to manage their prostate cancer. Our Focal One pipeline remains strong, and we continue to see broad acceptance of Focal One amongst leading academic and community medical practices. We also continue to see strong engagement across our regional capital and clinical sales teams, as they build world-class robotic HIFU treatment programs with the goal of helping more urology practices remain at the forefront of prostate cancer management.”

Business Update

- On May 6, 2024, the Company announced that final results from a large, prospective, multicenter, non-inferiority study, the HIFI Study, comparing Focal One® high intensity focused ultrasound (HIFU) versus radical prostatectomy (RP) were presented at the 119th American Urological Association Annual Meeting (AUA 2024), which took place from May 3-6, 2024, in San Antonio, Texas, USA. Professor Pascal Rischmann of Rangueil University Hospital in Toulouse, France, and lead investigator of the HIFI Study, highlighted the final results from the study during an oral presentation at the AUA plenary session, “Paradigm-shifting, Practice-changing Clinical Trials in Urology”.

- On February 1, 2024, the Company announced that it completed enrollment for its Phase 3 study (Endo-HIFU-R2) evaluating Focal One High-Intensity Focused Ultrasound (HIFU) therapy for the treatment of deep infiltrating rectal endometriosis. Results from the Phase 3 study are expected in the second half of 2024.

- On January 2, 2024, the Company announced the appointments of Ken Mobeck as its Chief Financial Officer of EDAP worldwide, and Francois Dietsch as Global Chief Accounting Officer. Both appointments became effective as of January 1, 2024.

Clinical Pipeline Update

Endometriosis Program

- On March 4, 2024, the Company announced that it received Breakthrough Device designation by the US Food and Drug Administration (FDA) for the treatment of deep infiltrating endometriosis (DIE). FDA's Breakthrough Device designation is granted to products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. This unique program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review.

- On February 1, 2024, EDAP announced completion of enrollment in the Phase 3 double blinded, randomized controlled trial evaluating Focal One HIFU for the treatment of deep infiltrating rectal endometriosis. Results from the study are expected in the second half of 2024.

Upcoming Meetings and Events

- Jefferies Global Healthcare Conference, June 5-6, 2024, in New York City

First Quarter 2024 Results

Total revenue for the first quarter of 2024 was EUR 14.9 million (USD 16.1 million), an increase of 0.8% as compared to total revenue of EUR 14.8 million (USD 15.9 million) for the same period in 2023.

Total revenue in the HIFU business for the first quarter of 2024 was EUR 5.8 million (USD 6.3 million), as compared to EUR 5.3 million (USD 5.7 million) for the first quarter of 2023. The Company recorded a 55.7% year-over-year growth in disposables revenues, reflecting strong procedure growth. During the quarter, the Company placed 7 Focal One systems, which included five capital sales, versus 7 Focal One placements in the first quarter of 2023.

Total revenue in the LITHO business for the first quarter of 2024 was EUR 2.3 million (USD 2.8 million), as compared to EUR 2.8 million (USD 3.0 million) for the first quarter of 2023. The decrease in LITHO revenue was driven by 2 lithotripsy units sold in the first quarter of 2024 as compared to 4 units sold in the first quarter of 2023.

Total revenue in the Distribution business for the first quarter of 2024 was EUR 6.9 million (USD 7.4 million), as compared to EUR 6.8 million (USD 7.3 million) for the first quarter of 2023. The increase in Distribution revenue was driven primarily by 11 ExactVu units sold during the first quarter of 2024 as compared to 8 units sold during the first quarter of 2023.

Gross profit for the first quarter of 2024 was EUR 6.4 million (USD 6.9 million), compared to EUR 6.0 million (USD 6.5 million) for the year-ago period. Gross profit margin on net sales was 42.8% in the first quarter of 2024, compared to 40.8% in the year-ago period. The increase in gross profit margin year-over-year was primarily due to the higher level of treatment driven revenues which generates higher gross margin.

Operating expenses were 11.2 million euros (12.1 million in US Dollars) for the first quarter, compared to 12.6 million euros (13.6 million in US Dollars) for the same period in 2023. The decrease in operating expenses was due to the recording in Q1 2023 of a one-time, non-recurring employee compensation expense. The impact from this one-time expense in Q1 2023 was offset by the continued investment in the Company's U.S. commercial operations.

Operating loss for the first quarter of 2024 was EUR 4.8 million (USD 5.2 million), compared to an operating loss of EUR 6.6 million (USD 7.1 million) in the first quarter of 2023.

Net loss for the first quarter of 2024 was EUR 4.5 million (USD 4.9 million), or EUR (0.12) per diluted share, as compared to net loss of EUR 7.5 million (USD 8.1 million), or EUR (0.20) per diluted share in the year-ago period.

Conference Call

A conference call and webcast to discuss the first quarter 2024 financial results will be hosted by Ryan Rhodes, Chief Executive Officer, Ken Mobeck, Chief Financial Officer, and François Dietsch, Chief Accounting Officer. Please refer to the information below for conference call dial-in information and webcast registration.

Date: Thursday, May 16th @ 8:30am Eastern Time
Domestic: 1-877-451-6152
International: 1-201-389-0879
Passcode (Conf ID): 13745791
Call me™:https://callme.viavid.com/viavid/?callme=true&passcode=13712293&h=true&info=company-email&r=true&B=6

- Participants can use Guest dial-in #s above and be answered by an operator OR click the Call me™ link for instant

telephone access to the event.
- Call me™ link will be made active 15 minutes prior to scheduled start time.

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1665376&tp_key=00daa24457

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, us.hifu-prostate.com and www.focalone.com.

Forward-Looking Statements
In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as “believe,” “can,” “contemplate,” “could,” “plan,” “intend,” “is designed to,” “may,” “might,” “potential,” “objective,” “target,” “project,” “predict,” “forecast,” “ambition,” “guideline,” “should,” “will,” “estimate,” “expect” and “anticipate,” or the negative of these and similar expressions, which reflect our views about future events and financial performance. 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 risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Other 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.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

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:	
	March 31, 2024 Euros	March 31, 2023 Euros	March 31, 2024 $US	March 31, 2023 $US
Sales of medical equipment	9,967	10,319	10,782	11,121
Net Sales of RPP and Leases	1,775	1,579	1,921	1,701
Sales of spare parts, supplies and Services	3,165	2,897	3,424	3,123
TOTAL NET SALES	**14,908**	**14,795**	**16,127**	**15,945**

Other revenues	—	—	—	—
TOTAL REVENUES	**14,908**	**14,795**	**16,127**	**15,945**
Cost of sales	(8,523)	(8,764)	(9,220)	(9,445)
GROSS PROFIT	**6,385**	**6,032**	**6,907**	**6,500**
Research & development expenses	(2,069)	(1,458)	(2,238)	(1,571)
S, G & A expenses	(9,132)	(11,130)	(9,879)	(11,995)
Total operating expenses	(11,201)	(12,588)	(12,117)	(13,566)
OPERATING PROFIT (LOSS)	**(4,816)**	**(6,556)**	**(5,210)**	**(7,066)**
Interest (expense) income, net	145	256	157	276
Currency exchange gains (loss), net	236	(1,145)	255	(1,234)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	**(4,435)**	**(7,445)**	**(4,798)**	**(8,024)**
Income tax (expense) credit	(111)	(46)	(120)	(49)
NET INCOME (LOSS)	**(4,546)**	**(7,491)**	**(4,918)**	**(8,073)**
Earning per share – Basic	(0.12)	(0.20)	(0.13)	(0.22)
Average number of shares used in computation of EPS	36,996,722	36,922,286	36,996,722	36,922,286
Earning per share – Diluted	(0.12)	(0.20)	(0.13)	(0.22)
Average number of shares used in computation of EPS for positive net income	36,996,722	36,922,286	36,996,722	36,922,286

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average three months' noon buying rate of 1 Euro = 1.0818 USD, and 2023 average three months noon buying rate of 1 Euro = 1.0777 USD

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

	March 31, 2024 Euros	December 31, 2023 Euros	March 31, 2024 $US	December 31, 2023 $US
Cash, cash equivalents and short-term treasury investments	38,441	43,471	41,482	48,087
Account receivables, net	17,009	19,238	18,355	21,281
Inventory	17,451	15,112	18,831	16,717
Other current assets	1,189	659	1,283	729
TOTAL CURRENT ASSETS	**74,091**	**78,480**	**79,951**	**86,814**
Property, plant and equipment, net	10,106	8,193	10,906	9,063
Goodwill	2,412	2,412	2,603	2,668
Other non-current assets	2,469	2,464	2,665	2,725
TOTAL ASSETS	**89,078**	**91,548**	**96,124**	**101,270**
Accounts payable & other accrued liabilities	18,659	18,435	20,135	20,392
Deferred revenues, current portion	4,123	4,049	4,449	4,479
Short term borrowing	2,719	2,466	2,934	2,728
Other current liabilities	2,791	2,646	3,012	2,927
TOTAL CURRENT LIABILITIES	**28,293**	**27,596**	**30,531**	**30,526**
Obligations under operating and finance leases non-current	2,498	1,315	2,696	1,454
Long term debt, non-current	1,621	1,997	1,749	2,209
Deferred revenues, non-current	598	643	645	712
Other long term liabilities	3,081	3,075	3,325	3,402
TOTAL LIABILITIES	**36,091**	**34,626**	**38,946**	**38,304**
TOTAL SHAREHOLDERS'EQUITY	**52,987**	**56,922**	**57,178**	**62,966**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**89,078**	**91,548**	**96,124**	**101,270**

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0791 USD, on March 31, 2024 and at the noon buying rate of 1 Euro = 1.1062 USD, on December 31, 2023.

EDAP TMS S.A.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of Euros)

	Three Months Ended March 31, 2024 (Euros)	Twelve Months Ended December 31, 2023 (Euros)	Three Months Ended March 31, 2024 ($US)	Twelve Months Ended December 31, 2023 ($US)
NET INCOME (LOSS)	**(4,546)**	**(21,178)**	**(4,918)**	**(22,930)**
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities[1]	1,340	9,403	1,450	10,181
OPERATING CASH FLOW	**(3,206)**	**(11,775)**	**(3,468)**	**(12,749)**
Increase/Decrease in operating assets and liabilities	(544)	(2,903)	(589)	(3,144)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**(3,750)**	**(14,678)**	**(4,057)**	**(15,892)**
Short term investments	—	(0)	—	(0)
Additions to capitalized assets produced by the company and other capital expenditures	(1,098)	(4,344)	(1,188)	(4,704)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(1,098)**	**(4,344)**	**(1,188)**	**(4,704)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**(167)**	**(911)**	**(181)**	**(986)**
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**(13)**	**268**	**(1,179)**	**2,130**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(5,029)**	**(19,666)**	**(6,605)**	**(19,452)**

[1] *including share based compensation expenses for 692 thousand of Euros for the three months ended March 31, 2024 and 6,865 thousand of Euros for the full year ended December 31, 2023.*

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average three months' noon buying rate of 1 Euro = 1.0818 USD, and 2023 average twelve months noon buying rate of 1 Euro = 1.0827 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended March 31, 2024
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	3,708		832		5,427		—	9,967	
Sales of RPPs & Leases	1,458		262		55		—	1,775	
Sales of spare parts & services	618		1,177		1,370		—	3,165	
TOTAL NET SALES	**5,784**		**2,271**		**6,852**		**—**	**14,908**	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	**5,784**		**2,271**		**6,852**		**—**	**14,908**	
GROSS PROFIT (% of Net Sales)	**3,003**	**51.9 %**	**949**	**41.8 %**	**2,433**	**35.5 %**	**—**	**6,385**	**42.8 %**
Research & Development	(1,752)		(125)		(192)		—	(2,069)	
Total SG&A plus depreciation	(5,195)		(439)		(2,502)		(996)	(9,132)	
OPERATING PROFIT (LOSS)	**(3,943)**		**384**		**(261)**		**(996)**	**(4,816)**	

Attachment

- EDAP Q1 2024 Financial Results PR FINAL