

EDAP Reports Third Quarter 2024 Financial Results

Nov 07,2024

- Reported Q3 worldwide revenue of EUR 13.1 million (USD 14.4 million), increasing 11.6% over Q3 2023
- Reported Q3 worldwide HIFU revenue of EUR 4.5 million (USD 4.9 million), increasing 48.2% over Q3 2023
- 34% year-over-year growth in U.S. Focal One HIFU procedures
- CMS increases Medicare Hospital Outpatient Focal One HIFU procedure payment by 5.4% for 2025
- Announced AI collaboration with Avenda Health for Focal One Robotic HIFU
- Company to host conference call and webcast today, November 7th, at 8:30 a.m. EDT

LYON, France, November 7, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the third quarter of 2024.

"We continued to make steady progress in growing our core Focal One business in the third quarter of 2024," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "HIFU revenue grew 48.2% on a year-over-year basis, reflecting strong growth in the number of Focal One procedures. As we continue to expand our innovation with the Focal One platform, we are now partnering with Avenda Health to introduce AI technology directly into the Focal One robotic system. During the quarter, EDAP also had strong engagement through numerous interactions with urology leaders across multiple scientific meetings around the world.

"Our clinical programs in benign prostatic hyperplasia (BPH) and endometriosis also continue to make important progress. We recently announced that the first patients were treated in our Phase I/II study evaluating Focal One Robotic HIFU for the treatment of BPH. We also continue to see positive results from the extension arm of our Phase 3 trial evaluating Focal One for the treatment of deep infiltrating endometriosis. We can now report that over 85% of the patients initially in the Sham treatment arm whose pelvic pain returned to their high baseline levels are now being treated with HIFU. We remain excited about this program as we continue to generate important clinical data that indicates robotic HIFU has significant potential to address this condition which impacts thousands of women each year.

"Similar to the second half of 2023, we have seen several engaged customers extend their purchasing decisions into the fourth quarter. We therefore expect to finish 2024 with a strong performance. I am pleased to note that we have already closed on our first Focal One system to an HCA hospital early in the fourth quarter, and our Focal One pipeline remains strong and growing as we prepare to enter 2025."

Business Update

 On November 2, 2024, the Center for Medicare and Medicaid Services, CMS, released the final payment rules for 2025. The HIFU procedure continues to be supported with favorable reimbursement with CMS finalizing a Medicare Hospital payment rate of \$9,247 as a national average, adjusted locally with the corresponding local wage index factor. The rate will become effective on January 1, 2025, and represents a 5.4% increase over the 2024 payment. This continues to support the favorable strategic business case for hospitals to both invest and integrate Focal One HIFU while providing greater access to this valuable, non-invasive treatment option.

CMS also released the physician fee schedule for 2025 which continues to provide strong physician reimbursement for HIFU with 17.73 work relative value units, or work RVUs, and 29.41 Total RVUs. These figures are significantly higher than any other prostate ablation procedure. Additionally, it provides physicians with a level of reimbursement that is more than 80% of the payment for performing surgery, including Robotic Radical Prostatectomy. The Company believes that this continued support of the defined reimbursement levels for the use of HIFU provides a financially sound and sustainable economic offering for both the hospital and the physician.

- On September 30, 2024, the Company appointed current Board Member, Lance Willsey, M.D., M.S. as Interim Chairman of the Board. Dr. Willsey is a trained urologist who has over 35 years of private and public board experience focused in the area of cancer diagnostics and therapeutics. He completed his surgical and urology training at the Massachusetts General Hospital and additional postgraduate training in the Steele Lab at Harvard University and the Dana Farber Cancer Institute. Dr. Willsey was first appointed to the EDAP Board of Directors in December 2023.
- On September 19, 2024, the Company announced a collaboration to develop personalized prostate cancer care utilizing Avenda Health's groundbreaking AI technology, Unfold AI, to launch the world's first Focal One, AI-assisted robotic HIFU procedures. <u>Unfold AI</u> is a multimodal AI decision support platform cleared by the U.S. Food and Drug Administration (FDA) that brings "superhuman" abilities to cancer surgeons and oncologists to power the future of cancer care. Unfold AI

builds 3D patient-specific cancer maps that reveal invisible tumor extent and enables physicians to avoid leaving cancerous tissue behind while sparing healthy surrounding tissue. By leveraging Unfold Al's planning with the Focal One robotic HIFU platform, EDAP and Avenda believe that urologists can provide a more tailored, patient-specific HIFU ablation procedure for their prostate cancer patients.

- On August 6, 2024, the Company announced that Focal One Robotic HIFU was featured at the 41st World Congress of Endourology and Uro-Technology (WCET 2024) meeting, which took place in Seoul, Korea, from August 12-16, 2024. The Company had a significant presence at WCET 2024, reflecting the increasing trend amongst urologists for utilizing non-invasive HIFU technology for the management of prostate cancer. In addition to providing hands-on Focal One simulations for urologists in attendance, this year's WCET meeting featured a moderated Focal One clinical procedure conducted by Dr. Tarik Benidir, Clinical Assistant Professor from the University of Florida.
- On July 8, 2024, the Company announced the appointment of Fran Schulz to its Board of Directors. Ms. Schulz is a
 seasoned executive with over 35 years of experience with EY who has spent her career working with large public and
 emerging private companies throughout the life sciences industry. She has deep experience guiding companies to execute
 a broad range of corporate deals including collaboration agreements, corporate spin-offs, reorganizations, and mergers and
 acquisitions, with personal involvement in over 100 total equity and debt transactions, raising over \$15 billion in aggregate.

Clinical Pipeline Update

Benign Prostate Hyperplasia (BPH) Program

• On October 1, 2024, the Company announced that the first patients were treated in Phase I/II study evaluating Focal One Robotic HIFU for the treatment of benign prostatic hyperplasia (BPH). The Phase I/II study is a company-sponsored, prospective, multicenter clinical trial designed as a two-part study. Part 1 of the Phase I/II study will take place at three leading academic prostate treatment centers in France with a recognized expertise in the treatment of BPH as well as in the use of Focal One HIFU technology. Part 1 is designed to define the optimal treatment parameters to effectively treat BPH and its related symptoms with minimal side effects. Part 2 of the study will expand patient enrollment across a larger number of treatment centers in order to validate the safety and efficacy of the parameters as defined in Part 1 of the study. In July, the Company received approval from the French National Agency for Medicines and Health Products Safety (ANSM) to initiate a Phase I/II clinical trial investigating Focal One Robotic HIFU in BPH.

Endometriosis Program

• On July 19, 2024, the Company announced interim results from its Phase 3 study evaluating robotic HIFU for the treatment of deep infiltrating endometriosis. The interim data show that robotic HIFU therapy continues to maintain an excellent safety profile, confirming positive safety data from prior Phase 1 and 2 studies in patients with deep infiltrating endometriosis. At three months post procedure, the study's primary endpoint of reduced acute pelvic pain in the HIFU treatment arm compared to the Sham treatment arm was not met. Significant improvements were observed across primary and secondary outcome measures (endometriosis and digestive symptoms) across the entire study population at three months. As measured by MRI, patients receiving robotic HIFU therapy experienced higher volume reductions in the endometriosis nodule as compared to patients in the Sham treatment arm.

The Phase 3 study continues per protocol, and more than 85% of the patients initially in the Sham treatment arm have now elected to receive HIFU therapy after their pelvic pain returned to baseline levels. Symptoms for the Sham patients have returned back to their high baseline levels after one year post procedure. In contrast, patients from the HIFU arm who were evaluated one year following robotic HIFU treatment have maintained a similar level of improvement over their baseline symptoms as measured at three months post-procedure. These findings are consistent with the significant reduction in lesion volume as measured by MRI which was observed in the HIFU arm only. This additional data continues to suggest that HIFU therapy is a safe, non-invasive treatment that has significant potential to reduce pain for women suffering from this debilitating condition. Between now and year-end, the Company expects to meet with the FDA to discuss this data and the next steps forward for this program.

Upcoming Meetings and Events

- Jefferies London Healthcare Conference from November 19-21, 2024, in London, U.K. EDAP management will be presenting on Tuesday, November 19th, at 8:30 AM GBT
- Piper Sandler 36th Annual Healthcare Conference, December 3-5, 2024, in New York City. EDAP management will be presenting on Tuesday, December 3rd at 4:00 pm EST.

Third Quarter 2024 Results

Total worldwide revenue for the third quarter of 2024 was EUR 13.1 million (USD 14.4 million), an increase of 11.6% as compared to worldwide revenue of EUR 11.7 million (USD 12.7 million) for the same period in 2023.

Total revenue in the HIFU business for the third quarter of 2024 was EUR 4.5 million (USD 4.9 million), as compared to EUR 3.0 million (USD 3.3 million) for the third quarter of 2023. Three Focal One systems were sold during the third quarter of 2024 versus one system sold in the third quarter of 2023. Worldwide disposables revenue grew 35.3% in the third quarter of 2024 over the prior year period, driven by 34% growth in Focal One procedures in the US.

Total revenue in the Distribution business for the third quarter of 2024 was EUR 6.6 million (USD 7.3 million), as compared to EUR 6.0 million (USD 6.5 million) for the third quarter of 2023. The increase in Distribution revenue was driven primarily by recurring revenues from laser sales.

Total revenue in the LITHO business for the third quarter of 2024 was EUR 2.0 million (USD 2.2 million), as compared to EUR 2.7 million (USD 2.9 million) for the third quarter of 2023. The decrease in LITHO revenue was driven by 3 lithotripsy units sold in the third quarter of 2024 as compared to 7 units sold in the third quarter of 2023.

Gross profit for the third quarter of 2024 was EUR 5.2 million (USD 5.7 million), compared to EUR 4.2 million (USD 4.5 million) for the same period in 2023. Gross profit margin on net sales was 39.4% in the third quarter of 2024, compared to 35.5% for the comparable period in Q3 2023. The increase in gross profit margin year-over-year was primarily due to a favorable product mix shift and better absorption of our fixed costs primarily attributed to the growth of the HIFU revenue.

Operating expenses were 11.0 million euros (USD 12.1 million) for the third quarter, compared to 9.7 million euros (USD 10.5 million) for the same period in 2023. The increase in operating expenses was primarily due to investments made to support Focal One commercial operations globally.

Operating loss for the third quarter of 2024 was EUR 5.8 million (USD 6.4 million), compared to an operating loss of EUR 5.6 million (USD 6.0 million) in the third quarter of 2023.

Net loss for the third quarter of 2024 was EUR 6.4 million (USD 7.0 million), or EUR (0.17) per share, as compared to net loss of EUR 3.9 million (USD 4.3 million), or EUR (0.11) per share in the third quarter of 2023.

Year-to-Date Results

Total worldwide revenue for the nine months ended September 30, 2024, was EUR 43.8 million (USD 47.6 million), an increase of 7.3% from total worldwide revenue of EUR 40.8 million (USD 44.2 million) for the same period in 2023.

Total revenue in the HIFU business for the nine months ended September 30, 2024, was EUR 15.1 million (USD 16.3 million), an increase of 14.5% as compared to EUR 13.1 million (USD 14.2 million) for the nine months ended September 30, 2023.

Total revenue in the Distribution business for the nine months ended September 30, 2024, was EUR 22.2 million (USD 24.1 million), an increase of 10.9% compared to EUR 20.0 million (USD 21.7 million) for the nine months ended September 30, 2023.

Total revenue in the LITHO business for the nine months ended September 30, 2024, was EUR 6.6 million (USD 7.1 million), a decrease of 14.4% from EUR 7.6 million (USD 8.3 million) for the nine months ended September 30, 2023.

Gross profit for the nine months ended September 30, 2024, was EUR 17.5 million (USD 19.0 million), compared to EUR 15.8 million (USD 17.2 million), for the nine months ended September 30, 2023. Gross profit margin on net sales was 39.9% for the nine months ended September 30, 2024, compared to 38.8% for the comparable period in 2023.

Operating expenses were EUR 34.3 million (USD 37.2 million) for the nine months ended September 30, 2024, compared to EUR 32.2 million (USD 34.8 million) for the same period in 2023.

Operating loss for the nine months ended September 30, 2024, was EUR 16.8 million (USD 18.2 million), compared to an operating loss of EUR 16.3 million (USD 17.7 million) for the nine months ended September 30, 2023.

Net loss for the nine months ended September 30, 2024, was EUR 17.1 million (USD 18.5 million), or EUR (0.46) per share, as compared to a net loss of EUR 16.1 million (USD 17.5 million), or EUR (0.44) per share for the nine months ended September 30, 2023.

As of September 30, 2024, the Company held cash and cash equivalents of EUR 25.5 million (USD 28.4 million) as compared to EUR 43.5 million (USD 48.1 million) as of December 31, 2023.

Conference Call Information

A conference call and webcast to discuss the third 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, November 7th @ 8:30am Eastern TimeDomestic:1-800-445-7795International:1-785-424-1699Passcode (Conf ID):EDAP

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1691338&tp_key=a13da04d10

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 <u>http://www.edap-tms.com</u>, us.hifu-prostate.com and <u>www.focalone.com</u>.

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.

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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 Mont	hs Ended:	Three Months Ended:		
	September 30, 2024	September 30, 2023	September 30, 2024	September 30,	
	2024 Euros	Euros	2024 \$US	2023 \$US	
Sales of medical equipment	8,393	7,190	9,240	7,775	
Net sales of RPP and leases	1,586	1,236	1,746	1,336	
Sales of spare parts, supplies and services	3,120	3,311	3,435	3,581	
TOTAL REVENUE	13,098	11,737	14,420	12,692	
Cost of sales	(7,944)	(7,574)	(8,746)	(8,191)	
GROSS PROFIT	5,154	4,162	5,675	4,501	
Research & development expenses	(1,716)	(1,628)	(1,889)	(1,761)	
Selling, general & administrative expenses	(9,271)	(8,086)	(10,207)	(8,745)	
Total operating expenses	(10,987)	(9,714)	(12,096)	(10,505)	
OPERATING LOSS	(5,833)	(5,552)	(6,422)	(6,004)	
Interest (expense) income, net	102	347	113	376	
Currency exchange gains (loss), net	(606)	1,303	(667)	1,409	
LOSS BEFORE INCOME TAXES	(6,337)	(3,901)	(6,976)	(4,219)	
Income tax (expense) credit, net	(62)	(45)	(69)	(49)	
NET LOSS	(6,399)	(3,946)	(7,045)	(4,268)	
Loss per share – Basic and diluted	(0.17)	(0.11)	(0.19)	(0.12)	
Average number of shares used in computation of basic					
and diluted EPS	37,233,406	37,007,031	37,233,406	37,007,031	

EDAP TMS S.A. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Nine Montl	hs Ended:	Nine Months Ended:		
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023	
	Euros	Euros	\$US	\$US	
Sales of medical equipment	29,478	27,312	32,006	29,555	
Net sales of RPP and leases	5,247	4,565	5,697	4,940	
Sales of spare parts, supplies and services	9,072	8,933	9,850	9,667	
TOTAL REVENUE	43,797	40,810	47,553	44,162	
Cost of sales	(26,338)	(24,961)	(28,597)	(27,011)	
GROSS PROFIT	17,458	15,849	18,956	17,151	
Research & development expenses	(5,862)	(4,762)	(6,364)	(5,154)	
Selling, general & administrative expenses	(28,393)	(27,419)	(30,828)	(29,671)	
Total operating expenses	(34,254)	(32,182)	(37,192)	(34,825)	
OPERATING LOSS	(16,796)	(16,332)	(18,236)	(17,674)	
Interest (expense) income, net	438	859	475	929	
Currency exchange gains (loss), net	(419)	(349)	(455)	(378)	
LOSS BEFORE INCOME TAXES	(16,777)	(15,823)	(18,216)	(17,123)	
Income tax (expense) credit, net	(300)	(312)	(326)	(337)	
NET LOSS	(17,077)	(16,135)	(18,542)	(17,460)	
Loss per share – Basic and diluted	(0.46)	(0.44)	(0.50)	(0.47)	
Average number of shares used in computation of basic and diluted EPS	37,149,121	36,972,681	37,149,121	36,972,681	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average nine months' exchange rate of 1 Euro = 1.0858 USD, and 2023 average nine months' exchange rate of 1 Euro = 1.0821 USD

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

	September 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short-term investments	25,482	43,471	28,399	48,087
Accounts receivable, net	16,175	19,238	18,026	21,281
Inventory	21,003	15,112	23,407	16,717
Other current assets	1,280	659	1,427	729
TOTAL CURRENT ASSETS	63,940	78,480	71,258	86,814
Property, plant and equipment, net	10,176	8,193	11,341	9,063
Goodwill	2,412	2,412	2,688	2,668
Other non-current assets	2,514	2,464	2,802	2,725
TOTAL ASSETS	79,043	91,548	88,089	101,270
Accounts payable & other accrued liabilities	18,823	18,435	20,978	20,392
Deferred revenues, current portion	5,402	4,049	6,020	4,479
Short term borrowing	2,480	2,466	2,764	2,728
Other current liabilities	2,676	2,646	2,983	2,927
TOTAL CURRENT LIABILITIES	29,381	27,596	32,744	30,526
Obligations under operating and finance leases non-current	2,135	1,315	2,380	1,454
Long-term debt, non-current	1,315	1,997	1,466	2,209
Deferred revenues, non-current	415	643	462	712
Other long-term liabilities	3,153	3,075	3,514	3,402
TOTAL LIABILITIES	36,400	34,626	40,567	38,304
TOTAL SHAREHOLDERS'EQUITY	42,642	56,922	47,523	62,966
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	79,043	91,548	88,089	101,270

NOTE: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.1145 USD, on September 30, 2024 and at the exchange rate of 1 Euro = 1.1062 USD, on December 31, 2023.

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

	Nine Months Ended September 30, 2024 (Euros)	Twelve Months Ended December 31, 2023 (Euros)	Nine Months Ended September 30, 2024 (\$US)	Twelve Months Ended December 31, 2023 (\$US)
NET LOSS	(17,077)	(21,178)	(18,542)	(22,930)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities ⁽¹⁾	4,544	9,403	4,934	10,181
OPERATING CASH FLOW	(12,533)	(11,775)	(13,608)	(12,749)
Increase/decrease in operating assets and liabilities	(2,261)	(2,903)	(2,455)	(3,144)
NET CASH USED IN OPERATING ACTIVITIES	(14,795)	(14,678)	(16,064)	(15,892)
Additions to capitalized assets produced by the company and other capital expenditures	(2,833)	(4,344)	(3,076)	(4,704)
NET CASH USED ININVESTING ACTIVITIES	(2,833)	(4,344)	(3,076)	(4,704)
NET CASH USED IN FINANCING ACTIVITIES	(819)	(911)	(889)	(986)
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	458	268	341	2,130
NET DECREASE IN CASH AND CASH EQUIVALENTS	(17,988)	(19,666)	(19,688)	(19,452)

⁽¹⁾ including share- based compensation expense of 2,382 thousand Euros for the nine months ended September 30, 2024 and 6,865 thousand Euros for the full year ended December 31, 2023.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average nine months' exchange rate of 1 Euro = 1.0858 USD, and 2023 average twelve months' exchange rate of 1 Euro = 1.0827 USD

EDAP TMS S.A. UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION nine months ended September 30, 2024 (Amounts in thousands of Euros)

	HIFU Division	ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of medical	0.000	2 202		18,203			20.479	
equipment Net sales of RPP and	8,882	2,392		10,203		—	29,478	
leases	4,287	753		207		—	5,247	
Sales of spare parts, supplies and services	1,885	3,406		3,781			9,072	
TOTAL REVENUE	15,055	6,551		22,190			43,797	
GROSS PROFIT (% of Net Sales)	7,010	46.6 % 2,733	41.7%	7,715	34.8 %		17,458	39.9%
Research & development expenses Selling, general &	(5,079)	(294)		(488)		_	(5,862)	
administrative expenses OPERATING INCOME	(16,166)	(1,385)		(7,748)		(3,094)	(28,393)	
(LOSS)	(14,235)	1,054		(521)		(3,094)	(16,796)	

NOTE: Reconciling Items include headquarters costs.

Attachment

EDAP Q3 2024 Financial Results PR Nov 7 2024 (FINAL)