

EDAP Announces Third Quarter 2023 Financial Results

Nov 09, 2023

- *Strong Q3 2023 U.S. Focal One® HIFU procedure growth of +150% year-over-year -*
- *Record nine months HIFU revenues reflecting growing demand -*
- *Two additional Focal One systems already placed in the fourth quarter -*
- *Announces immunotherapy clinical research collaboration with Mount Sinai, Department of Urology -*
- *Company to host conference call and webcast today, Thursday, November 9th at 8:30 am EDT -*

LYON, France, November 9, 2023 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited financial results for the third quarter ending September 30, 2023.

"We continue to see stronger awareness and acceptance of focal therapy as a necessity in the management and treatment of prostate cancer," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "Within this category, Focal One Robotic High-Intensity Focal Ultrasound (HIFU) continues to be embraced as the leading platform of choice amongst both urologists and their patients. Reflecting this growing demand, we continue to see robust procedure growth among our installed base, with the number of Focal One HIFU procedures in the U.S. increasing by 150% year-over-year in the third quarter. As the number of procedures grows, we expect our positive momentum to continue based on excellent patient outcomes and the strategic investments we are making into our commercial and clinical teams to support the growing demand for Focal One HIFU."

"Entering the fourth quarter of 2023, our pipeline remains very strong, and we expect demand for the Focal One platform will continue to grow in a balanced manner across both academic and community urology practices," continued Mr. Rhodes. "With \$50.5 million in cash, our balance sheet remains strong and we will continue to strategically invest across our commercial operations to drive productivity and support the growing demand for Focal One Robotic HIFU. As we approach the new year, EDAP continues to build momentum in our business, and we are well positioned as a market leader in focal therapy."

Business Update

- Placed two Focal One systems during the third quarter of 2023. One Focal One unit was sold to University of Florida, and the second Focal One unit was placed at Cleveland Clinic, Abu Dhabi. Following the close of the third quarter, the Company has placed an additional two Focal One systems, including one in the U.S., reflecting increasing recognition among clinicians and providers that Focal One is becoming an essential option to effectively treat select prostate cancer patients.
- In July, the Company announced reimbursement approval in Switzerland for the use of HIFU in the treatment of prostate cancer; reimbursement took effect on July 1, 2023. Switzerland is a member of the DACH market region (including Germany, Austria and Switzerland) with over 100 million combined total inhabitants. Switzerland has many hospitals ranked amongst the best 250 in the world according to Newsweek's "The World's Best Hospitals 2023". Included in this list is the University of Zurich, an active and prominent Focal One site and the leading innovation center for HIFU in the country. The University of Zurich is also a member of the League of European Research Universities, placing it among Europe's most prestigious research institutions.
- During the third quarter of 2023, Focal One was showcased at multiple regional, national and international scientific meetings through booth demonstrations as well as poster and podium presentations led by some of the most prominent specialists in the field of prostate cancer and focal therapy, including 13th International Symposium on Focal Therapy in Washington, DC (Sep 7-9), and the first Society of Urologic Oncology-approved Fellows Focal Therapy Course hosted by Cleveland Clinic (Sep 21-22).

Clinical Pipeline Update

Rectal Endometriosis Program

- The ongoing Phase 3 double-blind, randomized controlled trial evaluating Focal One HIFU for the treatment of deep infiltrating rectal endometriosis has already enrolled 50 of the 60 planned patients as of today, and enrollment is expected to be completed before year-end.

- In October, positive results from the previously reported Endo-HIFU-R1 Phase 2 study in deep-infiltrating rectal endometriosis were presented by Professor Gil Dubernard, Head of Gynecology-Obstetric Department, Croix-Rousse University Hospital, Lyon, France, at the European Society for Gynecological Endoscopy Annual Congress in Brussels, Belgium. Yesterday, Professor Dubernard also presented the results from this important study at the 52nd Meeting of the American Association of Gynecologic Laparoscopists (AAGL) in Nashville, TN.

Immunotherapy Clinical Research Collaboration with Mount Sinai Department of Urology

During the third quarter, EDAP entered into a clinical research collaboration with the prestigious Icahn School of Medicine at Mount Sinai Department of Urology in New York to accelerate the understanding of the role of immunotherapy treatment in conjunction with high intensity focused ultrasound (HIFU) in patients with prostate cancer. Focal therapy using HIFU delivers precise ablative energy to a targeted prostate lesion and existing research shows such treatment increases the immune response. The purpose of the collaboration is to understand if HIFU in combination with immunotherapy can generate measurable oncologic results in patients with prostate cancer. The research is being supervised by an internationally recognized leader in the field, Dr. Ashutosh Tewari, the Chairman of the Urology at the Icahn School of Medicine at Mount Sinai Hospital.

Upcoming Corporate Presentations

- EDAP will present on November 14 at the upcoming Jefferies LLC Global Healthcare Conference (November 14-16, London, UK)
- EDAP will participate in a fireside chat on November 29 at the upcoming Piper Sandler 35th Annual Healthcare Conference (November 28-30, New York City)

Third Quarter 2023 Results

Total revenue for the third quarter of 2023 was EUR 11.7 million (USD 12.7 million), a decrease of 4.1% as compared to total revenue of EUR 12.2 million (USD 12.3 million) for the same period in 2022.

Total revenue in the HIFU business for the third quarter of 2023 was EUR 3.0 million (USD 3.3 million), as compared to EUR 3.5 million (USD 3.5 million) for the third quarter of 2022. The decrease was driven by 1 Focal One system sold in the third quarter 2023 versus 3 systems sold in the third quarter of 2022. Despite the modest decrease in overall HIFU sales, the Company recorded a 49.2% year over year growth in disposables revenues, reflecting strong procedure growth.

Total revenue in the LITHO business for the third quarter of 2023 was EUR 2.7 million (USD 2.9 million), as compared to EUR 2.2 million (USD 2.2 million) for the third quarter of 2022. The increase in LITHO revenue was driven by 7 lithotripsy units sold in the third quarter of 2023 as compared to 2 units sold in the third quarter of 2022.

Total revenue in the Distribution business for the third quarter of 2023 was EUR 6.0 million (USD 6.5 million), as compared to EUR 6.6 million (USD 6.6 million) for the third quarter of 2022. The decline in Distribution revenue was driven primarily by 9 ExactVu units sold during the third quarter of 2023 as compared to 12 units sold during the third quarter of 2022.

Gross profit for the third quarter of 2023 was EUR 4.2 million (USD 4.5 million), compared to EUR 5.0 million (USD 5.0 million) for the year-ago period. Gross profit margin on net sales was 35.5% in the third quarter of 2023, compared to 41.0% in the year-ago period. The decrease in gross profit margin year-over-year was primarily due to three main factors: the adverse impact from delayed sales of U.S. Focal One systems in the quarter, higher mix of distribution product with lower gross margin and continued investments in the U.S. field service and clinical application organizations to further support HIFU adoption and long-term revenue growth.

Operating expenses were EUR 9.7 million (USD 10.5 million) for the third quarter of 2023, compared to EUR 7.2 million (USD 7.2 million) for the same period in 2022. The increase in operating expenses was primarily due to the continued strategic and planned build-out of the U.S. team and commercial infrastructure and increased marketing activities.

Operating loss for the third quarter of 2023 was EUR 5.6 million (USD 6.0 million), compared to an operating loss of EUR 2.1 million (USD 2.2 million) in the third quarter of 2022.

Net loss for the third quarter of 2023 was EUR 3.9 million (USD 4.3 million), or EUR 0.11 per diluted share, as compared to net income of EUR 0.0 million (USD 0.0 million), or EUR 0.00 per diluted share in the year-ago period.

Year-to-Date Results

Total revenue for the nine months ended September 30, 2023, was EUR 40.8 million (USD 44.2 million), an increase of 3.6% from total revenue of EUR 39.4 million (USD 41.7 million) for the same period in 2022.

Total revenue in the HIFU business for the nine months ended September 30, 2023, was EUR 13.1 million (USD 14.2 million), an increase of 28.1% as compared to EUR 10.3 million (USD 10.9 million) for the nine months ended September 30, 2022.

Total revenue in the LITHO business for the nine months ended September 30, 2023, was EUR 7.6 million (USD 8.3 million), a

decrease of 4.0% from EUR 8.0 million (USD 8.4 million) for the nine months ended September 30, 2022.

Total revenue in the Distribution business for nine months ended September 30, 2023, was EUR 20.0 million (USD 21.7 million), a 5.4% decrease compared to EUR 21.2 million (USD 22.4 million) for the nine months ended September 30, 2022.

Gross profit for the nine months ended September 30, 2023, was EUR 15.8 million (USD 17.2 million), compared to EUR 17.0 million (USD 18.0 million), for the year-ago period. Gross profit margin on net sales was 38.8% for the nine months ended September 30, 2023, compared to 43.1% for the comparable period in 2022. The decrease in gross profit margin year-over-year was primarily due to three main factors: Distribution product mix, global inflationary price pressure on components which increased manufacturing costs, and continued investments in our U.S. service and clinical application organizations to support HIFU and long-term revenue growth.

Operating expenses were EUR 32.2 million (USD 34.8 million) for the nine months ended September 30, 2023, compared to EUR 19.7 million (USD 20.8 million) for the same period in 2022. The increase in operating expenses is mainly due to the strategic and planned build-out of the U.S. team and commercial infrastructure, and non-recurring expenses linked to the leadership succession plan.

Operating loss for the nine months ended September 30, 2023, was EUR 16.3 million (USD 17.7 million), compared to an operating loss of EUR 2.7 million (USD 2.8 million) for the nine months ended September 30, 2022.

Net loss for the nine months ended September 30, 2023, was EUR 16.1 million (USD 17.5 million), or EUR 0.44 per diluted share, as compared to a net income of EUR 2.2 million (USD 2.3 million), or EUR 0.06 per diluted share in the year-ago period.

As of September 30, 2023, the Company held cash and cash equivalents of EUR 47.7 million (USD 50.5 million) as compared to EUR 63.1 million (USD 67.5 million) as of December 31, 2022.

Conference Call

A conference call and webcast to discuss the third quarter 2023 financial results will be hosted Ryan Rhodes, Chief Executive Officer, François Dietsch, Chief Financial Officer and Ken Mobeck, Chief Financial Officer of the U.S. subsidiary, today, Thursday, November 9th, 2023, at 8:30am EDT. Please refer to the information below for conference call dial-in information and webcast registration.

Date: Thursday, November 9th @ 8:30am Eastern Time
Domestic: 1-877-451-6152
International: 1-201-389-0879
Passcode (Conf ID): 13741382
Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1635563&tp_key=28f6dfe71c

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.

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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, 2023 Euros	September 30, 2022 Euros	September 30, 2023 \$US	September 30, 2022 \$US
Sales of medical equipment	7,190	8,319	7,775	8,333
Net Sales of RPP and Leases	1,236	1,214	1,336	1,216
Sales of spare parts, supplies and Services	3,311	2,710	3,581	2,714
TOTAL NET SALES	11,737	12,243	12,692	12,263
Other revenues	—	—	—	—
TOTAL REVENUES	11,737	12,243	12,692	12,263
Cost of sales	(7,574)	(7,226)	(8,191)	(7,238)
GROSS PROFIT	4,162	5,017	4,501	5,026
Research & development expenses	(1,628)	(1,361)	(1,761)	(1,363)
S, G & A expenses	(8,086)	(5,805)	(8,745)	(5,815)
Total operating expenses	(9,714)	(7,165)	(10,505)	(7,178)
OPERATING PROFIT (LOSS)	(5,552)	(2,148)	(6,004)	(2,152)
Interest (expense) income, net	347	(4)	376	(4)
Currency exchange gains (loss), net	1,303	3,020	1,409	3,025
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(3,901)	867	(4,219)	869
Income tax (expense) credit	(45)	(854)	(49)	(856)
NET INCOME (LOSS)	(3,946)	13	(4,268)	13
Earning per share – Basic	(0.11)	0.00	(0.12)	0.00
Average number of shares used in computation of EPS	37,007,031	33,696,543	37,007,031	33,696,543
Earning per share – Diluted	(0.11)	0.00	(0.12)	0.00
Average number of shares used in computation of EPS for positive net income	37,007,031	34,612,773	37,007,031	34,612,773

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average three months' noon buying rate of 1 Euro = 1.0814 USD, and 2022 average three months noon buying rate of 1 Euro = 1.0017 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, 2023 Euros	September 30, 2022 Euros	September 30, 2023 \$US	September 30, 2022 \$US
Sales of medical equipment	27,312	26,969	29,555	28,563
Net Sales of RPP and Leases	4,565	4,176	4,940	4,423
Sales of spare parts, supplies and Services	8,933	8,245	9,667	8,733
TOTAL NET SALES	40,810	39,391	44,162	41,719
Other revenues	—	—	—	—
TOTAL REVENUES	40,810	39,391	44,162	41,719
Cost of sales	(24,961)	(22,416)	(27,011)	(23,741)
GROSS PROFIT	15,849	16,975	17,151	17,978
Research & development expenses	(4,762)	(3,615)	(5,154)	(3,829)
S, G & A expenses	(27,419)	(16,047)	(29,671)	(16,995)
Total operating expenses	(32,182)	(19,662)	(34,825)	(20,824)
OPERATING PROFIT (LOSS)	(16,332)	(2,687)	(17,674)	(2,846)
Interest (expense) income, net	859	(62)	929	(66)
Currency exchange gains (loss), net	(349)	6,001	(378)	6,355
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(15,823)	3,251	(17,123)	3,443
Income tax (expense) credit	(312)	(1,054)	(337)	(1,117)
NET INCOME (LOSS)	(16,135)	2,197	(17,460)	2,327
Earning per share – Basic	(0.44)	0.07	(0.47)	0.07
Average number of shares used in computation of EPS	36,972,681	33,544,003	36,972,681	33,544,003
Earning per share – Diluted	(0.44)	0.06	(0.47)	0.07
Average number of shares used in computation of EPS for positive net income	36,972,681	34,301,115	36,972,681	34,301,115

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average nine months' noon buying rate of 1 Euro = 1.0821 USD, and 2022 average nine months noon buying rate of 1 Euro = 1.0591 USD

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

	September 30, 2023 Euros	December 31, 2022 Euros	September 30, 2023 \$US	December 31, 2022 \$US
Cash, cash equivalents and short-term treasury investments	47,717	63,136	50,505	67,539
Account receivables, net	16,305	14,943	17,258	15,985
Inventory	15,338	11,780	16,234	12,601
Other current assets	910	660	964	706
TOTAL CURRENT ASSETS	80,270	90,518	84,960	96,832
Property, plant and equipment, net	8,058	5,984	8,529	6,401
Goodwill	2,412	2,412	2,553	2,580
Other non-current assets	2,525	2,210	2,672	2,364
TOTAL ASSETS	93,265	101,123	98,714	108,177
Accounts payable & other accrued liabilities	16,923	13,087	17,912	14,000
Deferred revenues, current portion	4,660	4,050	4,932	4,333
Short term borrowing	1,649	1,846	1,745	1,975
Other current liabilities	2,716	2,725	2,875	2,916
TOTAL CURRENT LIABILITIES	25,948	21,708	27,464	23,223
Obligations under operating and finance leases non-current	1,374	1,222	1,454	1,308
Long term debt, non-current	2,396	3,587	2,536	3,837
Deferred revenues, non-current	648	264	686	282

Other long term liabilities	2,813	2,710	2,978	2,899
TOTAL LIABILITIES	33,180	29,492	35,118	31,549
TOTAL SHAREHOLDERS'EQUITY	60,085	71,632	63,595	76,628
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	93,265	101,123	98,714	108,177

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0584 USD, on September 30, 2023 and at the noon buying rate of 1 Euro = 1.0697 USD, on December 31, 2022.

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

	Nine Months Ended September 30, 2023 (Euros)	Twelve Months Ended December 31, 2022 (Euros)	Nine Months Ended September 30, 2023 (\$US)	Twelve Months Ended December 31, 2022 (\$US)
NET INCOME (LOSS)	(16,135)	(2,933)	(17,460)	(3,085)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	6,685	4,225	7,234	4,444
OPERATING CASH FLOW	(9,450)	1,292	(10,226)	1,359
Increase/Decrease in operating assets and liabilities	(804)	(4,316)	(870)	(4,539)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(10,254)	(3,024)	(11,096)	(3,180)
Short term investments	(0)	—	(0)	—
Additions to capitalized assets produced by the company and other capital expenditures	(3,500)	(2,378)	(3,787)	(2,501)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(3,500)	(2,378)	(3,787)	(2,501)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(1,255)	21,741	(1,358)	22,869
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(410)	(388)	(792)	(3,053)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(15,419)	15,952	(17,034)	14,134

⁽¹⁾ including share-based compensation expenses for 5,152 thousand of Euros for the nine months ended September 30, 2023 and 2,103 thousand of Euros for the full year ended December 31, 2022.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average nine months' noon buying rate of 1 Euro = 1.0821 USD, and 2022 average twelve months noon buying rate of 1 Euro = 1.0519 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
Nine months ended September 30, 2023
(Amounts in thousands of Euros)

	HIFU Division	ESWL Division	Distribution Division	Reconciling Items	Total After Consolidation
Sales of goods	7,828	3,134	16,350	—	27,312
Sales of RPPs & Leases	3,660	686	219	—	4,565
Sales of spare parts & services	1,655	3,828	3,449	—	8,933

TOTAL NET SALES	13,143		7,649		20,018		—		40,810	
Other revenues	—		—		—		—		—	
TOTAL REVENUES	13,143		7,649		20,018		—		40,810	
GROSS PROFIT (% of Net Sales)	6,341	48.2 %	2,962	38.7 %	6,546	32.7 %	—		15,849	38.8 %
Research & Development	(3,900)		(532)		(330)		—		(4,762)	
Total SG&A plus depreciation	(13,731)		(2,448)		(7,423)		(3,818)		(27,419)	
OPERATING PROFIT (LOSS)	(11,289)		(18)		(1,208)		(3,818)		(16,332)	

Attachment

- [EDAP Q3 2023 Financial Results PR 9 nov 2023 FINAL](#)