

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

August 28, 2024

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
4/6 Rue du Dauphine
69120 Vaulx-en-Velin - France

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 28, 2024

EDAP TMS S.A.

/s/ KEN MOBECK

KEN MOBECK

CHIEF FINANCIAL OFFICER

EDAP Reports Second Quarter 2024 Financial Results

- Record Q2 2024 total worldwide revenue of EUR 15.8 million (USD 17.0 million) increased 10.6% over Q2 2023
- Record first half 2024 total worldwide revenue of EUR 30.7 million (USD 33.1 million) increased 5.6% over first half 2023
- Strong Q2 2024 U.S. Focal One[®] HIFU procedure growth of +63% year-over-year
- Company to host conference call and webcast today, August 28th, at 8:30 a.m. EDT

LYON, France, August 28, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the second quarter of 2024.

“We continue to see growing demand for our proprietary and leading Focal One robotic HIFU technology platform. In the second quarter, we placed five Focal One systems, which included placements with two additional National Cancer Institute (NCI) designated comprehensive cancer centers. A growing number of top tier cancer research and treatment centers continue to adopt Focal One to help patients manage their prostate cancer, which reflects the innovation and positive clinical outcomes of our leading robotic HIFU platform,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “We also experienced strong year over year procedure growth, which points towards the growing adoption of robotic HIFU amongst urologists across both academic and community hospitals.

“There is also an increasing body of clinical evidence that supports the continued adoption of Focal One as a frontline treatment for localized prostate cancer. The final results from the groundbreaking, prospective HIFI study were presented at this year’s EAU and AUA scientific meetings. This data clearly demonstrates that Focal One robotic HIFU is at least as effective as radical prostatectomy as a first line treatment for localized disease, but with the added potential for improved functional outcomes with respect to both the preservation of urinary continence and sexual function. We believe the HIFI study helps pave the way for broader adoption of our HIFU technology. We expect the results from the HIFI study, in combination with the recent investments in our commercial team, should help drive strong adoption of Focal One throughout the second half of the year.”

Business Update

- On August 27, 2024, Marc Oczachowski resigned as Chairman of the Company’s Board of Directors in order to allow him more time to focus on other endeavors. In order to provide for a smooth transition for the Board of Directors, the effective date of the resignation will be September 30, 2024.
- On July 8, 2024, the Company appointed 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.
- 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 included a featured semi-live Focal One clinical procedure conducted by Dr. Tarik Benidir, Clinical Assistant Professor from the University of Florida.

- On June 3, 2024, the Company appointed Damien Desmedt and Alexander Fromm to further strengthen the EDAP's European and Middle Eastern commercial leadership. Mr. Desmedt was appointed Vice President of Sales for Europe, Middle East, Africa, and India (EMEAI), and Mr. Fromm was appointed General Manager for Switzerland and will oversee several strategic European territories.
- 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".

Clinical Pipeline Update

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, with several patients initially in the Sham treatment arm having elected and already received HIFU therapy after their pelvic pain returned to baseline levels.

Benign Prostate Hyperplasia (BPH) Program

- On July 26, 2024, the Company received approval from the French National Agency for Medicines and Health Products Safety (ANSM) to initiate a Phase 1-2 Clinical Trial investigating Focal One Robotic HIFU in the treatment of Benign Prostate Hyperplasia (BPH). This company-sponsored multicenter study is designed as a 2-phase study: the first phase will take place at two 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. This first phase is designed as a HIFU dose escalation protocol aimed at defining the optimal treatment parameters to effectively treat BPH and its related symptoms with minimal side effects. The second phase 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 defined during the first phase of the study.

Upcoming Meetings and Events H.C. Wainwright Healthcare Conference, Tuesday, September 10th, in New York City

Second Quarter 2024 Results

Total worldwide revenue for the second quarter of 2024 was EUR 15.8 million (USD 17.0 million), an increase of 10.6% as compared to worldwide revenue of EUR 14.3 million (USD 15.5 million) for the same period in 2023.

Total revenue in the HIFU business for the second quarter of 2024 was EUR 4.8 million (USD 5.2 million), as compared to EUR 4.9 million (USD 5.3 million) for the second quarter of 2023. Three Focal One systems were sold during the second quarter of 2024 versus four systems sold in the second quarter of 2023. Despite the 1 unit decrease year over year, the Company recorded a 29.4% year-over-year growth in worldwide disposables revenues, driven by the 63% Focal One procedure growth in the US.

Total revenue in the Distribution business for the second quarter of 2024 was EUR 8.7 million (USD 9.4 million), as compared to EUR 7.2 million (USD 7.8 million) for the second quarter of 2023. The increase in Distribution revenue was driven primarily by 12 ExactVu units sold during the second quarter of 2024 as compared to 9 units sold during the second quarter of 2023.

Total revenue in the LITHO business for the second quarter of 2024 was EUR 2.3 million (USD 2.5 million), as compared to EUR 2.2 million (USD 2.4 million) for the second quarter of 2023. The increase in LITHO revenue was driven by 3 lithotripsy units sold in the second quarter of 2024 as compared to 2 units sold in the second quarter of 2023.

Gross profit for the second quarter of 2024 was EUR 5.9 million (USD 6.4 million), compared to EUR 5.7 million (USD 6.1 million) for the year-ago period. Gross profit margin on net sales was 37.5% in the second quarter of 2024, compared to 39.6% for the comparable period in Q2 2023. The decrease in gross profit margin year-over-year was primarily due to product mix shift and higher cost of goods sold.

Operating expenses were 12.1 million euros (USD 13.0 million) for the second quarter, compared to 9.9 million euros (USD 10.7 million) for the same period in 2023. The increase in operating expenses was due to the continued investments made in the global commercial and R&D functions in anticipation of growing demand for Focal One.

Operating loss for the second quarter of 2024 was EUR 6.1 million (USD 6.6 million), compared to an operating loss of EUR 4.2 million (USD 4.6 million) in the second quarter of 2023.

Net loss for the second quarter of 2024 was EUR 6.1 million (USD 6.6 million), or EUR (0.16) per share, as compared to net loss of EUR 4.7 million (USD 5.1 million), or EUR (0.13) per share in the second quarter of 2023.

Year-to-Date Results

Total worldwide revenue for the six months ended June 30, 2024, was EUR 30.7 million (USD 33.1 million), an increase of 5.6% from total worldwide revenue of EUR 29.1 million (USD 31.5 million) for the same period in 2023.

Total revenue in the HIFU business for the six months ended June 30, 2024, was EUR 10.6 million (USD 11.4 million), an increase of 4.5% as compared to EUR 10.1 million (USD 11.0 million) for the six months ended June 30, 2023.

Total revenue in the Distribution business for the six months ended June 30, 2024, was EUR 15.6 million (USD 16.8 million), a 11.4% increase compared to EUR 14.0 million (USD 15.1 million) for the six months ended June 30, 2023.

Total revenue in the LITHO business for the six months ended June 30, 2024, was EUR 4.6 million (USD 4.9 million), a decrease of 8.5% from EUR 5.0 million (USD 5.4 million) for the six months ended June 30, 2023.

Gross profit for the six months ended June 30, 2024, was EUR 12.3 million (USD 13.3 million), compared to EUR 11.7 million (USD 12.7 million), for the six months ended June 30, 2023. Gross profit margin on net sales was 40.1% for the six months ended June 30, 2024, compared to 40.2% for the comparable period in 2023.

Operating expenses were EUR 23.3 million (USD 25.1 million) for the six months ended June 30, 2024, compared to EUR 22.5 million (USD 24.3 million) for the same period in 2023.

Operating loss for the six months ended June 30, 2024, was EUR 11.0 million (USD 11.8 million), compared to an operating loss of EUR 10.8 million (USD 11.7 million) for the six months ended June 30, 2023.

Net loss for the six months ended June 30, 2024, was EUR 10.7 million (USD 11.5 million), or EUR (0.29) per share, as compared to a net loss of EUR 12.2 million (USD 13.2 million), or EUR (0.33) per share for the six months ended June 30, 2023.

As of June 30, 2024, the Company held cash and cash equivalents of EUR 30.2 million (USD 32.4 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 second 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: Wednesday, August 28th @ 8:30am Eastern Time
Domestic: 1-877-300-8521
International: 1-412-317-6026
Passcode (Conf ID): 7219730
Call me™: LINK (will be activated 15 minutes prior to scheduled start time)

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1679882&tp_key=f499a45540

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	
	June 30, 2024 Euros	June 30, 2023 Euros	June 30, 2024 \$US	June 30, 2023 \$US
Sales of medical equipment	11,118	9,804	11,948	10,657
Net sales of RPP and leases	1,886	1,751	2,027	1,903
Sales of spare parts, supplies and services	2,787	2,724	2,995	2,961
TOTAL NET SALES	15,791	14,278	16,970	15,522
Other revenues	—	—	—	—
TOTAL REVENUES	15,791	14,278	16,970	15,522
Cost of sales	(9,872)	(8,623)	(10,609)	(9,374)
GROSS PROFIT	5,919	5,655	6,361	6,148
Research & development expenses	(2,077)	(1,677)	(2,232)	(1,823)
Selling, general & administrative expenses	(9,989)	(8,203)	(10,736)	(8,917)
Total operating expenses	(12,066)	(9,880)	(12,967)	(10,740)
OPERATING PROFIT (LOSS)	(6,147)	(4,225)	(6,606)	(4,592)
Interest (expense) income, net	190	255	204	278
Currency exchange gains (loss), net	(49)	(508)	(52)	(552)
LOSS BEFORE INCOME TAXES	(6,005)	(4,477)	(6,454)	(4,867)
Income tax (expense) credit	(127)	(221)	(136)	(240)
NET LOSS	(6,132)	(4,698)	(6,590)	(5,107)
Loss per share – Basic and diluted	(0.16)	(0.13)	(0.18)	(0.14)
Avg number of shares used in computation of basic and diluted EPS	37,205,307	36,985,934	37,205,307	36,985,934

NOTE: Translated to U.S. dollars at the 2024 average three months' exchange rate of 1 Euro = 1.0747 USD, and 2023 average three months' exchange rate of 1 Euro = 1.0871 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	June 30	June 30	June 30
	2024	2023	2024	2023
	Euros	Euros	\$US	\$US
Sales of medical equipment	21,085	20,123	22,735	21,782
Net sales of RPP and leases	3,661	3,329	3,948	3,604
Sales of spare parts, supplies and services	5,952	5,622	6,418	6,085
TOTAL NET SALES	30,698	29,074	33,102	31,472
Other revenues	—	—	—	—
TOTAL REVENUES	30,698	29,074	33,102	31,472
Cost of sales	(18,394)	(17,387)	(19,834)	(18,821)
GROSS PROFIT	12,304	11,687	13,267	12,651
Research & development expenses	(4,146)	(3,135)	(4,470)	(3,393)
Selling, general & administrative expenses	(19,121)	(19,333)	(20,618)	(20,928)
Total operating expenses	(23,267)	(22,467)	(25,088)	(24,321)
OPERATING PROFIT (LOSS)	(10,963)	(10,781)	(11,821)	(11,670)
Interest (expense) income, net	335	511	361	554
Currency exchange gains (loss), net	187	(1,653)	202	(1,789)
LOSS BEFORE INCOME TAXES	(10,440)	(11,922)	(11,258)	(12,905)
Income tax (expense) credit	(238)	(267)	(257)	(289)
NET LOSS	(10,678)	(12,189)	(11,514)	(13,194)
Loss per share – Basic and diluted	(0.29)	(0.33)	(0.31)	(0.36)
Average number of shares used in computation of basic and diluted EPS	37,104,348	36,954,439	37,104,348	36,954,439

NOTE: Translated to U.S. dollars at the 2024 average six months' exchange rate of 1 Euro = 1.0783 USD, and 2023 average six months' exchange rate of 1 Euro = 1.0825 USD

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

	June 30, 2024 Euros	December 31, 2023 Euros	June 30, 2024 \$US	December 31, 2023 \$US
Cash, cash equivalents and short-term investments	30,212	43,471	32,361	48,087
Accounts receivable, net	18,214	19,238	19,510	21,281
Inventory	17,962	15,112	19,240	16,717
Other current assets	937	659	1,004	729
TOTAL CURRENT ASSETS	67,326	78,480	72,114	86,814
Property, plant and equipment, net	9,976	8,193	10,686	9,063
Goodwill	2,412	2,412	2,583	2,668
Other non-current assets	2,453	2,464	2,628	2,725
TOTAL ASSETS	82,167	91,548	88,011	101,270
Accounts payable & other accrued liabilities	18,133	18,435	19,422	20,392
Deferred revenues, current portion	4,828	4,049	5,171	4,479
Short term borrowing	1,780	2,466	1,907	2,728
Other current liabilities	2,705	2,646	2,897	2,927
TOTAL CURRENT LIABILITIES	27,445	27,596	29,397	30,526
Obligations under operating and finance leases non-current	2,246	1,315	2,406	1,454
Long term debt, non-current	1,256	1,997	1,346	2,209
Deferred revenues, non-current	548	643	587	712
Other long-term liabilities	3,036	3,075	3,252	3,402
TOTAL LIABILITIES	34,531	34,626	36,987	38,304
TOTAL SHAREHOLDERS' EQUITY	47,636	56,922	51,024	62,966
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	82,167	91,548	88,011	101,270

NOTE: Translated to U.S. dollars at the exchange rate of 1 Euro = 1.0711 USD, on June 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)

	Six Months Ended June 30, 2024 (Euros)	Twelve Months Ended December 31, 2023 (Euros)	Six Months Ended June 30, 2024 (\$US)	Twelve Months Ended December 31, 2023 (\$US)
NET LOSS	(10,678)	(21,178)	(11,514)	(22,930)
Adjustments to reconcile net loss to net cash provided by operating activities ⁽¹⁾	2,935	9,403	3,164	10,181
OPERATING CASH FLOW	(7,744)	(11,775)	(8,350)	(12,749)
Net Decrease in operating assets and liabilities	(2,192)	(2,903)	(2,364)	(3,144)
NET CASH USED IN OPERATING ACTIVITIES	(9,936)	(14,678)	(10,714)	(15,892)
Additions to capitalized assets produced by the company and other capital expenditures	(1,854)	(4,344)	(1,999)	(4,704)
NET CASH USED IN INVESTING ACTIVITIES	(1,854)	(4,344)	(1,999)	(4,704)
NET CASH USED IN FINANCING ACTIVITIES	(1,433)	(911)	(1,545)	(986)
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(35)	268	(1,467)	2,130
NET DECREASE IN CASH AND CASH EQUIVALENTS	(13,258)	(19,666)	(15,726)	(19,452)

⁽¹⁾ including share-based compensation expenses of Euro 1,502 thousand for the six months ended June 30, 2024 and Euro 6,865 thousand for the full year ended December 31, 2023.

NOTE: Translated to U.S. dollars at the 2024 average six months' exchange rate of 1 Euro = 1.0783 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
Six months ended June 30, 2024
(Amounts in thousands of Euros)

	HIFU		ESWL		Distribution		Reconciling	Total After	
	Division		Division		Division		Items	Consolidation	
Sales of goods	6,335		1,718		13,032		—	21,085	
Sales of RPPs & leases	3,004		533		124		—	3,661	
Sales of spare parts & services	1,239		2,301		2,412		—	5,952	
TOTAL NET SALES	10,577		4,553		15,569		—	30,698	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	10,577		4,553		15,569		—	30,698	
GROSS PROFIT (% of Net Sales)	4,993	47.2%	2,034	44.7%	5,278	33.9%	—	12,304	40.1%
Research & development expenses	(3,623)		(216)		(307)		—	(4,146)	
Selling, general & administrative expenses	(10,846)		(914)		(5,143)		(2,218)	(19,121)	
OPERATING PROFIT (LOSS)	(9,477)		904		(173)		(2,218)	(10,963)	