

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

March 27, 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 [x] 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: March 27, 2024

EDAP TMS S.A.

/s/ KEN MOBECK

KEN MOBECK

CHIEF FINANCIAL OFFICER

EDAP Reports Fourth Quarter and Full-Year 2023 Financial Results

- Record Q4 2023 total revenue of EUR 19.6 million (\$21.3 million USD) increased 24.8% over Q4 2022
- Record Q4 2023 HIFU revenue of EUR 7.5 million (\$8.1 million USD), an increase of 38.8% over Q4 2022
- Record full-year 2023 total revenue of EUR 60.4 million (\$65.4 million USD) increased 9.6% over full-year 2022
- Record full-year 2023 HIFU revenue of EUR 20.6 million (\$22.3 million USD), an increase of 31.7% over full-year 2022
- Strong Q4 2023 U.S. Focal One® HIFU procedure growth of +136% year-over-year
- Company to host conference call and webcast today, March 27th, at 8:30 a.m. EDT

LYON, France, March 27, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited financial results for the fourth quarter and full-year 2023.

“We are pleased to report strong revenue and system placements in the fourth quarter and full-year 2023, reflecting growing demand for Focal One and ExactVu,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “Focal One’s best-in-class robotic HIFU platform, attractive reimbursement, and the continued investments we are making in our regional clinical teams are all helping to drive demand for our technology among both academic and community hospitals. The continued robust growth in U.S. Focal One HIFU procedures also speaks to the growing number of urologists who recognize the value of robotic HIFU in the management of prostate cancer. By providing a non-invasive, non-surgical, and radiation-free treatment approach with excellent oncologic outcomes, we are seeing growing patient awareness of the Focal One treatment option, which we anticipate will provide further momentum for our business.

“Looking ahead, I believe 2024 is shaping up to be another strong year for EDAP. We anticipate continued growth and adoption of Focal One among urologists, further establishing EDAP as the leading company in therapeutic robotic HIFU applications for prostate cancer. I’m also excited about the opportunities for our pipeline, as we recently announced the FDA’s granting of Breakthrough Device designation for Focal One for the treatment of deep infiltrating endometriosis. With enrollment in our Phase 3 study recently completed, we expect our rectal endometriosis program to gain visibility in 2024, as we seek to address a significant unmet need in women’s health with Focal One robotic HIFU therapy.”

Business Update

- 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. The Focal One system being granted a Breakthrough Device designation underscores the significance of this innovative development for DIE patients.
- 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.
- On December 12, 2023, the Company announced that the French National Authority for Health (“HAS”) released a favorable recommendation for the reimbursement of high-intensity focused ultrasound (HIFU) therapy in the treatment of prostate cancer. The positive opinion from HAS is an important milestone along the regulatory pathway of securing final reimbursement in France.

- On December 6, 2023, the Company announced the appointment of Lance Willsey, M.S., M.D. to its Board of Directors. Dr. Willsey is a urologist who has an aggregate of 36 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 Harvard University and the Dana Farber Cancer Institute.
- On November 30, 2023, the Company announced that it received the Industry Category Award from the French National Institute for Intellectual Property (INPI) based on the Company's innovative therapeutic ultrasound technology. The Industry Category Award from INPI recognizes EDAP as a developer of medical solutions based on the use of therapeutic ultrasound.

Clinical Pipeline Update

Rectal Endometriosis Program

- On February 1st, 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.
- 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. On November 8, 2023, Pr. Dubernard presented results of the study at the 52nd Meeting of the American Association of Gynecologic Laparoscopists (AAGL) in Nashville, TN.

Upcoming Meetings and Events

In the second quarter of 2024, EDAP expects to have its largest presence ever at both the European Association of Urology Meeting, which is taking in Paris (April 5-8), and the American Urology Association Meeting, which is taking place in San Antonio, Texas (May 3-6). The EAU and AUA meetings are the two of the most widely attended largest urology-focused conferences in the world and are considered the most highly influential, global medical meetings focused on urology.

Fourth Quarter 2023 Results

Total revenue for the fourth quarter of 2023 was EUR 19.6 million (USD 21.3 million), an increase of 24.8% as compared to total revenue of EUR 15.7 million (USD 16.2 million) for the same period in 2022.

Total revenue in the HIFU business for the fourth quarter of 2023 was EUR 7.5 million (USD 8.1 million), as compared to EUR 5.4 million (USD 5.5 million) for the fourth quarter of 2022. The increase was driven by 10 Focal One systems sold in the fourth quarter of 2023 versus 7 systems sold in the fourth quarter of 2022. The Company recorded a 88.6% year-over-year growth in disposables revenues, reflecting strong procedure growth.

Total revenue in the LITHO business for the fourth quarter of 2023 was EUR 2.3 million (USD 2.5 million), as compared to EUR 3.6 million (USD 3.7 million) for the fourth quarter of 2022. The decrease in LITHO revenue was driven by 3 lithotripsy units sold in the fourth quarter of 2023 as compared to 11 units sold in the fourth quarter of 2022.

Total revenue in the Distribution business for the fourth quarter of 2023 was EUR 9.9 million (USD 10.7 million), as compared to EUR 6.7 million (USD 7.0 million) for the fourth quarter of 2022. The increase in Distribution revenue was driven primarily by 20 ExactVu units sold during the fourth quarter of 2023 as compared to 11 units sold during the fourth quarter of 2022.

Gross profit for the fourth quarter of 2023 was EUR 8.6 million (USD 9.3 million), compared to EUR 7.2 million (USD 7.4 million) for the year-ago period. Gross profit margin on net sales was 43.7% in the fourth quarter of 2023, compared to 45.9% in the year-ago period. The decrease in gross profit margin year-over-year was primarily due to a higher level of distribution product revenues 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 12.0 million (USD 13.1 million) for the fourth quarter of 2023, compared to EUR 8.8 million (USD 9.1 million) for the same period in 2022. The increase in operating expenses was primarily due to the continued build-out of the U.S. team and commercial infrastructure as well as increased marketing activities.

Operating loss for the fourth quarter of 2023 was EUR 3.5 million (USD 3.8 million), compared to an operating loss of EUR 1.6 million (USD 1.6 million) in the fourth quarter of 2022.

Net loss for the fourth quarter of 2023 was EUR 5.0 million (USD 5.5 million), or EUR (0.14) per diluted share, as compared to net loss of EUR 5.1 million (USD 5.3 million), or EUR (0.14) per diluted share in the year-ago period.

Full-Year 2023 Results

Total revenue for the twelve months ended December 31, 2023, was EUR 60.4 million (USD 65.4 million), an increase of 9.6% from total revenue of EUR 55.1 million (USD 58.0 million) for the same period in 2022.

Total revenue in the HIFU business for the twelve months ended December 31, 2023, was EUR 20.6 million (USD 22.3 million), an increase of 31.7% as compared to EUR 15.6 million (USD 16.4 million) for the twelve months ended December 31, 2022.

Total revenue in the LITHO business for the twelve months ended December 31, 2023, was EUR 9.9 million (USD 10.7 million), a decrease of 14.3% from EUR 11.6 million (USD 12.2 million) for the twelve months ended December 31, 2022.

Total revenue in the Distribution business for twelve months ended December 31, 2023, was EUR 29.9 million (USD 32.4 million), a 7.2% increase compared to EUR 27.9 million (USD 29.4 million) for the twelve months ended December 31, 2022.

Gross profit for the twelve months ended December 31, 2023, was EUR 24.4 million (USD 26.4 million), compared to EUR 24.2 million (USD 25.4 million), for the year-ago period. Gross profit margin on net sales was 40.4% for the twelve months ended December 31, 2023, compared to 43.9% 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 44.2 million (USD 47.9 million) for the twelve months ended December 31, 2023, compared to EUR 28.5 million (USD 29.9 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 twelve months ended December 31, 2023, was EUR 19.8 million (USD 21.5 million), compared to an operating loss of EUR 4.3 million (USD 4.5 million) for the twelve months ended December 31, 2022.

Net loss for the twelve months ended December 31, 2023, was EUR 21.2 million (USD 22.9 million), or EUR (0.57) per diluted share, as compared to a net loss of EUR 2.9 million (USD 3.1 million), or EUR (0.09) per diluted share in the year-ago period.

As of December 31, 2023, the Company held cash and cash equivalents of EUR 43.5 million (USD 48.1 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 fourth quarter and year-end 2023 financial results will be hosted by Ryan Rhodes, Chief Executive Officer, Ken Mobeck, Chief Financial Officer, and François Dietsch, Chief Accounting Officer., today, Wednesday, March 27th, 2024, at 8:30am EDT. Please refer to the information below for conference call dial-in information and webcast registration.

Date: Wednesday, March 27th @ 8:30am Eastern Time

Domestic: 1-877-451-6152

International: 1-201-389-0879

Passcode (Conf ID): 13744102

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=1653981&tp_key=0c7b100f3f

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:	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
	Euros	Euros	\$US	\$US
Sales of medical equipment	15,021	11,493	16,292	11,840
Net Sales of RPP and Leases	1,611	1,441	1,747	1,484
Sales of spare parts, supplies and Services	2,981	2,784	3,233	2,868
TOTAL NET SALES	19,613	15,718	21,272	16,192
Other revenues	—	—	—	—
TOTAL REVENUES	19,613	15,718	21,272	16,192
Cost of sales	(11,051)	(8,500)	(11,986)	(8,756)
GROSS PROFIT	8,562	7,218	9,286	7,436
Research & development expenses	(2,201)	(1,304)	(2,387)	(1,344)
S, G & A expenses	(9,842)	(7,484)	(10,674)	(7,709)
Total operating expenses	(12,042)	(8,788)	(13,061)	(9,053)
OPERATING PROFIT (LOSS)	(3,481)	(1,570)	(3,775)	(1,617)
Interest (expense) income, net	220	297	239	306
Currency exchange gains (loss), net	(1,450)	(4,075)	(1,573)	(4,198)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(4,710)	(5,348)	(5,109)	(5,509)
Income tax (expense) credit	(332)	217	(361)	224
NET INCOME (LOSS)	(5,043)	(5,130)	(5,469)	(5,285)
Earning per share – Basic	(0.14)	(0.14)	(0.15)	(0.14)
Average number of shares used in computation of EPS	37,066,627	36,863,623	37,066,627	36,863,623
Earning per share – Diluted	(0.14)	(0.14)	(0.15)	(0.14)
Average number of shares used in computation of EPS for positive net income	37,066,627	36,863,623	37,066,627	36,863,623

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average three months' noon buying rate of 1 Euro = 1.0846 USD, and 2022 average three months noon buying rate of 1 Euro = 1.0302 USD

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

	Year Ended:		Year Ended:	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
	Euros	Euros	\$US	\$US
Sales of medical equipment	42,333	38,462	45,835	40,456
Net Sales of RPP and Leases	6,176	5,617	6,687	5,908
Sales of spare parts, supplies and Services	11,914	11,030	12,899	11,602
TOTAL NET SALES	60,423	55,108	65,421	57,966
Other revenues	—	—	—	—
TOTAL REVENUES	60,423	55,108	65,421	57,966
Cost of sales	(36,012)	(30,916)	(38,991)	(32,519)
GROSS PROFIT	24,411	24,193	26,430	25,447
Research & development expenses	(6,963)	(4,920)	(7,539)	(5,175)
S, G & A expenses	(37,261)	(23,530)	(40,343)	(24,751)
Total operating expenses	(44,224)	(28,450)	(47,882)	(29,925)
OPERATING PROFIT (LOSS)	(19,813)	(4,257)	(21,452)	(4,478)
Interest (expense) income, net	1,079	235	1,168	248
Currency exchange gains (loss), net	(1,799)	1,926	(1,948)	2,025
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(20,533)	(2,096)	(22,232)	(2,205)
Income tax (expense) credit	(644)	(837)	(698)	(880)
NET INCOME (LOSS)	(21,178)	(2,933)	(22,930)	(3,085)
Earning per share – Basic	(0.57)	(0.09)	(0.62)	(0.09)
Average number of shares used in computation of EPS	36,996,722	34,392,598	36,996,722	34,392,598
Earning per share – Diluted	(0.57)	(0.09)	(0.62)	(0.09)
Average number of shares used in computation of EPS for positive net income	36,996,722	34,392,598	36,996,722	34,392,598

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average twelve months' noon buying rate of 1 Euro = 1.0827 USD, and 2022 average twelve months noon buying rate of 1 Euro = 1.0519 USD

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

	December 31, 2023 Euros	December 31, 2022 Euros	December 31, 2023 \$US	December 31, 2022 \$US
Cash, cash equivalents and short-term treasury investments	43,471	63,136	48,087	67,539
Account receivables, net	19,238	14,943	21,281	15,985
Inventory	15,112	11,780	16,717	12,601
Other current assets	659	660	729	706
TOTAL CURRENT ASSETS	78,480	90,518	86,814	96,832
Property, plant and equipment, net	8,193	5,984	9,063	6,401
Goodwill	2,412	2,412	2,668	2,580
Other non-current assets	2,464	2,210	2,725	2,364
TOTAL ASSETS	91,548	101,123	101,270	108,177
Accounts payable & other accrued liabilities	18,435	13,087	20,392	14,000
Deferred revenues, current portion	4,049	4,050	4,479	4,333
Short term borrowing	2,466	1,846	2,728	1,975
Other current liabilities	2,646	2,725	2,927	2,916
TOTAL CURRENT LIABILITIES	27,596	21,708	30,526	23,223
Obligations under operating and finance leases non-current	1,315	1,222	1,454	1,308
Long term debt, non-current	1,997	3,587	2,209	3,837
Deferred revenues, non-current	643	264	712	282
Other long term liabilities	3,075	2,710	3,402	2,899
TOTAL LIABILITIES	34,626	29,492	38,304	31,549
TOTAL SHAREHOLDERS' EQUITY	56,922	71,632	62,966	76,628
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	91,548	101,123	101,270	108,177

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

	Year Ended December 31, 2023 (Euros)	Twelve Months Ended December 31, 2022 (Euros)	Year Ended December 31, 2023 (\$US)	Twelve Months Ended December 31, 2022 (\$US)
NET INCOME (LOSS)	(21,178)	(2,933)	(22,930)	(3,085)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	9,403	4,225	10,181	4,444
OPERATING CASH FLOW	(11,775)	1,292	(12,749)	1,359
Increase/Decrease in operating assets and liabilities	(2,903)	(4,316)	(3,144)	(4,539)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(14,678)	(3,024)	(15,892)	(3,180)
Short term investments	—	—	—	—
Additions to capitalized assets produced by the company and other capital expenditures	(4,344)	(2,378)	(4,704)	(2,501)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(4,344)	(2,378)	(4,704)	(2,501)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(911)	21,741	(986)	22,869
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	268	(388)	2,130	(3,053)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(19,666)	15,952	(19,452)	14,134

⁽¹⁾ including share based compensation expenses for 6,865 thousand of Euros for the year ended December 31, 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 twelve months' noon buying rate of 1 Euro = 1.0827 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
twelve months ended December 31, 2023
(Amounts in thousands of Euros)

	HIFU		ESWL		Distribution		Reconciling	Total After	
	Division		Division		Division		Items	Consolidation	
Sales of goods	13,510		3,844		24,980		—	42,333	
Sales of RPPs & Leases	4,935		955		286		—	6,176	
Sales of spare parts & services	2,152		5,109		4,653		—	11,914	
TOTAL NET SALES	20,596		9,908		29,919		—	60,423	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	20,596		9,908		29,919		—	60,423	
GROSS PROFIT (% of Net Sales)	10,484	50.9%	3,640	36.7%	10,287	34.4%	—	24,411	40.4%
Research & Development	(5,755)		(764)		(444)		—	(6,963)	
Total SG&A plus depreciation	(19,507)		(3,107)		(10,091)		(4,556)	(37,261)	
OPERATING PROFIT (LOSS)	(14,778)		(232)		(248)		(4,556)	(19,813)	