

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

May 17, 2023

Commission File Number: 0-29374

EDAP TMS S.A.
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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: May 17, 2023

EDAPTMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER



EDAP Announces First Quarter 2023 Financial Results

- Record first quarter revenue -

- Positive results from two studies reconfirm safety and efficacy of Focal One -

- Company to host conference call and webcast today, Wednesday, May 17th at 8:30 am EDT -

LYON, France, May 17, 2023 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced today unaudited financial results for the first quarter ended March 31, 2023.

“After achieving record results in the fourth quarter of 2022, we continued to see growing demand through the first quarter of 2023, with our strongest Q1 revenue performance on record,” said Ryan Rhodes, Chief Executive Officer of EDAP. “We placed seven Focal One units, including six equipment sales and one operating lease. Based upon the positive feedback from urologists, particularly at this year’s recent EAU & AUA meetings, we expect momentum for the Focal One platform to continue throughout 2023, driven by our state-of-the-art technology, our positive clinical outcomes demonstrating excellent oncologic control, and our world-class sales and customer support team.”

“Beyond our commercial performance, we also announced positive results from two clinical studies utilizing Focal One, both conducted at leading academic urology centers. Results from these studies clearly demonstrate the safety, efficacy, and benefits of Focal One that support both continued growth and increased utilization of the technology. As Focal One continues to grow, we are also making commercial progress in other areas. We recently received approval of ExactVuTM micro-ultrasound in Japan, representing a significant regulatory milestone for EDAP that introduces this innovative platform to the world’s second largest medical device market. As we continue to invest in expanding both clinical and commercial activities to drive bottom line performance, we maintain a strong cash position to support both short and long-term growth.”

Business Update:

- Placed six Focal One machines in the U.S., including five equipment sales and one operating lease. One additional Focal One unit was sold outside of the U.S. in the first quarter of 2023. We observed continued strong momentum in securing new placements across both academic medical centers and community hospitals, as clinicians and providers increasingly recognize Focal One HIFU as an essential option for select patients diagnosed with prostate cancer.
 - In January, the Company announced positive clinical results from the Endo-HIFU-R1 Phase 2 study evaluating the safety of therapeutic HIFU for the treatment of rectal endometriosis. Of the 60 patients evaluated, 96.7% demonstrated positive safety with no or non-significant adverse events (Clavien 1), 3.3% presented Clavien 2 complications and zero patients presented Clavien 3 complications. Positive effects were also observed in endometriosis symptom reduction and improvement of quality of life at one, three and six months. A significant reduction of the volume of lesions was also observed upon MRI evaluation at six months.
 - In March, the Company announced positive results from the largest, multicenter, non-inferiority study ever conducted to prospectively evaluate HIFU against radical prostatectomy (RP) as a first line treatment for patients with localized prostate cancer (grade groups <3) at the 38th Annual Congress of the European Association of Urology (EAU). Results demonstrated salvage treatment free survival rate (STFS) at 30 months of 90.1% in the HIFU-treated arm versus 86.8% in patients who underwent RP. In addition, risk of salvage treatment was greater than 1.2-fold higher after RP. International Continence Society (ICS) scores as a measure of urinary incontinence were significantly lower after HIFU and IIEF-5 as a measure of erectile function decreased significantly less after HIFU than after RP, despite the HIFU-treated group being an average of 9.6 years older.
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- In April, EDAP received approval from Japan's Pharmaceutical and Medical Devices Agency ("PMDA") for commercialization of ExactVu. ExactVu is a 29 MHz micro-ultrasound platform allowing urologists unparalleled visualization of prostate ultrasound images, detection of suspicious areas in real-time and biopsy results representing cancer aggressiveness. The Japanese market is the second largest global market for advanced medical device technology, with prostate cancer as the most common cancer diagnosis in Japanese men with over 100,000 new prostate cancer diagnoses annually.
- Also in April, the Company hosted a global webcast featuring a live broadcast of a Focal One procedure performed by Andre Abreu, MD and Amir H. Lebastchi, MD, Assistant Professors of Clinical Urology at Keck Medicine of the University of Southern California (USC), the first U.S. institution to acquire and adopt EDAP's robotic HIFU technology.
- Several plenary presentations and instructional courses were delivered by leading academic urologists at the Annual Meeting of the American Urological Association (AUA), held April 28th to May 1st, showcasing the Focal One platform's ability to meet accepted oncological standards for management of prostate cancer, while preserving sexual function and urinary control. Additionally, ExactVu was featured in the AUA Accredited Hands-on Ultrasound Skills Training Course under the guidance of expert faculty.

First Quarter 2023 Results

Total revenue for the first quarter 2023 was EUR 14.8 million (USD 15.9 million), an increase of 13.8% as compared to total revenue of EUR 13.0 million (USD 14.5 million) for the same period in 2022.

Total revenue in the HIFU business for the first quarter 2023 was EUR 5.3 million (USD 5.7 million), an increase of 39.5% as compared to EUR 3.8 million (USD 4.3 million) for the first quarter of 2022. The increase was driven by six Focal One units sold in the first quarter 2023 versus four units sold in the first quarter 2022.

Total revenue in the LITHO business for the first quarter 2023 was EUR 2.8 million (USD 3.0 million), as compared to EUR 2.2 million (USD 2.5 million) for the first quarter of 2022. The improvement was driven by four lithotripsy unit sold in the first quarter of 2023 as compared to one unit sold in the first quarter of 2022.

Total revenue in the Distribution business for the first quarter 2023 was EUR 6.8 million (USD 7.3 million), as compared to EUR 7.0 million (USD 7.8 million) for the first quarter of 2022. The decrease was driven primarily by eight ExactVu units sold during the first quarter of 2023 as compared to nine units sold during the first quarter of 2022.

Gross profit for the first quarter 2023 was EUR 6.0 million (USD 6.5 million), compared to EUR 5.8 million (USD 6.4 million) for the year-ago period. Gross profit margin on net sales was 40.8% in the first quarter of 2023, compared to 44.3% in the year-ago period. The decrease in gross profit rate year-over-year was primarily due to investments in service and applications in the U.S.

Operating expenses were EUR 12.6 million (USD 13.6 million) for the first quarter of 2023, compared to EUR 5.9 million (USD 6.6 million) for the same period in 2022. The significant increase in operating expenses is mainly due to the ongoing build-out of the U.S. team and commercial infrastructure, and non-recurring expenses linked to the leadership succession plan.

Operating loss for the first quarter of 2023 was EUR 6.6 million (USD 7.1 million), compared to an operating loss of EUR 0.1 million (USD 0.1 million) in the first quarter of 2022.

Net loss for the first quarter of 2023 was EUR 7.5 million (USD 8.1 million), or EUR 0.2 per diluted share, as compared to net income of EUR 0.4 million (USD 0.4 million), or EUR 0.01 per diluted share in the year-ago period.

As of March 31, 2023, the company held cash and cash equivalents of EUR 58.3 million (USD 63.4 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 first quarter 2023 financial results will be hosted by Ryan Rhodes, Chief Executive Officer, François Dietsch, Chief Financial Officer and Ken Mobeck, Chief Financial Officer of the U.S. subsidiary, today Wednesday, May 17th, 2023 at 8:30am EDT. Please refer to the information below for conference call dial-in information and webcast registration.

Date:	Wednesday, May 17th @ 8:30am Eastern Time
Domestic:	1-877-451-6152
International:	1-201-389-0879
Passcode:	13738488
CallMe™:	LINK (active 15 minutes prior to conference call)
Webcast:	https://viaid.webcasts.com/starthere.jsp?ei=1612697&tp_key=a5bd40c443

About the Endo-HIFU-R1 Phase 2 Study

The Endo-HIFU-R1 Phase 2 study was designed and conducted to evaluate the safety and efficacy of therapeutic high-Intensity focused ultrasound (HIFU) for the treatment of rectal endometriosis with EDAP's Focal One® Robotic HIFU device. At six-months follow up, of the 60 patients enrolled and treated with Focal One HIFU across four centers in France between August 2020 and March 2022, 96.7% demonstrated positive safety with no or non-significant adverse events (Clavien 1), 3.3% presented Clavien 2 complications and zero patients presented Clavien 3 complications. Additional endpoints included evaluation of the effect of HIFU treatment on endometriosis symptoms and Quality of Life (QoL). A significant decrease in endometriosis symptom level (acute pelvic pain, dyspareunia, diarrhea, constipation, rectal bleeding, false urges, tenesmus, rectal spasms, posterior pelvic pain and asthenia) and an improvement in almost all evaluated QoL criteria (physical functioning, role limitation due to emotional problems, energy – fatigue, emotional well-being, social functioning, bodily pain, general health, and on physical and mental global score components) were observed at the first post-treatment evaluation at one month, and those benefits were maintained at three and six months following HIFU treatment. The study also blindly evaluated the evolution of nodule volume via MRI, with a significant reduction of the volume of lesions observed at six months. Results from the study were presented by study coordinator, Pr. Gil Dubernard of Croix Rousse University Hospital (Lyon, France) at the Paris Santé Femmes French Congress on Friday, January 27, 2023.

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:	
	March 31, 2023 Euros	March 31, 2022 Euros	March 31, 2023 \$US	March 31, 2022 \$US
Sales of medical equipment	10,319	8,966	11,121	10,021
Net Sales of RPP and Leases	1,579	1,317	1,701	1,472
Sales of spare parts, supplies and Services	2,897	2,715	3,123	3,035
TOTAL NET SALES	14,795	12,998	15,945	14,527
Other revenues	—	—	—	—
TOTAL REVENUES	14,795	12,998	15,945	14,527
Cost of sales	(8,764)	(7,238)	(9,445)	(8,090)
GROSS PROFIT	6,032	5,760	6,500	6,437
Research & development expenses	(1,458)	(1,081)	(1,571)	(1,208)
S, G & A expenses	(11,130)	(4,787)	(11,995)	(5,351)
Total operating expenses	(12,588)	(5,868)	(13,566)	(6,559)
OPERATING PROFIT (LOSS)	(6,556)	(109)	(7,066)	(122)
Interest (expense) income, net	256	(29)	276	(32)
Currency exchange gains (loss), net	(1,145)	569	(1,234)	636
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(7,445)	432	(8,024)	483
Income tax (expense) credit	(46)	(72)	(49)	(81)
NET INCOME (LOSS)	(7,491)	360	(8,073)	402
Earning per share – Basic	(0.20)	0.01	(0.22)	0.01
Average number of shares used in computation of EPS	36,922,286	33,466,136	36,922,286	33,466,136
Earning per share – Diluted	(0.20)	0.01	(0.22)	0.01
Average number of shares used in computation of EPS for positive net income	36,922,286	34,031,361	36,922,286	34,031,361

NOTE: Translated for convenience of the reader to U.S. dollars at the 2023 average three months' noon buying rate of 1 Euro = 1.0777 USD, and 2022 average three months noon buying rate of 1 Euro = 1.1177 USD

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

	March 31, 2023 Euros	December 31, 2022 Euros	March 31, 2023 \$US	December 31, 2022 \$US
Cash, cash equivalents and short-term treasury investments	58,310	63,136	63,394	67,539
Account receivables, net	17,297	14,943	18,805	15,985
Inventory	12,449	11,780	13,535	12,601
Other current assets	1,116	660	1,213	706
TOTAL CURRENT ASSETS	89,171	90,518	96,946	96,832
Property, plant and equipment, net	6,969	5,984	7,577	6,401
Goodwill	2,412	2,412	2,622	2,580
Other non-current assets	2,214	2,210	2,407	2,364
TOTAL ASSETS	100,766	101,123	109,552	108,177
Accounts payable & other accrued liabilities	18,134	13,087	19,715	14,000
Deferred revenues, current portion	4,076	4,050	4,431	4,333
Short term borrowing	1,358	1,846	1,477	1,975
Other current liabilities	2,687	2,725	2,921	2,916
TOTAL CURRENT LIABILITIES	26,255	21,708	28,544	23,223
Obligations under operating and finance leases non-current	1,074	1,222	1,168	1,308
Long term debt, non-current	3,183	3,587	3,460	3,837
Deferred revenues, non-current	549	264	597	282
Other long term liabilities	2,753	2,710	2,993	2,899
TOTAL LIABILITIES	33,813	29,492	36,761	31,549
TOTAL SHAREHOLDERS' EQUITY	66,953	71,632	72,791	76,628
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	100,766	101,123	109,552	108,177

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0872 USD, on March 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)

	Three Months Ended March 31, 2023 (Euros)	Twelve Months Ended December 31, 2022 (Euros)	Three Months Ended March 31, 2023 (\$US)	Twelve Months Ended December 31, 2022 (\$US)
NET INCOME (LOSS)	(7,491)	(2,933)	(8,073)	(3,085)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	4,626	4,225	4,985	4,444
OPERATING CASH FLOW	(2,865)	1,292	(3,087)	1,359
Increase/Decrease in operating assets and liabilities	71	(4,316)	76	(4,539)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(2,794)	(3,024)	(3,011)	(3,180)
Additions to capitalized assets produced by the company and other capital expenditures	(1,519)	(2,378)	(1,637)	(2,501)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(1,519)	(2,378)	(1,637)	(2,501)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(858)	21,741	(925)	22,869
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	346	(388)	1,428	(3,053)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(4,826)	15,952	(4,145)	14,134

⁽¹⁾ including share based compensation expenses for 2,660 thousand of Euros for the three months ended March 31, 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 three months' noon buying rate of 1 Euro = 1.0777 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
three months ended March 31, 2023
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	3,462		1,148		5,709		—	10,319	
Sales of RPPs & Leases	1,242		272		64		—	1,579	
Sales of spare parts & services	546		1,365		986		—	2,897	
TOTAL NET SALES	5,251		2,785		6,760		—	14,795	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	5,251		2,785		6,760		—	14,795	
GROSS PROFIT (% of Net Sales)	2,647	50.4%	1,113	40.0%	2,271	33.6%	—	6,032	40.8%
Research & Development	(1,138)		(197)		(122)		—	(1,458)	
Total SG&A plus depreciation	(4,485)		(1,137)		(2,761)		(2,747)	(11,130)	
OPERATING PROFIT (LOSS)	(2,976)		(222)		(611)		(2,747)	(6,556)	