

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

November 16, 2022

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

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## 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: November 16, 2022

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH  
FRANCOIS DIETSCH  
CHIEF FINANCIAL OFFICER

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# EDAP Reports Third Quarter 2022 Results

- Generated Q3 2022 total revenue of approximately EUR 12.2 million (USD 12.3 million), an increase of 29.7 % as compared to EUR 9.4 million (USD 11.1 million) for Q3 2021; nine-month year-to-date revenue increased 30.9% compared to the same period in 2021
- Generated HIFU sales of EUR \$3.5 million (USD 3.5 million), representing growth of 81% over EUR 1.9 million (USD 2.3 million) for Q3 2021
- Reimbursement increase finalized: U.S. Centers for Medicare and Medicaid Services (CMS), in its final Outpatient Prospective Payment System (OPPS) rule for CY23, increased reimbursement for HIFU prostate ablation from APC Level 5 to Level 6 which increases hospital reimbursement by more than 90%
- Exited the quarter with a strong cash position of EUR 68.3 million (USD 66.8 million) as of September 30, 2022
- Conference call and webcast scheduled for tomorrow, Thursday, November 17, at 8:30 am ET

LYON, France, November 16, 2022 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the third quarter 2022.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "For the third quarter 2022, we generated robust year-over-year revenue growth of nearly 30%, driven by continued strength in our HIFU business, which contributed revenue growth of 81% over the prior year period. This was a record calendar third quarter for our company. Clearly, our recent efforts to bolster our U.S. commercial presence are having a significant positive impact, and I believe we are well positioned to complete the year with significant momentum."

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, "We successfully executed in the third quarter to drive adoption of Focal One HIFU as the leading non-invasive focal therapy platform. Three new hospitals purchased Focal One systems in the quarter, and we continue to see increased adoption of Focal One amongst our growing installed base. We believe the increase in 2023 reimbursement for HIFU ablation will significantly improve access in the number of facilities that choose to invest in Focal One Robotic HIFU as part of a comprehensive approach to the management of prostate cancer."

## Year-to-Date Results

Total revenue for the nine months ended September 30, 2022, was EUR 39.4 million (USD 41.7 million), an increase of 30.9% from total revenue of was EUR 30.1 million (USD 35.9 million) for the same period in 2021.

Total revenue in the HIFU business for the nine months ended September 30, 2022, was EUR 10.3 million (USD 10.9 million), an increase of 79.7% as compared to EUR 5.7 million (USD 6.8 million) for the nine months ended September 30, 2021.

Total revenue in the LITHO business for the nine months ended September 30, 2022, was EUR 8.0 million (USD 8.4 million), an increase of 3.9% from EUR 7.7 million (USD 9.1 million) for the nine months ended September 30, 2021.

Total revenue in the Distribution business for the nine months ended September 30, 2022, was EUR 21.2 million (USD 22.4 million), a 26.6% increase compared to EUR 16.7 million (USD 19.9 million) for the nine months ended September 30, 2021.

Gross profit for the nine months ended September 30, 2022, was EUR 17.0 million (USD 18.0 million), compared to EUR 12.2 million (USD 14.6 million) for the year-ago period. Gross profit margin on net sales was 43.1% for the nine months ended September 30, 2022, compared to 40.6% for the comparable period in 2021. The increase in gross profit year-over-year was due to higher sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 19.7 million (USD 20.8 million) for the nine months ended September 30, 2022, compared to EUR 14.3 million (USD 17.0 million) for the same period in 2021.

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Operating loss for the nine months ended September 30, 2022, was EUR 2.7 million (USD 2.8 million), compared to an operating loss of EUR 2.1 million (USD 2.5 million) for the nine months ended September 30, 2021.

Net income for the nine months ended September 30, 2022, was EUR 2.2 million (USD 2.3 million), or EUR 0.07 per diluted share, as compared to a net loss of EUR 0.7 million (USD 0.8 million), or EUR (0.02) per diluted share in the year-ago period.

As of September 30, 2022, the company held cash, cash equivalents and short term investments of EUR 68.3 million (USD 66.8 million), as compared to EUR 47.2 million (USD 53.4 million) as of December 31, 2021.

### **Third Quarter 2022 Results**

Total revenue for the third quarter 2022 was EUR 12.2 million (USD 12.3 million), a 29.7% increase as compared to total revenue of EUR 9.4 million (USD 11.1 million) for the same period in 2021.

Total revenue in the HIFU business for the third quarter 2022 was EUR 3.5 million (USD 3.5 million), an increase of 80.9% as compared to EUR 1.9 million (USD 2.3 million) for the third quarter of 2021.

Total revenue in the LITHO business for the third quarter 2022 was EUR 2.2 million (USD 2.2 million), a decrease of 12.1% from was EUR 2.5 million (USD 2.9 million) for the third quarter of 2021.

Total revenue in the Distribution business for the third quarter 2022 was EUR 6.6 million (USD 6.6 million), a 30.9% increase compared to EUR 5.0 million (USD 5.9 million) for the third quarter of 2021.

Gross profit for the third quarter 2022 was EUR 5.0 million (USD 5.0 million), compared to EUR 3.6 million (USD 4.2 million) for the year-ago period. Gross profit margin on net sales was 41.0% in the third quarter of 2022, compared to 38.4% in the year-ago period. The increase in gross profit year-over-year was driven by the higher sales effect on fixed costs.

Operating expenses were EUR 7.2 million (USD 7.2 million) for the third quarter of 2022, compared to EUR 5.5 million (USD 6.5 million) for the same period in 2021.

Operating loss for the third quarter of 2022 was EUR 2.1 million (USD 2.2 million), compared to an operating loss of EUR 1.9 million (USD 2.2 million) in the third quarter of 2021.

Net income for the third quarter of 2022 was EUR 0.0 million (USD 0.0 million), or EUR 0.00 per diluted share, as compared to a net loss of EUR 1.0 million (USD 1.2 million), or EUR (0.03) per diluted share in the year-ago period.

### **Conference Call**

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30am EDT tomorrow, November 17, 2022. Please refer to the information below for conference call dial-in information and webcast registration.

#### **Conference Call & Webcast**

**Thursday, November 17, 2022 @ 8:30am Eastern Time**

Domestic:	877-451-6152
International:	201-389-0879
Passcode:	13733576
Webcast link:	<a href="#">Here</a>

Following the live call, a replay will be available on the Company's website, [www.edap-tms.com](http://www.edap-tms.com) under "Investors Information."

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## **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>, and [us.hifu-prostate.com](http://us.hifu-prostate.com) and [www.focalone.com](http://www.focalone.com).

## **Forward-Looking Statements**

In addition to historical information, this press release contains forward-looking statements. 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 the length and severity of the COVID-19 pandemic, including its impacts across our businesses on demand for our devices and services. 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.

## **Company Contact**

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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, 2022 Euros	September 30, 2021 Euros	September 30, 2022 \$US	September 30, 2021 \$US
Sales of medical equipment	8,319	5,788	8,333	6,799
Net Sales of RPP and Leases	1,214	1,104	1,216	1,297
Sales of spare parts, supplies and Services	2,710	2,548	2,714	2,993
<b>TOTAL NET SALES</b>	<b>12,243</b>	<b>9,440</b>	<b>12,263</b>	<b>11,089</b>
Other revenues	—	—	—	—
<b>TOTAL REVENUES</b>	<b>12,243</b>	<b>9,440</b>	<b>12,263</b>	<b>11,089</b>
Cost of sales	(7,226)	(5,815)	(7,238)	(6,831)
<b>GROSS PROFIT</b>	<b>5,017</b>	<b>3,625</b>	<b>5,026</b>	<b>4,258</b>
Research & development expenses	(1,361)	(1,064)	(1,363)	(1,250)
S, G & A expenses	(5,805)	(4,446)	(5,815)	(5,222)
Total operating expenses	(7,165)	(5,510)	(7,178)	(6,472)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,148)</b>	<b>(1,885)</b>	<b>(2,152)</b>	<b>(2,215)</b>
Interest (expense) income, net	(4)	(22)	(4)	(25)
Currency exchange gains (loss), net	3,020	1,003	3,025	1,178
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>867</b>	<b>(904)</b>	<b>869</b>	<b>(1,062)</b>
Income tax (expense) credit	(854)	(111)	(856)	(130)
<b>NET INCOME (LOSS)</b>	<b>13</b>	<b>(1,015)</b>	<b>13</b>	<b>(1,192)</b>
Earning per share – Basic	0.00	(0.03)	0.00	(0.04)
Average number of shares used in computation of EPS	33,696,543	33,448,136	33,696,543	33,448,136
Earning per share – Diluted	0.00	(0.03)	0.00	(0.04)
Average number of shares used in computation of EPS for positive net income	34,612,773	33,448,136	34,612,773	33,448,136

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.0017 USD, and 2021 average three months noon buying rate of 1 Euro = 1.1747 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, 2022	September 30, 2021	September 30, 2022	September 30, 2021
	Euros	Euros	\$US	\$US
Sales of medical equipment	26,969	19,176	28,563	22,858
Net Sales of RPP and Leases	4,176	3,581	4,423	4,269
Sales of spare parts, supplies and Services	8,245	7,331	8,733	8,739
<b>TOTAL NET SALES</b>	<b>39,391</b>	<b>30,088</b>	<b>41,719</b>	<b>35,866</b>
Other revenues	—	4	—	5
<b>TOTAL REVENUES</b>	<b>39,391</b>	<b>30,092</b>	<b>41,719</b>	<b>35,871</b>
Cost of sales	(22,416)	(17,881)	(23,741)	(21,315)
<b>GROSS PROFIT</b>	<b>16,975</b>	<b>12,211</b>	<b>17,978</b>	<b>14,556</b>
Research & development expenses	(3,615)	(2,840)	(3,829)	(3,385)
S, G & A expenses	(16,047)	(11,444)	(16,995)	(13,642)
Total operating expenses	(19,662)	(14,284)	(20,824)	(17,027)
<b>OPERATING PROFIT (LOSS)</b>	<b>(2,687)</b>	<b>(2,073)</b>	<b>(2,846)</b>	<b>(2,471)</b>
Interest (expense) income, net	(62)	122	(66)	145
Currency exchange gains (loss), net	6,001	1,574	6,355	1,876
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>3,251</b>	<b>(378)</b>	<b>3,443</b>	<b>(450)</b>
Income tax (expense) credit	(1,054)	(288)	(1,117)	(343)
<b>NET INCOME (LOSS)</b>	<b>2,197</b>	<b>(665)</b>	<b>2,327</b>	<b>(793)</b>
Earning per share – Basic	0.07	(0.02)	0.07	(0.02)
Average number of shares used in computation of EPS	33,544,003	32,881,747	33,544,003	32,881,747
Earning per share – Diluted	0.06	(0.02)	0.07	(0.02)
Average number of shares used in computation of EPS for positive net income	34,301,115	32,881,747	34,301,115	32,881,747

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average nine months' noon buying rate of 1 Euro = 1.0591 USD, and 2021 average nine months noon buying rate of 1 Euro = 1.1920 USD

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

	September 30, 2022 Euros	December 31, 2021 Euros	September 30, 2022 \$US	December 31, 2021 \$US
Cash, cash equivalents and short-term treasury investments	68,329	47,183	66,845	53,405
Account receivables, net	15,131	12,118	14,802	13,716
Inventory	9,561	7,499	9,353	8,487
Other current assets	1,007	581	985	658
<b>TOTAL CURRENT ASSETS</b>	<b>94,027</b>	<b>67,382</b>	<b>91,985</b>	<b>76,267</b>
Property, plant and equipment, net	6,133	5,173	6,000	5,855
Goodwill	2,412	2,412	2,359	2,730
Other non-current assets	2,230	2,260	2,181	2,558
<b>TOTAL ASSETS</b>	<b>104,801</b>	<b>77,226</b>	<b>102,525</b>	<b>87,409</b>
Accounts payable & other accrued liabilities	13,366	10,786	13,076	12,208
Deferred revenues, current portion	4,230	3,408	4,138	3,857
Short term borrowing	1,237	1,914	1,210	2,167
Other current liabilities	2,688	1,843	2,629	2,086
<b>TOTAL CURRENT LIABILITIES</b>	<b>21,521</b>	<b>17,951</b>	<b>21,053</b>	<b>20,318</b>
Obligations under operating and finance leases non-current	1,583	1,318	1,548	1,492
Long term debt, non-current	4,021	4,930	3,934	5,580
Deferred revenues, non-current	331	440	324	498
Other long term liabilities	3,104	2,534	3,037	2,868
<b>TOTAL LIABILITIES</b>	<b>30,560</b>	<b>27,172</b>	<b>29,896</b>	<b>30,755</b>
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>74,242</b>	<b>50,054</b>	<b>72,629</b>	<b>56,655</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>104,801</b>	<b>77,226</b>	<b>102,525</b>	<b>87,409</b>

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 0.9783 USD, on September 30, 2022 and at the noon buying rate of 1 Euro = 1.1319 USD, on December 31, 2021.



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

	Nine Months Ended September 30, 2022 (Euros)	Twelve Months Ended December 31, 2021 (Euros)	Nine Months Ended September 30, 2022 (\$US)	Twelve Months Ended December 31, 2021 (\$US)
<b>NET INCOME (LOSS)</b>	<b>2,197</b>	<b>700</b>	<b>2,327</b>	<b>825</b>
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities <sup>(1)</sup>	2,931	3,225	3,104	3,801
<b>OPERATING CASH FLOW</b>	<b>5,128</b>	<b>3,925</b>	<b>5,431</b>	<b>4,626</b>
Increase/Decrease in operating assets and liabilities	(1,505)	520	(1,594)	613
<b>NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES</b>	<b>3,623</b>	<b>4,445</b>	<b>3,837</b>	<b>5,239</b>
Short term investments (2)	(17,952)	—	(19,013)	—
Additions to capitalized assets produced by the company and other capital expenditures	(1,786)	(1,638)	(1,892)	(1,931)
<b>NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES</b>	<b>(19,739)</b>	<b>(1,638)</b>	<b>(20,905)</b>	<b>(1,931)</b>
<b>NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES</b>	<b>21,399</b>	<b>20,266</b>	<b>22,663</b>	<b>23,887</b>
<b>NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	<b>(2,089)</b>	<b>(585)</b>	<b>(9,717)</b>	<b>(3,992)</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,193</b>	<b>22,488</b>	<b>(4,123)</b>	<b>23,204</b>

<sup>(1)</sup> including share based compensation expenses for 1,345 thousand of Euros for the nine months ended September 30, and 1,900 thousand of Euros for the full year ended December 31, 2021.

<sup>(2)</sup> short term investments are comprised of money market funds.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average nine months' noon buying rate of 1 Euro = 1.0591 USD, and 2021 average twelve months noon buying rate of 1 Euro = 1.1787 USD

**EDAP TMS S.A.**  
**UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**nine months ended September 30, 2022**  
**(Amounts in thousands of Euros)**

	<b>HIFU</b>		<b>ESWL</b>		<b>Distribution</b>		<b>Reconciling</b>	<b>Total After</b>	
	<b>Division</b>		<b>Division</b>		<b>Division</b>		<b>Items</b>	<b>Consolidation</b>	
Sales of goods	5,657		2,914		18,398		—	26,969	
Sales of RPPs & Leases	3,166		792		218		—	4,176	
Sales of spare parts & services	1,441		4,261		2,543		—	8,245	
<b>TOTAL NET SALES</b>	<b>10,264</b>		<b>7,967</b>		<b>21,159</b>		<b>—</b>	<b>39,391</b>	
Other revenues	—		—		—		—	—	
<b>TOTAL REVENUES</b>	<b>10,264</b>		<b>7,967</b>		<b>21,159</b>		<b>—</b>	<b>39,391</b>	
<b>GROSS PROFIT (% of Net Sales)</b>	<b>5,587</b>	<b>54.4%</b>	<b>3,319</b>	<b>41.7%</b>	<b>8,069</b>	<b>38.1%</b>	<b>—</b>	<b>16,975</b>	<b>43.1%</b>
Research & Development	(2,584)		(714)		(318)		—	(3,615)	
Total SG&A plus depreciation	(6,560)		(2,042)		(5,711)		(1,733)	(16,047)	
<b>OPERATING PROFIT (LOSS)</b>	<b>(3,557)</b>		<b>563</b>		<b>2,040</b>		<b>(1,733)</b>	<b>(2,687)</b>	