

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 24, 2022

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 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): _____

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 24, 2022

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Second Quarter 2022 Results

- Announced Focal One® HIFU reimbursement raised to urology APC Level 6 under CMS Outpatient Prospective Payment System (OPPS) proposed rule for CY23
- Second quarter 2022 total revenue of approximately EUR 14.2 million (USD 15.0 million), an increase of 36.7% as compared to EUR 10.4 million (USD 12.4 million) for the second quarter 2021
- 79% growth in HIFU revenues for the first half of 2022 compared to same period in 2021
- Strong cash position of \$48.5 million as of June 30, 2022
- Company to host Focal One Expert User Panel event in New York City on Thursday, September 29
- Second quarter conference call and webcast scheduled for tomorrow, Thursday, August 25, at 8:30 am ET

LYON, France, August 24, 2022 -- EDAP TMS SA (Nasdaq: EDAP) (the “Company”), a global leader in robotic energy-based therapies, announced today unaudited financial results for the second quarter 2022.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: “For the second quarter 2022, we generated strong year-over-year revenue growth of nearly 37% driven by contribution from all three business segments, including our core HIFU business, which grew nearly 50% over the prior year period. The measured investments that we continue to make in our US team and infrastructure continue to bear fruit as HIFU, and specifically Focal One, becomes integral to the modern prostate cancer treatment paradigm.”

“Our pipeline of sales prospects continues to grow, driven by a combination of new world-renowned healthcare institutions that have adopted Focal One, and champion this technology, and our growing presence at important medical meetings such as the annual meeting of the American Urological Association this past May. These trends, together with the proposed increase in reimbursement for CY23 indicated in the preliminary CMS Outpatient Prospective Payment System (OPPS) rule, give me great optimism for the future adoption of our Focal One platform.” Mr. Oczachowski concluded.

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, “Following the close of the second quarter, we learned that the Centers for Medicare and Medicaid Services, in its proposed OPPS rule for calendar year 2023, raised Focal One HIFU reimbursement to APC Level 6 from Level 5 currently. It is difficult to overstate the positive impact such a change would have on expanding patient procedure access should the increase stand in the final rule, which we expect to be published in November. We are very pleased with this proposed increase to hospital reimbursement and believe it more accurately reflects the significant clinical value that HIFU brings to the urology suite.”

“We also will be hosting an in-person Focal One Expert User Panel Event in New York City in September, to coincide with Prostate Cancer Awareness Month. The event will feature presentations from several renowned thought leaders and will also include a demonstration of the Focal One procedure.”

Year-to-Date Results

Total revenue for the six months ended June 30, 2022, was EUR 27.1 million (USD 29.5 million), an increase of 31.5% from total revenue of was EUR 20.7 million (USD 24.8 million) for the same period in 2021.

Total revenue in the HIFU business for the six months ended June 30, 2022, was EUR 6.8 million (USD 7.4 million), an increase of 78.8% as compared to EUR 3.8 million (USD 4.6 million) for the six months ended June 30, 2021.

Total revenue in the LITHO business for the six months ended June 30, 2022, was EUR 5.8 million (USD 6.3 million), an increase of 11.6% from EUR 5.2 million (USD 6.2 million) for the six months ended June 30, 2021.

Total revenue in the Distribution business for the six months ended June 30, 2022, was EUR 14.6 million (USD 15.9 million), a 24.8% increase compared to EUR 11.7 million (USD 14.0 million) for the six months ended June 30, 2021.

Gross profit for the six months ended June 30, 2022, was EUR 12.0 million (USD 13.0 million), compared to EUR 8.6 million (USD 10.3 million) for the year-ago period. Gross profit margin on net sales was 44.0% for the six months ended June 30, 2022, compared to 41.6% 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 12.5 million (USD 13.6 million) for the six months ended June 30, 2022, compared to EUR 8.8 million (USD 10.5 million) for the same period in 2021.

Operating loss for the six months ended June 30, 2022, was EUR 0.5 million (USD 0.6 million), compared to an operating loss of EUR 0.2 million (USD 0.2 million) for the six months ended June 30, 2021.

Net income for the six months ended June 30, 2022, was EUR 2.2 million (USD 2.4 million), or EUR 0.06 per diluted share, as compared to a 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 June 30, 2022, the company held cash and cash equivalents of EUR 46.3 million (USD 48.5 million), as compared to EUR 47.2 million (USD 53.4 million) as of December 31, 2021.

Second Quarter 2022 Results

Total revenue for the second quarter 2022 was EUR 14.2 million (USD 15.0 million), a 36.7% increase as compared to total revenue of EUR 10.4 million (USD 12.4 million) for the same period in 2021.

Total revenue in the HIFU business for the second quarter 2022 was EUR 3.0 million (USD 3.2 million), an increase of 49.3% as compared to EUR 2.0 million (USD 2.4 million) for the second quarter of 2021.

Total revenue in the LITHO business for the second quarter 2022 was EUR 3.6 million (USD 3.8 million), an increase of 55.7% from was EUR 2.3 million (USD 2.7 million) for the second quarter of 2021.

Total revenue in the Distribution business for the second quarter 2022 was EUR 7.6 million (USD 8.1 million), a 25.5% increase compared to EUR 6.1 million (USD 7.3 million) for the second quarter of 2021.

Gross profit for the second quarter 2022 was EUR 6.2 million (USD 6.6 million), compared to EUR 4.2 million (USD 5.1 million) for the year-ago period. Gross profit margin on net sales was 43.8% in the second quarter of 2022, compared to 40.7% 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 6.6 million (USD 7.0 million) for the second quarter of 2022, compared to EUR 4.6 million (USD 5.6 million) for the same period in 2021.

Operating loss for the second quarter of 2022 was EUR 0.4 million (USD 0.5 million), compared to an operating loss of EUR 0.4 million (USD 0.5 million) in the second quarter of 2021.

Net income for the second quarter of 2022 was EUR 1.8 million (USD 1.9 million), or EUR 0.05 per diluted share, as compared to a net loss of EUR 0.4 million (USD 0.5 million), or EUR 0.01 per diluted share in the year-ago period.

In-person Focal One Expert User Panel Event

The management team of EDAP will host a In-person Focal One Expert User Panel Event in New York City on Thursday, September 29.

<https://lifesci.rampard.com/WebcastingAppv5/Events/eventsDispatcher.jsp?Y2lk=MjAxNg==>

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, August 25, 2022. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, August 25, 2022 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13731177

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1558239&tp_key=295933838c

Following the live call, a replay will be available on the Company's website, www.edap-tms.com under "Investors Information."

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.

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.

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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:	
	June 30, 2022 Euros	June 30, 2021 Euros	June 30, 2022 \$US	June 30, 2021 \$US
Sales of medical equipment	9,684	6,696	10,245	8,051
Net Sales of RPP and Leases	1,646	1,265	1,741	1,521
Sales of spare parts, supplies and Services	2,820	2,387	2,984	2,870
TOTAL NET SALES	14,151	10,349	14,969	12,443
Other revenues	—	1	—	2
TOTAL REVENUES	14,151	10,350	14,969	12,445
Cost of sales	(7,949)	(6,134)	(8,409)	(7,376)
GROSS PROFIT	6,201	4,216	6,560	5,069
Research & development expenses	(1,174)	(925)	(1,242)	(1,112)
S, G & A expenses	(5,455)	(3,718)	(5,770)	(4,470)
Total operating expenses	(6,629)	(4,642)	(7,012)	(5,582)
OPERATING PROFIT (LOSS)	(427)	(427)	(452)	(513)
Interest (expense) income, net	(29)	(20)	(31)	(25)
Currency exchange gains (loss), net	2,412	82	2,551	98
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	1,955	(365)	2,068	(439)
Income tax (expense) credit	(128)	(58)	(136)	(70)
NET INCOME (LOSS)	1,827	(424)	1,933	(509)
Earning per share – Basic	0.05	(0.01)	0.06	(0.02)
Average number of shares used in computation of EPS	33,469,053	32,220,414	33,469,053	32,220,414
Earning per share – Diluted	0.05	(0.01)	0.06	(0.02)
Average number of shares used in computation of EPS for positive net income	34,130,859	32,220,414	34,130,859	32,220,414

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.0579 USD, and 2021 average three months noon buying rate of 1 Euro = 1.2024 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, 2022 Euros	June 30, 2021 Euros	June 30, 2022 \$US	June 30, 2021 \$US
Sales of medical equipment	18,650	13,387	20,287	16,075
Net Sales of RPP and Leases	2,963	2,477	3,223	2,975
Sales of spare parts, supplies and Services	5,536	4,784	6,021	5,744
TOTAL NET SALES	27,148	20,648	29,531	24,794
Other revenues	—	4	—	5
TOTAL REVENUES	27,148	20,653	29,531	24,799
Cost of sales	(15,190)	(12,066)	(16,524)	(14,488)
GROSS PROFIT	11,958	8,587	13,008	10,311
Research & development expenses	(2,255)	(1,776)	(2,453)	(2,132)
S, G & A expenses	(10,242)	(6,998)	(11,141)	(8,403)
Total operating expenses	(12,497)	(8,774)	(13,594)	(10,536)
OPERATING PROFIT (LOSS)	(539)	(188)	(586)	(225)
Interest (expense) income, net	(58)	143	(63)	172
Currency exchange gains (loss), net	2,981	571	3,243	685
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	2,384	527	2,593	632
Income tax (expense) credit	(200)	(177)	(218)	(213)
NET INCOME (LOSS)	2,184	350	2,375	420
Earning per share – Basic	0.07	0.01	0.07	0.01
Average number of shares used in computation of EPS	33,467,594	30,705,356	33,467,594	30,705,356
Earning per share – Diluted	0.06	0.01	0.07	0.01
Average number of shares used in computation of EPS for positive net income	34,075,033	31,994,402	34,075,033	31,994,402

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average six months' noon buying rate of 1 Euro = 1.0878 USD, and 2021 average six months noon buying rate of 1 Euro = 1.2008 USD

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

	June 30, 2022 Euros	December 31, 2021 Euros	June 30, 2022 \$US	December 31, 2021 \$US
Cash, cash equivalents and short-term treasury investments	46,334	47,183	48,507	53,405
Account receivables, net	15,888	12,118	16,633	13,716
Inventory	7,906	7,499	8,277	8,487
Other current assets	725	581	759	658
TOTAL CURRENT ASSETS	70,853	67,382	74,176	76,267
Property, plant and equipment, net	5,820	5,173	6,093	5,855
Goodwill	2,412	2,412	2,525	2,730
Other non-current assets	2,210	2,260	2,314	2,558
TOTAL ASSETS	81,294	77,226	85,107	87,409
Accounts payable & other accrued liabilities	11,348	10,786	11,881	12,208
Deferred revenues, current portion	3,958	3,408	4,143	3,857
Short term borrowing	1,906	1,914	1,995	2,167
Other current liabilities	2,590	1,843	2,711	2,086
TOTAL CURRENT LIABILITIES	19,802	17,951	20,730	20,318
Obligations under operating and finance leases non-current	1,427	1,318	1,494	1,492
Long term debt, non-current	4,390	4,930	4,596	5,580
Deferred revenues, non-current	351	440	368	498
Other long term liabilities	3,060	2,534	3,204	2,868
TOTAL LIABILITIES	29,029	27,172	30,391	30,755
TOTAL SHAREHOLDERS' EQUITY	52,265	50,054	54,716	56,655
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	81,294	77,226	85,107	87,409

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0469 USD on June 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)

	Six Months Ended June 30, 2022 (Euros)	Twelve Months Ended December 31, 2021 (Euros)	Six Months Ended June 30, 2022 (\$US)	Twelve Months Ended December 31, 2021 (\$US)
NET INCOME (LOSS)	2,184	700	2,375	825
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	1,967	3,225	2,140	3,801
OPERATING CASH FLOW	4,151	3,925	4,515	4,626
Increase/Decrease in operating assets and liabilities	(2,901)	520	(3,156)	613
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	1,250	4,445	1,359	5,239
Additions to capitalized assets produced by the company and other capital expenditures	(1,192)	(1,638)	(1,297)	(1,931)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(1,192)	(1,638)	(1,297)	(1,931)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	34	20,266	37	23,887
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(941)	(585)	(4,997)	(3,992)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(849)	22,488	(4,898)	23,204

⁽¹⁾ including share based compensation expenses for 936 thousand of Euros for the six months ended June 30, 2022 and 1,900 thousand of Euros for the full year ended December 31, 2021.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average six months' noon buying rate of 1 Euro = 1.0878 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
SIX MONTHS ENDED JUNE 30, 2022
(Amounts in thousands of Euros)

	HIFU		ESWL		Distribution		Reconciling	Total After	
	Division		Division		Division		Items	Consolidation	
Sales of goods	3,606		2,291		12,753		—	18,650	
Sales of RPPs & Leases	2,252		569		141		—	2,963	
Sales of spare parts & services	937		2,917		1,682		—	5,536	
TOTAL NET SALES	6,795		5,777		14,576		—	27,148	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	6,795		5,777		14,576		—	27,148	
GROSS PROFIT (% of Net Sales)	3,797	55.9%	2,536	43.9%	5,624	38.6%	—	11,958	44.0%
Research & Development	(1,560)		(466)		(229)		—	(2,255)	
Total SG&A plus depreciation	(3,990)		(1,356)		(3,696)		(1,201)	(10,242)	
OPERATING PROFIT (LOSS)	(1,752)		714		1,699		(1,201)	(539)	