

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, 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): _____

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, 2022

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports First Quarter 2022 Results

- First quarter 2022 revenue of approximately EUR 13.0 million (USD 14.5 million), an increase of 26% as compared to EUR 10.3 million (USD 12.4 million) for the first quarter 2021
- Four Focal One units sold in Q1 2022 versus zero in Q1 2021
- Strong cash position of \$51.6 million as of March 31, 2022
- Company to host a conference call tomorrow, Wednesday, May 18, at 8:30 am ET

LYON, France, May 17, 2022 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the first quarter 2022.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "As we announced in our business update press release just a few weeks ago, the first quarter was one in which the positive impact of our new U.S. organization, led by CEO Ryan Rhodes, was featured prominently. We ended 2021 on a strong note and continued that momentum into Q1 by adding three more highly regarded U.S. academic medical centers to our client roster, including New York-Presbyterian/Weill Cornell Medical Center, Beth Israel Deaconess Lahey Health, an affiliate of Harvard Medical School, and University of California Davis Medical Center in Sacramento. We also sold a Focal One outside of the U.S.

"Combined with another strong quarter from our distribution business, we grew revenue 26% year-over-year in the first quarter. We have a very rich pipeline of US prospects – both academic medical centers and community hospitals – and I am confident that we will continue to convert these to Focal One reference sites this year as acceptance of focal therapy as a treatment option within the urology suite continues to gain acceptance."

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, "2022 represents the first year in which we entered the year with a right-sized U.S. organization capable of capturing the significant untapped opportunity at a time when more and more urologists are recognizing the value of HIFU along the prostate cancer care continuum. The interest in our technology that we saw at last week's American Urology Association meeting confirms that we are in the right place at the right time, with a cutting-edge platform that can truly make a positive difference in the lives of prostate cancer patients. I believe we are set up for a successful year even while we continue to make measured investments in our U.S. infrastructure."

First Quarter 2022 Results

Total revenue for the first quarter 2022 was EUR 13.0 million (USD 14.5 million), an increase of 26% as compared to total revenue of EUR 10.3 million (USD 12.4 million) for the same period in 2021.

Total revenue in the HIFU business for the first quarter 2022 was EUR 3.8 million (USD 4.3 million), as compared to EUR 1.8 million (USD 2.2 million) for the first quarter of 2021. The increase was driven by four Focal One units sold in the first quarter 2022 versus zero units sold in the first quarter 2021.

Total revenue in the LITHO business for the first quarter 2022 was EUR 2.2 million (USD 2.5 million), as compared to EUR 2.9 million (USD 3.5 million) for the first quarter of 2021. The decline was driven by one lithotripsy unit sold in the first quarter of 2022 as compared to six units sold in the first quarter of 2021.

Total revenue in the Distribution business for the first quarter 2022 was EUR 7.0 million (USD 7.8 million), as compared to EUR 5.6 million (USD 6.7 million) for the first quarter of 2021. The increase was driven primarily by nine ExactVu units sold during the first quarter of 2022 as compared to five units sold during the first quarter of 2021.

Gross profit for the first quarter 2022 was EUR 5.8 million (USD 6.4 million), compared to EUR 4.4 million (USD 5.2 million) for the year-ago period. Gross profit margin on net sales was 44.3 % in the first quarter of 2022, compared to 42.4% in the year-ago period.

Operating expenses were EUR 5.9 million (USD 6.6 million) for the first quarter of 2022, compared to EUR 4.1 million (USD 5.0 million) for the same period in 2021.

Operating loss for the first quarter of 2022 was EUR 0.1 million (USD 0.1 million), compared to an operating profit of EUR 0.2 million (USD 0.3 million) in the first quarter of 2021.

Net income for the first quarter of 2022 was EUR 0.4 million (USD 0.4 million), or EUR 0.01 per diluted share, as compared to net income of EUR 0.8 million (USD 0.9 million), or EUR 0.03 per diluted share in the year-ago period.

As of March 31, 2022, the company held cash and cash equivalents of EUR 46.5 million (USD 51.6 million) as compared to EUR 47.2 million (USD 53.4 million) as of December 31, 2021.

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, May 18, 2022. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Wednesday, May 18, 2022 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13728747

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1541898&tp_key=e83b07e195

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 focalone.com, <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.

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:	
	Mar. 31, 2022 Euros	Mar. 31, 2021 Euros	Mar. 31, 2022 \$US	Mar. 31, 2021 \$US
Sales of medical equipment	8,966	6,691	10,021	8,023
Net Sales of RPP and Leases	1,317	1,212	1,472	1,453
Sales of spare parts, supplies and Services	2,715	2,396	3,035	2,873
TOTAL NET SALES	12,998	10,299	14,527	12,349
Other revenues	0	3	0	3
TOTAL REVENUES	12,998	10,302	14,527	12,353
Cost of sales	(7,241)	(5,932)	(8,093)	(7,112)
GROSS PROFIT	5,757	4,371	6,434	5,241
Research & development expenses	(1,081)	(851)	(1,208)	(1,020)
S, G & A expenses	(4,787)	(3,281)	(5,351)	(3,934)
Total operating expenses	(5,868)	(4,132)	(6,559)	(4,954)
OPERATING PROFIT (LOSS)	(111)	239	(125)	287
Interest (expense) income, net	(29)	164	(32)	196
Currency exchange gains (loss), net	569	489	636	587
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	429	892	480	1,070
Income tax (expense) credit	(72)	(119)	(81)	(143)
NET INCOME (LOSS)	357	773	399	927
Earning per share – Basic	0.01	0.03	0.01	0.03
Average number of shares used in computation of EPS	33,466,136	29,189,955	33,466,136	29,189,955
Earning per share – Diluted	0.01	0.03	0.01	0.03
Average number of shares used in computation of EPS for positive net income	34,031,361	30,352,216	34,031,361	30,352,216

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.1177 USD, and 2021 average three months noon buying rate of 1 Euro = 1.1990 USD

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

	Mar. 31, 2022 Euros	Dec. 31, 2021 Euros	Mar. 31, 2022 \$US	Dec. 31, 2021 \$US
Cash, cash equivalents and short-term treasury investments	46,498	47,183	51,579	53,405
Account receivables, net	11,953	12,118	13,259	13,716
Inventory	7,342	7,499	8,144	8,487
Other current assets	771	581	855	658
TOTAL CURRENT ASSETS	66,565	67,382	78,838	76,267
Property, plant and equipment, net	5,251	5,173	5,825	5,855
Goodwill	2,412	2,412	2,675	2,730
Other non-current assets	2,221	2,260	2,464	2,558
TOTAL ASSETS	76,448	77,226	84,801	87,409
Accounts payable & other accrued liabilities	9,881	10,786	10,961	12,208
Deferred revenues, current portion	3,501	3,408	3,884	3,857
Short term borrowing	857	1,914	950	2,167
Other current liabilities	1,977	1,843	2,193	2,086
TOTAL CURRENT LIABILITIES	16,216	17,951	17,988	20,318
Obligations under operating and finance leases non-current	1,159	1,318	1,286	1,492
Long term debt, non-current	4,952	4,930	5,482	5,580
Deferred revenues, non-current	338	440	375	498
Other long term liabilities	3,031	2,534	3,363	2,868
TOTAL LIABILITIES	25,688	27,172	28,494	30,755
TOTAL SHAREHOLDERS' EQUITY	50,761	50,054	56,307	56,655
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	76,448	77,226	84,801	87,409

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1093 USD on March 31, 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)

	3-months ended Mar. 31, 2022 Euros	12-months ended Dec. 31, 2021 Euros	3-months ended Mar. 31, 2022 \$US	12-months ended Dec. 31 2021 \$US
NET INCOME (LOSS)	360	700	402	825
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	1,127	3,225	1,259	3,801
OPERATING CASH FLOW	1,487	3,925	1,662	4,626
Increase/Decrease in operating assets and liabilities	(399)	520	(446)	613
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	1,087	4,445	1,215	5,239
Short term investments ⁽²⁾	-	-	-	-
Additions to capitalized assets produced by the company and other capital expenditures	(692)	(1,638)	(774)	(1,931)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(692)	(1,638)	(774)	(1,931)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	(943)	20,266	(1,054)	23,887
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(137)	(585)	(1,213)	(3,992)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(685)	22,488	(1,826)	23,204

(1) including Share based compensation expenses for 583 thousands of Euros at the end of March 2022, and 1,9 million of Euros at the end of December 2021

(2) Short term investments are comprised of money market funds

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.1177 USD and at the 2021 average twelve months' noon buying rate of 1 Euro = 1.1787 USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2022
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items		Total After Consolidation	
Sales of goods	2,406		510		6,049				8,966	
Sales of RPPs & Leases	965		284		68				1,317	
Sales of spare parts & services	446		1,431		838				2,715	
TOTAL NET SALES	3,817		2,225		6,955				12,998	
Other revenues	0		0		0				0	
TOTAL REVENUES	3,817		2,225		6,955				12,998	
GROSS PROFIT (% of Total Revenues)	2,030	53.2%	973	43.7%	2,754	39.6%			5,757	44.3%
Research & Development	(729)		(243)		(109)				(1,081)	
Total SG&A plus depreciation	(1,716)		(701)		(1,803)		(567)		(4,787)	
OPERATING PROFIT (LOSS)	(415)		29		842		(567)		(111)	