

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 17, 2021

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
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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: November 17, 2021

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Third Quarter 2021 Results and Provides Operational Update

- Year-to-date revenue of approximately EUR 30.1 million (USD 35.9 million) increased 14.4% year-over-year
- Q3 revenue of EUR 9.4 million (USD 11.1 million), flat with Q3 2020, reflecting lingering impact of COVID-19 on capital equipment sales
- Year-to-date US HIFU treatment volumes increased 58% over the comparable period in 2020; strong leading indicator of Focal One adoption by urologists
- Strong cash position of EUR 45.4 million (USD 52.6 million)
- Company to host a conference call tomorrow, Thursday, November 18, at 8:30 am ET

LYON, France, November 17, 2021 -- EDAP TMS SA (Nasdaq: EDAP) (the “Company”), a global leader in robotic energy-based therapies, announced today unaudited financial results for the third quarter of 2021 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP’s Chairman and Chief Executive Officer, said: “We are pleased with the continued strong growth in U.S. HIFU treatment volumes, which increased 58% year-to-date over the comparable period in 2020. This is a very positive sign as it reflects the growing adoption of focal therapy by urologists. Regarding our third quarter revenue, the COVID-19 pandemic continued to weigh on hospital capital spending, and this was further impacted by several machine placements that were delayed until the early days of the fourth quarter due to logistical challenges that were exacerbated by the resurgence of the pandemic in many parts of the world. Our leading indicators are strong, we are well financed, and I believe we are well positioned to exit the year with renewed momentum.”

Nine Months 2021 Results

Total revenue for the nine months ended September 30, 2021 was EUR 30.1 million (USD 35.9 million), an increase of 14.4% from total revenue of 26.3 million (USD 29.8 million) for the same period in 2020.

Total revenue in the HIFU business for the nine months ended September 30, 2021 was EUR 5.7 million (USD 6.8 million), a decline of 18.9% as compared to EUR 7.1 million (USD 8.0 million) for the nine months ended September 30, 2020.

Total revenue in the LITHO business for the nine months ended September 30, 2021 was EUR 7.7 million (USD 9.1 million), an decrease of 7.4% from EUR 8.3 million (USD 9.4 million) for the nine months ended September 30, 2020.

Total revenue in the Distribution business for the nine months ended September 30, 2021 was EUR 16.7 million (USD 19.9 million), a 52.4% increase compared to EUR 11.0 million (USD 12.4 million) for the nine months ended September 30, 2020.

Gross profit for the nine months ended September 30, 2021 was EUR 12.2 million (USD 14.6 million), compared to EUR 11.4 million (USD 12.8 million) for the year-ago period. Gross profit margin on net sales was 40.6% for the nine months ended September 30, 2021, compared to 43.2% for the comparable period in 2020. The decrease in gross profit year-over-year was due to lower sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 14.3 million (USD 17.0 million) for the nine months ended September 30, 2021, compared to EUR 12.8 million (USD 14.5 million) for the same period in 2020.

Operating loss for the nine months ended September 30, 2021 was EUR 2.1 million (USD 2.5 million), compared to an operating loss of EUR 1.5 million (USD 1.6 million) for the nine months ended September 30, 2020.

Net loss for the nine months ended September 30, 2021 was EUR 0.7 million (USD 0.8 million), or EUR (0.02) per diluted share, as compared to a net loss of EUR 2.5 million (USD 2.8 million), or EUR (0.09) per diluted share in the year-ago period.

Third Quarter 2021 Results

Total revenue for the third quarter 2021 was EUR 9.4 million (USD 11.1 million), roughly flat with total revenue of EUR 9.4 million (USD 11.2 million) for the same period in 2020.

Total revenue in the HIFU business for the third quarter 2021 was EUR 1.9 million (USD 2.3 million), a decline of 25.6% as compared to EUR 2.6 million (USD 3.0 million) for the third quarter of 2020.

Total revenue in the LITHO business for the third quarter 2021 was EUR 2.5 million (USD 2.9 million), an increase of 3.0% from EUR 2.4 million (USD 2.9 million) for the third quarter of 2020.

Total revenue in the Distribution business for the third quarter 2021 was EUR 5.0 million (USD 5.9 million), a 13.4% increase compared to EUR 4.4 million (USD 5.2 million) for the third quarter of 2020.

Gross profit for the third quarter 2021 was EUR 3.6 million (USD 4.3 million), compared to EUR 4.0 million (USD 4.7 million) for the year-ago period. Gross profit margin on net sales was 38.4% in the third quarter of 2021, compared to 42.0% in the year-ago period. The decrease in gross profit year-over-year was due to lower sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 5.5 million (USD 6.5 million) for the third quarter of 2021, compared to EUR 4.3 million (USD 5.0 million) for the same period in 2020.

Operating loss for the third quarter of 2021 was EUR 1.9 million (USD 2.2 million), compared to an operating loss of EUR 0.3 million (USD 0.3 million) in the third quarter of 2020.

Net loss for the third quarter of 2021 was EUR 1.0 million (USD 1.2 million), or EUR (0.03) 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.

As of September 30, 2021, the company held cash and cash equivalents of EUR 45.4 million (USD \$52.6 million), as compared to EUR 24.7 million (USD 30.2 million) as of December 31, 2020.

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 18, 2021. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, November 18, 2021 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13724088

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1503943&tp_key=7d846a9985

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:	
	Sept. 30, 2021 Euros	Sept. 30, 2020 Euros	Sept. 30, 2021 \$US	Sept. 30, 2020 \$US
Sales of medical equipment	5,788	5,984	6,799	7,080
Net Sales of RPP and Leases	1,104	1,207	1,297	1,428
Sales of spare parts, supplies and Services	2,548	2,255	2,993	2,668
TOTAL NET SALES	9,440	9,446	11,089	11,176
Other revenues	-	(13)	-	(16)
TOTAL REVENUES	9,440	9,433	11,089	11,160
Cost of sales	(5,815)	(5,469)	(6,831)	(6,470)
GROSS PROFIT	3,625	3,964	4,258	4,690
Research & development expenses	(1,064)	(1,090)	(1,250)	(1,289)
S, G & A expenses	(4,446)	(3,167)	(5,222)	(3,748)
Total operating expenses	(5,510)	(4,257)	(6,472)	(5,037)
OPERATING PROFIT (LOSS)	(1,885)	(293)	(2,215)	(347)
Interest (expense) income, net	(22)	(12)	(25)	(14)
Currency exchange gains (loss), net	1,003	(574)	1,178	(679)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(904)	(879)	(1,062)	(1,040)
Income tax (expense) credit	(111)	(122)	(130)	(145)
NET INCOME (LOSS)	(1,015)	(1,001)	(1,192)	(1,185)
Earning per share – Basic	(0.03)	(0.03)	(0.04)	(0.04)
Average number of shares used in computation of EPS	33,448,136	29,144,010	33,448,136	29,144,010
Earning per share – Diluted	(0.03)	(0.03)	(0.04)	(0.04)
Average number of shares used in computation of EPS for positive net income	33,448,136	29,144,010	33,448,136	29,144,010

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average three months' noon buying rate of 1 Euro = 1.1747 USD, and 2020 average three months noon buying rate of 1 Euro = 1.1832 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:	
	Sept. 30, 2021 Euros	Sept. 30, 2020 Euros	Sept. 30, 2021 \$US	Sept. 30, 2020 \$US
Sales of medical equipment	19,176	16,083	22,858	18,204
Net Sales of RPP and Leases	3,581	3,409	4,269	3,858
Sales of spare parts, supplies and Services	7,331	6,795	8,739	7,691
TOTAL NET SALES	30,088	26,287	35,866	29,753
Other revenues	4	11	5	12
TOTAL REVENUES	30,092	26,298	35,871	29,765
Cost of sales	(17,881)	(14,948)	(21,315)	(16,919)
GROSS PROFIT	12,211	11,350	14,556	12,846
Research & development expenses	(2,840)	(3,058)	(3,385)	(3,461)
S, G & A expenses	(11,444)	(9,743)	(13,642)	(11,027)
Total operating expenses	(14,284)	(12,800)	(17,027)	(14,488)
OPERATING PROFIT (LOSS)	(2,073)	(1,451)	(2,471)	(1,642)
Interest (expense) income, net	122	(51)	145	(58)
Currency exchange gains (loss), net	1,574	(631)	1,876	(714)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(378)	(2,133)	(450)	(2,415)
Income tax (expense) credit	(288)	(351)	(343)	(397)
NET INCOME (LOSS)	(665)	(2,484)	(793)	(2,812)
Earning per share – Basic	(0.02)	(0.09)	(0.02)	(0.10)
Average number of shares used in computation of EPS	32,881,747	29,142,788	32,881,747	29,142,788
Earning per share – Diluted	(0.02)	(0.09)	(0.02)	(0.10)
Average number of shares used in computation of EPS for positive net income	32,881,747	29,142,788	32,881,747	29,142,788

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average nine months' noon buying rate of 1 Euro = 1.1920 USD, and 2020 average nine months noon buying rate of 1 Euro = 1.1319 USD

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

	September 30, 2021 Euros	December 31, 2020 Euros	September 30, 2021 \$US	December 31, 2020 \$US
Cash, cash equivalents and short-term treasury investments	45,411	24,696	52,572	30,201
Account receivables, net	10,153	12,339	11,754	15,090
Inventory	8,523	7,989	9,866	9,771
Other current assets	585	369	677	451
TOTAL CURRENT ASSETS	64,672	45,393	74,869	55,513
Property, plant and equipment, net	4,927	5,599	5,704	6,847
Goodwill	2,412	2,412	2,792	2,949
Other non-current assets	1,675	1,790	1,939	2,189
TOTAL ASSETS	73,686	55,193	85,304	67,498
Accounts payable & other accrued liabilities	8,586	10,485	9,940	12,823
Deferred revenues, current portion	3,538	2,701	4,096	3,304
Short term borrowing	1,359	2,638	1,574	3,227
Other current liabilities	1,428	5,679	1,653	6,945
TOTAL CURRENT LIABILITIES	14,911	21,504	17,263	26,298
Obligations under operating and finance leases non-current	1,287	1,653	1,490	2,022
Long term debt, non-current	5,271	1,143	6,102	1,397
Deferred revenues, non-current	698	926	808	1,132
Other long term liabilities	3,478	3,720	4,026	4,549
TOTAL LIABILITIES	25,646	28,945	29,689	35,399
TOTAL SHAREHOLDERS' EQUITY	48,040	26,248	55,615	32,099
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	73,686	55,193	85,304	67,498

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1577 USD, on September 30, 2021 and at the noon buying rate of 1 Euro = 1.2229 USD, on December 30, 2020.

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

	9 months ended Sept. 30, 2021 (Euros)	12 months ended Dec. 31, 2020 (Euros)	9 months ended Sept. 30 2021 (\$US)	12 months ended Dec. 31, 2020 (\$US)
NET INCOME (LOSS)	(655)	(1,704)	(793)	(1,955)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	2,553	3,790	3,043	4,349
OPERATING CASH FLOW	1,888	2,087	2,250	2,394
Increase/Decrease in operating assets and liabilities	(113)	(110)	(135)	(126)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	1,774	1,977	2,115	2,269
Additions to capitalized assets produced by the company and other capital expenditures	(988)	(2,011)	(1,178)	(2,307)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(988)	(2,011)	(1,178)	(2,307)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	20,384	3,201	24,299	3,673
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(455)	642	(2,865)	3,118
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	20,716	3,810	22,371	6,752

⁽¹⁾ including share based compensation expenses for 1,154 thousand of Euros at the end of September 2021 and 160 thousand of Euros at the end of December 2020.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2021 average nine months' noon buying rate of 1 Euro = 1.1920 USD, and 2020 average twelve months noon buying rate of 1 Euro = 1.1474USD

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2021
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items		Total After Consolidation	
Sales of goods	1,844		2,675		14,657				19,176	
Sales of RPPs & Leases	2,617		767		197				3,581	
Sales of spare parts & services	1,251		4,226		1,854				7,331	
TOTAL NET SALES	5,713		7,667		16,708				30,088	
Other revenues	4		0		0				4	
TOTAL REVENUES	5,717		7,667		16,708				30,092	
GROSS PROFIT (% of Total Revenues)	2,150	37.6%	3,526	46.0%	6,536	39.1%			12,211	40.6%
Research & Development	(1,955)		(652)		(232)				(2,840)	
Total SG&A plus depreciation	(3,463)		(2,289)		(4,237)		(1,455)		(11,444)	
OPERATING PROFIT (LOSS)	(3,269)		585		2,067		(1,455)		(2,073)	