

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

March 30, 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 [x] 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: March 30, 2021

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Fourth Quarter 2020 Results and Provides Operational Update

- Generated record fourth quarter revenue of EUR 15.4 million (USD 18.3 million), an increase of 28% year-over-year; HIFU revenue up 51% year-over-year
- Generated €41.7 million revenue and profitable operating result for the full year 2020.
- Completed sales to renowned healthcare institutions, such as University of California, San Francisco Medical Center and Cleveland Clinic
- Strong and increased cash position of EUR 24.7 million (USD 30.2 million) as of December 31, 2020
- Company to host a conference call tomorrow, March 31, at 8:30 am ET

LYON, France, March 30, 2021 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the fourth quarter of 2020 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "During the fourth quarter and full year 2020, we made great strides toward our mission of becoming a leader in the field of high intensity focused ultrasound. We delivered sequential revenue growth each quarter of the year notwithstanding the impact of the pandemic. We ended on a high note by delivering 28% year-over-year total revenue growth and 51% year-over-year HIFU revenue growth during the quarter, and in the process welcomed University of California, San Francisco Medical Center (UCSF) and Cleveland Clinic to our growing roster of highly regarded Focal One customers. This success was driven not only by the growing recognition of Focal One as a new treatment paradigm in the non-invasive ablation of cancerous prostate tissue, but also our strategic licensing agreement with Exact Imaging, and its lead product Exact Vu, which provides us with a comprehensive urology solution.

"Notably, we achieved all of this while delivering operating profitability for both the fourth quarter and full year and ended the year with an increased cash position of EUR 24.7 million. I believe we are well positioned to continue this momentum through 2021."

Fourth Quarter 2020 Results

Total revenue for the fourth quarter 2020 was EUR 15.4 million (USD 18.3 million), an increase of 28.2% compared to total revenue of EUR 12.0 million (USD 13.3 million) for the same period in 2019.

Total revenue in the HIFU business for the fourth quarter 2020 was EUR 4.4 million (USD 5.2 million), a 50.8% increase compared to EUR 2.9 million (USD 3.2 million) for the fourth quarter of 2019.

Total revenue in the LITHO business for the fourth quarter 2020 was EUR 4.6 million (USD 5.5 million), a 10.6% increase compared to EUR 4.2 million (USD 4.6 million) for the fourth quarter of 2019.

Total revenue in the Distribution business for the fourth quarter 2020 was EUR 6.4 million (USD 7.6 million), a 29.7% increase compared to EUR 4.9 million (USD 5.5 million) for the fourth quarter of 2019.

Gross profit for the fourth quarter 2020 was EUR 7.0 million (USD 8.4 million), compared to EUR 5.1 million (USD 5.7 million) for the year-ago period. Gross profit margin on net sales was 45.8% in the fourth quarter of 2020, compared to 43.0% in the year-ago period. The increase in gross profit year-over-year was due to higher HIFU equipment sales.

Operating expenses were EUR 5.3 million (USD 6.3 million) for the fourth quarter of 2020, compared to EUR 5.1 million (USD 5.6 million) for the same period in 2019.

Operating profit for the fourth quarter of 2020 was EUR 1.7 million (USD 2.1 million), compared to an operating profit of EUR 0.08 million (USD 0.09 million) in the fourth quarter of 2019.

Net income for the fourth quarter of 2020 was EUR 0.8 million (USD 0.9 million), or EUR 0.03 per diluted share, as compared to a net loss of EUR 1.0 million (USD 1.1 million), or EUR (0.03) per diluted share in the year-ago period.

Full Year 2020 Results

Total revenue for the full year 2020 was EUR 41.7 million (USD 47.8 million), a decrease of 7% compared to total revenue of EUR 44.9 million (USD 50.2 million) for the full year 2019. Full year revenue reflects the impact of the ongoing COVID-19 pandemic on the company's activities.

Total revenue in the HIFU business for the full year 2020 was EUR 11.4 million (USD 13.1 million), a 19% decrease compared to EUR 14.1 million (USD 15.8 million) for the full year 2019.

Total revenue in the LITHO business for the full year 2020 was EUR 12.9 million (USD 14.8 million), a 9.2% decrease compared to 14.2 million (USD 15.9 million) for the full year 2019.

Total revenue in the Distribution business for the full year 2020 was EUR 17.3 million (USD 19.9 million), a 4.6% increase compared to EUR 16.6 million (USD 18.5 million) for the full year 2019.

Gross profit for the full year 2020 was EUR 18.4 million (USD 21.1 million), compared to EUR 21.0 million (USD 23.5 million) for the full year 2019. Gross profit margin on net sales was 44.1% for the full year 2020, compared to 46.8% in the prior year. The decline in gross profit year-over-year was due in part to lower sales in the HIFU business driven by COVID-19.

Operating expenses were EUR 18.1 million (USD 20.8 million) for the full year 2020, compared to EUR 18.8 million (USD 21.0 million) for the full year 2019.

Operating profit for the full year 2020 was EUR 0.3 million (USD 0.3 million), compared to an operating profit of EUR 2.2 million (USD 2.5 million) for the full year 2019.

Net loss for the full year 2020 was EUR 1.7 million (USD 2.0 million), or EUR (0.06) per diluted share, as compared to a net income of EUR 1.5 million (USD 1.7 million), or EUR 0.05 per diluted share in the prior year.

As of December 31, 2020, the Company recorded a strong cash position of EUR 24.7 million (USD 30.2 million).

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, March 31, 2021. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Wednesday, March 31, 2021 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13717550

Webcast: <http://public.viavid.com/index.php?id=143913>

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:	
	Dec. 31, 2020 Euros	Dec. 31, 2019 Euros	Dec. 31, 2020 \$US	Dec. 31, 2019 \$US
Sales of medical equipment	11,439	7,972	13,661	8,876
Net Sales of RPP and Leases	1,336	1,719	1,596	1,914
Sales of spare parts, supplies and Services	2,587	2,259	3,089	2,515
TOTAL NET SALES	15,363	11,950	18,346	13,305
Other revenues	1	37	2	42
TOTAL REVENUES	15,364	11,988	18,348	13,346
Cost of sales	(8,335)	(6,848)	(9,953)	(7,624)
GROSS PROFIT	7,029	5,139	8,394	5,722
Research & development expenses	(1,439)	(844)	(1,718)	(939)
S, G & A expenses	(3,871)	(4,216)	(4,622)	(4,694)
Total operating expenses	(5,310)	(5,060)	(6,341)	(5,633)
OPERATING PROFIT (LOSS)	1,720	79	2,053	88
Interest (expense) income, net	(46)	(43)	(55)	(48)
Currency exchange gains (loss), net	(728)	(652)	(869)	(726)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	945	(616)	1,129	(685)
Income tax (expense) credit	(165)	(362)	(197)	(403)
NET INCOME (LOSS)	780	(978)	932	(1,088)
Earning per share – Basic	0.03	(0.03)	0.03	(0.04)
Average number of shares used in computation of EPS	29,164,983	29,047,028	29,164,983	29,047,028
Earning per share – Diluted	0.03	(0.03)	0.03	(0.04)
Average number of shares used in computation of EPS for positive net income	30,222,258	29,047,028	30,222,258	29,047,028

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average three months' noon buying rate of 1 Euro = 1.1942 USD, and 2019 average three months noon buying rate of 1 Euro = 1.1133 USD

EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Twelve Months Ended:		Twelve Months Ended:	
	Dec. 31, 2020 Euros	Dec. 31, 2019 Euros	Dec. 31, 2020 \$US	Dec. 31, 2019 \$US
Sales of medical equipment	27,523	30,111	31,581	33,678
Net Sales of RPP and Leases	4,745	5,747	5,445	6,428
Sales of spare parts, supplies and Services	9,382	9,001	10,765	10,067
TOTAL NET SALES	41,649	44,859	47,791	50,173
Other revenues	12	52	14	59
TOTAL REVENUES	41,662	44,912	47,805	50,231
Cost of sales	(23,283)	(23,909)	(26,716)	(26,741)
GROSS PROFIT	18,379	21,002	21,089	23,490
Research & development expenses	(4,496)	(3,728)	(5,159)	(4,169)
S, G & A expenses	(13,614)	(15,074)	(15,621)	(16,859)
Total operating expenses	(18,110)	(18,802)	(20,780)	(21,029)
OPERATING PROFIT (LOSS)	269	2,201	309	2,461
Interest (expense) income, net	(98)	(146)	(112)	(163)
Currency exchange gains (loss), net	(1,359)	136	(1,559)	152
Other income, net	-	-	(1)	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,188)	2,191	(1,363)	2,451
Income tax (expense) credit	(516)	(679)	(592)	(760)
NET INCOME (LOSS)	(1,704)	1,512	(1,955)	1,691
Earning per share – Basic	(0.06)	0.05	(0.07)	0.06
Average number of shares used in computation of EPS	29,148,108	29,016,118	29,148,108	29,016,118
Earning per share – Diluted	(0.06)	0.05	(0.07)	0.06
Average number of shares used in computation of EPS for positive net income	29,148,108	29,615,466	29,148,108	29,615,466

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average twelve months' noon buying rate of 1 Euro = 1.1474 USD, and 2019 average twelve months noon buying rate of 1 Euro = 1.1184 USD

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

	Dec. 31, 2020 Euros	Sept. 30, 2020 Euros	Dec. 31, 2020 \$US	Sept. 30, 2020 \$US
Cash, cash equivalents and short-term treasury investments	24,696	19,929	30,201	23,364
Account receivables, net	12,339	11,572	15,090	13,567
Inventory	7,989	9,455	9,771	11,084
Other current assets	369	604	451	708
TOTAL CURRENT ASSETS	45,393	41,560	55,513	48,722
Property, plant and equipment, net	5,599	5,928	6,847	6,950
Goodwill	2,412	2,412	2,949	2,827
Other non-current assets	1,790	1,739	2,189	2,039
TOTAL ASSETS	55,193	51,639	67,498	60,538
Accounts payable & other accrued liabilities	10,485	9,122	12,823	10,694
Deferred revenues, current portion	2,701	2,695	3,304	3,160
Short term borrowing	2,638	1,459	3,227	1,711
Other current liabilities	5,679	5,825	6,945	6,829
TOTAL CURRENT LIABILITIES	21,504	19,102	26,298	22,394
Obligations under operating and finance leases non-current	1,653	1,724	2,022	2,021
Long term debt, non-current	1,143	1,219	1,397	1,429
Deferred revenues, non-current	926	821	1,132	963
Other long term liabilities	3,720	3,626	4,549	4,251
TOTAL LIABILITIES	28,945	26,493	35,399	31,059
TOTAL SHAREHOLDERS' EQUITY	26,248	25,146	32,099	29,480
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	55,193	51,639	67,498	60,538

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2229 USD on December 31, 2020 and at the noon buying rate of 1 Euro = 1.1723 USD, on September 30, 2020

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

	Dec. 31, 2020 Euros	Sept. 30, 2020 Euros	Dec. 31, 2020 \$US	Sept. 30 2020 \$US
NET INCOME (LOSS)	(1,704)	(2,484)	(1,955)	(2,812)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	3,790	2,211	4,349	2,503
OPERATING CASH FLOW	2,087	(273)	2,394	(309)
Increase/Decrease in operating assets and liabilities	(110)	(1,735)	(126)	(1,964)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	1,977	(2,008)	2,269	(2,273)
Short term investments ⁽²⁾	-	(1,708)	-	(1,933)
Additions to capitalized assets produced by the company and other capital expenditures	(2,011)	(1,508)	(2,307)	(1,707)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(2,011)	(3,216)	(2,307)	(3,640)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	3,201	2,248	3,673	2,544
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	642	312	3,118	1,281
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,810	(2,665)	6,752	(2,088)

⁽¹⁾ including Share based compensation expenses for 160 thousands of Euros at the end of December 2020, and 134 thousands of Euros at the end of September 2020

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

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average twelve months' noon buying rate of 1 Euro = 1.1474 and 2020 average nine months' noon buying rate of 1 Euro = 1.1319 USD.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2020
(Amounts in thousands of Euros)

	HIFU Division	ESWL Division	Distribution Division	Reconciling Items	Total After Consolidation
Sales of goods	6,000	6,248	15,274		27,523
Sales of RPPs & Leases	3,594	927	224		4,745
Sales of spare parts & services	1,831	5,707	1,844		9,382
TOTAL NET SALES	11,425	12,882	17,342		41,649
Other revenues	12	0	0		12
TOTAL REVENUES	11,438	12,882	17,342		41,662
GROSS PROFIT					
(% of Total Revenues)	6,293 55.0 %	5,649 43.9%	6,436 37.1%		18,379 44.1%
Research & Development	(2,583)	(1,555)	(358)		(4,496)
Total SG&A plus depreciation	(4,156)	(3,016)	(4,976)	(1,465)	(13,614)
OPERATING PROFIT (LOSS)	(445)	1,078	1,102	(1,465)	269