

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, 2020

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: March 30, 2020
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Record Full Year 2019 Results and Provides Operational Update

- Record full year 2019 revenues of €44.9 million, representing 14.6% year-over-year growth
- HIFU full year 2019 revenue growth of 28% driven by 54% growth in US installed base
- Record 46.8% gross profit margin driven by HIFU growth
- Profitable for the full year 2019 with operating income of €2.2 million
- Solid balance sheet with EUR 20.9 million (USD 23.4 million) in cash, €1.4 million of positive cash flow generated in 2019
- CEO Marc Oczachowski to succeed Philippe Chauveau as Chairman of the Board of Directors
- Company to host a conference call tomorrow, March 31 at 8:30 am EDT

LYON, France, March 30, 2020 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in robotic energy based therapies, announced today financial results for the fourth quarter and full year of 2019 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, said: “We are proud of our team for a very successful year in 2019, which was our first full year of U.S. FDA approval for Focal One®, our latest generation high Intensity Focused Ultrasound (HIFU) robotic device for the targeted ablation of prostate tissue. During the year, we placed Focal One devices at many highly regarded healthcare institutions, including Mayo Clinic, Houston Methodist Hospital, University of California at Irvine Medical Center and University of Chicago Medicine, among others. We ended the year with a strong sales pipeline and good momentum both in the U.S. and worldwide.

“As far as financial results, we grew our company sales by 14.5% year-over-year, which was driven by HIFU sales growth of 28%. We expanded our gross margins to a record 46.8%, which represents an increase of 362 basis points in 2019 as higher margin HIFU sales led to higher profitability. The Company has now been profitable for five consecutive quarters, and we have a strong balance sheet with EUR 20.9 million in cash. We are looking forward to the commencement of U.S. reimbursement for Focal One in 2021, which has the potential to be a significant catalyst for further adoption.

“The COVID-19 virus represents a major new challenge for all of us, and we are proactively taking measures across all areas of our business. Our number one priority is the health and safety of our employees and to ensure uninterrupted service to our existing customers. Due to this ongoing pandemic, we anticipate the likelihood of an impact to our near-term revenue as procedures are delayed and the sales cycle for new installations becomes elongated. However, we are pleased with the momentum with which we entered 2020, and we believe we have the resources to successfully navigate this crisis.”

“Finally, we are announcing today that Philippe Chauveau is stepping down from his role as Chairman of the Board but will continue to serve as a Director until June of this year, as part of a long-established transition plan. Philippe’s insights have been invaluable since joining our Board in 1997,” Mr. Oczachowski concluded.

EDAP’s Chief Executive Officer, Marc Oczachowski, has been selected by the Board to replace Mr. Chauveau as Chairman. Mr. Oczachowski has worked at EDAP in various roles of increasing responsibility since 1997, becoming Chief Operating Officer in November 2004 and Chief Executive Officer in March 2007. He has served as a Director on EDAP’s Board since 2017.

“I am humbled that my fellow directors have nominated me to assume the role of Chairman, and I remain steadfast in my commitment to maintain our position as a leading global innovator in the use of therapeutic ultrasound,” Mr. Oczachowski commented.

Full Year 2019 Results

Total revenue for the full year of 2019 was EUR 44.9 million (USD 50.2 million), a 14.6% increase compared to EUR 39.2 million (USD 46.2 million) for the full year of 2018.

Total revenue in the HIFU business for the full year of 2019 was EUR 14.1 million (USD 15.8 million), a 28.1% increase compared to EUR 11.0 million (USD 13.0 million) for the full year of 2018.

For the full year of 2019, total revenue for the UDS division was EUR 30.8 million (USD 34.4 million), a 9.3% increase compared to EUR 28.1 million (USD 33.2 million) during the year-ago period.

Gross profit for the full year of 2019 was EUR 21.0 million (USD 23.5 million), compared to EUR 16.9 million (USD 19.9 million) for the year-ago period. Gross profit margin on net sales was 46.8% for the full year 2019 compared to 43.2% for the full year 2018.

Operating expenses were EUR 18.8 million (USD 21.0 million) for the full year of 2019, compared to EUR 18.2 million (USD 21.5 million) for the same period in 2018.

Operating profit for the full year of 2019 was EUR 2.2 million (USD 2.5 million), compared to an operating loss of EUR 1.3 million (USD 1.5 million) in the full year of 2018.

Net income for the full year of 2019 was EUR 1.5 million (USD 1.7 million), or earnings of EUR 0.05 per diluted share, as compared to a net loss of EUR 0.3 million (USD 0.4 million), or a loss of EUR 0.01 per diluted share in the year-ago period.

As of December 31, 2019, cash and cash equivalents were EUR 20.9 million (USD 23.4 million).

Fourth Quarter 2019 Results

Total revenue for the fourth quarter 2019 was EUR 12.0 million (USD 13.3 million), a 9.8% decrease compared to EUR 13.3 million (USD 15.1 million) for the fourth quarter of 2018.

Total revenue in the HIFU business for the fourth quarter 2019 was EUR 2.9 million (USD 3.2 million), a 33.1% decrease compared to EUR 4.3 million (USD 4.9 million) for the fourth quarter of 2018. The year-over-year decline was due to two Focal One units sold during the fourth quarter of 2019 compared to four Focal One units sold in the year ago period.

For the three months ended December 31, 2019, total revenue for the UDS division was EUR 9.1 million (USD 10.1 million), a 1.6% increase compared to EUR 8.9 million (USD 10.2 million) during the year-ago period.

Gross profit for the fourth quarter 2019 was EUR 5.1 million (USD 5.7 million), compared to EUR 6.0 million (USD 6.8 million) for the year-ago period. Gross profit margin on net sales was 43.0% in the fourth quarter of 2019, compared to 45.0% in the year-ago period. The decline in gross profit year-over-year was due to in part to lower sales in HIFU business as compared to the year-ago period.

Operating expenses were EUR 5.1 million (USD 5.6 million) for the fourth quarter of 2019, compared to EUR 5.1 million (USD 5.8 million) for the same period in 2018.

Operating profit for the fourth quarter 2019 was EUR 0.1 million (USD 0.1 million), compared to EUR 0.8 million (USD 1.0 million) in the fourth quarter of 2018.

Net loss for the fourth quarter 2019 was EUR 1.0 million (USD 1.1 million), or EUR (0.03) per diluted share, as compared to net income of EUR 1.0 million (USD 1.2 million), or EUR 0.04 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 on Tuesday, March 31, 2020. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Tuesday, March 31, 2020 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13700921

Webcast: <http://public.viavid.com/index.php?id=138743>

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 for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology 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 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. 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 device, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference also may 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)

	<u>Three Months Ended:</u>		<u>Three Months Ended:</u>	
	December 31, 2019 Euros	December 31, 2018 Euros	December 31, 2019 \$US	December 31, 2018 \$US
Sales of medical equipment	7,972	9,275	8,876	10,546
Net Sales of RPP and Leases	1,719	1,566	1,914	1,781
Sales of spare parts, supplies and Services	2,259	2,442	2,515	2,776
TOTAL NET SALES	11,950	13,283	13,305	15,103
Other revenues	37	5	42	6
TOTAL REVENUES	11,988	13,288	13,346	15,109
Cost of sales	(6,848)	(7,306)	(7,624)	(8,307)
GROSS PROFIT	5,139	5,982	5,722	6,801
Research & development expenses	(844)	(947)	(939)	(1,077)
S, G & A expenses	(4,216)	(4,188)	(4,694)	(4,762)
Total operating expenses	(5,060)	(5,136)	(5,633)	(5,840)
OPERATING PROFIT (LOSS)	79	846	88	962
Interest (expense) income, net	(43)	(20)	(48)	(23)
Currency exchange gains (loss), net	(652)	222	(726)	253
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(616)	1,048	(685)	1,191
Income tax (expense) credit	(362)	(15)	(403)	(17)
NET INCOME (LOSS)	(978)	1,033	(1,088)	1,174
Earnings per share – Basic	(0.03)	0.04	(0.04)	0.04
Average number of shares used in computation of EPS	29,047,028	28,997,866	29,047,028	28,997,866
Earnings per share – Diluted	(0.03)	0.04	(0.04)	0.04
Average number of shares used in computation of EPS for positive net income	29,047,028	29,345,366	29,047,028	29,345,366

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average three months' noon buying rate of 1 Euro = 1.1133 USD, and 2018 average three months noon buying rate of 1 Euro = 1.1370 USD.

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

	<u>Twelve Months Ended:</u>		<u>Twelve Months Ended:</u>	
	December 31, 2019 Euros	December 31, 2018 Euros	December 31, 2019 \$US	December 31, 2018 \$US
Sales of medical equipment	30,111	25,070	33,678	29,543
Net Sales of RPP and Leases	5,747	5,086	6,428	5,994
Sales of spare parts, supplies and Services	9,001	9,007	10,067	10,614
TOTAL NET SALES	44,859	39,163	50,173	46,151
Other revenues	52	19	59	23
TOTAL REVENUES	44,912	39,183	50,231	46,173
Cost of sales	(23,909)	(22,266)	(26,741)	(26,238)
GROSS PROFIT	21,002	16,917	23,490	19,935
Research & development expenses	(3,728)	(4,088)	(4,169)	(4,817)
S, G & A expenses	(15,074)	(14,144)	(16,859)	(16,668)
Total operating expenses	(18,802)	(18,232)	(21,029)	(21,485)
OPERATING PROFIT (LOSS)	2,201	(1,315)	2,461	(1,549)
Interest (expense) income, net	(146)	797	(163)	939
Currency exchange gains (loss), net	136	538	152	634
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	2,191	20	2,451	23
Income tax (expense) credit	(679)	(358)	(760)	(422)
NET INCOME (LOSS)	1,512	(338)	1,691	(399)
Earnings per share – Basic	0.05	(0.01)	0.06	(0.01)
Average number of shares used in computation of EPS	29,016,118	28,997,866	29,016,118	28,997,866
Earnings per share – Diluted	0.05	(0.01)	0.06	(0.01)
Average number of shares used in computation of EPS for positive net income	29,620,357	28,997,866	29,620,357	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average twelve months noon buying rate of 1 Euro =1.1184 USD, and 2018 average twelve months noon buying rate of 1 Euro = 1.1784 USD.

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

	Dec. 31, 2019 Euros	Sept. 30, 2019 Euros	Dec. 31, 2019 \$US	Sept. 30, 2019 \$US
Cash, cash equivalents and short- term investments	20,886	17,665	23,449	19,264
Total current assets	42,097	42,383	47,263	46,219
Total current liabilities	17,493	17,463	19,640	19,044
Shareholders' Equity	27,359	27,477	30,716	29,964

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1227 USD, on Dec. 31, 2019 and at the noon buying rate of 1 Euro = 1.0905 USD, on Sept. 30, 2019.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2019
(Amounts in thousands of Euros)

	HIFU Division		UDS Division		Corporate	Total After Consolidation	
Sales of goods	8,311		21,800			30,111	
Sales of RPPs & Leases	4,162		1,585			5,747	
Sales of spare parts & services	1,618		7,383			9,001	
TOTAL NET SALES	14,092		30,768			44,859	
Other revenues	52		-			52	
TOTAL REVENUES	14,144		30,768			44,912	
GROSS PROFIT (% of Total Revenues)	7,991	56.5%	13,011	42.3%		21,002	46.8%
Research & Development	(1,962)		(1,766)			(3,728)	
Total SG&A plus depreciation	(5,571)		(8,206)		(1,297)	(15,074)	
OPERATING PROFIT (LOSS)	459		3,039		(1,297)	2,201	