

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 13, 2019

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: November 13, 2019
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports 2019 Third Quarter and Nine Months Results

- 67.8% growth in HIFU revenue through the nine month period ended September 30 over the comparable period in 2018
- 48.2% Gross margin for the nine month period ended September 30 compared to 42.3% for the comparable period in 2018
- Fourth consecutive quarter of profitability
- Continued to drive US sales strategy towards reference centers with sale of Focal One to Mayo Clinic
- Company to host a conference call on November 14, 2019 at 8:30am EST

LYON, France, **November 13, 2019** -- EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in therapeutic ultrasound, announced today financial results for the third quarter and nine months of 2019 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, said, “During the third quarter, we were able to sustain the sales momentum that carried us through the first half of the year. We sold an additional two Focal One units, including one to the world renowned Mayo Clinic bringing our year-to-date total to nine. At the same time, our pipeline continues to grow, particularly in the U.S., where we are still in the early stages of our hospital and physician education and outreach efforts. As a recognized leader in therapeutic ultrasound, we believe we have established a solid foundation from which to drive future growth.”

Third Quarter 2019 Results

Total revenue for the third quarter 2019 was EUR 10.3 million (USD 11.3 million), a 26.7% increase compared to EUR 8.1 million (USD 9.5 million) for the third quarter of 2018.

Total revenue in the HIFU business for the third quarter 2019 was EUR 2.8 million (USD 3.1 million), a 44.4% increase compared to EUR 1.9 million (USD 2.3 million) for the third quarter of 2018.

For the three months ended September 30, 2019, total revenue for the UDS division was EUR 7.5 million (USD 8.3 million), a 21.2% increase compared to EUR 6.2 million (USD 7.2 million) during the year-ago period.

Gross profit for the third quarter 2019 was EUR 4.7 million (USD 5.1 million), compared to EUR 3.4 million (USD 3.9 million) for the year-ago period. Gross profit margin on net sales was 45.3% in the third quarter of 2019, compared to 41.5% in the year-ago period.

Operating expenses were EUR 4.4 million (USD 4.9 million) for the third quarter of 2019, compared to EUR 4.1 million (USD 4.7 million) for the same period in 2018.

Operating profit for the third quarter 2019 was EUR 0.3 million (USD 0.3 million), compared to an operating loss of EUR 0.7 million (USD 0.8 million) in the third quarter of 2018.

Net income for the third quarter 2019 was EUR 0.8 million (USD 0.9 million), or earnings of EUR 0.03 per diluted share, as compared to a net loss of EUR 0.7 million (USD 0.8 million), or a loss of EUR 0.02 per diluted share in the year-ago period.

First nine months 2019 Results

Total revenue for the first nine months of 2019 was EUR 32.9 million (USD 36.9 million), a 27.1% increase compared to EUR 25.9 million (USD 30.9 million) for the first nine months of 2018.

Total revenue in the HIFU business for the first nine months of 2019 was EUR 11.2 million (USD 12.6 million), a 67.8% increase compared to EUR 6.7 million (USD 8.0 million) for the nine months ended September 30, 2018.

For the nine months ended September 30, 2019, total revenue for the UDS division was EUR 21.7 million (USD 24.3 million), a 13.0% increase compared to EUR 19.2 million (USD 22.9 million) during the year-ago period.

Gross profit for the first nine months of 2019 was EUR 15.9 million (USD 17.8 million), compared to EUR 10.9 million (USD 13.0 million) for the year-ago period. Gross profit margin on net sales was 48.2% compared to 42.3% in the year-ago period.

Operating expenses were EUR 13.7 million (USD 15.4 million) for the first nine months of 2019, compared to EUR 13.1 million (USD 15.6 million) for the same period in 2018.

Operating profit for the first nine months of 2019 was EUR 2.1 million (USD 2.4 million), compared to an operating loss of EUR 2.2 million (USD 2.6 million) in the first nine months of 2018.

Net income for the first nine months of 2019 was EUR 2.5 million (USD 2.8 million), or earnings of EUR 0.08 per diluted share, as compared to a net loss of EUR 1.4 million (USD 1.6 million), or a loss of EUR 0.05 per diluted share in the year-ago period.

As of September 30, 2019, cash and cash equivalents were EUR 17.7 million (USD 19.3 million).

Conference Call

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30 am EDT on Wednesday November 14, 2019. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, November 14, 2019 @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13695746

Webcast: <http://public.viavid.com/index.php?id=136640>

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 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 may contain 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, regulatory approvals, market acceptance and the continued market potential for our HIFU and lithotripsy devices. 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)

	Three Months Ended:		Three Months Ended:	
	September 30, 2019 Euros	September 30, 2018 Euros	September 30, 2019 \$US	September 30, 2018 \$US
Sales of medical equipment	6,877	4,866	7,571	5,665
Net Sales of RPP and Leases	1,228	1,040	1,352	1,210
Sales of spare parts, supplies and Services	2,187	2,227	2,407	2,592
TOTAL NET SALES	10,292	8,132	11,330	9,467
Other revenues	15	-	17	-
TOTAL REVENUES	10,307	8,132	11,347	9,467
Cost of sales	(5,641)	(4,759)	(6,209)	(5,540)
GROSS PROFIT	4,667	3,374	5,137	3,928
Research & development expenses	(886)	(941)	(975)	(1,095)
S, G & A expenses	(3,522)	(3,112)	(3,877)	(3,623)
Total operating expenses	(4,408)	(4,053)	(4,852)	(4,718)
OPERATING PROFIT (LOSS)	259	(679)	285	(791)
Interest (expense) income, net	(40)	289	(44)	336
Currency exchange gains (loss), net	684	(140)	753	(163)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	903	(530)	994	(617)
Income tax (expense) credit	(120)	(163)	(132)	(189)
NET INCOME (LOSS)	783	(692)	862	(806)
Earning per share – Basic	0.03	(0.02)	0.03	(0.03)
Average number of shares used in computation of EPS	28,997,886	28,997,866	28,997,886	28,997,866
Earning per share – Diluted	0.03	(0.02)	0.03	(0.03)
Average number of shares used in computation of EPS for positive net income	29,622,866	28,997,866	29,622,866	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average three months' noon buying rate of 1 Euro = 1.1008 USD, and 2018 average three months noon buying rate of 1 Euro = 1.1641 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:	
	September 30, 2019 Euros	September 30, 2018 Euros	September 30, 2019 \$US	September 30, 2018 \$US
Sales of medical equipment	22,139	15,795	24,797	18,833
Net Sales of RPP and Leases	4,028	3,520	4,512	4,197
Sales of spare parts, supplies and Services	6,742	6,565	7,551	7,828
TOTAL NET SALES	32,909	25,880	36,860	30,858
Other revenues	15	14	17	17
TOTAL REVENUES	32,924	25,894	36,877	30,874
Cost of sales	(17,061)	(14,959)	(19,110)	(17,836)
GROSS PROFIT	15,863	10,935	17,768	13,038
Research & development expenses	(2,884)	(3,140)	(3,231)	(3,744)
S, G & A expenses	(10,857)	(9,956)	(12,161)	(11,870)
Total operating expenses	(13,742)	(13,096)	(15,392)	(15,615)
OPERATING PROFIT (LOSS)	2,121	(2,161)	2,376	(2,576)
Interest (expense) income, net	(103)	817	(115)	974
Currency exchange gains (loss), net	788	316	883	377
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	2,807	(1,028)	3,144	(1,226)
Income tax (expense) credit	(317)	(343)	(356)	(409)
NET INCOME (LOSS)	2,490	(1,371)	2,789	(1,635)
Earning per share – Basic	0.09	(0.05)	0.10	(0.06)
Average number of shares used in computation of EPS	28,997,866	28,997,866	28,997,866	28,997,866
Earning per share – Diluted	0.08	(0.05)	0.09	(0.06)
Average number of shares used in computation of EPS for positive net income	29,623,683	28,997,866	29,623,683	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2019 average nine months' noon buying rate of 1 Euro = 1.1201 USD, and 2018 average nine months noon buying rate of 1 Euro = 1.1923 USD.

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

	September 30, 2019 Euros	June 30, 2019 Euros	September 30, 2019 \$US	June 30, 2019 \$US
Cash, cash equivalents and short-term investments	17,665	16,257	19,264	18,491
Total current assets	42,383	40,749	46,219	46,348
Total current liabilities	17,463	16,357	19,044	18,604
Shareholders' Equity	27,477	26,780	29,964	30,460

June 30, 2019 \$US

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0905 USD, on September 30, 2019 and at the noon buying rate of 1 Euro = 1.1374 USD, on June 30, 2019.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2019
(Amounts in thousands of Euros)

	HIFU Division		UDS Division		Reconciling Items	Total After Consolidation	
Sales of goods	7,142		14,997			22,139	
Sales of RPPs & Leases	2,861		1,166			4,028	
Sales of spare parts & services	1,217		5,525			6,742	
TOTAL NET SALES	11,220		21,689			32,909	
Other revenues	15		-			15	
TOTAL REVENUES	11,235		21,689			32,924	
GROSS PROFIT (% of Total Revenues)	6,542	58.2%	9,321	43.0%		15,863	48.2%
Research & Development	(1,522)		(1,362)			(2,884)	
Total SG&A plus depreciation	(3,979)		(5,879)		(999)	(10,857)	
OPERATING PROFIT (LOSS)	1,041		2,080		(999)	2,121	