

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

April 1, 2019

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: April 1, 2019
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Q4 and Full Year 2018 Results
Reports record revenues for the fifth consecutive year

- Record fiscal year 2018 revenues of €39.2 million
- Q4 2018 HIFU net sales increased 79% year-over-year
- Profitable and cash flow positive during the fourth quarter of 2018
- Completed first U.S. sale of Focal One at the end of 2018
- Ended the year with a strong cash position of \$22.3 million

LYON, France, April 1, 2019 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in therapeutic ultrasound, announced today financial results for the fourth quarter and full year 2018 and provided a strategic and operational update.

Marc Oczachowski, EDAP's Chief Executive Officer, said: “We are very pleased to report our fifth consecutive year of growth during 2018, achieving total revenue of €39.2 million. As announced, one of the major milestones during the year was FDA clearance of Focal One in June, and just six months later, we completed the first U.S. sale of Focal One to the John Wayne Cancer Institute. We followed that up with three additional U.S. Focal One sales in less than sixty days. Our HIFU sales and marketing development teams have also been very active outside of the U.S., with the opening of new markets and further expansion in existing countries such as Brazil.

“We experienced very strong momentum during the fourth quarter in the adoption of our HIFU technology in the U.S. and internationally. Our teams are fully focused on leveraging this positive trend to further develop our sales pipeline for 2019,” Mr. Oczachowski concluded.

Fourth Quarter 2018 Results

Total revenue for the fourth quarter 2018 was €13.3 million (USD 15.1 million), an increase of 25.0% compared to €10.6 million (USD 12.6 million) for the fourth quarter of 2017.

Total revenue in the HIFU business for the fourth quarter was €4.3 million (USD 4.9 million), a 77.1% increase compared to €2.5 million (USD 2.9 million) for the fourth quarter of 2017. During the quarter, EDAP sold four Focal One devices (including the first one in the U.S.) versus one Focal one in the same period of 2017, and recorded a 14.1% increase in HIFU treatment revenues.

For the three months ended December 31, 2018, total revenue for the Lithotripsy division was €8.9 (USD 10.2 million), a 9.4% increase compared to €8.2 million (USD 9.7 million) during the year-ago period.

Gross profit for the fourth quarter 2018 was €6.0 million (USD 6.8 million), compared to €4.4 million (USD 5.3 million) for the year-ago period. Gross profit margin on net sales was 45.0% in the fourth quarter of 2018, compared to 41.8% in the year-ago period.

Operating expenses were €5.1 million (USD 5.8 million) for the fourth quarter of 2018, compared to €4.6 million (USD 5.5 million) for the same period in 2017.

The Company recorded an operating profit for the fourth quarter 2018 of €0.8 million (USD 1.0 million), compared to an operating loss of € 0.2 million (USD 0.2 million) in the fourth quarter of 2017.

The Company recorded a net profit for the fourth quarter 2018 of €1.0 million (USD 1.2 million), or a profit of €0.04 per diluted share, as compared to a net loss of €0.1 million (USD 0.1 million), or a loss of €0.00 per diluted share in the year-ago period.

Year Ended 2018 Results.

Total revenue for 2018 was €39.2 million (USD 46.2 million) an increase of 9.6% compared to €35.7 million (USD 40.7 million) for the year ended December 31, 2017.

Total revenue in the HIFU business for 2018 was €11.0 million (USD 13.0 million), an increase of 16.1% compared to €9.5 million (USD 10.8 million) for the year ended December 31, 2017. During the year 2018, EDAP sold seven HIFU devices, compared to five HIFU devices sold during the year 2017.

Total revenue for the UDS division for 2018 was €28.1 million (USD 33.2 million), growth of 7.3% compared to €26.2 million (USD 29.9 million). During the year 2018, EDAP sold 33 Lithotripsy devices compared to 40 Lithotripsy devices during the year ago period. The increase was driven by a 31.8% growth in the sales of distribution products.

Gross profit for 2018 was €16.9 million (USD 19.9 million) with gross profit margin on net sales of 43.2% compared to 41.5% during the prior year period.

The Company recorded an operating loss for 2018 of €1.3 million (USD 1.5 million) compared to an operating loss of €2.0 million (USD 2.3 million) during the prior year period.

Full-year net loss was €0.3 million (USD 0.4 million), or a loss of €0.01 per diluted share, as compared to a net loss of €0.7 million (USD 0.8 million), or a loss of €0.02 per diluted share in 2017. Full-year 2018 net loss included non-cash interest income of €0.9 million to adjust the accounting fair value of the outstanding warrants.

As of December 31, 2018, cash and cash equivalents were €19.5 million (USD 22.3 million).

Conference Call

An accompanying conference call will be conducted by Philippe Chauveau, Chairman of the Board; Marc Oczachowski, Chief Executive Officer; and François Dietsch, Chief Financial Officer, to review the results. The call will be held at 8:30 AM ET, on Tuesday April 2, 2019. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Tuesday, April 2nd @ 8:30am Eastern Time

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13687660

Webcast: <http://public.viavid.com/index.php?id=133296>

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 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 and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. 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.

Company Contact

Blandine Confort

Investor Relations / Legal Affairs

EDAP TMS SA

+33 4 72 15 31 50

bconfort@edap-tms.com

Investor Contact

Jeremy Feffer

LifeSci Advisors, LLC

212-915-2568

jeremy@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:	
	December 31, 2018 Euros	December 31, 2017 Euros	December 31, 2018 \$US	December 31, 2017 \$US
Sales of medical equipment	9,275	7,213	10,546	8,552
Net Sales of RPP and Leases	1,566	1,219	1,781	1,446
Sales of spare parts, supplies and Services	2,442	2,177	2,776	2,581
TOTAL NET SALES	13,283	10,610	15,103	12,578
Other revenues	5	16	6	20
TOTAL REVENUES	13,288	10,626	15,109	12,598
Cost of sales	(7,306)	(6,193)	(8,307)	(7,342)
GROSS PROFIT	5,982	4,433	6,801	5,256
Research & development expenses	(947)	(1,099)	(1,077)	(1,302)
S, G & A expenses	(4,188)	(3,513)	(4,762)	(4,164)
Total operating expenses	(5,136)	(4,611)	(5,840)	(5,467)
OPERATING PROFIT (LOSS)	846	(178)	962	(211)
Interest (expense) income, net	(20)	414	(23)	490
Currency exchange gains (loss), net	222	(134)	253	(159)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	1,048	100	1,191	119
Income tax (expense) credit	(15)	(192)	(17)	(227)
NET INCOME (LOSS)	1,033	(91)	1,174	(108)
Earning per share – Basic	0.04	(0.00)	0.04	(0.00)
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	0.04	(0.00)	0.04	(0.00)
Average number of shares used in computation of EPS for positive net income	29,345,366	28,997,866	29,345,366	28,997,866

NOTE: Translated for convenience of the reader to U.S. dollars at the 2018 average three months' noon buying rate of 1 Euro = 1.1370 USD, and 2017 average three months noon buying rate of 1 Euro = 1.1855 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, 2018 Euros	December 31, 2017 Euros	December 31, 2018 \$US	December 31, 2017 \$US
Sales of medical equipment	25,070	22,580	29,543	25,732
Net Sales of RPP and Leases	5,086	5,095	5,994	5,806
Sales of spare parts, supplies and Services	9,007	8,011	10,614	9,130
TOTAL NET SALES	39,163	35,686	46,151	40,668
Other revenues	19	60	23	68
TOTAL REVENUES	39,183	35,746	46,173	40,736
Cost of sales	(22,266)	(20,938)	(26,238)	(23,861)
GROSS PROFIT	16,917	14,808	19,935	16,875
Research & development expenses	(4,088)	(3,881)	(4,817)	(4,423)
S, G & A expenses	(14,144)	(12,954)	(16,668)	(14,762)
Total operating expenses	(18,232)	(16,835)	(21,485)	(19,185)
OPERATING PROFIT (LOSS)	(1,315)	(2,027)	(1,549)	(2,310)
Interest (expense) income, net	797	2,643	939	3,011
Currency exchange gains (loss), net	538	(909)	634	(1,036)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	20	(294)	23	(335)
Income tax (expense) credit	(358)	(388)	(422)	(442)
NET INCOME (LOSS)	(338)	(681)	(399)	(776)
Earning per share – Basic	(0.01)	(0.02)	(0.01)	(0.03)
Average number of shares used in computation of EPS	28,997,866	28,961,928	28,997,866	28,961,928
Earning per share – Diluted	(0.01)	(0.02)	(0.01)	(0.03)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,961,928	28,997,866	28,961,928

NOTE: Translated for convenience of the reader to U.S. dollars at the 2018 average twelve months noon buying rate of 1 Euro =1.1784 USD, and 2017 average twelve months noon buying rate of 1 Euro = 1.1396 USD.

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

	Dec. 31, 2018	Sept. 30, 2018	Dec. 31, 2018	Sept. 30, 2018
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short term investments	19,464	15,942	22,298	18,528
Total current assets	40,378	36,110	46,257	41,968
Total current liabilities	16,812	14,092	19,260	16,378
Shareholders' Equity	24,964	23,874	28,599	27,748

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1456 USD, on Dec. 31, 2018 and at the noon buying rate of 1 Euro = 1.1623 USD, on Sept. 30, 2018.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2018
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	Corporate	Total After Consolidation
Sales of goods	5,494	19,576		25,070
Sales of RPPs & Leases	3,750	1,336		5,086
Sales of spare parts & services	1,780	7,227		9,007
TOTAL NET SALES	11,025	28,139		39,163
Other revenues	19	-		19
TOTAL REVENUES	11,044	28,139		39,183
GROSS PROFIT (% of Total Revenues)	5,732 51.9%	11,185 39.7%		16,917 43.2%
Research & Development	(2,394)	(1,694)		(4,088)
Total SG&A plus depreciation	(5,664)	(7,234)	(1,246)	(14,144)
OPERATING PROFIT (LOSS)	(2,325)	2,257	(1,246)	(1,315)