

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

May 15, 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: May 15, 2019
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports 2019 First Quarter Results

- HIFU revenue growth of 58.6% year-over-year
- Profitable for second consecutive quarter
- Total Q1 revenues of EUR 10.1 million; strongest Q1 to date
- Improved Q1 gross profit margin by 4.2 percentage points vs prior year

LYON, France, May 15, 2019 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in therapeutic ultrasound, announced today financial results for the first quarter of 2019, and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, said: “We are very pleased with these strong Q1 results showing high growth in our HIFU revenues which helped drive another quarter of global profitability. This is consistent with our 2018 results and demonstrates the continued momentum of our HIFU business, particularly in the U.S. We are excited by the strong interest and traction we experienced during the AUA meeting last week in Chicago. We look forward to providing further updates on potential additional sales in the U.S. and other key territories in the coming months.”

First Quarter 2019 Results

Total revenue for the first quarter 2019 was EUR 10.1 million (USD 11.5 million), a 10.6% increase compared to EUR 9.2 million (USD 11.3 million) for the first quarter of 2018.

Total revenue in the HIFU business for the first quarter 2019 was EUR 3.9 million (USD 4.4 million), a 58.6% increase compared to EUR 2.4 million (USD 3.0 million) for the first quarter of 2018.

For the three months ended March 31, 2019, total revenue for the UDS division was EUR 6.3 million (USD 7.1 million), a 6.8% decrease compared to EUR 6.7 million (USD 8.3 million) during the year-ago period.

Gross profit for the first quarter 2019 was EUR 4.9 million (USD 5.5 million), compared to EUR 4.0 million (USD 4.9 million) for the year-ago period. Gross profit margin on net sales was 48.0% in the first quarter of 2019, compared to 43.8% in the year-ago period.

Operating expenses were EUR 4.7 million (USD 5.3 million) for the first quarter of 2019, compared to EUR 4.4 million (USD 5.4 million) for the same period in 2018.

Operating profit for the first quarter 2019 was EUR 0.2 million (USD 0.2 million), compared to an operating loss of EUR 0.4 million (USD 0.5 million) in the first quarter of 2018.

Net income for the first quarter 2018 was EUR 0.3 million (USD 0.4 million), or earnings of EUR 0.01 per diluted share, as compared to a net income of EUR 0.1 million (USD 0.1 million), or earnings of EUR 0.00 per diluted share in the year-ago period.

As of March 31, 2019, cash and cash equivalents were EUR 18.6 million (USD 20.8 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 Thursday May 16, 2019. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, May 16 @ 8:30am Eastern Time

Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13690430
Webcast: <http://public.viavid.com/index.php?id=134411>

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 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.

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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:	
	March 31, 2019 Euros	March 31, 2018 Euros	March 31, 2019 \$US	March 31, 2018 \$US
Sales of medical equipment	6,546	5,751	7,432	7,085
Net Sales of RPP and Leases	1,371	1,210	1,556	1,491
Sales of spare parts, supplies and Services	2,215	2,197	2,515	2,707
TOTAL NET SALES	10,131	9,158	11,503	11,283
Other revenues	-	-	-	-
TOTAL REVENUES	10,131	9,158	11,503	11,283
Cost of sales	(5,266)	(5,147)	(5,979)	(6,341)
GROSS PROFIT	4,865	4,011	5,523	4,942
Research & development expenses	(1,013)	(1,000)	(1,150)	(1,232)
S, G & A expenses	(3,644)	(3,413)	(4,137)	(4,205)
Total operating expenses	(4,657)	(4,413)	(5,287)	(5,437)
OPERATING PROFIT (LOSS)	208	(402)	236	(495)
Interest (expense) income, net	(31)	639	(35)	787
Currency exchange gains (loss), net	265	(15)	301	(18)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	443	223	503	274
Income tax (expense) credit	(115)	(134)	(131)	(165)
NET INCOME (LOSS)	328	89	372	109
Earning per share – Basic	0.01	0.00	0.01	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	0.01	0.00	0.01	0.00
Average number of shares used in computation of EPS for positive net income	29,656,133	29,345,366	29,656,133	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 = 1.1353 USD, and 2018 average three months noon buying rate of 1 Euro = 1.2320 USD.

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

	Mar. 31, 2019 Euros	Dec. 31, 2018 Euros	Mar. 31, 2019 \$US	Dec. 31, 2018 \$US
Cash, cash equivalents and short-term investments	18,555	19,464	20,834	22,298
Total current assets	39,904	40,378	44,806	46,257
Total current liabilities	16,837	16,812	18,905	19,260
Shareholders' Equity	25,266	24,964	28,370	28,599

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1228 USD, on March 31, 2019 and at the noon buying rate of 1 Euro = 1.1456 USD, on December 31, 2018.

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

	HIFU Division		UDS Division		Reconciling Items		Total After Consolidation	
Sales of goods	2,503		4,043				6,546	
Sales of RPPs & Leases	958		413				1,371	
Sales of spare parts & services	405		1,809				2,215	
TOTAL NET SALES	3,866		6,265				10,131	
Other revenues	-		-				-	
TOTAL REVENUES	3,866		6,265				10,131	
GROSS PROFIT (% of Total Revenues)	2,231	57.7%	2,634	42.0%			4,865	48.0%
Research & Development	(537)		(476)				(1,013)	
Total SG&A plus depreciation	(1,298)		(1,916)		(430)		(3,644)	
OPERATING PROFIT (LOSS)	396		242		(430)		208	