
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 17, 2016

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 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 Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 17, 2016
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Achieves 79% Growth in HIFU Revenue for First Nine Months of 2016

Highlights at the end of September 30, 2016:

- Total cumulated revenue in 2016 up 22% year-over-year;
- Driven by HIFU growth, Gross Margin increases to 45%;
- 111% growth in HIFU revenues in Q3 of 2016 compared to Q3 2015;
- Company continues to show operating profit in 2016 at the end of Q3;
- Strong cash position of EUR 18.8 million as of September 30, 2016.

LYON, France, Nov. 17, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today financial results for the third quarter and nine months ended September 30, 2016, and provided an update on strategic and operational accomplishments.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We performed extremely well through the first nine months of 2016, with total revenues up 22% versus a year ago and, more importantly, HIFU division revenues up 79% from the year-ago period."

"As recently announced, we achieved new installations in prestigious academic centers in the US such as Duke University Hospital, and we continue to actively work in building a strong academic and scientific presence in the US. This is part of our strategy to penetrate the US market with HIFU on a strong clinical basis with leading institutions around the country."

Mr. Oczachowski concluded, "Recent publications in both the New England Journal of Medicine and European Urology are providing extremely encouraging indications that further position HIFU as a modern standard of care therapy for the treatment of prostate cancer. We will be pleased to further discuss these excellent results during our quarterly conference call on Thursday the 17th of November."

Third Quarter 2016 Results

Total revenue for the third quarter 2016 was EUR 8.0 million (USD 8.9 million), a 24.7% year-over-year increase compared to EUR 6.4 million (USD 7.1 million) for the third quarter 2015.

Total revenue in the HIFU business for this quarter was EUR 2.5 million (USD 2.8 million) compared to EUR 1.2 million (USD 1.3 million) for the third quarter 2015.

For the three months ended September 30, 2016, total revenue for the Lithotripsy division was EUR 5.4 million (USD 6.1 million), compared to EUR 5.2 million (USD 5.8 million), during the year ago period.

Gross profit for the third quarter 2016 was EUR 3.5 million (USD 3.9 million), compared to EUR 2.6 million (USD 2.9 million) for the year ago period. Gross profit margin on net sales was 43.2% in the third quarter of 2016, compared to 40.2% in the year ago period.

Operating expenses were EUR 3.8 million (USD 4.2 million) for the third quarter 2016, compared to EUR 2.8 million (USD 3.2 million) for the same period in 2015.

Operating loss for the third quarter 2016 was EUR 0.3 million (USD 0.4 million), compared with EUR 0.3 million (USD 0.3 million) in the third quarter of 2015.

Net income for the third quarter 2016 was EUR 1.3 million (USD 1.4 million), or EUR 0.04 per diluted share, as compared to net loss of EUR 4.8 million (USD 5.4 million), or EUR 0.19 per diluted share, in the year ago period. Net income in the third quarter of 2016 included non-cash interest income of EUR 1.5 million to adjust the accounting fair value of the outstanding warrants.

First Nine Months 2016 Results

Total revenue for the first nine months of 2016 was EUR 24.9 million (USD 27.8 million), up 21.8% compared to EUR 20.5 million (USD 22.7 million) for the first nine months of 2015.

Gross profit for the first nine months of 2016 was EUR 11.2 million (USD 12.5 million) and gross profit margin on net sales was 45.0%, compared to 41.5 % in the year ago period.

The Company recorded an operating profit for the first nine months of 2016 of EUR 0.1 million (USD 0.1 million), compared with an operating loss of EUR 1.1 million (USD 1.2 million) in the first nine months of 2015.

Net income for the first nine months of 2016 was EUR 5.1 million (USD 5.7 million), or EUR 0.19 per diluted share, as compared to a net loss of EUR 6.8 million (USD 7.5 million), or EUR 0.27 per diluted share, in the first nine months of 2015. Net loss in the first nine months of 2016 included non-cash interest income of EUR 4.4 million to adjust the accounting fair value of the outstanding warrants.

At September 30, 2016, cash and cash equivalents, including short-term treasury investments, were EUR 18.8 million (USD 21.2 million).

Conference Call

EDAP will hold a conference call on Thursday, November 17th, 2016 at 8:30 a.m. EST to discuss the results and provide an update on recent business developments. The dial-in numbers are 1-888-348-6419 in the U.S., and 1-412-902-4235 for international callers. The conference ID number for both is 10095751. A live webcast of the conference call will be available online from the investor relations page of the Company's corporate website at www.edap-tms.com.

After the live event, the webcast will remain available on EDAP's website, www.edap-tms.com, through December 19, 2016. In addition, a dial-in replay of the call will be available. The replay dial-in numbers are 1-844-512-2921 for domestic callers and 1-412-317-6671 for international callers. Please use event passcode 10095751.

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved for commercial distribution in Europe and some other countries including Mexico and Canada, and has received 510(k) clearance by the U.S. FDA. The Company also markets an innovative robot-assisted HIFU device, the Focal One®, dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. For more information on the Company, please visit <http://www.edap-tms.com>, and <http://www.hifu-planet.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.

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

	<u>Three Months Ended:</u>		<u>Three Months Ended:</u>	
	September 30, 2016 Euros	September 30, 2015 Euros	September 30, 2016 \$US	September 30, 2015 \$US
Sales of goods	5,218	3,754	5,836	4,178
Net Sales of RPP and Leases	1,098	1,138	1,228	1,266
Sales of spare parts and Services	1,674	1,514	1,873	1,685
TOTAL NET SALES	7,990	6,406	8,936	7,129
Other revenues	2	1	2	1
TOTAL REVENUES	7,992	6,407	8,938	7,130
Cost of goods	(3,099)	(2,262)	(3,466)	(2,517)
Cost of RPP and Leases	(459)	(648)	(514)	(721)
Cost of spare parts & services	(979)	(921)	(1,095)	(1,025)
Cost of sales	(4,537)	(3,830)	(5,075)	(4,262)
GROSS PROFIT	3,454	2,578	3,864	2,868
Research & development expenses	(1,032)	(612)	(1,154)	(682)
Marketing & Sales expenses	(2,028)	(1,518)	(2,269)	(1,689)
G & A expenses	(725)	(704)	(811)	(783)
Total operating expenses	(3,786)	(2,834)	(4,234)	(3,154)

OPERATING PROFIT (LOSS)	(332)	(257)	(371)	(286)
Interest (expense) income, net	1,502	(4,460)	1,680	(4,963)
Currency exchange gains (loss), net	130	(80)	145	(89)
Other income (loss), net	-	(2)	-	(2)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	1,301	(4,798)	1,455	(5,340)
Income tax (expense) credit	(40)	(31)	(44)	(35)
NET INCOME (LOSS)	1,261	(4,830)	1,411	(5,375)
Earnings per share – Basic	0.04	(0.19)	0.05	(0.22)
Average number of shares used in computation of Basic EPS	28,727,616	24,972,752	28,727,616	24,972,752
Earnings per share – Diluted	0.04	(0.19)	0.05	(0.22)
Average number of shares used in computation of Diluted EPS	30,251,966	24,972,752	30,251,966	24,972,752

NOTE: Translated for convenience of the reader to U.S. dollars at the 2016 average three months' noon buying rate of 1 Euro = 1.1184 USD, and 2015 average three months' noon buying rate of 1 Euro = 1.1128 USD.

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

	<u>Nine Months Ended:</u>		<u>Nine Months Ended:</u>	
	<u>September</u> <u>30,</u> <u>2016</u> <u>Euros</u>	<u>September</u> <u>30,</u> <u>2015</u> <u>Euros</u>	<u>September</u> <u>30,</u> <u>2016</u> <u>\$US</u>	<u>September</u> <u>30,</u> <u>2015</u> <u>\$US</u>
Sales of goods	16,480	12,857	18,356	14,275
Net Sales of RPP and Leases	3,675	3,258	4,094	3,617
Sales of spare parts and Services	4,752	4,344	5,293	4,822
TOTAL NET SALES	24,907	20,458	27,742	22,714
Other revenues	10	3	11	4
TOTAL REVENUES	24,917	20,461	27,753	22,717
Cost of goods	(8,660)	(7,303)	(9,646)	(8,108)
Cost of RPP and Leases	(1,972)	(1,940)	(2,197)	(2,154)
Cost of spare parts & services	(3,076)	(2,730)	(3,427)	(3,030)
Cost of sales	(13,709)	(11,972)	(15,269)	(13,292)
GROSS PROFIT	11,208	8,489	12,484	9,425
Research & development expenses	(2,733)	(2,125)	(3,044)	(2,359)
Marketing & Sales expenses	(6,041)	(4,926)	(6,728)	(5,469)
G & A expenses	(2,377)	(2,534)	(2,648)	(2,813)
Total operating expenses	(11,151)	(9,585)	(12,420)	(10,641)
OPERATING PROFIT (LOSS)	57	(1,096)	63	(1,217)
Interest (expense) income, net	4,393	(5,804)	4,893	(6,444)
Currency exchange gains (loss), net	801	223	892	247
Other income (loss), net	(0)-	(5)	(1)	(5)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	5,250	(6,682)	5,848	(7,419)
Income tax (expense) credit	(130)	(100)	(145)	(112)
NET INCOME (LOSS)	5,120	(6,783)	5,703	(7,530)
Earnings per share – Basic	0.19	(0.27)	0.21	(0.30)
Average number of shares used in computation of Basic EPS	27,497,107	24,942,689	27,497,107	24,942,689
Earnings per share – Diluted	0.19	(0.27)	0.21	(0.30)
Average number of shares used in computation of Diluted EPS	29,045,939	24,942,689	29,045,939	24,942,689

NOTE: Translated for convenience of the reader to U.S. dollars at the 2016 average nine months' noon buying rate of 1 Euro = 1.1138 USD, and 2015 average nine months' noon buying rate of 1 Euro = 1.1102 USD.

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

	Sept. 30, 2016	June 30, 2016	Sept. 30, 2016	June 30, 2016
	Euros	Euros	\$US	\$US
Cash, cash equivalents and short term investments	18,837	21,940	21,170	24,203
Total current assets	40,694	40,963	45,734	45,188
Total current liabilities	14,547	14,817	16,349	16,345
Shareholders' Equity	25,739	24,358	28,926	26,870

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1238 USD on September 30, 2016 and at the noon buying rate of 1 Euro = 1.1031 USD, on June 30, 2016

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2016
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	FDA Corporate	Total After Consolidation
Sales of goods	6,047	10,433		16,480
Sales of RPPs & Leases	2,633	1,042		3,675
Sales of spare parts & services	543	4,209		4,752
TOTAL NET SALES	9,223	15,684		24,907
Other revenues	6	4		10
TOTAL REVENUES	9,229	15,688		24,917
GROSS PROFIT (% of Total Revenues)	5,337 58%	5,871 37%		11,208 45%
Research & Development	(1,781)	(952)	-	(2,733)
Total SG&A plus depreciation	(3,027)	(4,440)	-	(8,418)
OPERATING PROFIT (LOSS)	529	479	-	(951) 57

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