

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 14, 2018

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: November 14, 2018
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports 2018 Third Quarter Results

- Generated revenue growth of more than 14% as compared to the third quarter of 2017
- Continued geographic expansion of Focal One with installations in Brazil and South Korea
- Since receiving FDA clearance for Focal One in June 2018, progressed through the lengthy capital equipment sales cycle with U.S. hospitals and health centers, and expect to announce agreements in the near-term
- Announced expiration of tranche of outstanding warrants underlying 3.3 million common shares on the form of ADRs

LYON, France, November 14, 2018 -- EDAP TMS SA (Nasdaq: EDAP) (“the Company”), the global leader in therapeutic ultrasound, announced today financial results for the third quarter and nine-month period of 2018 and provided a strategic and operational update. Management will host a conference call on Thursday, November 15th at 8:30 ET.

Marc Oczachowski, EDAP’s Chief Executive Officer, said: “During the third quarter, we demonstrated solid sales momentum, reporting revenue growth of 14.2% over the third quarter of 2017, as we continued to execute on our strategy of expanding the global commercial footprint of Focal One. Notably, we announced the installation of our third Focal One device in Brazil and the first in South Korea. We believe this reflects the significant need of both urologists and their patients for a next-generation HIFU device that can provide minimally invasive but highly targeted ablation of prostate tissue while avoiding the significant side effects associated with more traditional treatments such as surgery.”

“In parallel, since receiving FDA clearance for Focal One in June, our commercial team in the U.S. has been engaged in ongoing discussions with leading hospitals and health centers, and notwithstanding the usual lengthy sales cycle, we believe we are close to signing agreements in the near-term,” Mr. Oczachowski continued. “When completed, this will represent a significant inflection point for our company, as a U.S. reference site using Focal One on a daily basis will be an invaluable tool to help drive future growth. We look forward to providing further updates on our progress.”

Third Quarter 2018 Results

Total revenue for the third quarter 2018 was EUR 8.1 million (USD 9.5 million), a 14.2% increase compared to EUR 7.1 million (USD 8.4 million) for the third quarter of 2017.

Total revenue in the HIFU business for the third quarter 2018 was EUR 1.9 million (USD 2.3 million), a 6% increase compared to EUR 1.8 million (USD 2.2 million) for the third quarter of 2017. During the third quarter of 2018, EDAP sold 1 HIFU device compared to none during the third quarter of 2017.

For the three months ended September 30, 2018, total revenue for the UDS division was EUR 6.2 million (USD 7.2 million), a 17% increase compared to EUR 5.3 million (USD 6.3 million) during the prior year period. During the third quarter of 2018, EDAP sold 4 lithotripsy devices compared to 6 lithotripsy devices sold during the third quarter of 2017. The quarter was impacted by a strong growth in our sales of Distribution products.

Gross profit for the third quarter 2018 was EUR 3.4 million (USD 3.9 million), compared to EUR 2.8 million (USD 3.3 million) for the year-ago period. Gross profit margin on net sales was 41.5% in the third quarter of 2018, compared to 39.4% in the third quarter of 2017.

Operating expenses were EUR 4.1 million (USD 4.7 million) for the third quarter of 2018, compared to EUR 3.8 million (USD 4.5 million) for the same period in 2017.

Operating loss for the third quarter 2018 was EUR 0.7 million (USD 0.8 million), compared to an operating loss of EUR 1.0 million (USD 1.2 million) in the third quarter of 2017.

Net loss for the third quarter 2018 was EUR 0.7 million (USD 0.8 million), or EUR 0.02 per diluted share, as compared to a net loss of EUR 0.5 million (USD 0.6 million), or EUR 0.02 per diluted share in the year-ago period. Net loss during the third quarter of 2018 included a non-cash interest income of EUR 0.3 million to adjust the accounting fair value of the outstanding warrants.

First Nine Months 2018 Results.

Total revenue for the first nine months of 2018 was EUR 25.9 million (USD 30.9 million) up 3.1% compared to 25.1 million (USD 28.2 million) during the first nine months of 2017.

Total revenue in the HIFU business for the nine months ended September 30, 2018 was EUR 6.7 million (USD 8.0 million) compared to EUR 7.1 million (USD 7.9 million) during the first nine months of 2017. During the first nine months of 2018, EDAP sold 3 HIFU devices, compared to 4 HIFU devices sold during the first nine months of 2017.

For the nine months ended September 30, 2018, total revenue for the UDS division was EUR 19.2 million (USD 22.9 million), a growth of 6.3% compared to EUR 18.1 million (USD 20.3 million). During the first nine months of 2018, EDAP sold 22 Lithotripsy devices compared to 21 Lithotripsy devices during the year ago period.

Gross profit for the first nine months of 2018 was EUR 10.9 million (USD 13.0 million) and gross profit margin on net sales was 42.3% compared to EUR 10.4 million (USD 11.7 million) and gross profit margin on net sales of 41.4% during the first nine months of 2017.

Operating loss for the first nine months of 2018 was EUR 2.2 million (USD 2.6 million) compared to an operating loss of EUR 1.8 million (USD 2.1 million) during the same period of 2017.

Net loss for the first nine months of 2018 was EUR 1.4 million (USD 1.6 million), or loss of EUR 0.05 per share, compared to net loss of EUR 0.6 million (USD 0.7 million), or earnings of EUR 0.02 per share during the first nine months of 2017. Net loss for the first nine months of 2018 included non-cash interest income of EUR 0.8 million to adjust the accounting fair value of the outstanding warrants.

As of September 30, 2018, cash and cash equivalents, including short-term treasury investments, were EUR 15.9 million (USD 18.5 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 November 15, 2018. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday November 15th @ 8:30am Eastern Time

Domestic: 800-289-0438
International 323-794-2423
Passcode: 9039159
Webcast: <http://public.viavid.com/index.php?id=131508>

Replays, Available through November 29, 2018:

Domestic: 844-512-2921
International 412-317-6671
Passcode: 9039159

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:	
	Sept. 30, 2018 Euros	Sept. 30, 2017 Euros	Sept. 30, 2018 \$US	Sept. 30, 2017 \$US
Sales of goods	4,866	3,889	5,665	4,606
Net Sales of RPP and Leases	1,040	1,277	1,210	1,512
Sales of spare parts, supplies and Services	2,227	1,955	2,592	2,316
TOTAL NET SALES	8,132	7,121	9,467	8,434
Other revenues	-	4	-	4
TOTAL REVENUES	8,132	7,124	9,467	8,438
Cost of sales	(4,759)	(4,317)	(5,540)	(5,114)
GROSS PROFIT	3,374	2,807	3,928	3,324
Research & development expenses	(941)	(918)	(1,095)	(1,087)
S, G & A expenses	(3,112)	(2,889)	(3,623)	(3,422)
Total operating expenses	(4,053)	(3,807)	(4,718)	(4,510)
OPERATING PROFIT (LOSS)	(679)	(1,001)	(791)	(1,185)
Interest (expense) income, net	289	821	336	972
Currency exchange gains (loss), net	(140)	(325)	(163)	(385)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(530)	(504)	(617)	(597)
Income tax (expense) credit	(163)	(21)	(189)	(25)
NET INCOME (LOSS)	(692)	(525)	(806)	(622)
Earning per share – Basic	(0.02)	(0.02)	(0.03)	(0.02)
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	(0.02)	(0.02)	(0.03)	(0.02)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,997,866	28,997,866	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 = 1.1641 USD, and 2017 average three months noon buying rate of 1 Euro = 1.1844 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>Nine Months Ended:</u>		<u>Nine Months Ended:</u>	
	Sept. 30, 2018 Euros	Sept. 30, 2017 Euros	Sept. 30, 2018 \$US	Sept. 30, 2017 \$US
Sales of goods	15,795	15,367	18,833	17,276
Net Sales of RPP and Leases	3,520	3,876	4,197	4,357
Sales of spare parts, supplies and Services	6,565	5,834	7,828	6,559
TOTAL NET SALES	25,880	25,076	30,858	28,192
Other revenues	14	43	17	48
TOTAL REVENUES	25,894	25,119	30,874	28,240
Cost of sales	(14,959)	(14,745)	(17,836)	(16,576)
GROSS PROFIT	10,935	10,375	13,038	11,663
Research & development expenses	(3,140)	(2,783)	(3,744)	(3,129)
S, G & A expenses	(9,956)	(9,441)	(11,870)	(10,614)
Total operating expenses	(13,096)	(12,224)	(15,615)	(13,742)
OPERATING PROFIT (LOSS)	(2,161)	(1,849)	(2,576)	(2,079)
Interest (expense) income, net	817	2,229	974	2,506
Currency exchange gains (loss), net	316	(775)	377	(871)
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,028)	(394)	(1,226)	(443)
Income tax (expense) credit	(343)	(196)	(409)	(220)
NET INCOME (LOSS)	(1,371)	(590)	(1,635)	(663)
Earning per share – Basic	(0.05)	(0.02)	(0.06)	(0.02)
Average number of shares used in computation of EPS	28,997,866	28,947,947	28,997,866	28,947,947
Earning per share – Diluted	(0.05)	(0.02)	(0.06)	(0.02)
Average number of shares used in computation of EPS for positive net income	28,997,866	28,947,947	28,997,866	28,947,947

NOTE: Translated for convenience of the reader to U.S. dollars at the 2018 average nine months' noon buying rate of 1 Euro = 1.1923 USD, and 2017 average nine months noon buying rate of 1 Euro = 1.1242 USD.

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

	Sept. 30, 2018 Euros	June 30, 2018 Euros	Sept. 30, 2018 \$US	June 30, 2018 \$US
Cash, cash equivalents and short term investments	15,942	17,203	18,528	20,087
Total current assets	36,110	38,535	41,968	44,997
Total current liabilities	14,092	16,016	16,378	18,702
Shareholders' Equity	23,874	24,535	27,748	28,648

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1623 USD, on Sept. 30, 2018 and at the noon buying rate of 1 Euro = 1.1677 USD, on June 30, 2018.

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2018
(Amounts in thousands of Euros)

	HIFU Division		UDS Division		Corporate	Total After Consolidation
Sales of goods	2,769		13,026			15,795
Sales of RPPs & Leases	2,564		957			3,520
Sales of spare parts & services	1,348		5,217			6,565
TOTAL NET SALES	6,681		19,200			25,880
Other revenues	14		-			14
TOTAL REVENUES	6,695		19,200			25,894
GROSS PROFIT (% of Total Revenues)	3,207	47.9%	7,728	40.3%		10,935
Research & Development	(1,971)		(1,169)			(3,140)
Total SG&A plus depreciation	(3,907)		(5,008)		(1,041)	(9,956)
OPERATING PROFIT (LOSS)	(2,161)		1,551		(1,041)	(2,161)