

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 18, 2015

Commission File Number: 000-29374

EDAP TMS S.A.
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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 18, 2015
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Third Quarter 2015 Financial Results and Operational Update

- Obtained FDA clearance for Ablatherm® HIFU in November
- Received first four U.S. orders for Ablatherm
- Record nine-month net sales of €20.5 million
- HIFU treatment-driven revenue increased 41% year-over-year
- Strong backlog for both lithotripsy and HIFU divisions entering Q4
- First Focal One® Device sold in South America

LYON, France, Nov. 18, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced financial results for the third quarter ended September 30, 2015 and provided an update on recent strategic and operational highlights.

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "Following the end of the third quarter, we achieved the most significant milestone in the Company's history with receipt of FDA clearance for Ablatherm HIFU. Bringing our HIFU technology to the U.S. market has been a key objective for several years, and this clearance is the result of the hard work and dedication of the entire EDAP team. We have already received Ablatherm Robotic HIFU orders from four U.S. urology Groups and academic centers, and numerous other inquiries regarding the product, which is indicative of the robust demand for HIFU among members of the U.S. urological community. We are initiating shipments of Ablatherm Robotic HIFU systems from our manufacturing facility in France this week, and we anticipate completing the installations very soon in key locations in the U.S."

"Our net sales for the first nine months of 2015 grew 3.3% over last year to a record €20.5 million on the strength of our lithotripsy business and procedure-driven HIFU revenues. Importantly, we have built a strong backlog which included 20 lithotripters and five HIFU devices as of the middle of the fourth quarter, giving us visibility into the end of the year and early 2016. Our business is clearly gaining momentum, and we believe that the FDA clearance of Ablatherm Robotic HIFU will provide a significant catalyst for future growth as we continue to ramp our commercial efforts in the U.S. We have established EDAP as the HIFU leader in Europe and other parts of the world, and I am confident that we can replicate that success in the United States."

Third Quarter 2015 Results

Total revenue for the third quarter of 2015 was EUR 6.4 million (USD 7.1 million), compared to EUR 6.9 million (USD 9.0 million) for the third quarter 2014, which included a EUR 0.5 million (USD 0.7 million) one-off revenue related to the licensing of a HIFU patent.

Total revenue in the HIFU business for this quarter was EUR 1.2 million (USD 1.3 million) compared to EUR 2.9 million (USD 3.9 million) for the third quarter 2014.

For the three months ended September 30, 2015, total revenue for the Lithotripsy division was EUR 5.2 million (USD 5.8 million), compared to EUR 4.0 million (USD 5.4 million), during the year ago period.

Gross profit for the third quarter 2015 was EUR 2.6 million (USD 2.9 million), compared to EUR 3.4 million (USD 4.4 million) for the year ago period. Gross profit margin on net sales was 40.2% in the third quarter of 2015, compared to 53.2% in the year ago period.

Operating expenses were EUR 2.8 million (USD 3.2 million) for the third quarter 2015, compared to EUR 3.1 million (USD 4.0 million) for the same period in 2014.

Operating loss for the third quarter 2015 was EUR 0.3 million (USD 0.3 million), compared with operating income of EUR 0.3 million (USD 0.4 million) in the third quarter of 2014, including the EUR 0.5 million (USD 0.7 million) one-off revenue for licensing of a HIFU patent)

Net loss for the third quarter 2015 was EUR 4.8 million (USD 5.4 million), or EUR 0.19 per diluted share, as compared to net income of EUR 6.6 million (USD 8.6 million), or EUR 0.26 per diluted share, in the year ago period. Net loss in the third quarter of 2015 included non-cash interest expense of EUR 4.5 million to adjust the accounting fair value of the outstanding warrants. This compares to non-cash interest income of EUR 6.5 million in the third quarter of 2014.

Results for the Nine Months Ended September 30, 2015

Total revenue for the first nine months of 2015 was EUR 20.5 million (USD 22.7 million), compared to EUR 20.3 million (USD 27.4 million) for the first nine months of 2014.

Gross profit for the period was EUR 8.5 million (USD 9.4 million) and gross profit margin was 41.5%, compared to 44.3 % in the year ago period.

Operating loss for the nine months of 2015 was EUR 1.1 million (USD 1.2 million), compared to EUR 0.7 million (USD 1.0 million) in the first nine months of 2014.

Net loss for nine months ended September 30, 2015 was EUR 6.8 million (USD 7.5 million), or EUR 0.27 per diluted share, as compared to net income of EUR 2.1 million (USD 2.9 million), or EUR 0.09 per diluted share, in the first nine months of 2014. Net loss in the first nine months of 2015 included a non-cash interest expense of EUR 5.9 million to adjust the accounting fair value of the outstanding warrants. This compares to non-cash interest income of EUR 3.0 million in the first nine months of 2014.

At September 30, 2015, cash and cash equivalents, including short-term treasury investments, were EUR 11.1 million (USD 12.4 million).

Conference Call

EDAP will hold a conference call on November 19, 2015 at 8:30 am. EST to discuss the results and provide an update on recent business developments, including the FDA clearance U.S. commercial launch of Ablatherm® HIFU. 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 10076376. 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, 2015. In addition, a dial-in replay of the call will be available until December 21, 2015. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 10076376.

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> | |
|-----------------------------------|---|---|--|--|
| | <u>September 30,</u> <u>2015</u> <u>Euros</u> | <u>September 30,</u> <u>2014</u> <u>Euros</u> | <u>September 30,</u> <u>2015</u> <u>\$US</u> | <u>September 30,</u> <u>2014</u> <u>\$US</u> |
| Sales of goods | 3,754 | 4,192 | 4,178 | 5,474 |
| Net Sales of RPP and Leases | 1,138 | 824 | 1,266 | 1,075 |
| Sales of spare parts and Services | 1,514 | 1,384 | 1,685 | 1,807 |
| TOTAL NET SALES | 6,406 | 6,400 | 7,129 | 8,356 |
| Other revenues | 1 | 511 | 1 | 667 |
| TOTAL REVENUES | 6,407 | 6,911 | 7,130 | 9,023 |
| Cost of goods | (2,262) | (2,163) | (2,517) | (2,825) |
| Cost of RPP and Leases | (648) | (442) | (721) | (577) |
| Cost of spare parts & services | (921) | (899) | (1,025) | (1,174) |
| Cost of sales | (3,830) | (3,505) | (4,262) | (4,576) |
| GROSS PROFIT | 2,578 | 3,406 | 2,868 | 4,447 |

| | | | | |
|---|----------------|--------------|----------------|--------------|
| Research & development expenses | (612) | (714) | (682) | (932) |
| Marketing & Sales expenses | (1,518) | (1,458) | (1,689) | (1,903) |
| G & A expenses | (704) | (895) | (783) | (1,169) |
| Total operating expenses | (2,834) | (3,067) | (3,154) | (4,004) |
| OPERATING PROFIT (LOSS) | (257) | 339 | (286) | 443 |
| Interest (expense) income, net | (4,460) | 6,484 | (4,963) | 8,466 |
| Currency exchange gains (loss), net | (80) | (245) | (89) | (320) |
| Other income (loss), net | (2) | (2) | (2) | (2) |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (4,798) | 6,577 | (5,340) | 8,587 |
| Income tax (expense) credit | (31) | (26) | (35) | (34) |
| NET INCOME (LOSS) | (4,830) | 6,551 | (5,375) | 8,554 |
| Earnings per share – Basic | (0.19) | 0.26 | (0.22) | 0.34 |
| Average number of shares used in computation of Basic EPS | 24,972,752 | 24,859,267 | 24,972,752 | 24,859,267 |
| Earnings per share – Diluted | (0.19) | 0.26 | (0.22) | 0.33 |
| Average number of shares used in computation of Diluted EPS | 24,972,752 | 25,623,929 | 24,972,752 | 25,623,929 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2015 average three months noon buying rate of 1 Euro = 1.1128 USD, and 2014 average three months noon buying rate of 1 Euro = 1.3057 USD.

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

| | Nine Months Ended: | | Nine Months Ended: | |
|---|--------------------------------|--------------------------------|-------------------------------|-------------------------------|
| | September 30, 2015 Euros | September 30, 2014 Euros | September 30, 2015 \$US | September 30, 2014 \$US |
| Sales of goods | 12,857 | 12,948 | 14,275 | 17,474 |
| Net Sales of RPP and Leases | 3,258 | 2,846 | 3,617 | 3,841 |
| Sales of spare parts and Services | 4,344 | 4,002 | 4,822 | 5,401 |
| TOTAL NET SALES | 20,458 | 19,797 | 22,714 | 26,716 |
| Other revenues | 3 | 511 | 4 | 690 |
| TOTAL REVENUES | 20,461 | 20,308 | 22,717 | 27,406 |
| Cost of goods | (7,303) | (7,322) | (8,108) | (9,881) |
| Cost of RPP and Leases | (1,940) | (1,583) | (2,154) | (2,137) |
| Cost of spare parts & services | (2,730) | (2,629) | (3,030) | (3,548) |
| Cost of sales | (11,972) | (11,535) | (13,292) | (15,566) |
| GROSS PROFIT | 8,489 | 8,773 | 9,425 | 11,840 |
| Research & development expenses | (2,125) | (2,332) | (2,359) | (3,147) |
| Marketing & Sales expenses | (4,926) | (4,521) | (5,469) | (6,102) |
| G & A expenses | (2,534) | (2,627) | (2,813) | (3,545) |
| Total operating expenses | (9,585) | (9,480) | (10,641) | (12,793) |
| OPERATING PROFIT (LOSS) | (1,096) | (707) | (1,217) | (954) |
| Interest (expense) income, net | (5,804) | 2,930 | (6,444) | 3,954 |
| Currency exchange gains (loss), net | 223 | (29) | 247 | (39) |
| Other income (loss), net | (5) | (6) | (5) | (8) |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | (6,682) | 2,188 | (7,419) | 2,953 |
| Income tax (expense) credit | (100) | (62) | (112) | (84) |
| NET INCOME (LOSS) | (6,783) | 2,126 | (7,530) | 2,869 |
| Earnings per share – Basic | (0.27) | 0.09 | (0.30) | 0.12 |
| Average number of shares used in computation of Basic EPS | 24,942,689 | 23,157,314 | 24,942,689 | 23,157,314 |
| Earnings per share – Diluted | (0.27) | 0.08 | (0.30) | 0.11 |
| Average number of shares used in computation of Diluted EPS | 24,942,689 | 25,296,513 | 24,942,689 | 25,296,513 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2015 average nine months noon buying rate of 1 Euro = 1.1102USD, and 2014 average nine months noon buying rate of 1 Euro = 1. 3495USD.

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

| | Sept. 30, 2015 Euros | June 30, 2015 Euros | Sept. 30, 2015 \$US | June 30, 2015 \$US |
|---|----------------------------|---------------------------|---------------------------|--------------------------|
| Cash, cash equivalents and short term investments | 11,073 | 11,851 | 12,359 | 13,219 |
| Total current assets | 27,003 | 28,442 | 29,802 | 31,725 |
| Total current liabilities | 12,570 | 13,942 | 14,030 | 15,552 |
| Shareholders' Equity | 8,914 | 13,383 | 9,949 | 14,928 |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1162 USD on September 30, 2015 and at the noon buying rate of 1 Euro = 1.1154 USD, on June 30, 2015

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
NINE MONTHS ENDED SEPTEMBER 30, 2015
(Amounts in thousands of Euros)

| | HIFU Division | UDS Division | FDA | Corporate | Total After Consolidation |
|---------------------------------|------------------|------------------|--------------|--------------|------------------------------|
| Sales of goods | 2,561 | 10,296 | | | 12,857 |
| Sales of RPPs & Leases | 2,099 | 1,158 | | | 3,258 |
| Sales of spare parts & services | 494 | 3,849 | | | 4,344 |
| TOTAL NET SALES | 5,155 | 15,303 | | | 20,458 |
| Other revenues | 2 | 1 | | | 3 |
| TOTAL REVENUES | 5,157 | 15,305 | | | 20,461 |
| GROSS PROFIT | 2,826 55% | 5,663 37% | | | 8,489 42% |
| (% of Total Revenues) | | | | | |
| Research & Development | (983) | (674) | (468) | -- | (2,125) |
| Total SG&A plus depreciation | (2,146) | (4,318) | -- | (996) | (7,460) |
| OPERATING PROFIT (LOSS) | (303) | 671 | (468) | (996) | (1,096) |

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