

Edgar Filing: EDAP TMS SA - Form 6-K

EDAP TMS SA
Form 6-K
March 15, 2007

=====

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

EDAP TMS S.A. Files

EDAP TMS S.A. Reports 2006 Results;
Ablatherm-HIFU Treatments Grow

March 14, 2007

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 Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

This report on Form 6-K with respect to the Company's 2006 annual results, is hereby incorporated by reference in the registration statement of EDAP TMS S.A. on Form F-3, file number 333-136811.

=====

EDAP TMS S.A. REPORTS 2006 RESULTS; ABLATHERM-HIFU TREATMENTS GROW

EUROPE'S RPP PROGRAM: ON TRACK TO GROUP PROFITABILITY
THE USA: EDAP'S NEW AND EXCITING OPPORTUNITY

LYON, France, March 14 /PRNewswire-FirstCall/ -- EDAP TMS S.A. (Nasdaq: EDAP), the global leader in High Intensity Focused Ultrasound (HIFU) treatment of prostate cancer and the international leader in the development, production, and distribution of a wide portfolio of minimally invasive medical devices primarily for the treatment of urological diseases today reported financial results for the fourth quarter and year ended December 31, 2006 and discussed its outlook for 2007 expected HIFU growth.

Key highlights include:

* EDAP achieved a 60% increase in RPP revenues even prior to the full

Edgar Filing: EDAP TMS SA - Form 6-K

effect of the company's new marketing initiatives. Revenue lines reflect the company's successful transition from a device development company to a full marketing and growth urology treatment standard of care business.

- * Ablatherm-HIFU is now available at more than 130 centers worldwide with accelerating center launches and treatment growth.
- * EDAP reclaimed full ownership of the US market with an approved trial protocol and trained centers.
- * EDAP's European installed base and strong cash position now afford the company a clear path to profitability in Europe by the end of 2008, including spending increases in marketing and clinical programs to drive Ablatherm-HIFU to an initial target run rate of 5% market share versus less than 2% today in Europe. This implies initial target run rate of 25% of total hospitals in Europe versus 10% today.
- * Ongoing clinicals confirm Ablatherm's unassailable technical superiority in outcomes, low side effects and consistency of results across centers in many countries.

EXECUTIVE COMMENTS

Marc Oczachowski, EDAP TMS Chief Operating Officer and CEO-elect commented: "We believe EDAP is in the best position of its corporate history. We own a therapeutic prostate cancer technology where global demand will only grow as more centers and patients learn of its benefits. We have a global sales network of senior urology device professionals working for EDAP plus more than 50 distribution partners. We have the financial resources to educate these important decision makers alongside an installed base of 130 plus trained HIFU centers where patients can immediately receive treatment near their home. We have clear clinical support showing repeatable outcomes in efficacy and quality of life preservation, thus clearly now establishing HIFU as a standard of care for prostate cancer. And we now have full access to the US market opportunity through reclaimed ownership of the clinical program at a time when HIFU is far more established and highly regarded as a high value future therapy. We are confident and excited to accelerate treatments where we are already approved, seek reimbursements to further patient access and secure US approval based on future excellent clinical outcomes at top US centers.

"EDAP is now on the path to breakeven due to our strong European investment in sales and marketing to expand the market opportunity for Ablatherm-HIFU as the clear market leader. The investments undertaken during 2006 are now well tested, marketing programs beginning to show clear results on which we will build a larger treatment base in HIFU. We expect a natural adoption curve as new centers begin HIFU therapy, but clearly see centers increase the treatment potential once fully trained and experienced in Ablatherm techniques.

"Going forward, EDAP will report results by two clear market opportunities. First, starting now, we will provide steady updates on centers, treatments and RPP penetration throughout Europe where our marketing programs will drive further adoption toward our ultimate goals of profitability and standard of care status.

"Second, we will report on the continued execution of our US program seeking FDA approval for a future market launch. We now own this market opportunity with already a significant part of the clinical program concluded -- securing the study protocol approval. During the transition we took the time and effort to cement a solid professional relationship with FDA and our clinical parties to ensure complete communication. We are now in the final stages of determining the

Edgar Filing: EDAP TMS SA - Form 6-K

business arrangements to support the trial going forward, but are not lacking in choices of suitable options to not only fully secure this program, but to do so in a manner more beneficial to EDAP than the prior agreement with HeathTronics. Our clinical centers are very enthusiastic, we are pleased with our opportunity to secure approval and feel confident we can achieve success based on our many years of European clinical experience demonstrating the consistency of Ablatherm outcomes. We believe the US program is now well on its way to a successful launch and a much greater market opportunity for EDAP."

FINANCIAL RESULTS

For the full year 2006, the company reported total revenues of EUR 20.2 million compared to EUR 20.7 million in 2005 including revenues directly related to sales of HIFU Revenue-Per-Procedure (RPP) of EUR 2.8 million compared to EUR 1.7 million in 2005, a 60% increase. As expected, these revenues reflect the successful shift of the business model from sales of devices to sales of procedures. This fundamental business model change was initiated in early 2006 to accelerate market adoption through ease of access to Ablatherm-HIFU. Company gross margins remained steady at 41 percent reflecting increased HIFU margin and slightly lower UDS margin due to changes in revenue mix.

Total expenses for 2006 increased 16%, mainly in sales, marketing and clinicals dedicated to building the Company's aggressive marketing strategy to drive new site adoption. During the first six months of 2006 the company strengthened its clinical team to achieve Ablatherm-HIFU's standard of care status in Europe. In the second half EDAP launched its first-ever marketing program to drive doctor and patient adoption based. Senior sales experts doubled the existing sales force starting in late 2006 focused on business growth in key European countries. The Company expects to see early results on its RPP program beginning in Q1 2007 and accelerating throughout the year.

EDAP's balance sheet remains strong with EUR 10.9 million (including EUR 1 million of short term treasury investments), enough to fully fund upcoming corporate operations and added marketing and sales expenses until profitability is achieved in Europe.

The Company reported for the full year 2006 an Operating Loss of EUR 3.1 million, in line with expectations and backed by the July 2006 PIPE funding. This is connected to the announced acceleration in clinical and marketing & sales expenses, to achieve undisputed standard of care status for HIFU and prepare for and aggressive promotion and marketing campaign for Ablatherm-HIFU in key European markets in 2007 and 2008.

Eric Soyer, EDAP TMS Chief Financial Officer, commented: "The 2006 results are in line with our expectations and previous announcements as we focused on expanding our HIFU RPP business, now established as EDAP's growth model. We clearly see this new business model offering HIFU treatments with no up-front capital investment for hospitals is perfectly adapted to meet market needs. Our 2006 RPP revenues reflect this adoption with a 60% increase compared to 2005, and we expect this trend to continue as we will see acceleration in 2007 from our aggressive marketing plans. By implementing this new strategy and while keeping a strong R&D focus, we successfully transitioned in 2006 from a manufacturing device oriented company, focused on confirming its clinical credibility and validating HIFU's technical superiority, to a marketing company fully dedicated to dramatically accelerating treatment growth."

HIFU DIVISION: RPP ABLATHERM-HIFU TREATMENTS DRIVING GROWTH

During 2006 the company built EDAP's first-ever marketing programs aimed at the broad medical and patient communities. EDAP's time and investment in

Edgar Filing: EDAP TMS SA - Form 6-K

clinical expertise and site build out prior to 2006 enabled a successful launch addressing major European markets. The company expects growing adoption by doctors due to both the attractiveness of Ablatherm-HIFU therapy compared to other treatment methodologies as well as market pressures from patient demand.

The added cost of reinforcing the European sales force as well as new marketing programs, as anticipated, pushed the HIFU division to a loss for the full year. However, seeing the full market opportunity in Europe and EDAP's strong corporate resources, management believes these investments will dramatically increase urologist and patient demand and grow the number of treatments, especially in the RPP program. The company is already seeing clear positive effects of growth in lowering costs of goods sold, mainly through the growing percentage of RPP treatments. These benefits will further accelerate as EDAP adds market scale. Gross margin reflects these shifts and continue to climb, achieving 53 percent for 2006. Total expenses in the HIFU division rose 15 percent, primarily in marketing and clinical activities.

EDAP Ablatherm-HIFU:

	2004	Annual Growth	2005	Annual Growth
Cumulative number of treatments	6,700	+2,100	8,800	+2
Number of RPP treatments	427	+194	621	
Number of HIFU treatment sites	63	+33	96	

During the course of 2006, EDAP launched 36 sites, sites bringing EDAP's global Ablatherm-HIFU center count to 132. Ablatherm institutions represent the best centers in their respective communities bringing top urology experts to support EDAP and Ablatherm-HIFU. Treatments as of December 31, 2006 totaled over 11,600 a 32% percent increase from 2005, and treatments for the whole year 2006 reached approximately 2,800, including 936 RPP treatments.

"EDAP reinforces its global leadership in HIFU for prostate cancer," said Oczachowski. "Only EDAP offers clear repeatability of outcomes demonstrated in dozens of peer reviewed articles, industry leading success in outcomes, clear quality of life preservation and consensus medical adoption of HIFU therapy due to rapid training and clear protocols established for different indications. With our broad user base, European centers can visit a nearby Ablatherm-HIFU center to experience the true excellence of this therapy from a peer user, then receive training to begin offering Ablatherm at their own center with full confidence in their ability to offer patients the best standard of care. Based on this strong and recognized clinical and technical superiority, we are now ready to roll-out our aggressive educational and marketing tools. We recently launched the first HIFU-Tour in Germany, which has been a great success already in bringing additional medical interest for starting treatments during 2007 at new centers plus building a broader referral network to current centers. Utilizing EDAP's strong presence in urology due to our lithotripsy leadership, we are well positioned to reach a far broader audience under these new education initiatives. EDAP also has more than 50 distributors worldwide now beginning to utilize the marketing tools to educate their contacts about the opportunity of Ablatherm."

Edgar Filing: EDAP TMS SA - Form 6-K

UDS DIVISION: LAUNCHING GLOBAL PLATFORM FOR UROLOGY SALES

The UDS division continues to provide a strong market presence in Europe and Asia as well as cover significant fixed costs in manufacturing and services for both divisions. In late 2006 the company expanded its presence with contracts to sell third-party products into EDAP's sales channel. The company continues to add contracts for additional product lines. This program leverages EDAP's fixed cost base with additional products offering incremental revenue and profit to EDAP without significant up front cost or additional fixed expense.

UDS results for the 2006 year reflect a change in mix within the global replacement cycle for lithotripters. A higher percentage of sales originated in Europe where mid-range units dominate the market as opposed to Asia where high-range units are preferred. Total sales remain strong with 38 units sold in 2006 as EDAP continues to add market share in replacement of aging lithotripters while continuing strong services and disposable revenues provide steady revenues.

As previously planned, UDS reported a loss of EUR 0.5 million in 2006 due to investments in new device developments to be launched in late 2007, aimed at sustaining the Company's market share in lithotripsy.

BOARD UPDATES

In line with its accelerated growth plans and clear global strategy, EDAP's Board is also changing. Siemens has resigned from its representation on EDAP's Board. Holger Schmidt, serving on EDAP's Board since 2001, has been replaced by Pr. Jean-Philippe Deschamps, effective March 2007. Deschamps is Professor of Technology and Innovation Management at IMD, in Lausanne, Switzerland. Prior to joining IMD in November 1996, he was based in Brussels as a corporate Vice-President with Arthur D. Little and Chairman of the firm's technology and innovation management practice, which he created in 1981. Before that, he was Arthur D. Little's first European practice leader for strategy and organization. He brings thirty years of international management consulting experience throughout Europe, North America, Asia and the Middle East to EDAP. He graduated from Ecole des Hautes Etudes Commerciales in Paris and received his MBA from INSEAD and from the Harvard Business School. Pr. Deschamps has focused his research activity on bringing revolutionary medical techniques to a standard of care status.

"We welcome Jean-Philippe Deschamps to the Board of Directors and look forward to his contributions as an expert in both technology and innovation management, expertise we believe will be very useful in the upcoming years as EDAP embarks on what is clearly becoming a significant growth opportunity for HIFU in Europe," said Philippe Chauveau, Chairman of EDAP. "The Board of Directors is becoming more active in supporting EDAP according to the successful transition well underway in moving this company from its roots as a research and manufacturing business to what is today one of the top marketing companies for HIFU therapies in the world. We are addressing numerous growth opportunities in Europe and hold high expectations for the United States. As such, our updated Board will bring more resources to successfully deliver on these initiatives."

Participation in Congresses

Consistent with its increased communication effort to establish high visibility for HIFU in the medical community, EDAP will be participating as a Gold Sponsor in the next European Association of Urology (EAU) meeting to be held in Berlin, Germany, March 21 - 24, 2007. The Company is pleased to welcome all interested parties to EDAP's booth and meet with EDAP's representatives. EDAP will present at the American Urology Association (AUA) conference to be held in Anaheim, CA, May 19-24, 2007. EDAP is also rolling out HIFU tours in Germany and other major European centers to accelerate adoption of

Edgar Filing: EDAP TMS SA - Form 6-K

Ablatherm-HIFU in response to clear market demand from both patients and physicians.

Conference Call and Webcast

The company will host a conference call to discuss the results and answer questions from investors on Thursday, March 15, 2007, at noon Eastern Time, 5:00 p.m. Paris Time. Representing the Company on the call will be Philippe Chauveau, Chairman of the Board, Marc Oczachowski, Chief Operating Officer and Eric Soyer, Chief Financial Officer. Interested investors may join the call live by dialing (866) 463-5401 from the United States or +1 (212) 457-9857 from international locations and entering PIN code 983898#. Investors may also listen to the live call online at <http://www.edap-tms.com>.

Investors unable to join the call can access a playback of the conference call by telephone or online. To access the replay, please dial (866) 439-4554 or +1 (212) 457-9844 and using access code 324765# beginning one hour after the end of the call until March 22, 2007, or visit the company's Web site at <http://www.edap-tms.com>.

About EDAP TMS S.A.

EDAP TMS S.A. develops and markets Ablatherm, the most advanced and clinically proven choice for High Intensity Focused Ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option 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. The company is also developing this technology for the potential treatment of certain other types of tumors. EDAP TMS S.A. also produces and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL).

For more information on the Company, contact Magnolia Investor Relations at (972) 801-4900, the Corporate Investor Relations Dept at +33 (0)4 78 26 40 46 or see the Company's Web sites at <http://www.edap-tms.com> and <http://www.hifu-planet.com>.

To sign up for alerts please visit:
<http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0>

In addition to historical information, this press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission. Ablatherm- HIFU treatment is in clinical trials but not yet FDA approved or marketed in the United States.

EDAP TMS S.A.

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

Three Months Ended:

Three Months Ended:

Edgar Filing: EDAP TMS SA - Form 6-K

	December 31, 2006 Euros	December 31, 2005 Euros	December 31, 2006 \$US	December 2005 \$US
Sales of medical equipment	1,957	3,245	2,559	3
Net Sales of RPP and Leases	1,035	894	1,353	1
Sales of spare parts, supplies and Services	1,918	2,263	2,508	2
TOTAL SALES	4,910	6,402	6,421	7
Warrants granted	---	(235)	---	7
TOTAL NET SALES	4,910	6,167	6,421	7
Other revenues	(25)	40	(32)	7
TOTAL REVENUES	4,885	6,207	6,389	7
Cost of sales	(3,100)	(3,625)	(4,054)	(4)
GROSS PROFIT	1,786	2,582	2,335	3
Research & development expenses	(573)	(434)	(750)	3
S,G&A expenses	(2,087)	(2,100)	(2,729)	(2)
Non-recurring operating expenses	(195)	---	(255)	3
Total operating expenses	(2,855)	(2,536)	(3,734)	(3)
OPERATING PROFIT (LOSS)	(1,070)	46	(1,399)	3
Interest (expense) income, net	66	100	86	3
Currency exchange gains (loss), net	(100)	(11)	(131)	3
Other income (loss), net	3	(13)	4	3
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,101)	122	(1,439)	3
Income tax (expense) credit	(14)	(76)	(18)	3
NET INCOME (LOSS)	(1,114)	45	(1,458)	3
Earning per share -- Basic	(0.13)	0.01	(0.17)	3
Average number of shares used in computation of EPS	8,817	7,783	8,817	7
Earning per share -- Diluted	(0.13)	0.01	(0.17)	7
Average number of shares used in computation of EPS for positive net income	9,536	8,417	9,536	8

NOTE: Translated for convenience of the reader to U.S. dollars at the 2006

Edgar Filing: EDAP TMS SA - Form 6-K

average three months noon buying rate of 1 Euro = 1.3077 USD, and 2005
average three months noon buying rate of 1 Euro = 1.1876 USD.

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

	Twelve Months Ended:		Twelve Months Ended:	
	December 31, 2006 Euros	December 31, 2005 Euros	December 31, 2006 \$US	December 2005 \$US
Sales of medical equipment	8,609	10,242	10,899	12,000
Net Sales of RPP and Leases	3,805	3,146	4,818	2,000
Sales of spare parts, supplies and Services	7,760	7,563	9,825	10,000
TOTAL SALES	20,174	20,952	25,542	25,000
Warrants granted	---	(235)	---	---
TOTAL NET SALES	20,174	20,717	25,542	25,000
Other revenues	91	93	115	---
TOTAL REVENUES	20,265	20,810	25,658	25,000
Cost of sales	(11,946)	(12,313)	(15,125)	(15,000)
GROSS PROFIT	8,319	8,497	10,533	10,000
Research & development expenses	(2,442)	(1,784)	(3,092)	(2,000)
S,G&A expenses	(8,703)	(8,036)	(11,019)	(9,000)
Non recurring operating expenses	(267)	---	(338)	---
Total operating expenses	(11,413)	(9,820)	(14,449)	(12,000)
OPERATING PROFIT (LOSS)	(3,094)	(1,323)	(3,917)	(1,000)
Interest (expense) income, net	153	135	194	---
Currency exchange gains (loss), net	(430)	218	(545)	---
Other income (loss), net	(5)	9	(6)	---
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(3,375)	(962)	(4,274)	(1,000)
Income tax (expense) credit	(56)	(103)	(70)	---
NET INCOME (LOSS)	(3,431)	(1,065)	(4,344)	(1,000)
Earning per share -- Basic	(0.39)	(0.14)	(0.49)	---
Average number of shares				

Edgar Filing: EDAP TMS SA - Form 6-K

used in computation of EPS	8,817	7,783	8,817	7
Earning per share -- Diluted	(0.39)	(0.14)	(0.49)	(
Average number of shares used in computation of EPS for positive net income	9,558	8,374	9,558	8

NOTE: Translated for convenience of the reader to U.S. dollars at the 2006 average twelve months noon buying rate of 1 Euro = 1.2661 USD, and 2005 average twelve months noon buying rate of 1 Euro = 1.2396 USD.

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

	Dec. 31, 2006 Euros	Sept. 30, 2006 Euros	Dec. 31, 2006 \$US	Sept. 30 2006 \$US
	-----	-----	-----	-----
Cash, cash equivalents and short term investments	10,924	10,540	14,417	13
Total current assets	26,393	27,542	34,831	34
Total current liabilities	10,926	11,828	14,419	15
Shareholders' Equity	19,300	20,463	25,471	25

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3197 USD, on December 31, 2006 and at the noon buying rate of 1 Euro = 1.2687 USD, on September 30, 2006.

EDAP TMS S.A.
CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
TWELVE MONTHS ENDED DECEMBER 31, 2006
(Amounts in thousands of Euros)

	EDAP S.A. HIFU Division	TMS S.A. UDS Division	EDAP TMS HQ	Consolidat Impact
	-----	-----	-----	-----
Sales of medical devices	2,633	5,975		(1
Sales of spare parts, supplies & services	5,000	6,578		(1
TOTAL NET				

Edgar Filing: EDAP TMS SA - Form 6-K

SALES	7,633	15,554	(3)
Other revenues	82	26	
TOTAL REVENUES	7,715	15,580	(3)
GROSS PROFIT	4,108 53%	4,511 29%	
Research & Development	(1,231)	(1,212)	
Total SG&A plus depreciation	(3,171)	(3,845)	(1,687)
Non-recurring expenses			(267)
OPERATING PROFIT (LOSS)	(294)	(546)	(1,954)

CONTACT: EDAP TMS S.A.
 Blandine Confort
 +33 4 78 26 40 46

Magnolia Investor Relations
 Matt Kreps
 972 801 4900

SOURCE EDAP TMS S.A.

-0-

03/14/2007

/CONTACT: Blandine Confort of EDAP TMS S.A., +33-4-78-26-40-46; or Matt Kreps of Magnolia Investor Relations, +1-972-801-4900, for EDAP TMS S.A./

/Web site: <http://www.edap-tms.com>

<http://www.hifu-planet.com>

<http://www.b2i.us/irpass.asp?BzID=1053&to=ea&s=0> /

(EDAP)

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: March 14, 2007

EDAP TMS S.A.

/S/ HUGUES DE BANTEL

 HUGUES DE BANTEL
 CHIEF EXECUTIVE OFFICER