

EDAP TMS SA  
Form 6-K  
January 17, 2006

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# 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

Presentation to Investors

Road Show U.S.A.

From Jan. 16, 2006 to Jan. 27, 2006

### 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             

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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: 01-17-2006

EDAP TMS S.A.

/S/ HUGUES DE BANTEL

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HUGUES DE BANTEL  
CHIEF EXECUTIVE OFFICER

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[LOGO OF EDAP TMS]

**EDAP TMS Investor Summary**  
**The world leader in HIFU for localized prostate cancer**

**Hugues de Bantel: Chief Executive Officer**  
**Philippe Chauveau: Chairman of the Board**  
**January 2006**

**Forward Looking Statements**

[LOGO OF EDAP TMS]

**This presentation contains, in addition to historical information, 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 the 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.**

**Company Overview**

[LOGO OF EDAP TMS]

**EDAP TMS S.A. is the world leader in High Intensity Focused Ultrasound treatment for prostate cancer.**

**The company develops and markets Ablatherm®-HIFU, a proven minimally invasive and effective treatment option for localized prostate cancer, preserving patient quality of life. The company is also developing this technology for the treatment of certain other types of tumors.**

**EDAP also develops and commercializes medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (ESWL), an established treatment choice.**

**EDAP TMS Global Operations  
EDAP is Addressing Two Major Pathologies in Urology:  
Prostate Cancer & Urinary Stones**

[LOGO OF EDAP TMS]

**HIFU**

**A new advance in the treatment of prostate cancer 50% gross margin\***

**Approved in Europe, Canada, Russia, Australia, South East Asia**

**Start of US clinical trials approved by FDA**

**High growth market**

**New market, reimbursement opportunities**

**Site and per-use options**

**Make-it-happen model**

**LITHOTRIPSY**

**A mature treatment for basic urological tract stones 30% gross margin\***

**Provides momentum for overall business**

**Driven by replacement**

**Gaining market share**

**Predictable margins and cycles**

**Worldwide network to build on**

**Bringing new products to the pipe**

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\*as of September 05

**Global Growth Platform**

[LOGO OF EDAP TMS]

**2004 operational turnaround demonstrated cash-positive capabilities in both divisions**

**In 2005, market expansion was driven by the following strategy:**

**Expanded mobile services base and treatments**

**Continued strong site and treatment growth rates**

**Launched Ablatherm®-HIFU in new countries**

**Secured reimbursements in key countries, including UK**

**Strengthened gross margins: 41%+ as of Sept. 05**

**Maintained growth in high margin services contracts**

**Used cash to fund marketing campaigns to patients and doctors in key countries, expand to new markets**

**Ready for FDA trials sponsored by HealthTronics (HTRN) starting early 2006**

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**Focus on Ablatherm®-HIFU**

[LOGO OF EDAP TMS]

**The Market Potential for Minimally Invasive Prostate Cancer  
Treatment Represents EDAP's High Growth Opportunity**

[GRAPHIC APPEARS HERE]

**The Ablatherm®-HIFU Solution**  
**EDAP is committed to:**

[LOGO OF EDAP TMS]

**Offer patients the best combination Safety and Efficacy**

**Full enlightenment of patients about existing treatment options**

**Preserve patient quality of life**

**Ablatherm-HIFU is The Solution for growing sensitivity and awareness from prostate cancer patients about:**

**Their safety**  
**Their health**  
**Their family life**  
**Their sexual drive**  
**Their future**

[GRAPHIC APPEARS HERE]

**Focus on Ablatherm®-HIFU**

[LOGO OF EDAP TMS]

**The New Integrated Imaging Ablatherm:  
The Most Advanced HIFU Technology with the New Dual Function Probe**

[GRAPHIC APPEARS HERE]



**Focus on Ablatherm®-HIFU  
Imaging & Treating Simultaneously**

[LOGO OF EDAP TMS]

**Imaging**

**From a transversal real-time image, the 7.5 MHz electronic ultrasound transducer can provide an accurate 3D reconstruction of the treatment area**

[GRAPHIC APPEARS HERE]

**Firing**

**High-energy ultrasound waves are focused through the rectal wall to the targeted prostate area without damaging surrounding tissues**

[GRAPHIC APPEARS HERE]

**Focus on Ablatherm®-HIFU  
Imaging and treating**

[LOGO OF EDAP TMS]

**The firing process is visible in real time on the echographic display**

[GRAPHIC APPEARS HERE]

**Robotized probe placement**

**5 axis computer controlled movements, a very sophisticated device with fully robotized motion control for precise probe positioning**

[GRAPHIC APPEARS HERE]

**HIFU Market**  
**Market Driving EDAP Forward**

[LOGO OF EDAP TMS]

**Prostate Cancer: 2<sup>nd</sup> most common cancer in American and European males:**

231,000 new cases per year in the USA\*

238,000 new cases per year in Europe\*\*

**Dramatic increase in worldwide public awareness:**

Increased sensitivity toward Quality of Life

Systematic PSA screening

Huge awareness campaigns

**Significant increase in Prostate Cancer cases:**

Increase in life expectancy

Aging baby boomers

**Growing awareness & concern related to significant side effects with traditional treatments**

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\* (Sources 2004 American Cancer Society)

\*\* (Sources: 2004, International Agency for Research on Prostate Cancer)

**HIFU Market**

[LOGO OF EDAP TMS]

**The current market scope for Ablatherm-HIFU is 70% of all prostate cancer cases**

[CHART APPEARS HERE]

**Today, less than 1% of these patients are treated with Ablatherm-HIFU!**

**HIFU Market**

[LOGO OF EDAP TMS]

**Currently Available Therapies for Localized Prostate Cancer**

**Current alternatives to HIFU:**

- Surgery
- Radiation
- Watchful Waiting
- Cryosurgery

**Europe\***

**USA\***

[CHART APPEARS HERE]

[CHART APPEARS HERE]

**Current Alternatives**

**Current Alternatives**

**Large number of treatments today performed by specialists other than urologists**

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\*Corporate estimates

**HIFU Market**  
**The Best Solution Available Today:**

[LOGO OF EDAP TMS]

- Optimal efficacy

[CHART APPEARS HERE]

- Preserving quality of life

**HIFU Market  
Our Proven Efficacy\***

[LOGO OF EDAP TMS]

[CHART APPEARS HERE]

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\* *C. Chaussy, S. Thüroff, G. Vallancien, W. Wieland, H.J. Kiel, A. Le Duc, F. Desgranchamps, J. de la Rosette, A. Gelet: High Intensity Focused Ultrasound and Localized Prostate Cancer: Efficacy Results of the European Multicentric Study, The Journal Of Urology, October 2003*

**Confirmed at Five Years\*\***

[CHART APPEARS HERE]

**Disease free progression at 5 years comparable to established treatment modalities**

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\*\* *Blana & al. Urology, 2004*

**HIFU Market**  
**Preservation of Quality of Life : Lowest Side Effects**

[LOGO OF EDAP TMS]

**Incontinence**

[CHART APPEARS HERE]

**Fistula**

[CHART APPEARS HERE]

**Impotence**

[CHART APPEARS HERE]

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*PCRI Literature Review 2005*

<sup>1</sup> *Journal of Urology 2003 (Dr Gelet) & WCE Congress 2003 (Dr D Hont)*

<sup>2</sup> *Contemporary Urology 2004*

<sup>3</sup> *Journal of Urology July & Nov. 2004, Surgeon 2005 Dec & Journal of Endourology July/August 2005*



**HIFU Market**

[LOGO OF EDAP TMS]

**Clinical Benefits: Preservation of Quality of Life**

<b>Non-Invasive:</b>	<b>No port, no seeds, no radiation</b>
<b>Effective:</b>	<b>Precise and definitive necrosis of the targeted area</b>
<b>Early Feedback:</b>	<b>Nadir PSA after only 3 months</b>
<b>Quality of Life:</b>	<b>Minimal side effects</b>
<b>Repeatable:</b>	<b>If needed at any time during follow up</b>
<b>Adaptable:</b>	<b>To the physician and the patient's therapeutic goals</b>
<b>No Therapeutic Impasse:</b>	<b>Alternative options still open post Ablatherm</b>

**HIFU Market**  
**Less Expensive than Radiation Therapies**

[LOGO OF EDAP TMS]

[CHART APPEARS HERE]

**HIFU Market  
2006 Market opportunities**

[LOGO OF EDAP TMS]

**Grow 2005 new markets: Canada, UK, Australia & Switzerland**

**Starting US clinical trials through relationship with HTRN**

**Priming the pump through cost-per-procedure (CPP) & mobile model**

**Approval and reimbursement in key markets:**

**national reimbursement process varies by country**

**dynamics of approval in the US**

**Huge potential through market education**

**Strengthen clinical credibility, support of key opinion leaders**

**Maintain technological Mastery / Leadership via strong IP**

**Expand HIFU to other pathologies**

**HIFU Market for Prostate Cancer**

[LOGO OF EDAP TMS]

**Growth Strategy Road Map**

**We have successfully met all major market challenges**

[CHART APPEARS HERE]

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**HIFU Market  
FDA Trials Road Map**

[LOGO OF EDAP TMS]

- 1- FDA approval obtained to start clinical trials in the US to prove efficacy
- 2- Finalization of contracts with 10 participating clinical institutions, a mix of high profile academic sites and private practices
- 3- Ablatherm devices are being deployed and clinical staff trained to start first cases
- 4- Expect 4 sites up and running by end of February 06, and the majority of sites to be treating patients by end of first quarter 06

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**HIFU Market  
Recent Market Expansion**

[LOGO OF EDAP TMS]

**Australia**

**Launched at St Vincent s Clinic, Sydney, on CPP basis in October 2005**

**Utilization for retreatment of brachytherapy and radiation failures**

**United Kingdom**

**Unit at Stepping Hill Hospital since April 2004**

**Set up Royal Marsden Hospital, London**

**October 2005 reimbursement approval by BUPA opened market to further sales**

**Launch at Guys Hospital, London**

**Launch of Mobile-HIFU, a private UK company**

**Additional selling activity in progress through distribution partner Sigmacon**

**HIFU Market**

[LOGO OF EDAP TMS]

**CPP Business Model = Growth Opportunity**

Cost-per-Procedure (CPP) performed is an easy and profitable way to make this technology available to a larger number of patients as well as hospitals and clinics

Mobile business facilitates rapid access to Ablatherm HIFU technology

No upfront investment from the hospital

**HIFU Market**

[LOGO OF EDAP TMS]

**Mobile Through Europe**

Deploy mobile units for France, Germany, Austria, Italy, Spain, UK, Belgium and other locations

63 sites using Ablatherm-HIFU on a mobile basis at December 05 end

[GRAPHIC APPEARS HERE]



**HIFU Market  
Momentum: CPP Growth**

[LOGO OF EDAP TMS]

[CHART APPEARS HERE]

[CHART APPEARS HERE]

**CPP Revenues in ( 000s)**

**Number of Treatments / CPPs**

Average 2005 selling CPP price : 2,807

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(\*) estimated at Dec. end 05

**Growth in HIFU Service Business  
Recurring and Very Profitable Maintenance Revenues**

[LOGO OF EDAP TMS]

**Maintenance contracts include supplies, professional services**

**Average maintenance contract is 10% of the equipment invoice price**

**Average gross margins on maintenance is 68%**

[CHART APPEARS HERE]

**HIFU Service Revenues in ( 000s)**

**HIFU Market  
German Mobile CPP Business Model**

[LOGO OF EDAP TMS]

**Cumulative estimated 500 treatments completed as of December end 2005**

**21 sites using the Ablatherm on a mobile CPP basis**

**Two Ablatherm mobile units**

**Revenues related to mobile CPP business**

[CHART APPEARS HERE]

**Number of treatments**

[CHART APPEARS HERE]

**Mobile revenue growth (in K )**

**HIFU Market  
Regulatory Approvals**

[LOGO OF EDAP TMS]

<b>Approvals</b>	<b>&amp;</b>	<b>Reimbursements</b>
<b>CE mark in 2000</b>		<b>Reimbursement in Germany &amp; Italy (up to 4,000)</b>
<b>Canada (2004)</b>		<b>Reimbursement in the UK by BUPA (up to £11,000)</b>
<b>Positive NICE guidance (April 2005)</b>		<b>Reimbursement by other UK providers</b>
<b>FDA approval obtained to start clinical trials</b>		
<b>Seeking US and Japan marketing approval for Ablatherm-HIFU</b>		

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**HIFU Market  
Growth Strategy**

[LOGO OF EDAP TMS]

**Leverage awareness using PR & web support**

**Build-up centers of excellence to maintain and strengthen our clinical credibility**

**Strong relationship with local urology communities and opinion leaders**

**Encourage urologists to capture the market from radio-oncologists**

**Develop mobile CPP HIFU solutions in selected European countries**

[GRAPHICS APPEAR HERE]

**HIFU Market**  
**Rapidly Accelerating Market Acceptance**

[LOGO OF EDAP TMS]

**9,000 estimated cumulative treatments as of December end 2005**

[CHART APPEARS HERE]

**Cumulative number of treatments**  
**45% CAGR**

**Currently 96 sites delivering treatment:**

[CHART APPEARS HERE]

**Cumulative sites using Ablatherm**  
**68% CAGR**

**Focus on Lithotripsy**

[GRAPHIC APPEARS HERE]

[LOGO OF EDAP TMS]

**Lithotripsy Leadership**

[LOGO OF EDAP TMS]

**Satisfied installed base of more than 400 lithotripters worldwide**

**A Leader in Asia, including Japan, and Europe due to customer proximity and provided services**

**IP Protection: 17 Lithotripsy Patents**

**Mature market with pressure on prices and margins;**

**Highly skilled staff, very low turnover**

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**Lithotripsy Market**

[LOGO OF EDAP TMS]

**LITHOTRIPSY: Worldwide Market Scope**

**Market Drivers:**

Service Capacity, Credibility & Proximity  
Technology  
Global reach

**Current Worldwide Installed Base > 3,000 Units Replacement Market > 300 Units / Year @ average \$250,000 (= \$75M / Year)**

**Service & Consumables Predictable Revenue @ 8-10% of Equipment sold per year**

Predictable, high-margin revenue

**Sales & Service Experience opens market to the Ablatherm-HIFU model**

Company's estimates

**Lithotripsy Market**  
**Geographical Distribution of Global Lithotripsy Market**

[LOGO OF EDAP TMS]

[GRAPHIC APPEARS HERE]

Company's estimates

**Lithotripsy Leadership**  
**EDAP TMS's Large Installed Base\***

[LOGO OF EDAP TMS]

[GRAPHIC APPEARS HERE]

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\* Company's figures at Dec. 05

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**Lithotripsy Strategy**

[LOGO OF EDAP TMS]

**LITHOTRIPSY: Provides Momentum for Overall Business**

**Improved products & marketing**

**Create key differentiators through services**

**Strong Project Sales Approach vs. Equipment Sales:**

**Equipment**

**Maintenance (on site, online, preventive, corrective maintenance services)**

**Training programs**

**Financing solutions**

**New products in the pipe**

**Contract Manufacturing**

**Financials**

**EDAP TMS Financials**

[LOGO OF EDAP TMS]

**Profit capable at both operating division levels**

**Well capitalized for additional investments in growth of new and current markets**

**Focus on cost controls, prudent investment of capital**

**Strong, improving margins throughout 2005:  
41% Company Gross Margin as of Sept. 05**

**Leverage in model for increased treatment volumes:  
Increased service revenues and incremental leverage to revenue growth**

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**Division Performance**  
**EDAP HIFU Division: Euro 000s\***

[LOGO OF EDAP TMS]

<b>First Nine Months</b>	<b>Revenue</b>	<b>Gross Margin</b>	<b>Operating Income (Loss)</b>
2005	5,033	50%	(333)
2004	5,064	45%	164

**TMS UDS (Lithotripsy) Division: Euro 000s\***

<b>First Nine Months</b>	<b>Revenue</b>	<b>Gross Margin</b>	<b>Operating Income (Loss)</b>
2005	11,686	30%	209
2004	13,214	31%	164

\* EDAP markets and sells Ablatherm®; TMS does all manufacturing and markets and sells Lithotripters;  
 See the 20F for a complete description

**Strong Balance Sheet**

[LOGO OF EDAP TMS]

All figures in 000s	Sept. 30, 2005 Euros	June 30, 2005 Euros	Sept. 30, 2005 \$US	June 30, 2005 \$US
<b>Balance Sheet and Liquidity</b>				
Cash and Cash Equivalents	7,463	8,222	8,999	9,947
Total Current Assets	22,014	23,254	26,545	28,133
Total Current Liabilities	9,786	10,089	11,800	12,205
Shareholders' Equity	16,953	17,543	20,442	21,224

Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.2058 USD, on September 30, 2005 and at the noon buying rate of 1 Euro = 1.2098 USD, on June 30, 2005.



## Income Statement

[LOGO OF EDAP TMS]

For the 12 Months Ending All figures in 000s	Dec. 31, 2004 Euros	Dec. 31, 2003 Euros	Dec. 31, 2004 \$US	Dec. 31, 2003 \$US
Total Revenues	22,163	18,473	27,654	21,079
Cost of Sales	(13,676)	(13,094)	(17,065)	(14,942)
Gross Profit	8,487	5,379	10,589	6,137
Interest, Currency, Taxes, Other	(319)	(855)	(398)	(976)
Total Operating Expenses	(9,317)	(13,500)	(11,624)	(15,404)
Net Income (Loss)	(1,149)	(8,976)	(1,433)	(10,243)
Basic EPS	(0.15)	(1.15)	(0.18)	(1.32)

2004 average Euro/\$US Exchange rate of 1 Euro = 1.2478 \$US

2003 average Euro/\$US Exchange rate of 1 Euro = 1.1411 \$US

EPS based on 7,782,000 average basic shares outstanding all periods

## Income Statement

[LOGO OF EDAP TMS]

<b>For the 9 Months Ending All figures in 000s</b>	<b>Sept. 30 2005 Euros</b>	<b>Sept. 30 2004 Euros</b>	<b>Sept. 30 2005 \$US</b>	<b>Sept. 30 2004 \$US</b>
Total Revenues	14,603	16,511	18,355	20,215
Cost of Sales	(8,688)	(10,158)	(10,920)	(12,437)
<b>Gross Profit</b>	<b>5,915</b>	<b>6,353</b>	<b>7,435</b>	<b>7,778</b>
Interest, Currency, Taxes, Other	259	50	325	61
<b>Total Operating Expenses</b>	<b>(7,285)</b>	<b>(7,181)</b>	<b>(9,156)</b>	<b>(8,792)</b>
<b>Net Income (Loss)</b>	<b>(1,111)</b>	<b>(778)</b>	<b>(1,396)</b>	<b>(953)</b>
Basic EPS	(0.14)	(0.10)	(0.18)	(0.12)

2005 average nine months Euro/\$US Exchange rate of 1 Euro = 1.2569 \$US

2004 average nine months Euro/\$US Exchange rate of 1 Euro = 1.2243 \$US

EPS based on 7,781,731 average basic shares outstanding all periods

**Investor Highlights**

[LOGO OF EDAP TMS]

**Focus on continued growth and expansion**

**Well positioned as the global leader in HIFU installations, treatment technology and clinical data**

**Compelling clinical benefits, growing market awareness breeding demand**

**Established successful model to enter and grow new key markets in Europe, Canada and the U.S.**

**Continued focus on reimbursement, market entry, site growth and treatment acceleration**

**Continued focus on revenues, costs and growth leading to profitability**

**Investor Highlights**  
**Committed Management**

[LOGO OF EDAP TMS]

**Management focus on increasing company valuation**

**Driving HIFU approval and reimbursement in all key markets with a focus on total number of treatments**

**Strengthening our marketing team to drive an international marketing campaign to educate doctors, patients and reimbursement providers**

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**Shareholders / Stock Performance**

[LOGO OF EDAP TMS]

**7,781,731 Outstanding shares\*:**

**6,715,873 ADRs (floating)**

**1,065,858 Ordinary shares (non-floating)**

**Strong Stock Performance late 2005, reflecting HIFU potential high growth and increasing interest.**

**Market Cap: \$51.7 million**

**TTM Revenues: \$26 million**

**Cash: \$9.7 million**

**Avg. Vol.: 28,000 shares**

**USD as of 1/13/06**

[CHARTS APPEAR HERE]

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\* At Dec. 31, 2005

**Thank you**

[LOGO OF EDAP TMS]

**Investor Relations:**

**France**  
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**+33 4 78 26 40 46**

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