#### 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 Communication with Its Investors** 

April 4-8, 2005

# 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 x Form 40-F o

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 o No x

#### **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 : April 4, 2005

EDAP TMS S.A.

/s/ HUGUES DE BANTEL

HUGUES DE BANTEL CHIEF EXECUTIVE OFFICER





# **EDAP TMS Investor Summary**

April 4-8, 2005

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



### **Forward Looking Statements**



This press release 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**



EDAP TMS S.A. develops and markets the 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 lower occurrence of side effects. The company is also developing this technology for the treatment of certain other types of tumors.

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



### 2004 EDAP Turnaround Results



- Four quarters of operating income in both divisions;
- Revenues increased 34%; operating expenses decreased 25%; net loss decreased 86%; gross margin at 38%
- Well capitalized with more than € 9.4 million (\$12.7 million) in cash at December end; continued emphasis on disciplined cash management
- Positioned for new growth markets in 2005



### 2005 Global Growth Strategy



#### HIFU

A new advance in the treatment of prostate cancer

2004 €7.0 million sales 46% gross margin

- Approved in Europe and Canada; US partnership with HTRN
- High growth market
- Accelerating treatment growth rates
- Make it happen model

#### **LITHOTRIPSY**

A mature treatment for basic urological tract stones

2004 €17.4 million sales 30% gross margin

- Provides momentum and cash flow for overall business
- Driven by replacement
- Gaining market share
- Increasing market share and service revenues



# 2005 Global Growth Strategy



- Service Business: Predictable, high margin & significant revenue
- Operating Income growth, cash flow growth
  Subject to non-cash expenses related to warrants issued
  to HTRN based on successful marketing milestones
- A Cash cushion for marketing development demands
- Expanded marketing and outreach programs

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# Focus on HIFU with Ablatherm®





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### **HIFU Market**



### HIFU with Ablatherm®: Market Scope

- Prostate Cancer: 2<sup>nd</sup> most common cancer in American and European males:
  - ▶ 230,000 new cases per year in the USA
  - ▶ 250,000 new cases per year in Europe
- Significant increase in the number of Prostate Cancer cases:
  - Increase in life expectancy
  - Aging baby boomers
- Dramatic increase in worldwide public awareness due to:
  - Systematic PSA screening
  - Huge awareness campaigns
  - Increased sensitivity towards Quality of Life



### **HIFU Market Position**



#### HIFU with Ablatherm®: Market Opportunities

#### Treatment alternatives:

- ▶ Current gold standard: Radical Surgery
- ▶ Radiation Therapy
- Cryotherapy

#### Market drivers / Key success points:

- ▶ Clinical credibility in Europe; Canadian launch April 2005; beginning US entry through relationship with HealthTronics (HTRN)
- ▶ Technological Mastery / Leadership
- ▶ Education
- Reimbursement in key markets
- ▶ Leadership in the treatment of Urological Diseases
- ▶ HIFU to be expanded to other pathologies



### **HIFU Leadership**



### HIFU with Ablatherm®: Our Strength

- High growth number of patients world-wide
- Clinical leadership:
  - ▶ Opinion leaders support in Europe
  - Peer reviewed clinical publications on localized Prostate Cancer @ 5 years and on Radiotherapy failures; EAU presentation at 8 years follow-up
  - Over 6,600 treatments performed to Dec. 2004
- Competition: welcome as it further opens the market while Ablatherm<sup>®</sup> clinical and technological credibility prevails
- Patents (IP protection): Over 50 HIFU patents
- Strong R&D through our partnership with INSERM



# **HIFU Opportunity**



#### HIFU with Ablatherm®

- World-wide market not yet educated
- Only 1% of European Prostate Cancer treated with HIFU technology
- Competition: Important to ensure proper marketing of HIFU technology and medical education
- Approval and reimbursement not achieved in all key markets
- Entry into Canada and the United States



# 2005 HIFU Strategic Actions



- Build strong recognition for HIFU with Ablatherm®
- Educate market through strong marketing action plan:
  - Physicians
  - ▶ Patients
  - Public Services
  - Politicians
- Increase the number of HIFU treatments:
  - ▶ Number of treatments with Ablatherm® measures HIFU success, now more than 6,600
- Accelerate approval and reimbursement process
- Take market share in North America:
  - Distribution in Canada
  - Working closely with US partner HealthTronics on FDA approval process



# Focus on Lithotripsy







# **Lithotripsy Market**



#### LITHOTRIPSY: Worldwide Market Scope

- Market Drivers:
  - ▶ Service Capacity, Credibility & Proximity
  - ▶ Technology
  - ▶ Global reach
- Current world-wide Installed Base > 3,000 Units Replacement Market > 300 Units / Year
   average \$250,000 (= \$75M / Year)
- Service & Consumables Predictable Revenue
  @ 10% of Equipment sold per year
  - ▶ Predictable
  - ▶ Significant, high-margin revenue
  - ▶ Sales & Service Experience opens market to the HIFU with Ablatherm® Model



# Lithotripsy Leadership



### LITHOTRIPSY: Our Strength

- Satisfied installed base: EDAP has more than 400 lithotripters installed world-wide
- Leader in Japan and Asia due to customer proximity and provided services
- Patents (IP Protection): 17 Lithotripsy Patents
- Mature Market with pressure on Prices and Margins;
  National Health Policies lead to increased equipment longevity
- Highly skilled staff, very low turnover



# **Lithotripsy Strategy**



### LITHOTRIPSY: Provides Momentum for Overall Business

- Improved products & marketing
- Create key differentiators through services
- Strong Project Sales Approach vs. Equipment Sales:
  - Audit & Consulting
  - **▶** Equipment
  - Maintenance (on site, on line, preventive, corrective maintenance services)
  - Training programs
  - Financing solutions



### **EDAP TMS Financials**



- Profitable at both operating division levels in 2004
- Well capitalized for additional investments in growth
- Focus on cost controls to preserve cash
- Strong, improving margins throughout 2004:
  38% Company Gross Margin
- Leverage in model for increased treatment volumes: Increased service revenues and incremental leverage to net income



# **Profitable at Division Levels**



#### EDAP - HIFU Division: Euro 000s\*

Year	Revenue	Gross Margin	Operating Income (Loss)
2004	6,969	46%	387
2003	2,959	31%	(5,802)

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

Year	Revenue	Gross Margin	Operating Income (Loss)
2004	17,385	30%	184**
2003	17,482	27%	(687)

<sup>\*</sup> EDAP markets and sells Ablatherm®, TMS does all manufacturing and markets and sells Lithotriptors; See the 20F for a complete description \*\* 358 excluding effect of HTRN warrants



# **Strong Balance Sheet**



All figures in 000s	Dec. 30, 2004 Euros	Sept. 30, 2004 Euros	Dec. 30, 2004 \$US	Sept. 30, 2004 \$US
Balance Sheet and Liquidity				
Cash and Cash Equivalents	9,398	9,075	12,723	11,269
Total Current Assets	22,025	23,128	29,818	28,718
Total Current Liabilities	8,038	8,829	10,881	10,963
Shareholders' Equity	17,964	18,168	24,320	22,560

December 31, 2004 Euro/\$US Exchange rate of 1 Euro = 1,3538 \$US September 30, 2004 Euro/\$US Exchange rate of 1 Euro = 1,2417 \$US



# **Income Statement**



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/SUS Exchange rate of 1 Euro = 1.2478 SUS 2003 average Euro/SUS Exchange rate of 1 Euro = 1.1411 SUS EPS based on 7.782,000 average basic shares outstanding all periods



# **Investor Highlights**



### 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 Lithotripsy business and cash position provide growth capital for future technologies
- Established successful model to enter and grow new key markets in Europe, Canada and the U.S.
- Continued focus on revenues, costs and growth leading to profitability



# **Investor Highlights**



### **Committed Management**

- 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



# Thank you



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