



**EDAP TMS**  
**Investor Presentation**

**Global Leader in  
Therapeutic  
Ultrasound**

May 2013



Bringing New Horizons to Therapy

*Leader in Therapeutic Ultrasound*

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**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 and, in particular, the regulatory review process in the United States by the Food and Drug Administration (the "FDA"). 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, any negative decision by the FDA or another regulatory authority and those described in the Company's filings with the Securities and Exchange Commission, including under "Forward-Looking Information", "Risk Factors" and "Operating and Financial Review and Prospects" in the Company's 2012 annual report on Form 20-F filed with the SEC on April 2, 2013.**



# Company Profile

## Two Major Urology Indications

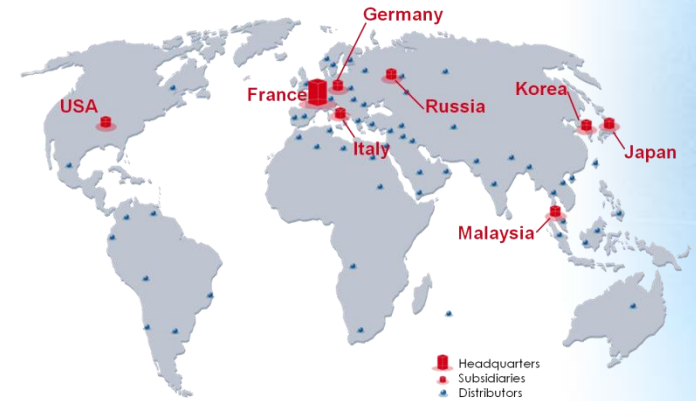
- Extracorporeal Shock Wave Lithotripsy (**ESWL**)  
for the treatment of urinary stones



- High Intensity Focused Ultrasound (**HIFU**)  
for the treatment of prostate cancer



## Global Presence



- 150 employees
- HQ in Lyon, France
- NASDAQ: EDAP



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# Lithotripsy

Extracorporeal Shock Wave  
Lithotripsy (“ESWL”)  
for the treatment of  
Urinary Stones



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# Robust Lithotripsy Business Driven by Innovation

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## Recognized as "Market Gold Standard"

- Used for ~70% of urinary tract stone treatments
- Non-invasive, no pain, no anesthetic

## Attractively positioned among global leaders

- One of the largest installed bases ( $\approx$  500 machines)
- Broad range of products with innovative & patented ECL shock wave technology (strong IP portfolio)

## Robust revenue platform

- Stable and mature replacement market with strong revenue stream from maintenance services
- Market share growth through innovation
- Significant market opportunity with totally renewed product range and recent market clearances in major markets



# Lithotripsy Growth Strategy

## Build US Presence to grow US sales

- Full range of products approved with US FDA 510(k)
- Hired two US-based Senior Sales managers
- CEO relocated to Austin, TX in August 2012

## Deepen Global Penetration

- Leverage from wide range of innovative devices serving all market segments
- Promote additional services to capitalize on global network (eg. Lumenis Urological Lasers in France, MMS Urodynamics products in Japan)
- Pursuing approvals in new markets for all products
- Expand network in high growth markets



Sonolith®  
i-move



Sonolith®  
i-sys



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# “HIFU”

High Intensity Focused Ultrasound  
for the treatment of  
Localized  
Prostate Cancer



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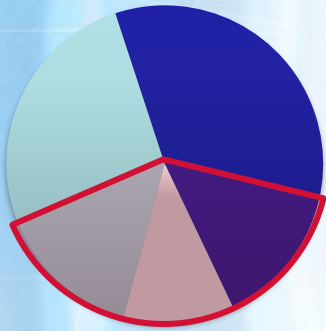
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# Localized Prostate Cancer Market Potential

## Treatment patterns for primary treatment

- Surgery
- Radiotherapy
- No Treatment



- ✓ 239,000 new cases diagnosed every year in U.S.<sup>1</sup> / 380,000 in EU<sup>2</sup>
- ✓ 35% undergo Radical Surgery, 45% Radiotherapy (20%-50% considered as “overtreatment” and “overly aggressive”)
- ✓ 20-25% undergo stressful Active Surveillance (“A.S.”)  
(1/3 leave A.S. within 1 year to get a radical treatment  
>50% initiate radical treatment within 5 years<sup>3</sup>)
- ✓ Cancer care has moved from a cure at all cost mentality to a balance of efficacy and quality of life preservation



**HIFU target market – primary treatment:**  
**100,000 treatments / year in U.S.**  
**200,000 treatments / year in EU**

<sup>1</sup>cancer.org ; <sup>2</sup> Eur. J. Cancer 46, 3040–3052 (2010); <sup>3</sup>J Urol. 2000 Jul;164(1):81-8.

# Localized Prostate Cancer Market Potential

## Treatment patterns for salvage treatment

- ✓ 90,000 radiotherapies per year in U.S. & 130,000 per year in EU
- ✓ Population of patients treated with radiation therapy is expanding
- ✓ 30%-40% fail after 5 years
- ✓ Majority of failed patients receives palliative hormonal treatment despite the fact that many have curable disease
- ✓ Current options have high morbidity.
- ✓ Robotic HIFU is an ideal therapy for these men



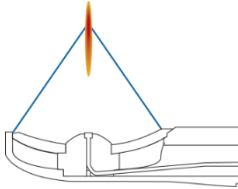
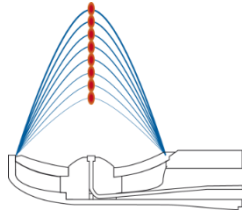


**HIFU target market – salvage treatment:**  
30,000 treatments / year in US  
45,000 treatments / year in EU

**HIFU total target market (primary+salvage):**  
130,000 treatments / year in U.S.  
245,000 treatments / year in EU



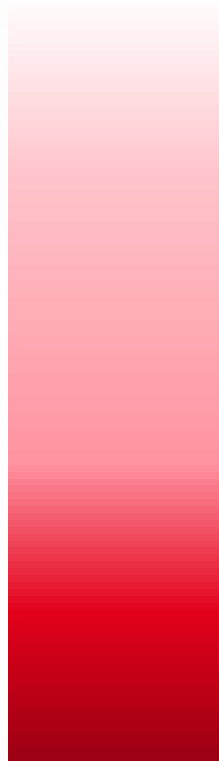
# Robotic HIFU range: different technical features

		
Robotic HIFU Technology	✓	✓
Real-time Imaging	✓	✓
Automatic Safety Features	✓	✓
HIFU Probe Focusing		
MRI Import		✓
MR / U/S elastic Fusion		✓
Contour tracking		✓
Treatment Validation and Completion		✓

# Robotic HIFU range: different clinical positioning

Technical Requirements

Radical  
Hemi-  
ablation  
Nerve-  
sparing  
Focal



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# Robotic HIFU range: full market coverage

**Ablatherm®**  
HIFU INTEGRATED IMAGING



Clinical indications

**Focal•One**



**Ablatherm Market**

**Focal•One Market**

Non Surgery-oriented urologists

Surgery-fan urologists

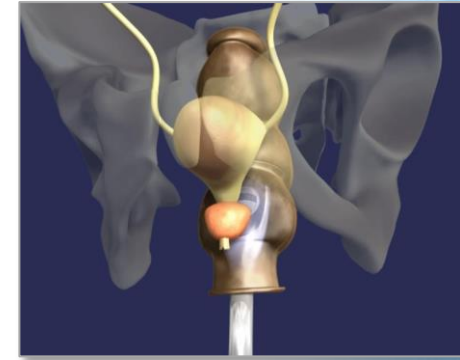
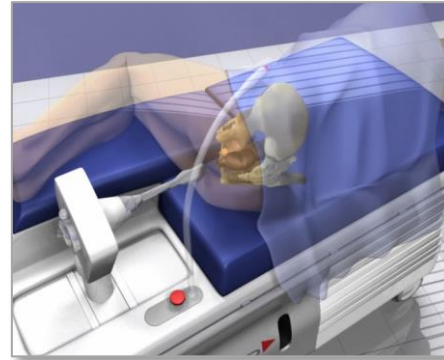


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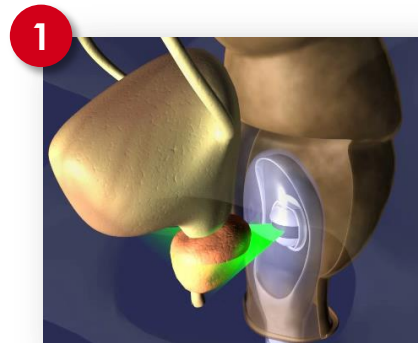
# Robotic HIFU Principles

**Non-invasive Transrectal treatment for accurate contact-free destruction of targeted area**

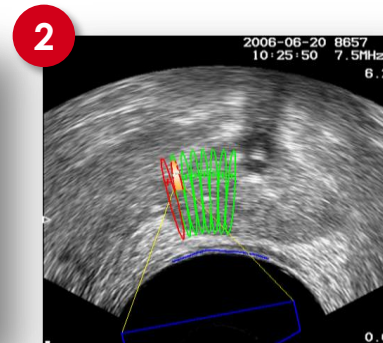


**Three major steps for a robotic treatment with automatic safety features:**

- ✓ Rectal Cooling System
- ✓ External Movement Detection
- ✓ Rectal Wall Position Monitoring



3D imaging



Treatment planning



Robotic therapy:  
real time control and  
applicator adjustment

# Clinical evidence

## Solid clinical backup

- 35,000 procedures performed & 70+ peer-reviewed publications
- 98% cancer specific survival at 10 years<sup>1</sup>
- 95% metastasis free rate at 10 years<sup>1</sup>
- Low morbidity:
  - ✓ 3.3% incontinence<sup>1</sup>
  - ✓ 65% preservation of erectile function<sup>2</sup> (85% with nerve-sparing strategy<sup>3</sup>)

 Entering the US market with a firmly established therapy is a unique opportunity.

**US Market entrance (and ROW inflection) awaits FDA decision**

<sup>1</sup> Thuroff et al. J. Urol. 2013 Feb 12 [Epub ahead of print]; <sup>2</sup> Ganzer et al. - 2013 BJUI [doi:10.1111/j.1464-410X.2012.11715.x]; <sup>3</sup> D'Hont et al. P088 EMUC 2012

# Ablatherm HIFU in the US: Next Steps

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## Validated steps (as of May 20, 2013):

- PMA Submitted to FDA in January 2013
- Administrative Acceptance in February 2013
- Filing Acceptance of PMA on March 26, 2013

## Upcoming steps:

- 100 days review meeting with FDA scheduled June 3, 2013
- Panel of experts meeting is likely
- Preparing marketing initiatives for commercial launch
- Initiating reimbursement process and market positioning





# EDAP's HIFU Development Pipeline & Upcoming Milestones

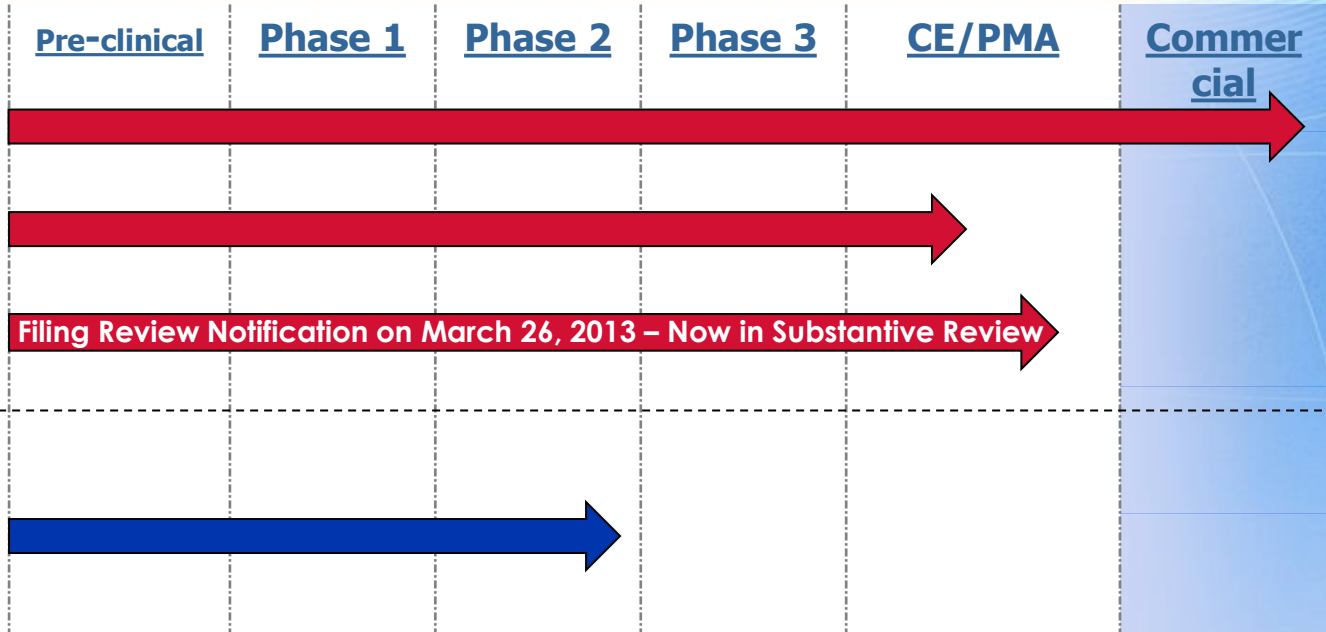
## Ablatherm HIFU

• Europe

• China

• United States

(beyond Prostate Cancer)  
HIFU for Liver Metastases  
(& Pancreatic cancer)



+ Robust portfolio of HIFU patents for a wide range of further oncology applications



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# Key Selected Financial Highlights

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## As of March 31, 2013:

- FY 2012 Euros 26.1 million (USD 33.7 million) total revenues, i.e 16.8% growth y/y
- 1st Quarter 2013 Euros 5.9 million (USD 7.8 million) total revenues, i.e 22.5% growth y/y
- US\$8.0 million outstanding debt with June 2014 maturity
- Cash position of EUR 7.3 million, or USD 9.3 million, as of March 31, 2013
- 18.8 million outstanding shares
- Full financial statements available at [investors.edap-tms.com/sec.cfm](http://investors.edap-tms.com/sec.cfm)



# Highlights

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## ➤ US market expansion

- ✓ Recent sales initiatives to drive penetration in US lithotripsy market
- ✓ Final sprint towards Ablatherm HIFU FDA clearance for prostate cancer
- ✓ Build US organization to grow HIFU and Litho revenues

## ➤ Significant market potential for HIFU proven treatment of prostate cancer

- ✓ Patient profile evolution drives potential
- ✓ New focal therapy treatment paradigm
  - UK NICE Guidance issued April 2012: *“potential for focal HIFU to avoid many of the complications of more radical treatment procedures”*
- ✓ Strong IP – comprehensive clinical data

## ➤ Robust lithotripsy business platform

- ✓ Expanding worldwide presence - Strong installed base
- ✓ Totally renewed range of products with latest innovation
- ✓ Robust revenue platform to reach operating profitability





**Thank You !**



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