



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

**Global Leader in  
Therapeutic  
Ultrasound**

May 2013



Bringing New Horizons to Therapy

*Leader in Therapeutic Ultrasound*

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# Company Profile

## Two Major Urology Indications

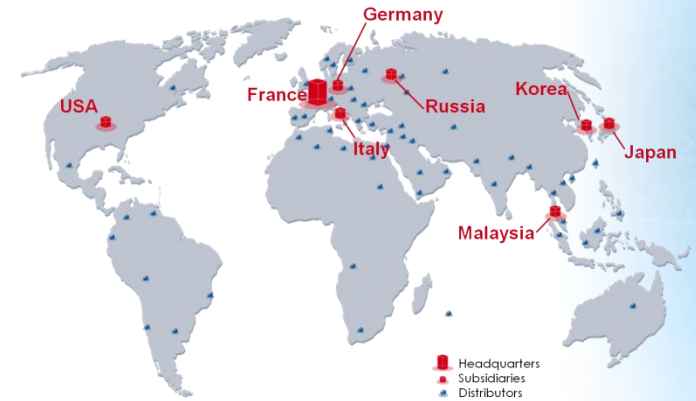
- **Extracorporeal Shock Wave Lithotripsy (“ESWL”)**  
for the treatment of urinary stones



- **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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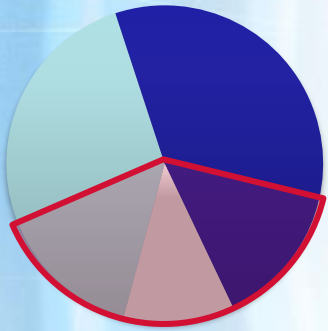
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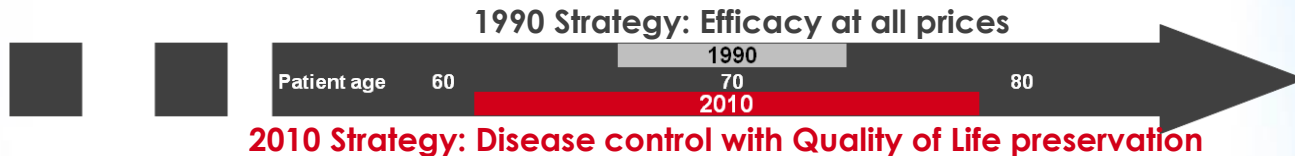
# Localized Prostate Cancer Market Potential

## 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



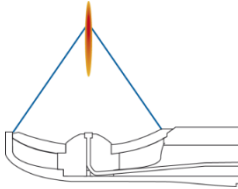
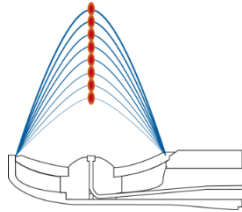


**HIFU target market – salvage treatment:**  
**30,000 treatments / year in US**  
**45,000 treatments / year in EU**

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



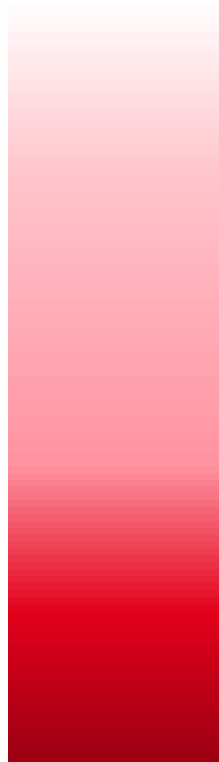
# Robotic HIFU range: different technical features

		
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**



Non Surgery-oriented urologists

Surgery-fan urologists

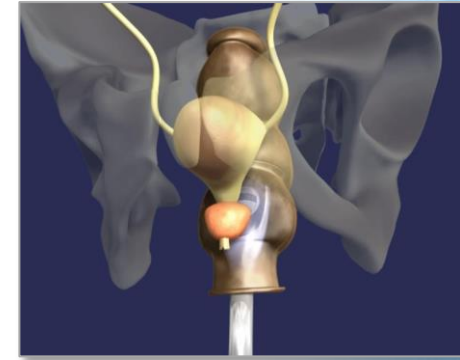
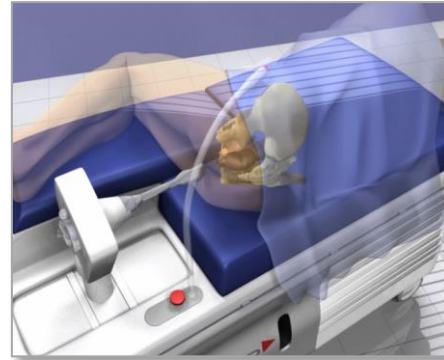


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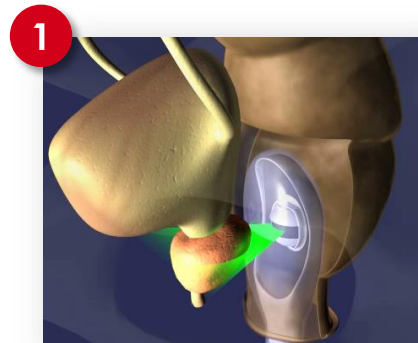
# Robotic HIFU Principles

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

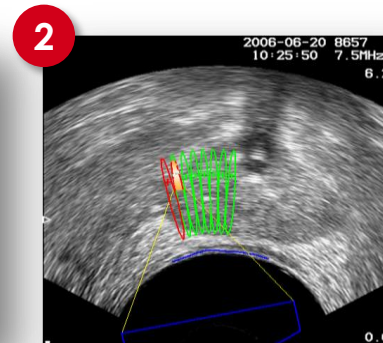


**Three major steps for a robotic treatment with automatic safety features:**

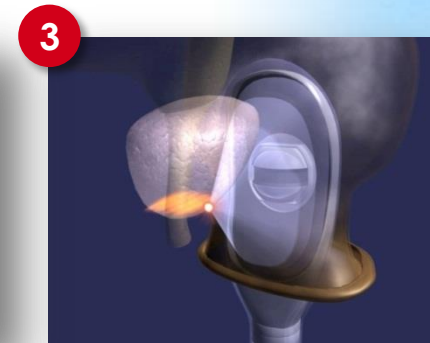
- ✓ Rectal Cooling System
- ✓ External Movement Detection
- ✓ Rectal Wall Position Monitoring



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

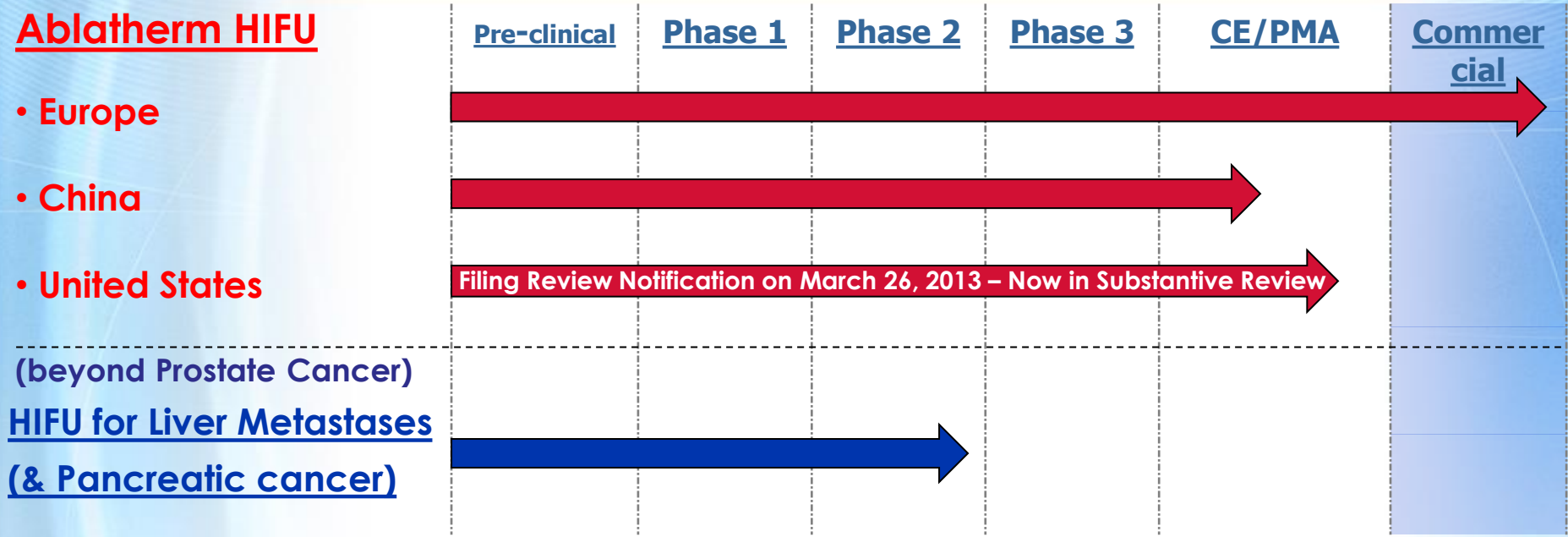
## Upcoming steps:

- 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



+ 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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