



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

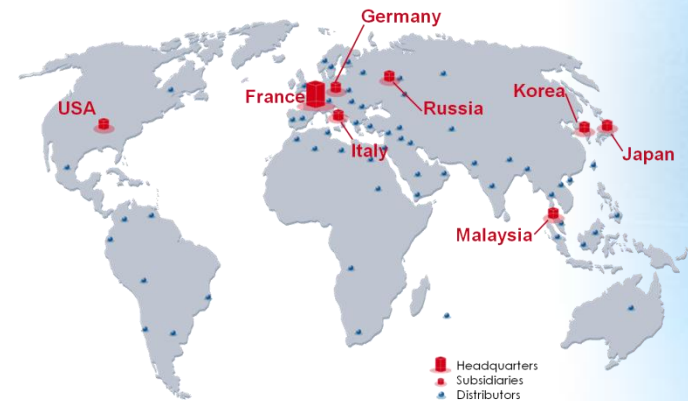
- Extracorporeal Shock Wave Lithotripsy (“ESWL”)
for the treatment of urinary stones



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



Global Presence



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





Lithotripsy

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



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Robust Lithotripsy Business Driven by Innovation

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



“HIFU”

High Intensity Focused Ultrasound
for the treatment of
Localized
Prostate Cancer



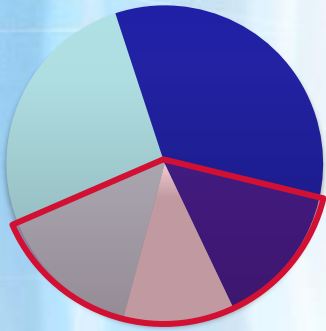
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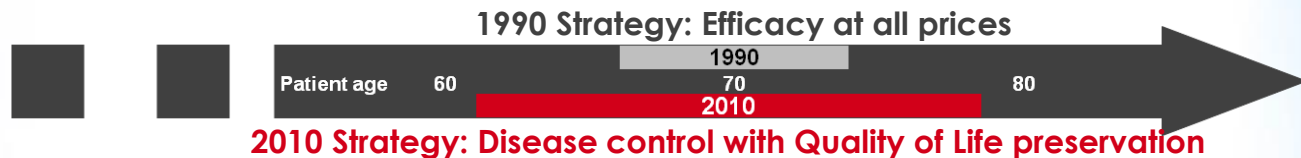
Localized Prostate Cancer Market Potential

Treatment patterns for primary treatment

- Surgery
- Radiotherapy
- No Treatment



- ✓ 239,000 new cases diagnosed every year in U.S.¹ / 380,000 in EU²
- ✓ 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 years³)
- ✓ 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

¹cancer.org ; ² Eur. J. Cancer 46, 3040–3052 (2010); ³J 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



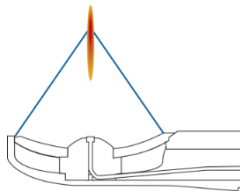
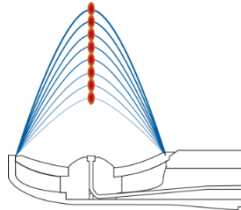
HIFU total target market (primary+salvage):

130,000 treatments / year in U.S.

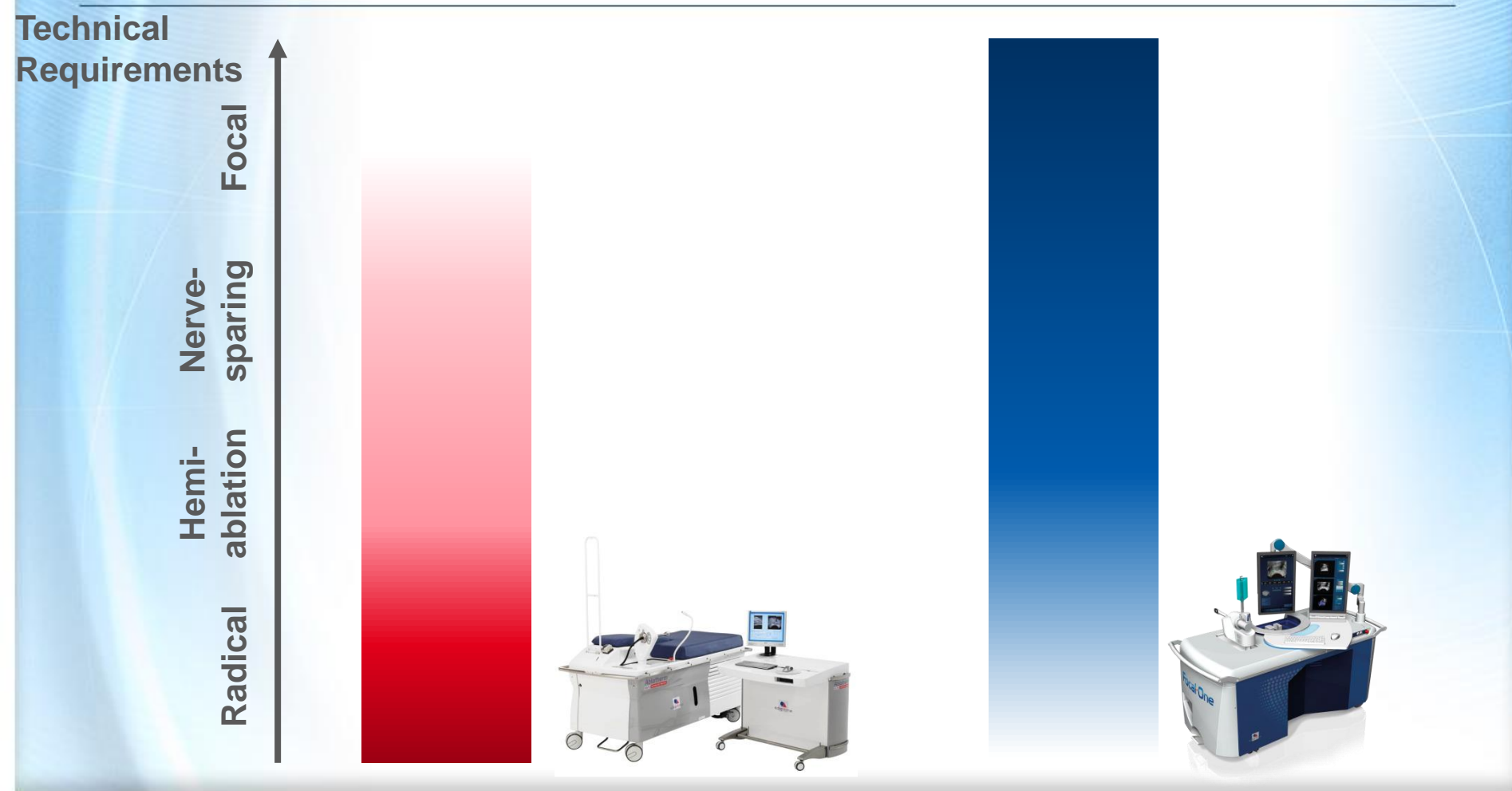
245,000 treatments / year in EU



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



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

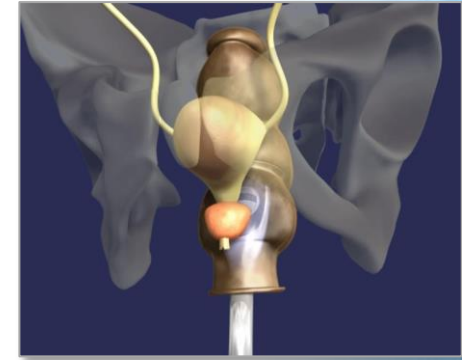
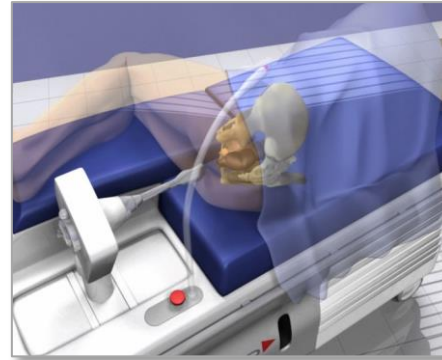


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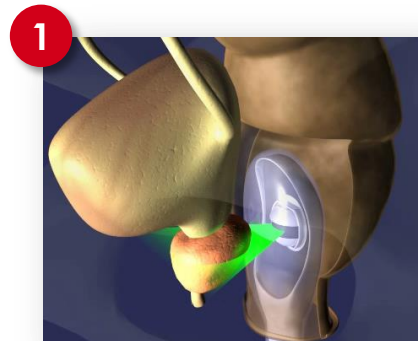
Robotic HIFU Principles

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

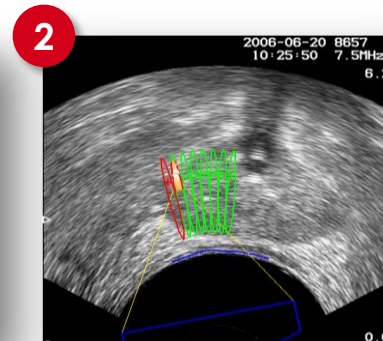


Three major steps for a robotic treatment with automatic safety features:

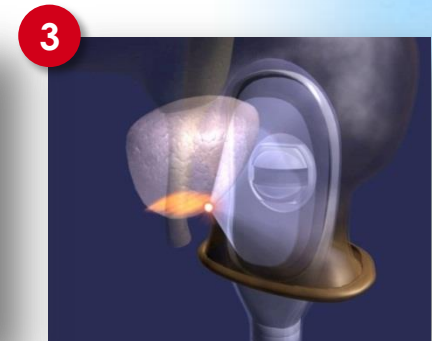
- ✓ Rectal Cooling System
- ✓ External Movement Detection
- ✓ Rectal Wall Position Monitoring



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 years¹
- 95% metastasis free rate at 10 years¹
- Low morbidity:
 - ✓ 3.3% incontinence¹
 - ✓ 65% preservation of erectile function² (85% with nerve-sparing strategy³)

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

US Market entrance (and ROW inflection) awaits FDA decision

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

Ablatherm HIFU in the US: Next Steps

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

Pre-clinical

Phase 1

Phase 2

Phase 3

CE/PMA

Commer
cial

Filing Review Notification on March 26, 2013 – Now in Substantive Review



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Key Selected Financial Highlights

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



Highlights

➤ 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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