



EDAP TMS
Investor Presentation

**Global Leader in
Therapeutic
Ultrasound**

May 2013



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, nor shall there be any sale of these securities in any jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Any offer or sale of securities may be made only by means of a prospectus and a related prospectus supplement (collectively, the “Prospectus”), which will be filed with the Securities and Exchange Commission.

The presentation is being furnished to you solely for your information, and may not be copied, reproduced, distributed or passed, directly or indirectly, in whole or in part, to any other person.

This presentation includes only summary information and does not purport to be complete. Any information in this presentation is subject to modification at any time and the Company undertakes no obligation to update you, except to the extent required by applicable law. If an offer of securities is made by the Company in the future, prospective investors should rely solely on the Prospectus, including the information incorporated by reference into the Prospectus. No reliance may be placed for any purposes whatsoever on the information contained in this presentation, or on its completeness, accuracy or fairness. It is the responsibility of each prospective investor to review the Prospectus, including the information incorporated by reference into the Prospectus, carefully and to make an independent assessment of the risks and merits of any such offering.



Forward-Looking Statements

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

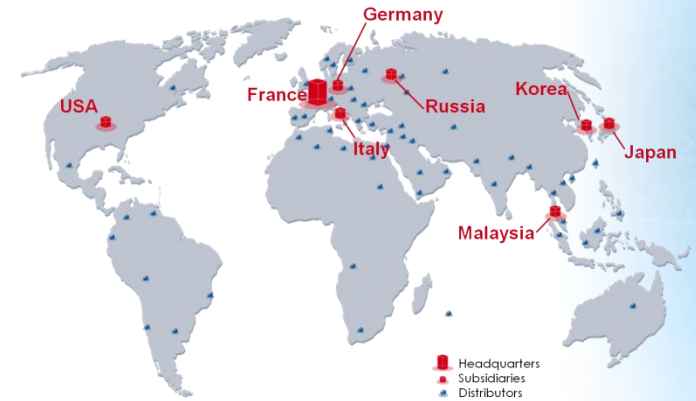
- **Extracorporeal Shock Wave Lithotripsy (“ESWL”)**
for the treatment of urinary stones



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



Global Presence



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



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound



Lithotripsy

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



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

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



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound



“HIFU”

High Intensity Focused Ultrasound
for the treatment of
Localized
Prostate Cancer



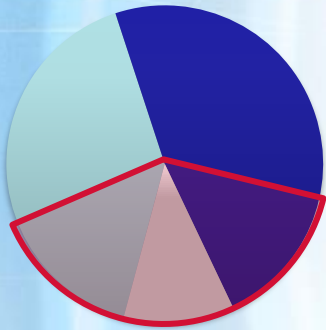
Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

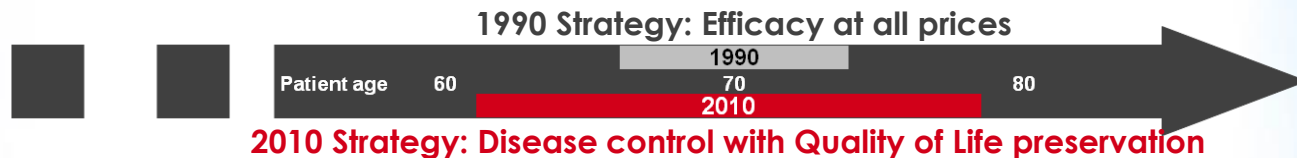
Localized Prostate Cancer Market Potential

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



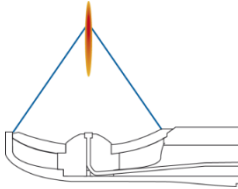
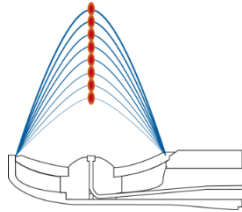


HIFU target market – salvage treatment:
30,000 treatments / year in US
45,000 treatments / year in EU

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



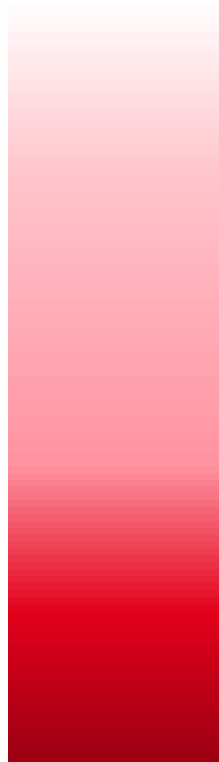
Robotic HIFU range: different technical features

		
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

Technical Requirements

Radical
Hemi-ablation
Nerve-sparing
Focal



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

Robotic HIFU range: full market coverage

Ablatherm®
HIFU INTEGRATED IMAGING



Clinical indications

Focal•One



Non Surgery-oriented urologists

Surgery-fan urologists

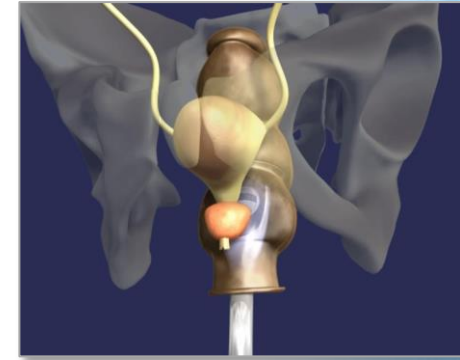
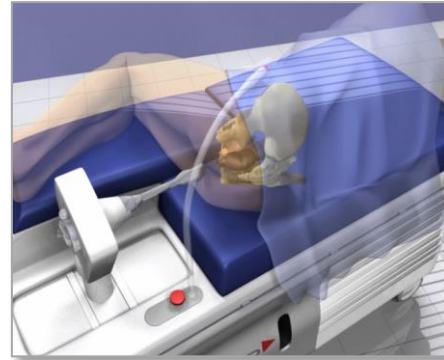


Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

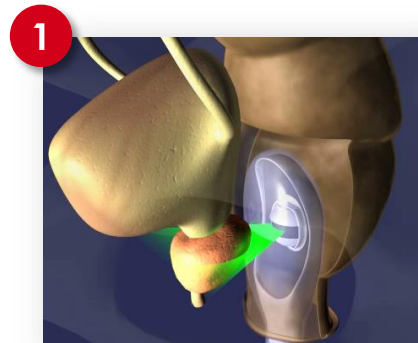
Robotic HIFU Principles

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

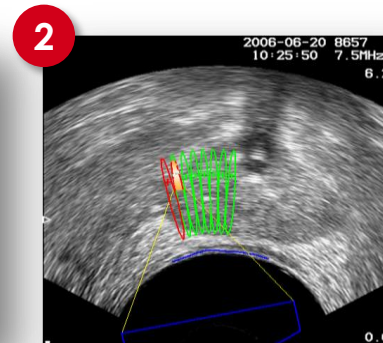


Three major steps for a robotic treatment with automatic safety features:

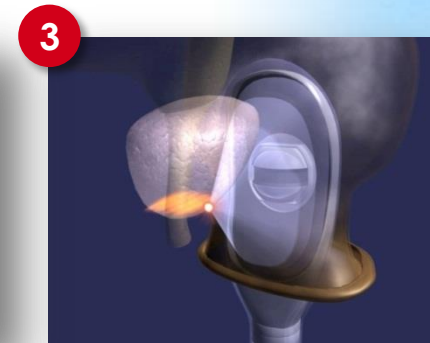
- ✓ Rectal Cooling System
- ✓ External Movement Detection
- ✓ Rectal Wall Position Monitoring



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):

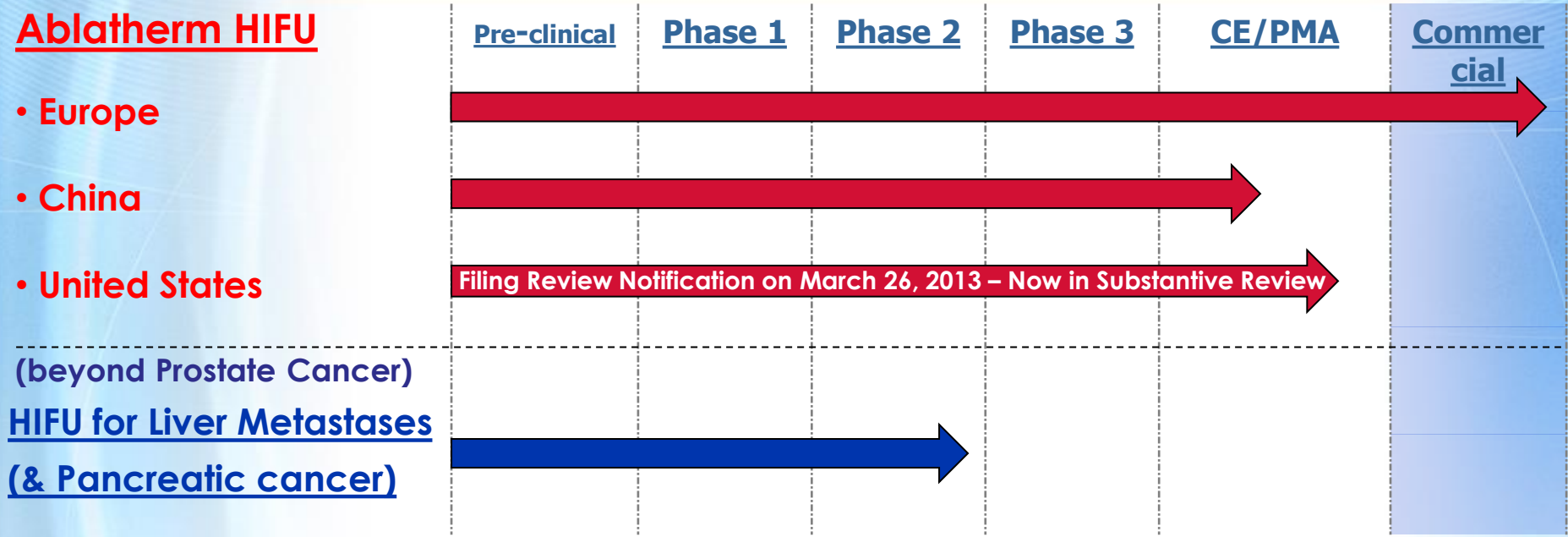
- PMA Submitted to FDA in January 2013
- Administrative Acceptance in February 2013
- Filing Acceptance of PMA on March 26, 2013

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



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



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound

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 !



Bringing New Horizons to Therapy

Leader in Therapeutic Ultrasound