

# edap tms

(NASDAQ: EDAP)

Global Leader in Therapeutic Ultrasound

edap tms  
Bringing New Horizons to Therapy



# Forward Looking Statements

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# Investment Highlights

Innovative minimally-invasive diagnostic and therapeutic platform using ultrasound-based technologies

## HIGH INTENSITY FOCUSED ULTRASOUND (HIFU) PLATFORM

Tool for minimally invasive soft tissue ablation, currently approved for treatment of prostate cancer

## ROBUST HIFU PIPELINE

Huge potential to leverage HIFU platform in endometriosis, liver cancer, pancreatic cancer, and other soft tissue ablation indications

## EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY (ESWL)

Portfolio provides multiple solutions for the destruction of kidney and other urinary stones

## COMPANY SNAPSHOT

Direct marketing worldwide through 6 subsidiaries (USA, Germany, Italy, Japan, Malaysia, South Korea) and 2 representative offices (Emirates, Russia)

200 total employees

50+ distributors in 50 countries

# HIFU Technology

HIFU principles are similar to sun beams going through a magnifying glass

## HIFU =

Acoustic pressure or vibrations delivered to targeted cells

Intense immediate tissue heating at focal point ( $+85^{\circ}\text{C}$ )

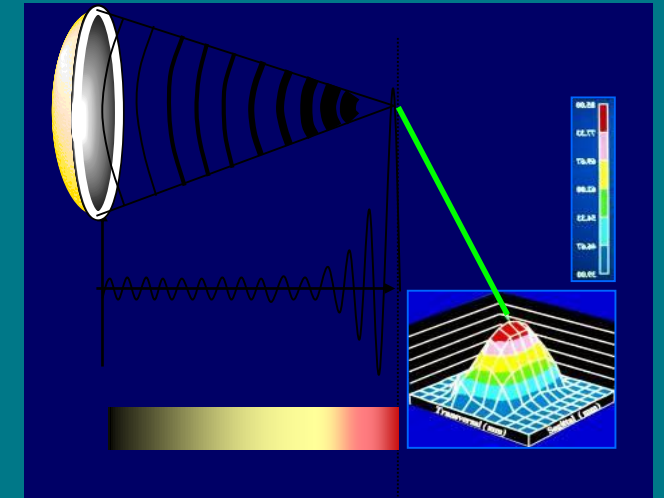
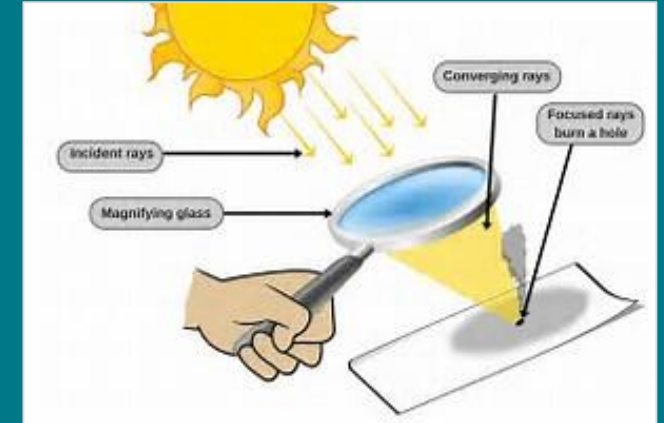
Creates cavitation i.e. tissue necrosis and cellular ablation



HIFU perfectly address medical needs for tissue ablation while preserving healthy surrounding tissue



EDAP's HIFU platform is a robotic device with highly precise mechatronics, providing image guidance with motion tracking and real-time treatment planning

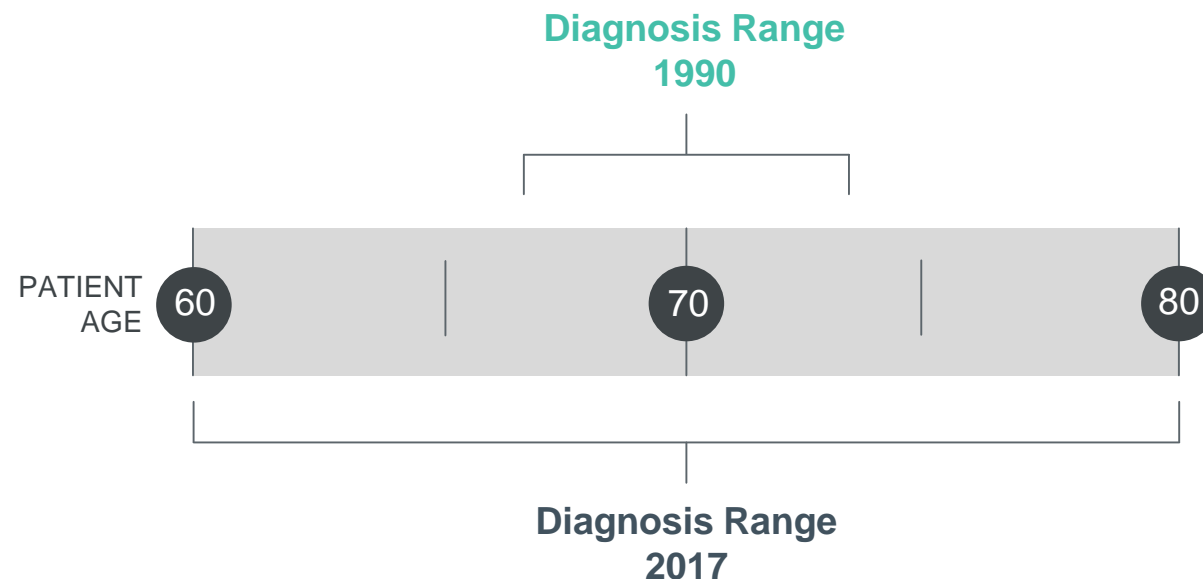


**Superior HIFU Expertise + Strong IP Portfolio**



# HIFU For Prostate Tissue Ablation

+2,9 million men in the U.S. live with prostate cancer



Prostate cancer is the most prevalent male cancer with approx. 700,000 new cases diagnosed annually worldwide

**35%** of patients undergo Radical Surgery, 45% Radiotherapy (20%-50% considered as “overtreatment” and “overly aggressive”)

**20-25%** of patients undergo stressful Active Surveillance or “A.S.” 1/3 of patients leave A.S. within 1 year for radical treatment; >50% initiate radical treatment within 5 years)

**40%** radiation failures: market caption opportunity with HIFU (80% cancer specific survival rate & 79.6% metastasis rate at 5 years)

# Strong Clinical Validation

## HIFU for Prostate Tissue Ablation

### HIGH EFFICACY

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>)

### ALSO AVAILABLE FOR SALVAGE TREATMENT

80% cancer specific survival

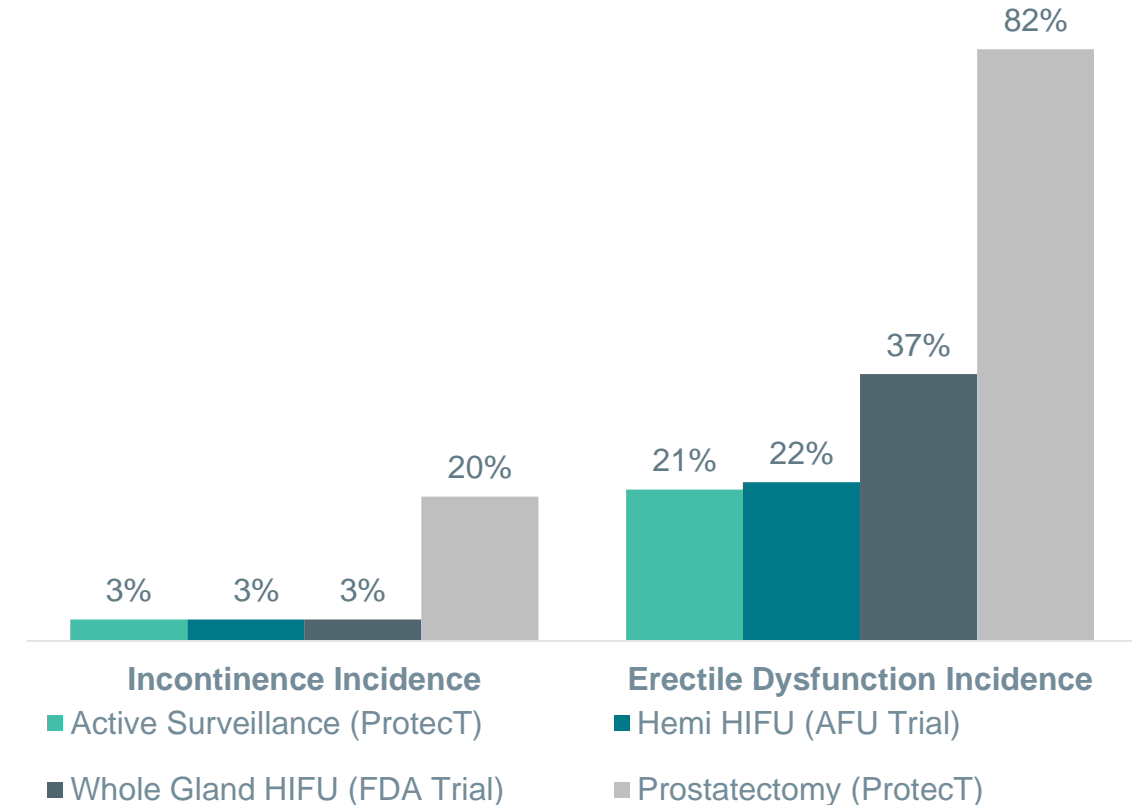
79.6% metastasis free rate at 5 years

<sup>1</sup> Thuroff et al. J. Urol. 2013 Feb; <sup>2</sup> Ganzer et al. - 2013 BJUI [doi:10.1111/j.1464-410X.2012.11715.];

<sup>3</sup> D'Hont et al. P088 EMUC 2012 ; \*Boorjian et al J Urol. 2008 Apr;179(4):1354-60;

Stephenson et al J Clin Oncol. 2009 Sep 10;27(26):4300-5

# Morbidity Comparison at 2 Years



#### Definitions:

ProtecT: ED = insufficient for intercourse, Incontinence = pad use

AFU: ED = SHIM < 17, Incontinence = pad use

FDA: ED = moderate/severe AE reporting, Incontinence = moderate/severe AE reporting

<sup>4</sup>Donovan et al NEJM 2016

<sup>5</sup>Rischmann et al European Urology 2016

<sup>6</sup>Sponsor Executive Summary PMA P13003 ([www.fda.gov](http://www.fda.gov))

# Strong Clinical Validation

## HIFU for Prostate Tissue Ablation

BJUI  
BJU International

THE JOURNAL  
of UROLOGY

American  
Urological  
Association

EUROPEAN  
UROLOGY

EAU

**Fourteen-year oncological and functional outcomes of high-intensity focused ultrasound in localized prostate cancer**

Roman Gansler, Hans-Martin Pfitzsch, Andreas Brändtner, Johannes Brandt, Dörner Koch\*, Wolf F. Meisand and Andreas Bönig

Center for Sexual Medicine, University of Regensburg, Regensburg and \*Department of Urology, Fourth Medical Faculty, Germany

**538 patients**  
**14 years of follow-up**

**Ganser et al. 2013**  
Regensburg, Germany

**Evolution and Outcomes of 3 MHz High Intensity Focused Ultrasound Therapy for Localized Prostate Cancer During 15 Years**

Stefan Thüroff\* and Christian Chauxy†

Department of Urology, University of Munich, Munich, Germany; †Urology, University of Regensburg, Regensburg, Germany

**702 patients**  
**15 years of follow-up**

**Thüroff et al. 2013**  
Munich, Germany

**Whole-gland Ablation of Localized Prostate Cancer with High-Intensity Focused Ultrasound: Oncologic Outcomes and Morbidity in 1002 Patients**

Indrakant Choudhary\*, Jean-Yves Chapelle\*, Olivier Roussel\*, Florence Migez-Lafont\*, Mary Colak\*, Nafise Tavakoli\*, Robert Marlet\*, Albert Guba\*

Department of Urology, University of Lyon, Lyon, France; \*Urology, University of Regensburg, Regensburg, Germany; †Urology, University of Regensburg, Regensburg, Germany

**1002 patients**  
**17 years of follow-up**

**Crouzet et al. 2013**  
Lyon, France

Ongoing clinical trials designed to improve treatment performance and outcomes



**+ 50,000**

HIFU treatments performed worldwide



**+ 80**

peer-reviewed publications



**+ 300**

HIFU centers in the world

# Product Offering & Positioning



	ABLATHERM FUSION <i>HIFU For Prostate Tissue Ablation</i>	FOCAL ONE <i>Premium Device for Focal Therapy in Prostate Ablation</i>
Diagnostic Information	Ultrasound + MRI Imaging	Ultrasound + MRI Imaging
Dynamic Focusing		✓
Mobile Unit	✓	
Targeted Customer	ASC & Small-Medium Hospitals	Large academic institutions
Price Point	\$320K	\$695K



# HIFU Platform Pipeline Opportunity: Rectal Endometriosis



**Affects approximately one in ten women of reproductive age**



**Current treatment modalities**

Rectal removal  
Invasive surgery



**HIFU treatment similar to prostate cancer treatment, endorectal approach**



**Clinical timeline**

Initiating phase 2 study in 2019  
CE mark submission in 2021

**AFFECTS 22 MILLION WOMEN GLOBALLY**

# HIFU Platform Pipeline Opportunity: Liver Cancer

## LIVER CANCER

Primary (Hepatocellular Carcinoma): 750,000 cases WW

Liver Metastases : 600,000 cases WW

EDAP's HIFU technology addresses liver cancer with an open-surgery approach.

## EDAP'S LIVER HIFU PLATFORM ALLOWS FOR

A necrosis of liver metastasis not accessible via surgery

A reduction of bleeding risks hence of surgery time

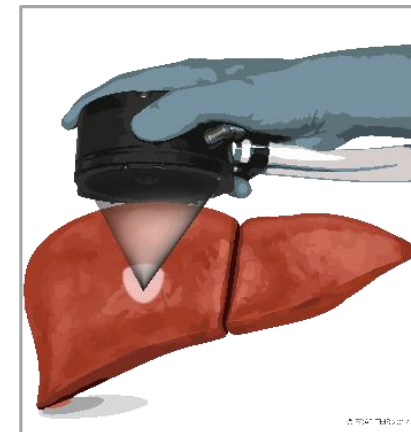
A preservation of liver volume

## CURRENT STATUS OF THE DEVELOPMENT PROGRAM:

**Phase I (single-center) Study:** Feasibility and Safety demonstrated, 26 patients treated, study soon finalized

**Phase II (multi-center) Study:** Efficacy to be demonstrated, 4 Liver HIFU platforms prototypes to be placed in clinical centers (2018-2019)

**CE mark submission anticipated in 2022**



# HIFU Platform – One EDAP HIFU in Each Operating Room

Diagnostic and Therapeutic Tool for Every OR to Serve Multiple Soft Tissue Ablation Indications

## Pursuing numerous specific indications...

- Pancreatic Cancer
  - Pre-clinical trials ongoing
  - Phase 1 study to be initiated in 2021
- Breast Cancer
  - Pre-clinical trials ongoing
- Gynecology
  - Treatment of placenta accrete
  - Pre-clinical trials to be initiated

## ...But ultimately a platform for broad applications

- “EDAP Inside”
  - HIFU as a useful diagnostic imaging tool
  - HIFU as a valuable therapeutic tool to treat any condition requiring soft tissue ablation

**EDAP's HIFU platform will be for soft tissue ablation what multi-purpose robotic systems are to surgery.**

# Lithotripsy for Treatment of Kidney Stones



Urinary stones are most the prevalent pathology of the urinary tract, affecting 5% to 7% of women and 10% to 12% of men



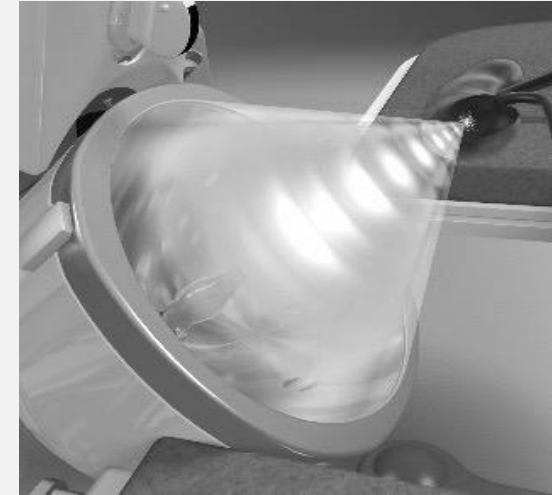
Lithotripsy provides an alternative to open kidney surgery, which is the the gold standard for most urinary stones



EDAP is one of the world leaders in the field with an installed base of more than 700 lithotripsy devices



Product portfolio: (a) Treatment of urinary stones is a mature market, but it is dynamic and subject to a burgeoning replacement cycle (b) EDAP market share...



# ESWL Platform



	Sonolith i-move	Sonolith i-sys
Concept System	Fully Modular	Fully Integrated and Robotized
Unique Patented VT	✓	✓
Exclusive ECL Technology	✓	✓
Targeted Customer	ASC & Partnership Model	Large academic institutions
Price Point	\$250K-\$420k	500K



# EDAP Product Categories Summary

## HIFU MARKET SIZE

### Prostate Cancer

- 700,000 new annual cases worldwide
- +165,000 new cases / year in the U.S.
- +2,9 million men in the U.S. live with prostate cancer

### Rectal Endometriosis

- 22 million women worldwide
- CE mark submission in 2021

### Liver Cancer

- 600,000 liver metastasis patients worldwide
- CE mark submission in 2022

### The potential for HIFU Ablation of Soft Tissue

- Diagnostic and therapeutic tool for every operating room
- Current focus on liver and pancreatic cancer, and endometriosis

## LITHOTRIPSY

### Stable Market Opportunity for Urinary Stones

- Affects 10-12% of men and 5-7% of women

### Market Leading Technology Via Multiple Techniques

- Electroconductive versus Piezoelectric

### Complete Stone Management

- Offering both fully-integrated and modular systems

### Solid Replacement Cycle Opportunity

- Modular offering may drive upgrade activity

# Experienced Management Team

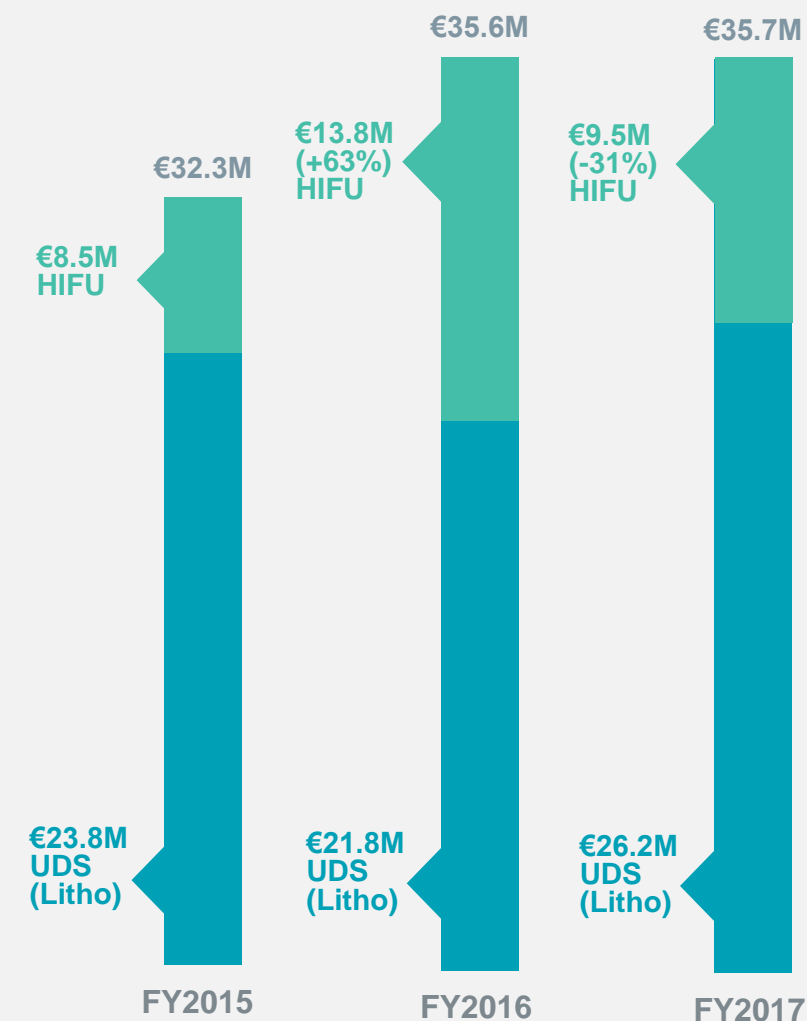
Executive	Title	Years at EDAP	Previous Experience
Marc Oczachowski	Chief Executive Officer	20	
Francois Dietsch	Chief Financial Officer	13	
Emmanuel Blanc	Chief Technology Officer	29	  
Hugo Embert	Chief Marketing Officer	10	 
Emmanuel Carre	VP, Industrial Operations	14	

# Key Financial Data

(in €Millions except per share data)

	Nine Months Ended September 30,		Twelve Months Ended December 31,	
	2018	2017	2017	2016
Revenue	€25.9	€25.1	€35.7	€35.6
Gross Profit	10.9	10.4	14.8	16.4
Gross Margin	42.3%	41.4%	41.4%	46.1%
Operating Profit (Loss)	(2.2)	(1.8)	(2.0)	0.4
Net Income (Loss)	(1.4)	(0.6)	(0.7)	3.8
Earnings (Loss) Per Share	(0.05)	(0.02)	(0.02)	0.13

## Revenue Growth



# Balance Sheet Highlights

	Balance Sheet As Of:		
(in €Millions)	September 30, 2018	December 31, 2017	December 31, 2016
Cash & Cash Equivalents	€ 15.9	€ 20.0	€ 22.0
Total Assets (excl. Cash)	8.2	7.2	5.8
Working Capital Requirements	7.0	5.9	5.7
% of net sales	19.0%	16.6%	16.2%
	31.0	33.2	33.5
Long-term Liabilities (*)	7.2	8.0	9.1
Shareholders' Equity	23.9	25.2	24.5
	31.0	33.2	33.5



Robust financial profile



Strong cash management,  
significant cash position of €15.9M  
as of September 30, 2018

(\*) includes non-cash fair value of warrants of €3.9M in 2016, €0.8M in 2017 and €0M as of Sept. 30, 2018

# Company Summary

Innovative minimally-invasive diagnostic and therapeutic tools using ultrasound-based technologies



## High Intensity Focused Ultrasound (HIFU)

Platform offers a minimally invasive tool for soft tissue ablation, currently approved for use in the treatment of prostate cancer

## Robust HIFU Pipeline

Opportunities to expand HIFU applications to treat endometriosis, liver cancer and pancreatic cancer

## Extracorporeal ShockWave Lithotripsy (ESWL)

Portfolio provides multiple solutions for the destruction of kidney and other urinary stones



An overhead view of four people working at a large, circular wooden table. The table is cluttered with various items: four computer monitors, several keyboards, mice, stacks of papers, folders, a small potted plant, a coffee cup, and a red wallet. The people are seated around the table, each with their own workspace. The text "THANK YOU!" is overlaid in the center of the image.

# THANK YOU!