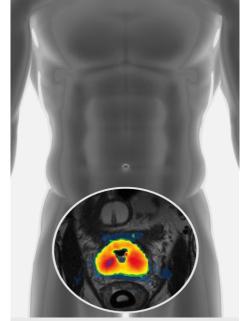
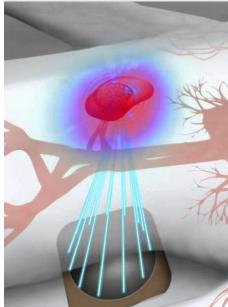
# PROFCUND MEDICAL

**Incision-free Surgery Real-Time MR Guided Ultrasound Therapies** 







TULSA-PRO®

**Prostate Disease** 

CORPORATE PRESENTATION | NOVEMBER 2017

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# FORWARD-LOOKING

#### **STATEMENTS**

Certain statements in this presentation and oral statements made during this meeting may contain "forward-looking statements" within the meaning of applicable securities laws, including the "safe harbour provisions" of the Securities Act (Ontario), with respect to Profound Medical Corporation ("Profound" or the "Company"). Such statements include all statements other than statements of historical fact contained in this presentation, such as statements that relate to the Company's current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to", "is/are projected to" or the negative of these terms, or other similar expressions, as well as future or conditional verbs such as "will", "should", and "could" intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its product, expectations regarding the use of its product and its revenue, expenses and operations, plans for and timing of expansion of its product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, manufacturers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in its product markets, competitive position and its expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound's business and the markets in which it operates.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, the risks and uncertainties discussed in the "Risk Factors" section in the Company's Annual Information Form dated March 28, 2017, such as successful completion of clinical trial phases with respect to Profound's device, obtaining regulatory approvals in relevant jurisdictions to market Profound's device, risks related to the regulation of Profound (including the healthcare markets, lack of funding may limit the ability to commercialize and market Profound's products, fluctuating input prices, international trade and political uncertainty, healthcare regulatory regime in relevant jurisdictions may affect the Company's financial viability, reimbursement models in relevant jurisdictions may not be advantageous), competition may limit the growth of Profound, if the Company breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business, loss of key personnel may significantly harm Profound's business and past performance is not indicative of future performance, and such other risks detailed from time to time in the other publicly filed disclosure documents of the Company which are available at www.sedar.com. The Company's forward-looking statements are made only as of the date of this presentation and, except as required by applicable law. Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by applicable law. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events co

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# INCISION-FREE PROCEDURES

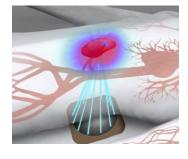
## **REAL-TIME MR GUIDED TREATMENTS**







Ultrasound 'Inside-Out'

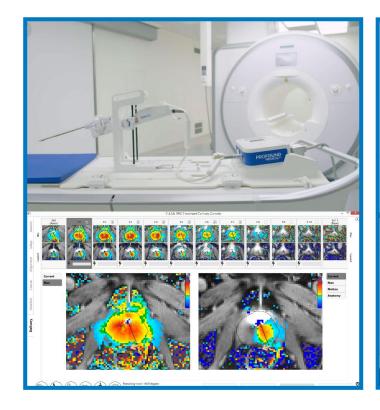


Ultrasound 'Outside-In'

Only company to provide a therapeutics platform that provides the precision of real-time MR imaging combined with the safety and ablation power of directional (inside-out) and focused (outside-in) ultrasound technology for the incision-free ablation of diseased tissue

# **TULSA-PRO & SONALLEVE**

# PLATFORM: REAL-TIME MR THERMOMETRY & CLOSED LOOP TEMPERATURE CONTROL





- Current applications Prostate (TULSA-PRO), uterine fibroids & bone metastases (Sonalleve)
- Future potential Abdominal cancers, hyperthermia for cancer therapy, pediatrics

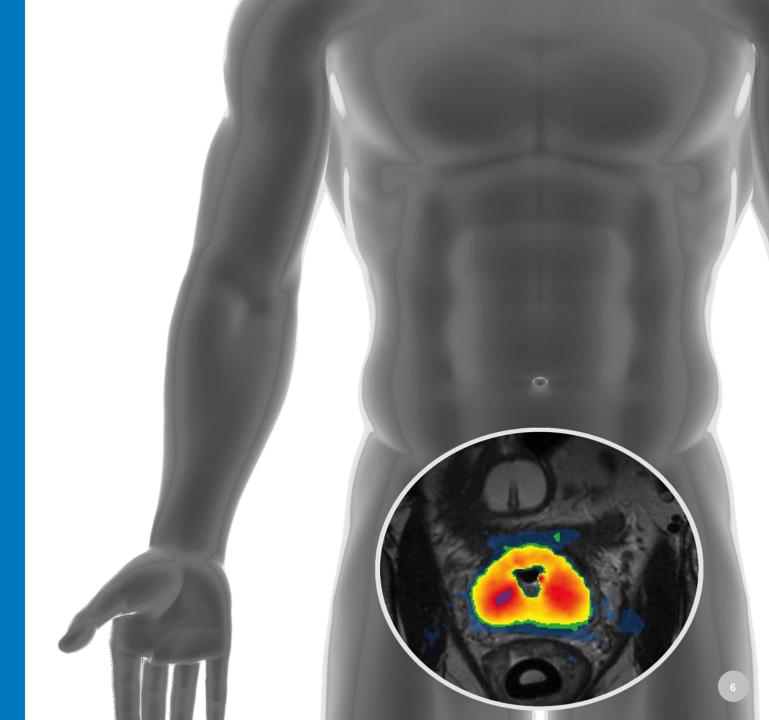
# **INCISION-FREE PROCEDURES**

# **REAL-TIME MR GUIDED TREATMENTS**

# Therapeutic solutions that are

- 1 Precise
- 2 Safe
- 3 Personalized

# Prostate Treatment



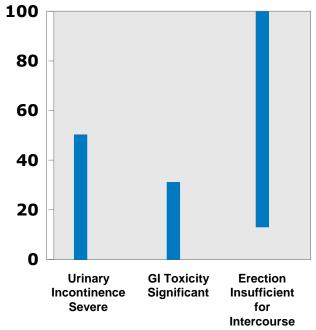
# TODAY'S THERAPIES SIDE EFFECTS

#### Functional Outcomes at 2 years1

	PROSTATECTOMY	RADIOTHERAPY	
URINARY INCONTINENCE	No control or frequent urinary leakage		
	10%	3%	
	Bothered by dripping or leaking urine		
	11%	2%	
BOWEL FUNCTION	Bowel urgency		
	14%	34%	
	Bothered by frequent bowel movements, pain, or urgency		
	3%	8%	
SEXUAL FUNCTION	Erection insufficient for intercourse		
	79%	61%	
	Bothered by sexual dysfunction		
	56%	48%	

#### Rate of complications reported with radical prostatectomy & radiotherapy<sup>2,3</sup>

(Variation as reported in 436 publications)



<sup>1.</sup> Resnick et al. Long-Term Functional Outcomes after Treatment for Localized Prostate Cancer; New England Journal of Medicine, 2013 (Jan): 368:436-4452.

<sup>2.</sup> Thompson (Chair) et al AUA prostate cancer clinical guideline update panel, "Guideline for the management of clinically localized prostate cancer: 2007 update," The Journal of Urology, 177: 2106-2331 (2007)3.

<sup>3.</sup> PMI 12-month Phase 1 Trial, GCP-10102 Table 10

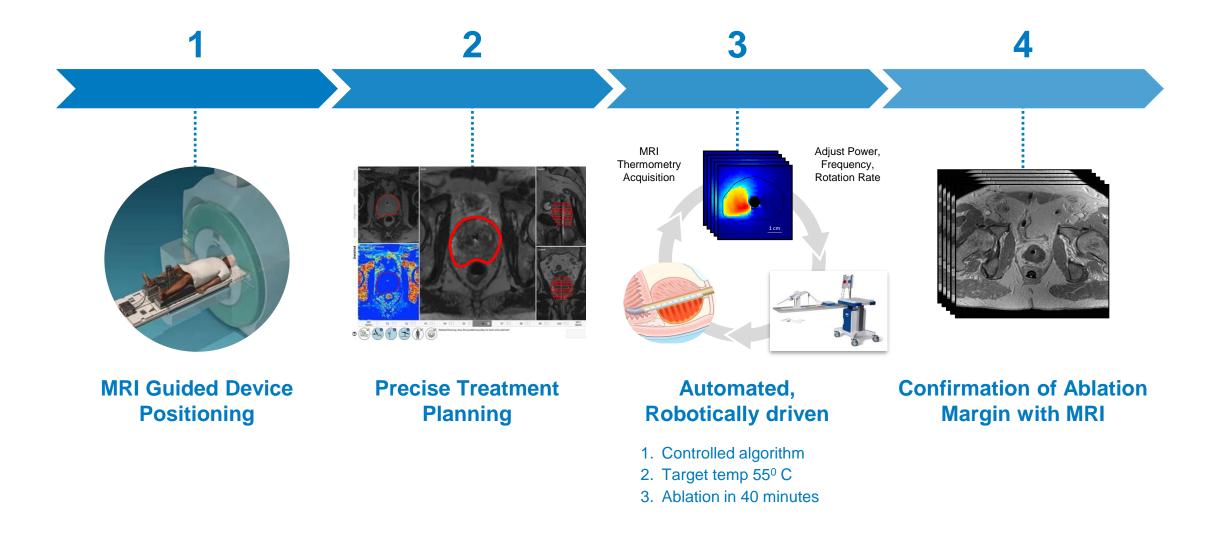
# TULSA-PRO EQUIPMENT

Compatible with MR from leading companies – Philips and Siemens



# UNIQUE INSIDE-OUT APPROACH

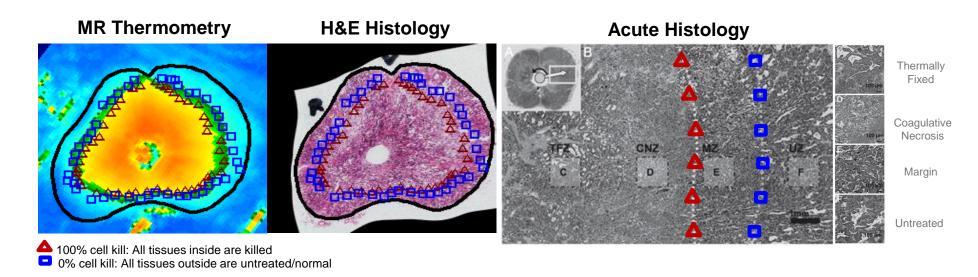
# **PROSTATE TREATMENT**



# TULSA-PRO'S PRECISION & PERSONALIZATION

#### **VALIDATED**

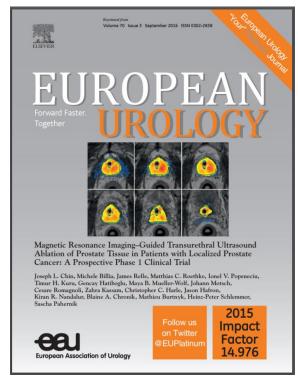
- Excellent agreement between MR Thermometry and H&E Histology: 1.4 ± 1.0 mm
- Sharp treatment margins: 1.3 ± 0.5 mm (acute), decreases to zero after 48h+



Boyes et al (2007) J Urol 178(3 Pt 1):1080-5; Chopra et al (2009) Phys Med Biol 54(9):2615-33; Siddiqui et al (2010) Urology 76(6):1506-11; Chopra et al (2012) Radiology 265(1):303-13; Burtnyk et al (2015) J Urol 193(5):1669-75; Ramsay et al, (2017) J Urol 197(1):255-261

# PHASE I CLINCIAL TRIAL COMPLETED

#### **SAFETY & FEASBILITY**



Chin et al, European Urology (2016) Bonekamp et al, Radiology (submitted)

#### **Study Population (N=30)**

Low (80%) & intermediate (20%) risk prostate cancer patients, ≥ 65 years old

#### **Treatment Plan**

 Imposed treatment margin, with 10% residual viable prostate around gland periphery

#### **Primary Endpoints & Outcomes**

- Safety Frequency and severity of adverse events
  - Erectile function (erection firmness sufficient for penetration, IIEF Item 2 ≥ 2)
     21/30 patients potent pre-treatment → 20/29 potent at 12 months
  - Urinary incontinence (pads): 0/30 patients at 12 months
  - No rectal fistula or bowel urgency
- Feasibility Conformal thermal ablation of target prostate volume
  - Median ultrasound treatment time: 36 min for 44 cc prostate volume
  - Median thermal ablation accuracy and precision: 0.1 ± 1.3 mm

#### **Secondary Endpoints & Outcomes**

- Quality of life IPSS, IIEF, UCLA-PCI-SF
  - Well-tolerated favorable safety profile with minor impact on urinary, erectile and bowel function at 12 months
- Prostate volume 88% reduction at 12 months
- PSA 87% decrease at 1 month, remained stable to 0.8 ng/ml at 12 months
- Prostate TRUS Biopsy
  - Positive clinically significant cancer: 9/29 patients (31%)
  - Positive any cancer: 16/29 (55%)
  - Positive biopsies had 61% reduction in total cancer length

# TACT PIVOTAL STUDY FOR FDA 510(k) REGISTRATION

## IN PROGRESS - N=110, Thirteen Sites, Treated 73 as at November 7, 2017

#### **Study Population**

• Low & intermediate risk prostate cancer patients, 45 – 80 years old

#### **Treatment Plan**

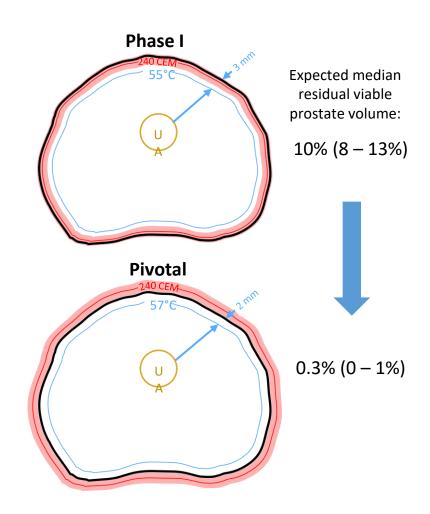
 Reduced margin, with < 1% residual viable prostate around gland periphery

#### **Primary Endpoints**

- · Safety Frequency and severity of adverse events
- Efficacy PSA reduction ≥ 75%
  - Proportion of patients achieving PSA nadir ≤ 25% of the pre-treatment baseline value
  - Performance goal for the success proportion is 50% of patients

#### **Secondary Endpoints**

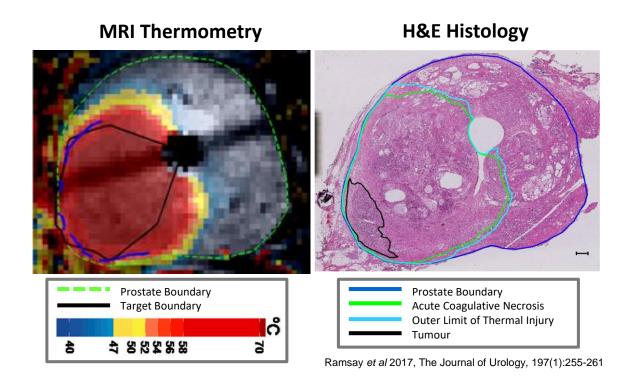
- Prostate volume reduction on MRI at 12 months
- PSA nadir & stability % patients with PSA ≤ 0.5 ng/ml at nadir & 12 months
- Prostate TRUS biopsy % patients with negative biopsy at 12 months
- Erectile function Change in % patients with IIEF-5 ≥ 17
- Erection firmness sufficient for penetration Change in % patients with IIEF item 2 ≥ 2
- Urinary incontinence Change in % patients using ≥ 1 pad / day
- Quality of life IPSS, IIEF-15 & EPIC-50
- Targeting accuracy Accuracy and precision of conformal thermal ablation of target prostate volume



# TARGETED ABLATION (FOCAL THERAPY)

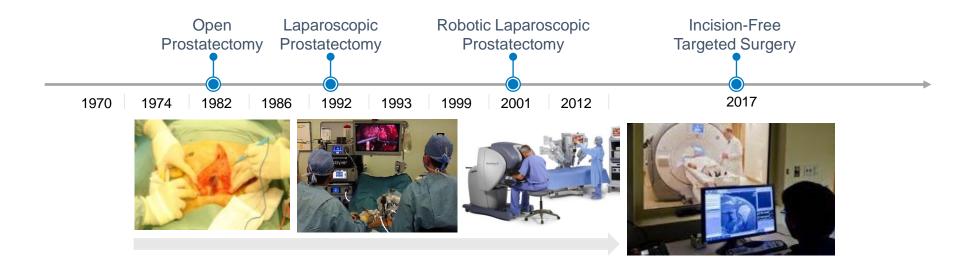
## **CLINICAL HISTOLOGY**

- Treat-and-resect clinical study, targeting MRI-visible lesion with TULSA (n=5)
- TULSA followed by Radical Prostatectomy on same day
- Demonstrated complete ablation of target lesion to prostate capsule on goldstandard whole-mount histology
- Treatment accuracy with respect to histology: -0.4 ± 1.7 mm
- All index tumors were inside the histological outer limit of thermal injury



# FROM OPEN SURGERY

# **TO INCISION-FREE SURGERY**



SURGERY TYPE	FULL PROSTATE REMOVAL	FLEXIBLE: FULL PROSTATE OR TARGETED CANCER ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Unchanged	Superior
Surgeon skill	Dependent	Closed loop process control
Cost of Surgery	Higher	Lower

## MARKET ENTRY STRATEGY

#### IN US & EUROPE

#### **TULSA-PRO**

- Precise
- Personalized
- · One & done

#### PROFOUND SURGERY

- Patients on active surveillance who prefer a safe intervention
- Patients who otherwise might be targets for Radiation

#### **SALES CHANNELS**

- Initial equipment sold through distribution partners Philips and Siemens
- Disposable used per patient sold directly to drive utilization



#### **Active Surveillance**

#### 5.8 Million patients<sup>1,2</sup>

- Live with psychological stress for 10-to-15 years
- Monitoring costs up to \$29,000<sup>3</sup>



#### **Radiation**

#### 300,000 patients per year<sup>4</sup>

- High rates of side effects
- · Multiple treatments over 30-to-60 days
- 30% patients fail treatment<sup>5</sup>



#### **Prostatectomy**

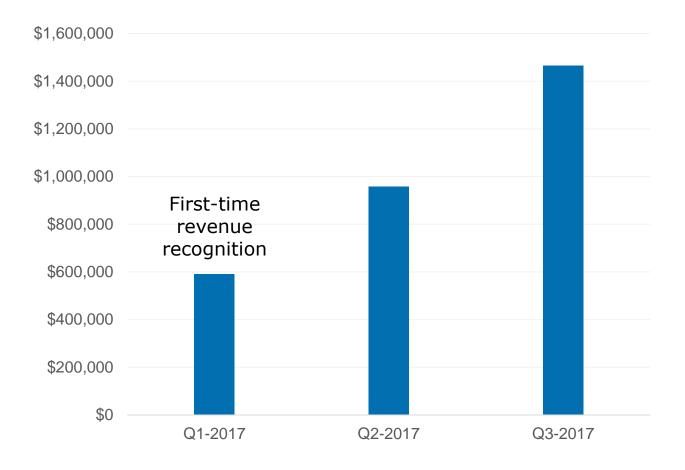
#### 400,000 patients per year<sup>6</sup>

- · Removal of whole prostate and associated tissue
- Side effects surgeon skill dependent
- Relatively longer recovery time

Less frequent treatments: HIFU, Cryotherapy, Brachytherapy, Hormone Therapy, Laser

# **EUROPEAN PILOT COMMERCIAL LAUNCH**

# **Revenue Ramp**



# REIMBURSEMENT ENVIRONMENT

# FOR PROSTATE

TSXV: PRN | OTCQX: PRFMF

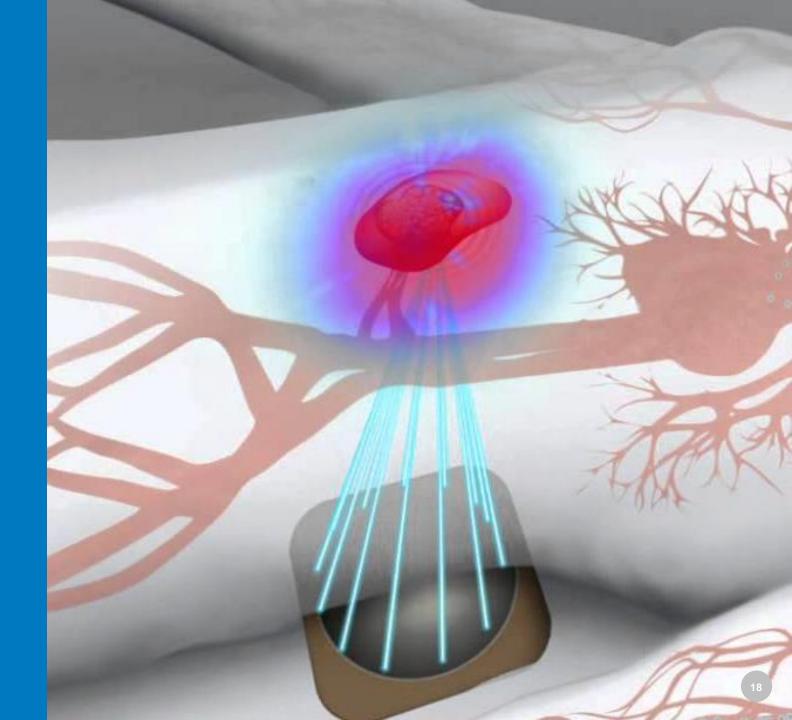
# No therapy is considered standard of care

PROCEDURE	APPROXIMATE HOSPITAL PAYMENT	APPROXIMATE SURGEON PAYMENT
Laparoscopic Radical Prostatectomy	\$10,000	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$20,000	Fee bundled into primary APC
Brachytherapy	\$8,000	\$2,200
Cryoablation	\$10,000	\$800

<sup>\*</sup> Payment is the sum of the indicated APC/CPT codes

<sup>\*\*</sup> Payments are for Medicare patients. Private payer payments for these procedures will vary and may result in higher payments than published Medicare

# Uterine Fibroid Treatment



# SONALLEVE

# **UTERINE FIBROID TREATMENT**



- MR-guided: Treatment planning based on 3D MR images
- Focused ultrasound heats noninvasively through intact skin
- Real-time MR imaging & temperature measurement
  - Verify treatment success
  - Risk mitigation

## **CE-Mark approval for:**

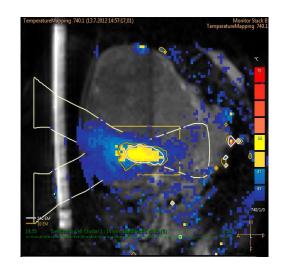
- Uterine Fibroid Therapy
- Bone Mets Pain Therapy

# > 100 peer reviewed publications

## **Compatible with Philips MRI**

- Ingenia 1.5T and 3.0T
- Achieva 1.5T & 3.0T





# SYMPTOM RELIEF AND DURABILITY

# **OVER 85% SUSTAINED SYMPTOM IMPROVEMENT**

In normal commercial use, over 85% of patients experienced sustained symptom improvement

Months	Months Patients available		Symptom improvement		
post-procedure fo	for follow-up	Improved	No relief	Worse	
3 months	105	90 (85.7%)	14 (13.3%)	1 (1%)	
6 months	99	92 (92.9%)	7 (7.1%)	0	
12 months	89	78 (87.6%)	11 (12.4%)	0	

Durability of the therapeutic effect compared to other uterine preserving treatments

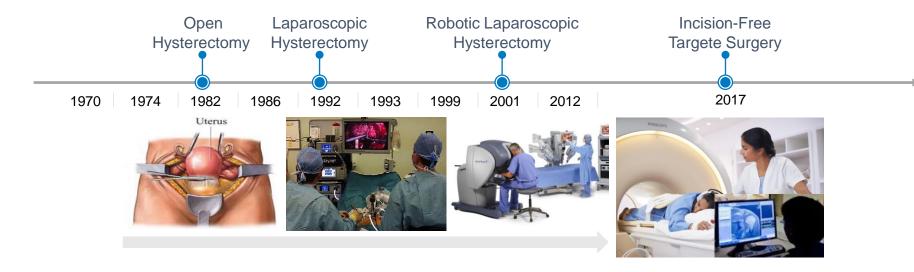
Need for alternative treatment	@ 12 month	@ 24 month	References
Myomectomy	10.6 %	13-16.5 %	1,2,3,4
UAE (Uterine Artery Embolization)	7-10 %	12.7-23.7 %	5,6,7
MR-HIFU/MRgFUSNPV >60%	6 %	13 %	8

<sup>&</sup>quot;Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park.

Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943–950, Apr. 2013.

# FROM OPEN SURGERY

# **TO INCISION-FREE SURGERY**



SURGERY TYPE	FULL UTERUS REMOVAL	TARGETED FIBROID ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Unchanged	Superior
Surgeon skill	Dependent	Ablation under real time imaging guidance
Cost of Surgery	Higher	Lower

# STRONG GLOBAL NETWORK

# OF SONALLEVE CLINICAL PARTNERS



# **IN SUMMARY**

#### **INVESTMENT HIGHLIGHTS**



#### **CE Mark**

Prostate ablation: 2016

#### FDA clinical trial

- Expected enrollment completion: Q1-2018
- Expected filing for 510(k): Year End-2018

#### Pilot commercial launch

- Key European and other CE mark jurisdictions
- Revenue ramp: Q1-2017 = \$600,000; Q2-2017 = \$1 million; Q3 = \$1.5 million; expect steady increase moving forward

**US launch expected H1-2019** 



#### **CE Mark**

Uterine fibroid treatment: 2009

Bone metastases treatment: 2011

FDA clinical trial: TBA