



PROFOUND

Customizable, Incision-Free
Ablation Therapies

Corporate Presentation | December 2019

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NASDAQ: PROF
TSX: PRN

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“My life should not
have to change”

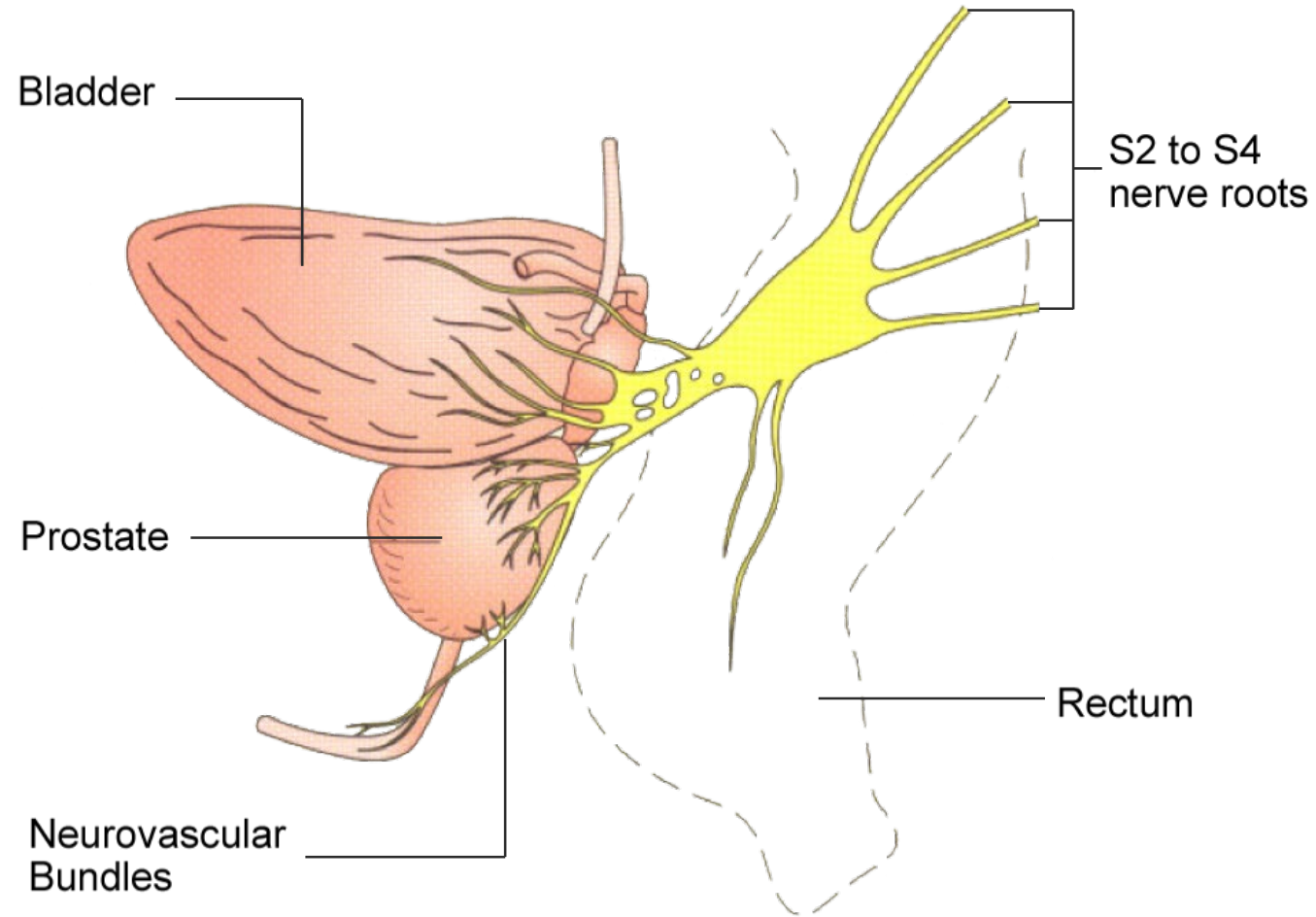
TULSA-PRO[®]

U.S. FDA Cleared, August 2019
Ablation of Prostate Tissue

PROFOUND



Prostate Anatomy



Current Landscape of Prostate Disease in the U.S.



2.9 million patients currently living with prostate cancer on active surveillance*



10 million patients living with Benign Prostatic Hyperplasia (“BPH”)**



Common treatment options associated with significant side effects such as incontinence and erectile dysfunction



175,000 new prostate cancer patients diagnosed each year*



300,000 BPH surgeries per year**

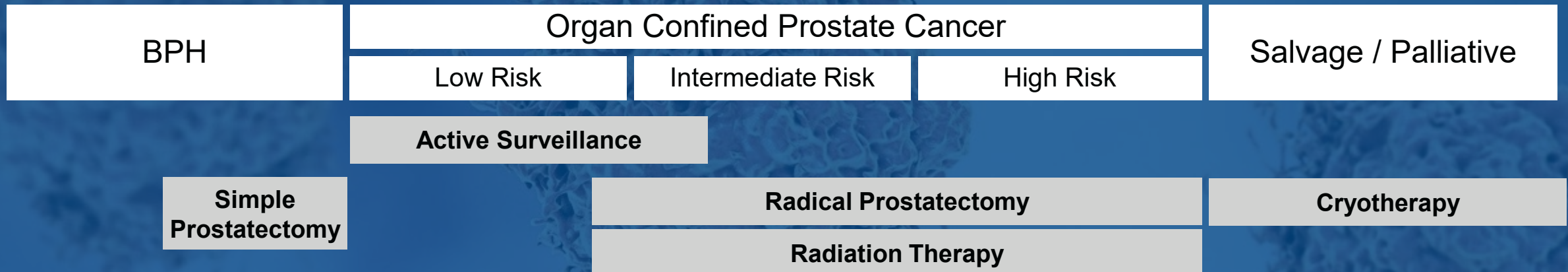


Radiation failure and palliative patients have limited re-treatment options

*American Cancer Society

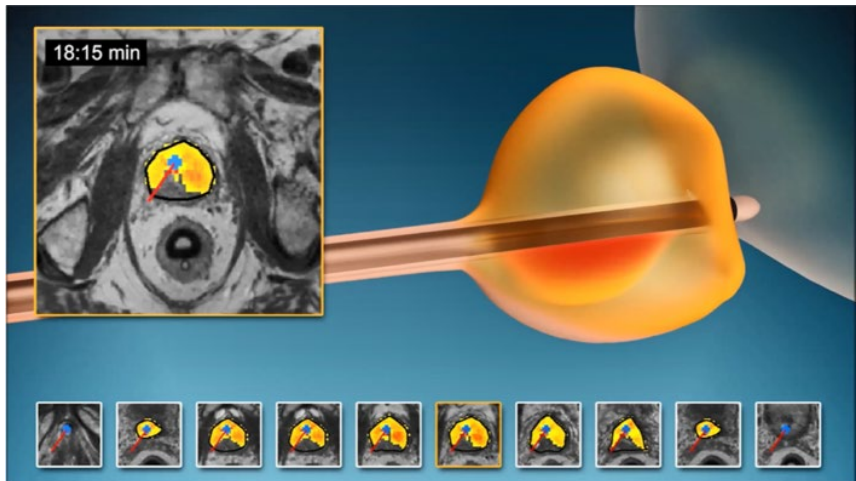
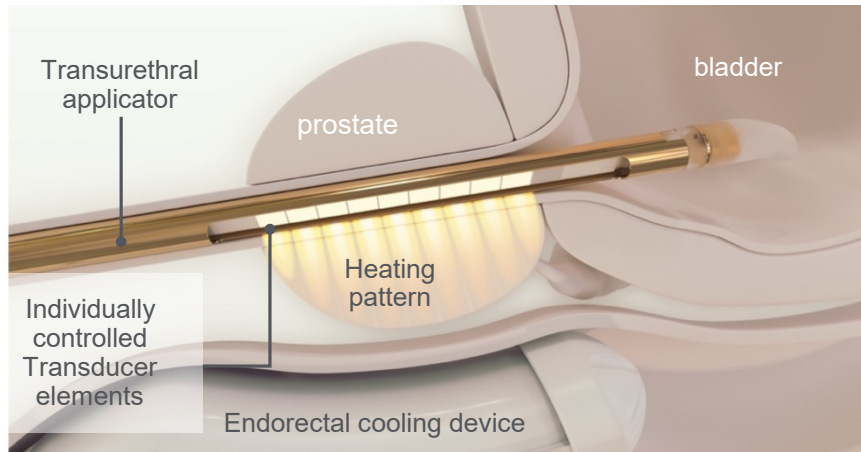
**Based upon CMS data

Today's Treatment Paradigm



TULSA-PRO

Customizable, Predictable, Incision-Free



1

Real-time MR imaging

- Customized treatment plan

2

Transurethral directional ultrasound for thermal ablation; water cooling of urethra and rectum

- Sweeping ultrasound, continuous rotation
- Capable of treating both large and small prostate volumes, anterior and posterior tissue
- Thermal protection of important anatomy

3

Closed-loop process control software

- Real-time temperature feedback provides for gentle and precise ablation

TULSA-PRO

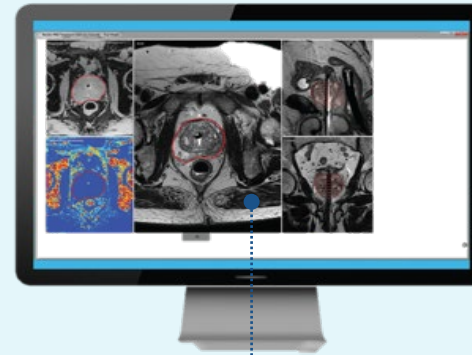
System Components



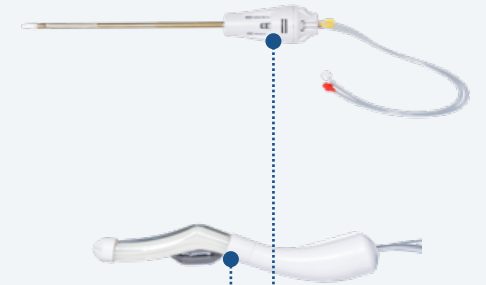
**Robotic Arm,
Computer Hardware**



**Energy
System**



**Surgeon Console
Control Room**



**Disposable
Applicators**

Capital Equipment

One-Time Consumables

- Compatible with MR from leading companies, Philips and Siemens
- Recurring revenue business model

TACT: Clinical Trial

Pivotal Study of Whole-Gland Ablation in a Clinically-Significant Patient Population

n=115

13 clinical sites

5 countries

45-80 years old

Prostate Cancer Risk
Intermediate (67%)
Low (33%)

PSA primary efficacy endpoint resolutely met:

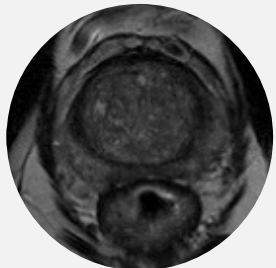
- PSA reduction $\geq 75\%$ achieved in **110 of 115 (96%)**
- Median (IQR) PSA reduction was **95% (91-98%)**
- Median (IQR) PSA nadir was **0.34 (0.12-0.56) ng/ml**

Prostate volume significantly reduced, demonstrating effective prostate ablation:

- Median perfused prostate volume decreased **91%**
 - from 37 cc to 3 cc
- Prostate ablation confirmed on Contrast Enhanced MRI

Prostate Volume Reduction

Screening
T2w MRI



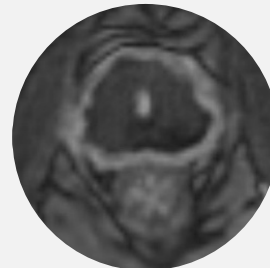
PSA 5.5 ng/ml
58 cc

Immediate Post
CE-MRI



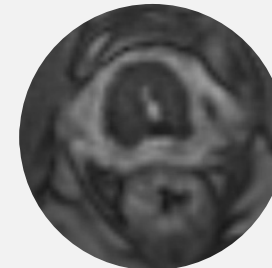
PSA 6.0 ng/ml

1-month Post
CE-MRI



PSA 0.3 ng/ml

3-months Post
CE-MRI



PSA < 0.1 ng/ml

12-months Post
CE-MRI



PSA < 0.1 ng/ml
0.5 cc

TACT Summary

Literature Review of Other Trials Provided for Context

	TACT Study	Literature Review		
	TULSA	Prostatectomy	Radiation	HIFU
Biopsy / Histology	21% Clinically Significant 14% Insignificant Disease (GG1, ≤2 cores, < 50% CCL) 65% Negative	16 – 24% +Margin ¹ (Meta-Analysis) 10 – 15% +Margin ² (RCT) 24% +Margin ³ (ProtecT)	28% Clinically Significant ⁴ 20% Insignificant Disease ⁴ (Positive w. treatment effect) 52% Negative ⁴	59 – 61% Negative ⁵⁻⁶ (Intent to treat) 63% Negative, after 40% having repeat HIFU and 39% ADT ⁷
Erectile Dysfunction erectons insufficient for penetration	23% Grade 2 Medication Indicated No Grade 3 ED	79% ⁹ (Range: 25 – 100%) ¹⁻⁴	63% ⁹ (Range: 7 – 85%) ¹⁻⁵	58% ⁷ (Range: 44 – 67%) ⁶⁻⁸
Urinary Incontinence moderate to severe	2.6% Grade 2 Pads Indicated No Grade 3 Incontinence	15% ⁹ (Range: 0 – 50%) ¹⁻⁴	4% ⁹ (Range: 2 – 15%) ¹⁻⁵	3% ⁵ (Range: 3 – 22%) ⁶⁻⁸
Urethral Stricture moderate to severe	2.6%	9% ¹¹ (Range: 3 – 26%) ¹⁻⁴	2% ¹¹ (Range: 1 – 9%) ¹⁻⁵	35% ⁵ (Range: 9 – 35%) ⁶⁻⁸
GI Toxicity moderate to severe diarrhea, urgency, incontinence, fistula	No GI Toxicity	15% ⁹ (Range: 0 – 24%) ¹⁻⁴	25% ^{9, 12} (Range: 0 – 40%) ¹⁻⁵	7% ⁵ (Range: 1 – 21%) ⁶⁻⁸

1. Tewari et al 2012 (Meta-Analysis)

2. Yaxley et al 2016 (RCT)

3. Hamdy et al 2016 (ProtecT)

4. Radiation Meta-Analysis (publication pending)

5. FDA IDE Study K153023

6. FDA IDE Study DEN150011

7. Crouzet et al, Eur Urol 2014 (1000+ patients, Whole-gland HIFU)

8. Thompson (Chair) et al, AUA prostate cancer clinical guideline update panel, J Urol 2007

9. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013

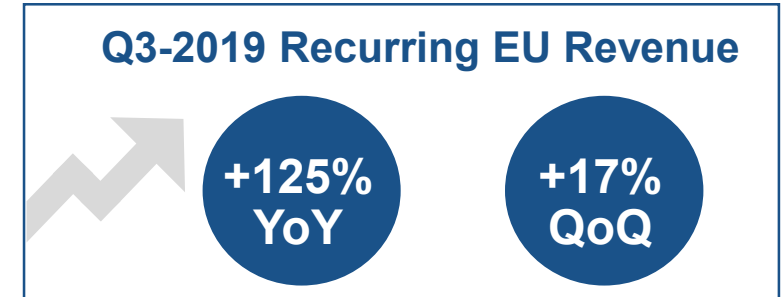
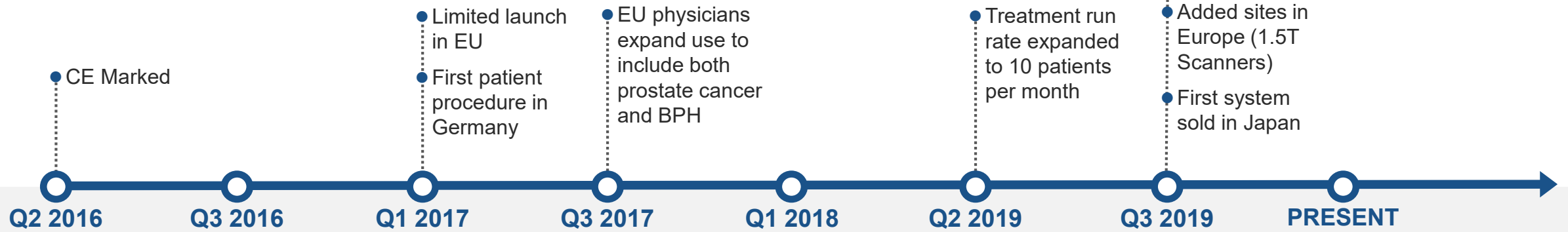
10. Potosky et al, Prostate Cancer Outcomes Study (PCOS), J NCI 2004

11. Elliott et al, CaPSURE database, J Urol 2007

12. Budaus et al, Review, Eur Urol 20012

Clinical & Commercial Development TULSA-PRO Timeline

Developments in Europe



Developments in U.S.

- Positive top-line TACT study results announced at American Urological Association's 2019 Annual Meeting Plenary Program
- 510(k) application filed
- FDA 510(k) clearance for ablation of prostate tissue
- U.S. commercial launch initiated
- Health Canada approved ("country of origin")
- First U.S. commercial site to be operational by YE19

Clinical Application

Learnings From Limited EU Launch

Benign	Organ Confined Prostate Cancer			Salvage / Palliative
	Low Risk	Intermediate Risk	High Risk	

Large prostate BPH ¹

- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion

Customized ablation ²⁻⁷

- Targeted ablation (focal, or regional)
- Large ablation (wide margins)
- Whole gland ablation (with urethral sparing)

Recurrence after radiation ⁸

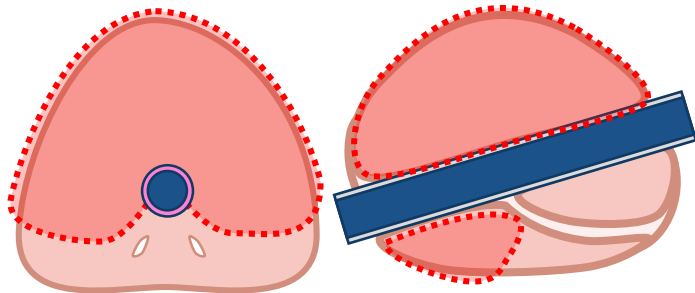
- Localized recurrences have limited options, and morbidity is high

Palliative locally advanced ⁹

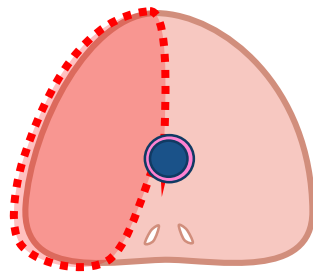
- Severe urinary symptoms including BOO with retention and/or intractable hematuria

Oligometastatic ¹⁰

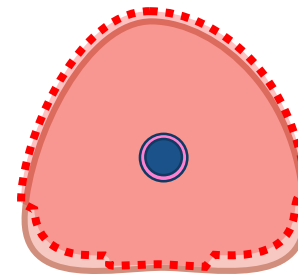
- Benefit to locally treat prostate
- Often radio-recurrent



Ablation of benign prostate tissue



Targeted ablation of diseased prostate tissue



Whole gland ablation with bilateral nerve sparing

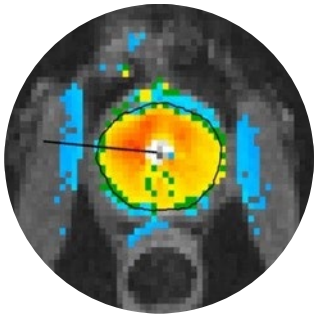
1. Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 (Under Review)
 2. Ramsey *et al*, The Journal of Urology, 2017
 3. Chin *et al*, European Urology, 2016
 4. Bonekamp *et al*, European Radiology, 2018
 5. Eggener *et al*, The Journal of Urology, 2019 (AUA Abstract)

6. Anttinen *et al*, International Journal of Hyperthermia, 2019
 7. Anttinen *et al*, Scandinavian Journal of Urology, 2019 (Under Review)
 8. Suomi *et al*, ISTU Barcelona, Spain, 2019 (Conference)
 9. Sainio *et al*, ISTU Barcelona, Spain, 2019 (Conference)
 10. Physician interest

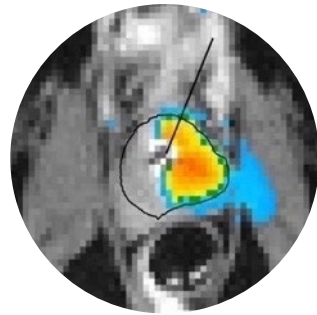
TULSA-PRO

Unique Flexibility

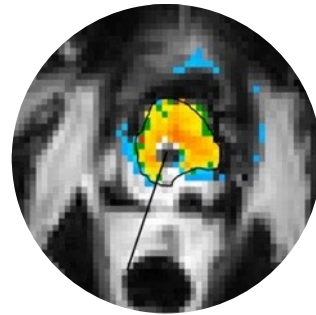
Whole Gland Ablation



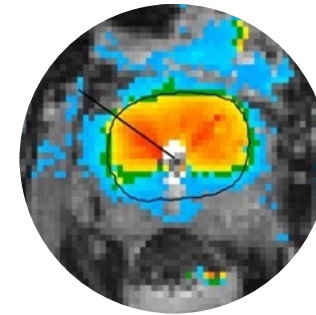
Targeted Ablation



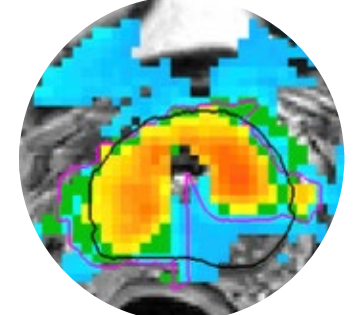
Post Radiation Failure Ablative Therapy



Targeted Ablation of a benign large prostate



Targeted Ablation of a benign large prostate with malignant lesion



Clinical Application & Adoption

Learnings From Limited EU Launch



Prostatectomy

Radiation

TULSA

Throughput: Procedures/Day

- 2 typically
- 3 on a longer day

- Multiple sessions:
5-to-40 over 4-to-8 weeks

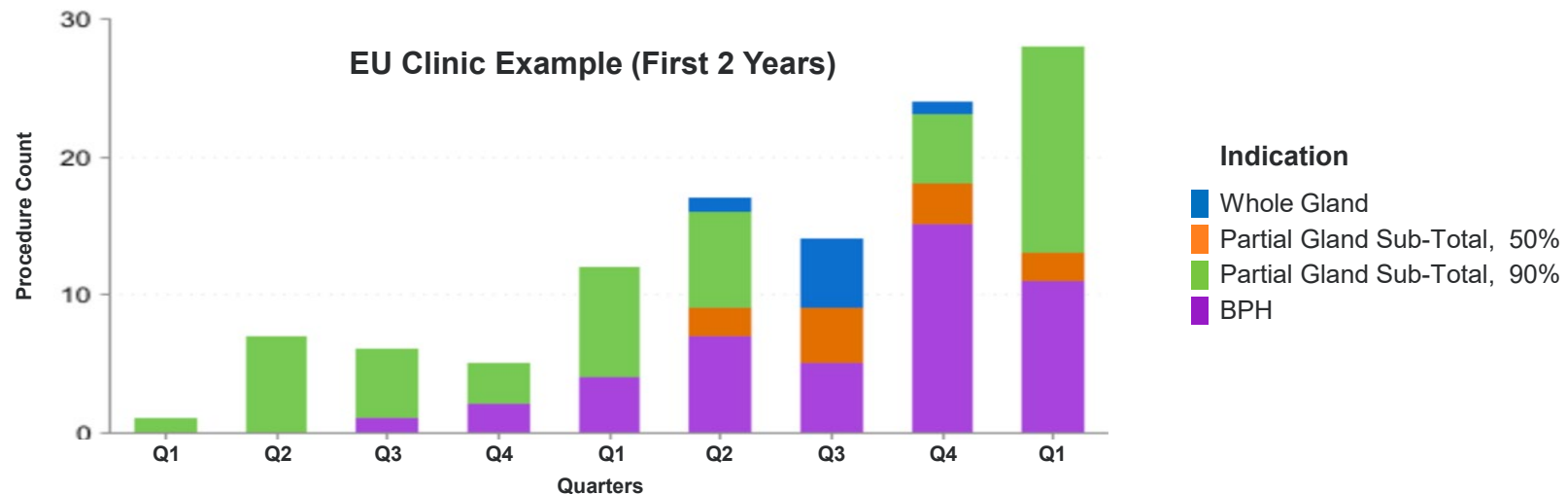
- 4 in a day
- Consistent treatment times

Patient Recovery

- Weeks

- Deterioration over time

- Outpatient procedure for most patients
- Generic analgesic needed for pain management after procedure



U.S. Market Entrance Strategy

TULSA-PRO



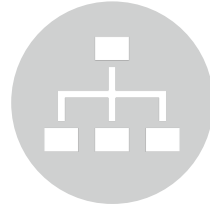
Increase Awareness

- TACT clinical data presented at >10 conferences (AUA, EAU, RSNA)
- TULSA-PRO and TACT clinical data presented to multiple institutions
- Low-cost / high-impact patient awareness initiatives



Early Adopter Pipeline

- Already visited about 75 potential users
- Includes top teaching hospitals, companies owning imaging centers with large footprint, and specialty urology practices



Potential Delivery Channels

- Opinion leading hospitals / Centers of Excellence
- Imaging centers
- Urology practice co-ops that focus on emerging technologies



Business Models

- Recurring revenue-only
- Capital + consumables sales



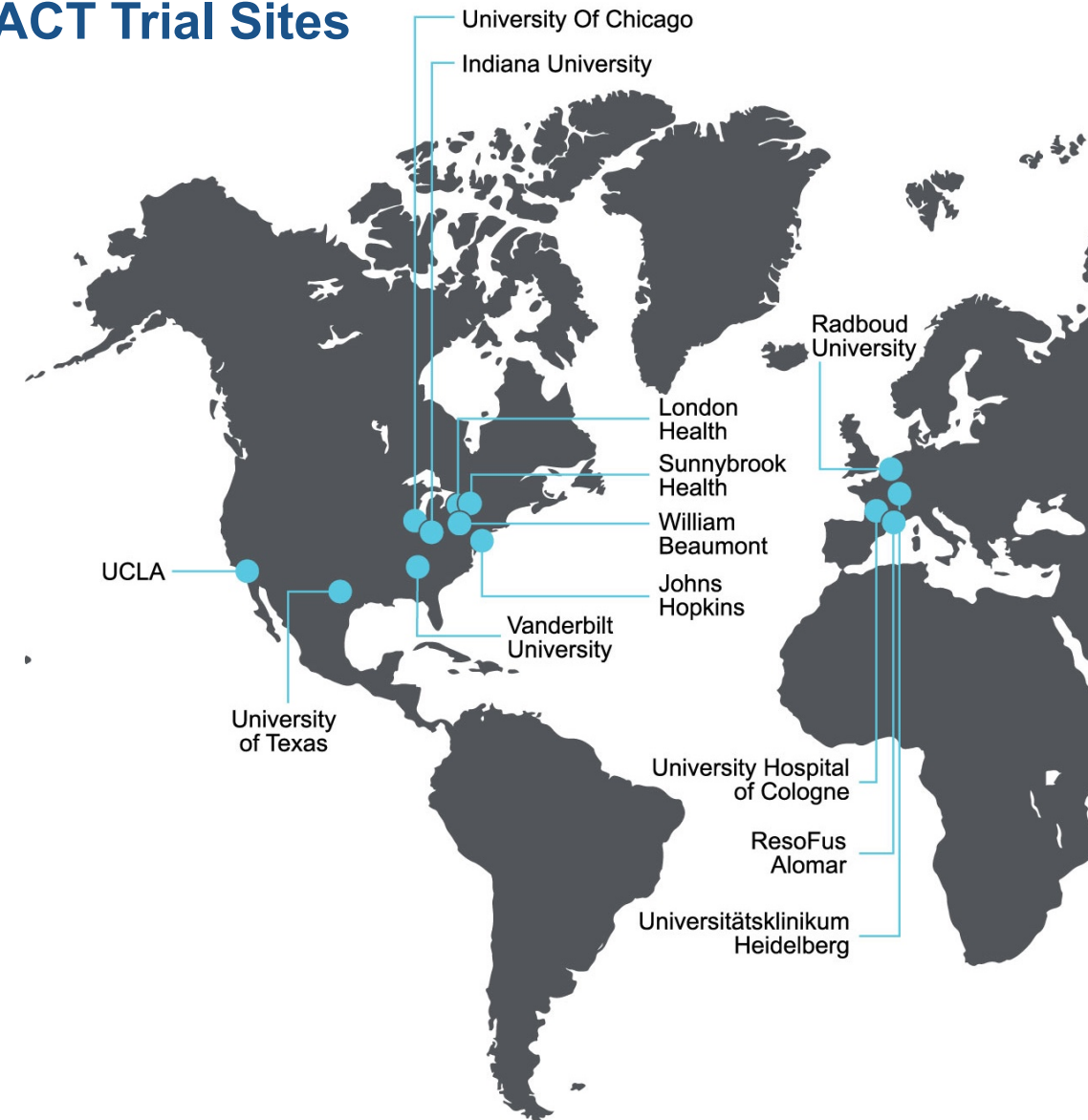
'Profound Genius Services'

- Start-up clinical support
- Flexibility – ablation of range of patients
- Productivity
- Patient awareness
- Reimbursement

Centers of Excellence

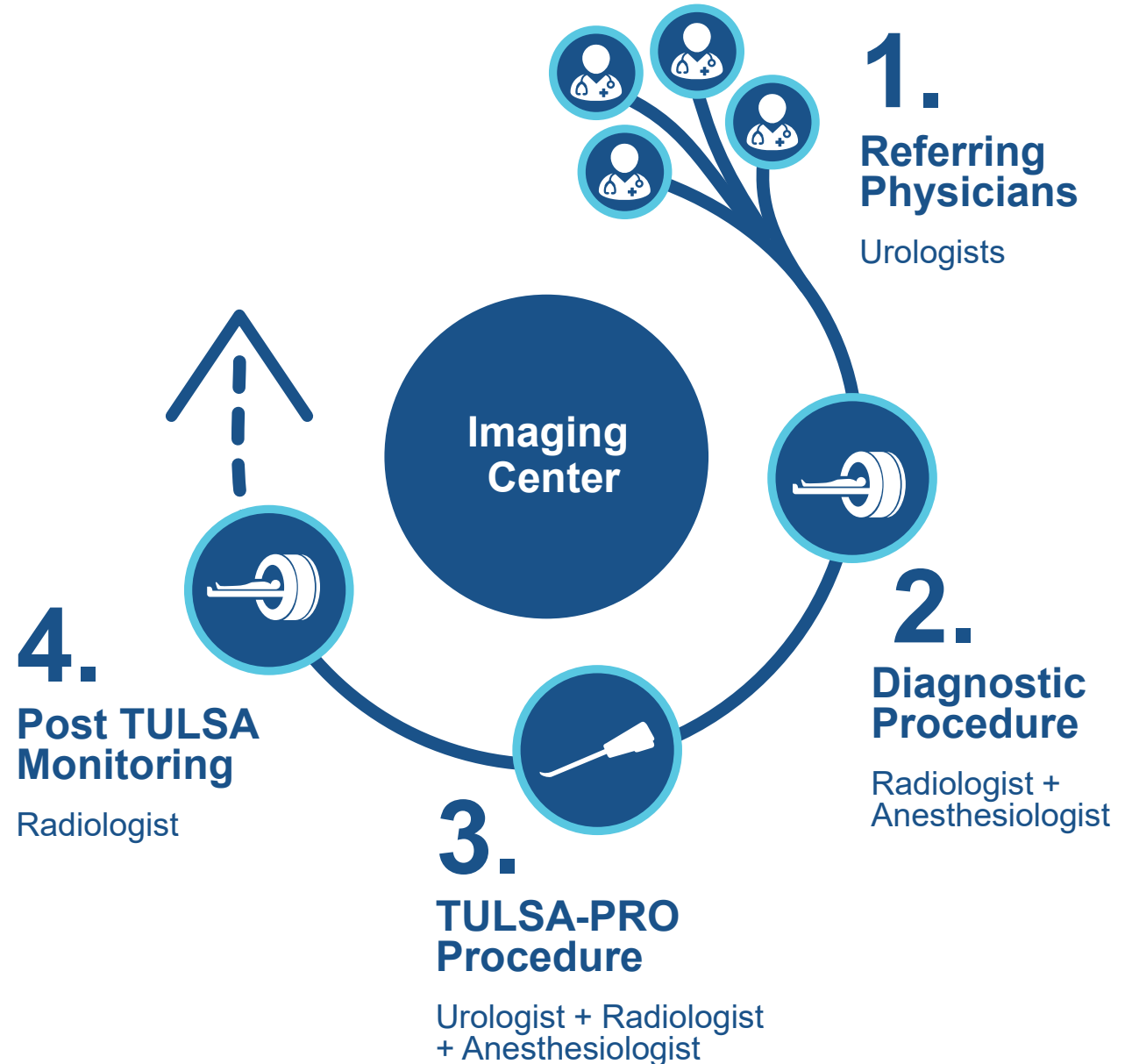
- Includes many of the TACT study sites
- Will likely be relatively low volume while TULSA is a patient self-pay procedure
- Best positioned to help drive long-term adoption by:
 - Participate in additional trials designed to support reimbursement
 - Training next generation of urologists
 - Presenting at medical conferences
 - Publish papers in relevant journals

TACT Trial Sites



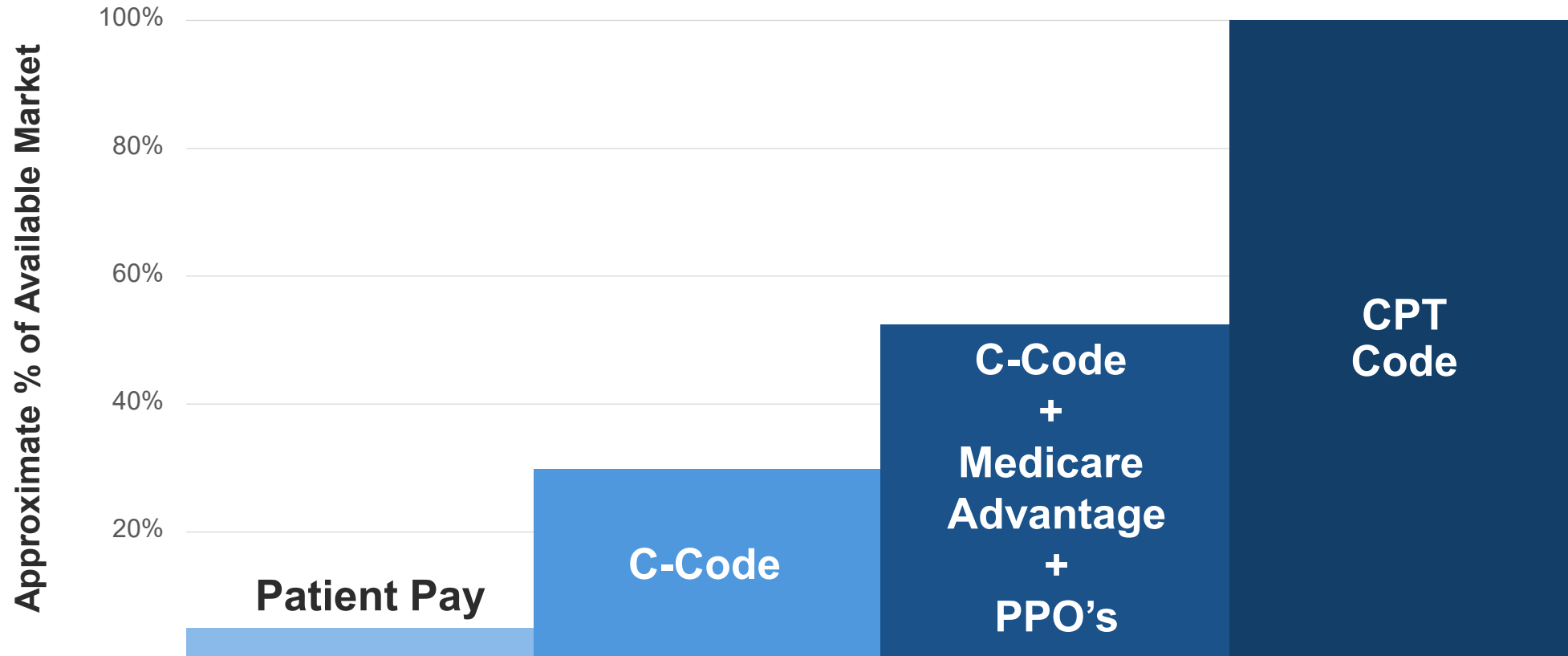
Commercial Imaging Centers

- 8,000 -10,000 imaging centers in U.S.; 40% owned by private equity or public companies
- Growing presence in urology due to MRI diagnostics, MRI-guided biopsy, MRI-guided follow-up
- Centers provide:
 - Service
 - Technology
 - In-house Radiologist(s)
 - Local Specialist Relationships (Urologists, Anesthesiologists)
 - Marketing
 - Payer Networks



Reimbursement Pathway

From “Cleared” to “Covered”



TULSA-PRO: Pre-Reimbursement “Patient Paid”

Significant Market Opportunity, Even With Low Single-Digit Initial Penetration Levels

New Prostate Cancer Diagnosis (U.S. + Canada)	180,000 ¹
BPH, Prostates, surgical candidates, Unusual shapes (U.S. + Canada)	400,000 ²
Total Opportunity, # of patients	580,000
Total Addressable Market, assuming patient paid is 5% of total opportunity	29,000 ³
Add selected International markets (UK, Germany, Japan)	14,500 ³
Total patient pay addressable market # of patients	43,500 ³
Addressable market, \$6,000 per patient (includes: disposable + amortized capital + service)	\$261,000,000 ³
Achievable share in X years, 25% (<11,000 patients per year) TULSA Installed base = 110 at treatment rate 100 patients/year	\$65,250,000 ^{3*}

* Represents approximately 1% of total current annual prostate surgery and/or radiation treatment market

1. Prostate cancer: 175,000 new prostate cancer diagnosed each year in US according to American Cancer Society
2. BPH: 300,000 surgeries based upon CMS data, + 1% of 10 Million BHP patients in United States + Canada
3. Figures are not Profound projections. Rather, they are being provided for illustration purposes only.

Reimbursement “C-Code”

- Applying for a new technology “C-Code” before end of 2019
- Typically takes 6 months to obtain a decision from CMS
- If approved, would provide for a 3-year period of reimbursement for facility costs
 - Patients would likely pay about \$2,000-\$4,000 out of their own pockets



Reimbursement “CPT Code” Publication Package

		Rationale	Level	N	US %	Start
1.	TACT 2.0 5-year	<ul style="list-style-type: none"> TULSA U.S. momentum at key teaching sites Increase US patient % Re-treat TACT 1.0 patients 	2b	115 (+35=150)	48% (60%)	Started
2.	BPH RCT 6-month	<ul style="list-style-type: none"> Anchor study for Level 1 data 	1b	144 in 2:1 96 TULSA	~100%	2020
3.	Salvage 1-year	<ul style="list-style-type: none"> Strong clinical value and entry into guidelines Need to sponsor or too slow with patient pay 	2b	68	~100%	2020
4.	Primary Cancer Meta-Analysis (Phase I, EU, Registry)	<ul style="list-style-type: none"> % Ablation vs. Outcomes 	2a			
5.	Single/Small-center Cancer RCT TULSA vs. Radiation (Turku, UWO, U.S.?)	<ul style="list-style-type: none"> Small RCT, 50+ pts, good chance to randomize Level 1 data in cancer, even if not traditional Offloads sponsor requirements from Profound 	1b	50 minimum	0% (more)	2020

AMA Requirements for Category I CPT Code

- FDA-cleared
- Performed widely by many physicians across U.S. (warrants new CPT code)
- Frequency consistent with intended clinical use consistent with current medical practice (mentioned in guidelines/policies)
- Clinical efficacy (documented in “top 5” peer-reviewed publications, judged by CPT Panel)
 - 1+ reference in a majority US patient population
 - 2+ references with no overlapping patients or authors
 - 1+ reference with Level of Evidence IIa (review of large long-term cohort studies) or Level I (randomized controlled trials)

Longer Term

Building an Incision- & Radiation-Free Ablative Therapeutic Platform

Oncology, Highly Symptomatic
Chronic Diseases



SONALLEVE



Current Approvals

Europe: CE Marked

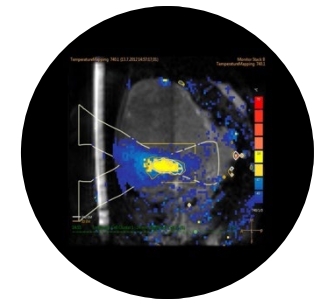
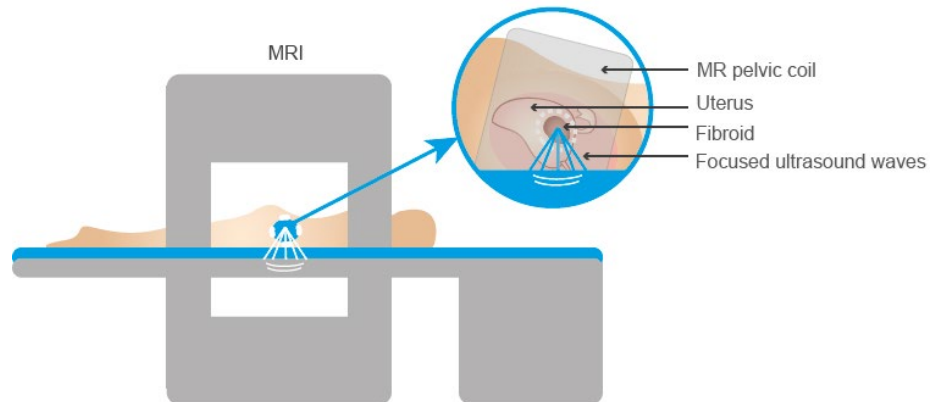
China: CNMPA Approved



Over 200 publications

from leading U.S. & European clinicians and hospitals

- **Uterine Fibroid Treatment**
- **Bone Metastasis Pain**
- **Pediatric Bone**
- **Hyperthermia**
- **Abdominal Cancer**



SONALLEVE

Market Development Strategy



U.S. & Western Markets

Partnered with Cologne University Hospital to develop critical clinical data for cancer and highly symptomatic chronic diseases

Enter U.S. market with Humanitarian Device Exemption indication (similar to orphan drug indication for rare diseases)

- Application filed with FDA
- FDA manufacturing site inspection completed successfully

Long term business model – recurring revenue



China

Philips as distribution partner

- Small Profound direct sales team

Marketing for treatment of uterine fibroids

Reference site in S. Korea, treating 200 patients/year

Potential applications include:

1. Pain management
2. Osteoid Osteoma
3. Pancreatic cancer
4. Hyperthermia
5. Neuro-modulation

In Summary



Introducing TULSA-PRO to U.S. Market

Business Model Designed to be Capital Efficient

- TULSA-PRO: focus on U.S.
- Sonalleve: focus on Asia with larger distribution partner

Future Investments

- Strategically expand U.S.-based sales team, continue work with MRI partners
- Additional clinical trials for TULSA-PRO for reimbursement
- Product enhancements

PROFOUND