Customizable, Incision-Free Ablation Therapies

Corporate Presentation | November 2019

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

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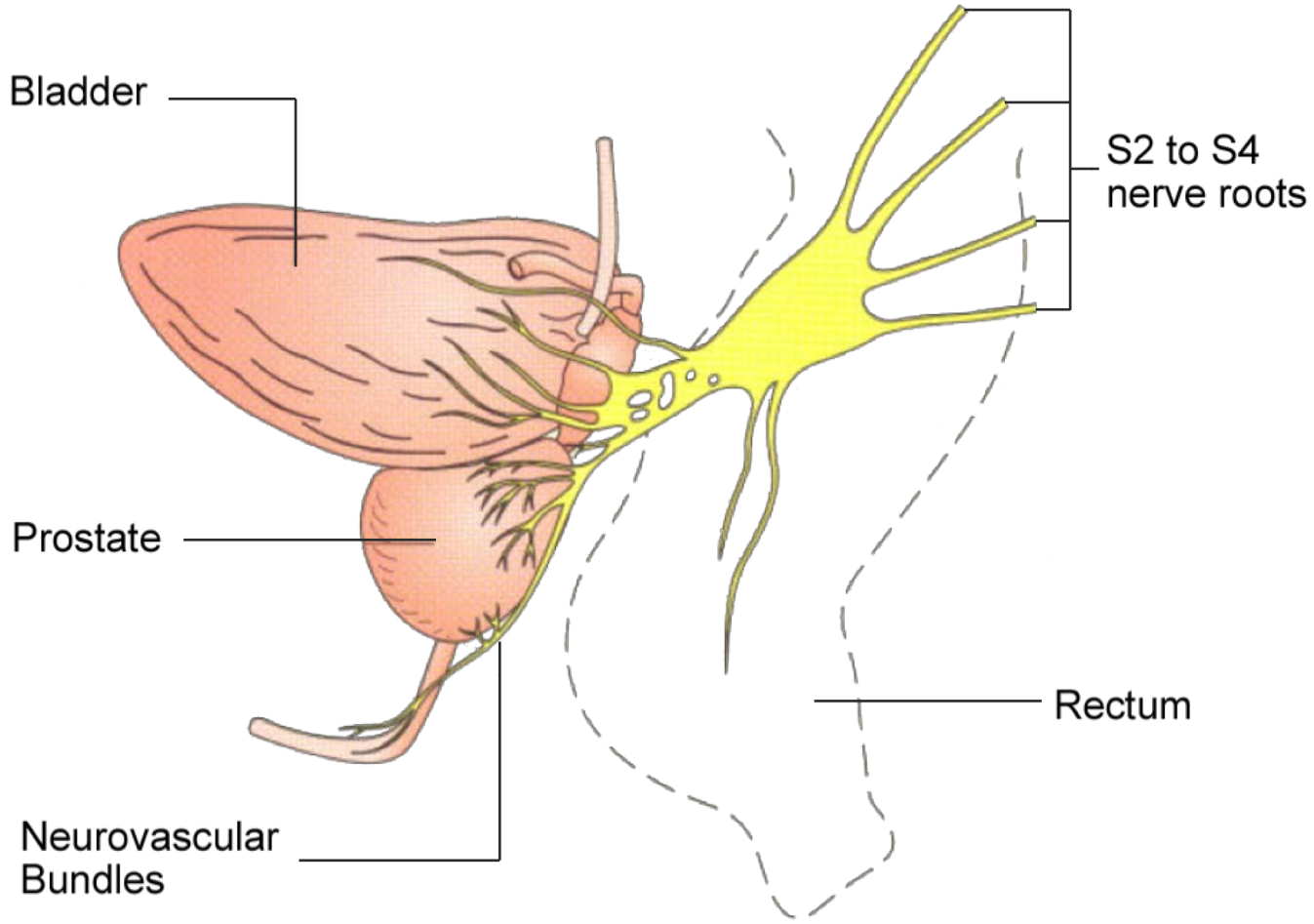
Prostate Anatomy



Source: Kirby (1997) An Atlas of Prostatic Diseases, The Encyclopedia of Visual Medicine Series.

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 disfunction

175,000 new prostate cancer patients diagnosed each year*

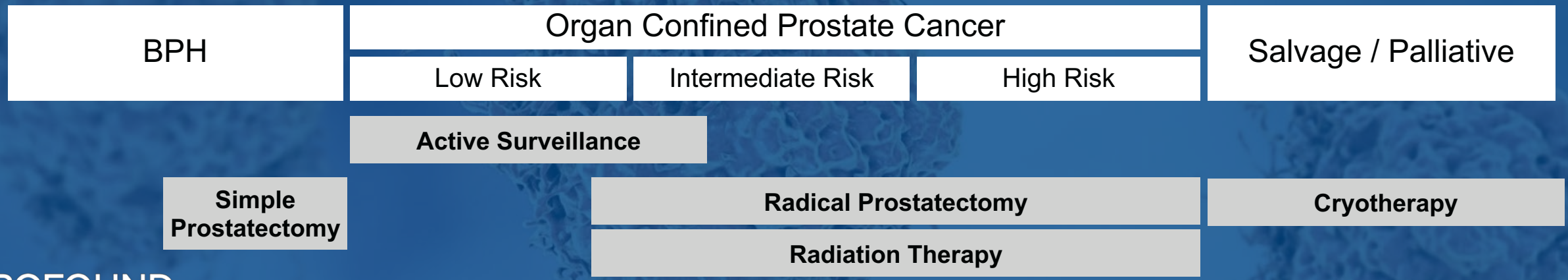
*American Cancer Society

300,000 BPH surgeries per year**

**Based upon CMS data

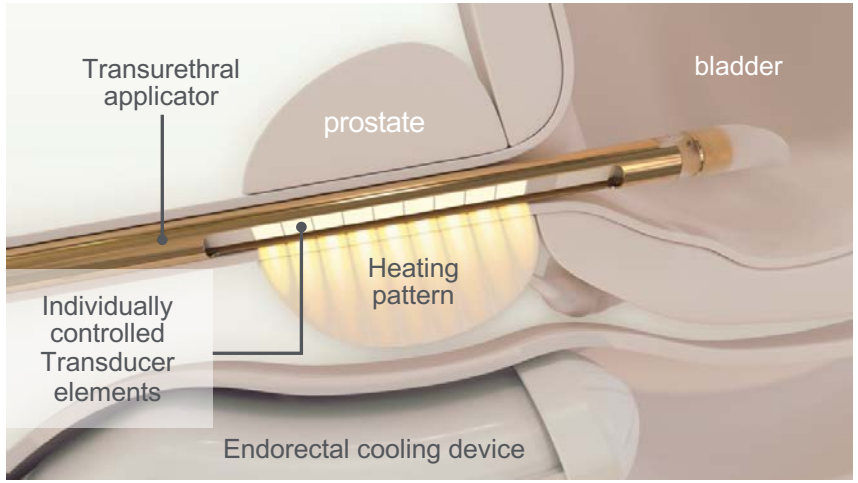
Radiation failure and palliative patients have limited re-treatment options

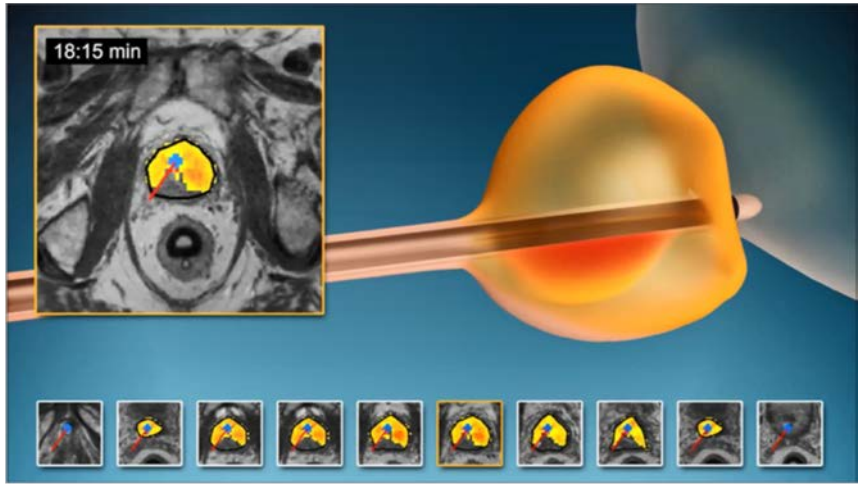
Todays Treatment Paradigm



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

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 ≥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

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 erections 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

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Clinical & Commercial Development

TULSA-PRO Timeline

Q3-2019 Recurring EU Revenue

+125% YoY

+17% QoQ

Q2 2016
- CE Marked

Q3 2016
- First patient enrolled in TACT pivotal trial

Q1 2017
- Limited launch in EU
- First patient procedure in Germany

Q3 2017
- EU physicians expand use to include both prostate cancer and BPH

Q1 2018
- Patient enrollment in TACT trial complete

Q2 2019
- Positive top-line TACT study results announced
- Late-breaking abstract presented at American Urological Association's 2019 Annual Meeting Plenary Program
- 510(k) application filled

Q3 2019
- First system sold in Japan
- 510(k) clearance to market TULSA-PRO in U.S. for ablation of prostate tissue

PRESENT
- U.S. commercial launch initiated
- First U.S. commercial site expected to be operational by end of 2019

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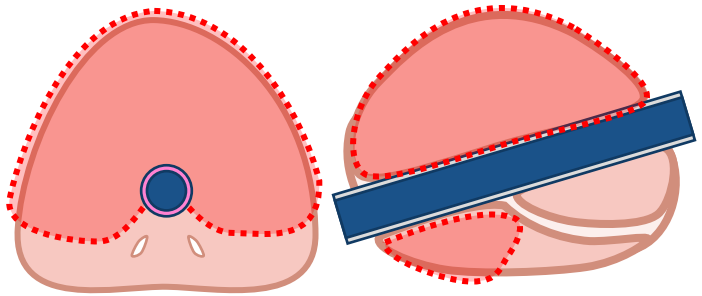
Clinical Application

Learnings From Limited EU Launch

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

Large prostate BPH [1]

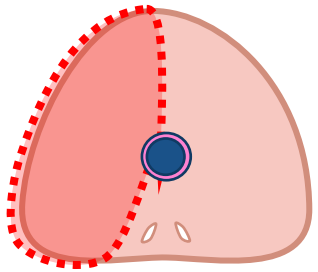
- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion



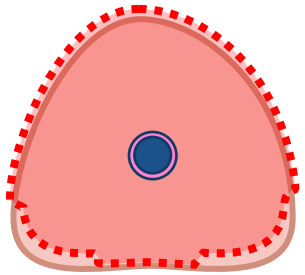
Ablation of benign prostate tissue

Customized ablation [2-7]

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



Targeted ablation of diseased prostate tissue



Whole gland ablation with bilateral nerve 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]

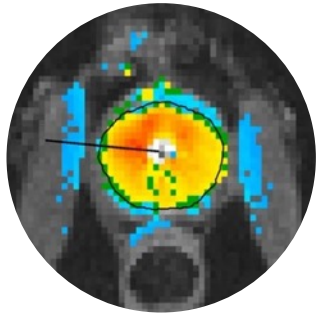
- Benefit to locally treat prostate
- Often radio-recurrent

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*

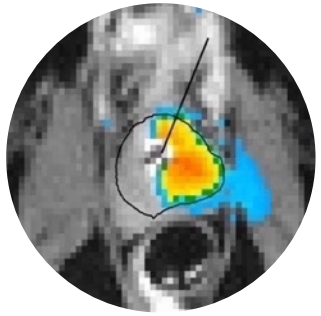
TULSA-PRO

Unique Flexibility

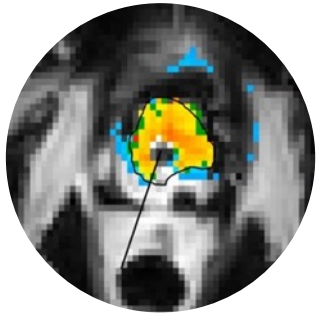
Whole Gland Ablation



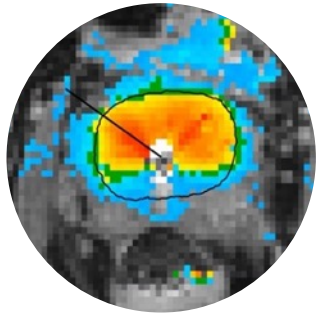
Targeted Ablation



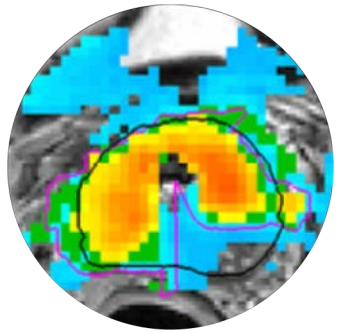
Post Radiation Failure Ablative Therapy



Targeted Ablation of a benign large prostate



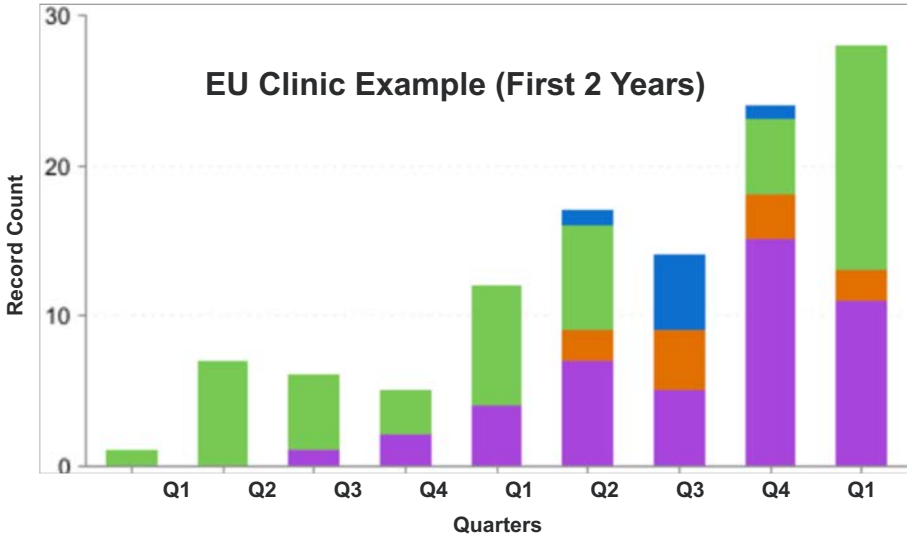
Targeted Ablation of a benign large prostate with malignant lesion



Clinical Application & Adoption

Learnings From Limited EU Launch

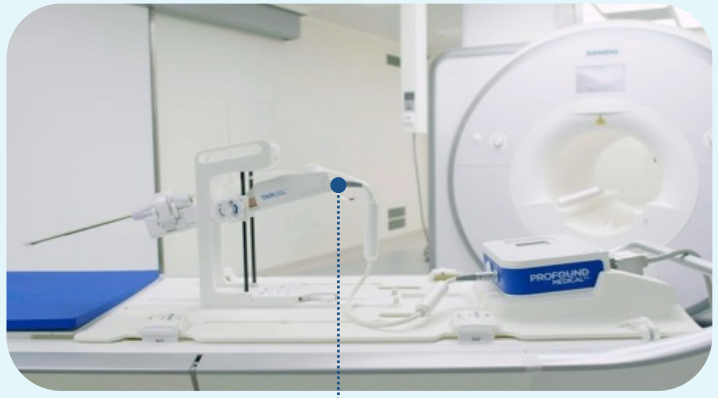
	Prostatectomy	Radiation	TULSA
Throughput: Procedures/Day	• 2 typically • 3 on a longer day	• Multiple sessions: 5-to-40 over 4-to-8 weeks	• 4 in a routine day • Consistent treatment times
Patient Recovery	• Weeks	• Deterioration over time	• Outpatient procedure for most patients • Generic analgesic needed for pain management after procedure



1. Initiated Q1-2017
2. Discovered potential to treat BPH patients, Q3
3. Streamlined procedure time
4. Increased utilization rate

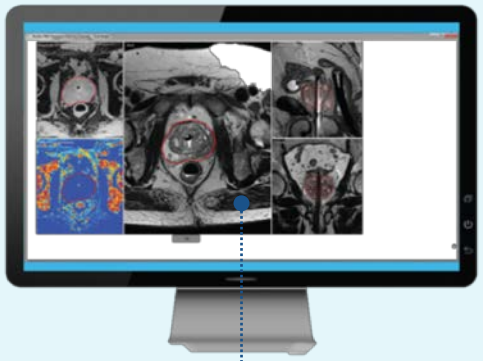
TULSA-PRO

System Components

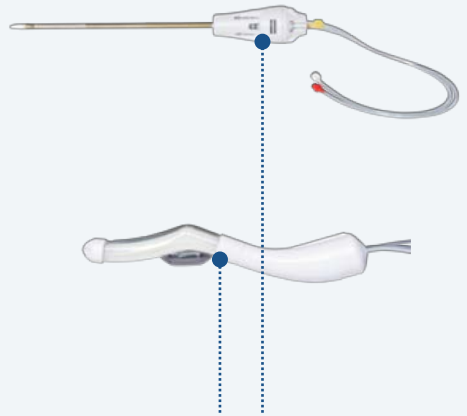


Robotic Arm,
Computer Hardware

Energy System



Surgeon Console
Control Room



Disposable Applicators

Capital Equipment

One-Time Consumables

Compatible with MR from leading companies, Philips and Siemens

U.S. Market Entrance Strategy

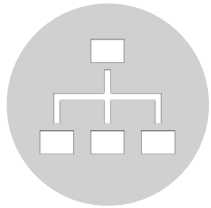
TULSA-PRO

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

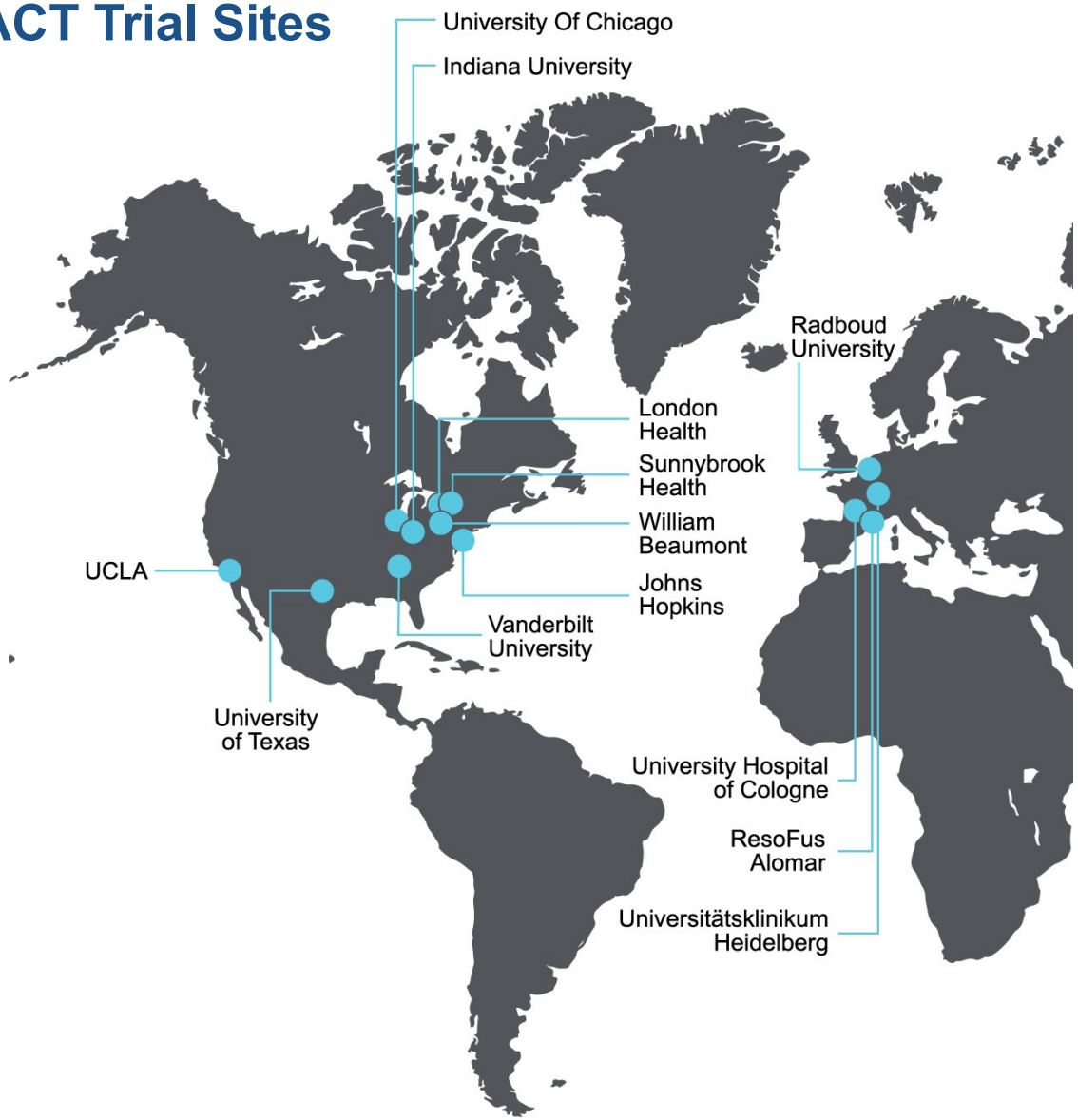
'Profound Genius Services'

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

Centers of Excellence

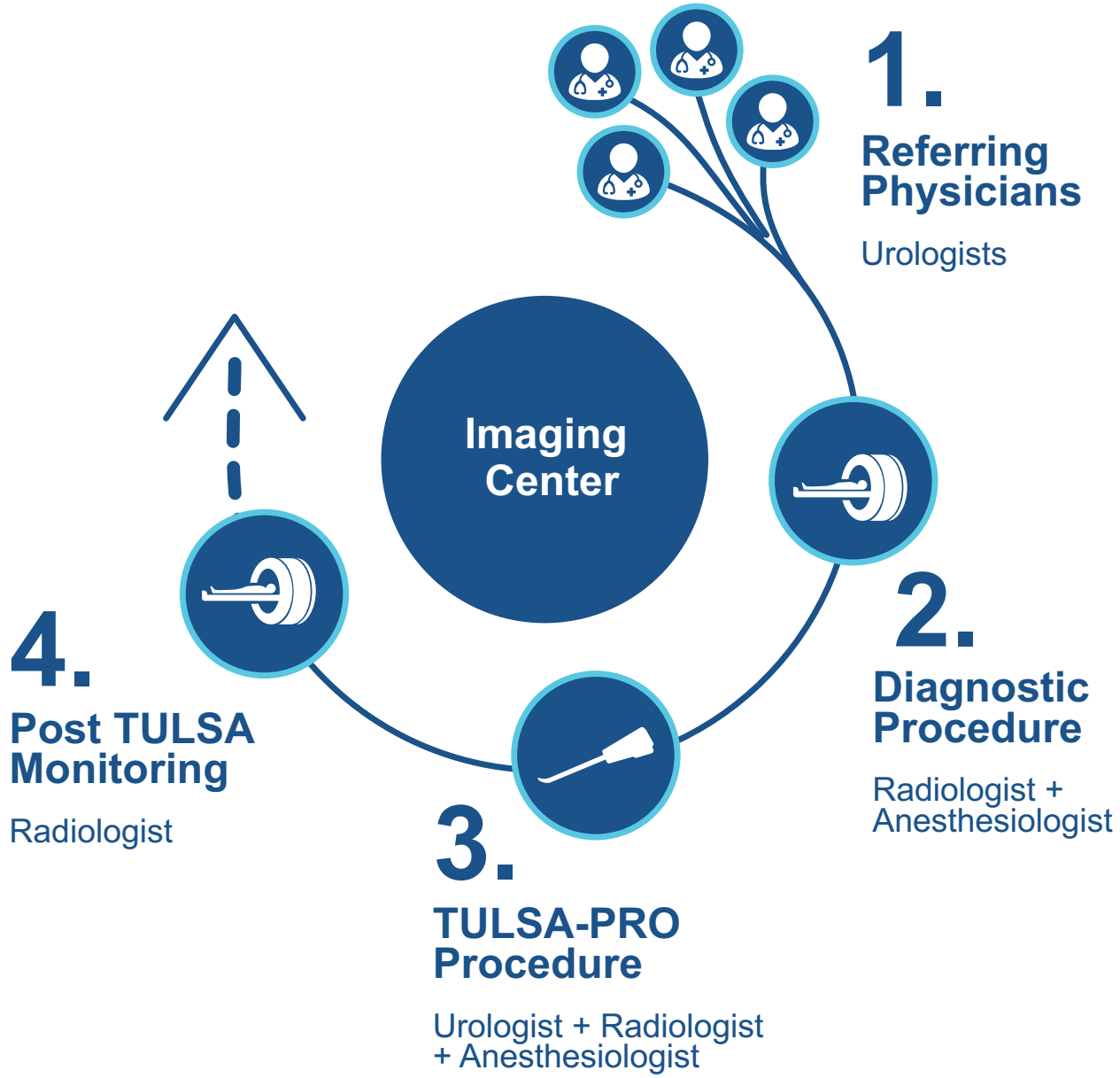
- Includes many of the TACT study sites
- Will likely be relatively low volume while TULSA is a patient self-pay procedure
- Best positioned to help drive long-term adoption by:
  - Participate in additional trials designed to support reimbursement
  - Training next generation of urologists
  - Presenting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



Building Our Brand

Low-Cost / High-Impact Patient Awareness Initiatives

Customer Branded Patient Marketing

- TULSA Patient Marketing
- TULSA Digital Marketing

Profound Branded Patient Marketing

- TULSA Patient Website
- Corporate Website Enhancements
- Video Patient & Physician Testimonials

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

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Reimbursement “CPT Code”

Publication Package

		Rationale	Level	N	US %	Start
1.	TACT 2.0 5-year	• 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	• Anchor study for Level 1 data	1b	144 in 2:1 96 TULSA	~100%	2020
3.	Salvage 1-year	• 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)	• % Ablation vs. Outcomes	2a			
5.	Single/Small-center Cancer RCT TULSA vs. Radiation (Turku, UWO, U.S.?)	• 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

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SONALLEVE

Current Approvals

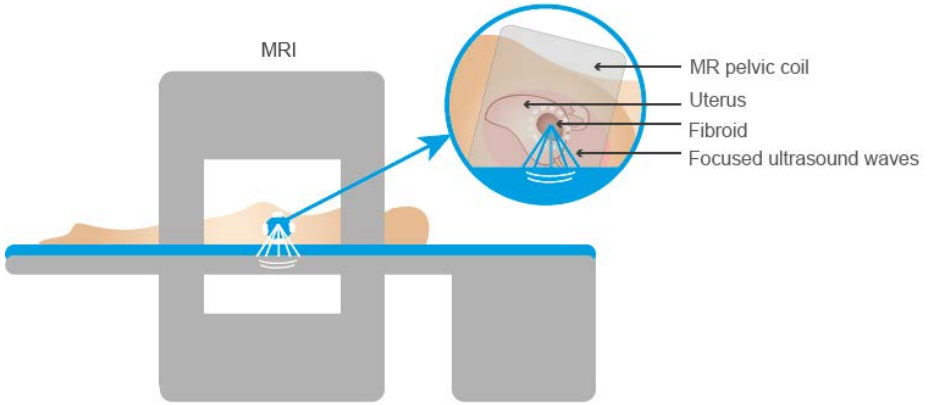
Europe: CE Marked

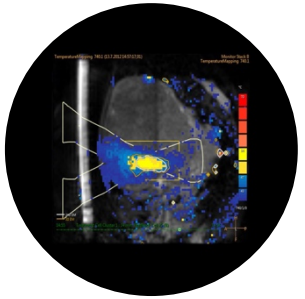
China: CNMPA Approved

Over 200 publications

from leading U.S. & European clinicians and hospitals

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





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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

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