

Corporate Presentation | December 2019 © 2019 Profound Medical Corp.

NASDAQ: PROF TSX: PRN

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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, such as risks related to our limited operating history and history of net losses; risks related to our ability to commercialize our approved products, including expanding our sales and marketing capabilities, increasing our manufacturing and distribution capacity, increasing reimbursement coverage for our approved products and achieving and maintaining market acceptance for our products; risks related to the regulation of our products, including in connection with obtaining regulatory approvals as well as post-marketing regulation; risks related to our successful completion of clinical trials with respect to our products and future product candidates; risks related to managing growth, including in respect of obtaining additional funding and establishing and maintaining collaborative partnerships, to achieve our goals; risks related to competition that may impact market acceptance of our products and limit our growth; risks relating to fluctuating input prices and currency exchange rates; risks related to the reimbursement models in relevant jurisdictions that may not be advantageous; risks related to reliance on third parties, including our collaborative partners, manufacturers, distributors and suppliers, and increasing the compatibility of our systems with MRI scanners; risks related to intellectual property, including license rights that are key to our business; and risks related to the loss of key personnel, 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 forwa

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Market & Industry Data

Market data and industry forecasts contained in this presentation have been obtained from industry publications, various publicly available sources and subscription-based reports as well as from management's good faith estimates, which are derived from management's knowledge of the industry and independent sources that management believes to be reliable. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. We have not independently verified any of the information from third-party sources nor has it ascertained the validity or accuracy of the underlying economic assumptions relied upon therein. We disclaim responsibility or liability in respect of any third-party sources of market and industry data or information, to the extent permitted by law. All figures contained on slides 6, 9, 19 and 22 are provided for illustrative purposes only.

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This presentation may contain financial forecasts with respect to our estimated future performance. Our independent auditors have not audited, reviewed, compiled or performed any procedures with respect to the projections for the purpose of their inclusion in this presentation and, accordingly, neither of them expressed an opinion or provided any other form of assurance with respect thereto for the purpose of this presentation. These projections should not be relied upon as being necessarily indicative of future results.

In this presentation certain of the above-mentioned projected financial information has been included for purposes of providing comparisons with historical data. The assumptions and estimates underlying the prospective financial information are inherently uncertain and are subject to a wide variety of significant business, economic and competitive risks and uncertainties that could cause actual results to differ materially from those contained in the prospective financial information. Accordingly, there can be no assurance that the prospective results are indicative of our future performance or that actual results will not differ materially from those presented in the prospective financial information. Inclusion of the prospective financial information in this presentation should not be regarded as a representation by any person that the results contained in the prospective financial information will be achieved.



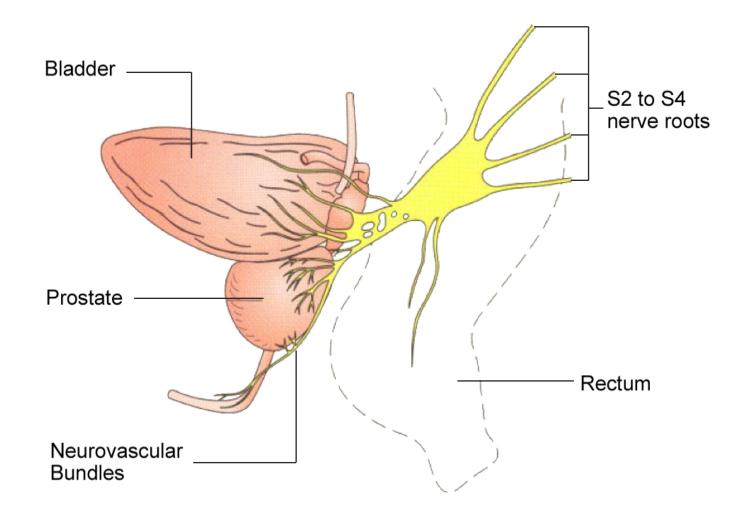
"My life should not have to change"

TULSA-PRO®

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



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 disfunction



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

6

Todays Treatment Paradigm

*American Cancer Society

BPH

Organ Confined Prostate Cancer

Low Risk Intermediate Risk High Risk

Active Surveillance

Radical Prostatectomy

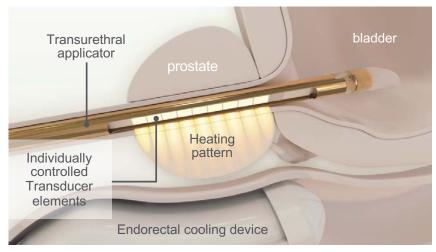
Radiation Therapy

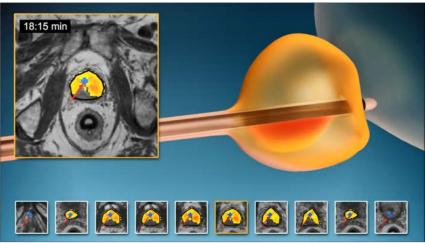
Salvage / Palliative

Cryotherapy

TULSA-PRO

Customizable, Predictable, Incision-Free







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

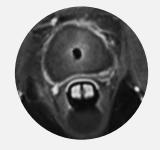
Prostate Volume Reduction

Screening T2w MRI



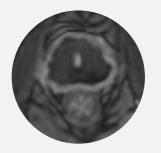
PSA 5.5 ng/ml 58 cc

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			
	TULSA			
Biopsy /	21% Clinically Significant			
Histology	14% Insignificant Disease (GG1, ≤2 cores, < 50% CCL)			
	65% Negative			
Erectile Dysfunction erections insufficient for penetration	23% Grade 2 Medication Indicated No Grade 3 ED			
Urinary	2.6%			
Incontinence moderate to severe	Grade 2 Pads Indicated No Grade 3 Incontinence			
Urethral Stricture moderate to severe	2.6%			
GI Toxicity moderate to severe diarrhea, urgency, incontinence, fistula	No GI Toxicity			

Prostatectomy	Radiation	HIFU		
16 – 24% +Margin ¹	28% Clinically Significant ⁴	59 – 61% Negative ⁵⁻⁶		
(Meta-Analysis)	20% Insignificant Disease 4	(Intent to treat)		
10 – 15% +Margin ² (RCT)	(Positive w. treatment effect)	63% Negative, after 40%		
24% +Margin ³ (ProtecT)	52% Negative ⁴	having repeat HIFU and 39% ADT ⁷		
79% ⁹	63% ⁹	58% ⁷		
(Range: 25 – 100%) ¹⁻⁴	(Range: 7 – 85%) ¹⁻⁵	(Range: 44 – 67%) ⁶⁻⁸		
15%°	4% ⁹	3% ⁵		
(Range: 0 – 50%) ¹⁻⁴	(Range: 2 – 15%) ¹⁻⁵	(Range: 3 – 22%) ⁶⁻⁸		
9% 11	2% ¹¹	35% ⁵		
(Range: 3 – 26%) ¹⁻⁴	(Range: 1 – 9%) ¹⁻⁵	(Range: 9 – 35%) ⁶⁻⁸		
15% ⁹	25% 9, 12	7% ⁵		
(Range: 0 – 24%) ¹⁻⁴	(Range: 0 – 40%) ¹⁻⁵	(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**

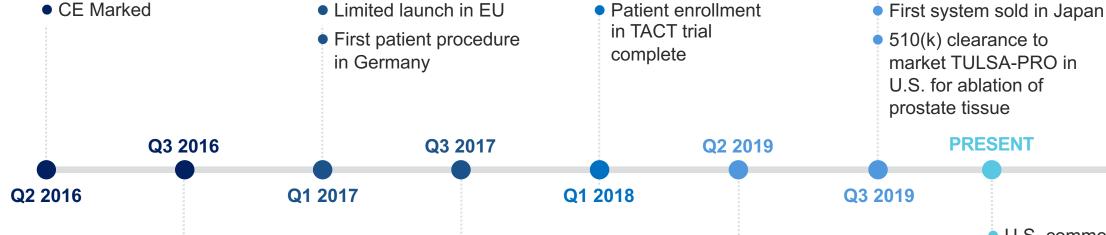
First patient

pivotal trial

enrolled in TACT



PRESENT



EU physicians expand

use to include both

prostate cancer and

BPH

- 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

- U.S. commercial launch initiated
- Health Canada approval ("country of origin")
- First U.S. commercial site expected to be operational by end of 2019



Clinical Application

Learnings From Limited EU Launch

Benign

Organ Confined Prostate Cancer

Salvage / Palliative

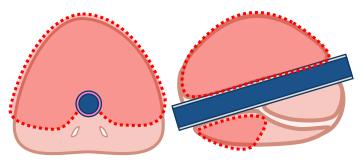
Low Risk

Intermediate Risk

High Risk

Large prostate BPH ¹

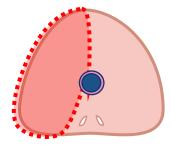
- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion



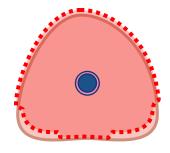
Ablation of benign prostate tissue

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



Elterman et al, Prostate Cancer and Prostate Diseases, 2019 (Under Review)

Ramsey et al, The Journal of Urology, 2017

Chin et al, European Urology, 2016 Bonekamp et al, European Radiology, 2018

al, The Journal of Urology, 2019 (AUA Abstract)

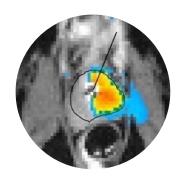
Anttinen et al, International Journal of Hyperthermia, 2019 Anttinen et al, Scandinavian Journal of Urology, 2019 (Under Review)

Suomi et al, ISTU Barcelona, Spain, 2019 (Conference) Sainio et al, ISTU Barcelona, Spain, 2019 (Conference)

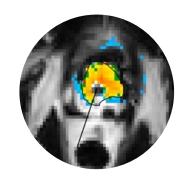
TULSA-PRO Unique Flexibility

Whole Gland Ablation

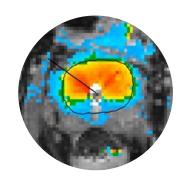
Targeted Ablation



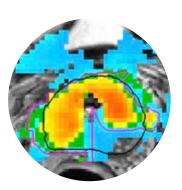
Post Radiation Failure Ablative Therapy



Targeted Ablation of a benign large prostate



Targeted Ablation of a benign large prostate with malignant lesion



Clinical Application & Adoption

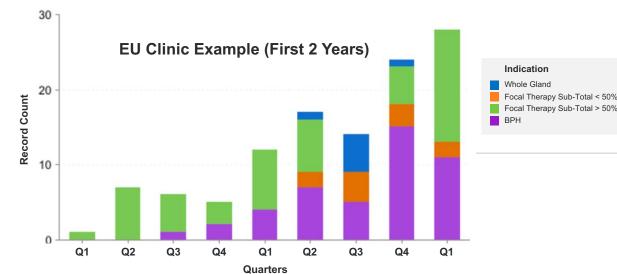
Learnings From Limited EU Launch







	Prostatectomy	Radiation	TULSA
Throughput: Procedures/Day	2 typically3 on a longer day	 Multiple sessions: 5-to-40 over 4-to-8 weeks 	4 in a routine dayConsistent treatment times
Patient Recovery	• Weeks	Deterioration over time	 Outpatient procedure for most patients Generic analgesic needed for pain management after procedure



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

TULSA-PRO

System Components



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 coops 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



Building Our Brand

Low-Cost / High-Impact Patient Awareness Initiatives

Customer Branded Patient Marketing

- TULSA Patient Marketing
- TULSA Digital Marketing

Profound Branded Patient Marketing

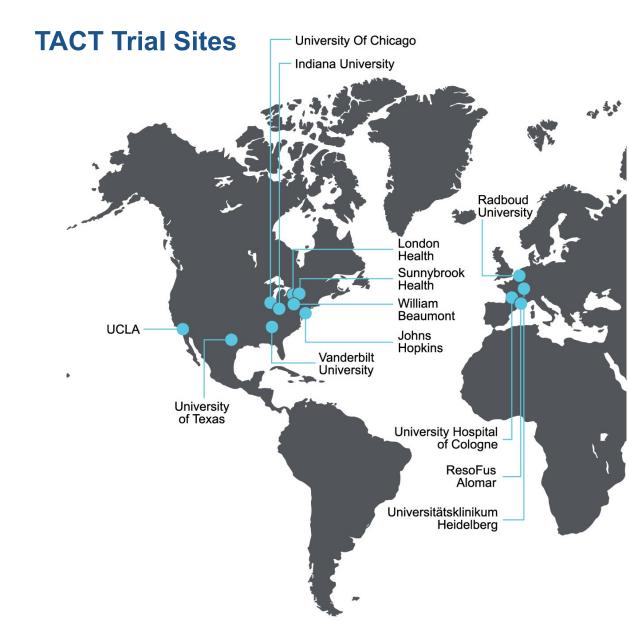
- TULSA Patient Website
- Corporate Website Enhancements
- Video Patient & Physician Testimonials





Centers of Excellence

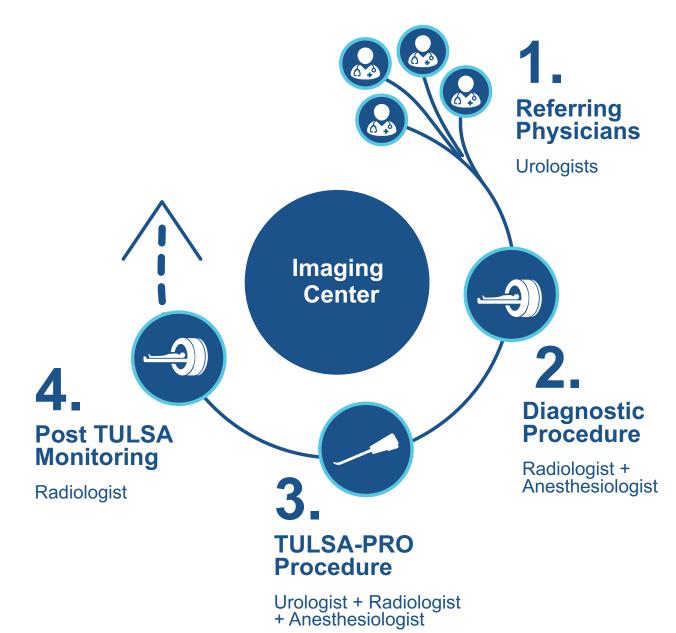
- Includes many of the TACT study sites
- Will likely be relatively low volume while TULSA is a patient self-pay procedure
- Best positioned to help drive long-term adoption by:
 - Participate in additional trials designed to support reimbursement
 - Training next generation of urologists
 - Presenting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





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



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 just 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 Stated + Canada

B. 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	 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 guidelinesNeed 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

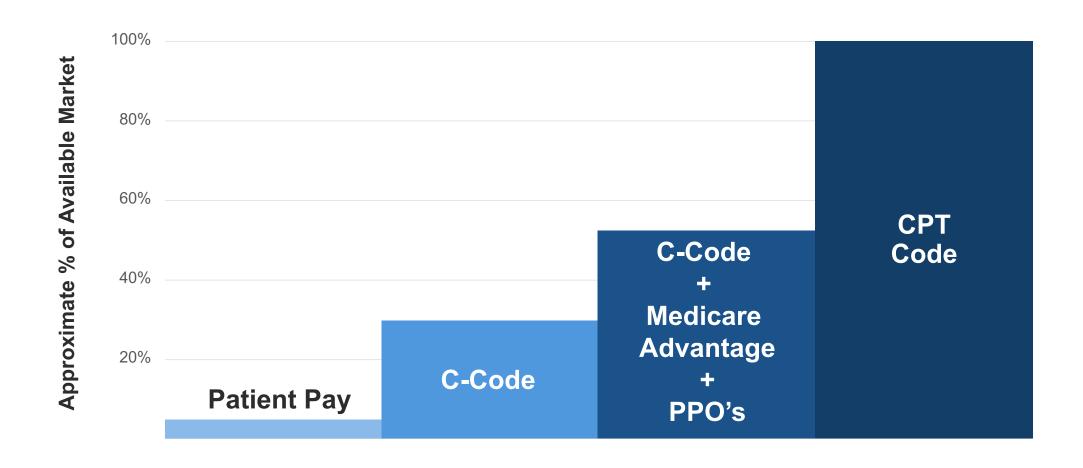
AMA Requirements for Category I CPT Code

- 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)



Reimbursement Pathway Summary

From "Cleared" to "Covered"





Longer Term

Building an Incision- & Radiation-Free Ablative Therapeutic Platform

Oncology, Highly Symptomatic Chronic Diseases



SONALLEVE





Current Approvals

Europe: CE Marked

China: CNMPA Approved

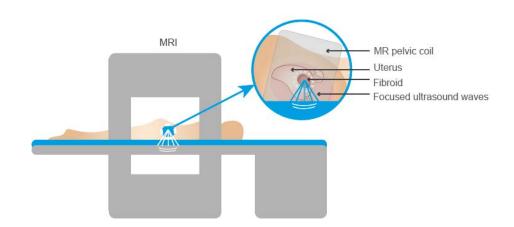


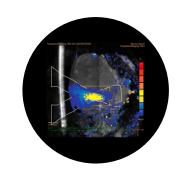


Over 200 publications

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







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