

Corporate Presentation | January 2021 © 2021 Profound Medical Corp.

NASDAQ: PROF

**TSX: PRN** 

#### Forward-Looking Information

Certain statements in this presentation may contain certain information that is "forward-looking information" or "forward-looking statements" within the meaning of applicable securities laws with respect to Profound Medical Corp. ("Profound" or the "Company"). Such statements include all 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 information can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "sefare 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", "would", and "could" intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to our expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its products, our expectations regarding commercializing our approved products and our ability to generate revenues and achieve profitability; our expectations regarding the impact of COVID-19 on our business, affairs, operations, financial condition, liquidity, availability of credit and results of operations; our expectations regarding the safety, efficacy and advantages of our products over our competitors and alternative treatment options; our expectations regarding our relationships with Philips and Siemens, and our ability to achieve compatibility of our approved products from third-party payers; our expectations regarding our relationships with MRI scanners produced by other manufacturers; our ability to attract, develop and maintain relationships with other suppliers, manufacturers, distributors and strategic partners; our expectations regarding our repoducts to cover additional

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 related to our limited operating history and history of net losses; risks relating to the extent and impact of COVID-19; risks related to our ability to commercialize our approved products, including expanding expanding our sales and marketing capabilities, increasing our manufacturing and distribution capacity, realizing the anticipated benefits of our commercial agreement with RadNet, 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 future 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 publ

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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 third-party 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. Although Profound believes it to be reliable, the Company has 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.

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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.

#### COVID-19

The COVID-19 outbreak has been declared a pandemic by the World Health Organization. It is too soon to gauge the impacts of the current outbreak, given the many unknowns related to COVID-19 including the duration and severity of the outbreak. COVID-19 is altering business and consumer activity in affected areas and beyond. The global response to the COVID-19 outbreak has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Additional measures may be implemented by one or more governments in jurisdictions where the Company operates. These measures have caused material disruption to businesses globally, resulting in an economic slowdown. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions required to contain the COVID-19 virus or remedy its impact, among others.

The actual and threatened spread of COVID-19 globally could also have a material adverse effect on the regional economies in which the Company operates, could continue to negatively impact stock markets, including the trading price of Profound's Common Shares, could adversely impact the Company's ability to raise capital, and could cause continued interest rate volatility and movements that could make obtaining financing more challenging or more expensive.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company' ability to conduct its businesses, including its ability to cultivate adoption of the TULSA-PRO technology, support clinical customers with the TULSA-PRO procedures and increase the utilization of the systems and disposable components.



# "My life should not have to change"

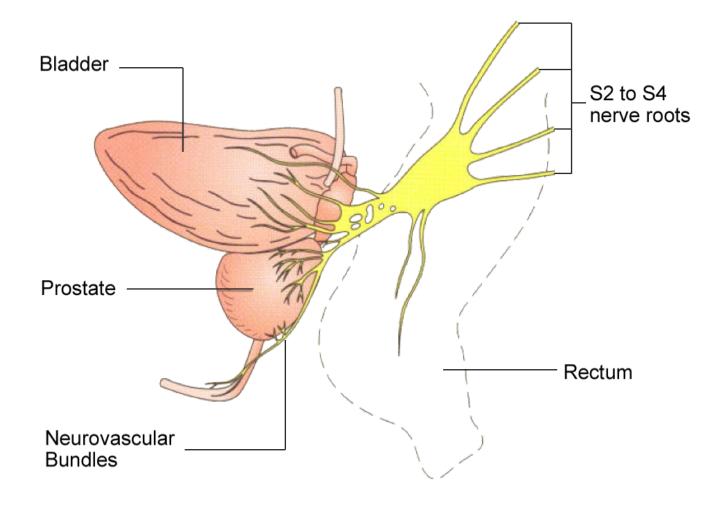
# TULSA-PRO®

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



#### **Prostate Disease**

Anatomy & Current Landscape in the United States ("U.S.")



~175,000

new prostate cancer cases per year

60%

are > 65 years

> 3M

men living with diagnosed prostate cancer

**10M** 

men living with Benign Prostatic Hyperplasia ("BPH")<sup>1</sup>

300,000

BPH surgical procedures per year<sup>1</sup>

#### **Common treatment options**

- 1. Surgery to remove prostate
- 2. Radiation to kill it in place

#### **Common sides effects**

- 1. Urinary and/or rectal incontinence
- 2. Erectile dysfunction



# TULSA-PRO Our Solution

How we see & plan



Real-time MRI Guidance

Ablation using real time MRI imaging and thermometry

How we ablate



Transurethral
Directional Thermal
Ultrasound

Transurethral heating of the prostate gently to 55° C without boiling tissue

How we control



Closed-loop Thermal Feedback

Robotic closed loop temperature control to enable whole gland ablation of any size prostate

Post-procedure, the dead prostate tissue is slowly resorbed by the body



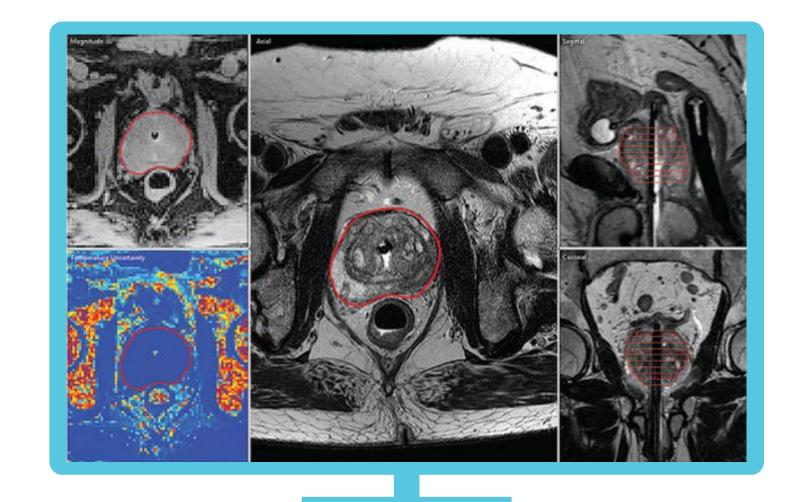
#### **TULSA-PRO**

Patient MRI Bore, Physicians Create 3D Treatment Plan Using Real-Time MRI Visualization

How we see & plan



Real-time MRI Guidance

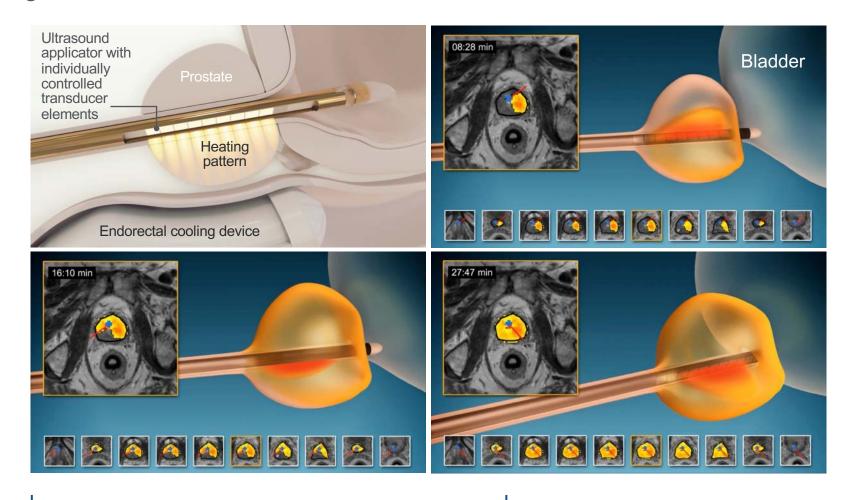




#### TULSA-PRO

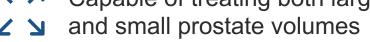
#### Transurethral Gentle Heating of Prostate to 55° C

# How we ablate **Transurethral Directional Thermal Ultrasound**





Capable of treating both large





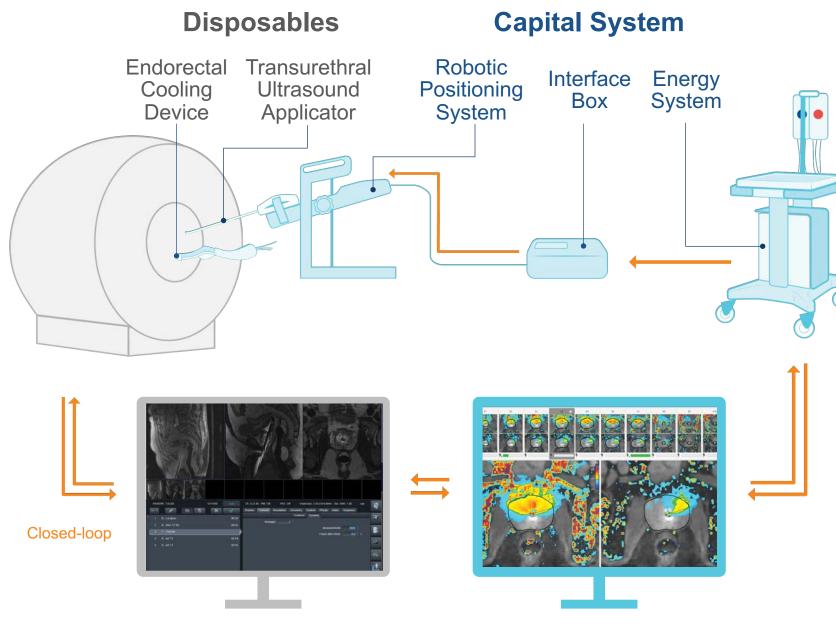
Thermal protection of important anatomy

# TULSA-PRO System Components

# How we control



Feedback





#### **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:

Median PSA reduction was 95%, stable to 2 years

Pre-Treatment	Nadir	1 year	2 years
6.3 ng/ml	0.34 ng/ml	0.53 ng/ml	0.63 ng/ml

80% of men

Extensive biopsy sampling demonstrated a histological benefit for nearly 80% of men

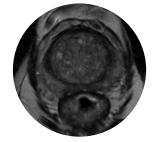
7% of men

Underwent additional intervention for their prostate cancer by 2 years, comparable to accepted rates of relapse after standard prostate cancer treatments

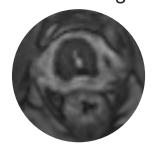
#### **Prostate volume significantly reduced:**

• Median prostate volume decreased **91%** from 37 cc to 3 cc

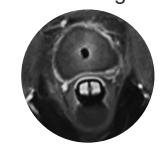
Screening: 58 cc PSA 5.5 ng/ml



**3-months Post** PSA < 0.1 ng/ml



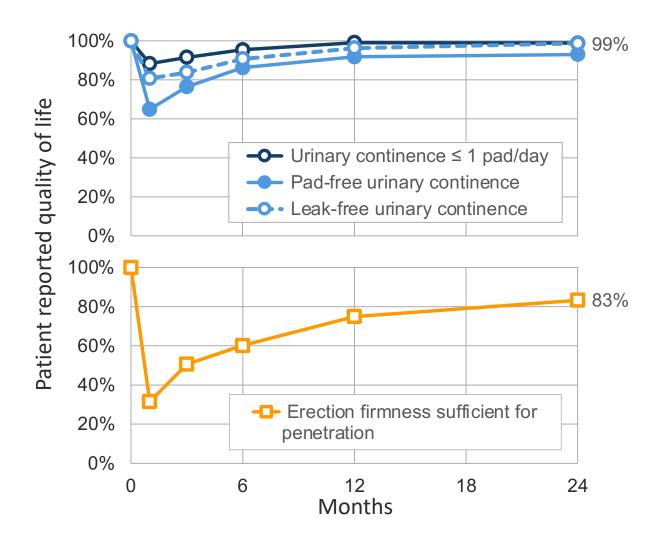
Immediate Post PSA 6.0 ng/ml



**12-months Post: 0.5 cc** PSA < 0.1 ng/ml



# TACT Safety & Patient Quality of Life



#### **Adverse Events**

- No grade ≥ 4 adverse events
- No intraoperative complications
- No rectal injury, no rectal fistula
- 7% of men experienced a serious adverse event, all resolved by 1 year

#### **Urinary Incontinence**

- No new onset between 1 and 2 years
- 1% patients reported one or more leak per day,
   7% wear a pad for security

#### **Erectile Dysfunction**

- One new onset between 1 and 2 years
- 0% severe ED (medication not helpful)
- Continued recovery of erectile function at 2 years, 17% previously potent patients reported erection firmness insufficient for penetration



#### Clinical Applications of TULSA-PRO

#### Ongoing Investigator-initiated Clinical Trials

Benign

#### Organ Confined Prostate Cancer

Low Risk

Intermediate Risk

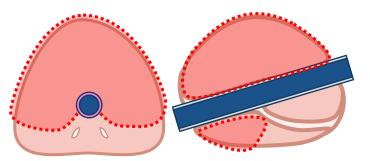
High Risk

Salvage / Palliative

#### Large prostate BPH 1,2

NCT03350529 to-date (n=10):

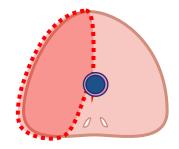
- IPSS 18.4 → 4.6 @ 6m
- IPSS QOL 4.1 → 0.6 @ 6m



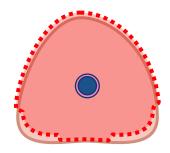
Ablation of benign prostate tissue

#### Customized ablation 3-8

NCT02766543 (n=115 + 35), TACT NCT03814252 (n=30), ongoing single-arm NCT03668652 (n=250), ongoing RCT vs. RP



Targeted ablation of diseased prostate tissue



Whole gland ablation with bilateral nerve sparing

- 1. Elterman et al, Journal of Endourology, 2020
- 2. Viitala et al, EAU 2020 (Conference presentation)
- 3. Ramsey et al, The Journal of Urology, 2017
- 4. Chin et al, European Urology, 2016
- 5. Bonekamp et al, European Radiology, 2018

- 6. Klotz et al, The Journal of Urology, 2020 (Accepted, pending publication)
- 7. Anttinen et al, International Journal of Hyperthermia, 2019
- 8. Anttinen et al, Scandinavian Journal of Urology, 2019
- 9. Anttinen et al, EU Open Science, 2020 (Submitted, not yet accepted)
- 10. Anttinen et al, Scandinavian Journal of Urology, 2020

#### Recurrence after radiation 9

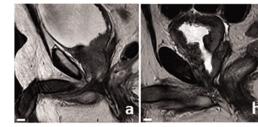
NCT03350529 to-date (n=11):

- 10/11 neg. in-field Bx @ 12m
- No change in IPSS, IIEF, EPIC SF / BF / UI @ 12m

#### Palliative locally advanced <sup>10</sup>

NCT03350529 to-date (n=10):

- 10/10 hematuria-free
- 7/10 catheter-free
   1/10 improved
   2/10 no change
- Hospitalization 7.3 → 1.4 days, within 6 months pre/post TULSA



#### **TULSA-PRO**

Flexibility to Treat Different Types of Patients

Whole Gland Ablation

**Unique Flexibility** 

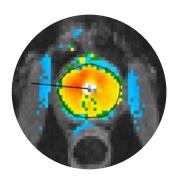
Analogous to surgery and radiation

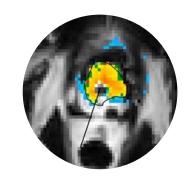
Whole gland post radiation failure

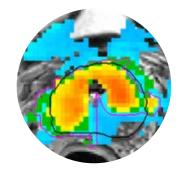
Malignant lesion with lower urinary tract symptoms

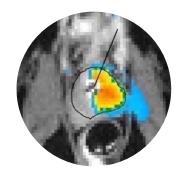
**Hemi-gland** 

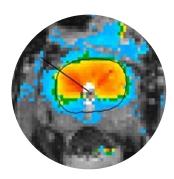
Benign large prostate with lower urinary tract symptoms











# 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 publications
- Low-cost / high-impact patient awareness initiatives
- TULSA patient website with center locator: www.tulsaprocedure.com



# TULSA-PRO at Imaging Centers

- Early adopter Urologists focused on emerging technologies
- Independent Imaging service provider companies
- Opinion leading hospitals / Centers of Excellence



# **Business Model**

 Recurring revenueonly



## 'Profound Genius Services'

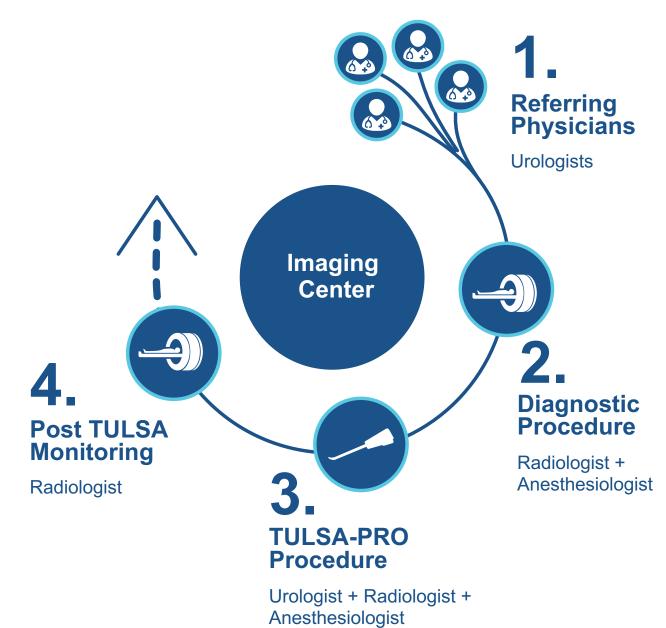
- Clinical proficiency demonstrate TULSA flexibility by treating full variety of patients
- Productivity number of patients/day
- Patient recruitment and satisfaction
- Reimbursement
- Innovation/publications



#### **Commercial Imaging Centers**

Recurring Revenue-Only

- 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





#### New TULSA-PRO Patient Website

www.tulsaprocedure.com

TULSA Center Locator Page

Detailed Information to Help Patients Understand Their Options

Contact Forms to Reach Out to Each Center Directly

**Patient Testimonials** 





# Longer Term

Building an Incision- & Radiation-Free Ablative Therapeutic Platform

Oncology, Highly Symptomatic Chronic Diseases



#### SONALLEVE





# **Current Approvals**

**Europe:** CE Marked

China: CNMPA Approved

**U.S.:** HDE Approved





### Over 200 Publications

from leading U.S. & European clinicians and hospitals

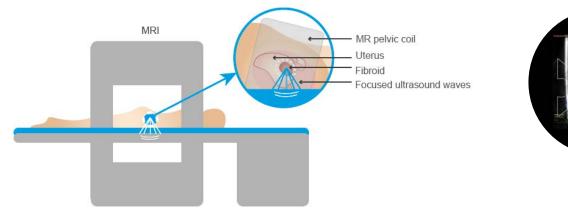
**Uterine Fibroid Treatment** 

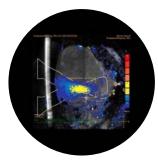
**Pain Management** 

**Pediatric Bone** 

**Hyperthermia** 

**Abdominal Cancer** 







### Business Model Capital Efficient

- TULSA-PRO: focus on U.S. commercial rollout
- Sonalleve: focus on Asia with larger distribution partner; work to expand approvals in U.S.

#### **Future Investments**

- Expand sales team
- Increase manufacturing capacity
- Support additional clinical trials with TULSA-PRO for reimbursement
- Continue further product enhancements

