Driving a new therapeutic standard in prostate cancer

September 2016
Forward-Looking Statements

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Although Profound has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Profound undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, other than as required by law.
Investment Highlights

• Proprietary technology to ablate prostate cancer in a single, two hour treatment by urologists

• Reduction in side effect frequency compared to current treatments

• Large and growing market: >500,000 new patients/year

• Commercial stage in Europe (CE Mark received) and commencing TACT pivotal trial in U.S.

• Validated technology; relationships with Siemens and Philips

• Attractive razor/razor blade model with high-value, one-time use consumables
Over 5.8 Million Men Living with Prostate Cancer

2.8M US\textsuperscript{4} men and 3M EU\textsuperscript{5} men are living with prostate cancer.

Over 524,000 new patients per year in initially targeted geographies: 181,000 US\textsuperscript{1} and 343,000 in EU\textsuperscript{2}.

Annual number of procedures = 1.5x new patients.

1. American Cancer Society
2. International Agency for Research on Cancer. WHO.
3. iData Research and company assumptions
4. seer.cancer.gov
5. European Alliance for Personalized Medicine, 2015
### Most Widely Used Therapies Today

<table>
<thead>
<tr>
<th>PROCEDURES</th>
<th>MONITORING</th>
<th>ACTIVE SURVEILLANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NO INCISION</strong></td>
<td>![X]</td>
<td>![✓]</td>
</tr>
<tr>
<td><strong>APPROACH</strong></td>
<td>Outside-In</td>
<td>Outside-In</td>
</tr>
<tr>
<td><strong>PROTECTION OF CRITICAL ANATOMY</strong></td>
<td>![X]</td>
<td>![X]</td>
</tr>
<tr>
<td><strong>COMPLICATIONS &amp; SIDE EFFECTS</strong></td>
<td>High rate of incontinence and impotency</td>
<td>High rates including damage to bowels</td>
</tr>
</tbody>
</table>
| **LIMITATIONS** | • Success related to skill of surgeon  
• Recovery time | • Damage to surrounding tissue  
• Risk of secondary cancers  
• Delayed onset of therapy & side effects  
• Multiple sessions over 30 to 60 days  
• 30% patients fail treatment\(^1\) | |

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# Less Frequently Used Therapies

<table>
<thead>
<tr>
<th>HIFU</th>
<th>CRYOTHERAPY</th>
<th>ANDROGEN DEPRIVATION THERAPY (Hormone Therapy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROCEDURE</strong></td>
<td>Focused ultrasound delivered via rectum</td>
<td>Under ultrasound guidance, hollow probes inserted into prostate; cold gases then passed through, creating ice balls that destroy prostate</td>
</tr>
<tr>
<td></td>
<td>Heats at up to &gt;100°C</td>
<td></td>
</tr>
<tr>
<td><strong>LIMITATIONS</strong></td>
<td>3+ hours</td>
<td>Rarely utilized; second line therapy if radiation fails</td>
</tr>
<tr>
<td></td>
<td>Potential thermal damage to nerves and bowels; Obstructive urinary complications</td>
<td>High rates of side effects, especially erectile dysfunction</td>
</tr>
<tr>
<td></td>
<td>Limited to average or smaller sized prostates</td>
<td></td>
</tr>
</tbody>
</table>
The Problem: Complication Rates & Side Effects

Severe Incontinence: 4% - 15%
Bowel Problems: 7% - 25%
Impotency: 58% - 79%

Current complication rates and variability may be correlated to lack of precision in treatment technologies available today:

- Lack of direct ability to control potential damage to critical anatomy
- Experience of the surgeon

- EDAP Technomed Inc., “EDAP Ablatherm® integrated imaging high intensity focused ultrasound (HIFU) indicated for the treatment of low risk, localized prostate cancer,” Sponsor Executive Summary (June 23) and Presentation Slides (July 30) from the Premarket Approval Application P130003 (2014)
- PMI 12-month Phase 1 Trial, GCP-10102 Table 10
# Functional Outcomes with Current Treatments

## Functional Outcomes at 2 years¹

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

## Rate of complications reported with radical prostatectomy & radiotherapy²,³

(Variation as reported in 436 publications)

3. PMI 12-month Phase 1 Trial, GCP-10102 Table 10
Our Solution: TULSA, “One & Done”

Ablate cancerous prostate tissue in a single 2 hour procedure

- No incision: minimizing recovery time
- Ablate prostate from inside-out: inherently safer than outside-in
- Precise ablation: robotic applicator, real-time MRI Guidance, real-time temperature guidance and control
- Actively protect (via cooling) critical anatomy that normally gets damaged causing side effects
TULSA Procedure

Please click here to view video
TULSA-PRO™ Device Technology

CONTROL ROOM

SCAN ROOM

EQUIPMENT ROOM
Automated, Precise Ablation from the Inside-Out

1. MRI Guided Device Positioning
2. Precise Treatment Planning by Urologist
3. Automated Temperature Feedback Controlled, Robotically driven
   - Controlled Algorithm Target Temp 57\(^\circ\) Celsius
   - Ablation in 40 minutes
4. Confirmation of Ablation Margin with MRI
Unique Active Cooling Protects Critical Anatomy
TULSA ablation is accurate to 1.3 mm, confirmed by contrast-enhanced MRI and histology in animal and human studies.

Thermal MRI measurement from TULSA procedure

High resolution contrast MRI confirms ablation accuracy

Also confirmed by gold standard whole-mount pathology

Chopra et al, Phys Med Biol. 2009; 54(9): 2615-33
Chin et al, European Urology (Sept 2016)
Opportunity is Well Protected by Strong IP

- Core patents focus on system and method to accurately treat tissue by measuring temperature and controlling ultrasound beam amplitudes and frequencies
  - Core claims include, but are not limited to, transurethral prostate treatment
  - Original core patents valid through 2026-2029
- Newer patents extend coverage to algorithms and devices used to deliver treatment
  - United States: 6 patents issued, 6 pending
  - PCT: 9 patents pending
Safety & Feasibility Clinical Trial: Completed

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>Determine safety and feasibility of MRI-TULSA for whole-gland prostate ablation in a primary treatment setting of localized prostate cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBJECTS</td>
<td>30 Patients (Inclusion criteria: Men ≥ 65 yr, organ confined PCa, PSA ≤ 10 ng/ml, Gleason score 3+3 or 3+4)</td>
</tr>
</tbody>
</table>
| OUTCOMES  | • 30 patients treated with at least 12 month follow-up  
• No intraoperative complications, no rectal injury or fistula  
• Erectile dysfunction rate of 8% (IIEF item 2 ≥ 2)  
• At 12 months, only 1 patient (3%) with Grade 1 urinary incontinence (no pads)  
• Functional quality-of-life outcomes back to baseline levels  
• Accuracy of thermal ablation +/- 1.3 mm |

Chin et al, “Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial,” European Urology (2016)
## TACT Pivotal Trial: IDE Approved

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>Further evaluate safety and efficacy of TULSA-PRO™ intended to ablate prostate tissue of patients with localized, organ-confined prostate cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBJECTS</td>
<td>110 Patients (Inclusion criteria: Males, age 45-80 yrs, organ confined PCa, PSA ≤ 15 ng/ml, Gleason score ≤ 3+4)</td>
</tr>
<tr>
<td>SITES</td>
<td>15 Sites, first patient September 2016</td>
</tr>
</tbody>
</table>

### OUTCOMES

**Primary Endpoints**
- Safety
- Efficacy

**Secondary Endpoints**
- Frequency and Severity of Adverse Events
- Rate of Erectile Dysfunction
- Rate of Urinary Incontinence
- PSA Levels and Stability
- Procedure Efficiency
- Resource Requirements for Reimbursement Purposes
Changing the Therapeutic Prostate Paradigm

Safe, Fast & Accurate

• No need to wait, reducing psychological distress

• Single treatment; quick 2 hour procedure

• No incision (minimally invasive) leads to a quick recovery

• Leveraging existing infrastructure and precision of MRI

Dr. Chin and world’s first TULSA-PRO™ patient
Multiple treatment approaches, including infrequently performed procedures, are already reimbursed

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>CODE</th>
<th>PAYMENT 2016</th>
<th>CODE</th>
<th>PAYMENT 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAPAROSCOPIC RADICAL PROSTATECTOMY WITH CC</td>
<td>DRG 666</td>
<td>$9,775</td>
<td>CPT 55866</td>
<td>$1,443</td>
</tr>
<tr>
<td>LAPAROSCOPIC RADICAL PROSTATECTOMY WITH MCC</td>
<td>DRG 665</td>
<td>$17,022</td>
<td>CPT 55866</td>
<td>$1,443</td>
</tr>
<tr>
<td>RADIATION THERAPY (IMRT SIMPLE, 40 SESSIONS)</td>
<td>APC 5623</td>
<td>$19,816</td>
<td>CPT 77387</td>
<td>Fee bundled into primary APC</td>
</tr>
<tr>
<td>BRACHYTHERAPY</td>
<td>APC 5532, 5613, 5374, 5614, 5624</td>
<td>$4,324¹</td>
<td>CPT 76873, 77318, 55875,55876, 77778</td>
<td>$2,206¹</td>
</tr>
<tr>
<td>CRYOABLATION</td>
<td>DRG 666</td>
<td>$9,775</td>
<td>CPT 55873</td>
<td>$793</td>
</tr>
</tbody>
</table>

¹. Payment is the sum of the indicated APC/CPT codes

The payments included in this worksheet are for Medicare patients, private payers payments for these procedures will vary and may result in higher payments than published Medicare rates.
Reimbursement For TULSA

• Positive feedback from reimbursement experts who have communicated with payers: “Clinical and economic and survival data from the TACT study may be sufficient to submit for reimbursement consideration”

• Simultaneously, plan to work with American Medical Association (AMA) and the American Urological Society (AUA) to directly apply for a category 1 CPT code using the data from TACT

• CMS has approved payment of approximately $8,200 for the procedure per patient for the TACT trial
TULSA Well-Suited for Accountable Care

TULSA is inherently less expensive than other therapies

• Cost of using the MR suite is significantly less than that of an operating room or a radiation therapy room

• Treatment time for TULSA is significantly shorter than that of other therapies

• TULSA is potentially a one time day therapy
TULSA: Clinical & Economic Value

TULSA can impact disease management choices as a result of its clinical & economic value.

- **Active Surveillance**: TULSA potentially reduces costs of active surveillance and total cost of prostate care by minimizing the need to wait.

- **Radiation**: TULSA potentially less expensive, one-time treatment, with minimal concern of therapy failure.

- **Prostatectomy**: TULSA potentially an alternative for patients who are candidates for radical prostatectomy but are concerned about side effects and recovery time from co-morbidities.
## Delivering Benefits Across Continuum

<table>
<thead>
<tr>
<th>PATIENTS</th>
<th>UROLOGISTS</th>
<th>PAYERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Single procedure</td>
<td>• Ability to treat patients who might otherwise go to radiation</td>
<td>• Faster procedure and shorter time in hospital</td>
</tr>
<tr>
<td>• Short duration ~ 2 hours</td>
<td>• Computer-driven procedure enables standardization across doctors</td>
<td>• Favorable side effect and complication profile</td>
</tr>
<tr>
<td>• Significant reduction of side effects and complications</td>
<td>• Enables urologist to use innovative/cutting-edge therapies remotely, in</td>
<td>• Change in risk-benefit analysis may cause patients on active surveillance to act earlier, reducing total/ongoing cost</td>
</tr>
<tr>
<td>• Faster recovery and return to normal activities</td>
<td>“control room” setting</td>
<td></td>
</tr>
</tbody>
</table>
Solid Path to Commercialization

• Co-marketing agreements signed with leading MR companies, Philips and Siemens, even prior to CE Mark

• Leverage brand, scale & installed base and co-market with partners
  • TULSA-PRO™ base units (robotic system & treatment delivery console) can be sold bundled with new MR sales or as a follow-on sale to broaden utility of MR installed base by Siemens and Philips

• Profound sales team to co-sell TULSA-PRO™ base units with MR companies and independently drive utilization (~$3,000 USD per patient) after the sale

• Establishing Centers of Excellence & reference hospitals

• Developing country-specific market entry strategies, with initial focus on Germany and opinion-leading sites
Key Upcoming Milestones

**TACT Trial:**
- First patient treated – September 2016
- Recruitment completed – End of Q2 2017
- Reporting Interim data (6 months) – End of Q4 2017
- Reporting Interim data (12 months) – End of Q2 2018
- FDA 510k submission – Early Q3 2018

**Commercial – Europe:**
- First revenue recognized – Q4 2016
- Focus on Germany & EU opinion leading sites
- Establishing Centers of Excellence & reference hospitals
- Market access and digital marketing to drive momentum
## Capitalization

<table>
<thead>
<tr>
<th>Exchange &amp; Ticker</th>
<th>TSXV: PRN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash</strong> (@ June 30, 2016)</td>
<td>$12.9MM</td>
</tr>
<tr>
<td>Debt:</td>
<td></td>
</tr>
<tr>
<td>FedDev</td>
<td>$0.8MM</td>
</tr>
<tr>
<td>HTX</td>
<td>$1.3MM</td>
</tr>
<tr>
<td>Knight</td>
<td>$4.0MM</td>
</tr>
<tr>
<td><strong>Common Shares</strong> (@ March 31, 2016)</td>
<td></td>
</tr>
<tr>
<td>Basic, Fully Diluted</td>
<td>39.5MM; 43.8MM</td>
</tr>
<tr>
<td><strong>Significant Shareholders:</strong></td>
<td></td>
</tr>
<tr>
<td>BDC</td>
<td>24.8%</td>
</tr>
<tr>
<td>Genesys</td>
<td>23.1%</td>
</tr>
<tr>
<td>Knight</td>
<td>7.7%</td>
</tr>
</tbody>
</table>