Real-time tissue classification and therapy

“Transforming continuum of care in prostate cancer”

Amir Tehrani, CEO

January 18, 2018
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Prostate cancer patients poorly served currently
Under-diagnosis of cancer; invasive therapies; 26k morbidities annually

CURRENT POSITION / PROBLEM

35% HIGH GRADE CANCER
- Whole gland therapy
- Prostatectomy
- 85% serious side effects

65% LOW GRADE CANCER
- Active surveillance
- 6 monthly biopsies

1M BIOPSIES
- 12-14 random cores
- c. 50% false negative rate
- >25% repeat rate*

14M PSA TESTS
- Screening mechanism

PB SOLUTION

FOCAL THERAPY
- Minimally invasive
- Reduce side effects

3D MAPPING
- Precise 3D mapping of tumour
- Gateway to focal therapy

ClariCore™
- Live tissue classification
- Directed vs blind coring
- Reduced false negative rate
- Increased diagnostic yield
- $900m pathology saving

ANNUAL US INCIDENCE

1M BIOPSIES
65% LOW GRADE CANCER
35% HIGH GRADE CANCER
14M PSA TESTS

*250k procedures p.a.
US prostate cancer market >$7 billion
Precision Biopsy US addressable market opportunity: >$2 billion

**DIAGNOSTICS/BIOPSY**
- Targeted tissue sampling
- 1m biopsy procedures in US
- *PB Assumption:*
  - $1,500 ASP compare to current ASP of $2000 (pathology)
  - $1.5 billion market opportunity

**THERAPY PLANNING**
- Localized 3D tumor mapping
- *PB assumption:*
  - 100K mapping procedures in US at $3,000 ASP compared to MRI ASP of $5000
  - $0.3B market opportunity

**PROSTATE BIOPSY**
- Targeted tissue sampling
- 1m biopsy procedures in US
- *PB Assumption:*
  - $1,500 ASP compare to current ASP of $2000 (pathology)
  - $1.5 billion market opportunity

**3D MAPPING**

**INTEGRATED FOCAL THERAPY**
- Minimally Invasive
- *PB assumption:*
  - 100K focal therapy procedures in US at $10,000 ASP (of which 50% to Precision Biopsy, remainder to doctor / clinic)
  - $0.5B market opportunity

**THERAPY**
**Precision Biopsy’s disruptive technology**

1. **ClariCore™ diagnostics**—spectroscopy technology in a biopsy needle

   1. Needle shines light onto prostate tissue at 1mm intervals
   2. Proprietary machine learning algorithm (AI) assesses reflection against spectral biomarkers found in prostate tumours
   3. Providing live tissue classification: benign or suspect
   4. Reduced pathology costs
      More / guided probing – higher diagnosis rates
## ClariCore

Clinical studies following FDA IDE grant in 2016

### COHORT A (COMPLETE)

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>TRIAL TYPE</th>
<th># PATIENTS</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Algorithm training</td>
<td>✓ Offline</td>
<td>✓ 203 (8 sites)</td>
<td>✓ All objectives met; high algorithm accuracy rate established &amp; validated (not yet published)</td>
</tr>
<tr>
<td>✓ System safety</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>✓ Tissue collection efficacy</td>
<td></td>
<td></td>
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<tr>
<td>✓ Patient tolerance (pain)</td>
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### COHORT B (PENDING Q1-18)

DE NOVO 510K TRIAL PATH

- Validate algorithm
- Demonstrate clinical benefit
- Live (real-time)
- 300
- Unlock FDA approval

- All objectives met; high algorithm accuracy rate established & validated (not yet published)
Precision Biopsy’s disruptive technology
2. 3D mapping – gateway to focal therapy

• Standalone MRI inaccurate
  – 1-10mm tissue classification error

• ClariCore can be adapted to map the tumor in 3D with high precision
  – Unlocks focal therapy

• Preservation of healthy tissue
  – Lumpectomy vs. mastectomy
  – Minimize side effects

• Moves treatment from hospital to clinic – reduced cost while incentivising urologist

• Two US academic centers (NYU & USC) aligned to conduct FIM studies in 2018
## Intellectual property

<table>
<thead>
<tr>
<th>ISSUED</th>
<th>PENDING</th>
<th>OTHER</th>
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<tbody>
<tr>
<td>• U.S. patent 8,406,858</td>
<td>• Real-time tissue classification device &amp; method</td>
<td>• Will be filing additional application on algorithm process, and continually adding to patent portfolio as the technology develops</td>
</tr>
<tr>
<td>– Real-time tissue classification device &amp; method</td>
<td>• Motorized tissue classification apparatus and method (ClariCore extended claims)</td>
<td>• Internal patent council + Senniger Powers LLP</td>
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<tr>
<td>– Issued claims cover ClariCore™ Optical Biopsy System</td>
<td>• European patent applications</td>
<td></td>
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<tr>
<td>• US patent 9,814,448</td>
<td></td>
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<tr>
<td>– Real-time tissue 3D mapping &amp; focal therapy</td>
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<tr>
<td>– Therapies include cryoablation, HIFU, RF, local drug delivery</td>
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<td></td>
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<tr>
<td>• US patent 9,814,449</td>
<td></td>
<td></td>
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<tr>
<td>– Motorized tissue classification apparatus &amp; method</td>
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<tr>
<td>– ClariCore system for biopsy, mapping, and focal therapy</td>
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## Competitive landscape
Diagnostics, 3D mapping, focal therapy

<table>
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<tr>
<th><strong>ClariCore™</strong></th>
<th><strong>COMPETITION</strong></th>
<th><strong>PROVIDERS</strong></th>
<th><strong>PB COMPETITIVE ADVANTAGES</strong></th>
</tr>
</thead>
</table>
| **Diagnostic/ Biopsy** | MR/Fusion biopsy systems | [eigen](#), [Philips](#), [bk medical](#), [Koelis](#) | • PB accurate to 1 mm tissue sampling resolution vs MRI at up to 10mm inaccuracy – missing the tumour target  
• ClariCore one time procedure (vs two step Scan + Biopsy)  
• Inexpensive |
| **3D Mapping/ Therapy Planning** | MRI + radiologist’s analysis of region of interests (ROI) | [Philips](#), [Toshiba](#), [Siemens](#) | • Per MR/Fusion diagnostics |
| **Therapy** | Radical Prostatectomy | [BARD](#) | • Invasive with high side effect rate |
| | Brachy therapy | | • Invasive with high side effect rate |
| | Ablation | [CryoAb](#), [Edap Tms](#), [Sonacare](#) | • Current ablation therapies are performed on whole gland or half-gland  
• With PB’s RF ablation system, the tumor is surrounded by multiple RF catheters to apply energy from the outside, surrounding entire tumour |
Key advisors and investigators
World Renowned from Leading Institutions

Neal Shore, MD (US Principal Investigator)
Director, Carolina Urologic Research Center
President, Large Urology Group Practice Association (LUGPA)

Alan Partin, MD
Chairman, Department of Urology
Johns Hopkins Brady Urological Institute

James Eastham, MD
Chief of Urology Service
Memorial Sloan Kettering Cancer Center

Andre Abreu, MD
Assistant Professor of Clinical Urology
Keck School of Medicine of USC

Hashim Ahmed, MD (EU Principal Investigator)
Professor and Chair of Urology
Imperial College of London

David Crawford, MD
Head of Section Urologic Oncology
University of Colorado Health Sciences Center

James Wysock, MD
Assistant Professor
New York University Langone Medical Center

Eric Barret, MD
Urologist
Institut Mutualiste Montsouris, Paris, France
Upcoming milestones

- **2018**
  - Initiate Cohort B Study
  - ClariCore™ CE Mark

- **2019**
  - Conclude Cohort B study
  - Series B

- **2020**
  - ClariCore™ FDA approval
  - 3D Mapping CE Mark
  - 3D Mapping FDA approval

- **2022**
  - Focal Therapy CE Mark & FDA approval
Unlocking a premium exit valuation

| Disruptive innovation solving an important problem | • PB solves for current poor detection rate (30%), high pathology cost, and marketability reduces need for prostatectomy (85% side-effect rate) |
| --- |
| Favorable market dynamics | • Large, growing market: 1m biopsies p.a in US + 200k prostatectomies (EU a similar market again)  
• Precision Biopsy targeting >$2bn addressable segments  
• Starting with the prostate; potentially applicable to lungs/kidney |
| Sustainable competitive advantage | • Heavy patent protection  
• Machine learning will drive improvement in algorithm |
| Route to widespread adoption | • Category III reimbursement code; add-on  
• Clear patient benefits  
• Focal therapy drives economics to the urologist |
| Capable management, aligned interests | • Expertise in commercial business development, prostate cancer diagnostics/therapeutics and product development |
| Potential for competitive tension | • CE mark and FDA approval to unlock options |
Thank you