

Real-time tissue classification and therapy

"Transforming continuum of care in prostate cancer"

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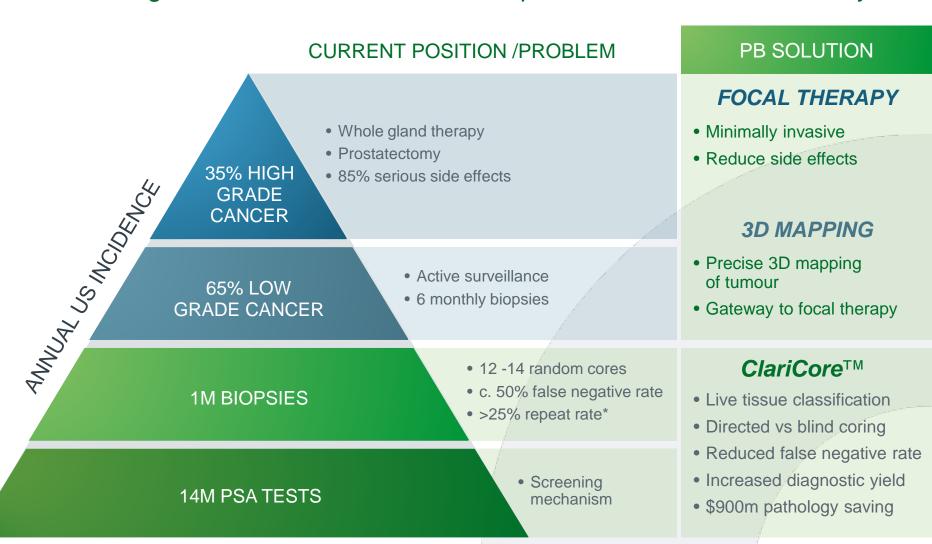
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## Prostate cancer patients poorly served currently

Under-diagnosis of cancer; invasive therapies; 26k morbidities annually



\*250k procedures p.a.

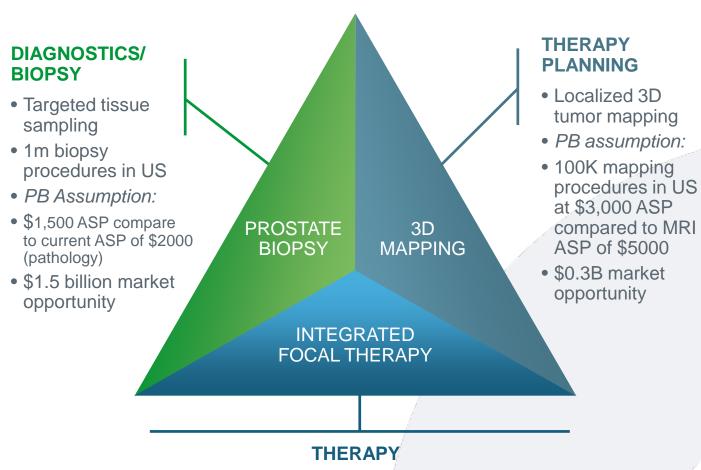
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### **US** prostate cancer market >\$7 billion

Precision Biopsy US addressable market opportunity: >\$2 billion



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



## Precision Biopsy's disruptive technology

1. ClariCore<sup>™</sup> diagnostics—spectroscopy technology in a biopsy needle



Needle shines light onto prostate tissue at 1mm intervals

Proprietary machine learning algorithm

(AI) assesses reflection against spectral biomarkers found in prostate tumours

Providing live tissue classification: benign or suspect

Reduced pathology costs

More / guided probing – higher diagnosis rates





### **ClariCore**

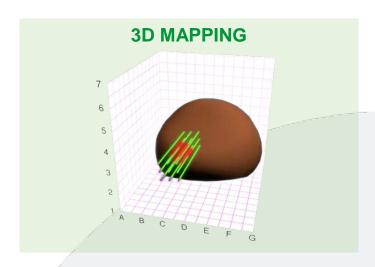
### Clinical studies following FDA IDE grant in 2016

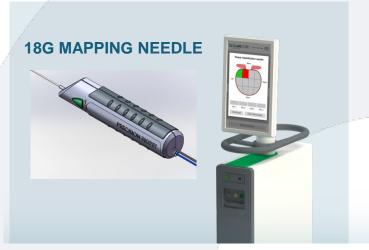
COHORT A (COMPLETE)		COHORT B (PENDING Q1-18) DE NOVO 510K TRIAL PATH
OBJECTIVE	<ul> <li>✓ Algorithm training</li> <li>✓ System safety</li> <li>✓ Tissue collection efficacy</li> <li>✓ Patient tolerance (pain)</li> </ul>	<ul> <li>Validate algorithm</li> <li>Demonstrate clinical benefit</li> </ul>
TRIAL TYPE	✓ Offline	Live (real-time)
# PATIENTS	✓ 203 (8 sites)	• 300
OUTPUT	✓ All objectives met; high algorithm accuracy rate established & validated (not yet published)	Unlock FDA approval



### **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**

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



# **Competitive landscape**

Diagnostics, 3D mapping, focal therapy

ClariCore <sup>™</sup>	COMPETITION	PROVIDERS	PB COMPETITIVE ADVANTAGES
Diagnostic/ Biopsy	MR/Fusion biopsy systems	bk medical	<ul> <li>PB accurate to 1 mm tissue sampling resolution vs MRI at up to 10mm inaccuracy – missing the tumour target</li> <li>ClariCore one time procedure (vs two step Scan + Biopsy)</li> <li>Inexpensive</li> </ul>
3D Mapping/ Therapy Planning	MRI + radiologist's analysis of region of interests (ROI)	TOSHIBA SIEMENS	Per MR/Fusion diagnostics
Therapy	Radical Prostatectomy		Invasive with high side effect rate
	Brachy therapy	BAIRD	Invasive with high side effect rate
	Ablation	Cryotherapy ablation  BTG  HIFU ablation  A edap tms  SONACARE	<ul> <li>Current ablation therapies are performed on whole gland or half-gland</li> <li>With PB's RF ablation system, the tumor is surrounded by multiple RF catheters to apply energy from the outside, surrounding entire tumour</li> </ul>



## 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)

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#### James Wysock, MD

Assistant Professor

New York University Langone Medical Center

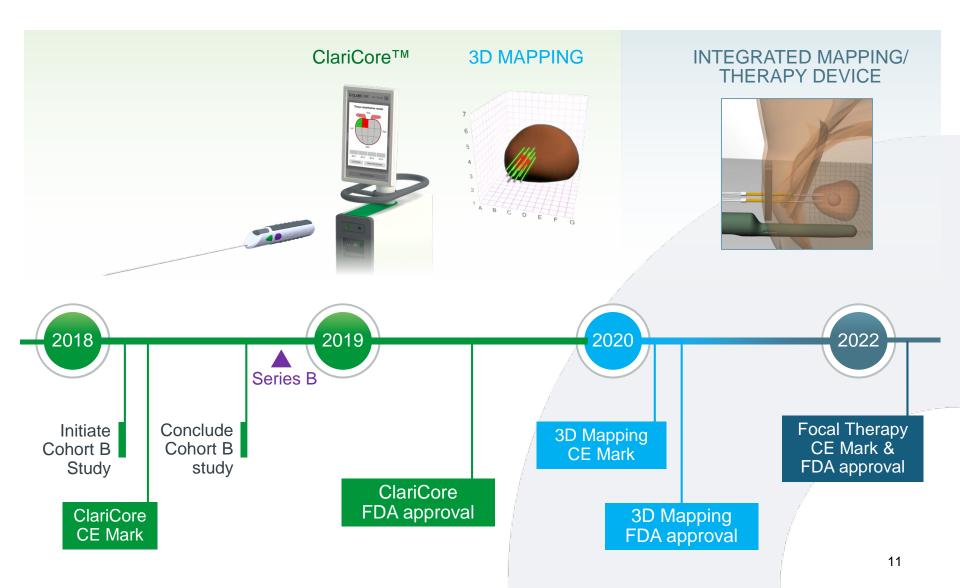
#### **Eric Barret, MD**

Urologist

Institut Mutualiste Montsouris, Paris, France



## **Upcoming milestones**





## 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	<ul> <li>Large, growing market: 1m biopsies p.a in US + 200k prostatectomies (EU a similar market again)</li> <li>Precision Biopsy targeting &gt;\$2bn addressable segments</li> <li>Starting with the prostate; potentially applicable to lungs/ kidney</li> </ul>	
Sustainable competitive advantage	<ul> <li>Heavy patent protection</li> <li>Machine learning will drive improvement in algorithm</li> </ul>	
Route to widespread adoption	<ul> <li>Category III reimbursement code; add-on</li> <li>Clear patient benefits</li> <li>Focal therapy drives economics to the urologist</li> </ul>	
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	



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# Thank you