



**PRO**SIGHT

## **XRF - GUIDED BIOPSY**

A Transformative Modality in Prostate Cancer

Maximizing Detection Rate and  
Cancer Characterization Accuracy

# ProSight at a Glance

PROSIGHT

Clinical Impact Achievable Goal	<b>Double</b> Cancer Detection Rate & Accuracy of Regular Prostate Biopsy Become Standard of Care in a \$10Bn market
Technologies Involved	Deep Tech: Cancer Biomarkers • X-Ray Fluorescence (XRF) • Cancer Biopsy & Diagnosis • AI-enhanced Algorithms • Cloud Cyber Security
IP	Granted (2015) • Pending (2021) • More Planned
Status	Clinical Proof of Concept <ul style="list-style-type: none"> <li>• Learning set: 600 patients</li> <li>• Initial validation set: 20 patients • 320 samples • 4,000 independent 1 mm voxels</li> </ul>
Regulatory path	510(k) FDA Submission - 12 months
Development Plan	ProSight 1.0 – Malignancy Imager Launch - 18 months ProSight 2.0 – Real-time XRF- Guided Biopsy - 27 months
Founders	Avi Simon; Dr. Meir Weksler; Yeda (WIS); WIS Scientists
Money injection to date	\$M 5.7
Current round & Use of Proceeds	\$11.5M (realistic prospects for 35% non-diluting funding) <ul style="list-style-type: none"> <li>• Product development - \$M 4</li> <li>• Clinical study - \$M 2</li> <li>• Regulatory process, launch, market adoption, reimbursement code - \$M 5.5</li> </ul>

# Need: Biopsy Accuracy is Key for Adequate Treatment

PROSIGHT

## Current Biopsy methods are INACCURATE

Systematic • Random (blind) → 30% False Neg → Repeat Biopsies

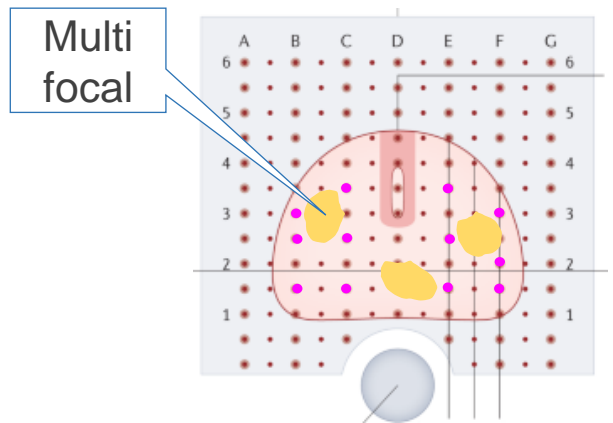
MRI-guided • Inaccurate ROI Definition • Benign Overlap (False Pos)

UNCERTAINTY

Under-detection of significant cancer  
Over-detection of insignificant cancer

UNCERTAINTY

Over / Under Treatment  
Limits Tailored Treatment



## Current Standard of Care

Screening • PSA, DRE

Needle Biopsy • 12 samples

Histopatholgy • grading & staging

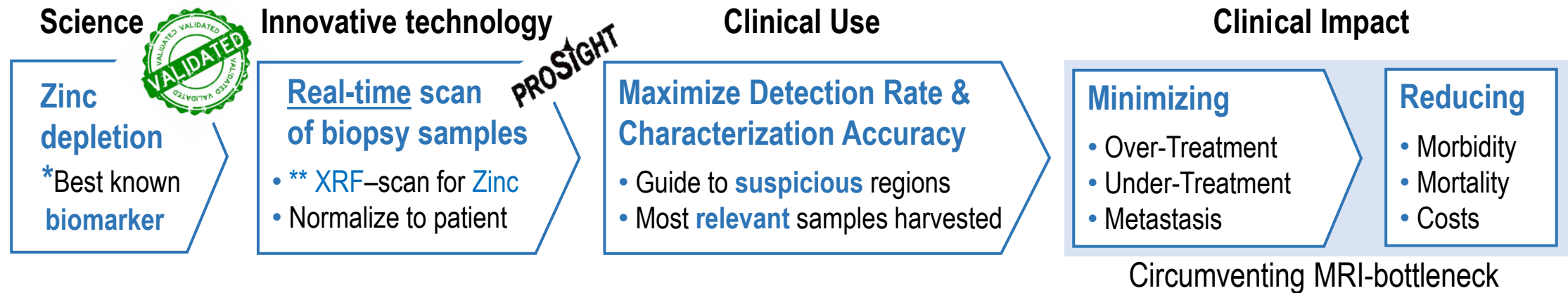
Genomic tests • Optional

Risk Stratification • 6 risk groups

Treatment • 3 main options

# Solution: ProSight - from Science to Clinical Use/Impact

PROSIGHT



**ProSight = High Detection Rate + Accurate Risk Stratification = Tailored Treatment Options**

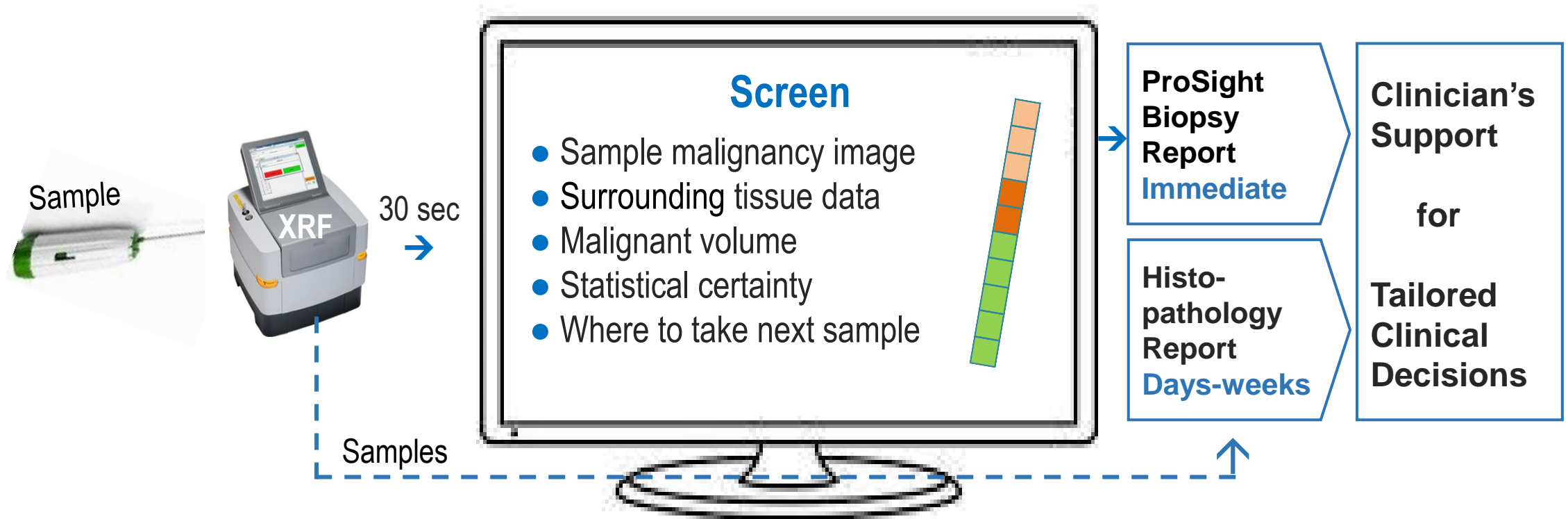
\* **1885 studies reported on Zn as prostate cancer biomarker:**

Zaichik V., *Biol Trace Elem Res.* 2021, 199(10):3593-3607. doi: 10.1007/s12011-020-02495-z.

\*\* **XRF** – X-Ray Fluorescence - Nondestructive method - used in medicine

# ProSight's Workflow-Neutral Clinical Flow

PROSIGHT



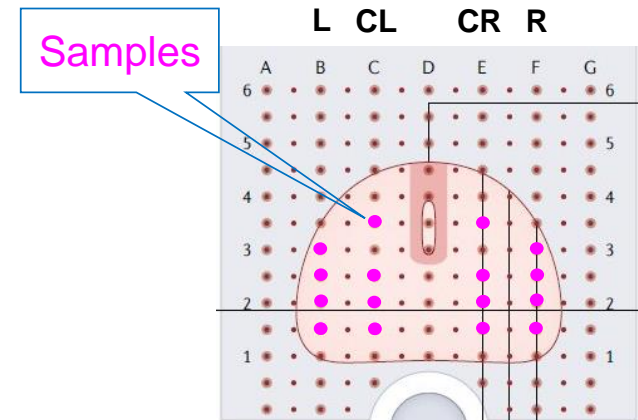
# Bottom Line: Clinical Validation vs Pathology at Ichilov Study Qualifies ProSight for Real-Time Biopsy Guidance

PROSIGHT

Row	Biopsy information	Left		Sample malignancy image	Center-Left		CenterRight		Sample malignancy image	Right	
		Pathology	Prosight		Pathology	Prosight	Pathology	Prosight		Pathology	Prosight
1	Grade	GG1	GG1		Neg	Neg	Neg	Neg		GG1	GG1
	% malignant	75%	67%		NA	NA	NA	NA		20%	14%
	Tissue type	SGH	SGH		SGH	SGH+MCI	SGH	SGH		SGH	SGH
2	Grade	GG1	GG1		Neg	Neg	GG1	GG1		Neg	Neg
	% malignant	65%	71%		NA	NA	40%	57%		NA	NA
	Tissue type	SGH	SGH		SGH	SGH+MCI	SGH	SGH		SGH	SGH
3	Grade	GG1	GG1		GG1	GG1	Neg	Neg		Neg	Neg
	% malignant	85%	75%		2%	10%	NA	NA		NA	NA
	Tissue type	SGH	SGH		SGH	SGH	SGH	SGH+MCI		SGH	SGH
4	Grade	GG1	GG1		GG1	GG1	GG1	GG2		Neg	Neg
	% malignant	2%	10%		5%	14%	40%	50%		NA	NA
	Tissue type	SGH	SGH		SGH	SGH	SGH	SGH		SGH	SGH

Lesion / pixel legend: Benign g3 g4 \* MCI

\* Note that MCI is always in the vicinity of positive samples - as predicted in the literature

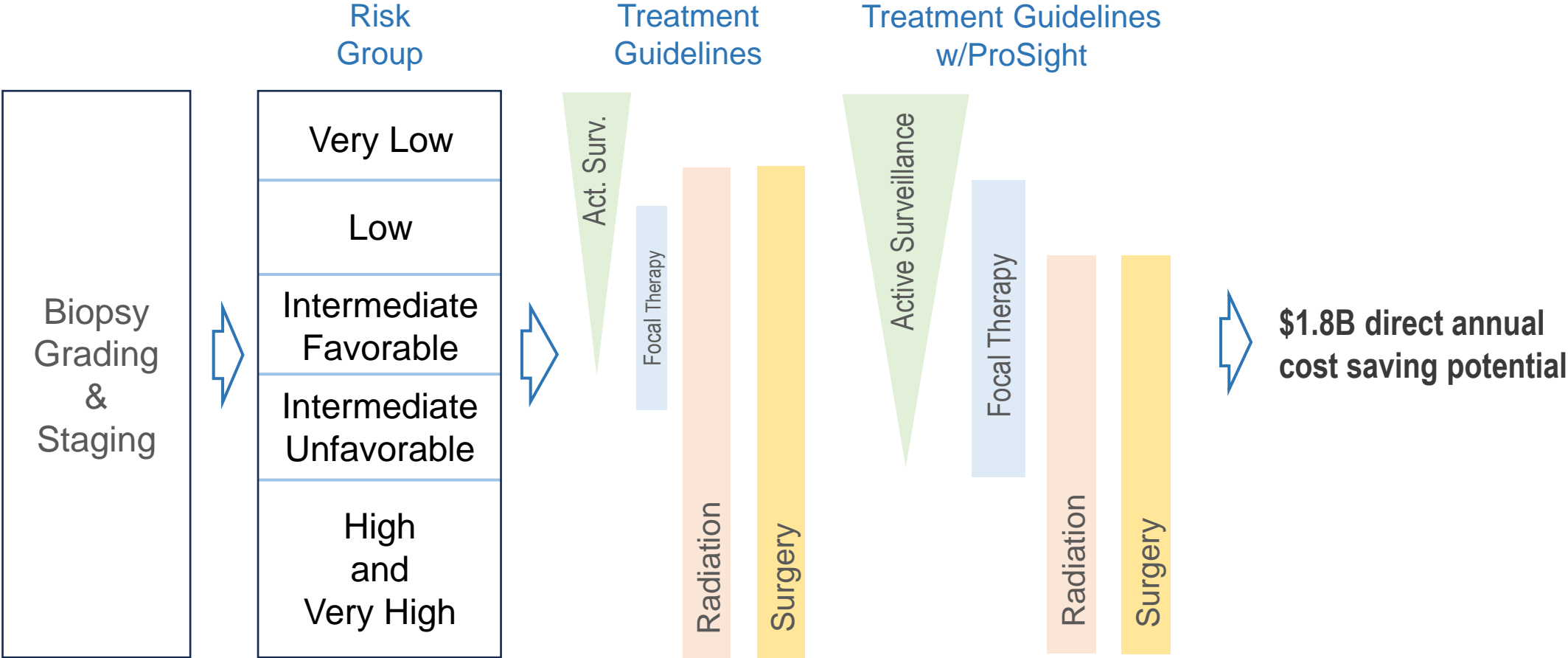


"Voxelized" sample

Sample Level		Lesion in Sample
Grade Group	Gleason Score	Gleason Pattern
GG1	6	g3+g3
GG2	7	g3+g4
GG3	7	g4+g3
GG4	8	4+4, 3+5, 5+3
GG5	9 or 10	4+5, 5+4, 5+5

Study Metrics	Prostate Level	Sample Level
Sensitivity	100%	89%
Specificity	96%	98%
Accuracy	97%	96%
FN	0%	2.2%
FP	2.5%	1.3%

# Clinical Relevance



# Potential Implications on Clinical Decisions

## Impacting

Sampling quality & characterization accuracy **OF ALL BIOPSIES:**

### Systematic Biopsy (ultrasound-based)

- Reduce false negative
- Increase positive yield
- Reduce repeat biopsies

### MRI-guided Biopsies

- Reduce false positive
- Minimize benign overlap
- Improve accuracy of ROI definition

## Clinical Decisions

### Reduce overtreatment

- Support more Active Surveillance
- Decide whether to send samples for genomic tests (sharply discriminate G2-G3)

### Personalize treatment

- Improve candidate selection for Focal Therapy
- Support decision of lymph node removal - based on personal nomograms

### Time next biopsy

- Extend intervals between biopsies (Fibro-muscular tissue dominance)
- Pull-in next biopsy (Glandular tissue dominance → Possible reclassification)



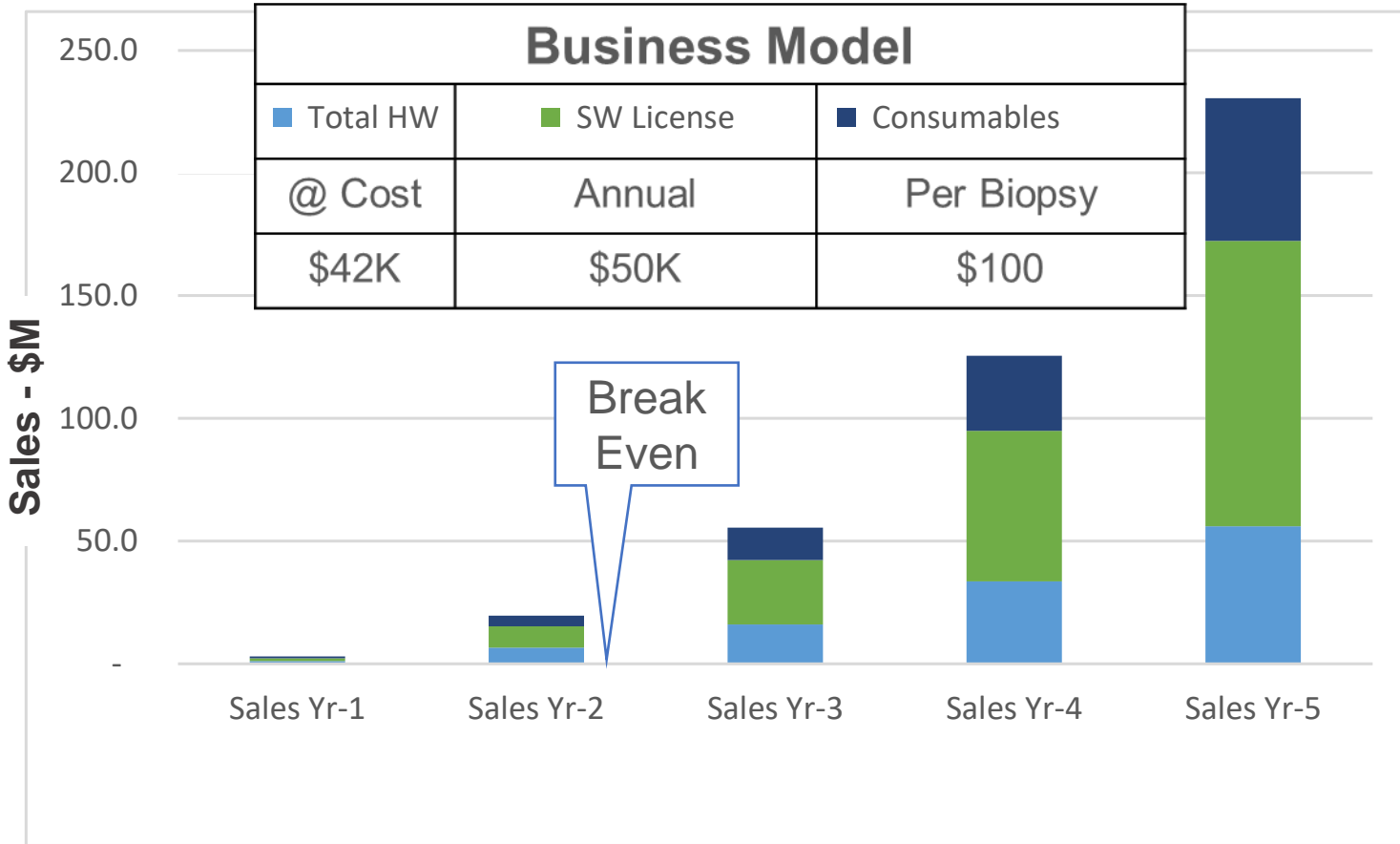
# Competitive Landscape

Biopsy → Risk Stratification → Treatment Decisions Support				
Biopsy Modality	Strength	Weakness	Players	Mrk. Size
*Systematic	Standard	Random, 30% FN	Commodity	\$10B
*MRI-US Fusion	Perceived High Standard	Inaccurate ROI definition	Eigen, Siemens...	
*Office MRI <sup>(23)</sup>	MRI replacing US	Same as MRI, expensive	Promaxo	New. TBD
*μ-US-Guided <sup>(14)</sup>	MRI equivalent?	Difficult analysis	Exact Imaging	
Genomic Tests	Doubtful Cases	Expensive, biopsy based	Genomic Health...	\$3B

\* **Verbal readiness to collaborate – one LOI signed**

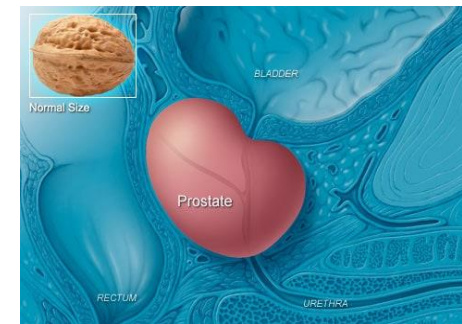
FN: false negative; FP: false positive; NPV: negative predictive value

# Business Model & Sales



## Assumptions

- 500 biopsies/year/site } = Clinic ROI: 1Yr
- \$350 reimbursement }
- Sales start – end of 2<sup>nd</sup> Yr, upon completion of 1<sup>st</sup> release
- 2<sup>nd</sup> release - in sales Yr 2



# Roadmap - 1<sup>st</sup> two Releases

Months

18

## 1<sup>st</sup> Release Product Launch

- Regulation:** ● Fast-lane FDA 510(k) ● Predicate device: MRI image-based-biopsy
- Features:** ● Malignancy image superimposed on ultrasound image  
● XRF scan in batches (less impact on the course of biopsy)
- Value:** ● Accurate cancer characterization

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## 2<sup>nd</sup> Release Product Launch

- Regulation:** ● Predicate device: XRF-Image-based biopsy ● acceptance studies
- New Features\*:** ● Real-time interactively guided biopsy
- Value:** ● Maximize detection rate & accuracy = tailored treatment

\* Full list of features will be released in the 3<sup>rd</sup> release (36 months)

## ABOUT THE FOUNDERS

**Roles** (startups & corporates): R&D; mass production; Division GM; Chief Marketing Officer; CEO; M&As; Chairman in several startups; consultancy for medical devices. **Projects:** military electro-optics; 1<sup>st</sup> local space telescope; multi-M\$ inspection for semiconductor industry; large-format digital printing; X1K faster electron microscopy. **Companies:** El-Op; Orbot (M&A - AMAT); Indigo-HP; Jemtex (M&A - Scitex); Opal, Applied Materials; IBEX.

# Team



**Avi Simon**

CEO, Co-Founder  
Mech. Eng.; MBA  
courses – Harvard;  
Accomplished Sculptor



**Dr. Meir Weksler**

CTO, Co-Founder  
PhD (Physics), Weizmann  
Institute of Science;  
Accomplished Poet



**Dr. Einat Zisman**

Business Development  
2 decades In Health-Med. CEO, Tissue  
Dynamics; CEO, FutuRx - Biotech  
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**Prof. Ilan Leibovitch**

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Former Head of Urology Dpt., Meir MC;  
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**Prof. Robert Lenkinski**

MRI expert in PCa  
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**Dr. Hagar Landsman**

Scientist - Data Mng.  
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scientist at Wisconsin University



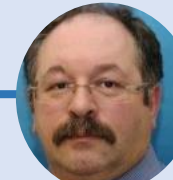
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**Roy Daya**

AI Advisor  
AI expert with over 10 years of experience  
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for global markets



**Dr. Eddie Friedman**

Medical Advisor  
Head, Uro-Pathology,  
Sheba MC



**Prof. Amos Breskin**

Scientific Advisor  
The 1<sup>st</sup> project leader – Weizmann  
Institute of Science



A one-stop-shop clinical routine that translates the most direct PCa biomarker, into a single, accurate, workflow-neutral method for assessing PCa aggressiveness, stratifying individual risk and offering tailored treatment recommendations.  
**POTENTIALLY THE NEXT STANDARD OF CARE**



**Thank You**

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