



PROSIGHT

XRF - GUIDED BIOPSY

The Next Standard of Care in Prostate Cancer Diagnosis

Maximizing Sampling Quality and
Cancer Characterization Accuracy

ProSight at a Glance

PROSIGHT

Clinical Impact Achievable Goal	Find all Tumors in the 1st Biopsy • Accurate Diagnosis • Earlier Detection Become Standard of Care in a \$10Bn Market
Technologies Involved	Deep Tech: Cancer Biomarkers • X-Ray Fluorescence (XRF) • Cancer Biopsy, Diagnosis & Risk Stratification • AI
IP	Granted • Pending • More Planned
Status	Clinical Proof of Concept – validation vs histopathology qualifies for guidance <ul style="list-style-type: none"> • Learning set: 600 patients • Initial validation set: 20 patients • 320 samples • 4,000 independent 1 mm 3D pixels
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 by Founders
Current round & Use of Proceeds	\$8M (+ \$4M in Grants) <ul style="list-style-type: none"> • Product development - \$4M • Clinical study - \$2M • Regulatory process, launch, market adoption, reimbursement code - \$6M

Need: Biopsy quality in prostate cancer is poor

Sampling errors and inaccurate cancer characterization

MRI-guided • Expert-dependent tumors definition • false positives
Systematic • Random (blind) • 30% false negative • repeat biopsies

UNCERTAINTY

Missed tumors • over / under treatment
• limits focal therapy (which is less radical)

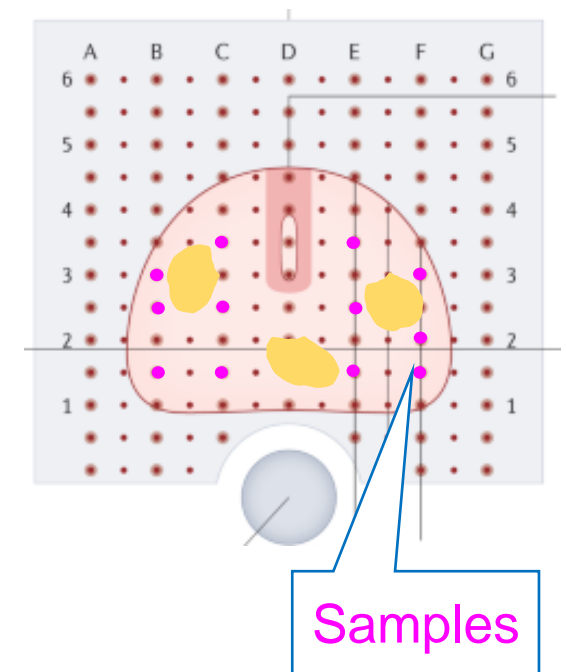
UNCERTAINTY

2nd highest cancer death rate • poor quality of life
• patient anxiety • high costs

* Given moderate performance of NCCN risk stratification ... treatment recommendations for adjacent risk-groups may be appropriate when using **more accurate risk stratification methods**... Current treatment recommendations are based on prognosis, rather than on **predictive biomarkers**.

* NCCN-guidelines – 2023, page 39

Real-time
biomarkers-based
inputs can avoid
missed tumors



Addressing the Need

Others

ProSight

Incremental Steps of Current Imaging Technologies (US & MRI)

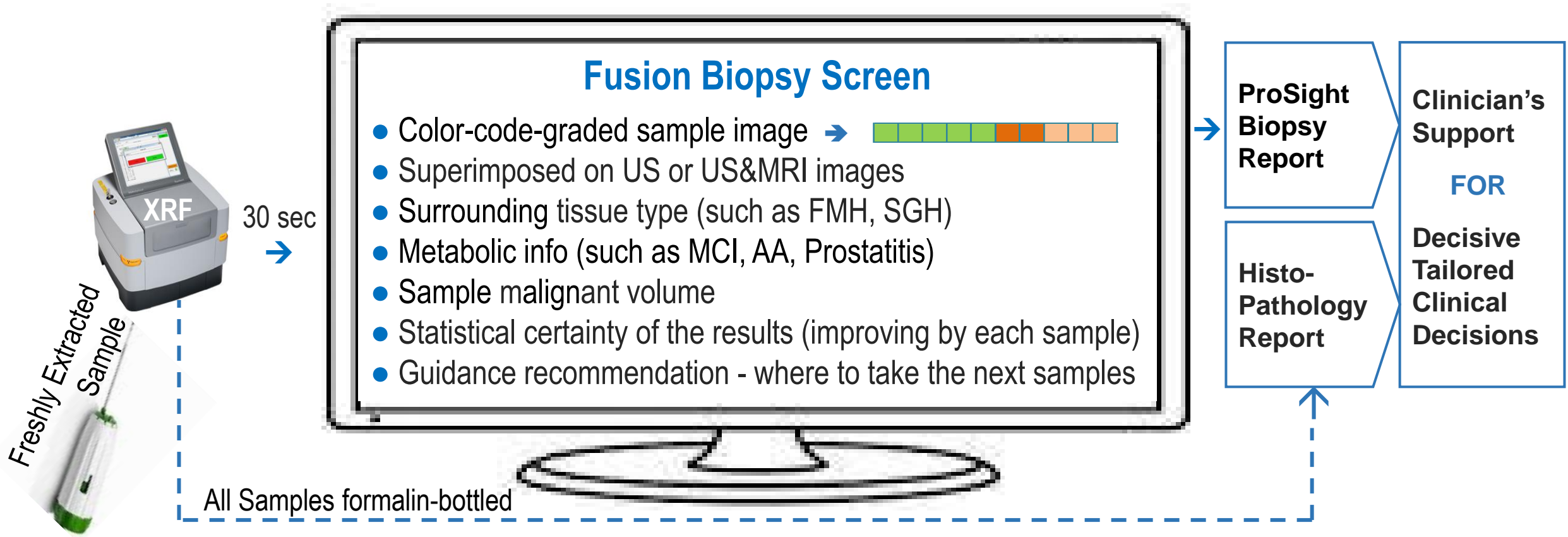
Adding a Novel Imaging Dimension

- **Improving US image**
 - *KOELIS* – Trinity®, reliable 3D-integrated US
 - *Exact Imaging* – high-resolution micro-US
 - *Eigen Health* – radiology AI software
 - *UC Care* – patient movements cancellation
- **Direct MRI-guided biopsy** (not fused onto US)
 - *Promaxo* – in-office mini-MRI biopsy
 - *Soteria Med.* – in-bore MRI biopsy

- **Overlaying new cancer markers on current images**
 - Zn depletion – proportionate to cancer grade
 - Tissue stiffness (cancer is denser)
 - Cancer/Benign indicative tissue type (SGH/FMH)*
 - Metabolic indicators – benign or pre-cancer
- **Data obtained by XRF scan of the fresh biopsy samples**
 - Non-destructive, allowing for standard pathological analysis
 - Real-time, ex-vivo, during-biopsy seamless integration of scan results onto existing MRI or US images
 - Guidance to suspicious regions, relevant samples harvested
 - Transparent to the patients

* SGH - Stromal-Glandular Hyperplasia; FMH - Fibro-Muscular Hypertrophy

ProSight's Workflow-Neutral Clinical Flow

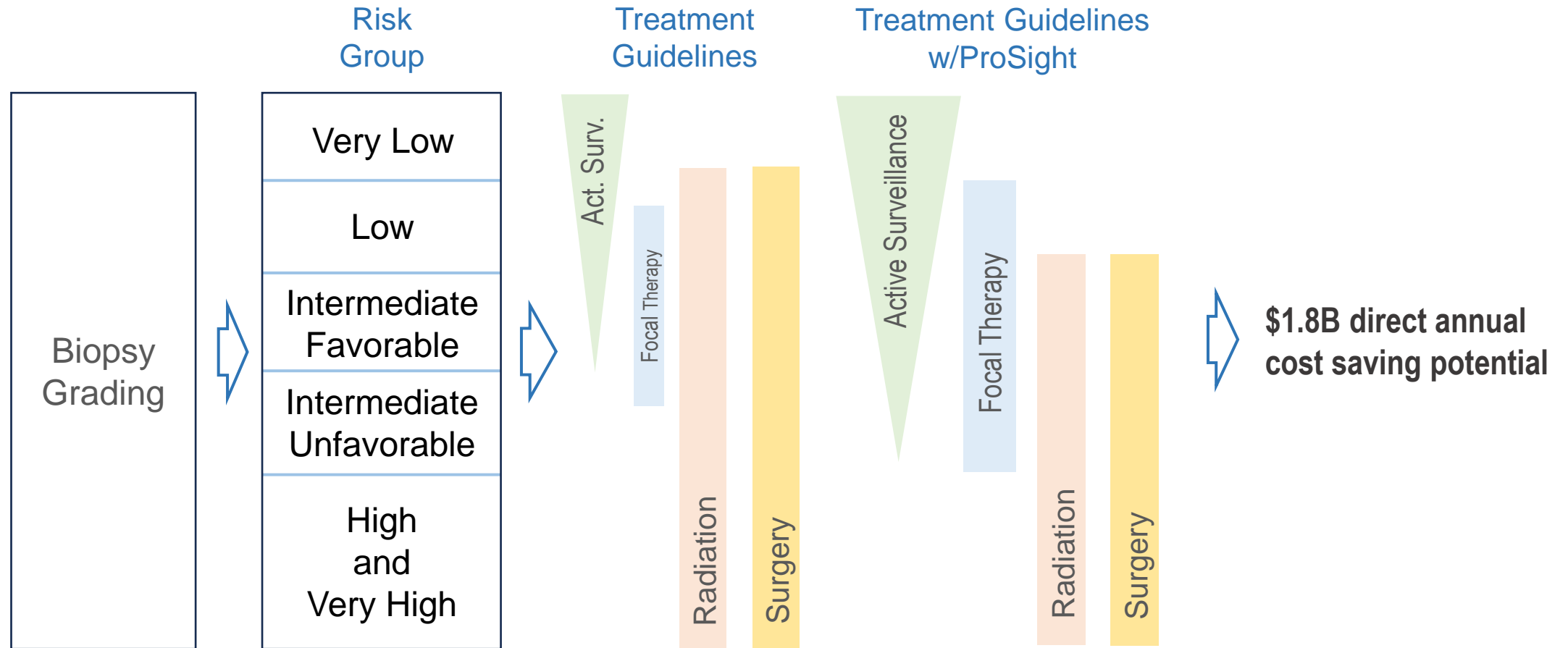


(9) Weksler, M., Simon, A., Lenkinski, R.E.; Landsman, H.; Matzkin, H.; Mabjeesh, N.; Leibovitch, I.; *Diagnostics* 2023, 13, 424. doi.org/10.3390/diagnostics13030424

ProSight Improves ALL Current Biopsy Procedures

- 1. Integration of ProSight's Biomarkers onto current images:**
Improving cancer characterization accuracy and earlier detection
- 2. Real-time guidance of ALL biopsy procedures:**
Providing immediate feedback on the samples, guiding urologists to suspicious regions, increasing positive yield → maximizing the likelihood of finding all tumors in same session
- 3. Improving MRI-guided biopsy:**
Reducing false positive to < 10%, increasing sensitivity to > 90%, reducing benign overlap
- 4. Transforming Regular, traditionally “blind” (US) biopsy:**
XRF-guided, reducing false negative to < 5%, minimizing repeat biopsies

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 (including in-bore MRI and mini-MRI)

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

Clinical Decisions

Reduce overtreatment

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

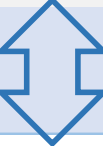
Personalize treatment

- 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)

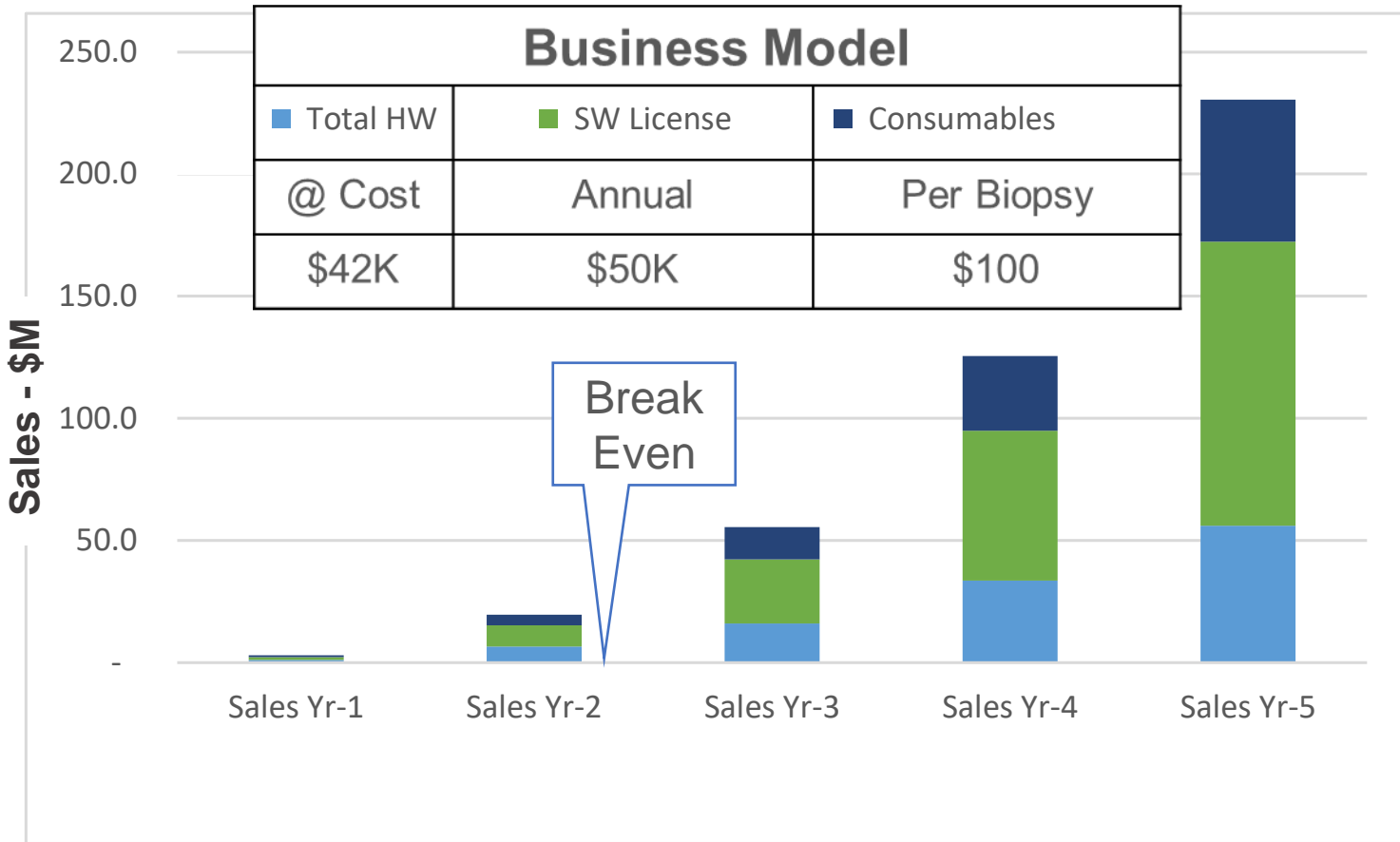
Competitive Landscape

Biopsy → Risk Stratification → Treatment Decisions Support				
Biopsy Modality	Strenght	Weakness	Players	Mrk. Size
*Systematic (US)	Standard	Random, 30% FN	Commodity	\$10B
*MRI-Guided	Percieved High Standard	Inaccurate ROI definition	Koelis, Eigen, Siemens, GE ...	
XRF-Guided	Biomarkers-guided	Not yet in the Market	ProSight, MRI-guided players	
*Office MRI ⁽²³⁾	MRI replacing US	Same as MRI, expensive	Promaxo	New TBD
*μ-US-Guided ⁽¹⁴⁾	MRI equivalent?	Difficult analysis	Exact Imaging	
Genomic Tests	Doubtful Cases	Expensive, biopsy based	Genomic Health, Myriad, MDX	\$3B

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

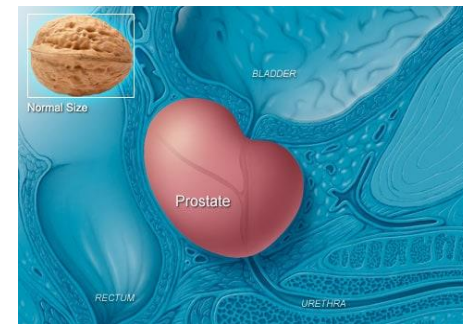
FN: false negative • ROI: region of interest

Business Model & Sales



Assumptions

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



Roadmap - 1st two Releases

Months

18

1st Release Product Launch

- Regulation:** ● Fast-lane FDA 510(k) ● Predicate device: MRI image-based-biopsy
- Features:** ● Sample grading and ProSight's Biopsy Report
- Value:** ● Accurate cancer characterization and well-differentiated risk stratification

27

2nd Release Product Launch

- Regulation:** ● Predicate device: XRF-Image-based biopsy
- Reimbursement:** ● Market acceptance studies for CPT code clearance
- New Features*:** ● XRF-guided, real-time interactive biopsy
- Value:** ● Maximize the **accuracy** of sampling, cancer characterization and risk stratification → tailored treatment

* Full list of features will be released in the 3rd 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; 1st 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
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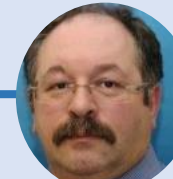
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The 1st project leader – Weizmann
Institute of Science



A transformative leap in prostate cancer:

A one-stop-shop clinical routine that translates in real-time, during biopsy, the most direct PCa biomarker into a single, accurate, workflow-neutral method for maximizing the likelihood of finding all tumors in the 1st biopsy

POTENTIALLY THE NEXT STANDARD OF CARE



Thank You

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www.prosight.site