



BIOMARKER-GUIDED BIOPSY

The Next Standard of Care in Prostate Cancer Diagnosis

A proprietary software platform transforms prostate cancer diagnostics by enabling real-time visualization of the most precise biomarker known to science, making precision diagnostics accessible to all patients



Executive Summary

ProSight is pioneering a **transformative biomarker-guided modality** in prostate cancer diagnosis, providing **real-time biopsy guidance** that revolutionizes tumor detection and characterization. Backed by strong IP, a proven team, and excellent clinical proof-of-concept, ProSight is positioned to become the new standard of care in prostate cancer biopsy, making **advanced precision diagnostics accessible to all patients**

Clinical Impact Maximizing diagnostic accuracy and detection rate, reducing missed tumors, enabling better patient outcomes and treatment decisions	Market Opportunity Addressing a \$10B global market with 5M+ annual biopsies and a clear unmet clinical need. Revenue based on annual license and per biopsy consumables	Validated Readiness Successful clinical studies for proof of concept with a prototype; sound FDA 510(k) regulatory strategy; peer-reviewed article published	Investment Ask Bridge round of \$300-600K via SAFE for derisking next Series A funding of \$8M (+ \$4M in grants)
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The Problem:

Diagnostic Limitations in Prostate Cancer

⚠ Diagnostic Inaccuracy

MRI-guided biopsies: 50% false positive rate
Ultrasound biopsies: 30% false negative rate

🔄 No real-time feedback

Missed tumors and false negatives lead to repeat invasive biopsies and delayed detection

👤 Expert Dependency

Current methods heavily rely on specialist expertise for MRI region of interest definition

💔 Patient Impact

Significant anxiety, discomfort, delayed treatment, over/under treatment, 2nd leading cause of cancer death in US men

💰 Economic Burden

Metastatic patient care costs 50x higher than non-metastatic care cost – earlier detection is essential

❓ Clinical Uncertainty

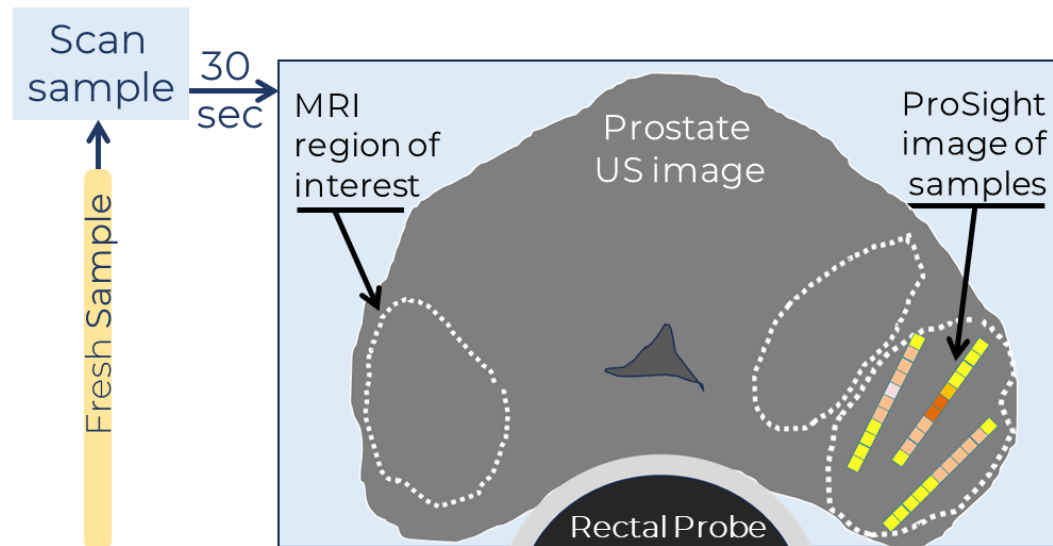
Difficulty differentiating between clinically significant cancer grades affects treatment decisions and outcomes

Industry Consensus

Stakeholders unanimously agree that new, **independent biomarkers** are essential for a significant leap beyond the incremental improvements currently practiced in prostate cancer diagnosis

Our Solution: Real-Time Biomarker-Guided Biopsy

Sample malignancy image overlaid on US & MRI



- ⌘ Proprietary software detects **zinc depletion** - the most reliable biomarker for prostate cancer
- 🔬 **Real-time analysis** during biopsy procedure using adapted off-the-shelf XRF technology for scanning
- 📊 Results **overlaid on current imaging** (US, μ US, MRI), allowing on-the-fly guidance to suspicious regions
- 📈 **Maximizes diagnostic accuracy** and likelihood of finding all tumors in the first biopsy
- 🏥 Decisive, tailored **treatment decisions**
- 👤 Reduces missed tumors and unnecessary procedures - **saving billions** while improving patient outcomes

ProSight transforms every biopsy into a precision-guided procedure

Clinical Validation & Results

Study Scope: concordance with gold standard

- ✓ Learning set (Sheba): 600 patients
- ✓ Calibration set (Ichilov): 10 patients
- ✓ Initial validation set (Ichilov): 20 patients
- ✓ 320 samples analyzed
- ✓ 4,000 independent 1mm 3D pixels

Peer-Reviewed Publication of Study

Journal: Diagnostics 2023

Citation: Weksler, M., Simon, A., Lenkinski, R.E.; Landsman, H.; Matzkin, H.; Mabjeesh, N.; Leibovitch, I.; Diagnostics 2023, 13, 424.

DOI: doi.org/10.3390/diagnostics13030424

Performance Metrics – Clinical Study

Specificity

98%

Accuracy

97%

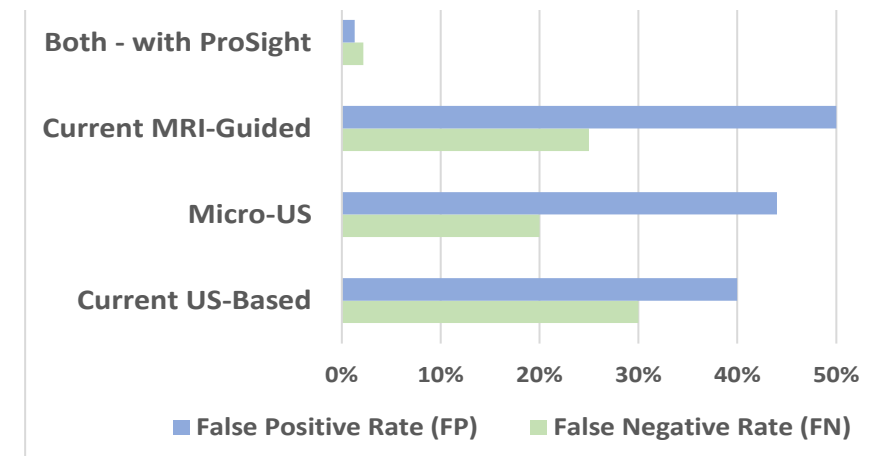
Sensitivity

94%

Prostatitis Identification

100%

Biopsy Imaging Discordance vs Gold Standard Histopathology



Competitive Landscape

Biopsy Approach	Real-Time Feedback	High Accuracy	Integration with MRI/US	Non-Destructive	Players
Systematic US-based - standard	✗	✗	✓	✓	Commodity
MRI-Guided / Fusion Biopsy	✗	🕒	✓	✓	Koelis, Eigen, Siemens, GE
Office Mini-MRI	✗	🕒	✓	✓	Promaxo, Soteria Med
μUS-Guided	✗	🕒	✓	✓	Exact Imaging
Biomarker-Guided	✓	✓	✓	✓	ProSight

- ✓ Compatible with ALL biopsy modalities, enhancing, rather than replacing existing products
- ✓ Expanding the Fusion Biopsy market, currently confined to MRI-guided, into systematic biopsy

Differentiation and Competitive Advantage

Direct vs. Indirect Indicators

ProSight	Imaging (MRI)
Direct multiparametric prostate cancer measure	Indirect image interpretation
Quantitative molecular analysis	Qualitative imaging
Objective biomarker data	Subjective assessment

Competitive barriers

- ✓ Algorithm Complexity (proprietary)
- ✓ Database Requirements
- ✓ Hardware Integration
- ✓ Patented 3D XRF scan

Key Advantages

- Real-time Feedback allows for on-the-fly biopsy improvement
- Non-destructive: Preserves tissue for histopathology
- Adapted off-the-shelf hardware
- Minimal Training: Automated analysis and reporting
- Transparent to the patient
- Potentially reducing the number of biopsy samples
- Cost-Effective: Lower per-procedure cost vs MRI
- Seamless integration with all imaging modalities (MRI, Ultrasound, micro-US, mini-MRI)

Zero disruption, maximum enhancement

Business Model & Go-to-Market Strategy

Revenue Model

- ✓ Hardware at cost
- ✓ Annual software license
- ✓ Per-procedure consumables
- ✓ Hospital/clinic ROI: ~ 1 year

Regulatory & Reimbursement

- ✓ FDA 510(k) pathway with clear predicate devices
- ✓ FDA-assisted regulatory plan to solidify process
- ✓ Market adoption studies for CPT code clearance
- ✓ Strong economic case: reducing repeat biopsies, earlier detection, and risk stratification

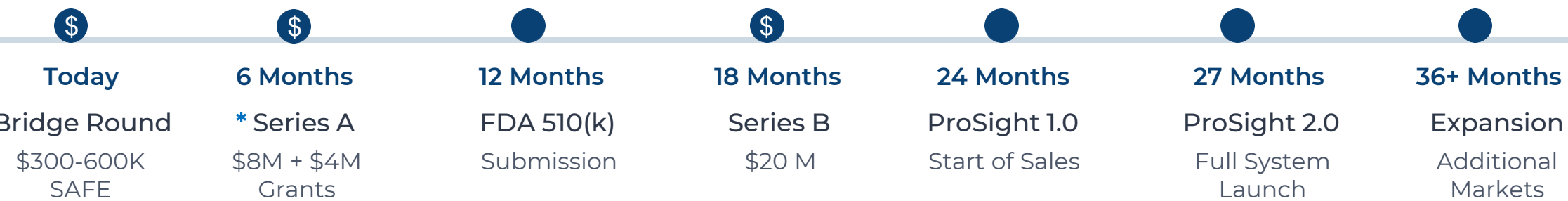
Market Strategy

- ✓ Initial focus on key US & EU medical centers
- ✓ Endorsement by KOLs
- ✓ Strategic partnerships with the leading players
- ✓ Integration with Fusion Biopsy Companies as a market penetration multiplier

Commercialization Timeline

- **12 months:** FDA 510(k) submission
- **18 months:** ProSight 1.0 (Malignancy Imager) launch
- **24 months:** Start of commercial sales
- **27 months:** ProSight 2.0 (Biomarker-Guided Biopsy) launch

Product Roadmap & Milestones



ProSight 1.0

Malignancy Imager - 18 Months

- ✓ Sample "heat maps" showing cancer characterization (Predicate: Dig. Pat., u-US, etc.)
- ✓ Comprehensive biopsy reports with biomarker data



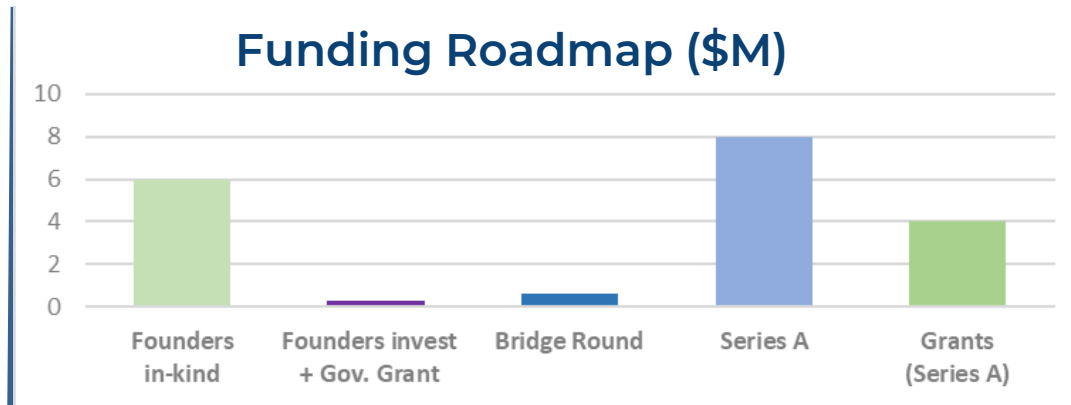
ProSight 2.0

Real-Time XRF-Guided Biopsy - 27 Months

- ✓ Interactive biomarker-guided biopsy capabilities (Predicate: ProSight)
- ✓ Enhanced AI algorithms with clinical data integration

* Timeline assumes Series A as planned

Financial Projections & Funding Requirements



Round A (Next Financial Milestone)

\$8M + \$4M in Grants



- ✓ Product development - \$4M
- ✓ Clinical study - \$2M
- ✓ Regulatory process, launch, market adoption - \$6M



Current Bridge Round

\$300K - \$600K

- ✓ SAFE agreement format
- ✓ 9-12 months runway
- ✓ Solidify regulatory and reimbursement pathways



Company Valuation (Series A)

\$18M Pre-Money

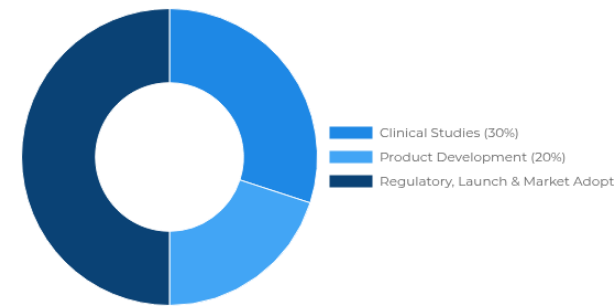
- ✓ Historic valuation (2012) - \$9M [WIS's holding 30%]
- ✓ Milestones since 2012: Clinical Study (2015) ✓ SW dev. & PoC (2021) ✓ IP (2015, 2023) ✓ article (2023) ✓ Industry contacts and LOI with MTT GmbH (2024)

Use of Proceeds

Current Bridge Round Allocation (\$300-600K)

Key Initiative	Budget (K\$)
FDA-assisted 510(k) plan	30
Reimbursement path assessment	50
Clinical utility demonstration (retrospective)	130
Preliminary design of Final XRF	300
Strategic relationships & KOLs	35
IP protection & grants application	30
Marketing & roadshow	30

Series A Funding Allocation (\$8M + \$4M Grants)



Key Investment Focus:

- FDA 510(k) submission within 12 months
- ProSight 1.0 launch at 18 months
- ProSight 2.0 launch at 27 months
- Establishing reimbursement pathway and market adoption

KOL's Opinions

Prof. Mark Emberton

OBE MD FRCS (Urology), Med.Sci. Dean, Faculty of Medical Sciences University College London

".... I am writing in support of Prosight technology, as I feel it may well have an **important place in the risk-stratification** of prostate cancer.

...it is the linkage between the zinc depletion and glandular proliferation that is novel. Importantly, this information can be derived **during the process** of tissue sampling – an intervention that is limited today by randomness.

...can assist in sampling the correct region of the prostate and therefore leads to more **representative tissue being harvested**.

... And, moreover, the technology compliments, and will almost certainly **add value, to the existing cornerstone which is multi-parametric MRI.**"

Prof. Robert Lenkinski

Vice Chairman of Research,
Radiology CPRIT Scholar
and Cancer Research
Southwestern , MC, Dallas

Prof. Neil M. Rofsky

Head of Radiology - Mount
Sinai; Former - Chairman,
Dpt. of Radiology
Southwestern , MC, Dallas

"...Prosight found a **reliable independent direct marker for PCa** ... it has the potential of improving the sensitivity of prostate biopsy ... and possibly provide in-situ, **real-time pre-diagnosis** for the Urologist during the biopsy itself.

As experts, pioneers, and inventors in the MRI field for Prostate Cancer

...their work led to a **crucial broader understanding** of the strength and fidelity of markers and physiological elements in the evolution of PCa. We were pleased to learn that their clinical study... showed that it is possible to ... determine the levels of epithelial content and low Zn content ... during biopsy and that it led to **very high pre-diagnostic accuracy...**"

Team



Avi Simon

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



Dr. Meir Weksler

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



Dr. Einat Zisman

BD
2 decades in Health-Med.
CEO, Tissue Dynamics; CEO,
FutuRx - Biotech Incubator;
CEO - Hadasit (TTO of
Hadassah MC); CBO - Yeda (TTO
of WIS). MBA-USC, Ph.D.-WIS,
B. Pharm – Hebrew University



Prof. Ilan Leibovitch

CMO
Former Head of Urology Dpt.,
Meir MC; Ass. Prof. of Surgery, Tel
Aviv Univ., Sackler School of
Medicine; former Chief of the
Oncological Urology Service, Dpt.
of Urology, Sheba MC; former
president of the Israeli
Urological Association

ABOUT THE FOUNDERS

Roles (startups & corp.): R&D; production; Div. GM; VP Marketing;
CEO; Chairman; M&As; consultancy in med-tech. **Projects:**
electro-optics; 1st local space telescope; automatic inspection for
S/C; digital printing; 10K beams electron microscopy. **Companies:**
El-Op; Orbot (exit: M&A/AMAT); Indigo (M&A/HP); Jemtex (exit:
M&A/Scitex); Opal, AMAT



Prof. Robert Lenkinski

MRI expert in PCa
Former - Vice Chairman of Research,
Radiology, CPRIT Scholar and Cancer
Research - South-Western, MC, Dallas



Dr. Hagar Landsman

Scientist - Data Mng.
Scientist at the Weizmann
Institute of Science. Formerly a
scientist at the UW



John Smith, M.D., J.D.

Regulatory Counsel
Hogan Lovells



Roy Daya

AI Advisor
AI expert, over 10 years of experience in
developing SW/HW AI-based products for
global markets



Dr. Eddie Friedman

Medical Advisor
Head, Uro-Pathology,
Sheba MC



Prof. Amos Breskin

Scientific Advisor
The 1st project leader –
Weizmann Institute of Science

ProSight offers clarity and confidence in prostate cancer diagnosis by providing instant, accurate insights during any biopsy type, helping clinicians identify more cases faster and making advanced diagnostics accessible to everyone

Thank You

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