

# MRI Imaging Agents for Cancer Detection

Imagion Biosystems Limited  
ASX:IBX

A Breakthrough in  
Molecular Magnetic  
Resonance Imaging



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# MagSense® mMRI Technology

## Transforming molecular imaging



### Specific

Provides molecular confirmation of cancer, not just “suspicion”.



### Safer

No radioactivity.  
Low dose produces contrast.



### Better Patient Care

Reduces need for biopsies and can detect small tumors.



### MRI-based Detection

Compatible across 50k+ MRI scanners in use globally.



### Platform Technology

Fits clinical workflow and can be used across many cancers.  
Theranostics potential.

## Clinical Pipeline



### HER2+ Breast Cancer

\$500M TAM \*

Ready for Phase 2



### Prostate Cancer

\$1B TAM \*

Ready for IND/Phase 1



### Ovarian Cancer

\$500MTAM \*

Ready for IND/Phase 1

# An Unmet Need in Cancer Diagnosis



## Screening

Indicates risk, but non-diagnostic. Requires confirmation before treatment.



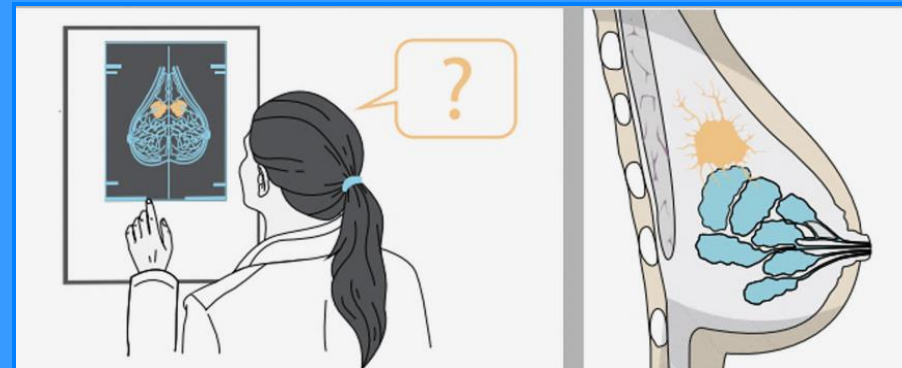
## Imaging

Identify “suspicious lesions” but can’t distinguish between benign or malignant.

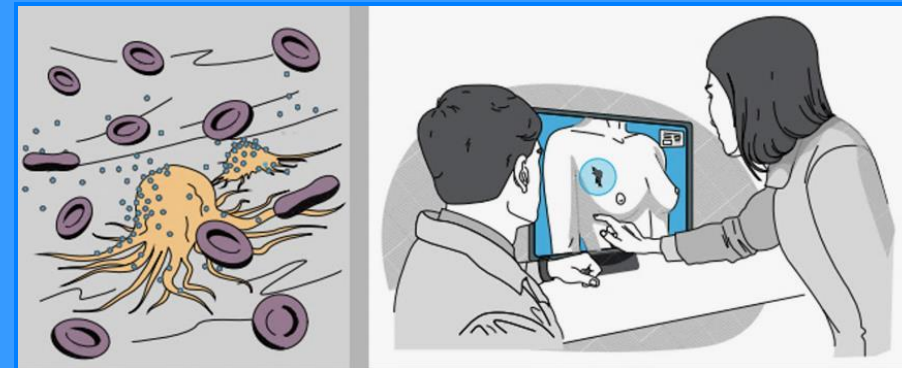


## Biopsy

Painful, complicated, error prone and challenging. Pathology assessments can take days.

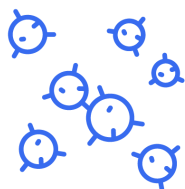


**Conventional Imaging** provides anatomical context but is not specific and can only identify a region of interest.

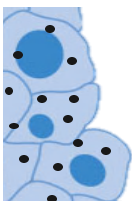


**MagSense<sup>®</sup> Imaging** uses molecularly targeted imaging agents to produce a distinct image pattern indicating the presence of a tumor.

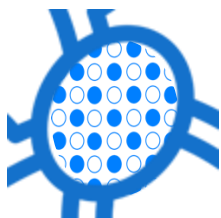
# How MagSense® molecular MRI works



MagSense particles are coated with unique targeting moiety and administered before MRI

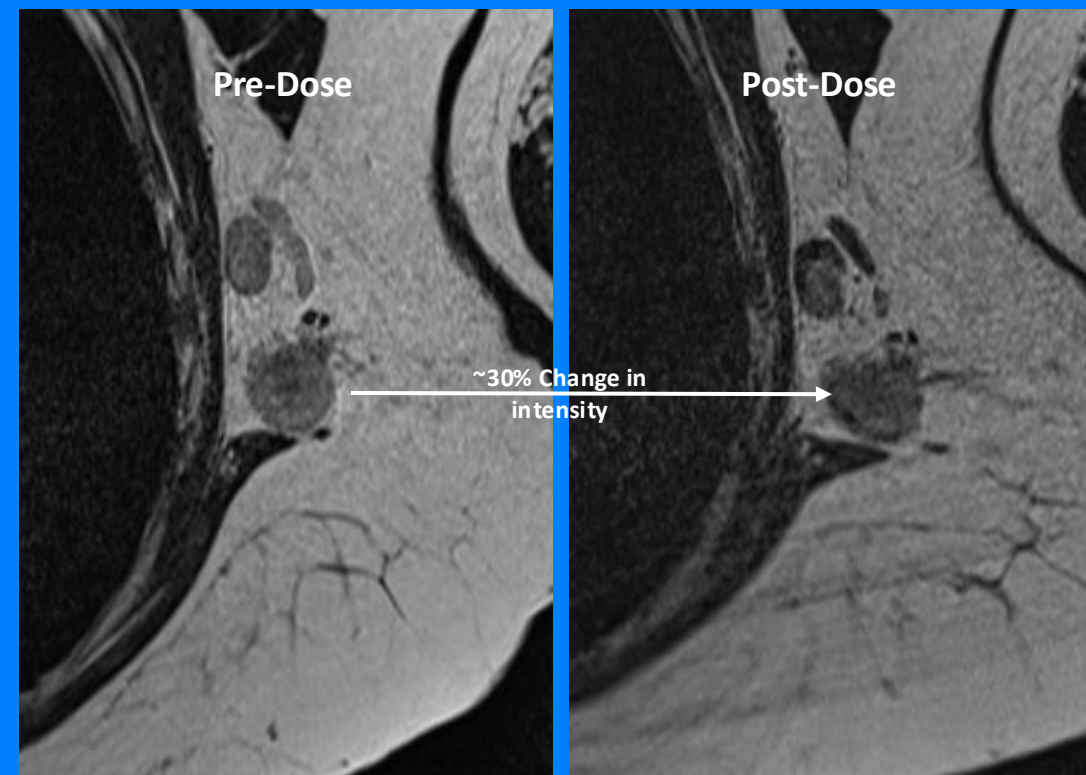


MagSense particles only bind to target type of cancer cells, if present



MagSense produces an identifiable change in image contrast which is easily detected

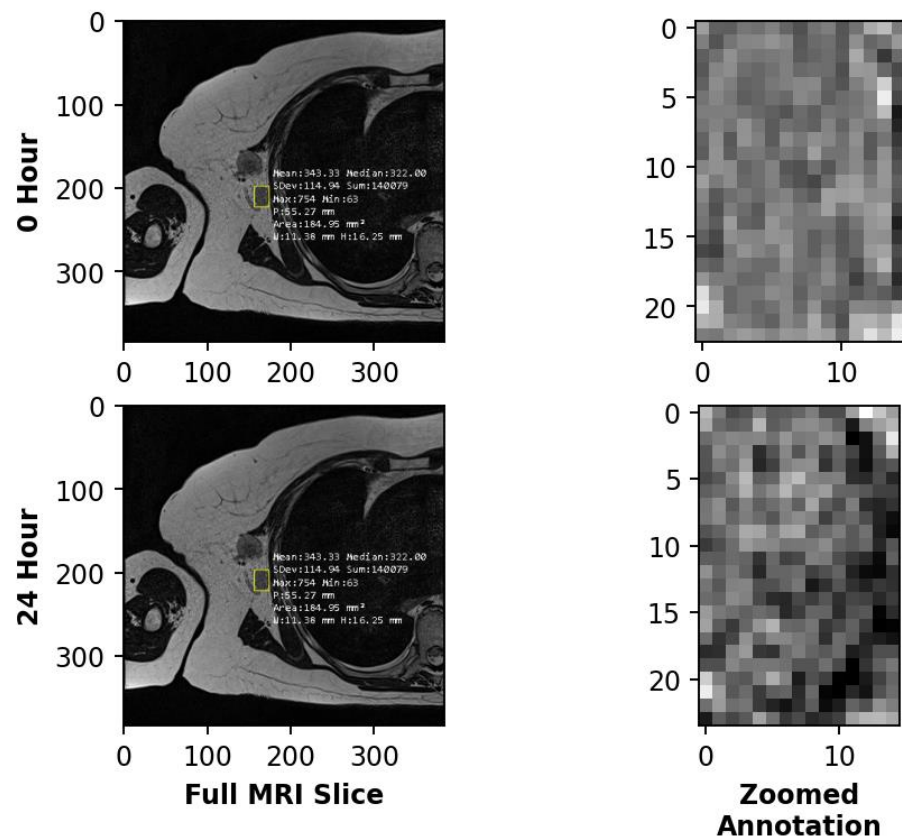
*MagSense® nanoparticles enable molecular imaging by producing an identifiable change in image contrast when cancer cells are present*





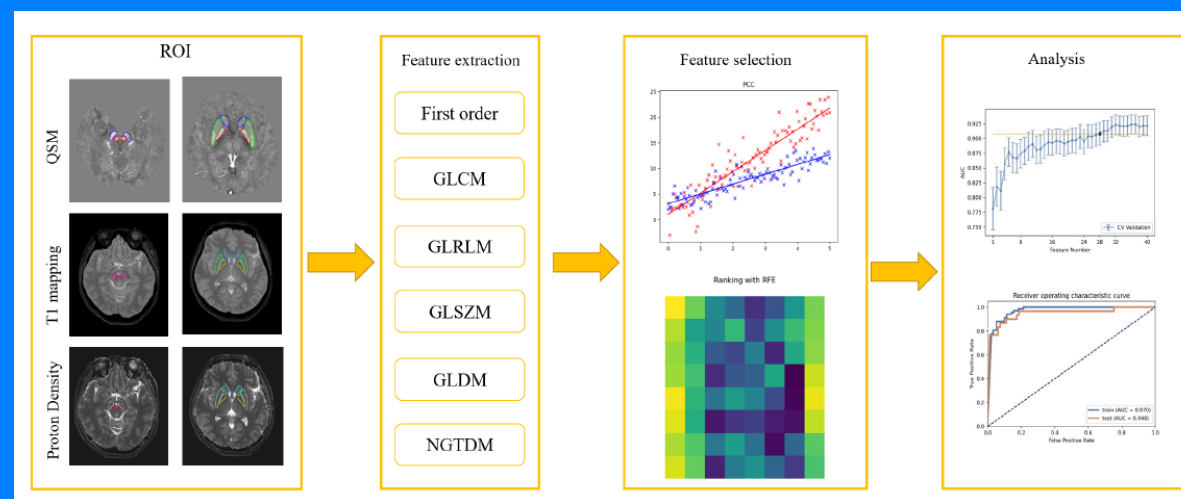
# mMRI Enables AI Detection

Subject 5, Node: 2



Unique quantitative signature allows for Artificial Intelligence and Machine Learning algorithms for automated detection.

Existing iron-based AI diagnostics already show proof of concept.



# Use Cases and Global Markets

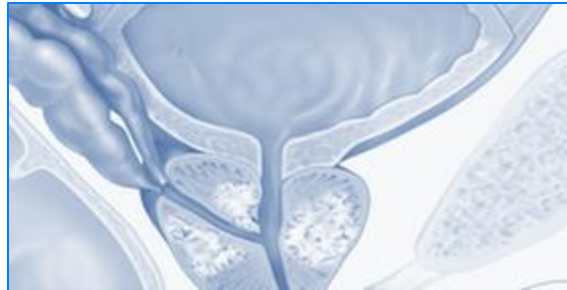
## Nodal Metastases in HER2+ Breast Cancer



**\$500M Market Opp.\***  
**Ready for IND/Phase 2**

- 400,000 HER2+ Breast Cancer diagnoses annually (~20% of all BC).
- HER2+ tumors tend to be one of the more aggressive forms of Breast Cancer.
- Lymph node analysis is SoC for cancer staging.
- Existing SoC (ultrasound) is regionally limited and non-diagnostic.

## Primary Tumor Detection of Prostate Cancer



**\$1.1B Market Opp.\***  
**Ready for IND/Phase 1**

- 1M+ Prostate biopsies/year in U.S.
- mpMRI has a >50% False Positive rate and a >15% False Negative rate.
- PSMA-PET is not typically used for primary tumor detection and subjects patients to radioactivity.
- Current SoC results in significant unnecessary biopsies with FP/FN.

## Early Detection of Ovarian Cancer



**\$500M Market Opp.\***  
**Ready for IND/Phase 1**

- 75% of cases diagnosed at late stage.
- CA-125 blood tests indicate risk, but are not predictive of disease.
- “Watchful waiting” by ultrasound is the existing SoC.
- >300,000 women/yr. diagnosed with ovarian cancer; ~2/3<sup>rd</sup>s die from the disease.



# Key Business Factors for MagSense® Imaging Agents

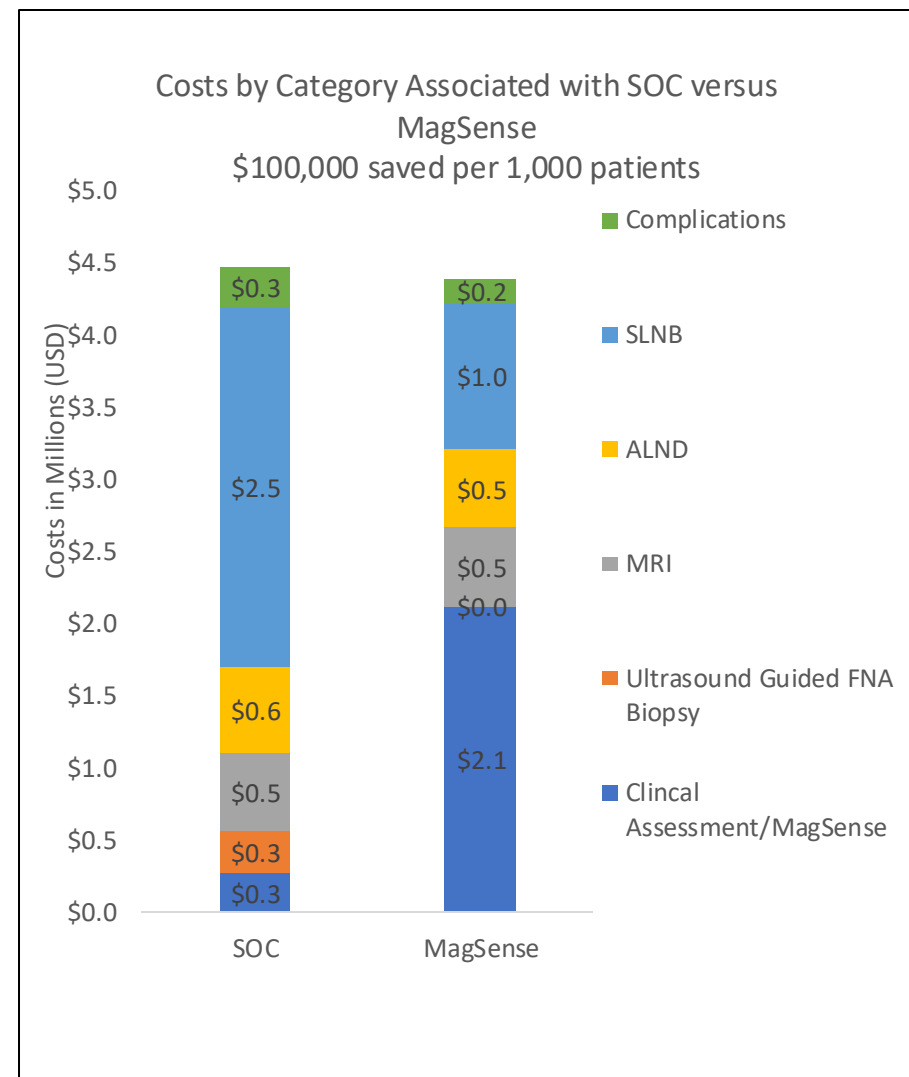
**Value Based Reimbursement** – Health economics supports \$1,200 to \$1,500 reimbursement rate, while still saving costs.

**High Gross Margin** – Imaging agent can be produced in commercial quantities by standard drug manufacturing methods at costs that support commercial partnering.

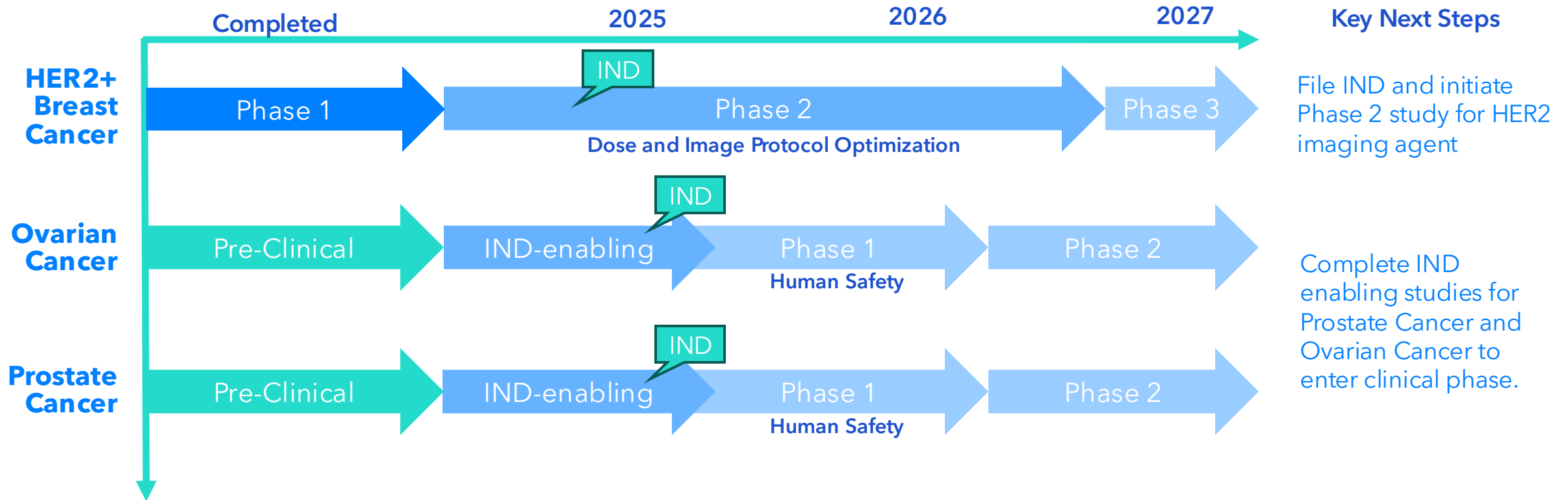
**Long Shelf Life** – Clinical lots have shown > 2yr stability and can be stored and supplied by the hospital pharmacy like GBCAs.

**Fits Existing Workflow** – Expands use of MRI within existing clinical workflows; compatible across 50,000+ scanners globally.

**Transformative** – AI detection could improve “diagnostic” utility of imaging and add value to the radiologist’s role in patient management.



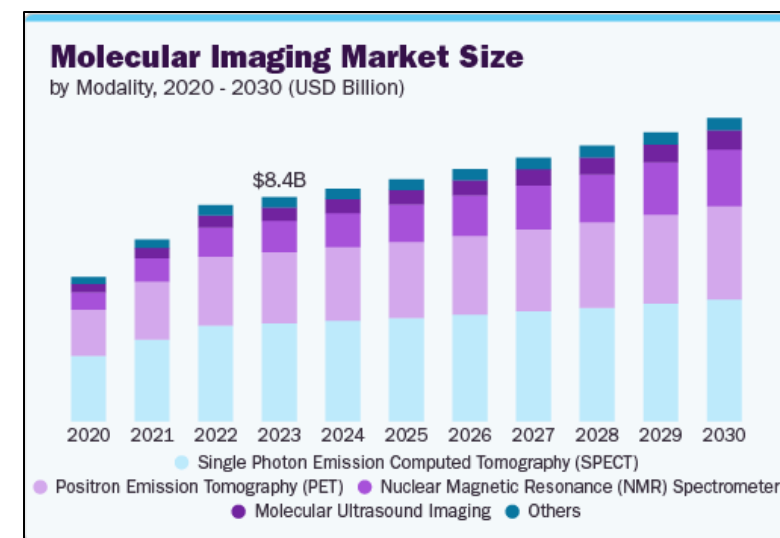
# Clinical Development Plan and Key Milestones



# Investment Rationale










# Molecular Imaging will Drive MRI Growth

1. Global cancer incidence to rise 77% by 2050<sup>1</sup>
2. Screening & Diagnostic Imaging market growing at 6.7% CAGR<sup>2</sup>
3. Molecular imaging to-date limited to methods using radioactivity due to MRI lacking specificity.
4. Almost 100% of contrast media products achieve regulatory approval.
5. *MagSense® imaging agents are completely differentiated and fit the existing medical imaging and contrast media business model.*



# Strategic Partnering

Incumbents continue making attractive deals for differentiated clinical-stage assets

Acquirer	Target	Value AUD	Year	Notes
 LANTHEUS™	 RAD RADIOPHARM THERANOSTICS	\$18M	2024	Strategic investment. Part of \$70M AUD financing transaction.
HOLOGIC®	 endomag+	\$310M	2024	\$35M revenue at time of transaction. Breast cancer
 Lilly	 ARMO BIOSCIENCES	\$1.6B	2018	Imuno-oncology agent. Acquired following successful Phase 3.
 LANTHEUS™	 Progenics® Pharmaceuticals	\$328M Est.	2019	All stock acquisition. Estimated market cap at transaction date.
 NOVARTIS	 Advanced Accelerator Applications	\$3.9B	2018	Acquired in Phase 3, pending FDA clearance. Radioligand therapy.



# 2025 – 2026 Corporate Focus

## Objectives for Value Creation

### Complete Phase 2 Study for HER2 Breast Cancer Program

- Obtain IND or like multinational regulatory jurisdiction and commence Phase 2 of clinical investigation
- Complete the Phase 2 study in 18-24 months
- Establish AI-based autodetection algorithms to improve sensitivity and accuracy of detection

### Advance Prostate Cancer Program to clinical phase

- Complete IND-enabling preclinical toxicology studies
- Submit IND, or like regulatory filing
- Initiate a Phase 1 study

### Advance Ovarian Cancer Program to clinical phase

- Complete IND-enabling preclinical toxicology studies
- Submit IND, or like regulatory filing
- Initiate a Phase 1 study

### Corp Development

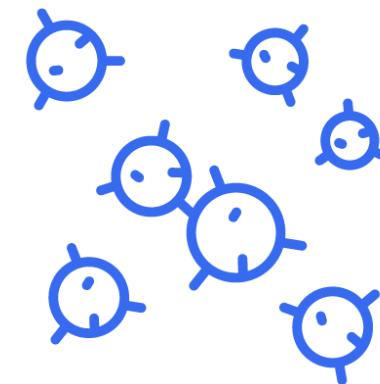
- Continue to meet with prospective global strategic industry and instrument partners
- Present data at key imaging meetings
- Identify regional commercial licensing opportunities

## Highlights

- US\$2.1B Market Opportunity
- Highly differentiated product lineup is first-of-its-kind in molecular imaging.
- Operating as a lean virtual biotech with low fixed G&A costs.
- Strategic partnering commercial model with potential for non-dilutive income and cost sharing.

## Upcoming Project Milestones

- IND approval for Phase 2 study of HER2 Breast Cancer
- Initiate IND-enabling studies for Prostate and Ovarian Cancer to advance to the clinic



## Capital Structure and Funding

- AUD \$2.67 cash on hand as of 31 Dec 2024
- AUD \$10.78M in funding available through Convertible Financing facility
- 201,341,415 fully paid ordinary shares - largely retail shareholder base



**Robert Proulx**  
Executive Chairman

Robert is an operationally oriented executive with over 30 years in life science & medical device product development & commercialization and has led the company through recent restructuring and recapitalization.



**Ward Detwiler**  
Chief Business Officer

Experienced early stage technology executive with a track record of bringing health technologies from concept to market.



**Melanie Leydin** CA FGIA  
Company Secretary & Non-Executive Director

Melanie is a Chartered Accountant and a Fellow of the Governance Institute of Australia with over 30 years of experience in Accounting and over 20 years in Board positions, currently the Managing Director of Vistra Australia.



**Brett Mitchell**  
Non-Executive Director

Mr. Mitchell is an experienced corporate finance executive with over 25 years of experience in the venture capital and equity capital markets, leading transactions in the mining, energy, technology and life sciences sectors.



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