

# MRI Imaging Agents for Cancer Detection

Imagion Biosystems Limited  
ASX:IBX

A Breakthrough in  
Molecular Magnetic  
Resonance Imaging



# Imagion 2.0

## Leadership



**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

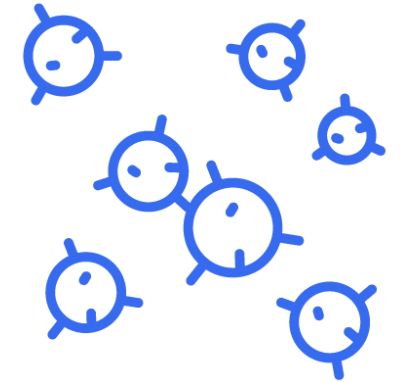
Melanie is a Chartered Accountant and a Fellow of the Governance Institute of Australia with over 30 years of experience in Accounting and over 20 years in Board positions, currently the Managing Director of Vistra Australia.



**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.

# A clinical stage biotechnology company developing magnetic nanoparticle-based imaging and drug delivery technologies



## Molecular Imaging

Targeted nanoparticles have the potential to improve cancer detection compared to conventional imaging technologies by adding molecular specificity and without using radioactivity.

## Drug Delivery

Nanoparticles provide large surface area as carriers for drugs or can be used as adjuvants in vaccines.

## Lead Product

A Phase 1 study for the detection of nodal metastases in HER2+ Breast Cancer has been completed. IND for a Phase 2 study in progress.

## Strong Pipeline

Imaging agents for primary tumor detection in Prostate Cancer and Ovarian Cancer ready for IND-enabling studies and clinical development.

# An Unmet Need in Cancer Diagnosis



## Screening

Conventional blood-based tests, like PSA or CA125, indicate risk of cancer but are not diagnostic. Newer methods like cfDNA or CTCs improve screening but require confirmation before treatment.



## Imaging

Current imaging methods can be used to identify a “region of interest” or a “suspicious lesion” but can’t distinguish between benign or malignant lesions.



## Biopsy

To confirm if a lesion is malignant, biopsies are taken which may be painful and cause patient complications. Subsequent pathology assessment of the tissue sample can take days. Obtaining tissue for many types of cancer can be challenging, e.g. lung, pancreatic and other deep body organ cancers.

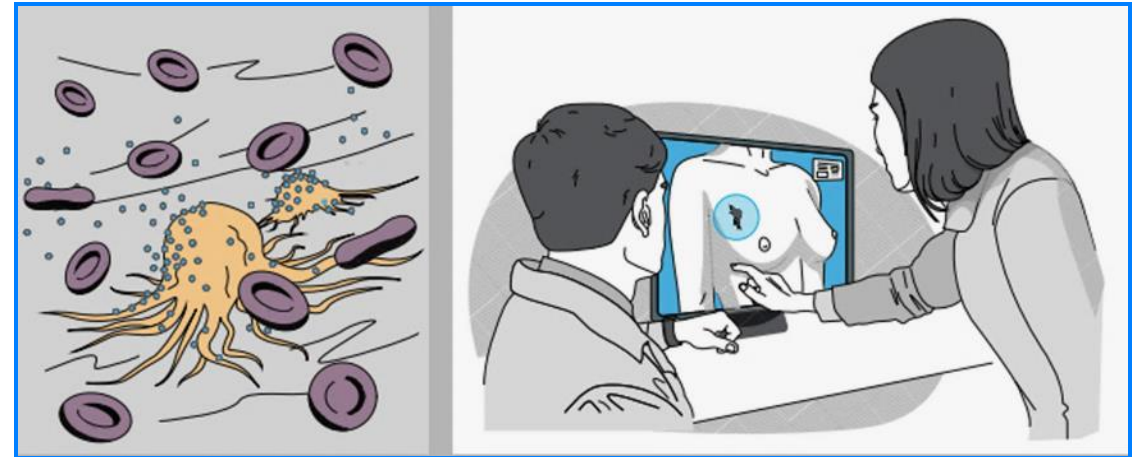
A biopsy and pathology assessment are required for most cancers

# Enabling Molecular Imaging



## Conventional Imaging

Images provide anatomical context but are not specific and can only identify a region of interest.



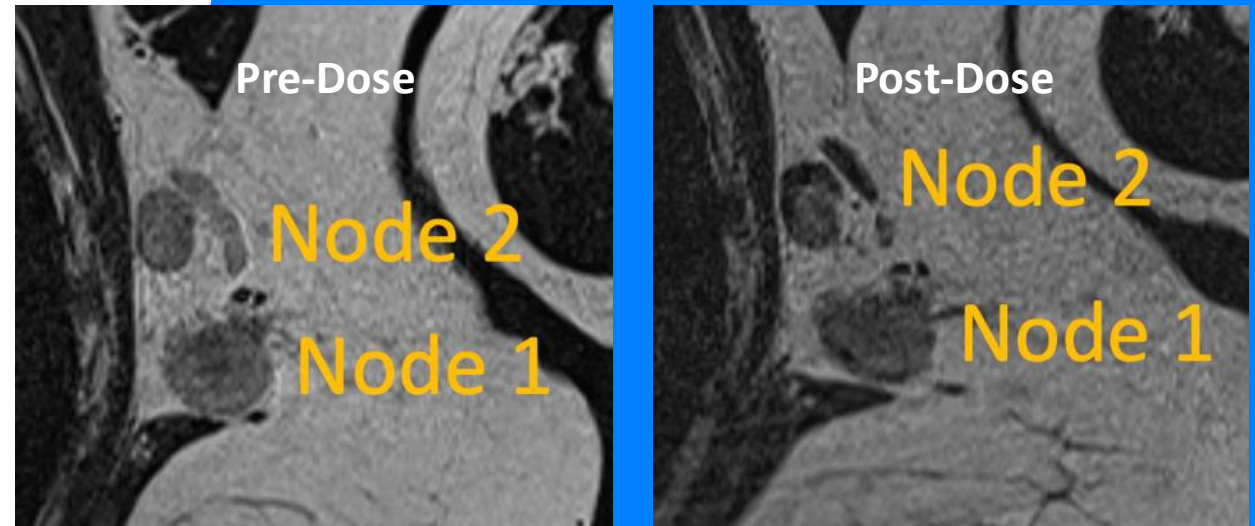
## MagSense® Imaging

Molecularly targeted imaging agents produce a distinct image pattern indicating the presence of a tumor.

# How molecular MRI works

- A targeting moiety (e.g. antibody or peptide) directs the nanoparticles to the target tissue to ensure cancer specific detection.
- When present in tissue, the magnetic nanoparticles create hypointense (dark) contrast in T2 MRI scans.
- The hypointense contrast indicative of the presence of the targeted MagSense® imaging agent can be differentiated from normal tissue.
- The change in contrast improves radiological review when combined with conventional imaging assessments, such as abnormalities in tissue size and shape.

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



**Node 1 shows a 27% change in signal intensity**  
**Node 2 shows a 36% change in signal intensity**

# MagSense<sup>®</sup> Molecular Imaging

MagSense<sup>®</sup> technology aims to transform how medical imaging can detect and diagnose cancer



## MRI-based Detection

Imaging agents work with existing MRI systems widely available in hospitals around the globe.



## Specific

Targeted imaging agents provide molecular confirmation of the presence of cancer not just a visual assessment of “suspicious” or abnormal lesions.



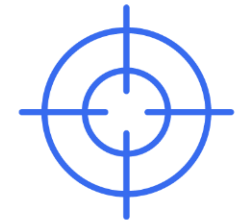
## Safer

Does not require use of radioactivity and is a safe and non-surgical solution to detect cancer and reduce the need for investigative biopsies.



## Earlier Detection

Would enable earlier detection of solid tumors when small and not easily visible by conventional methods and/or difficult and risky to biopsy.



## Platform Technology

Fits with existing diagnostic protocols and can be used for many cancers as well as other diseases.

# Clinical Study – IBI010103

## Detection of Nodal Metastases in HER2+ Breast Cancer

- A Phase 1 Study with 13 HER2+ Breast Cancer patients from 4 sites in Australia.
- Imaging agent was safe and well tolerated in all 13 patients with no AE/SAEs reported related to the imaging agent.
- Blinded review by independent expert panel of radiologists has corroborated detectable magnetic signature.
- Can improve on ultrasound which is limited to assessment for abnormal size/shape and could reduce need for SLNB/ALND.
- Plans for an IND and multisite Phase 2 study in process.

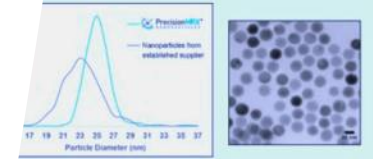
...tion of Lymph Node Involvement in Subjects with Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer: A First-In-Human Phase 1 Study Using the MagSense®  
**Jane Fox<sup>1</sup>, Natalie Young<sup>2</sup>, Steven D. Reich<sup>3</sup>, Marie Zhang<sup>3</sup>, Robert P. ...**  
<sup>1</sup>Monash Health Moorabbin, 86; Centre Road, Bentleigh East, Victoria, 3165; <sup>2</sup>Austin Health, 145 Studley Rd, Heidelberg, Victoria, 3084

### Objective

...proof-of-principle for the HER2 targeted ... of this first-in-human study is an initial ... of the injectable imaging agent. A ... the confirmation that the route of ... the imaging agent to reach the patient's ... es of the study include a comparison of ... esonance imaging (MRI) and a novel ... etic relaxometry (SPMR). Results of the ... andard clinical tissue histopathology to ... to whether the MagSense® HER2 Imaging ... aging modalities, might provide improved ... l decision making.

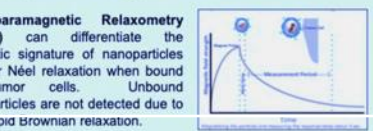
### Magnetic Nanoparticles

... is designed for use with the magnetic relaxometry ... ast agent.



Diameter	PDI	# of Ab/NP	% of free Ab
70-80 nm	<0.10	3-5	<10%

... $\text{Fe}_3\text{O}_4$ ) cores are made with high magnetic relaxivity ( $r_2 = \text{M}^{-1} \text{s}^{-1}$  at 7 T) providing excellent Néel relaxation and T2 ... dispersed with narrow size distribution and exhibit high ... molecular imaging agent, cores are encapsulated with a ... with carboxylate ( $\text{COO}^-$ ) surface. Polyethylene Glycol (PEG) ... conjugated onto the polymer surface.



...paramagnetic Relaxometry (SPMR) can differentiate the ... etic signature of nanoparticles ... their Néel relaxation when bound ... tumor ... cells. Unbound ... oparticles are not detected due to ... r rapid Brownian relaxation.

... are very grateful to all the patients for their selfless ... k. Our sincere thanks to the investigators, the staff and ... their efforts.  
 ... lia.jayalakshmi@imagionbio.com

### Study Design

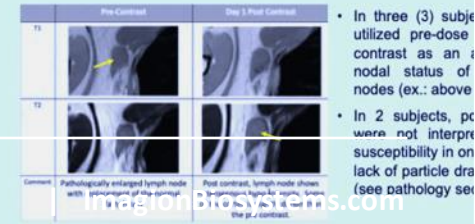
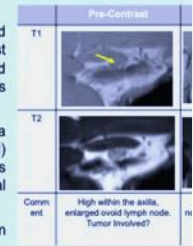
- Patient Eligibility**
- Newly diagnosed HER2-positive breast cancer patients prior to treatment
  - Suspicion of nodal disease by clinical evaluation, e.g., ultrasound or biopsy
- Study Protocol**
- Breast MRI on Day 1 prior to MagSense® HER2 administration (pre-dose)
  - Subcutaneous injection (peri-tumoral or areolar) of 30mg dose of MagSense®
  - Breast MRI on Day 2 (~ 24 hours post-dose)
  - Breast MRI on Day 4 (~ 72 hours post dose) for patients 1-6 only
  - Following last MRI, either dissected nodes if surgery planned before surgery biopsy (core needle) of a clinically "suspectious" lymph node obtained
  - Dissected nodes or biopsied tissue(s) analyzed ex vivo for magnetic histology
  - Day 7 safety follow up and Day 28 study completion

### Safety & Tolerability

- A Safety Review Committee (SRC) reviewed safety data following ... of patients (N=6).
- No dose limiting toxicities reported.
- Injection Site Reactions (ISR) – majority reported as mild or moderate discoloration at the injection site.
- No imaging agent or procedure related adverse events (AEs) reported
- Subjects enrolled after the SRC review show similar safety and tolerability

### MR Imaging Results

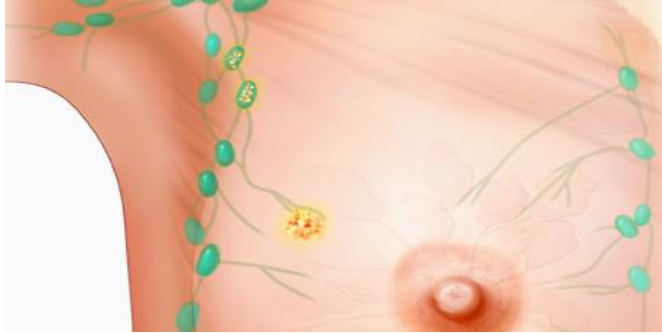
- MRI measurements were conducted using a 1.5T or 3T clinical standardized 20-minute breast imaging protocol of the ipsilateral axillary region
- A central radiology group was used to evaluate all patient images and images to post-dose images. Nodes were assessed by both conventional measures such as size and morphology as well as for changes in contrast intensity (as observed by the radiologist) between pre-dose and post-dose images was considered sufficient to have observable presence of metastatic disease
- Nodes were scored as "suspectious", or "normal" or "indeterminate" based on post-dose.
- Central Radiologists reported interpretable contrast change in post-dose images for both normal and enlarged nodes vs. pre-dose images in four (4) of six (6) subjects.
- Post-dose normal nodes displayed a uniformly dark contrast (right panel) whereas post-dose enlarged nodes (below panel) showed a central heterogeneous hypointensity.
- There was no intensity change from post-dose Day 2 to Day 4



- In three (3) subjects, the contrast was utilized pre-dose as an indicator of nodal status of nodes (ex.: above)
- In 2 subjects, post-dose contrast was not interpreted as a lack of particle drainage (see pathology report)

\* MR Imaging protocols were established with collaboration from Siemens Healthineers



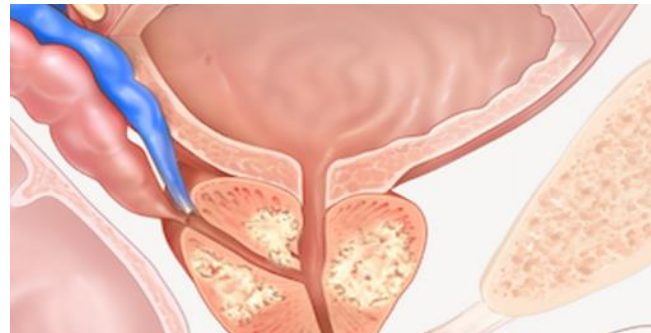


### Detection of Nodal Metastases in HER2+ Breast Cancer

Following primary tumor diagnosis determine if the cancer has spread to the lymph nodes.

Improves on existing standard-of-care (ultrasound) which is limited to a small number of nodes and to assessment for abnormal size/shape only.

Reduces the need for biopsy and provides additional context for treatment and surgical planning.



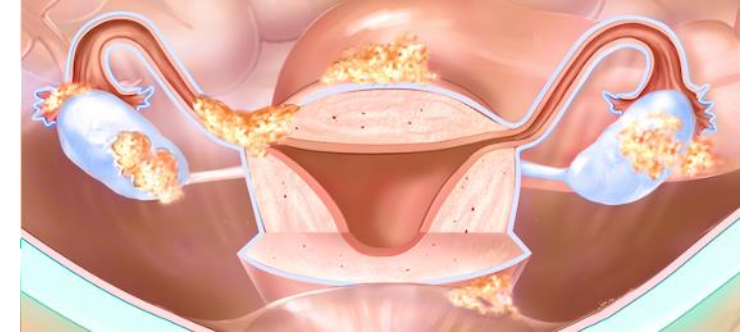
### Primary Tumor Detection in Prostate Cancer

Following elevated PSA blood test, the MagSense® PSMA test would identify if there is a prostate tumor.

Reduces biopsies to only those who test positive by MagSense® PSMA.

Avoids use of radiotracer (PET) testing for primary diagnosis.

Augments biopsy procedure by improving MRI-guided biopsy.



### Early Detection of Ovarian Cancer

Following primary tumor diagnosis determine if the cancer has spread to the lymph nodes.

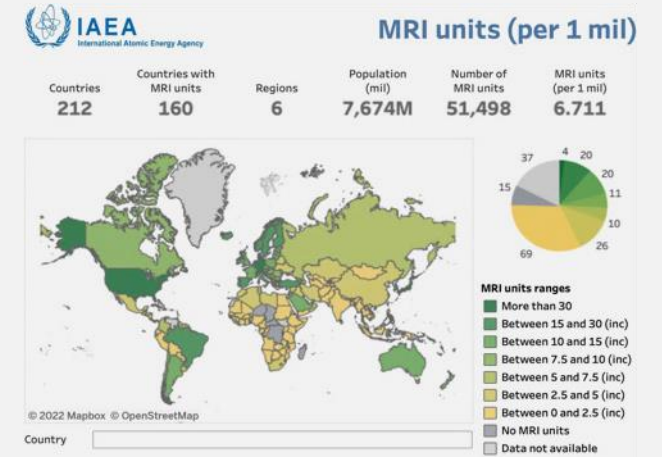
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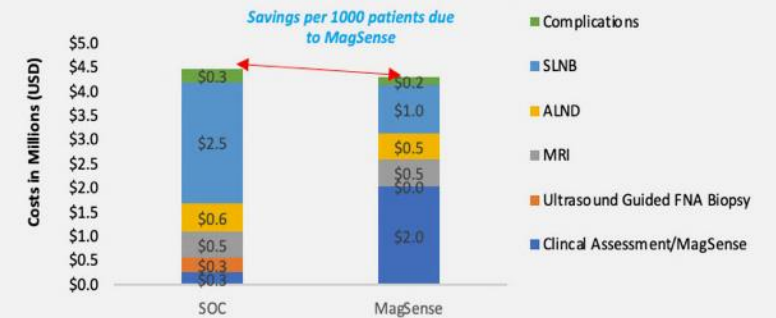
# Rationale for MRI Imaging Agents

Expanding access, Improving outcomes

1. There are >50,000 MRI scanners available globally (5x as many as PET imaging systems).
2. MagSense® imaging agents have long shelf life and can be stored and supplied by the hospital pharmacy without the costs and constraints like radiotracers.
3. Biopsies are expensive and invasive. PET imaging uses radioactivity, and conventional MRI contrast agents (Gadolinium) are non-specific and not typically used in cancer detection.
4. The health economics of using MagSense® mMRI are favorable because it fits within the existing clinical workflow, adds value to the radiologist's role in patient management and eliminates unnecessary and costly invasive procedures, such as biopsies.













Costs by Category Associated with SOC versus MagSense



# Focus on Strategic Partnering

1. Use of contrast media is well established across medical imaging technologies with molecular imaging being most dynamic and driving growth.
2. Global cancer incidence continues to rise<sup>1</sup> with Screening & Diagnostic Imaging being one of the fastest growing healthcare spend sectors as service providers seek ways to improve determining malignant vs. benign.<sup>2</sup>
3. MagSense<sup>®</sup> imaging agents are completely differentiated and fit the existing medical imaging and contrast media business model.
4. Incumbents continue making attractive deals for differentiated clinical-stage assets.
  - 2024 Hologic acquired Endomagnetics for \$300M

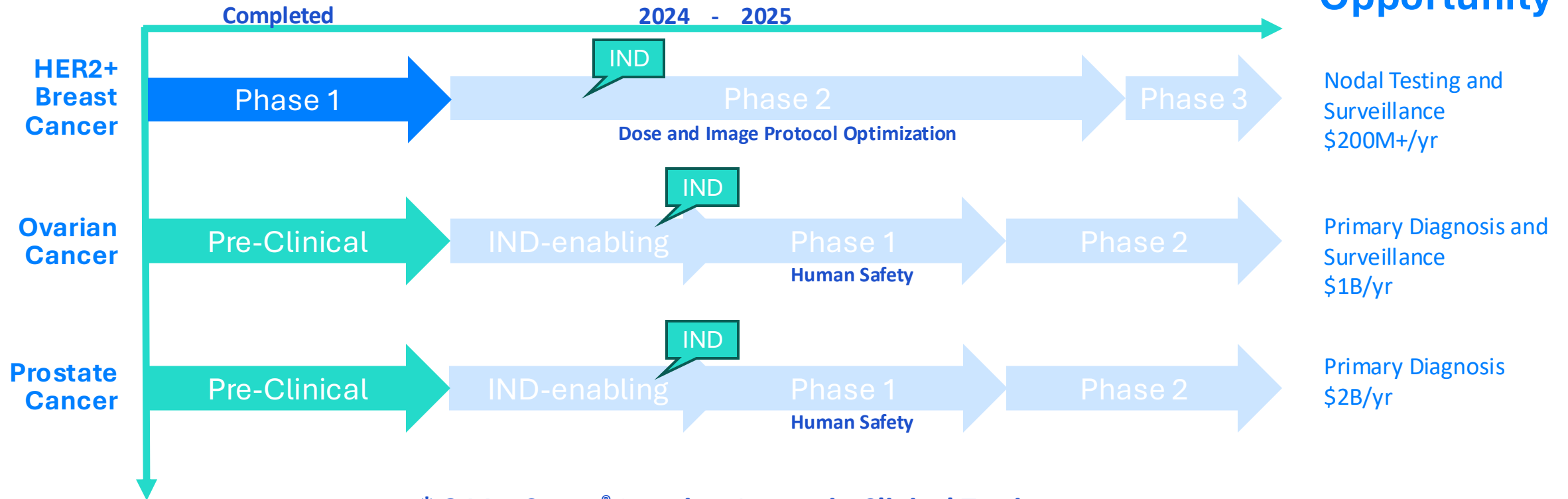


Acquirer	Target	Value AUD	Year	Notes
		\$18M	2024	Strategic investment. Part of \$70M AUD financing transaction.
		\$310M	2024	\$35M revenue at time of transaction. Breast cancer
		\$1.6B	2018	Imuno-oncology agent. Acquired following successful Phase 3.
		\$328M Est.	2019	All stock acquisition. Estimated market cap at transaction date.
		\$3.9B	2018	Acquired in Phase 3, pending FDA clearance. Radioligand therapy.

# Path to Growth and Value

Clinical Development Plan and Key Milestones

**\$3-4B Market Opportunity**



**\* 3 MagSense® Imaging Agents in Clinical Testing**



# Current Status and Priorities

## Shareholder General Meeting

- December 9<sup>th</sup> at 10:30am AEDT – see Nov 7<sup>th</sup> Notice of Meeting
- Approve issuance of shares to complete \$3M capital raise

## Clinical development of the MagSense<sup>®</sup> imaging agent(s) to be resumed with new funding

- Filing IND for MagSense<sup>®</sup> HER2 Phase 2 study the priority
- Advancement of Prostate or Ovarian Cancer imaging agent dependent on funds available

## Upcoming Strategic Partnering Venues

- Radiological Society of North America (RSNA)
- San Antonio Breast Cancer Symposium (SABCS)



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