

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

15 August 2024

Investor presentation

MELBOURNE – Imagion Biosystems (ASX:IBX), a company dedicated to improving healthcare through the early detection of cancer, today advises it has released the attached investor presentation which will be presented to investors at 10:00am (AEST) Thursday, 15 August 2024.

Highlights from the presentation include:

- Explanation of and reasons for the resolutions proposed for shareholder approval
- Update on our business plan and key milestones
- Q&A session with our leadership team

— ENDS —

About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and precision diagnostic molecular imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible.

For more information, visit <https://imagionbiosystems.com/investor-hub/>

Authorisation & Additional information

This announcement was authorised by the Board of Imagion Biosystems Limited.

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MRI Imaging Agents for Cancer Detection

Imagion Biosystems Limited
ASX:IBX

A Breakthrough in
Molecular Magnetic
Resonance Imaging

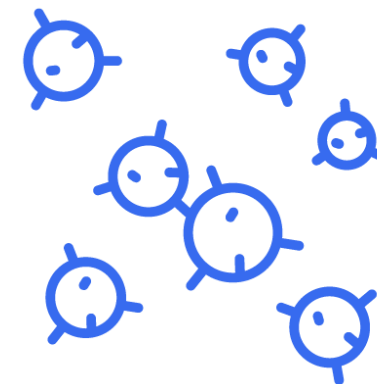




Imagion Biosystems Overview

Imagion
Biosystems
ASX:IBX

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.

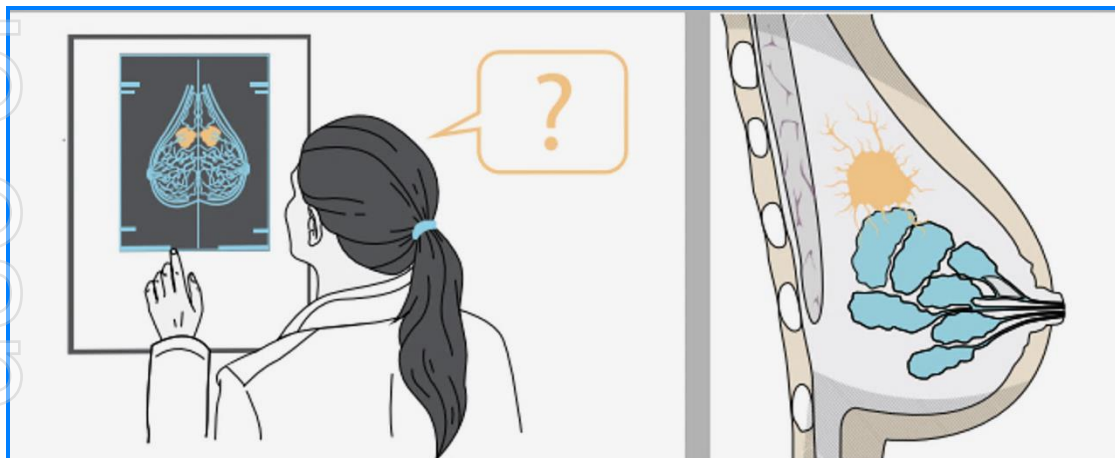


Biopsy

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.

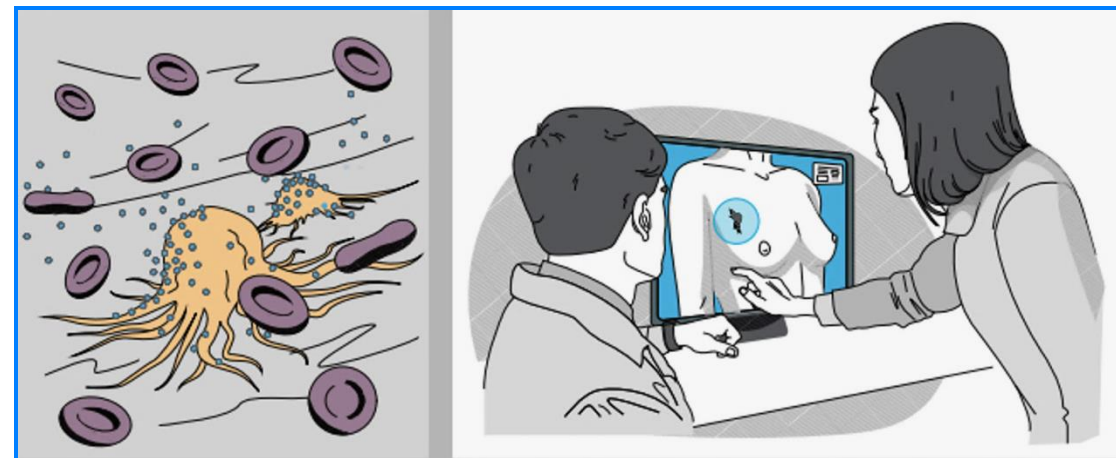
A biopsy and pathology assessment are required for most cancers

Enabling Molecular Imaging



Conventional Imaging

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



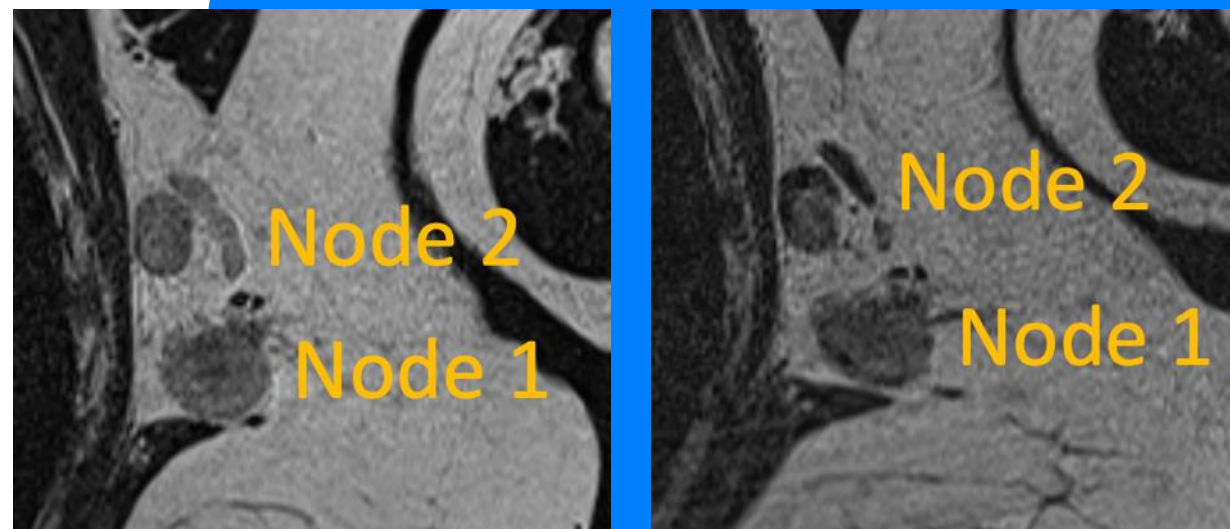
MagSense[®] Imaging

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[®] Molecular Imaging

MagSense[®] 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

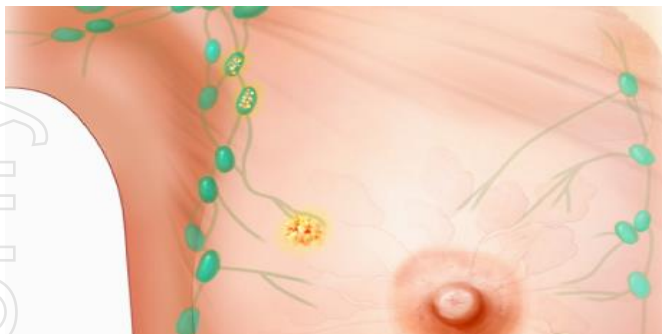
Would enable earlier detection of solid tumors when small and not easily visible by conventional methods and/or difficult and risky to biopsy.



Platform Technology

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

MagSense[®] Use Cases



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.



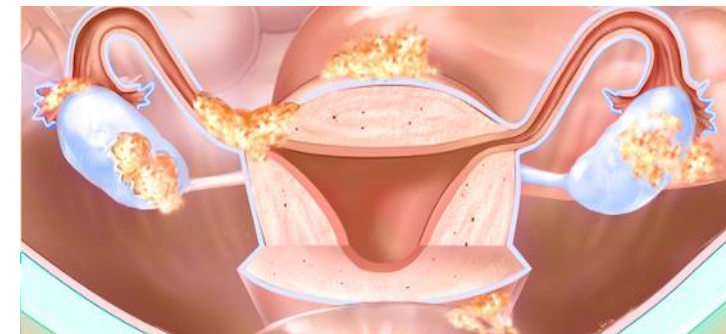
Primary Tumor Detection in Prostate Cancer

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.

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.

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 Fox¹, Natalie Young², Steven D. Reich³, Marie Zhang³, Robert P. ...
¹Monash Health Moorabbin, 86; Centre Road, Bentleigh East, Victoria, 3165; ²Austin Health, 145 Studley Rd, Heidelberg, Victoria, 3084

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

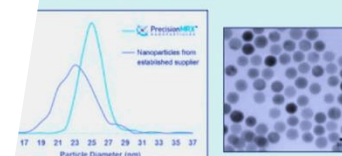
- Breast MRI on Day 1 prior to MagSense® HER2 administration (pre-dose)
- Subcutaneous injection (peri-tumoral or areolar) of 30mg dose of MagSense®
- Breast MRI on Day 2 (~24 hours post-dose)
- Breast MRI on Day 4 (~72 hours post-dose) for patients 1-6 only
- Following last MRI, either dissected nodes if surgery planned before surgery or a core needle biopsy (core needle) of a clinically "suspicious" lymph node obtained
- Dissected nodes or biopsied tissue(s) analyzed *ex vivo* for magnetic resonance histology
- Day 7 safety follow up and Day 28 study completion

Objective

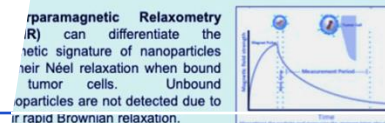
The primary objective of this first-in-human study is an initial proof-of-principle for the HER2 targeted imaging agent. Secondary objectives include the confirmation that the route of administration of the imaging agent to reach the patient's lymph nodes is feasible. The objectives of the study include a comparison of standard clinical tissue histopathology to whether the MagSense® HER2 imaging agent, when used in combination with standard clinical tissue histopathology, might provide improved decision making.

Magnetic Nanoparticles

The MagSense® HER2 imaging agent is designed for use with the magnetic relaxometry (MR) imaging agent.



The MagSense® HER2 imaging agent is designed for use with the magnetic relaxometry (MR) imaging agent. The agent is composed of iron oxide (Fe₃O₄) cores made with high magnetic relaxivity ($r_2 = 10^5 \text{ s}^{-1} \text{ T}^{-2}$ at 7 T) providing excellent Néel relaxation and T2 relaxation. The cores are dispersed with narrow size distribution and exhibit high molecular imaging agent, cores are encapsulated with a polyethylene glycol (PEG) conjugated onto the polymer surface.



The MagSense® HER2 imaging agent is designed for use with the magnetic relaxometry (MR) imaging agent. The agent is composed of iron oxide (Fe₃O₄) cores made with high magnetic relaxivity ($r_2 = 10^5 \text{ s}^{-1} \text{ T}^{-2}$ at 7 T) providing excellent Néel relaxation and T2 relaxation. The cores are dispersed with narrow size distribution and exhibit high molecular imaging agent, cores are encapsulated with a polyethylene glycol (PEG) conjugated onto the polymer surface.

Safety & Tolerability

- A Safety Review Committee (SRC) reviewed safety data following the study of patients (N=6).
- No dose limiting toxicities reported.
- Injection Site Reactions (ISR) – majority reported as mild or moderate redness and 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 MRI scanner. A standardized 20-minute breast imaging protocol of the ipsilateral axillary region was used.
- A central radiology group was used to evaluate all patient images and contrast change from pre-dose 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. A change in contrast intensity of 30% or more was considered sufficient to have observable presence of contrast.
- Nodes were scored as "suspicious", or "normal" or "indeterminate" based on the post-dose images.

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.

Subject	Pre-Contrast	Post-Contrast
T1		
T2		

Comment: High within the axilla, enlarged ovoid lymph node. Tumor involved?

In three (3) subjects, the contrast change was utilized pre-dose to post-dose contrast as an indicator of nodal status of nodes (ex.: above).

In 2 subjects, pre-dose images were not interpretable due to susceptibility in one of the nodes (lack of particle dose) (see pathology section).

Subject	Pre-Contrast	Post-Contrast
T1		
T2		

Comment: Pathologically enlarged lymph node with pre-contrast contrast. Post-contrast, lymph node shows a central hypointensity, consistent with the presence of the contrast agent.

Improving Radiological Review

- Radiological assessment is often subjective, with significant inter-operator differences in interpretation.
- Development of automated software solutions will allow reliable, automated detection for easier, accurate reads.
- Using common post-processing techniques, such as subtraction, only areas with MagSense® particles remain in the image.
- Machine Learning can be applied to create SaaMD automated detection solutions.



Pre-Contrast



Post-Contrast

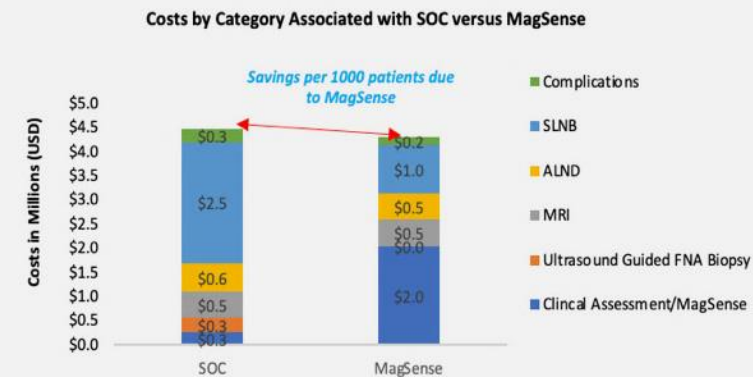
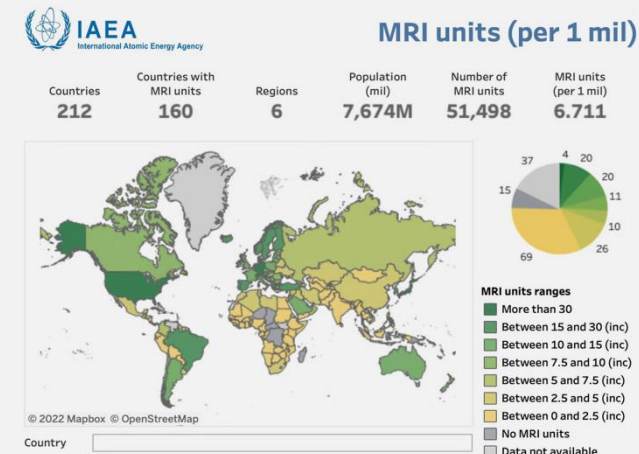


Subtraction

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.



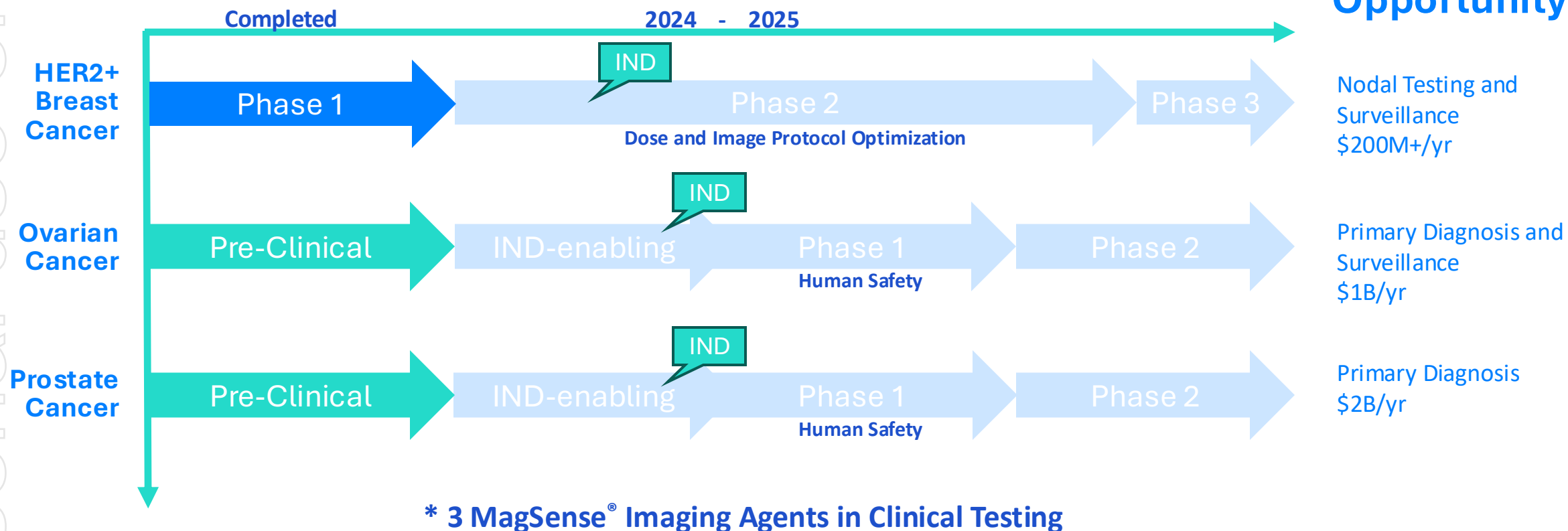
Investor Rationale



Path to Growth and Value

Clinical Development Plan and Key Milestones










\$3-4B Market Opportunity



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 rise¹ with Screening & Diagnostic Imaging being one of the fastest growing healthcare spend sectors as service providers seek ways to improve determining malignant vs. benign.²
3. MagSense® 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
 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.

Imagion 2.0

Restructured Operations and 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.

Imagion 2.0

Investor Summary



Key Clinical Milestone Achieved

Strong Pipeline

Significantly reduced operating costs

- Phase 1 study in 13 HER2+ breast cancer patients completed
 - Safety and tolerability endpoints achieved
- Independent radiological review corroborates clinical utility for nodal detection

- MagSense[®] HER2 being readied for IND application for Phase 2 study to optimize dose and imaging protocols.
- MagSense[®] imaging agents for prostate cancer and ovarian cancer ready for IND-enabling studies.

- Eliminated costs of R&D and Manufacturing obligations in favor of outsourcing to CROs and CMOs.
- Reduced Management and Board to essentials to maintain compliance.
- Operating as a “virtual” entity.
- Will fund R&D on a “pay-as-you-go” basis keeping spending in line with secured funding
- Cash burn reduced to <\$100K / mos. excluding funding R&D.



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