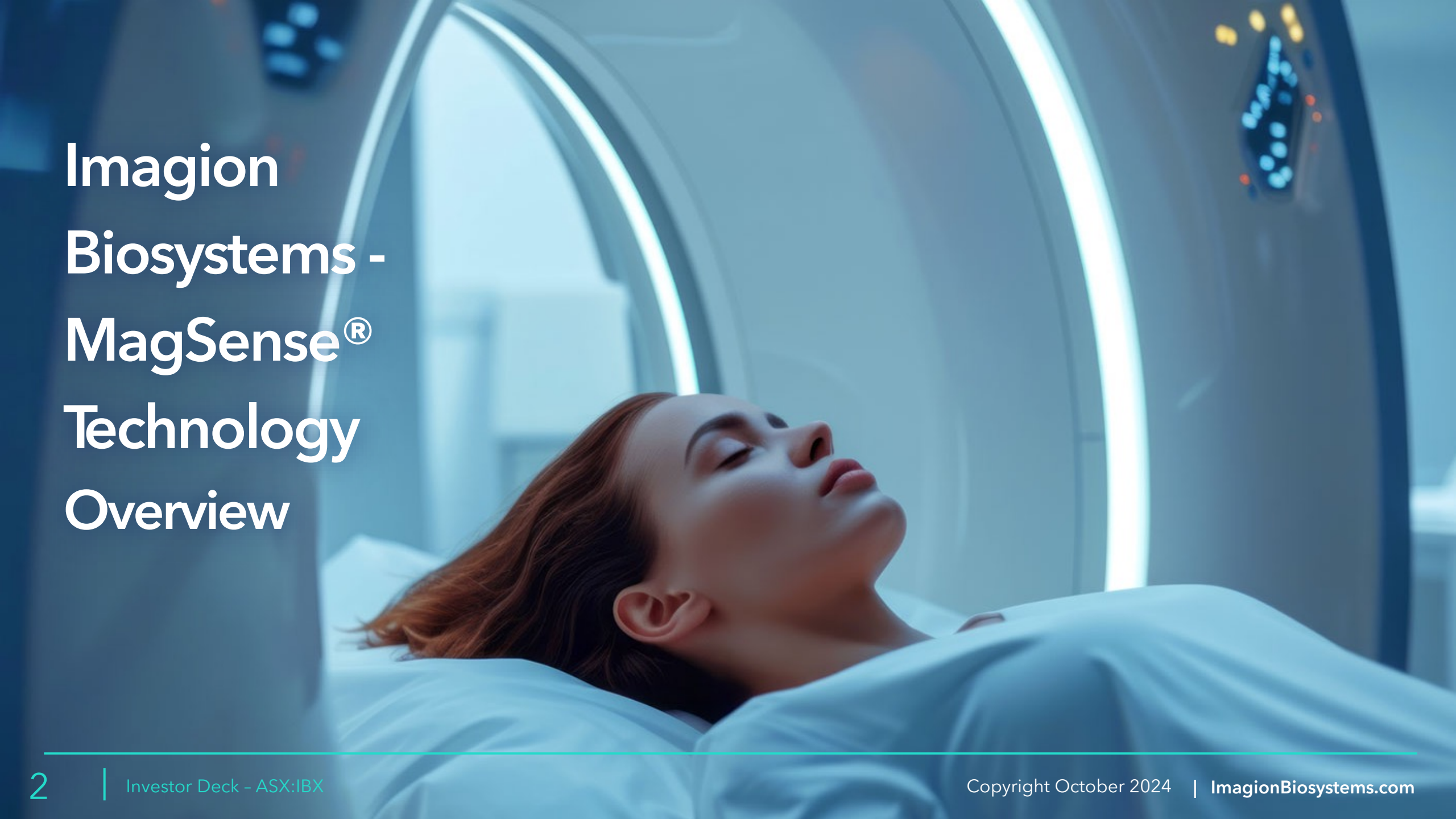
IMAGION BIOSYSTEMS

Imagion Biosystems Limited
ASX:IBX

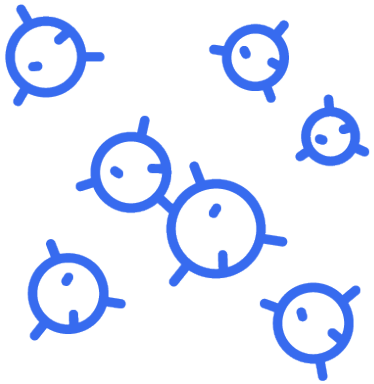
A Breakthrough in Cancer Detection

Molecular Magnetic Resonance Imaging

Imagion Biosystems - MagSense® Technology Overview



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

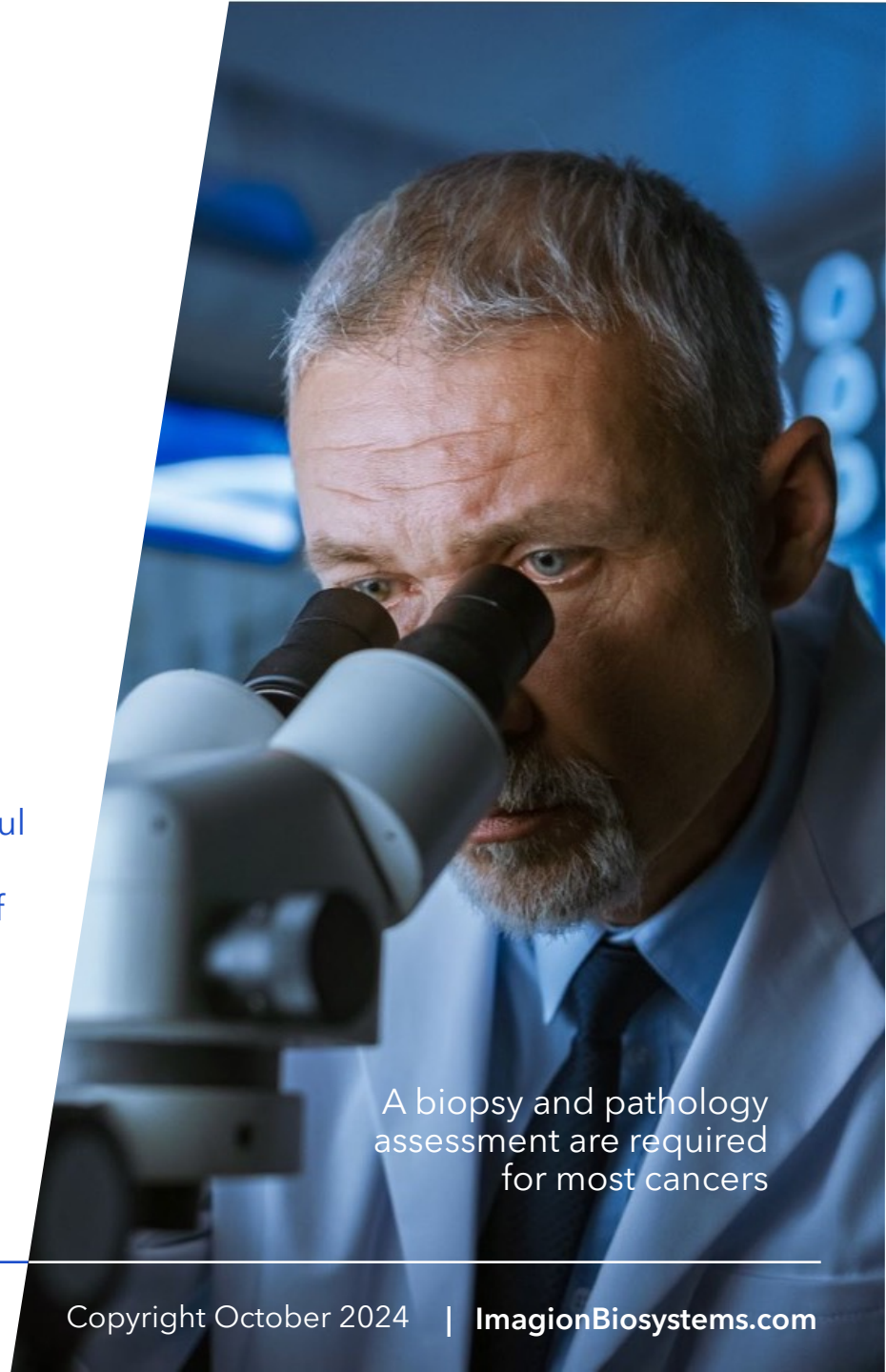
Conventional blood-based tests, like PSA or CA125, indicate risk of cancer but are not diagnostic. Newer methods like cfDNA or CTCs improve screening but require confirmation before treatment.

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

Imagion 2.0 - Investor Summary

Corporate and Operational Restructuring Completed

Key Clinical Milestone Achieved

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

Strong Pipeline

- 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.

Significantly Reduced Operating Costs

- 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 significantly

New Leadership Team

Robert Proulx
Executive Chairman
Robert is a veteran executive of the life science and medical device sectors 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 including MRI image software from concept to market.

Melanie Leydin
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.

Current Issued Capital	
Ordinary Shares	35,646,551
Performance Rights	3,275,000
Options (at various prices and dates)	17,607,515
Convertible Notes	4,342,000

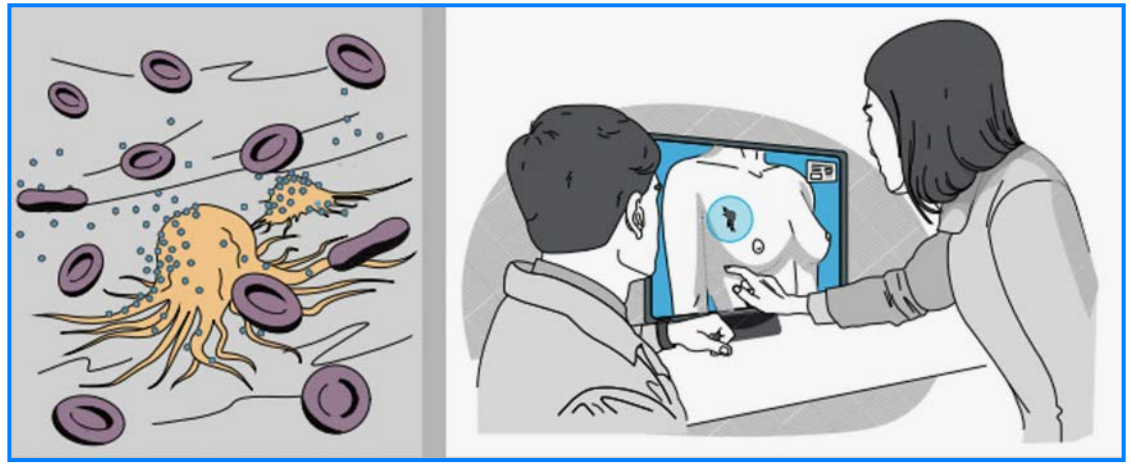
MagSense® Technology

A Breakthrough

IBX Enables Molecular Imaging

Conventional Imaging

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



MagSense®Imaging

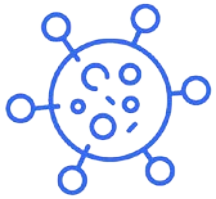
Molecularly targeted imaging agents produce a distinct image pattern indicating the presence of a tumor.

MagSense® Molecular Imaging

MagSense® technology aims to transform how medical imaging can detect and diagnose cancer

MRI-based Detection

Imaging agents work with exiting 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.

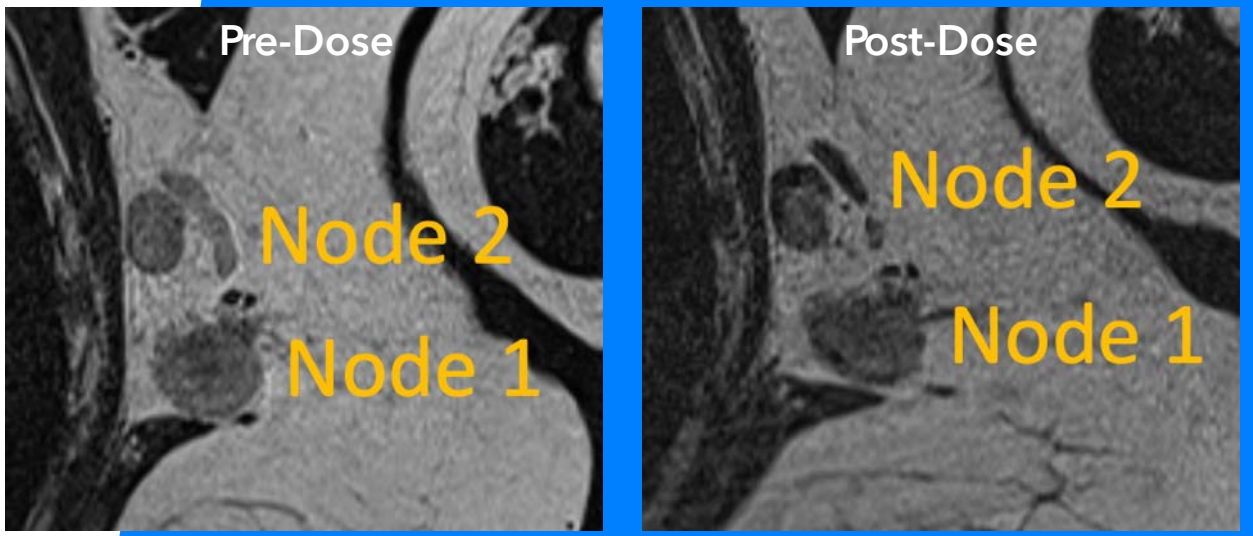
Platform Technology

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

How IBX molecular MRI works

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

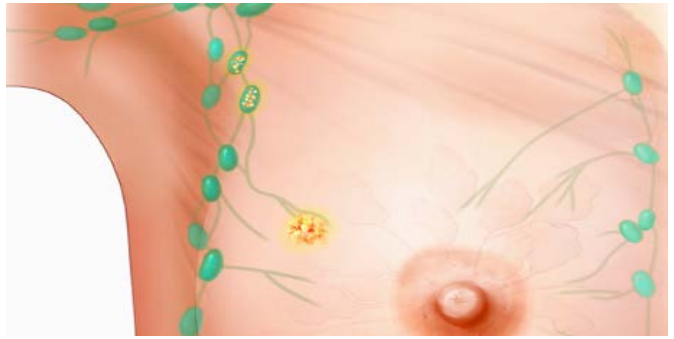
- A targeting moiety (*e.g.* antibody or peptide) directs the nanoparticles to the target tissue to ensure cancer specific detection.
- When present in tissue, the magnetic nanoparticles create hypointense (dark) contrast in T2 MRI scans.
- The hypointense contrast indicative of the presence of the targeted 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.



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

$3-4B Market Opportunity

MagSense® Use Cases



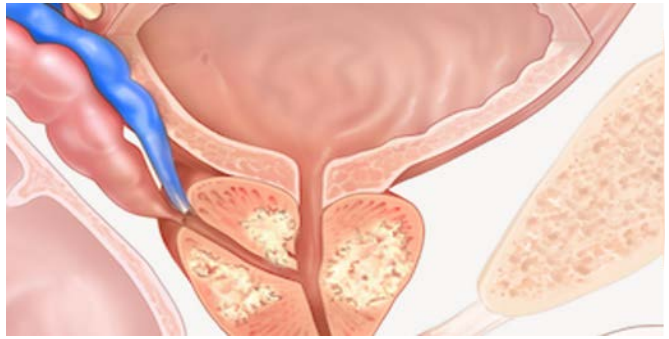
Detection of Nodal Metastases in HER2+ Breast Cancer

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.

Nodal Testing and Surveillance $200M+/yr



Primary Tumor Detection in Prostate Cancer

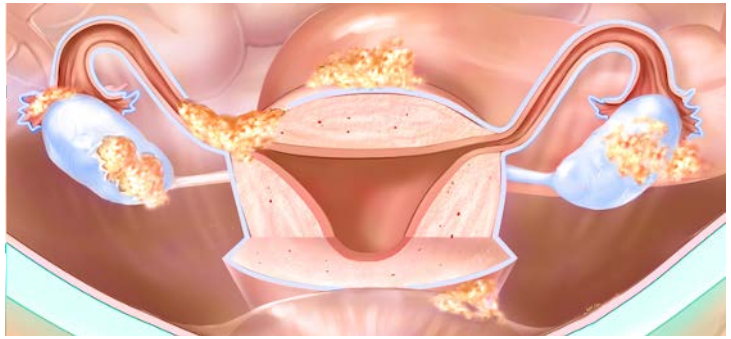
Following elevated PSA blood test, the MagSense® PSMA test would identify if there is a prostate tumor.

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.

Primary Diagnosis and Surveillance $1B/yr



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.

Primary Diagnosis $2B/yr

Phase 1 Study – Completed

Detection of Nodal Metastases in HER2+ Breast Cancer

- A Phase 1 Study with 13 HER2+ Breast Cancer patients from 4 sites in Australia. IBI010103
- 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.
- Next step - IND and multisite Phase 2 study in process.


ion of Lymph Node Involvement in Subjects with Human Epidermal Gr
A First-In-Human Phase 1 Study Using the MagSense®
Jane Fox[1], Natalie Young[2], Steven D. Reich[3], Marie Zhang[3], Robert P
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 biop
Study Protocol
Breast MRI on Day 1 prior to MagSense® HER2 administration (pre-dose
Subcutaneous injection (peri-tumoral or areolar) of 30mg dose of MagSe
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 sy
biopsy (core needle) of a clinically "suspicious" 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 mod
discoloration at the injection site.
No imaging agent or procedure related adverse events (AEs) rep
Subjects enrolled after the SRC review show similar safety and tol
MR Imaging Results
MRI measurements were conducted using a 1.5T or 3T clinical
standardized 20-minute breast imaging protocol of the ipsilateral axillary
A central radiology group was used to evaluate all patient images and
images to post-dose images. Nodes were assessed by both conven
measures such as size and morphology as well as for changes in co
30% change in contrast intensity (as observed by the radiologist) betwe
dose images was considered sufficient to have observable presence of
Nodes were scored as "suspicious", or "normal" or "indeterminate" b
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) subje
utilized pre-dose
contrast as an
nodal status of
nodes (ex.: above
In 2 subjects, pc
were not interpre
susceptibility in on
lack of particle dra
(see pathology se
are very grateful to all the patients for their selfless
their efforts.
lia.jayalakshmi@imagionbio.com
* MR Imaging protocols were established with collaboration from Siemens Healthineers

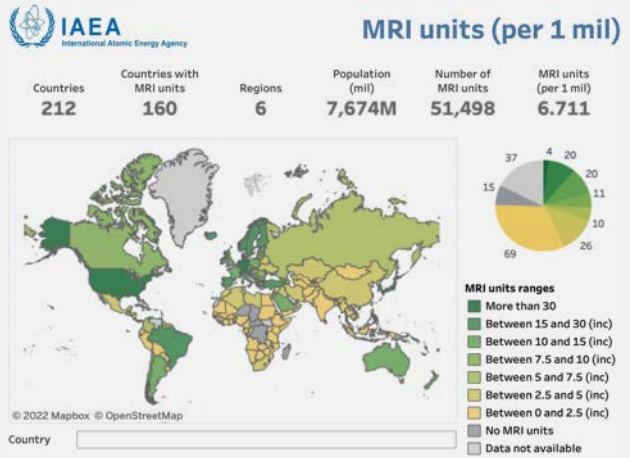
MagSense® will Improve Radiological Review

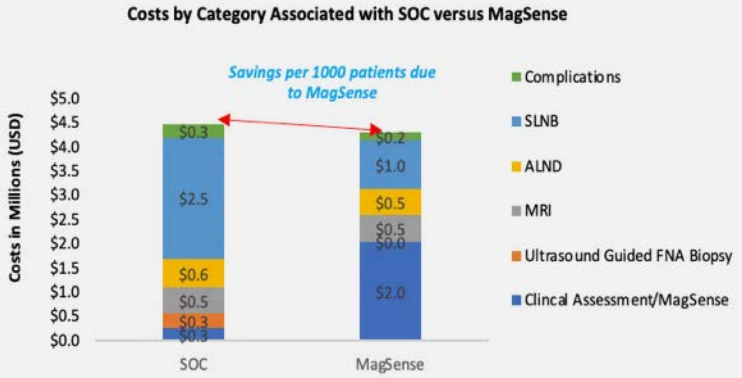
- Radiological assessment is often subjective, with significant inter-operator differences in interpretation.
- **Automated software for detection and segmentation of MagSense® tagged cells will enable:**
  - **Faster, more accurate reads**
  - **Longitudinal tracking/patient monitoring**
  - **Accelerated product adoption**
- Numerous companies and universities have existing software models that can be the basis for our tool.
- Adding automated detection solutions (SaaMD) will improve the diagnostic utility and increase the NPV.

Rationale for MagSense® Imaging Agents

Large addressable markets ($B's), Expanding access, and Improving outcomes

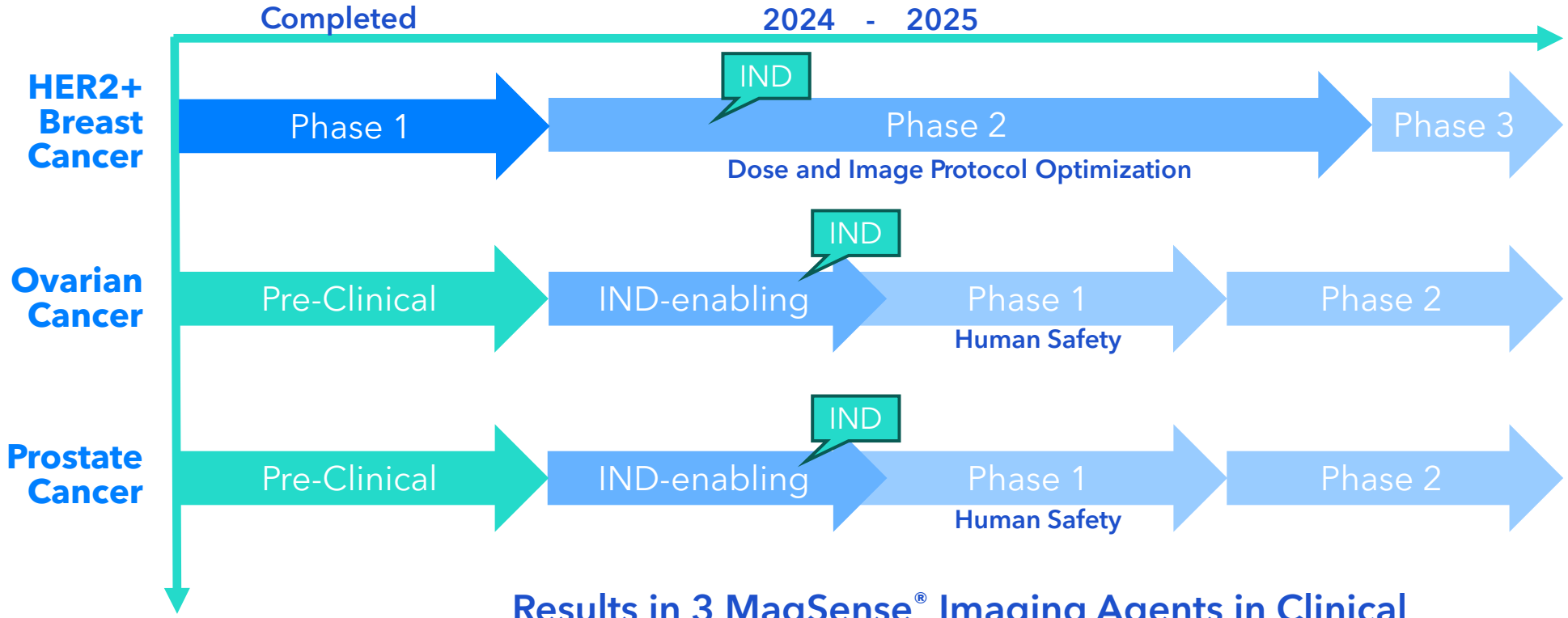
1. There are >50,000 MRI scanners available globally (5x as many as PET imaging systems).
2. MagSense® imaging agents have long shelf life and can be stored and supplied by the hospital pharmacy without the costs and constraints like radiotracers.
3. Biopsies are expensive and invasive. PET imaging uses 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.





Path to Growth and Key Value Catalysts

Clinical Development Plan and Key Milestones



Near-Term Funding Needs

File IND and initiate Phase 2 study for HER2 imaging agent

Complete IND enabling studies for Prostate Cancer and Ovarian Cancer to enter clinical phase.

Results in 3 MagSense® Imaging Agents in Clinical Testing and improved valuation of IBX

Investor Rationale

Focus on Strategic Partnering

Sources: (1) JAMA Oncology. 2022. Medicare Payment Advisory Commission (MedPAC) and Centers for Medicare and Medicaid Services (CMS). Mordor Intelligence. Global Contrast Media Market

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[1] 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

Comparable Transactions

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.

Investment Proposition

1. MagSense® imaging agents have a high probability of receiving regulatory approval - nearly 100% of contrast media submitted to the FDA are approved.
2. Progressing through each stage in clinical development increases the overall probability of success.
3. Since all MagSense® imaging agents work and are detected in the same way, each successive step for one agent derisks steps for each additional agent.
4. Strategic partnerships have higher probability and higher value at later stages of clinical development.

Example Probability of Success at Stage	
IND Enabling	24%
Phase 1	28%
Phase 2	30%
Phase 3	59%
Registration	90%

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