

# A Breakthrough for Cancer Detection

Molecular Magnetic Resonance Imaging

Imagion Biosystems Limited ASX:IBX





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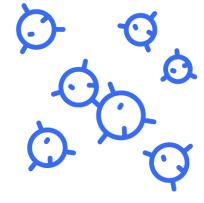
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#### **Overview**

### A clinical stage biotechnology company developing a new class of molecular imaging technology for the early detection of cancer



#### MagSense® Molecular Imaging

Improves cancer detection compared to conventional imaging technologies by adding molecular specificity without using radioactivity.

Highly differentiated and first-of-its-kind in molecular imaging.

#### **Strong Pipeline Addressing Large Markets**

- ➤ HER2 Breast Cancer
- Prostate Cancer
- Ovarian Cancer

#### **Company Highlights**

- Positive FDA interactions sets stage for Investigational New Drug (IND) application to be filed in Q3 '25.
- Phase 2 Study for the MagSense® HER2 imaging agent to commence following FDA approval of the IND.



#### The Unmet Need



#### Screening

Blood-based tests indicate risk but are non-diagnostic and require confirmation before treatment.



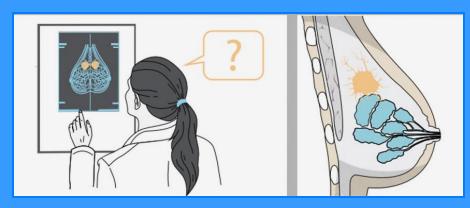
#### **Biopsy**

Provide certainty but are invasive, painful, error prone and challenging, often resulting in side effects or complications. Pathology assessments can take days.



#### **Current Imaging**

Non-invasive but non-specific. Cannot differentiate benign lesions from malignant tumors with certainty. Gadolinium-based contrast agents are not able to be molecularly targeted.



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



## MagSense® Imaging Agents



#### Specific

Provides molecular confirmation of cancer, not just "suspicion".



No radioactivity.

Low dose produces contrast.



Reduces need for biopsies and can detect small tumors.



#### **MRI-based Detection**

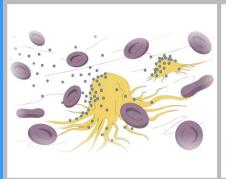
Compatible across 50k+ MRI scanners in use globally.



#### **Platform Technology**

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

#### **Changing How We See Cancer**





MagSense® Imaging uses molecularly targeted imaging agents to produce a distinct image pattern. Combined with the anatomical information of high-resolution MRI it provides certainty in radiological review.

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### How MagSense® molecular MRI works



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

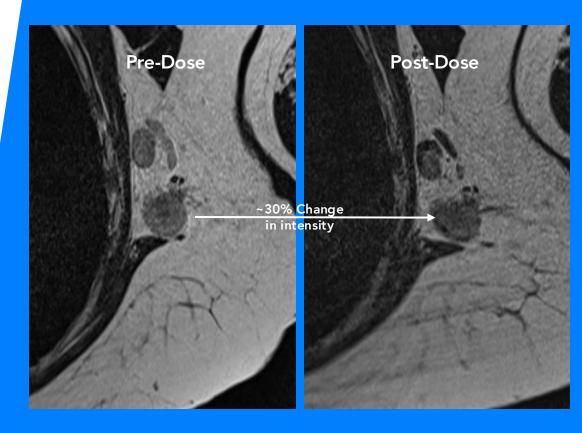


MagSense particles only bind to target type of cancer cells, if present



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

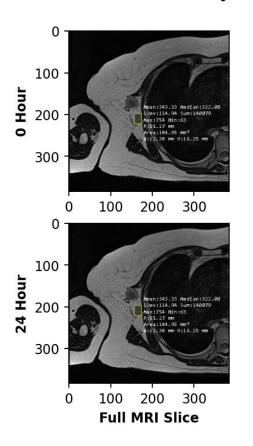
MagSense® nanoparticles enable molecular imaging by producing an identifiable change in image contrast when cancer cells are present

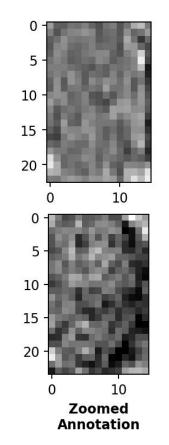




### **Al Enabling**

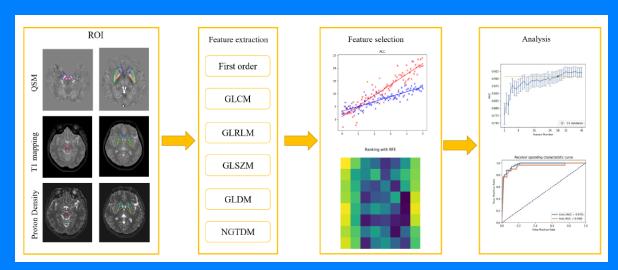
Subject 5, Node: 2





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

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



https://archive.ismrm.org/2021/3258.html



## Our Pipeline - \$2B Markets

## Nodal Metastases in HER2+ Breast Cancer

- 400,000 HER2+ Breast Cancer diagnoses annually
- HER2+ tumors tend to be more aggressive forms of Breast Cancer
- Lymph node analysis is SoC for cancer staging
- Existing SoC (ultrasound) is regionally limited and nondiagnostic

## Primary Tumor Detection of Prostate Cancer

- 1M+ Prostate biopsies/year in US
- 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

## Early Detection of Ovarian Cancer

- 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>rds</sup> die from the disease



## Investment Rationale

#### Large Markets with an Unmet Medical Need

- Global cancer incidence to rise 77% by 2050 with screening & diagnostic imaging costs growing at 6.7% CAGR
- Molecular imaging to-date limited to methods using radioactivity due to MRI lacking specificity.

#### Clear Path to Clinical Utility

- Almost 100% of contrast media products achieve regulatory approval.
- Fits existing clinical workflows and is compatible across 50,000+ MRI scanners in use globally.
- Combined with AI detection could expand "diagnostic" utility of imaging

#### **Commercially Attractive for Strategic Partnering**

- Health economics support value-based reimbursement pricing while still saving healthcare system costs.
- High gross margins support commercial partnering business model.

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





## **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.



## **Company & Leadership**

- Scientifically proven, novel-platform addressing multi billion dollar market.
- Strong clinical value proposition with high margins and reimbursement potential.
- Experienced team in the development of Medical Device and Medical Imaging technologies.
- Track record of successful regulatory approvals for image-based technology.
- Commercially focused with experience in bringing new technologies to market.
- Operating as a virtual company with low fixed costs.



Robert Proulx MAICD **Executive Chairman** 

Robert has been CEO and Chairman of Imagion since 2015 bringing the technology and company from early proof of concept to clinical stage.



Melanie Levdin 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



Dr. Susan Harvey Medical Affairs Advisor

Dr. Harvey is an experienced breast radiologist and the co-founder of Curing Women's Cancer. Previously she served as VP of Worldwide Medical Affairs at Hologic and Director of Breast Imaging at Johns Hopkins Medicine



Ward Detwiler Chief Business Officer

Ward is an experienced senior executive in the medical imaging field. Most recently, he was cofounder and CEO of of SpinTech MRI, a quantitative MRI software company focused on rapid imaging and new biomarker detection.



**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.



Dr. Kayat-Bittencourt Clinical Advisor

Dr. Kayat Bittencourt is the Vice Chair of Innovation at University Hospitals and an Associate Professor of Radiology at Case Western Reserve University. He is a leader in the field of prostate cancer research using multiparametric MRI.



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