# CHANGING THE WAY WE LOOK AT CANCER

IMAGION BIOSYSTEMS ASX : IBX EGM 13 NOVEMBER 2023



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### **Executive Summary**

- 1st-mover expanding biomedical access and application impact of SPIONs (superparamagnetic iron oxide nanoparticles)
- MagSense<sup>®</sup> technology improves clinicians' ability to visualize tumors and metastases with standard MRI instruments
- MagSense<sup>®</sup> HER2 imaging agent was safe and welltolerated in Phase 1 clinical trial
- MagSense<sup>®</sup> product pipeline targets deadliest and frequently metastatic cancers

#### Imagion Biosystems, Ltd. ASX: IBX

Imagion is delivering molecular spatial resolution in Magnetic Resonance Imaging to change the way we look at cancer



### MagSense<sup>®</sup> - Molecularly Targeted Magnetism



Superparamagnetic Iron Oxide Nanoparticles (SPIONs)



improve bioavailability

Conjugation of targeting molecules confers specificity Versatile synthesis platform enables biomedical application diversity

- Positive and negative MRI contrast
- Therapeutic hyperthermia (e.g., tumor ablation)
- Nanoparticle-based vaccines

#### Tunable polymer coatings optimize performance

- Bioavailability
- Immune response
- Target-ability

Array of chemistries facilitates drug-loading and biomolecular targeting

- Proteins and peptides
- Small molecules and toxins.



### How MagSense<sup>®</sup> Works

MagSense® nanoparticles are directed to the tumor and 'sense' MRI magnetism on tumor binding

#### 01. Inject

Single, low-dose MagSense<sup>®</sup> imaging agent injection

#### 02. Target

MagSense<sup>®</sup> nanoparticles are biomolecularly targeted with highly specific, high-affinity binders

#### 03. Bind

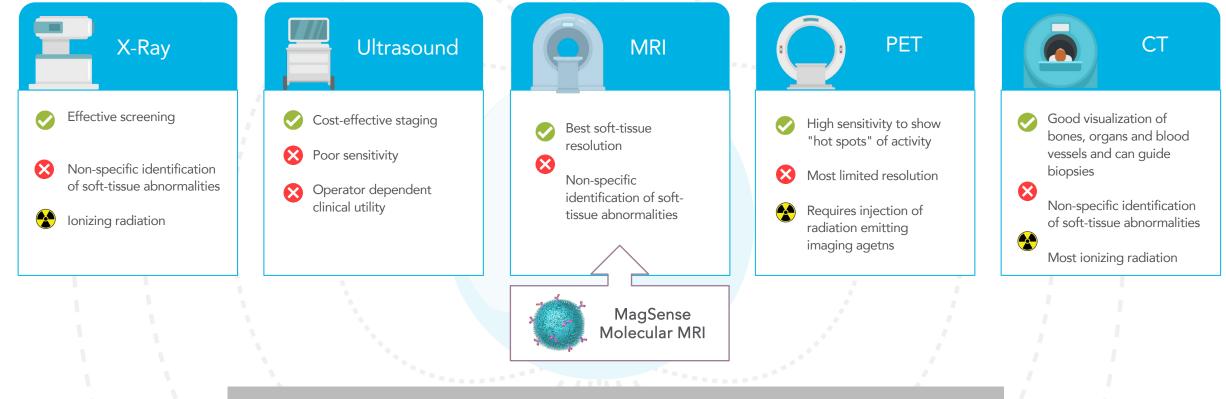
Tumor binding makes MagSense<sup>®</sup> nanoparticles' superparamagnetism detectable for MRI imaging

#### 04. Clear

MagSense<sup>®</sup> nanoparticles are safely cleared by the liver where the iron core is metabolized to ferritin in the hemoglobin production pathway



### Molecular MRI Changes the Way We Look at Cancer Diagnostic imaging is fundamental in precision oncology



Molecular MRI differentiates benign from malignant lesions

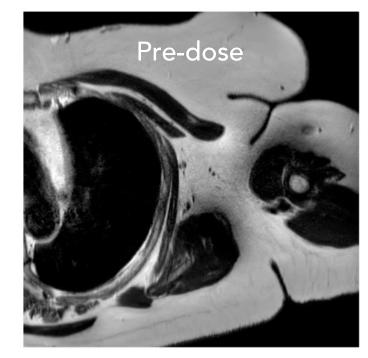


# MagSense<sup>®</sup> HER2 Imaging Agent

### MagSense® HER2 Imaging Agent

Changing the way we look at HER2+ Breast Cancer

- Detection of nodal metastases in HER2+ breast cancer
- Safe & well-tolerated in 13 patient Phase 1 trial (enrollment completed July, 2023)
  - 3 patients no / limited lymph drainage
  - 2 patients excess MRI susceptibility
- Full results reported December, 2023 at San Antonio Breast Cancer Symposium
  - 7/8 interpretable patients yield accurate molecular MRI
    - Blinded review by independent radiologists has corroborated pathologists' findings
    - 1 pt had incomplete pathology







### MagSense® Molecular MRI Makes the Difference

#### Homogeneous Hypointensity by Normal Lymph Nodes

#### Heterogeneous Hypointensity in Suspicious Lymph Nodes



#### Predose

Enlarged axillary lymph node with replacement of the normal fatty hilum

#### **Tumor Involved?**

#### Postdose

Predose

Enlarged, ovoid

axillary lymph node

**Tumor Involved?** 

Uniformly darkened lymph node suggests

Benign / Normal





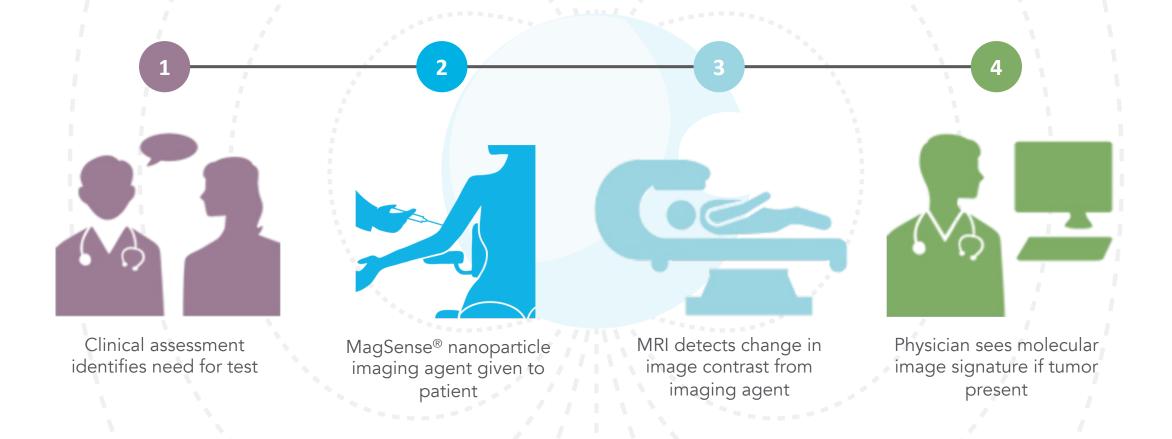
#### Postdose

Heterogenous hypointensity and slightly darkened cortex confirms Metastatic Disease



### MagSense<sup>®</sup> Fits Clinical Workflows

MagSense<sup>®</sup> delivers molecular discrimination with conventional MRI instruments



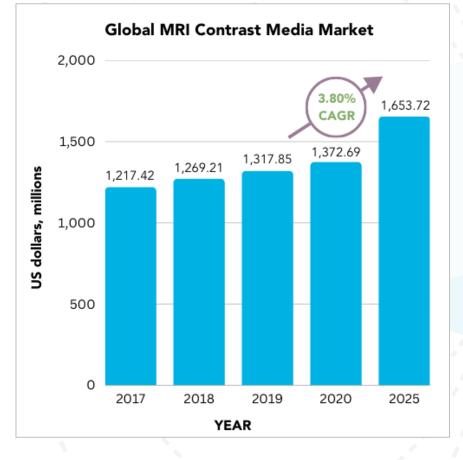


# Imagion's Approach

### Market Fundamentals & Momentum Support MagSense®

#### • Increasing chronic disease incidence

- Accelerating Neurovascular & Cardiovascular applications
- Rising cancer incidence
  - Global cancer burden grew 26% last decade<sup>1</sup>
  - By 2030: ~22M New Cancer Diagnoses & ~13M Cancer Deaths<sup>2</sup>
- Precision oncology producing an ever-expanding oncology therapeutic arsenal
  - Companion Dx opportunities
- Increasing procedure volume focused on 'malignant vs. benign?'
  - Screening & Diagnostic Imaging: Fastest growing healthcare services spend / Medicare beneficiary<sup>3</sup>

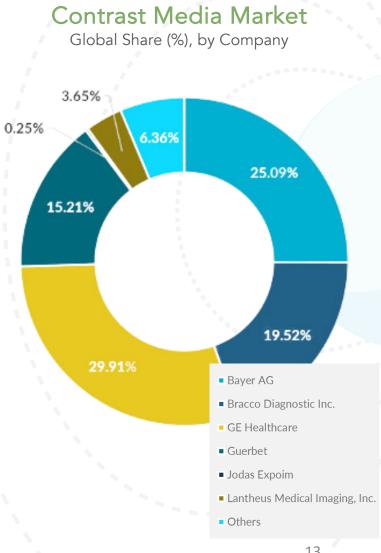


Sources: (1) JAMA Oncology. 2022. (2) International Agency for Research on Cancer. (3) Medicare Payment Advisory Commission (MedPAC) and Centers for Medicare and Medicaid Services (CMS). Mordor Intelligence. Global Contrast Media Market



### MagSense<sup>®</sup>: Imagion's Compelling Investment Thesis

- GE, Bayer, & Bracco dominate imaging contrast media market
  - Highly consolidated market ripe for disruption
  - Molecular imaging subsector is most dynamic and driving growth •
- Accelerating approvals for imaging contrast reagents globally
  - Market still responding to FDA's >5 year-old safety warning on Gadolinium-based agents
  - SPIONs are the safe and efficient alternative
- Molecular imaging advantage: Immuno-MRI applications will outpace Immuno-PET
  - MRI is >4X Global installed base of PET scanners •
  - Positron emission constrains supply chain and clinical application
  - Accelerating demand for non-invasive evaluation of treatment efficacy & prognosis prediction



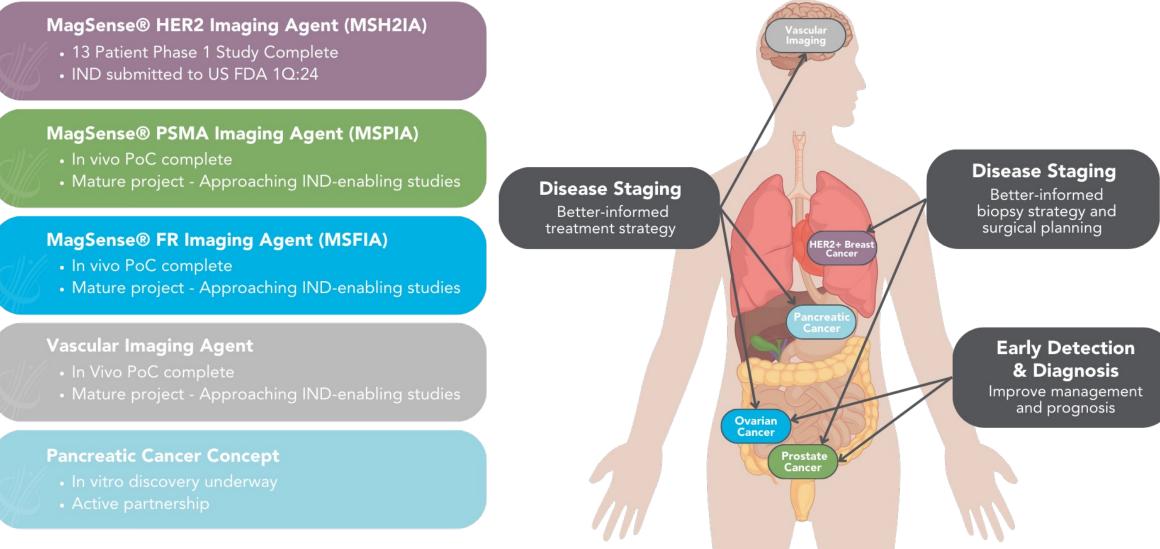


### Differentiated in Consolidating Competitive Landscape

	GE HealthCare	BAYER ER R	BRACCO	Guerbet   🏭	LANTHEUS"	JODAS	IMAGIÓN.
Private / Public: Mkt Cap	NASDAQ: GEHC \$29.5B Mkt Cap	OTC: BAYRY \$52.9B Mkt Cap	Private; ~\$1.4B '22 Revenue; 3450 FTEs	Euronext: GBT €258M Mkt Cap	NASDAQ: LNTH \$4.5B Mkt Cap	Private; ~\$68M Rev 2021	ASX: IBX \$15M Mkt Cap
Radiopharm Segment(s)	XR, XR-fluoro, CT, U/S, MRI, MRA, PET, SPECT	XR, XR-fluoro, CT, MRI, MRA Tx: Phase 1: BAY2315497 is anti- PSMA targeted <sup>227</sup> Th	XR, XR-fluoro, CT, U/S, MRI, MRA, PET, SPECT	XR, XR-fluoro, CT, MRI, MRA	U/S, PET, SPECT Tx: Azedra® <\$10M annual Revenue	XR, XR-fluro, MRI, MRA	MRI, MRA
Operating Footprint	Chicago HQ; Global footprint	Berlin HQ; Global footprint	Milan HQ; commercial partnership channels reach >100 countries	Villepint HQ; commercial partnership channels reach >80 countries	Boston HQ; PR, Canada & Australia ops; distribution deals to EU, APAC, & LatAm	Hyderabad HQ; Product approvals in EU & Russia	San Diego HQ; Australia ops
Pipeline Promise	Ph1: 1 <sup>st</sup> Mn-based MRI contrast agent	Tx: Xofigo® \$250M annual Revenue	Gadopiclenol	Collaboration	Phase 3: Point Biopharma collaboration anti- PSMA <sup>177</sup> Lu- PNT2002		1 <sup>st</sup> Mover Molecular MRI: Ph1 Complete for MagSense HER2 Imaging Agent (MSH2IA)



### MagSense<sup>®</sup> Molecular MRI: Transforming Precision Oncology



## Building Imagion's Business

### **Approaching MagSense® Partnerships**

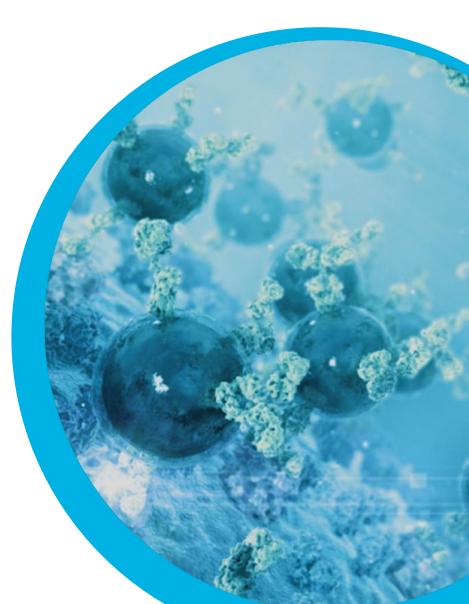
- Niche-leading incumbents continue making attractive deals for differentiated clinical-stage assets
  - Upfronts: <\$1M to >\$30M
  - Clinical and Regulatory Milestones
  - Sales Milestones & up to double-digit Royalties

#### • MagSense<sup>®</sup> products are disruptive - enabling Molecular MRI

- Primary Diagnosis
- Primary staging & treatment planning
- Companion Diagnostics

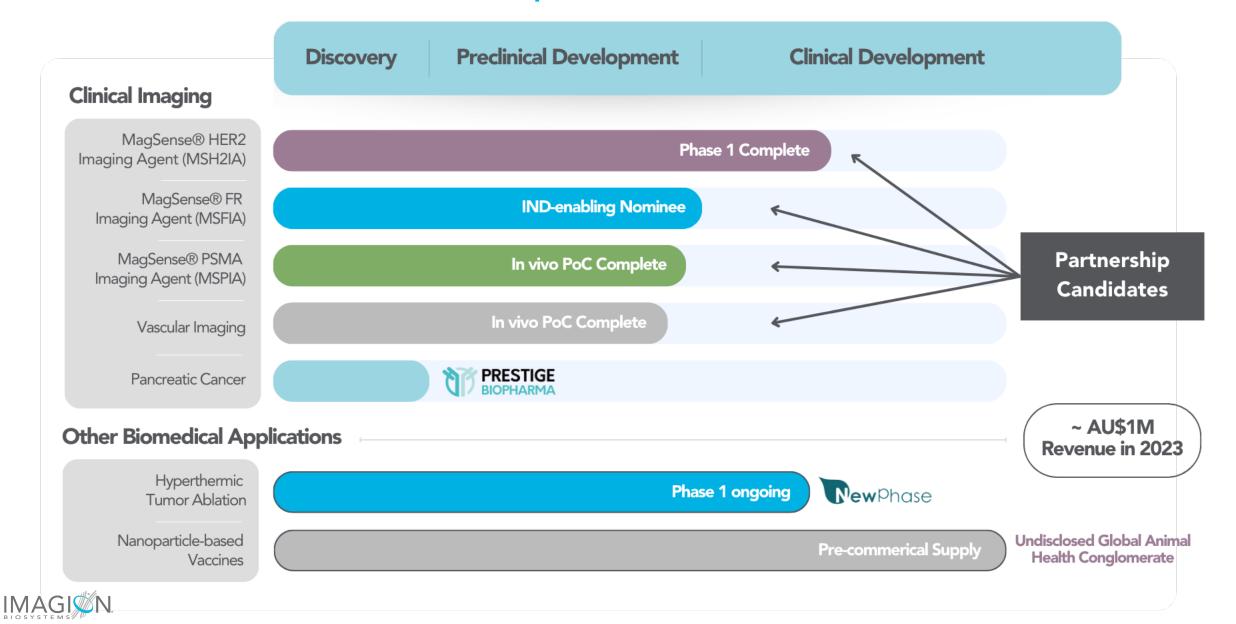
#### 1<sup>st</sup> collaboration candidate: MagSense® HER2 Imaging Agent

- >2M Women Diagnosed with Breast Cancer Annually
- HER2+ patients constitute 20% of Global Breast Cancer population
- \$100M \$250M Addressable Market Opportunity





### SPIONs: Core of Capital-efficient Business Model



### Investment Highlights







#### Key Initial Clinical Milestones Achieved

- MSH2IA safe and well tolerated in Phase I study
- Successful pre-IND with US FDA Q1:24 IND Submission

#### MagSense®: Differentiated Molecular MRI Product Pipeline

- First 3 products address \$4-5B markets for noninvasive detection of cancers
- Reduces need to rely on invasive biopsies
- Earlier detection known to improve patient outcomes

#### Imagion's SPION Technology Advancing Biomedical Applications

- Hyperthermic tumor ablation
- Nanoparticle-based vaccines
- Magnetic particle imaging

#### Strong Leadership and Advisory Boards

- Talented and experienced leadership with strong track-record in lifesciences & drug development
- Multi-specialty Advisory Boards with collective expertise in oncology, medical imaging, nanotechnology



### **Experienced Board & Management**

Commercially focused team with deep industry & clinical experience



ISAAC BRIGHT, MD CHIEF EXECUTIVE OFFICER

• >20 years entrepreneur & VC investor in biotherapeutics, diagnostics, and medtech



GEOFF HOLLIS CFO & COSEC

• ASX experienced CFO with over 20 years as a Chartered Accountant



#### MARIE ZHANG, PH.D. VP RESEARCH & DEVELOPMENT

- Over 20 years in drug development
- Leadership in early stage and start-up founder



#### ROBERT PROULX NON-EXECUTIVE CHAIRMAN

- Over 25 years in life science
  & medical devices
- Product development & commercialization



#### DAVID LUDVIGSON NON-EXEC DIRECTOR

- Over 35 years in pharma, medical devices
- Corporate strategy, M&A, & financing



MICHAEL HARSH NON-EXEC DIRECTOR

- Former CTO of GE Healthcare
- Over 35 years in medical imaging product development



- MARK VAN ASTEN NON-EXEC DIRECTOR
- Strong track record in diagnostics & healthcare
- Over 25 years commercializing diagnostic products



#### JOVANKA NAUMOSKA NON-EXEC DIRECTOR

- Attorney with over 20 years experience advising research organisations
- Expertise in commercialisation, regulatory compliance, governance & risk management



#### DIANNE ANGUS NON-EXEC DIRECTOR

• Over 20 years in Australian & US listed Biotechnology companies



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