IMAGION BIOSYSTEMS

Investor Presentation

6 February 2023

Imagion Biosystems Limited

ImagionBiosystems.com

ASX:IBX

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Imagion Biosystems Overview

We are a clinical stage medical imaging company developing next generation molecular imaging technologies

- Innovative medical imaging using bio-safe magnetic nanoparticles to detect cancer and other diseases
- Proprietary MagSense® technology is non-invasive and non-radioactive and provides more specific & sensitive detection for cancer than current imaging technologies
- Multiple commercial opportunities with magnetic nanoparticles:
  - Imaging agents for use with mainstream clinical Magnetic Resonance Imaging (MRI) systems
  - Doctor's office testing with our proprietary Magnetic Relaxometry (MRX) system
  - Therapy and/or drug delivery

Imagion Biosystems
ASX:IBX

- Market cap: ~$25 million
- Cash at 31 Dec 2022: $4.4 million
- Aug 2022 –MagSense® imaging agent for HER2 Breast Cancer reported for first patient cohort as safe and well tolerated
- Sep 2022 –Preclinical research for prostate cancer detection presented at World Molecular Imaging Conference
- Dec 2022 -Clinical data from the first cohort of the MagSense® HER2 Breast Cancer Phase I study presented
- Feb 2023 -Company announces strategy to prioritize development and commercialization of the MagSense® nanoparticle technology w/ MRI

Investment Highlights

Key Initial Clinical Milestones Achieved

- First product for HER2 breast cancer shown to be safe and well tolerated in Phase I study
- Clinical data support potential use with both proprietary detection technology and conventional MRI

Product Pipeline Addresses Large Markets & Unmet Needs

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

MagSense® Technology Will Transform Cancer Diagnosis

- Identifies molecular signature rather than identifying "suspicious lesions"
- Works with conventional MRI and does not require radioactivity

Multiple Revenue Opportunities

- To be sold as reimbursed single use consumable with high gross margins
- Alignment with strategic partners to commercialise in global markets
- Utility extendable to therapeutic applications and delivering drugs

Strong Leadership and Advisory Boards

- Experienced and skill diverse board of directors and management team
- Clinical and Scientific Advisory Boards with collective expertise in oncology, medical imaging, nanotechnology and clinical trial design

01

A Global Medical Need

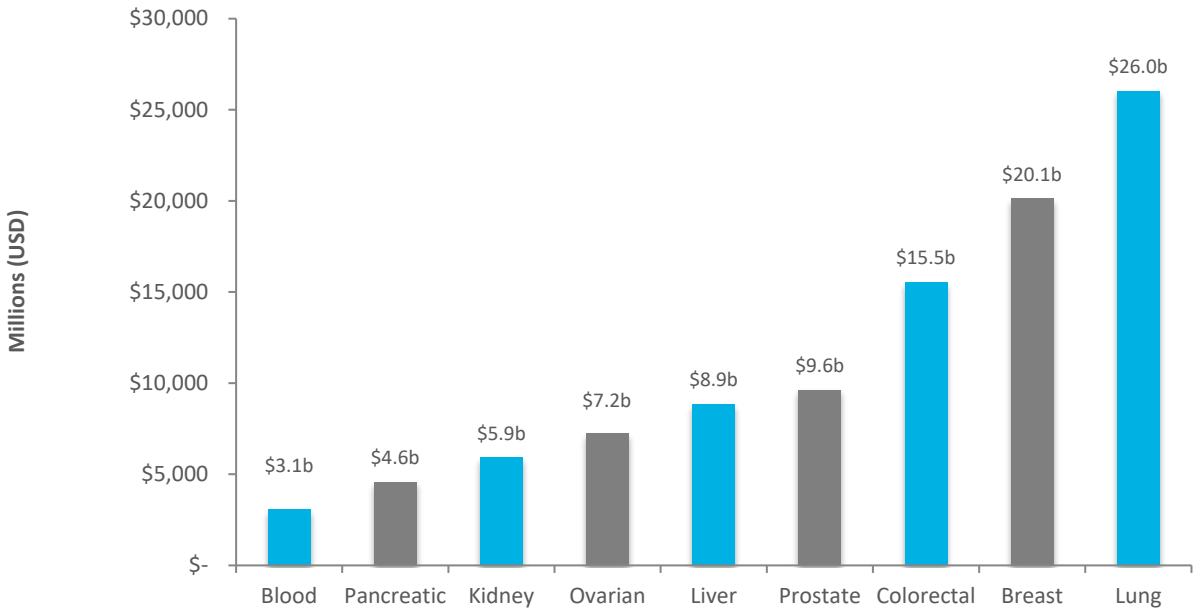
Each year cancer kills 9 million people globally

$100 billion spent annually to diagnose or detect cancer, yet cancer continues to be a leading cause of mortality and morbidity.

A Growing Global Health Problem

1 in 3 people are affected by cancer

US$100 BILLION CANCER DIAGNOSTICS MARKET



** Source: Transparency Market Research – Global Cancer Diagnostics Market 2014-2020*

Clear Unmet Medical Need

Anatomical images can't differentiate benign from malignant lesions

X-Ray (Mammography)

Mammography used for screening for breast cancer but limited to identifying "areas of interest"

Exposure to ionizing radiation

Ultrasound

Inexpensive but poor sensitivity for detecting tumors – tumors must be billions of cells in size

Magnetic Resonance (MRI)

Good image resolution but limited to identifying suspicious lesions even with conventional contrast agents

Computed Tomography (CT)

Can provide good anatomical context for guiding biopsy but not diagnostic

Exposure to ionizing radiation

Position Emission Tomography (PET)

High-sensitivity with limited resolution and expensive

Requires use of radioactive tracer

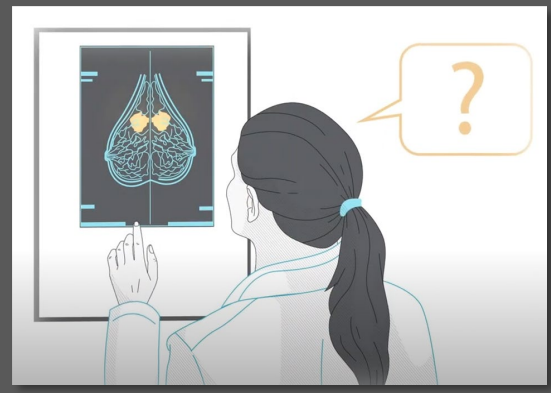
02

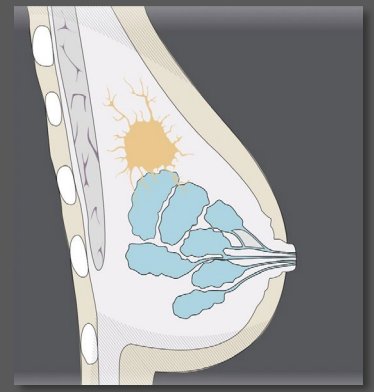
MagSense® Technology

Enabling Molecular Imaging

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

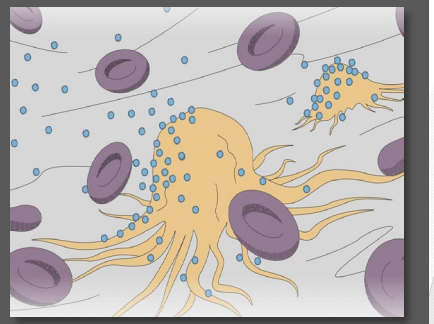
- **Non-invasive** – a safe and non-surgical solution to detect cancer
- **No radioactivity** – uses bio-safe magnetic nanoparticles to "tag" cancer cells
- **Specific** – use of targeted imaging agent provides molecular confirmation of the presence of cancer not just a suspicion
- **Platform technology** – can be used for many cancers as well as other diseases

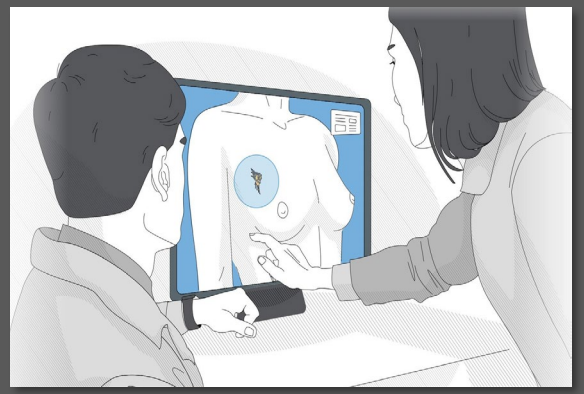




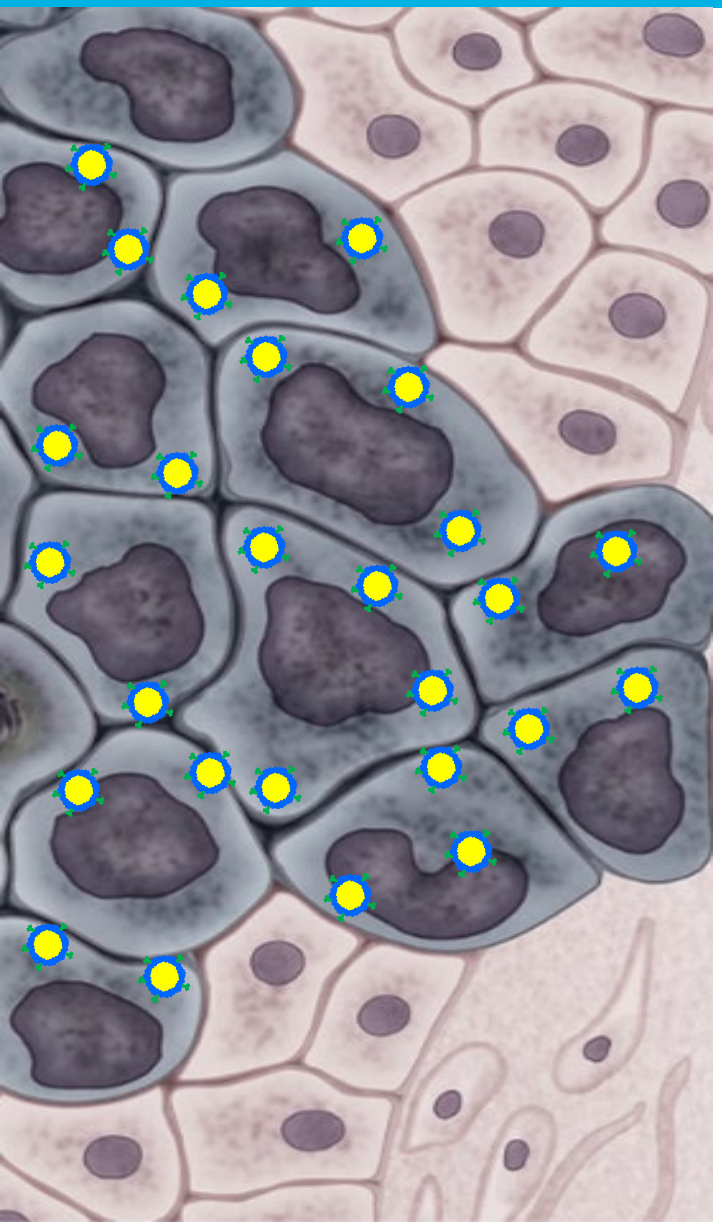
Conventional methods are not specific and can only identify a region of interest

MagSense® nanoparticles produce a molecular signature indicating the presence of a tumor





How It Works



Bio-safe magnetic nanoparticles are attracted to the tumor and detected

Patients are given a low dose injection of the nanoparticle imaging agent

Targeting molecules affixed to the nanoparticles, ensure high specificity for the cancer, and cause the nanoparticles to find and bind to tumor cells

Once attached to the tumor the magnetic property of the particles is detectable by magnetic sensors and can be imaged by MRI

The tiny nanoparticles are cleared by the body through the liver with the iron core being “repurposed” to produce ferritin used in hemoglobin production

MagSense® Molecular Imaging

1

Clinical assessment identifies need for test

2

MagSense® nanoparticle imaging agent given to patient

3

MRI detects change in image contrast from imaging agent

4

Physician sees molecular image signature if tumor present

Works within current cancer diagnosis and staging protocols.

How It Works - Video

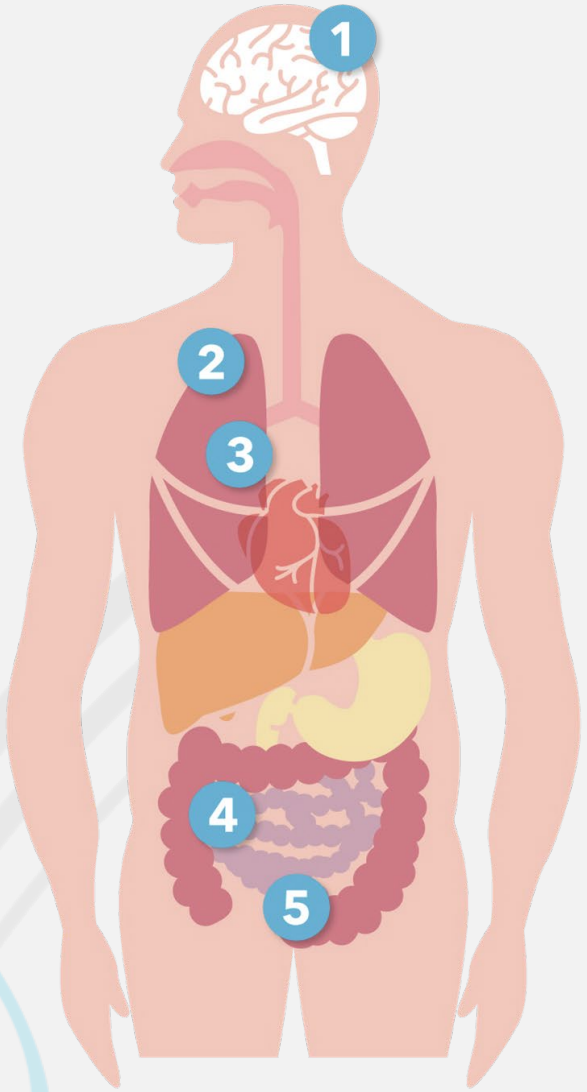
Click play to watch video in browser

Broad Commercial Applicability

MagSense® imaging agents can be developed for many types of solid tumors and can be used at multiple stages of diagnosis including primary diagnosis, staging, and monitoring the effectiveness of therapy.

Each type of cancer will have a unique and specific formulation for the cancer of interest creating a portfolio of imaging agents and a recurring revenue stream for each indication of use.

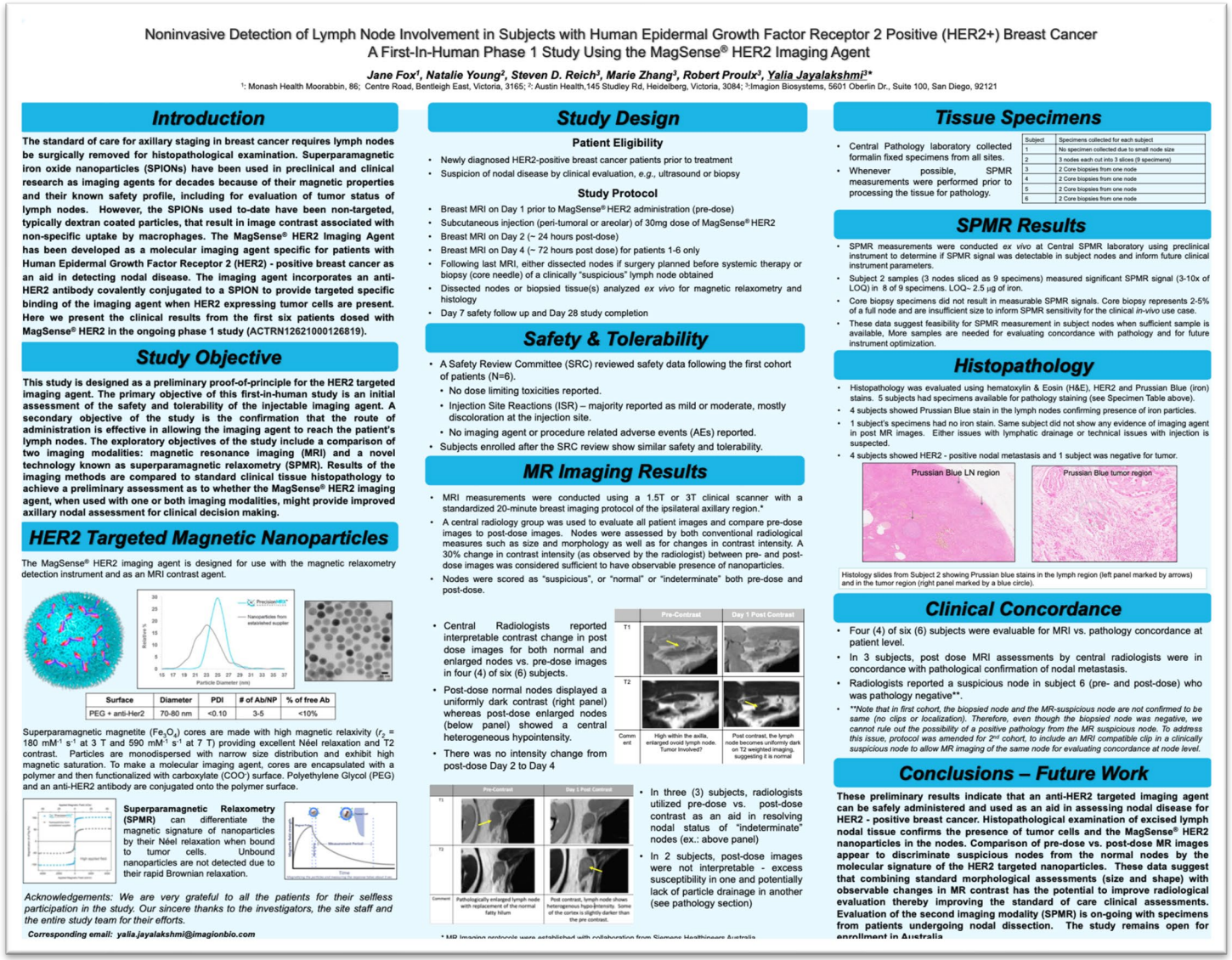
1. Brain Cancer
2. Lung Cancer
3. Breast Cancer
4. Ovarian Cancer
5. Prostate Cancer



The Phase I Clinical Study

Detection of Nodal Metastases in HER2+ Breast Cancer

- No issues of safety or tolerability related to the imaging agent reported to date
- Data reported show the imaging agent results in a detectable magnetic signature by both imaging methods - MRI and MRX
- Blinded review by independent expert panel of radiologists has corroborated findings
- Trial to remain open for enrolment during 2023 to provide additional data to inform future study design and evaluate diagnostic performance



Noninvasive Detection of Lymph Node Involvement in Subjects with Human Epidermal Growth Factor Receptor 2 Positive (HER2+) Breast Cancer
A First-In-Human Phase 1 Study Using the MagSense® HER2 Imaging Agent

*Jane Fox[1], Natalie Young[2], Steven D. Reich[3], Marie Zhang[3], Robert Proulx[3], Yalia Jayalakshmi[3]**
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Introduction

The standard of care for axillary staging in breast cancer requires lymph nodes be surgically removed for histopathological examination. Superparamagnetic iron oxide nanoparticles (SPIONs) have been used in preclinical and clinical research as imaging agents for decades because of their magnetic properties and their known safety profile, including for evaluation of tumor status of lymph nodes. However, the SPIONs used to-date have been non-targeted, typically dextran coated particles, that result in image contrast associated with non-specific uptake by macrophages. The MagSense® HER2 Imaging Agent has been developed as a molecular imaging agent specific for patients with Human Epidermal Growth Factor Receptor 2 (HER2) - positive breast cancer as an aid in detecting nodal disease. The imaging agent incorporates an anti-HER2 antibody covalently conjugated to a SPION to provide targeted specific binding of the imaging agent when HER2 expressing tumor cells are present. Here we present the clinical results from the first six patients dosed with MagSense® HER2 in the ongoing phase 1 study (ACTRN12621000126819).

Study Objective

This study is designed as a preliminary proof-of-principle for the HER2 targeted imaging agent. The primary objective of this first-in-human study is an initial assessment of the safety and tolerability of the injectable imaging agent. A secondary objective of the study is the confirmation that the route of administration is effective in allowing the imaging agent to reach the patient's lymph nodes. The exploratory objectives of the study include a comparison of two imaging modalities: magnetic resonance imaging (MRI) and a novel technology known as superparamagnetic relaxometry (SPMR). Results of the imaging methods are compared to standard clinical tissue histopathology to achieve a preliminary assessment as to whether the MagSense® HER2 imaging agent, when used with one or both imaging modalities, might provide improved axillary nodal assessment for clinical decision making.

HER2 Targeted Magnetic Nanoparticles

The MagSense® HER2 imaging agent is designed for use with the magnetic relaxometry detection instrument and as an MRI contrast agent.

Surface	Diameter	PDI	# of Ab/NP	% of free Ab
PEG + anti-Her2	70-80 nm	<0.10	3-5	<10%

Superparamagnetic magnetite (Fe_3O_4) cores are made with high magnetic relaxivity (r_2 = 180 mM^{-1} s^{-1} at 3 T and 590 mM^{-1} s^{-1} at 7 T) providing excellent Néel relaxation and T2 contrast. Particles are monodispersed with narrow size distribution and exhibit high magnetic saturation. To make a molecular imaging agent, cores are encapsulated with a polymer and then functionalized with carboxylate (COO^-) surface. Polyethylene Glycol (PEG) and an anti-HER2 antibody are conjugated onto the polymer surface.

Superparamagnetic Relaxometry (SPMR) can differentiate the magnetic signature of nanoparticles by their Néel relaxation when bound to tumor cells. Unbound nanoparticles are not detected due to their rapid Brownian relaxation.

Acknowledgements: We are very grateful to all the patients for their selfless participation in the study. Our sincere thanks to the investigators, the site staff and the entire study team for their efforts.

Corresponding email: yalia.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® HER2
- 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 systemic therapy or biopsy (core needle) of a clinically "suspicious" lymph node obtained
- Dissected nodes or biopsied tissue(s) analyzed *ex vivo* for magnetic relaxometry and histology
- Day 7 safety follow up and Day 28 study completion

Safety & Tolerability

- A Safety Review Committee (SRC) reviewed safety data following the first cohort of patients (N=6).
  - No dose limiting toxicities reported.
  - Injection Site Reactions (ISR) – majority reported as mild or moderate, mostly 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 scanner with a standardized 20-minute breast imaging protocol of the ipsilateral axillary region.*
- A central radiology group was used to evaluate all patient images and compare pre-dose images to post-dose images. Nodes were assessed by both conventional radiological measures such as size and morphology as well as for changes in contrast intensity. A 30% change in contrast intensity (as observed by the radiologist) between pre- and post-dose images was considered sufficient to have observable presence of nanoparticles.
- Nodes were scored as "suspicious", or "normal" or "indeterminate" both pre-dose and 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, radiologists utilized pre-dose vs. post-dose contrast as an aid in resolving nodal status of "indeterminate" nodes (ex.: above panel)
- In 2 subjects, post-dose images were not interpretable - excess susceptibility in one and potentially lack of particle drainage in another (see pathology section)

* MR imaging protocols were established with collaboration from Siemens Healthineers Australia

Tissue Specimens

- Central Pathology laboratory collected formalin fixed specimens from all sites.
- Whenever possible, SPMR measurements were performed prior to processing the tissue for pathology.

Subject	Specimens collected for each subject
1	No specimen collected due to small node size
2	3 nodes each cut into 3 slices (9 specimens)
3	2 Core biopsies from one node
4	2 Core biopsies from one node
5	2 Core biopsies from one node
6	2 Core biopsies from one node

SPMR Results

- SPMR measurements were conducted *ex vivo* at Central SPMR laboratory using preclinical instrument to determine if SPMR signal was detectable in subject nodes and inform future clinical instrument parameters.
- Subject 2 samples (3 nodes sliced as 9 specimens) measured significant SPMR signal (3-10x of LOQ) in 8 of 9 specimens. LOQ~ 2.5 µg of iron.
- Core biopsy specimens did not result in measurable SPMR signals. Core biopsy represents 2-5% of a full node and are insufficient size to inform SPMR sensitivity for the clinical *in-vivo* use case.
- These data suggest feasibility for SPMR measurement in subject nodes when sufficient sample is available, More samples are needed for evaluating concordance with pathology and for future instrument optimization.

Histopathology

- Histopathology was evaluated using hematoxylin & Eosin (H&E), HER2 and Prussian Blue (iron) stains. 5 subjects had specimens available for pathology staining (see Specimen Table above).
- 4 subjects showed Prussian Blue stain in the lymph nodes confirming presence of iron particles.
- 1 subject's specimens had no iron stain. Same subject did not show any evidence of imaging agent in post MR images. Either issues with lymphatic drainage or technical issues with injection is suspected.
- 4 subjects showed HER2 - positive nodal metastasis and 1 subject was negative for tumor.

Histology slides from Subject 2 showing Prussian blue stains in the lymph region (left panel marked by arrows) and in the tumor region (right panel marked by a blue circle).

Clinical Concordance

- Four (4) of six (6) subjects were evaluable for MRI vs. pathology concordance at patient level.
- In 3 subjects, post dose MRI assessments by central radiologists were in concordance with pathological confirmation of nodal metastasis.
- Radiologists reported a suspicious node in subject 6 (pre- and post-dose) who was pathology negative**.
- ***Note that in first cohort, the biopsied node and the MR-suspicious node are not confirmed to be same (no clips or localization). Therefore, even though the biopsied node was negative, we cannot rule out the possibility of a positive pathology from the MR suspicious node. To address this issue, protocol was amended for 2nd cohort, to include an MRI compatible clip in a clinically suspicious node to allow MR imaging of the same node for evaluating concordance at node level.*

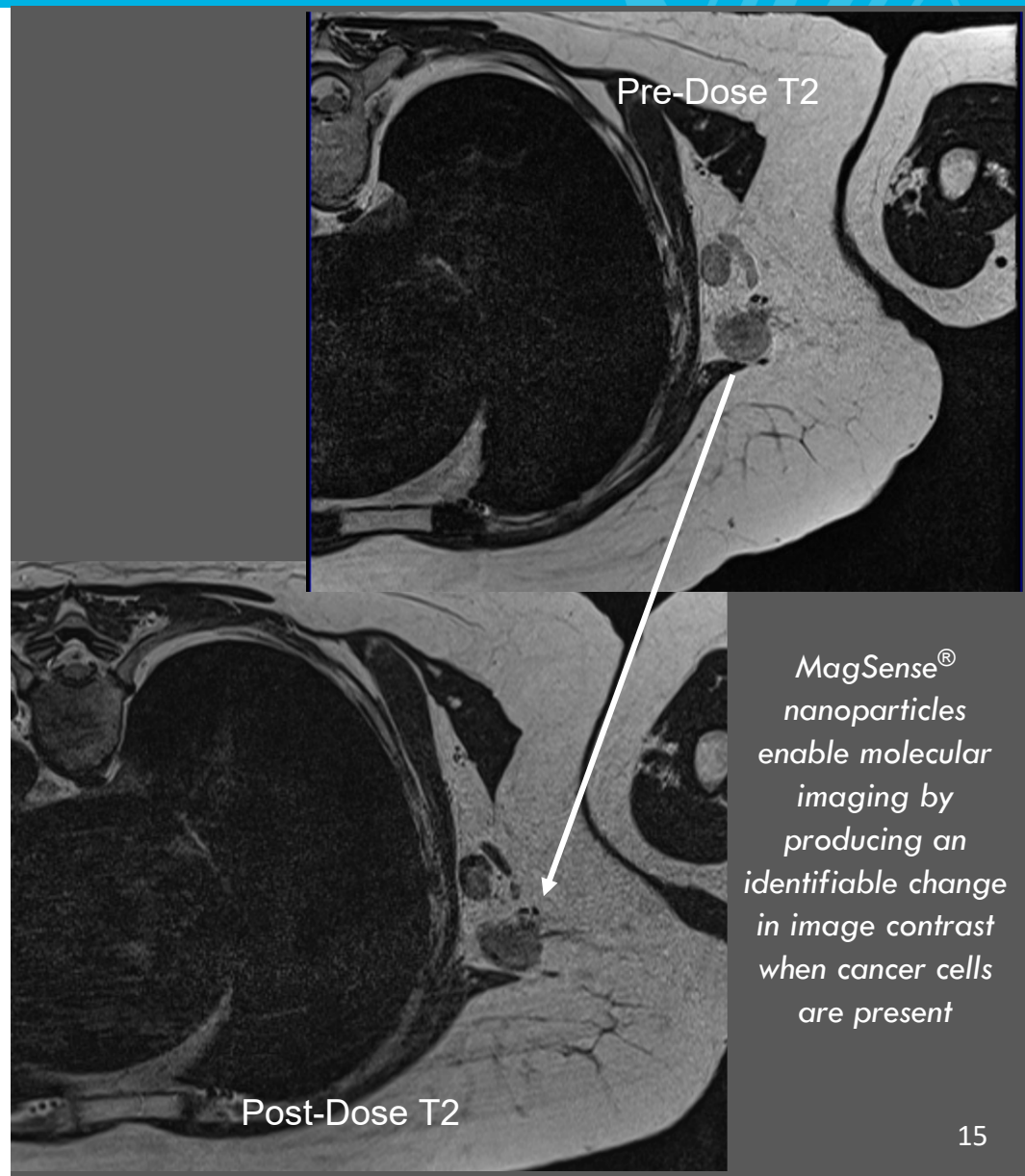
Conclusions – Future Work

These preliminary results indicate that an anti-HER2 targeted imaging agent can be safely administered and used as an aid in assessing nodal disease for HER2 - positive breast cancer. Histopathological examination of excised lymph nodal tissue confirms the presence of tumor cells and the MagSense® HER2 nanoparticles in the nodes. Comparison of pre-dose vs. post-dose MR images appear to discriminate suspicious nodes from the normal nodes by the molecular signature of the HER2 targeted nanoparticles. These data suggest that combining standard morphological assessments (size and shape) with observable changes in MR contrast has the potential to improve radiological evaluation thereby improving the standard of care clinical assessments. Evaluation of the second imaging modality (SPMR) is on-going with specimens from patients undergoing nodal dissection. The study remains open for enrollment in Australia.

MagSense® Imaging with MRI

Changing the way we look at cancer

- Data from the Phase I study indicates our molecularly targeted nanoparticles could be effective in detecting nodal disease when used in conjunction with conventional MRI scanners
- Improves radiological review compared to standard of care use of ultrasound and anatomical evaluation only
- Works within current standard of care diagnosis and staging protocols with MRI systems widely available in hospitals around the globe, making it easier to undertake clinical studies, and making market access easier and faster
- Could eliminate unnecessary biopsies, or node removals, done today for most patients (to confirm cancer whether node suspicious or negative) reducing incidence of lymphedema and associated morbidity and reducing time to clinical decision and treatment
- Would save health providers US$ millions per year compared to the current standard of care



03

Growth Strategy

Leveraging MRI

Accelerating our path to commercial product

The Market

- Increases addressable market by now targeting the large installed base of existing MRI sites worldwide
- Makes total addressable market (TAM) of AU$500m per year in HER2 Breast Cancer immediately accessible

Path to Commercialisation

- Path to market simpler, eliminating the challenges and costs of introducing a new piece of capital equipment
- Cost and time to commercialise reduced
- Improves ease of clinical adoption and subsequent commercial returns

R&D Benefits

- Pipeline of targeted imaging agents for additional disease classes including prostate and ovarian cancers already in process
- Partnerships to explore the utility of MRX technology for use in doctor's offices

Business Strategy

Use MagSense® HER2 Test as a commercial launchpad

Current Phase 1 study provides proof-of-concept that MagSense® imaging is effective and provides path to commercialization

Expand the pipeline

Build a pipeline of diagnostic imaging agents targeting other cancers and diseases with high unmet medical need

Collaborate in other biomedical applications

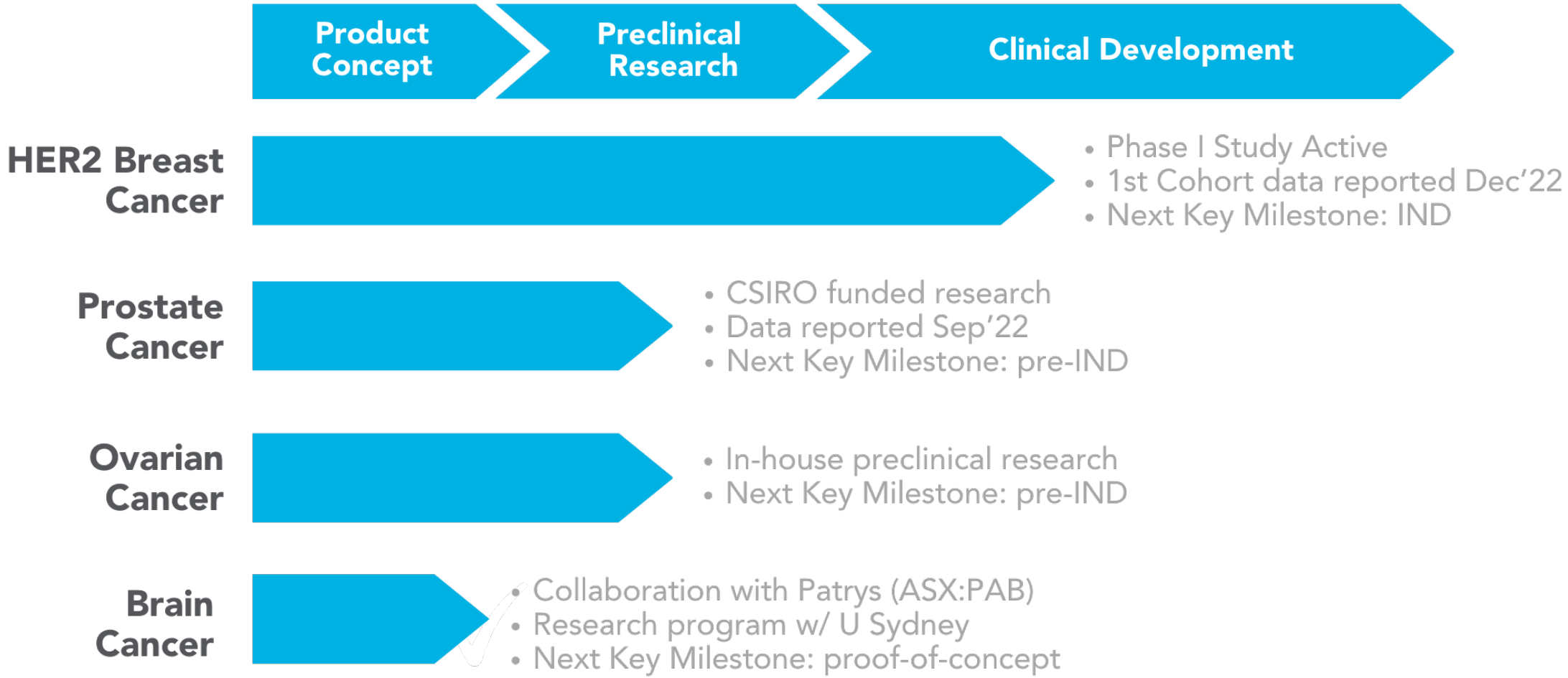
Generate revenue through collaboration with 3rd parties to leverage our nanoparticle expertise in other areas such as vaccines and therapy

Create a high-value biomedical portfolio

Align with strategic partners to commercialize our proprietary imaging and therapeutic products

MagSense® Product Pipeline

Applying targeted imaging to other cancers



Note: The pipeline above provides no guidance as to timing and is indicative and subject to change

Compelling Business Model

Proprietary Consumables Drive Growth & Profitability

Injectable MagSense® Imaging Agents

Each Cancer Test Billable
~$1,500 USD*
~80% Gross Margin*

Direct Sales

Tests can be sold to any hospital or clinic with conventional clinical MRI scanners

Partnerships

Enables strategic commercial partnerships with medical imaging player(s)

Licensing

Licensing/milestone fees and shared revenue or royalties on sales

04

Leadership and Financials

Experienced Board and Management

Commercially focused team with deep industry & clinical experience

ROBERT PROULX
CHAIRMAN & CEO

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

YALIA JAYALAKSHMI
CHIEF DEVELOPMENT OFFICER

- Over 25 years clinical translation of drug, device, nanoparticle delivery and diagnostic imaging product delivery

MICHAEL HARSH
NON-EXEC DIRECTOR

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

DAVID LUDVIGSON
NON-EXEC DIRECTOR

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

DIANNE ANGUS
NON-EXEC DIRECTOR

- Over 20 years in Australian & US listed Biotechnology companies

GEOFF HOLLIS
CFO & COSEC

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

MARIE ZHANG
VP R&D

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

MARK VAN ASTEN
NON-EXEC DIRECTOR

- Strong track record in diagnostics & healthcare
- Over 25 years commercializing diagnostic products

JOVANKA NAUMOSKA
NON-EXEC DIR

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

Scientific Advisory Board

Collective expertise in oncology, medical imaging, nanotechnology, clinical trial design

DR JOHN HAZLE
SCIENTIFIC ADVISORY BOARD CHAIR

- Board certified in medical physics
- 30 years in pre-clinical & clinical imaging research
- Chairs Cancer Research at UT Graduate School of Biomedical Sciences

PROF LISA HORVARTH

- Director, Department of Medical Oncology, Chris O'Brien Lifehouse
- Head of Clinical Prostate Cancer Research, Garvan Institute of Medical Research

DR ROBERT IVKOV

- Expertise in radiation oncology and development and characterization of magnetic nanoparticles

PROF ANDREW SCOTT AM

- Director, Department of Molecular Imaging, Olivia Newton-John Cancer Research Institute
- Experience in pre-clinical development and first in-human trials.

DR PAUL GRINT

- Expertise in commercialization of molecules
- Over 20 years experience in biologics and small molecule R&D

Collaborators and Partners

MD Anderson Cancer Center - In 2015 the MD Anderson established a Magnetic Relaxometry Research Laboratory to help validate the Imagion technology for various cancer targets

UC San Diego - Radiologists with expertise in biomagnetism have been helping develop the analytical algorithms associated with magnetic relaxometry measurements and magnetic resonance imaging

Siemens - A research collaboration was established with Siemens Healthineers of Australia to assist with the optimization of MRI protocols currently being used in the MagSense® HER2 Breast Cancer Phase I study

Monash University - A $50k CSIRO grant supports pre-clinical research at Monash University's Biomedicine Discovery Institute for prostate cancer imaging. Work commenced later in 2021

Patrys Limited - A collaborative research program with Patrys Limited aims to combine technologies to improve brain tumor imaging and diagnosis. Research engagement with The University of Sydney

Global Cancer Technology - A Joint Development Agreement aims to develop GCT's novel nanoscintillator technology for the treatment of breast cancer. Preliminary work commenced under this agreement in 2021

NewPhase - Imagion supplies NewPhase with iron oxide nanoparticles for incorporation into their magnetic hyperthermia treatment for cancer. The high quality of Imagion's nanoparticles enables effective heating of cancer cells resulting in cell death

Massachusetts General Hospital - A Sponsored Research Agreement aims to evaluate the use of iron oxide nanoparticles for use in vascular, or other MR imaging applications

World class scientific collaborations & partnerships:

Capital and Financial Snapshot

Imagion ended Q4 2022 with $4.4 million

- R&D tax incentive of $2.5 million received in Q42022
- Widely held register with over 8,500 shareholders

Ordinary shares on issue	1,121 million
Listed and unlisted options	290 million
Share price (3 February 2023)	$0.022
12-month range	$0.02 - $0.071
Average daily volume (12 months to 3 February 2023)	2.4 million shares
Market capitalization (3 February 2023)	$25 million
Cash (31 December 2022)	$4.4 million
Shareholder spread (3 February 2023)	Top 20 shareholders own 20%

Historical Cash Flows

	2020				2021				2022			
Operating	Q1 AUD '000	Q2 AUD '000	Q3 AUD '000	Q4 AUD '000	Q1 AUD '000	Q2 AUD '000	Q3 AUD '000	Q4 AUD '000	Q1 AUD ’000	Q2 AUD ’000	Q3 AUD ‘000	Q4 AUD ‘000
Receipts from customers	50	26	82	65	41	48	34	84	95	143	88	88
Payments - R&D	(492)	(1,036)	(794)	(790)	(490)	(645)	(640)	(749)	(839)	(956)	(873)	(1,077)
Payments - other	(1,183)	(925)	(1,085)	(798)	(1,002)	(1,322)	(1,572)	(1,510)	(1,518)	(1,672)	(2,022)	(1,978)
Interest - net	(8)	(9)	(9)	(9)	(3)	3	(2)	(1)	(15)	(42)	(58)	(21)
Grants and R&D incentive	-	2,197	22	16	-	2,612	-	-	-	-	22	2,501
Other	23	22	26	26	46	-	-	-	-	-	27	33
Total operating	**(1,610)**	**275**	**(1,758)**	**(1,491)**	**(1,408)**	**695**	**(2,180)**	**(2,176)**	**(2,277)**	**(2,527)**	**(2,816)**	**(454)**
Investing												
Payments – assets (net)	-	-	(4)	(4)	(20)	(91)	(95)	(103)	(182)	15	(300)	(2)
Financing												
Proceeds - shares (net)	-	2,195	4,403	5,563	-	-	-	-	-	-	-	-
Proceeds - options	-	-	1,568	1,038	1,334	253	134	3,785	-	-	3	-
Repayment of borrowings (leases)	(97)	(67)	(173)	(144)	(142)	(66)	(74)	(77)	(53)	(236)	(369)	(307)
Other	-	234	-	-	-	-	-	-	-	-	-	-
Total financing	**(97)**	**2,362**	**5,799**	**6,457**	**1,192**	**187**	**59**	**3,708**	**(53)**	**(236)**	**(366)**	**(307)**
Net cashflows	**(1,707)**	**2,637**	**4,037**	**4,962**	**(236)**	**791**	**(2,216)**	**1,429**	**(2,512)**	**(2,748)**	**(3,481)**	**(763)**
Forex	4	(9)	(18)	(107)	43	130	273	(21)	(253)	641	267	(97)
Cash at start	**3,402**	**1,698**	**4,327**	**8,345**	**13,201**	**13,007**	**13,928**	**11,986**	**13,394**	**10,629**	**8,522**	**5,307**
Cash at end	**1,698**	**4,327**	**8,345**	**13,201**	**13,007**	**13,928**	**11,986**	**13,394**	**10,629**	**8,522**	**5,307**	**4,446**

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