



## **MagSense™ Technology**

Early Detection of Cancer Through Targeted Imaging

ASX:IBX

[www.imagionbiosystems.com](http://www.imagionbiosystems.com)

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# IMAGION BIOSYSTEMS AT-A-GLANCE



*New medical imaging technologies for the early detection of cancer*

Imagion Biosystems  
ASX:IBX

Australian Medical Device Company  
developing bio-safe medical imaging  
technologies.

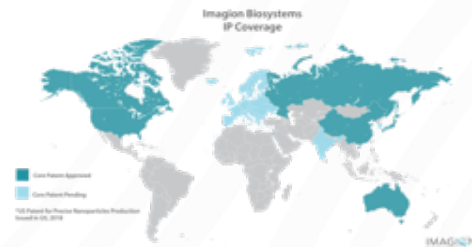
Market cap: ~\$12 million  
Net cash: (30 June 2019) \$1.1M  
(+\$2M via R&D tax credit in July)  
Listed on the ASX: June 2017  
Head office: San Diego  
Registered office: Melbourne

## Recent Milestones:

July 2019  
Received *"Breakthrough Device"*  
designation by U.S. FDA  
May 2019  
Completed toxicology testing with no  
adverse results

[www.imagionbiosystems.com](http://www.imagionbiosystems.com)

- Innovative **medical imaging** using **magnetic nanoparticles** to identify and stage cancer early
- **Proprietary** MagSense™ technology is **non-invasive** and provides more specific & sensitive detection for cancer than current imaging technologies
- **Multiple commercial opportunities:**
  - Proprietary MagSense™ imaging technology
  - Magnetic Resonance Imaging (MRI) contrast agent
  - Therapy and/or drug delivery
- MagSense™ technology **complements existing imaging** and is more cost effective than many existing imaging technologies
- **First-in-human** studies on-track for 2020 – targeting metastatic breast cancer



Patents are already issued, or are pending, in all the major markets, making the lions share of the global markets available for commercialization.

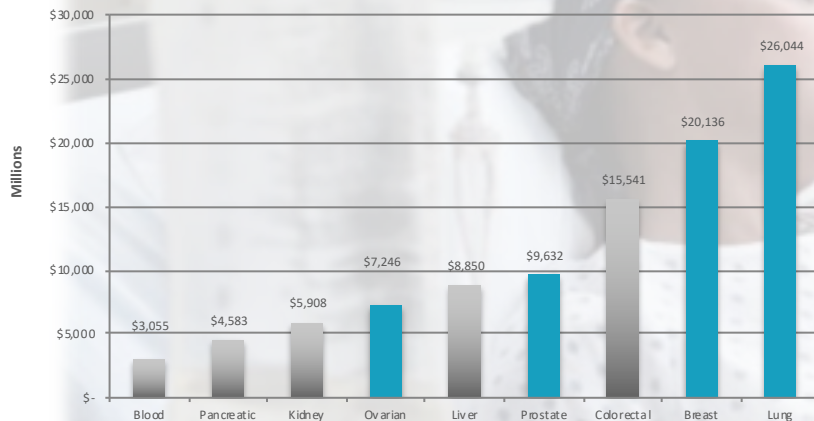
**Patents are valid through 2029.**

# A GROWING GLOBAL HEALTH PROBLEM

*1 in 3 people are affected by cancer*



## CANCER DIAGNOSTICS - \$100B MARKET



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

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



# CLEAR UNMET MEDICAL NEED

50 years since last new imaging technology was introduced



Current Imaging Technologies:  • Only identify a “region of interest”  • Expose patients to radiation  • Require invasive biopsies		X-RAY (MAMMOGRAPHY) 1895 (1913)	ULTRASOUND 1956	COMPUTED TOMOGRAPHY (CT) 1972	MAGNETIC RESONANCE (MRI) 1971	POSITRON EMISSION TOMOGRAPHY (PET) 1973
	Primary Use	Best for looking at structural anomalies such as broken bones; chest X-rays used for assessing pneumonia.	Relatively inexpensive and fast method to look at internal organs and body structures or gross abnormalities such as areas of inflammation or infection.	Scan times typically shorter than MRI so often used for urgent assessment. Can generate 3D images. Better for imaging the lungs than MRI.	Good for soft tissue imaging such as ligaments and tendons, the brain, and many internal organs. Detail able to pick up small lesions not detectable by CT.	High sensitivity detection of radioactive tracer but often has significant off-target or background signal.
	Use in Cancer	Mammograms used for screening for breast cancer	Used to detect ovarian cancer & to guide needle biopsies	Staging of solid tumors, guiding biopsy & monitor recurrence	Best for brain cancers and for planning surgery or radiation treatment	Identification of metastatic lesions
	Risk	Exposes patient to carcinogenic ionizing radiation; not good for women with dense breast tissue	Poor sensitivity requires billions of cells before detecting tumors, resulting in late stage identification	Exposes patient to carcinogenic ionizing radiation	No significant risk	Exposes patient to systemic administration of a radiation emitting tracer

***“Despite technical advances in many areas of diagnostic radiology, the detection and imaging of human cancer remains poor. “***

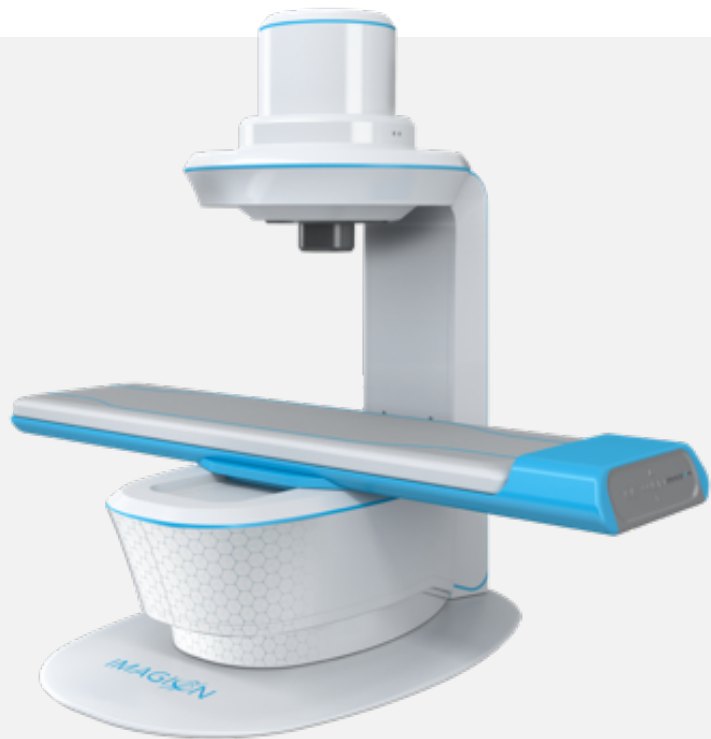
Journal of Clinical Oncology, 2008 New Technologies for Human Cancer Imaging Vol 26 No 24

# MEDICAL IMAGING BREAKTHROUGH



*MagSense™ Technology will transform cancer diagnosis*

- **Non-invasive** – a safe and non-surgical solution to detect cancer
- **No radioactivity** - uses bio-safe magnetic nanoparticles to “tag” cancer cells
- **Platform technology** – can be used for many cancers as well as other diseases, e.g. infection and cardiovascular
- **Proprietary** - patent issued in most major global markets
- **Breakthrough** - Technical feasibility and safety profile vetted, designated as a “breakthrough device” by FDA
- **First indication** – metastatic breast cancer, provides shortest path to commercialization
- **First-in-human** – ready for clinical studies - a catalyst for valuation and partnering



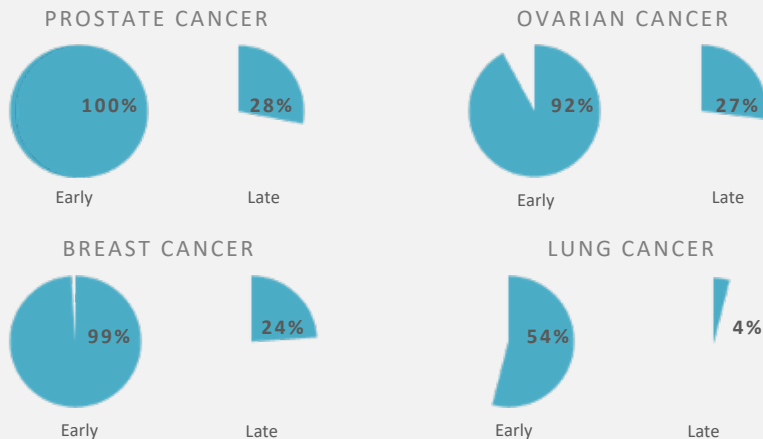
# A CHANCE TO IMPROVE OUTCOMES



## *Better sensitivity could mean earlier detection*

MagSense™ technology is expected to have sensitivity comparable to PET without use of radioactivity, making it better for routine use in early detection and resulting in more successful treatments and patient outcomes.

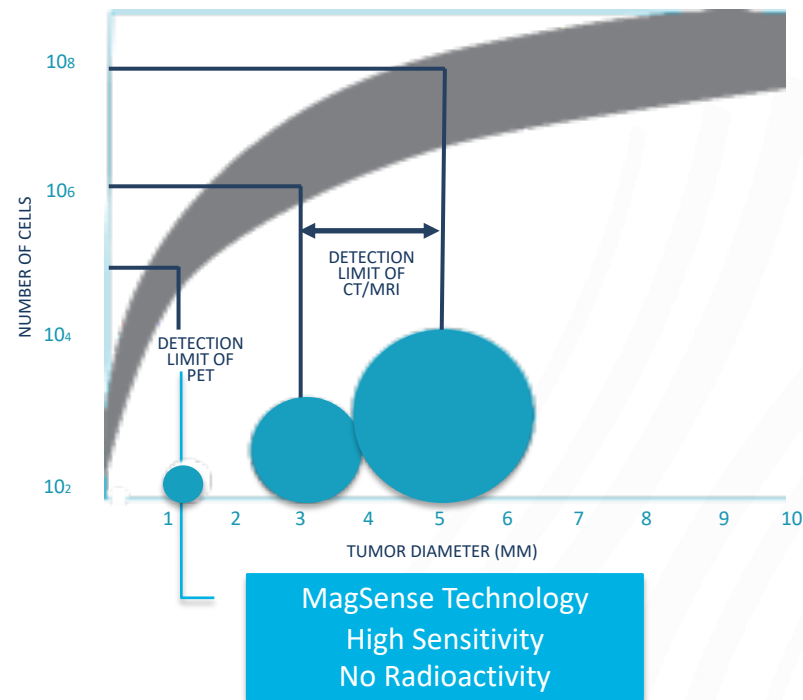
### SURVIVAL RATE - EARLY VERSUS LATE DIAGNOSIS:



\* Source: SEER Cancer statistics, National Cancer Institute, 2013

***“Early detection of many diseases, particularly cancers, is key to successful treatment.”***

Chemical Reviews 2015 Nanoparticles in Medicine Vol 115



# BROAD COMMERCIAL APPLICABILITY

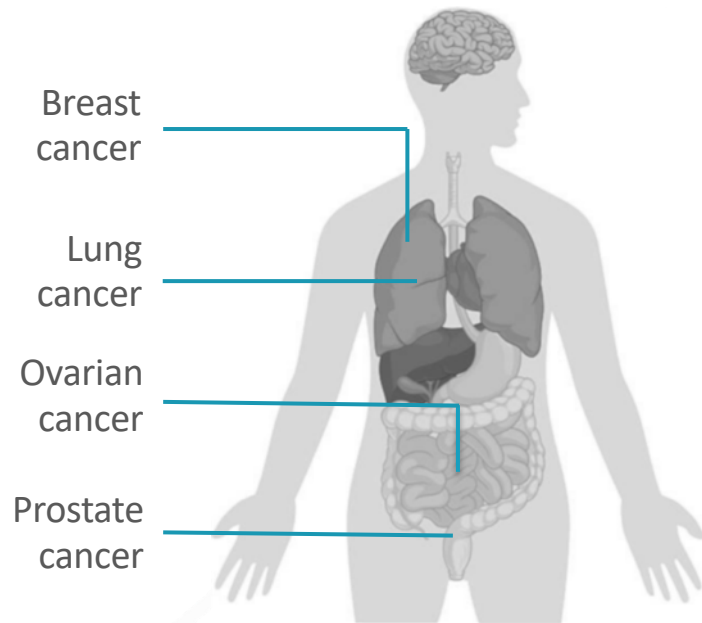


*Can be used for many types of cancer and at multiple stages of diagnosis*

## MAGSENSE NANOPARTICLES

- Are **bio-functionalized** to ensure high specificity for targeting different types of cancers, or other diseases.
- Can be used at multiple stages including primary diagnosis, staging, and monitoring the effectiveness of therapy.
- Are compatible with Imagion's proprietary MagSense technology and with existing installed MRI systems as an **MRI contrast agent**.
- Use **known safe materials**, including iron-oxide cores which are already cleared for multiple clinical uses including therapeutic applications.

## Multiple Clinical Targets



# TRANSFORMATIVE FOR MEDICAL IMAGING



Designated by FDA as a “**Breakthrough Device**”

## The MagSense™ HER2 Metastatic Breast Cancer Test

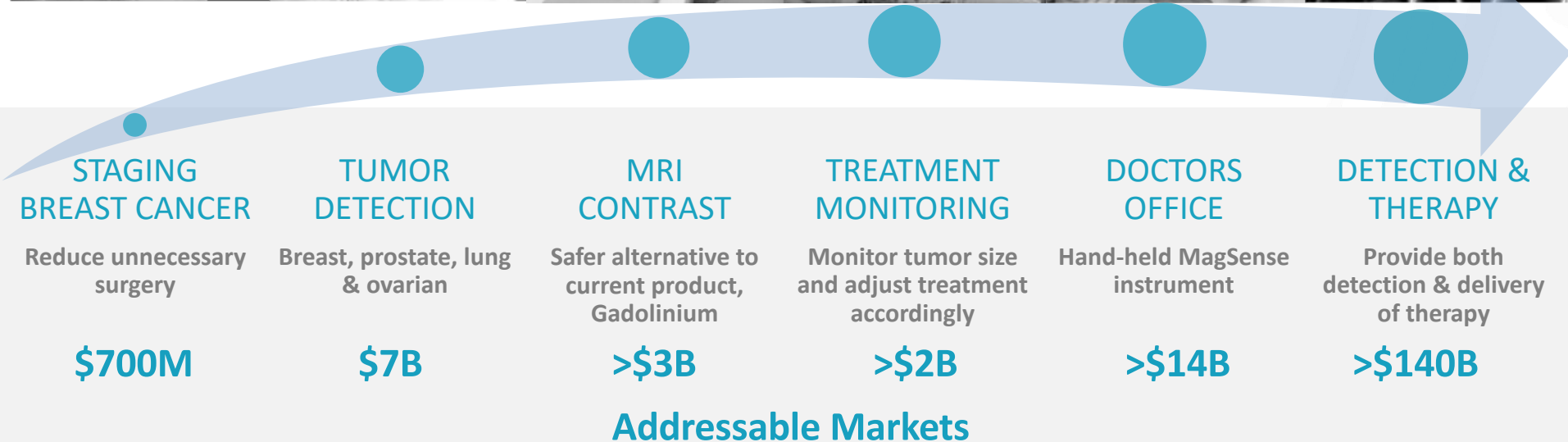
- Works within current standard cancer diagnosis and staging protocols.
- Replaces current non-functional imaging such as MRI or ultrasound used to assess for enlarged lymph nodes but which cannot determine if tumor cells are present.
- Would eliminate unnecessary biopsies for patients that do not have metastatic spread to the lymph nodes.
- Would reduce incidence of lymphedema and associated morbidity.

*The MagSense™ system and test has been designated by the FDA as a **Breakthrough Device** - reserved for products that provide for more effective treatment or diagnosis.*



# INVESTMENT RATIONALE

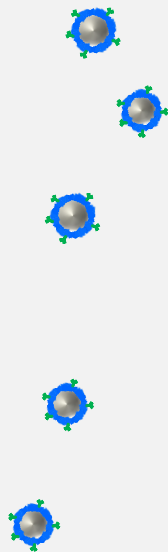
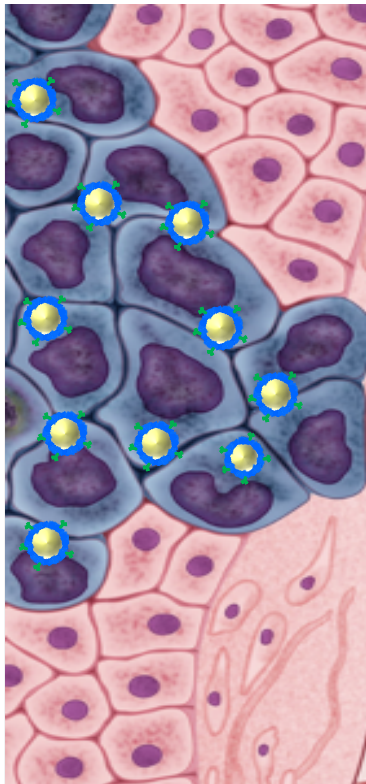
*Strategic plan provides path to future products & shareholder value*



# HOW IT WORKS



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



- Nanoparticles, specific for the cancer, bind to tumor cells.
- Nanoparticles demagnetize or “relax” after exposure to a low magnetic field.
- Nanoparticles attached to cancer cells “relax” more slowly than particles in circulation acting as a magnetic beacon.
- Ultra-sensitive detectors locate the presence of attached nanoparticles.



# PRE-CLINICAL RESEARCH

*Product performance verified in pre-clinical models*



## SPECIFICITY

- In vitro cell based studies confirm specificity for HER2 expressing breast cancer cells.
- Animal studies confirm in vivo selectivity for HER2 expressing breast cancer tumours.

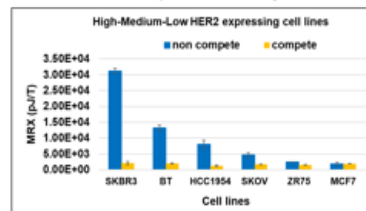
## SENSITIVITY

- In vitro cell based studies indicate target level of sensitivity should be achievable.
- In vitro and in vivo animal studies indicate little non-specific background.

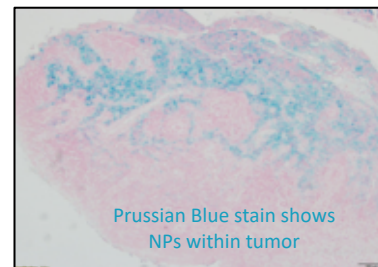
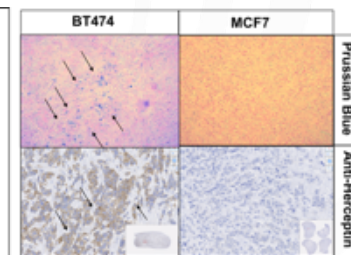
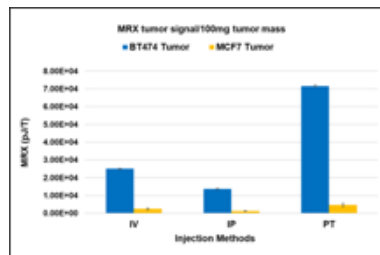
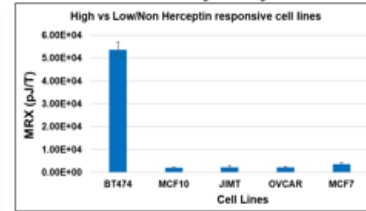
## SAFETY

- GLP-compliant toxicology and toxicokinetic study showed no adverse effects.

Cell Competition Assay



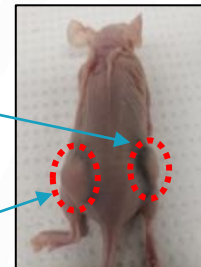
Cell Selectivity Assay



Dual Tumor Model

NPs go to HER2+ Tumor

No NPs in HER2- Tumor

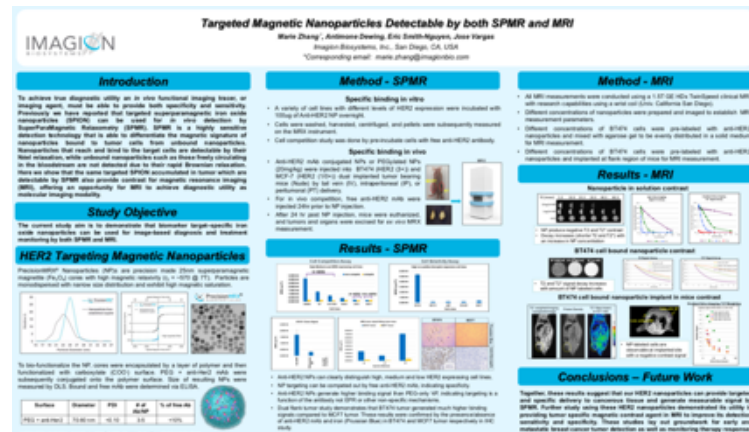


# IMPROVING MRI DIAGNOSTIC UTILITY



*Additional commercial opportunity as an MRI contrast agent*

- MagSense™ iron oxide nanoparticles generate T2\* MRI contrast even at low concentrations.
- Targeted nanoparticles would change MRI from identifying a region of interest to imaging for specific tumor cells.
- MRI utility provides additional or alternative development path expanding and further de-risks venture investment. \*
- Favorable commercialization path eliminates need to sell new instrumentation and leverages installed base of >5000 clinical MRI scanners.



Presented at the World Molecular Imaging Conference 2019

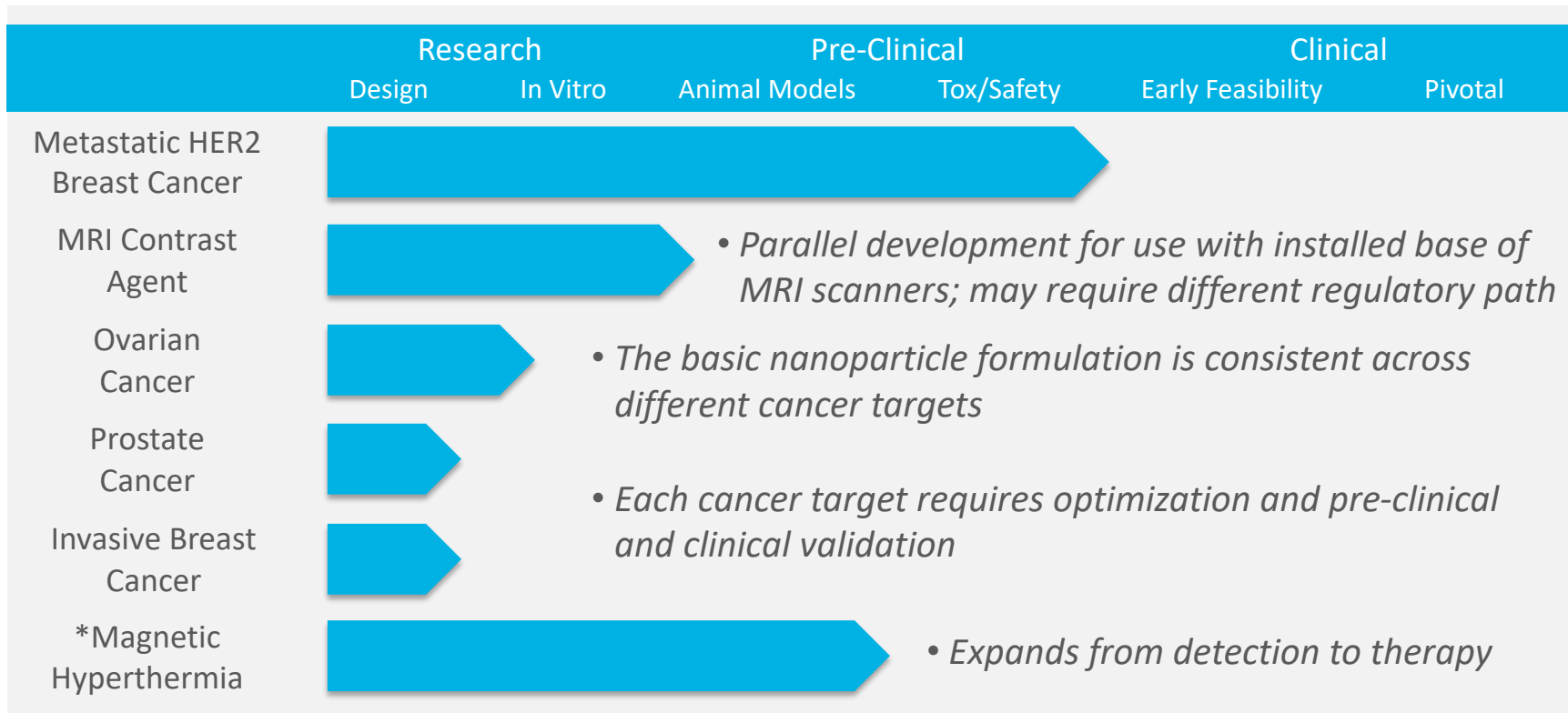
**MRI Contrast Agents - \$3B Annual Market**

\* Further development of the MRI contrast agent capabilities is not the current priority due to the more favorable regulatory environment for the MagSense technology as a medical device.

# STRONG R&D PIPELINE



## Product Applications Under Development



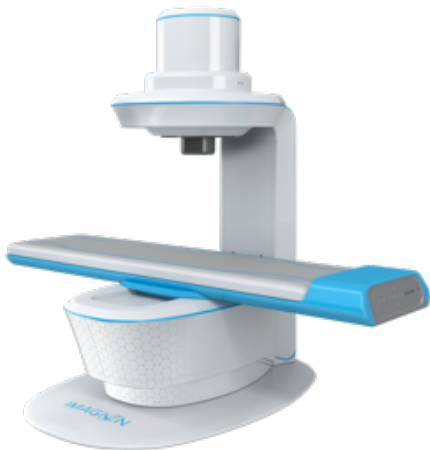
\* in collaboration with 3<sup>rd</sup> party

# COMPELLING BUSINESS MODEL



*Proprietary consumable drives growth & profitability*

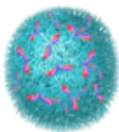
## ONE INSTRUMENT



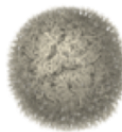
US\$500K Capital  
Sale

50% Gross Margin

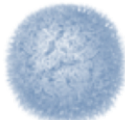
## MANY TESTS



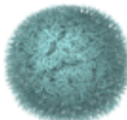
HER2 Breast  
Cancer



Ovarian  
Cancer



Prostate  
Cancer



Lung Cancer



US\$1,500 / Test

80% Gross Margin



## PRINTER / INK REVENUE MODEL

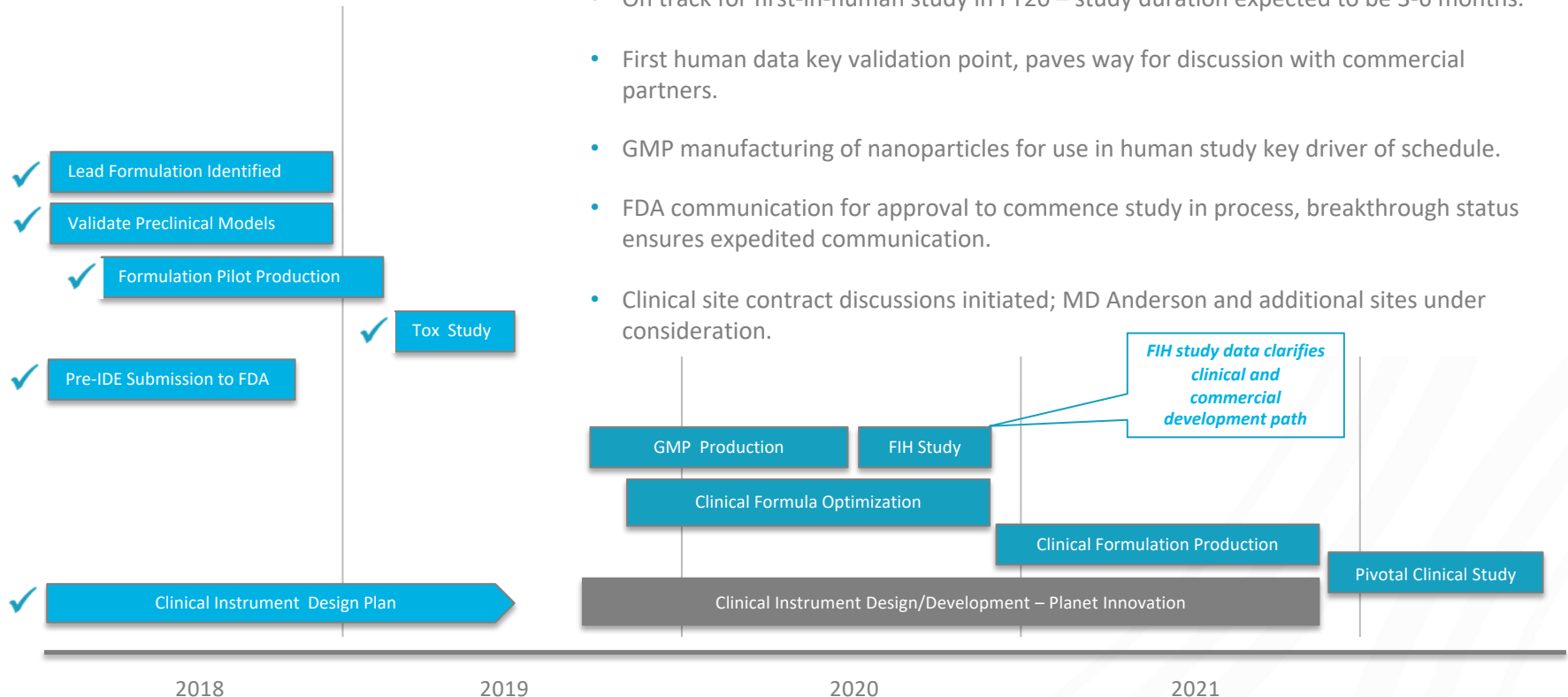
*35% capacity utilization  
A\$2.2 million annual  
revenue per instrument*

Revenue through  
licensing/partnership fees  
Royalties or revenue share  
on tests

# MILESTONES AND VALUATION DRIVERS



*Indicative development timeline and key inflection points in first indication\**



\* This development timeline is indicative only, and subject to change.

# EXPERIENCED TEAM

*Commercially focused team with deep industry & clinical experience*



**ROBERT PROULX**  
CHAIRMAN & CEO

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



**MICHAEL HARSH**  
NON EXEC DIRECTOR

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



**DAVID LUDVIGSON**  
NON EXEC DIRECTOR

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



**BRONWYN LE GRICE**  
NON EXEC DIRECTOR

- 18 years in Australian commercial healthcare & technology markets



**BRIAN CONN**  
CFO

- CFO for early & growth stage biotech
- 25 years raising both public & private capital & M&A



**MARIE ZHANG PHD**  
VP R&D

- 20 years in drug development
- Leadership in early stage and startup founder



**MARK VAN ASTEN**  
NON EXEC DIRECTOR

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



**JOVANKA NAUMOSKA**  
NON EXEC DIR & COSEC

- Australian attorney with expertise in regulatory compliance, governance & risk management

*World class scientific collaborations & partnerships:*



**JOHN HAZLE PHD**  
CHAIR - SAB

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



# CAPITAL STRUCTURE

*No debt, one class of common stock*



Ordinary shares on issue	327.37M*
Share price (24 Oct 2019)	0.040
Average daily volume	281K
Market capitalization (24 Oct 2019)	13.09M
Net cash (30 June 2019)	\$1.1M (+ further \$2M via R&D tax credit in July)
Major Shareholders (as of 19 <sup>th</sup> Aug 2019)	
	Manhattan Scientifics Inc 19.8%
	Mr Kemper Shaw 9.82%
	Drake Special Situations LLC 7.72%
	William Taylor Nominees 6.70%
	Board & Management * 0.41%



\*Does not include Long Term Investment plan, which allocates a total of 12,100,000 shares to the Key Management Group and a total of 3,450,000 shares to NEDs and employees, vesting on performance rights.



# INVESTMENT HIGHLIGHTS



## LARGE OPPORTUNITY

\$100B cancer diagnostic market

Growing 7% annually

Medical imaging commands largest share

Huge medical need for early diagnosis



## UNIQUE TECHNOLOGY

New form of medical imaging

Molecularly specific & non-invasive

More sensitive than current methods

Protected by eight patents



## COMMERCIAL STRATEGY

\$2B initial market focus

Applies to many types of cancer

Printer-ink revenue model

Potential for therapeutics & research markets



## READY TO ENTER THE CLINIC

Technical feasibility demonstrated

Safety profile of technology vetted

FDA “breakthrough device” designation

First-in-human data readout expected in 2020



IMAGION BIOSYSTEMS

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