



# Company Overview

June 2017

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

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## **Currency translation**

*All figures in this presentation are expressed in US Dollars or where identified as Australian Dollars (AUD or A\$) are converted, where relevant, at an exchange rate of [0.75] USD/AUD.*



# MagSense™ Technology

WHERE BIOTECHNOLOGY & NANOTECHNOLOGY MEET

Revolutionizing Cancer Diagnosis

Optimizing Patient Care and Reducing  
Mortality Rates through the Early  
Detection of Cancer



# Investment Highlights

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## **\$100 Billion**

Annual global spending on cancer diagnosis in imaging and pathology

## **8 Patents**

Core technology covered in major markets through to 2029

## **“Printer & Ink” model**

Product includes both the instrument and a diagnostic consumable

## **\$2 Billion**

Addressable markets for first cancer targets: breast, prostate, ovarian.

Additional targets being explored.

## **Platform Technology**

Not limited to initial targets or cancer diagnostics.

Other potential opportunities include theranostics and reagents

## **Key Collaborations**

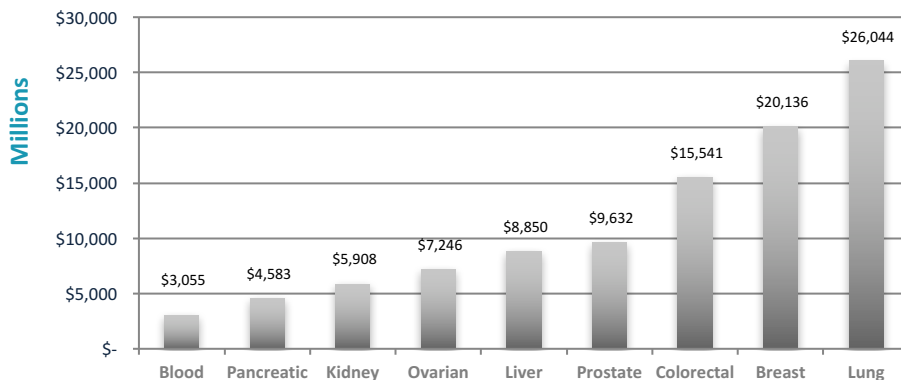
Pre-clinical partnerships already under way with pre-eminent medical research institutes



# The Opportunity in Cancer Diagnostics

## \$100B Global Cancer Diagnostics Market

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



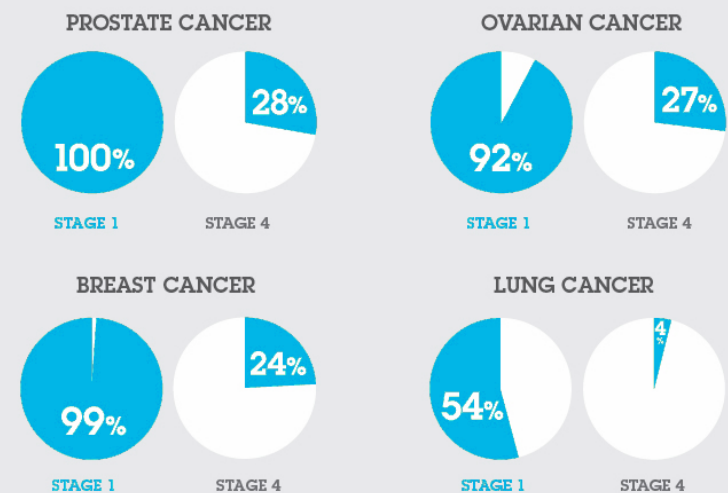
*“Early detection in order to improve breast cancer outcome and survival remains the cornerstone of breast cancer control.”*

WHO breast cancer: prevention and control

## Market Characteristics

- Large market growing 7% annually
- Imaging makes up the largest proportion
- Early detection significantly reduces mortality rates
- Unmet need for early detection that is reliable, specific and non-invasive

5-year survival rate, depending on **early** or **late** diagnosis:



Source: SEER Cancer Statistics, National Cancer Institute, 2013  
<https://www.ohsu.edu/xd/health/services/cancer/about-us/early-detection-vision/why-focus-on-early-detection.cfm>



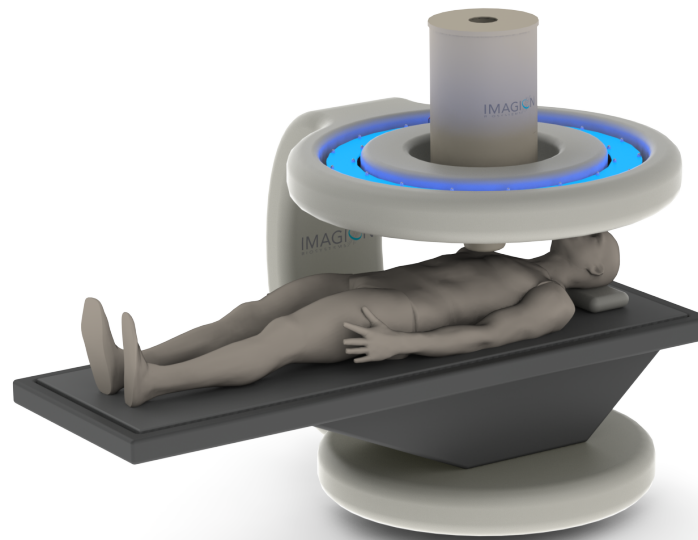
# Advantages of MagSense™ Technology

## Improved Sensitivity

- 1000x more sensitive than current imaging methods.
- Early small tumors (~1mm) not readily detectable with current medical imaging technologies.

## Better Patient Experience

- Minimizes need for surgical procedures.
- Does not use ionizing radiation or radioactive tracers.
- Early tumor detection reduces risk of metastases.
- Magnetizing and measuring the nanoparticles takes only a few minutes.



**Rendering of MagSense™ SQD Clinical Instrument**

*Human studies have not yet been conducted*

## Non-invasive

- A low dose of cancer specific nanoparticles are administered by simple intravenous injection.
- The patient is positioned under the detector and the nanoparticles are briefly magnetized and detected.

## Specific

- Bio-specific antibodies on the nanoparticles target delivery to specific cancer tumor types, differentiating benign from malignant lesions.
- Ultra-sensitive detector locates only nanoparticles bound to target cells and not circulating nanoparticles.



# Competitive Position

## Reduced Patient Risks

- MagSense™ technology uses a significantly lower magnetic field than MRI, and a routine examination is completed in minutes.
- Unlike PET or X-ray methods which expose patients to radioactivity, super-paramagnetic nanoparticles are considered biologically safe and applied at a low dose.

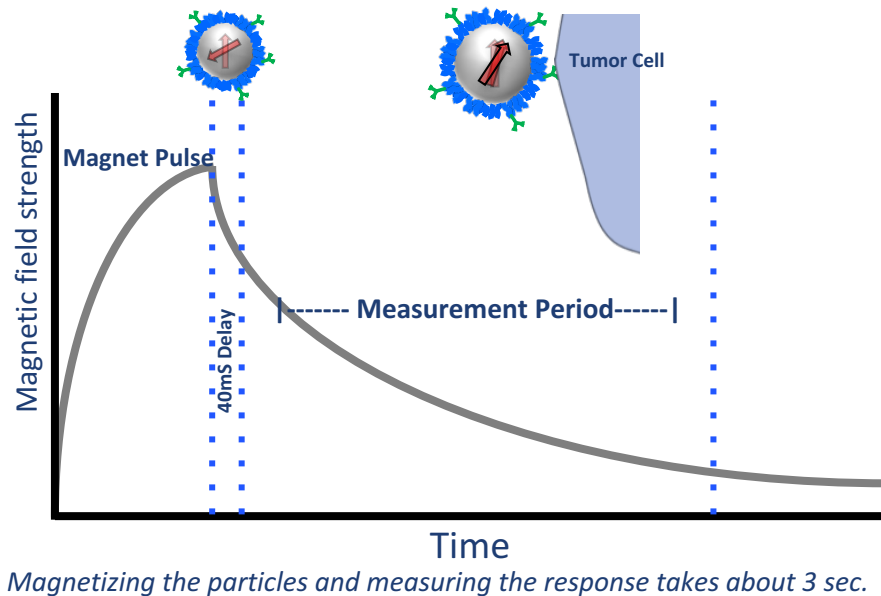
## Less Expensive

- Unlike most imaging methods, the MagSense™ instrument is relatively inexpensive and does not require a specialized high cost shielded environment.
- The cost of a MagSense™ nanoparticle test will be less expensive than MRI or PET procedures, and directly competitive with more invasive procedures.

Method	MagSense Magnetic Relaxometry	MRI Magnetic Resonance Imaging	PET Positron Emission Tomography	Ultrasound	X-Ray/CT
Detection Threshold	< 1 million cells	millions of cells	N/A	4 billion cells	N/A
Quantitative	Yes	Yes	No	No	No
Specificity	Yes	No	No	No	No



# MagSense™ Technology



- All nanoparticles lose their magnetization (i.e. “relax”) after the low magnetic field is turned off
- A nanoparticle attached to a bio-marked cancer cell will relax more slowly than an unattached particle
- Bio-specific antibodies on the nanoparticles cause the particles to stick to the specific targeted tumor types
- Our ultra-sensitive detectors are able to locate and quantify the relaxation of only the attached nanoparticles





# Near-term Addressable Markets – US\$2 Billion

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## Breast Cancer

- Invasion of the regional lymph nodes is an early hallmark of metastatic breast cancer
- Imaging methods are neither sensitive enough nor bio-specific to detect localized nodal spread

### US\$250M Annual Market

- ~ 1.6 M new breast cancer cases annually
- 15% - 20% Her2+ incidence = 240,000 - 320,000 Her2+ breast cancer cases annually
- Lymph node biopsy costs \$2500 - \$7000; FNA costs \$100 - \$250 each; SLNB costs \$10K - \$15K

## Prostate Cancer

- For patients with PSA blood biomarker test, only 30% have cancer
- Grey scale ultrasound has an poor accuracy and low positive predictive value

### US\$1.5 Billion Annual Market

- 1.1M new prostate cancer cases annually
- 1M biopsies in US alone
- Biopsy cost is \$1500 - \$6000

## Ovarian Cancer

- For patients with persistent elevated CA-125 blood biomarker test
- Trans-vaginal ultrasound has poor sensitivity and high false positives
- 70% mortality for treatment methods initiated post ultrasound detection due to late stage

### US\$200M Annual Market

- ~ 250,000 new ovarian cancer cases annually
- Transvaginal ultrasound costs an average of \$525 (range \$250 - \$1100)



# Strategic Relationships

## Pre-Clinical Collaborations

Research collaborations are in place with some of the world's pre-eminent cancer medical centers to demonstrate *in vivo* detection of breast, prostate, and ovarian cancer in pre-clinical models.



Dr. John Hazle  
Chairman, Dept Imaging Physics

Dr. John Babich  
Prof. Radiopharmaceutical Sci

Dr. Helen Hathaway  
Faculty UNM School of Medicine

### Ovarian cancer

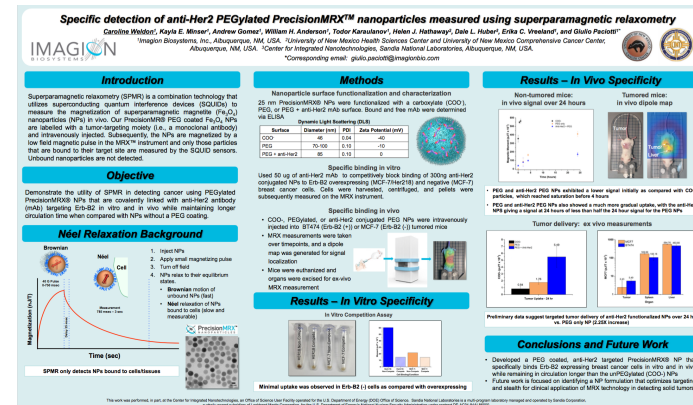
- **Presenting 4 posters at 2017 AACR**
- **2 grants submitted to NIH for computational methods**

### Prostate cancer

- **Instrument installation expected H1 '17**
- **Grant submitted to the NIH**

### Breast cancer

- **Presented at the 2016 San Antonio Breast Cancer Symposium**
- **Presenting at 2017 AACR**



# Board and Management

## Robert Proulx Chairman & CEO

- Operationally oriented executive
- 25 years experience in life science and medical device product development and commercialization

## David Ludvigson Non Exec Director CEO Nanomix

- Financial and operating executive
- 35 years experience in pharma, medical device and computer products
- Significant experience in corporate strategy, M&A, and financing

## Michael Harsh Non Exec Director Founder Terapede Systems

- Former VP & CTO of GE Healthcare's Medical Imaging Business
- 35 years experience in Engineering and product development of medical imaging technologies including MRI, X-ray, and ultra sound

## John Hazle PhD Non Exec Director Chair Imaging Physics MD Anderson

- Board certified for both therapeutic and diagnostic medical physics
- 30 years experience in pre-clinical and clinical medical imaging research
- Chairs Cancer Research programs at UT Graduate School of Biomedical Sciences

## Jovanka Naumoska Director / Secretary Business Mgr ANSTO

- Australian attorney with expertise in regulatory compliance, corporate, governance and risk, general and commercial liability, & intellectual property

## Mark Van Asten Non Exec Director Founder Diagnostic Technology Pty Ltd

- Australian business executive with strong background in diagnostics and healthcare
- 25 years experience in market development and commercializing diagnostic products

## Brian Conn CFO

- Financial executive with strong background in early and growth stage biotech
- 25 years experience in raising both public and private capital and M&A activities

## Giulio Paciotti PhD VP R&D

- Former CSO at CytImmune Sciences developer of gold nanoparticle therapeutic
- 25 years experience in tumor biology research and cancer related product development

## Peter DiChiara Non Exec Director Partner Carmel, Milazzo & DiChiara

- 30 years experience on securities issuance, regulatory compliance and corporate governance.
- Licensed as both as an attorney and certified public accountant in the State of New York



# IPO/Capital Structure

## Imagion lists on the Australian Securities Exchange (ASX) on 21 June 2017

- A\$12 million raised as part of IPO
- IPO funds initial commercial product development & achieve first-in-human clinical study

Shares issued to Seed Shareholders	62,183,576
Shares issued to Mason Group	3,333,333
Shares issued to Manhattan Scientifics	64,099,476
Shares issued under the IPO	60,000,000
Shares issued to Lead Manager	14,000,000
Shares issued to Consultants	450,000
Subtotal	<b>204,066,385</b>
Rights over Shares issued to Key Management Group <sup>(1)</sup>	12,100,000
Rights over Shares issued to Employees of Imagion US <sup>(2)</sup>	2,550,000
Rights over Shares issued to non-executive Directors <sup>(3)</sup>	900,000
Total Shares	<b>219,616,385</b>
Enterprise Value at \$0.20 per share	31,929,277
Market Capitalization at \$0.20c per share	43,929,277

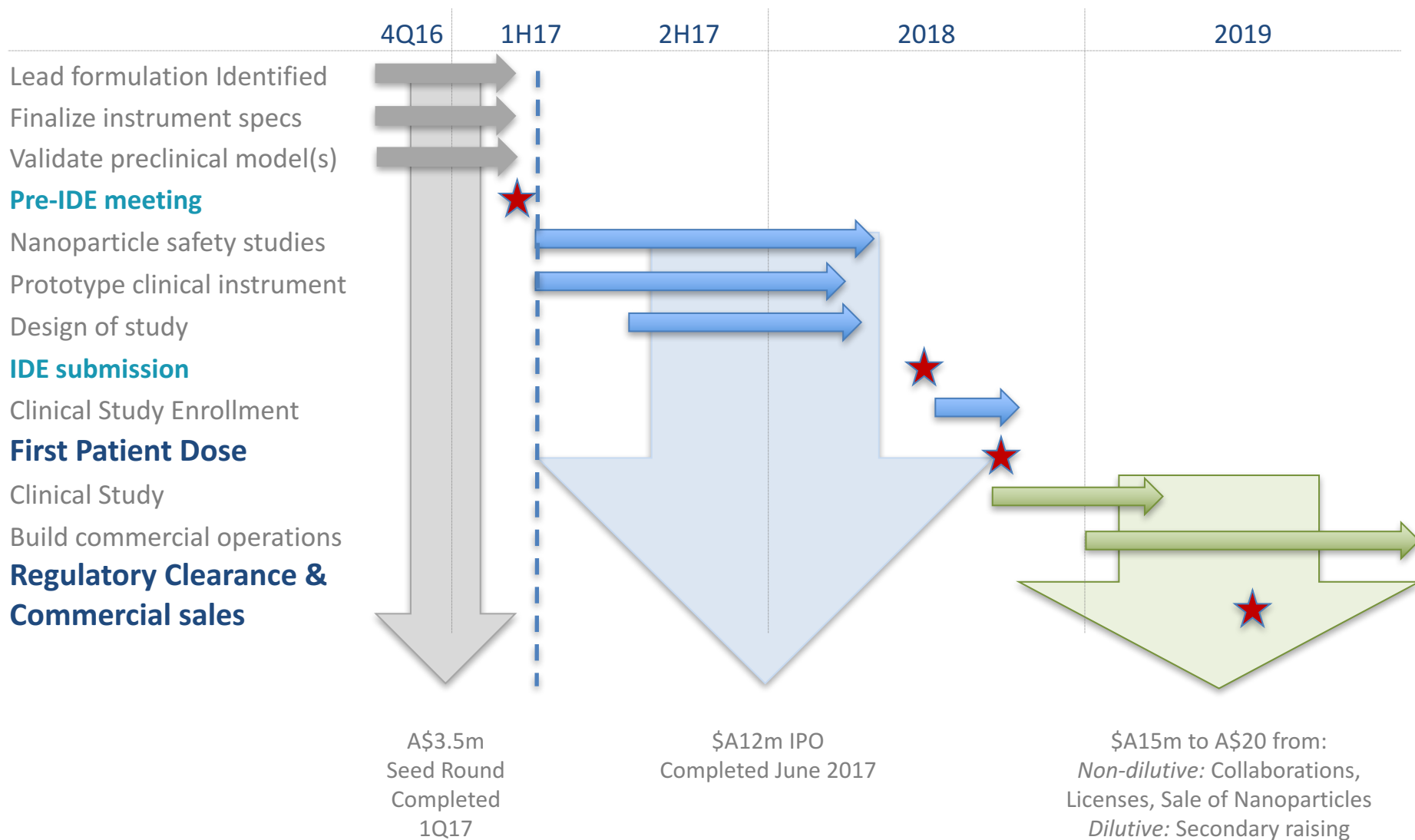
1) Up to 12,100,000 rights over Shares will be issued to the Key Management Group as an initial grant under the Long Term Incentive Plan, which will vest over 2 years and be subject to certain performance milestones being met.

2) A total of 2,550,000 rights over Shares will be issued to employees of Imagion US under the Long Term Incentive Plan, which will vest quarterly over 2 years, and will not be subject to performance milestones.

3) A total of 900,000 rights over Shares will be issued to non-executive Directors under the Long Term Incentive Plan, which will vest at 2 years after Listing.'

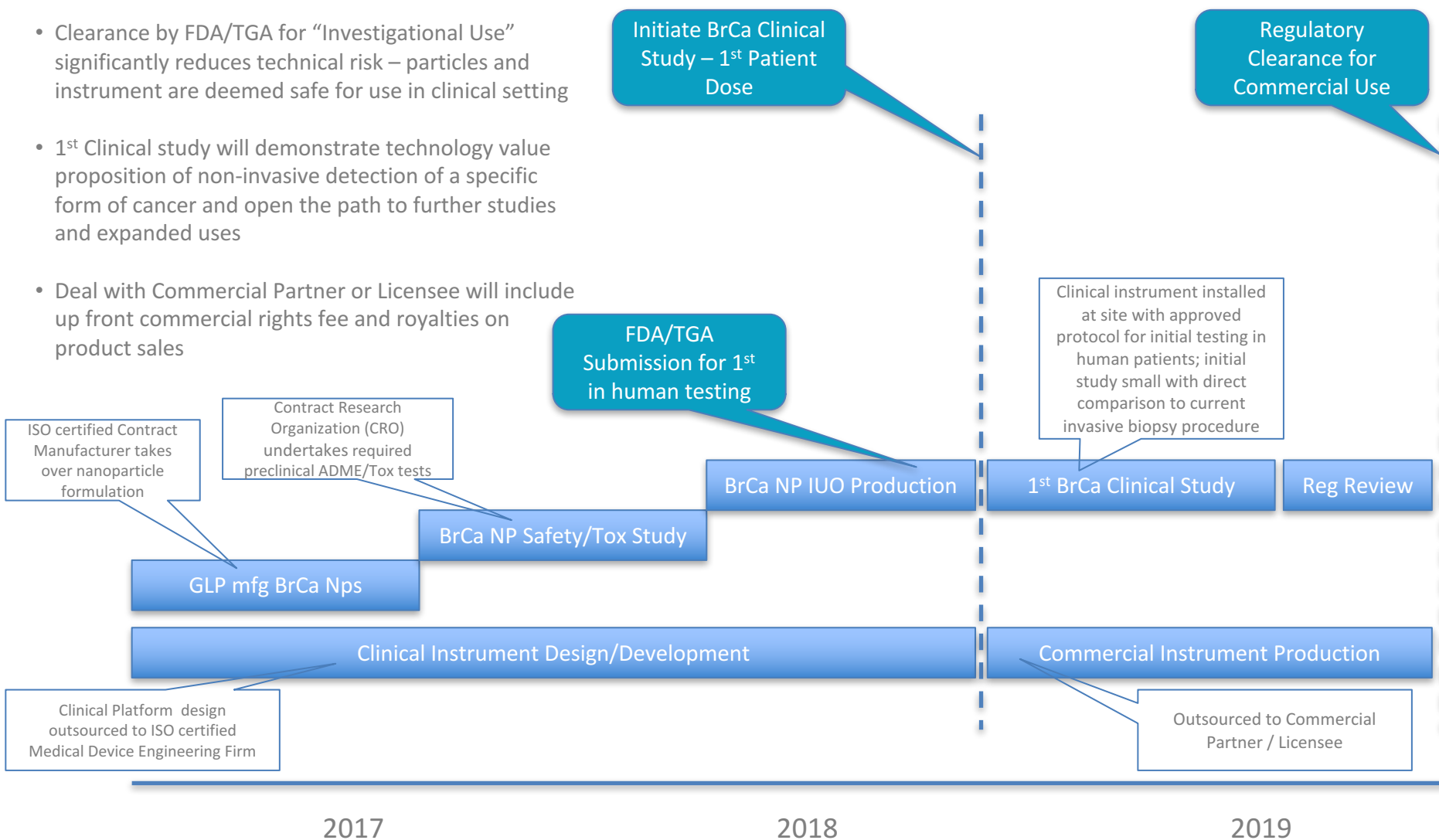


# Use of Funds and Timeline



# Milestones and Value Inflection Points

- Clearance by FDA/TGA for “Investigational Use” significantly reduces technical risk – particles and instrument are deemed safe for use in clinical setting
- 1<sup>st</sup> Clinical study will demonstrate technology value proposition of non-invasive detection of a specific form of cancer and open the path to further studies and expanded uses
- Deal with Commercial Partner or Licensee will include up front commercial rights fee and royalties on product sales



# Imagion Biosystems Message Map

## Technology

FDA "Medical Device" opinion reduces clinical study requirements

Predicate devices like EndoMag have gained clearance

PEG and mAbs have been FDA cleared

SQUIDs have been FDA cleared for use in MEG

Iron oxide nanoparticles have been used for 15+ years as MRI contrast agent

Preclinical collaborations in place with key research institutions: MD Anderson, Weill Cornell

Using same SQUID detector configuration as in preclinical prototypes

Technology has 10+ yrs of R&D

Strong IP position

Contracting with ISO 13485 Medical Device mfg to design/develop system

Revenue opportunities in commercializing the nanoparticles as MRI contrast agent and as RUO product

Contracting with ISO 13485 CMO for GLP/GMP nanoparticle production

## Business Operations



Opportunities to expand beyond cancer and into therapeutic applications

Initial proof-of-principle publication dating to 2011

Multiple clinical cancer targets under development: Breast, Prostate, Ovarian

Strong Board & Mgmt w/ medical device commercial experience

~\$23M (US\$17m) invested in development to-date

> US\$9m in grant applications submitted or in preparation

Multiple avenues to monetize the technology through licensing and/or partnering

## Markets

~1500 Cancer Centers in the US for diagnosis and treatment

47 NCI designated Comprehensive Cancer Centers in the US

Breast Cancer Dx is a global US\$20B industry growing at 8%

60 PET Imaging Centers and 21 Cancer Treatment Centers in the UK

Opportunities to expand market with extended "intended use" to monitoring therapy and recurrence

54 PET Imaging Centers and 84 Cancer Treatment Centers in Australia

Platform technology with broad applicability

\$100M in revenue achievable with 100 instruments and just 3 tests per day at \$1000/test

Printer/Ink business model w/ most revenue generated through high gross margin (80%) consumable

M&A comps for Device/Dx companies show 3x-5x revenue

## Business Valuation



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