PITT STREET RESEARCH

Imagion Biosystems

Detecting cancers earlier

Share Price: A$0.029

Imagion Biosystems (ASX: IBX) is at a pivotal point of its history, about to take its MagSense technology into Phase 2.

ASX: IBX

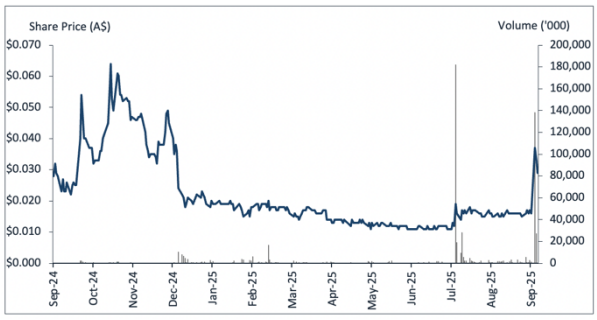
Sector: Healthcare

11 September 2025

Market cap. (A$ m)	7.1
# shares outstanding (m)	246.3
# shares fully diluted (m)	377.7
Market cap ful. dil. (A$ m)	10.8
Free float	100%
52-week high/low (A$)	0.064 / 0.011
Avg. 12M daily volume ('1000)	2,439.9
Website	imagionbiosystems.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.123-0.149
WACC	14.7%

Source: Pitt Street Research

MagSense is a better solution

MagSense is a first-of-its-kind imaging agent with potential to diagnose cancers, starting with HER2+ breast cancer. Compared to other agents, MagSense has the potential to be safer and better at identifying cancers at an earlier stage, which for patients can mean intervention is cheaper, less invasive and more likely to succeed. It is also less invasive and painful then mechanisms such as biopsies. MagSense works seamlessly with existing MRI scanners and clinical workflows and Imagion has developed a capital-light business model.

A clear pathway to the creation of shareholder approval

Since Imagion listed, investors have been unfairly impatient with the company, but it has come a long way since its listing. Imagion has delivered successful Phase 1 results in what was the first ever clinical study of a molecular MRI contrast agent. The company is now at a pivotal point. Having obtained strong Phase 1 data, Imagion intends to file an Investigational New Drug application and then conduct a Phase 2 study in HER2+ breast cancer. We see partnering interest as a plausible scenario, particularly if MagSense can show strong interim data. We would also note that as a diagnostic imaging agent, MagSense is more likely to succeed in clinical development compared to drugs or devices.

We think the success of peers such as Telix, Clarity and even Radiopharm Theranostics depict potential for a re-rating. Moreover, the growth in the use of imaging agents in medicine generally and M&A activity in the space; demonstrates that there is an opportunity for Imagion to make a difference.

Valuation range of $0.123-$0.149 per share

We have modelled several scenarios for Imagion. In the scenario that we think is most plausible to ponder at this stage we value it at $0.123 per share in our base case and $0.149 per share in our bull case, which amount to valuations of $46.6m and $56.5m respectively. Higher upside is possible if MagSense is commercialised against further indications Please see page 15 for more details on our valuation and page 18 for the key risks.

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Table of Contents

The Investment Case for Imagion Biosystems

1) **Imagion's MagSense imaging agent has potential to revolutionise cancer screening** by detecting cancers (i.e. molecular confirmation rather than suspicion) and detecting them earlier. In detecting cancers earlier, it means cancers can be treated through less invasive and toxic ways and the possibility of success can be higher.
2) **MagSense represents an improvement for patients.** There is no exposure to radioactivity, it may reduce the need for biopsies and by detecting them earlier can increase the likelihood of successful treatment. Moreover, the few options available today have some limitations such as only being able to be used during surgeries that can only occur when cancer is diagnosed. If MagSense can gain broader approval, there is potential for it to gain a foothold in the market.
3) **MagSense can be rolled out quickly**. It is compatible across all the world's MRI scanners and can be used across many cancers. We note again that if MagSense can receive approval to a greater extent and can show it is superior to what is already on the market, then oncologists will be highly eager to use it.
4) **MagSense is to enter Phase 2 for HER2+ breast cancer.** Human safety has been proven in Phase 1 and an IND is pending. This study will assess Dose and Image protocol optimisation.
5) **Higher chance of approval.** While MagSense imaging agent technology is the first-of-its-kind, it's not a 'never been tried before' approach or unproven medical imaging technique. MagSense is a contrast media product, a category where the chances of regulatory approval are much higher. The Company has worked through the fundamental technical risks and likely only needs to show non-inferiority to ultrasounds to gain approval.
6) **Imagion has a major market opportunity before it.** MagSense's TAM just for HER2+ breast cancer is $500m. Prostate cancer is $1bn and ovarian cancer is $500m. Looking at the market from a patient perspective, there are 400,000 annual diagnoses of HER2+ breast cancer in the US alone as well as 1 million biopsies for prostate cancer.
7) **Imagion will have a lucrative business model.** As an imaging agent, Imagion could charge premium pricing and potentially deliver high margins when it comes to market. We will delve more into this in our report.
8) **There is a high chance of strategic partnering or M&A, even prior to commercialisation** and this could derive upside for shareholders even prior to clinical trial success and commercialisation. Investors need only look at IBX's peer Radiopharm Theranostics for proof – it received an $18m investment from Lantheus as part of a $70m financing transaction.
9) **Imagion has a quality leadership team.** It has an experienced team with years of experience in medical imaging, corporate financing and bringing new technologies to market. The company is chaired by Robert Proulx who has led the company for a decade and successfully bought MagSense from a proof of concept to the clinic. Its leadership team also includes Ward Detwiler who founded an MRI quantitative imaging company, Dr Susan Harvey former VP of Worldwide Medical Affairs at Hologic as well as Dr Kayat Bittencourt who is a leader in the field of cancer radiology.
10) **We believe Imagion is undervalued** at its current market value with it trading barely above cash backing. Our valuation of the company is

A$0.123-0.149 per share and this could be the tip of the iceberg given it only assumes MagSense is commercialised for one indication.

Imagion's focus has been on commercialising a diagnostic imaging technology known as MagSense.

Overview of MagSense

Since Imagion's 2017 IPO, its focus has been on commercialising a diagnostic imaging technology known as MagSense. MagSense's name is derived from magnetisable iron oxide nanoparticles, and the Sense part is where antibody-iron conjugates are used to detect where in the body the antibodies have gone to.

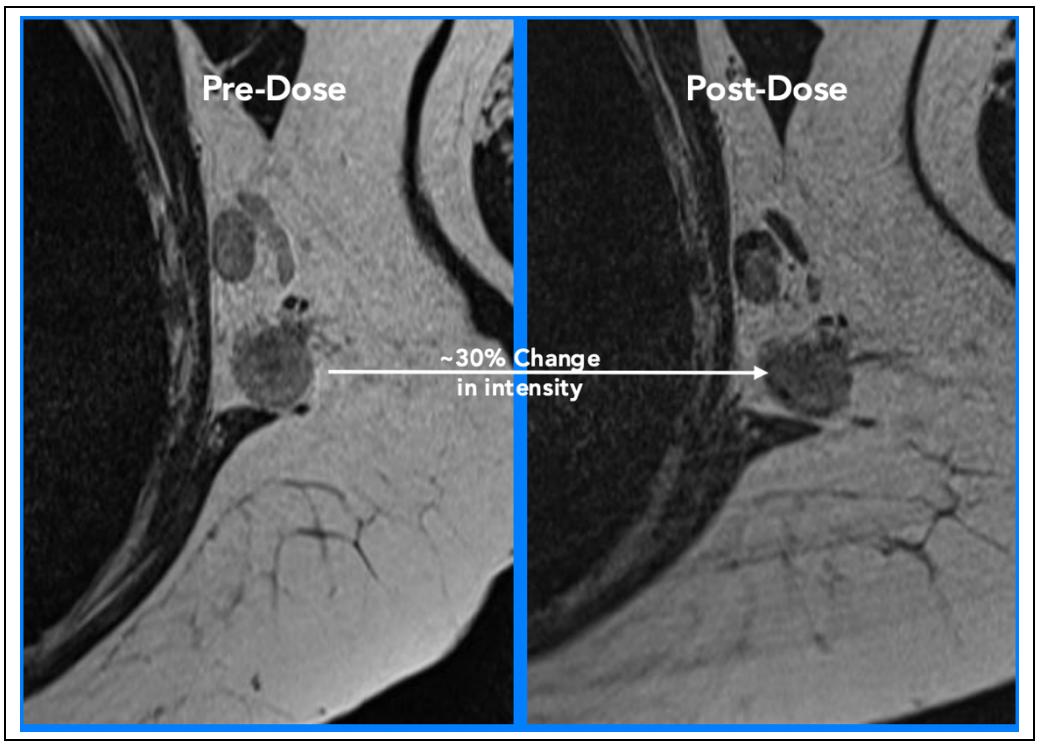
How MagSense works

MagSense uses the unique properties of specialised nanoparticles to detect diseased areas, such as cancer, present in the human body based on their distinct cell features.

MagSense uses the unique properties of specialised nanoparticles to detect diseased areas, such as cancer, present in the human body based on their distinct cell features. These nanoparticles are conjugated with targeting molecules, such as antibodies or small molecules to enable them to bind with specific antigens present on the surface of the target cells. Upon binding, the nanoparticles are detectable by their magnetic signature, which is not exhibited by any other structure in the human body. MagSense gets injected (usually intravenously) to a patient's body, and an MRI scan can be administered within the next 24 hours. This MRI scan will reveal a distinct pattern if cancer cells are present.

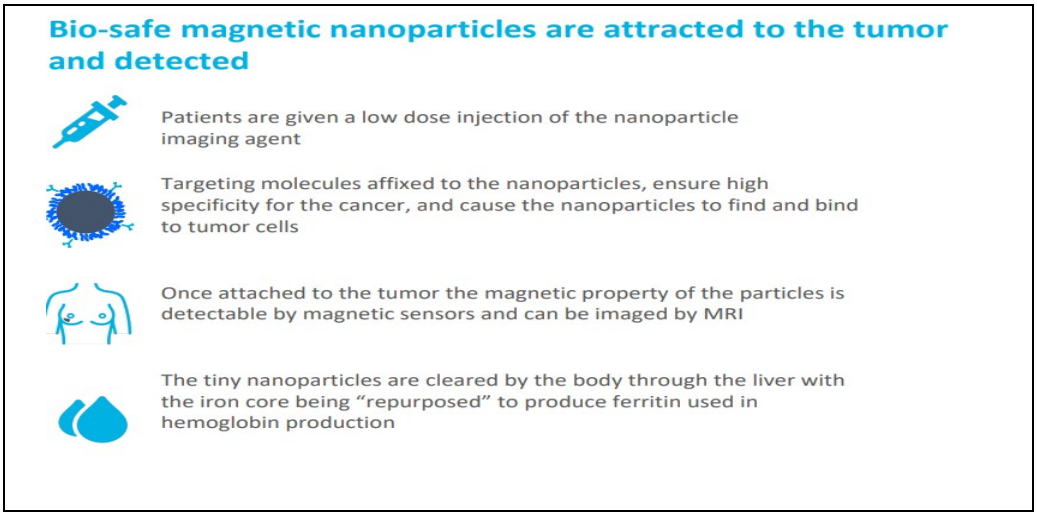
Where MagSense is superior is that the 'contrast' created by the iron particles is different when the antibodies have bound to their target. Hence, MagSense is more accurate for identifying diseased tissue, even with tumours as small as one millimetre being detectable when they wouldn't with MRI or CT scans (Figure 1). In being able to detect cancers when they are smaller (i.e. at earlier stages), better treatment options may be possible (Figure 2 and Figure 3).

Figure 1: MagSense in action



Source: Company

Figure 2: How MagSense works

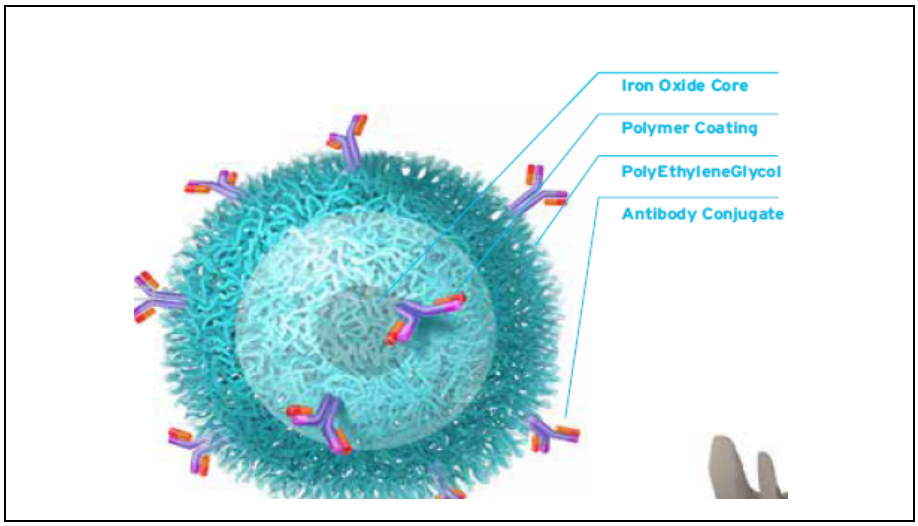


Source: Company

MagSense is a solution of uniformly formed superparamagnetic 25 nm magnetite (Fe3O4) nanoparticle.

MagSense is a solution of uniformly formed superparamagnetic 25 nm magnetite (Fe3O4) nanoparticle. The particles have a protective coating of polymer which provides the ability to make it biofunctional. Polyethylene glycol is added to the nanoparticles to make them 'stealth' to a body's immune system – allowing them to remain in circulation for a long time. These nanoparticles will be synthesised using a proprietary method that will allow them to be manufactured with an extremely narrow tolerance of core particle size, shape and magnetic properties, and will provide high detection sensitivity.

Figure 3: MagSense nanoparticles



Source: Company

After the synthesis of the nanoparticles, the formulation will be packaged and supplied to customers by Imagion as a single-use vial/pre-packaged syringe. For each type of cancer test, an optimum dose or volume of nanoparticles will have to be determined during clinical studies. Based on human studies, Imagion has found that nanoparticle volumes administered to patients have a wide tolerance and are generally safe. The reason different formulations of target nanoparticles will likely be needed is because there is no single 'pan cancer' biomarker available.

MagSense's development

MagSense was developed in the 1990s and Imagion was founded in 2016 to buy the project.

MagSense was developed in the 1990s by Dr. Edward Flynn, a nuclear physicist who was then a researcher at Los Alamos National Laboratory. He founded a company called Senior Scientific to commercialise MagSense. This company was bought by New York-based Manhattan Scientifics and Imagion was formed and bought the project in 2016.

The company listed in 2017 and the FDA granted MagSense a Breakthrough Device designation in July 2019 as part of the Company's plan to develop a proprietary detection platform. Although this is less relevant now considering the transition to using MagSense as an MRI imaging agent, this achievement cannot be forgotten – it will help its cause when it eventually seeks FDA approval given it will be familiar with the technology.

IBX's initial intent was to commercialise MagSense through its own machines rather than MRI scans. In 2020, the company pivoted to having them work in conventional MRI scans as it saw far greater potential for adoption than under a model where customers had to buy whole new machines. Thereafter, the first clinical study of MagSense commenced in the following year. The company's move eliminated millions in development, reduced costs for clinical studies and made the commercial case easier. We view the pivot to MRI as a positive sign that management is business not technology focused and at the time, investors gave the company credit.

The key milestone in the company's history was completing Phase 1. The study, which read out in 2023, evaluated 13 patients across four clinics in Australia and showed that the product was safe and well-tolerated and, importantly, blinded[1] radiologists could use MagSense images to distinguish suspicious lymph nodes infiltrated with metastatic HER2+ tumour cells, from non-cancerous lymph node activity. Normal lymph nodes were recognised by a uniformly dark contrast distributed throughout the entire node.

Tumour-metastasised lymph nodes were observed to have heterogeneous scattered darkening. Importantly, MRI assessment of post-MSH2IA imaging achieved parity or outperformed standard-of-care axillary ultrasound imaging in all 8 of these patients. Molecular MRI with MSH2IA achieved nearly perfect patient-level concordance as all but one of the patients identified with tumour-metastasised lymph nodes post MagSense imaging were confirmed by pathological analysis to have metastatic disease. Moreover, the study saw no safety issues, toxicity or adverse events observed in any of the patients.

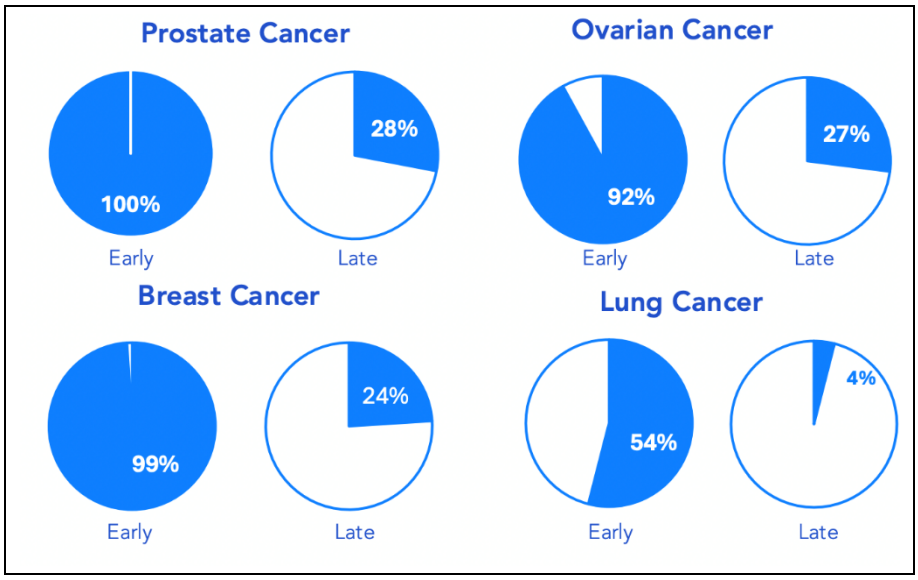
Why MagSense is needed and the difference it can make

There is a significant unmet need for diagnostic systems that can monitor as well as quantify disease progression in an economical and non-invasive manner. We think that MagSense tests are likely to emerge as an ideal diagnostic modality for the monitoring of breast cancer disease progression.

Current options tend to be invasive and painful biopsies as well as imaging agents that often fall short until it is too late.

If you look at the current diagnostic options, they all have shortcomings that MagSense does not. Cancer imaging and imaging agents in general are not specific and can only identify regions of interest. They may not necessarily identify the presence of a tumour. Gadolinium-based contrast agents are impossible to be molecularly targeted. In many instances, they may not be able to identify the presence of a cancer until it is advanced, and by that time, it may be more difficult to treat (Figure 4).

Figure 4: Cancer 5-year survival rates (early vs late-stage diagnosis)



Source: Company

[1] Blinded not in the sense of the radiologists not having eyesight but blinded to the fact that MagSense was being used

The only option that provides certainty is a biopsy where surgeons remove a tissue or cell sample from the body, then examine them under a microscope. As goes without saying, they are invasive and painful, but also error prone, challenging and leave patients vulnerable to side effects or complications. Adding insult to injury, assessments can take several days.

Imaging agents not as radical an idea as you may think

Some lay persons may find the idea of a drug being injected into a person's veins just to try and diagnose a cancer 'invasive'. They may also have negative ideas about imaging 'agents', particularly those that are radioactive. But MagSense provides molecular confirmation of cancer, has no radioactivity, and only requires a low dose to see the contrast needed.

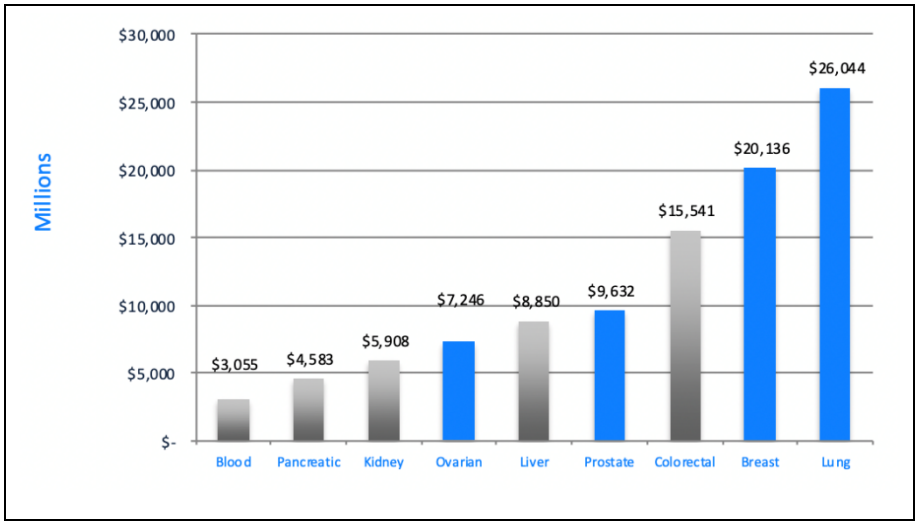
We would also note that imaging agents have been around for decades. Indeed, the first widely used contrast agent used in 1906, just 11 years after X-rays were discovered[2]. This was Collargol, which was used in X-rays but was eventually replaced by newer and safer contrast agents. The first use of radioactive isotopes for cancer occurred in the 1940s, at a time when X-rays were the only imaging technique[3]. They have gotten better and better over the years in conjunction with imaging techniques like CT scans and MRI. But, as we will outline shortly, today's imaging agents for cancers have limitations which MagSense does not.

The opportunity in cancer diagnostics

Cancer diagnostics is estimated to be a $100bn market, growing at 7% CAGR.

There is an enormous opportunity in cancer diagnostics. There are varying estimates but one (from Transparency Market Research) suggests cancer diagnostics is a $100bn market, growing at 7% CAGR (Figure 5).

Figure 5: Cancer diagnostic market



Source: Company

[2] Kinch, M. and Woodward. P. 2017, *Analysis of FDA-approved imaging agents*, Drug Discovery Today, Mar 21;22(7):1077-1083. Doi:10.1016/j.drudis.2017.03.006
[3] https://archive.cancerworld.net/e-grandround/imaging-in-oncology-over-a-century-of-advances/

The World Health Organisation forecasted last year that over 35 million new cancer cases would occur in 2050, up 77% from 2022 levels[4]. This is due to population ageing and growth, as well as changes to people's exposure to risk factors including air pollution, tobacco, alcohol and obesity. Cancer mortality in low HDI and medium HDI countries is projected to be almost double in 2050. But this burden could be eased if cancers can be diagnosed earlier with solutions by MagSense.

Imagion has told investors that it has a $500m TAM with HER2+ Breast cancer, a $1bn TAM with Prostate Cancer and a $500m TAM with Ovarian Cancer[5]. We will delve into each of these in turn.

HER2+ Breast cancer

The HER2+ subtype of breast cancer is an aggressive phenotype demonstrating high chances of recurrence and metastasis.

The HER2+ subtype of breast cancer is an aggressive phenotype of cancer, so-called because of the HER2 protein (Human epidermal growth factor receptor 2) which overexpresses in the surface of cancer cells in instances of this cancer. The overexpression leads to uncontrolled cell proliferation and thus faster tumour growth and progression, leading to high chances of recurrence and metastasis. Every year, HER2+ breast cancer accounts for almost 15–20% of the ~2.3 million breast cancer patients globally. This translates to 345,000–460,000 patients with HER2+ breast cancer every year. The high patient population represents a significant addressable market for diagnostics companies such as Imagion.

It is against this indication where IBX is most advanced against with successful Phase 1 data. As we noted earlier, the Phase 1 trial (completed in 2023) showed it was generally safe, well tolerated and a clinically feasible adjunct to MRI for detecting HER2+ breast cancer in axillary lymph nodes – the radiologists could distinguish lymph nodes with HER2+ metastases from those with benign conditions using the imaging agent.

There are some target therapies that are FDA approved for HER2+ breast cancer including trastuzumab, pertuzumab and fam-trastuzumab deruxtecan-nxki (Enhertu). But imaging agents are a different story where there are no FDA approved products. The standard of care is an ultrasound followed by a biopsy where pathologists look for Immunohistochemistry and Fluorescence In Situ Hybridisation (FISH).

There is really only one current option – Pegulicianine; but it can only be used during lumpectomies, where cancer is already detected.

The closest thing to an FDA-approved agent is pegulicianine (Lumisight) that was approved by the FDA in April 2024 for use during lumpectomies, helping surgeons detect cancer tissue in the surgical cavity immediately after the tumour's removal. Lumisight is a fluorescent imaging drug that is administered intravenously before surgery and is a peptide-dye conjugate consisting of a tumour-seeking peptide that is linked to a fluorophore (a dye that emits light when stimulated). The idea is that the drug will accumulate in area with high protease activity (i.e. tumour sights) and when cleaved by tumour-associated proteases, the fluorescent dye is 'turned on' and becomes visible fluorescent under near-infrared light. The advantages are that there is no radiation involved and detects residual disease before closing the site, avoiding the need for follow-up surgeries for this purpose.

But it is only approved for uses during lumpectomies, as a means of ensuring the tumour mass is fully eliminated. It doesn't tell you if the primary tumour has spread to the lymph nodes. The clinical trial leading to its approval (conducted in over 300 patients) found that it detected the presence of

[4] World Health Organisation data
[5] Investor presentation June 2025, slide 7.

tumours more accurately than the placebo to the point where more than 20 of those patients in the study had tumours totally undetected by the procedure. But once again, it is not approved for use outside of lumpectomies.

As a result, radiologist rely on anatomical evaluation of the lymph nodes, looking for irregularities in size and shape to identify "suspicious" nodes that then are biopsied.

Prostate cancer

Prostate cancer is the biggest potential market for MagSense with a $1bn TAM by the company's estimation and a patient population of more than 1 million.

Prostate cancer is the biggest potential market for MagSense with a $1bn TAM by the company's estimation and a patient population of more than 1 million. The challenges for MagSense in prostate cancer are two-fold. First, that it is less advanced than it is with HER2+ breast cancer. The second is that there are several approved agents including Axumin, Telix's Illuccix, Gozetotide and Posluma. The first to be approved were only for recurrent cancer, but more recent ones have been approved for earlier stage cancer.

Nonetheless, there is still an opportunity for MagSense if it can be more efficacious and safer than alternatives. Consider Telix's Illucix for instance – it is a radiation-based agent. We know in general that cumulative radiation exposure can lead to an increased risk of cancer, and this is a warning that Telix itself has not shied away from[6]. Granted, the clinical evidence has found adverse reactions are low (i.e. >1%). It can also be affected by a patient's PSA levels and by the site of disease. The performance of Illuccix for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy is affected by a patient's Gleason score[7]. It is a similar story with other agents including Posluma[8] and Axumin[9]. Although PET imaging is highly sensitive, it has poor resolution so its use in treatment planning is limited.

If MagSense can gain approval and enter this market as an alternative with no radiation and a better capability, for example similar sensitivity to PET but with MRI high resolution, we see strong potential for it to gain a foothold in the market.

Ovarian cancer

The only approved agent is Cytalux (pafolacianine) which got the green light in late 2021. It targets the folate receptor alpha, which is overexpressed on many ovarian cancer cells. It is injected 1-9 hours prior to surgery, then binds to positive cells and illuminates under near-infrared light, allowing surgeons to see tumours not visible under normal light or by touch. Again, it is only approved for use during surgeries. This agent has a higher potential for side effects than any we mentioned for prostate cancer with up to 13% of patients experiencing nausea and 5% vomiting[10]. There is potential for cells to light up even if they are not cancerous or those that are cancerous may not light up.

But Cytalux doesn't address the fundamental problem in ovarian cancer which is earlier detection. Ultrasound requires an adnexal mass to be 5cm in size, which is typically late stage. To date there have been no improvements in imaging that address earlier detection of ovarian cancers. Again, if MagSense can show a higher degree of safety and efficacy compared to

[6] https://ir.telixpharma.com/news-releases/news-release-details/illuccix-approved-us-patient-selection-pre-taxane-rlt
[7] Ibid.
[8] https://www.posluma.com/patient/
[9] https://www.axumin.com/about/safety-side-effects
[10] https://cytalux.com/ovarian-cancer-stories-and-support/

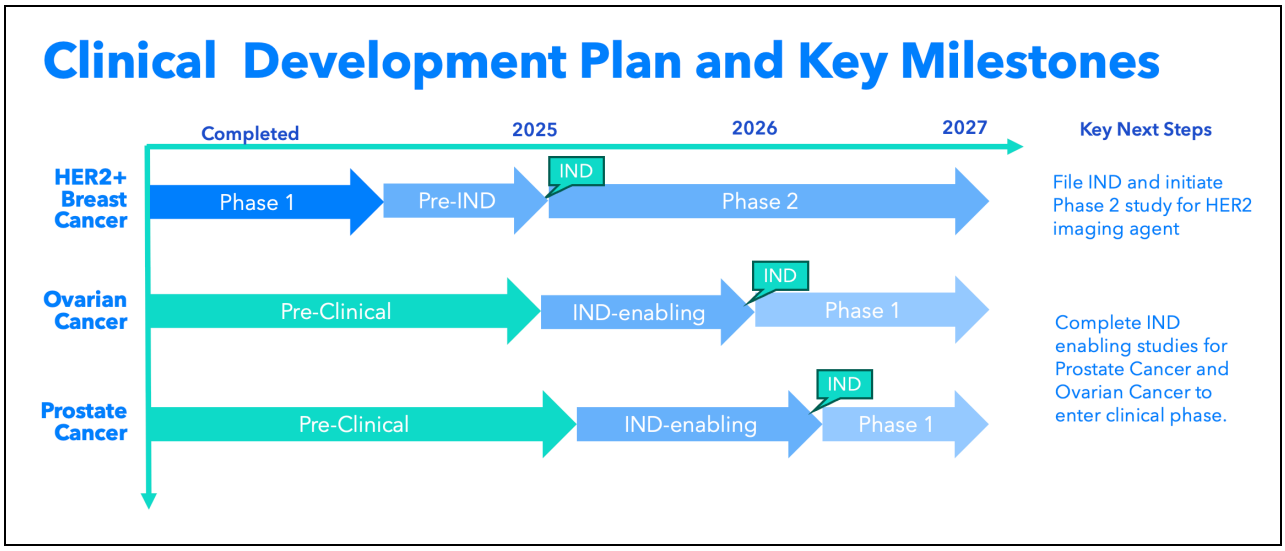
today's standard of care methods it will have potential to quickly gain ground in the market.

Imagion's next steps

The plan is to file an Investigational New Drug (IND) application in the fourth quarter of the 2025 calendar year then undertake Phase 2.

IBX's plan is to file an Investigational New Drug (IND) application in the before the end of the 2025 calendar year (Figure 6). The company is currently manufacturing the MagSense agent for the clinical trial and has enlisted Dr William Dooley as the Principal Investigator of for the study, a surgical oncologist at the University of Oklahoma Health Sciences College of Medicine. Dr Dooley is a renowned cancer expert having developed and directed the Johns Hopkins Breast Centre which became an award-winning model for cancer care. He then moved to Oklahoma and transformed breast cancer treatment amongst the under-served and disparity populations in Oklahoma, transforming the OU Breast Institute into the first National Accreditation Program for Breast Centres-certified breast centre in Oklahoma.

Figure 6: Imagion's progress



Source: Company

In July 2025, Imagion reported the receipt of a written response from the FDA and engaged in in-person meetings with the American regulator. No issues were identified that could negatively impact the current plans and the parties discussed future clinical and commercial development considerations.

Imagion's future model

As imaging agents are consumable diagnostics rather than large one-off purchases, there is the prospect of positive economics and high gross profits.

As imaging agents are consumable diagnostics rather than large one-off purchases, there is the prospect of positive economics and high gross profits. Companies can charge multiple thousands of dollars per dose, especially if tied to cancer staging or therapy selection. Moreover, imaging agents can be modular, the same targeting ligand can be used for therapy, diagnostics or CDx (companion diagnostics).

MagSense is not a 'never been tried before' drug or unproven medical device. Rather, MagSense is an imaging agent (a contrast media product), a category

where the chances of regulatory approval are much higher. There is no longer fundamental technical risk and likely only needs to show non-inferiority to ultrasounds to gain approval.

The promise of AI

We see potential for AI-based diagnostics to play a major role in healthcare and for Imagion to play a part in its rise. Imagion plans to develop AI-compatible imaging protocols for use in its Phase 2 trial and has secured a partnership with Wayne State University.

WSU will work with Imagion to determine the lowest effective dose of MagSense, establish optimised MRI sequences and transfer the protocols to clinical sites. Imagion already has had a long-standing collaboration with Siemens world leader in MRI, to support Imagion's clinical studies. The collaboration WSU will also focus on quantitative imaging techniques that will run on Siemens' scanners (as well as other commercial systems) to provide highly specific data that can be integrated into AI models to improve cancer detection accuracy.

Down the track, AI could also help fine-tune molecules for better bioavailability, stability in vivo (i.e. in the body) reduced toxicity and off-target binding minimisation. AI may even be able to help discovery new molecular imaging agents by predictive modelling techniques that could predict how molecules will behave as imaging agents.

The Challenges facing Imagion and its peers could be an opportunity

Distribution can be difficult for imaging agent developers, but this can be an opportunity for MagSense to stand above its peers.

The key challenges facing imaging agent developers are with distribution, which can be complex for radioactive agents, as well as training. This is particularly because some agents, such as PET tracers can have short half-lives and so they may require radiopharmacy hubs, daily production or kit-based models. Some (i.e. fluorescent agents) require specialised imaging hardware.

But MagSense imaging agents can be stocked at hospital pharmacies and have a long shelf-life making them fit easily into the hospital workflows and provides the opportunity to generate revenues from clinical partnerships and the sale of 'kits' rather than just the agent. Telix's Illuccix has been more successful than it otherwise would be for that reason. Compare this to Cytalux that has slower adoption due to integration needs and niche surgical applicability. This is where MagSense could make a difference if it:

- Gains approval for multiple indications,
- Can obtain commercial partnerships that can help with its distribution,
- Can have a commercial model that means less regulatory hassle for customers than its peers (i.e. through kits).

There's major activity brewing in the space

Large pharmaceutical companies are aggressively expanding into radioligand therapies and diagnostic imaging.

Large pharmaceutical companies are aggressively expanding into radioligand therapies and diagnostic imaging. Novartis laid the groundwork with Pluvicto, triggering a wave of acquisitions. Companies like Eli Lilly, Bristol Myers Squibb, and AstraZeneca followed suit—making high-value deals to secure radiopharma assets, the latter made a $2bn bid for Fusion Pharmaceuticals. Companies in the space are taking steps to preserve their position by buying complementary technologies and manufacturing infrastructure. In the last 12 months (i.e. since September 2024) look at Telix's buy of radiopharmacy chain RLS, Sanofi's $300m acquisition of a 16% stake in OranoMed, a biopharma with expertise in nuclear manufacturing and Lantheus' purchase of Evergreen Theragnostics for $250m upfront and up to $752.5m in milestones, gaining a whole new neuroendocrine PET agent (Octevy).

Peers

Telix Pharmaceuticals (ASX: TLX) is the leader amongst radiopharmaceutical companies, having successfully developed and commercialised Illuxic. Notwithstanding a recent setback[11], Illucix has been a major success, re-rating Telix into the billions of dollars in market capitalisation, with the product enjoying several hundred millions of dollars of revenue per year. Illucix is a PET radiopharmaceuticals that binds to prostate-specific membrane antigen, a protein highly overexpressed on the surface of prostate cancer cells. It is injected intravenously and tumours 'light up' on a PET scan. It was first approved in the USA in 2021 and was approved in a handful of European jurisdictions and in Brazil during the 1st half of 2025.

Clarity Pharmaceuticals (ASX:CU6) - developing PSMA-targeted radiopharmaceuticals for prostate cancer imaging and therapy. It specialises in Targeted Copper Theranostics (TCTs) which all leverage a specialised copper-chelator that ensures the radioactive copper remains stably attached to the targeting molecule, preventing unwanted leakage. Clarity has several programs but its most advanced is SAR-bisPSMA which is in two Phase III trials (AMPLIFY for biochemical recurrence) and CLARIFY (pre-prostatectomy). The company is capped at over A$1bn given the clinical progress it has made, and optimism that it can have the same success as Telix.

Radiopharm Theranostics (ASX: RAD) – Radiopharm is a clinical-stage developer of radiopharmaceutical products for both diagnostic imaging and therapeutic use in oncology. Targets include fatty acid synthase (for brain metastases, RAD 101), integrin αvβ6 (RAD 301), HER2, PD-L1 (lung cancer), and more, spanning both diagnostic imaging and radiotherapeutic agents. It is in Phase 2b of an imaging trial for RAD 101 targeting brain metastases. Its near $60m market cap should give Imagion investors hope that shares could re-rate as it moves towards and enters Phase 2.

[11] In August 2025, the FDA declined to approve its drug for kidney cancer (Zircaix), requesting additional data to prove the scaled-up commercial manufacturing process is comparable to the one used in clinical trials.

Imagion's management

The company's current board and leadership composition is as follows (Figure 7):

Figure 7: Imagion's leadership composition

Board of Directors	
Name and Designation	**Profile**
Robert Proulx Executive Chairman	Mr Proulx has been CEO and Chairman of Imagion since 2015 bringing the technology and company from early proof of concept to clinical stage.
Ward Detwiler Chief Business Officer	Mr. Detwiler is an experienced senior executive in the medical imaging field. Most recently, he was co-founder and CEO of SpinTech MRI, a quantitative MRI software company focused on rapid imaging and new biomarker detection.
Melanie Leydin Non-Executive Director & Company Secretary	Ms Leydin 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 Australia.
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.
Nina Webster Non-Executive Director	Dr Webster is an experienced biotech executive with broad background in drug development and commercialisation. She is currently CEO and Managing Director of Dimerix (ASX:DXB).
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 Breast Imaging at Johns Hopkins Medicine.
Dr Kayat Bittencourt Clinical Advisor	Dr 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.

Source: Company

Valuation of $0.123-0.149 per share

We value Imagion at $0.123 per share in our base case and $0.149 per share in our bull case.

We value Imagion at $0.0123 per share in our base case and $0.149 per share in our bull case under the current number of shares on issue (Figure 8 and Figure 9). These figures represent upside of 326% and 415% respectively and are arguably conservative because this only accounts for HER2+ breast cancer. We have also modelled a scenario where MagSense is commercialised for other indications and there is even further upside here, but we will address our 'base case' first. Our assumptions are as follows:

- **Revenue model.** We have assumed the company licenses out MagSense and retains a 20% royalty. We assume MagSense passes Phase 2 and Phase 3 and enters commercialisation in FY30 (i.e. the year commencing 1 July 2029).

  We assume a starting price of US$1,750 which is higher than Imagion has previously guided to but accounts for cost inflation occurring prior to MagSense's commercialisation, then further cost inflation of 3% per annum to MagSense's price.
- **Partnering and milestone payments**. We have assumed Imagion received ~US$45m in milestone payments prior to commercialisation accounting for trial successes, approval and early sales milestones. We have also presumed Imagion bears *some* of its development costs ($35m) which enables a higher royalty than would otherwise be the case. We acknowledge there is scope for debate as to what exactly the milestone payments will be, but the only other alternative to partnering is significantly high shareholder dilution or debt. There is a case to be made that US$45m could be conservative for the whole Phase 2 to commercialisation journey given Radiopharm Diagnostics' deal.
- **Market size and penetration.** We model the HER2+ breast cancer market via annual cases diagnosed which is 400,000 per year. We assume MagSense eventually penetrates 25% of the market which derives US$247.3m in revenue and US$49.5m in royalty revenue.
- **Costs and margins.** Once MagSense is commercialised, we assume an 45% pre-tax margin in our base case and 55% in our bull case, assuming Imagion's eventual partner bears some of the R&D costs.
- **Discount rate.** We arrive at a WACC of 14.7% reflecting a 4% risk-free rate of return, a 7% equity premium and a 1.5x beta.
- **Period.** We assume approval in FY30 and for 10 years market exclusivity after that. No terminal growth is assumed for conservatism's sake.
- **Tax rate.** We assume a 21% corporate tax rate in conjunction with the US federal rate.
- **Exchange rate.** We assume A$1 is US$0.66.

Figure 8: Our Imagion assumptions

Assumptions	Base	Bull
Market size		
HER2+ (annual cases diagnosed)	400,000	400,000
Prostate cancer (biopsies)	1,000,000	1,000,000
Ovarian cancers (annual cases diagnosed)	300,000	300,000
Discount rate		
Risk free rate of Return	4%	4%
Equity premium	7%	7%
Beta	1.5	1.5
Discount rate	14.7%	14.7%
Tax Rate	21%	21%
Pre-tax margin	45%	55%
Cost Inflation	3%	3%
Royalty	20%	20%
Estimated pricing ($US)	1,750	1,750
Estimated pricing ($A)	2,652	2,652
USD/AUD	0.66	0.66

Estimates: Pitt Street Research

Figure 9: Imagion valuation

IBX Valuation	Base	Bull
NPV (US$)	$ 30,319,032	$ 36,702,985
AUD/USD	0.65	0.65
rNPV (A$)	**$ 46,644,665**	**$ 56,466,130**
Shares on issue (diluted)	377,748,202	377,748,202
Implied price	**$ 0.123**	**$ 0.149**
Current share price	$ 0.029	$ 0.029
Premium	*326%*	*415%*

Estimates: Pitt Street Research

More upside?

There could be further upside if Imagion is commercialised for prostate and ovarian cancers. We've modelled $0.189 per share in a base case and $0.239 per share in a bull case.

We also modelled a scenario under which Imagion also commercialises MagSense for prostate cancer and ovarian cancer. We assume it takes a further 3 years to commercialise them both and they receive 10 years each. In both cases, we also assume a 25% market penetration. The only other differences are that we assume:

- A further $20m in milestone payments for regulatory approval and first sales (cumulatively – we assume lower payments given we presume by that point MagSense would already be approved for HER2).
- A lower pre-tax margin, 35% in our base case and 45% in our bull case to account for potentially higher overheads.
- We further discount our cash flows by a risk factor of 50%.

The result is $0.189 in our base case and $0.239 In our bull case (Figure 10). We are sticking with $0.123/$0.149 per share as our formal valuation of Imagion for now, but we hope in providing this scenario as well that investors can see that the company's immediate opportunity could be just the beginning.

Figure 10: Hypothetical Imagion valuation

IBX Valuation	Base	Bull
NPV (US$)	$ 92,761,824	$ 117,137,536
Risk Factor	50%	50%
rNPV (US$)	$ 46,380,912	$ 58,568,768
AUD/USD	0.65	0.65
rNPV (A$)	**$ 71,355,249**	**$ 90,105,797**
Shares on issue (diluted)	377,748,202	377,748,202
Implied price	**$ 0.189**	**$ 0.239**
Current share price	$ 0.029	$ 0.029
Premium	*551%*	*723%*

Estimates: Pitt Street Research

We foresee the stock being re-rated to our valuation range driven by the following factors:

- Imagion entering and passing Phase 2 with MagSense against HER2 breast cancer,
- Potential partnering/licensing agreements,
- M&A activity or R&D work in the broader medical imaging agent space which would raise awareness about MagSense's potential,
- Imagion advancing MagSense for other indications.

Risks

We see the risk of failure of forthcoming trials as the biggest risks facing the company.

Other risks include:

- **Regulatory risk**. There is a risk that MagSense may not be approved by regulators. Even if data suggests efficacy, the FDA may not find the data acceptable or decline to approve MagSense on other grounds such as the potential for negative interaction with other drugs. Even when approved, there is the risk that approval may be withdrawn, or that further regulations may be imposed on the company to be able to continue to market, manufacture and/or produce the drug.
- **Market acceptance risk**: There is the risk that even if the drug passes clinical trials, it will fail to be approved and/or attract a strong following in its applicable markets.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.
- **Capital risk**. The prospect of IBX needing debt or equity sources of funding cannot be entirely ruled out. In such an event, there is no guarantee that the company will be able to raise such capital, let alone on favourable terms. Even if successful, this would be dilutive to existing shareholders.

Risks related to pre-revenue Life Science companies in general.

The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.

Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the term 'speculative' can reasonably be applied to the entire sector.

The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology or medical device stock mentioned on this report, including Imagion.

Appendix I – Capital Structure

Class	In Millions	% of dully diluted
Ordinary shares	246,341,415	65.2%
Options	124,832,514	33.0%
Performance shares	2,400,000	0.6%
Convertible notes	4,174,273	1.1%
Fully diluted shares	**377,748,202**	

Source: Company

Appendix II – Glossary

Antibodies – Immune system proteins that can bind to an antigen and help neutralise the potentially harmful effects of the cells carrying the antigen. Antibodies are often used in diagnostics.

Antigens – A foreign substance capable of inducing an immune response in the body, especially the production of antibodies.

Biopsy – Removal of a sample of tissue from the body for diagnostic purposes.

Biomarker – A naturally occurring molecule/gene/characteristic that can be used to detect or diagnose any physiological condition.

GMP – Short for Good Manufacturing Practice; the set of standards laid down by regulators such as the FDA to produce clinical-grade pharmaceuticals. cGMP refers to 'current' Good Manufacturing Practice, since GMP standards tend to change over time.

HER2 – The protein targeted by the cancer antibody drug Herceptin that is overexpressed on breast cancer cells.

Ligand – An ion or molecule that binds to central metal atom to form a coordination complex.

Liquid biopsy – A test done on a sample of blood to look for cancer cells from a tumour that are circulating in the blood or for pieces of DNA from tumour cells that are in the blood.

Lymph nodes – Points in the lymphatic system rich in immune system cells designed to filter harmful substances.

Magnetometer – An instrument that measures the direction and/or strength of a magnetic field.

MagSense – Imagion's diagnostic imaging technology, which involves nanoparticles, labelled with cell-specific antibodies, which are re-magnetised, and their location detected using SQUID.

Magnetomotive ultrasound imaging – A technique under development that indirectly visualises nanoparticles.

Magnetic relaxometry (MRX) – A technique utilising super-paramagnetic nanoparticles to detect various diseases using antibodies.

Metastasis – The process by which cancer cells spread from their original, or primary, tumour to another part of the body to form new, or secondary, tumours

Nanoparticle – Any microscopic particle less than about 100 nanometres in diameter.

PSA – Prostate-Specific antigen levels. This can indicate prostate problems including prostate cancer but it can indicate other conditions like prostatitis.

Radiotracer – A chemical compound in which one or more atoms have been replaced by radionuclide; these compounds are used to explore the mechanisms of a chemical reaction by tracing the path that radioisotope follows from reactants to products.

Recurrance – Where cancer 'recurs'.

SQUID – Short for Superconducting Quantum Interference Device, a highly sensitive magnetometer made up of Josephson junctions.

Superparamagnetic – A form of magnetism that appears in small ferromagnetic or ferromagnetic nanoparticles.

Superparamagnetic relaxometry – A technology that uses SQUID sensors and superparamagnetic nanoparticles to detect cancer and other diseases.

Appendix III – Papers relevant to Imagion's technology

In previous reports on Imagion, we have published appendices with papers where MagSense is mentioned. We invited readers interested to view those previous reports. We thought we would publish a list of recent academic literature exploring the use of medical imaging agents and nanoparticles generally for cancer detection and imaging. We conclude our list with a handful of articles focused on iron-oxide nanoparticles which is what MagSense is.

Chapman, S. et. al (2013) Nanoparticles for cancer imaging: The good, the bad, and the promise, Nano Today, Oct; 8(5) 454-460.

This outlines core challenges and capabilities of nanoparticle-based imaging agents across MRI, PET, SPECT, and ultrasound, emphasising the need for improved contrast, biodistribution control, and multi-functionality.

Khorasani A, Shahbazi-Gahrouei D, Safari A. (2023) *Recent metal nanotheranostics for cancer diagnosis and therapy: a review*. Diagnostics. 2023;13(5):833.

This open-access review examines metal nanoparticles—such as gold, gadolinium, iron, bismuth, tungsten, and others—as contrast agents across imaging modalities including CT, MRI, PET, and X-ray. It highlights their advantages like ease of functionalisation, low toxicity, and strong performance for tumour visualisation and treatment

Pallares RM, et. al (2022) *Nanoparticle diagnostics and theranostics in the clinic*. Journal of Nuclear Medicine. 2022;63(12):1802–1808.

This article surveys nanoparticle-based imaging agents already in clinical use and those in translational development. Emphasis is on real-world applications and the pathway from preclinical innovation to clinical reality.

Al-Thani AN, et. al (2024). *Nanoparticles in cancer theragnostic and drug delivery: a comprehensive review*. Life Sciences. 2024;352:122899

A broad survey of various nanoparticles—including gold, iron oxide, silica, quantum dots, carbon nanotubes, and liposomes—highlighting their diagnostic and therapeutic performance, along with toxicity and future clinical prospects.

Brown N, Rocchi P, Carmès L, et al. (2023) ***Tuning ultrasmall theranostic nanoparticles for MRI contrast and radiation dose amplification*****. arXiv [Preprint]. 2023 Oct 2.**

This article focuses on the use of AGulX nanoparticles. It finds that increasing Bi3+ in the nanoparticles is associates with more DNA damage and improves in vivo efficacy with a statistically significant delay in tumour growth and 33% complete regression. The safety was also confirmed.

Zhang D. et. al (2025) ***Iron oxide nanoparticle-based T_1 contrast agents for magnetic resonance imaging: a review*****.** Nanomaterials**. 2025;15(1):33.**
This review explores how iron oxide nanoparticles (or specifically Iron oxide nanoparticle-based T1 contrast agents for MRI) serve as safer, biocompatible alternatives to gadolinium-based agents—covering synthesis methods, structural design, T_1 contrast performance factors, responsive contrast strategies, biodistribution, clearance, and translational challenges.

Ghazi R. et. al (2025) ***Iron oxide based magnetic nanoparticles for hyperthermia, MRI and drug delivery applications: a review*****.** RSC Advances**. 2025;15:11587–11616.**
This open-access review highlights IONPs' multifunctionality across imaging (MRI contrast), targeted drug delivery, and hyperthermia, while addressing challenges like biocompatibility, aggregation, and toxicity.

Panda J, Das D. (2025) ***Superparamagnetic iron oxide nanoparticle-based nanosystems for cancer theranostics*****.** Global Translational Medicine**. 2025;4(2):31–50.**
This article reviews SPIONs' (Superparamagnetic Iron Oxide Nanoparticles) synthesis and stabilisation (via organic/inorganic coatings), multifunctional uses (MRI imaging, hyperthermia, drug delivery), surface functionalisation strategies, and translational barriers.

Mirzaei N, Wärnberg F, Zaar P, et al. (2023) ***Ultra-low dose of superparamagnetic iron oxide nanoparticles for sentinel lymph node detection in patients with breast cancer*****.** Annals of Surgical Oncology**. 2023;30:5685–5689.**
This clinical study demonstrates the feasibility of detecting sentinel lymph nodes in breast cancer patients using very low doses of SPIONs.

Appendix IV – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018 and the designation of Financial Modelling & Valuation Analyst by the Corporate Finance Institute. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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