PITT STREET RESEARCH

Imagion Biosystems

Advancing MagSense

Share Price: A$0.015

Imagion Biosystems (ASX:IBX) continues to progress its MagSense technology. Imagion is completing a phase 1 trial (in-human study) of MagSense for HER2-positive breast cancer, and in pre-clinical stages for diagnosis of prostate, ovarian, and brain cancers.

ASX:IBX

Sector: Health Care Equipment & Services

25 July 2023

Market cap. (A$m)	16.8
# shares outstanding (m)	1,284.0
# share fully diluted	1,411.0
Market cap ful. Dil. (A$m)	21.2
Free float	100%
12 months high/low (A$)	0.044 / 0.012
Average daily volume (x1,000)	2,064.1
Website	www.imagionbiosystems.com

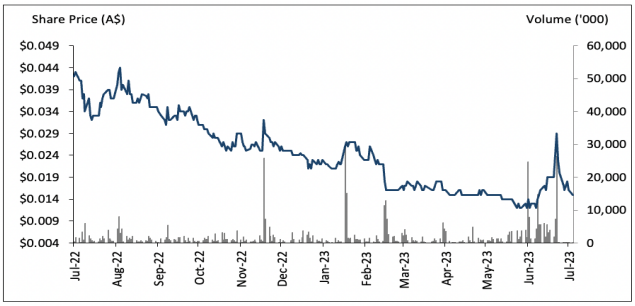
Source: Company, Pitt Street Research

The next steps

The company is now planning a multi-site phase 2 clinical trial in the US and hopes to file an Investigational New Drug (IND) application in Q4 2023 or Q1 2024. It is completing a study design based on positive feedback from the FDA about the key elements of the company's proposed Phase 2 study design and has provided further guidance and recommendations, consistent with regulatory oversight for products at MagSense's stage (namely, entering Phase 2).

In February 2023, Imagion received encouraging feedback on MagSense technology from an independent panel of breast cancer radiologists, which highlighted the potential use of its imaging agent for detection of tumour cells in lymph nodes by an MRI scanner.

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



Source: Refinitiv Eikon, Pitt Street Research

MagSense offers significant promise

MagSense is likely to be a game changing solution at addressing the unmet need for non-invasive and non-radioactive diagnostic methods that are more effective than solutions on the market today. Existing mechanisms are often unable to detect early-stage cancers and may only be able to identify areas of interest for follow-up scanning as opposed to confirming cancer. MagSense can be used with conventional MRI scanners in existing clinical practice, thereby reducing costs for clinicians.

Valuation metrics	
DCF valuation range (A$)	0.036-0.055
WACC	10.6%
Terminal growth rate	2%

Source: Pitt Street Research

Imagion is undervalued based on our estimates

As outlined in our initiation report, we value Imagion at $83.1m in our base case and $126.7m in our optimistic case using a DCF approach – assuming successful commercialisation of MagSense. Our valuation equates to 3.6c per share and 5.5c per share respectively taking into account anticipated dilution in the next few years. At the current number of shares, however, this is 7.3c per share base case and 11.2c per share bull case. Please refer to page 6 for further detail on our valuation and page 7 for the key risks.

Subscribe to our research HERE

Analysts: Stuart Roberts, Nick Sundich

Tel: +61 (0)4 4724 7909

Stuart.Roberts@pittstreetresearch.com

Nick.Sundich@pittstreetresearch.com

Table of Contents

Re-introduction to Imagion Biosystems

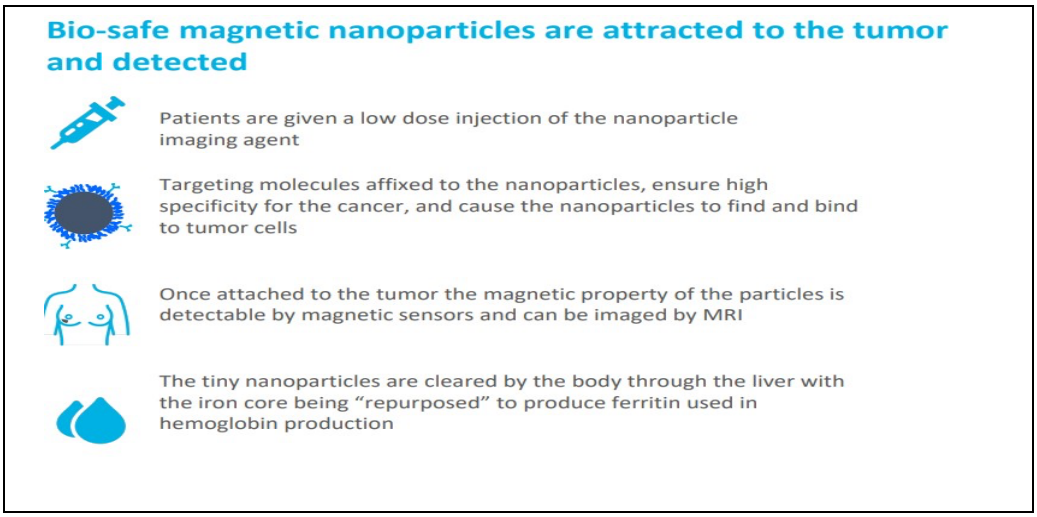
MagSense is better than other imaging modalities such as PET or non-targeted MRI

Who is Imagion Biosystems (ASX:IBX)? Imagion Biosystems (Imagion) is an Australian diagnostic imaging technology developer responsible for the MagSense technology.

What is MagSense? MagSense is a diagnostic imaging technology, specifically an agent that can be implemented into mainstream clinical scanners. It is better than other imaging modalities such as PET or non-targeted MRI as it does not involve ionizing radiation, radioactive tracers and does not provide specific detection of the cancer for non-targeted MRI.

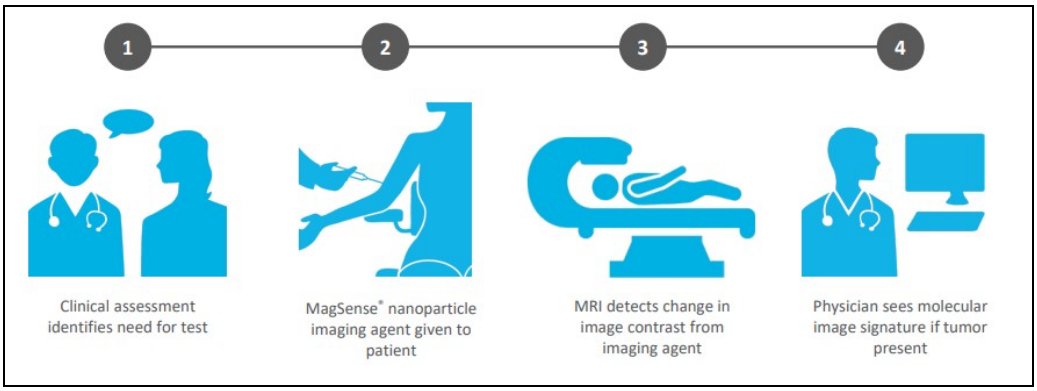
How does MagSense work? A typical MagSense procedure (Figures 1 and 2) will involve the administration of a small intravenous injection (or injection via another route of administration) of cancer-specific targeting nanoparticles to patients followed by an MRI scan the same day (or next day). The MRI scan will reveal a distinct pattern if cancer cells are present. When combined with conventional information such as irregular tissue morphology, the image contrast created by MagSense® imaging agent provides added context for the radiological review.

Figure 1: How MagSense works



Source: Company

Figure 2: MagSense' use in the context of its use



Source: Company

Why is MagSense superior to alternative imaging agents? MagSense works as a superior imaging because the magnetic property of the bio-safe nanoparticles allows the MRI scanner to detect the nanoparticles with an image pattern that is distinct when the antibody has bound the nanoparticles to its target. And the detection of these magnetic nanoparticles allows a radiologist to determine if cancer cells are present. This is an improvement from the status quo where imaging it focused on identifying general anatomical or morphological irregularities. They cannot identify cancer cells specifically, just a region of interest. The company is targeting to use MagSense for diagnosing multiple oncology indications including HER2 breast cancer, prostate cancer, ovarian cancer and brain cancer.

How far has Imagion progressed MagSense? Imagion is completing a first-in-human study of the MagSense technology in HER2-positive breast cancer (targeting HER2 expression). In February 2023, a review of interim data from the study by an independent group of radiologists deduced that MagSense was detectable in patient's lymph nodes and that using MRI with MagSense, radiologists could observe a differentiated image between normal lymph nodes and nodes that could contain cancer cells.

The next step for the company is a Phase 2 study which it plans to undertake in the US.

The next step for the company is a Phase 2 study which it plans to undertake in the US, with the eventual goal being commercialisation of the technology. Imagion hopes to file an Investigational New Drug (IND) application with the FDA in Q4 of 2023 or Q1 of 2024, with the intention of commencing a trial thereafter. The company has received positive feedback from the FDA about the key elements of the company's proposed Phase 2 study design and has provided further guidance and recommendations, consistent with regulatory oversight for products at MagSense's stage (namely, entering Phase 2).

Besides breast cancer, MagSense is under preclinical development for its application in diagnosis of prostate and ovarian cancers. The technology is also being researched in brain cancer diagnosis under product concept stage. Further, Imagion is exploring the use of its nanoparticles as a vascular imaging aid in the diagnosis of cardiovascular diseases.

The global cancer diagnostics market is worth US$177bn today and is likely to reach US$336bn by 2031.

What is the opportunity for MagSense? As outlined in our initiation report, the global cancer diagnostics market is worth US$177bn today and is likely to reach US$336bn by 2031 as cancer cases continue to rise. The rising demand for non-invasive cancer diagnostic procedures from the patient and physician community clearly indicates the significant opportunity for Imagion in the field of cancer diagnostics.

Breast cancer in particular is a big opportunity. In the US alone, 39.5m mammograms as performed annually according to FDA statistics. And it is estimated that 50% of women experience false-positive results at least once during a period of 10 years while undergoing annual mammography procedures. Additionally, breast cancer is often detected at later stages because mammograms are unable to detect the cancer when it is still in the initial stage. Imagion's technology presents a solution to this challenge by allowing early detection and continuous monitoring of disease progression. The technology is currently in phase 1 showing encouraging results.

The market opportunity for HER2-positive breast cancer alone is significant given that MagSense can eliminate lymphadenectomy in possibly 50% of the patients and remove uncertainties related to mammograms.

Progress Imagion has made

Moving to the next stage

Although Imagion has not yet completed the MagSense HER2 Phase 1 Study, this milestone is immanent. The study has achieved its enrolment target and it will formally cease new enrolments at the end of July. Data from the study has indicated that it has been a complete success. MagSense was detectable by both imaging methods employed in the study (the company's proprietary magnetic relaxometry technology and conventional MRI) and it was safe and tolerable with no issues reported.

During 2017 and 2018, Imagion worked on further developing the technology from the basic proof-of-principle to a state of readiness for moving into clinical testing. By September 2018, Imagion had initiated manufacturing of the first batch of nanoparticles as per GMP standards, which was needed for clinical testing. Imagion commenced pre-clinical safety and toxicology studies for its lead indication in February 2019. Notably, the FDA granted MagSense the Breakthrough Device designation in July 2019. Although this is less relevant now considering the transition to using MagSense as an 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.

In H1 2021, Imagion started the enrolment for phase 1 trial for MagSense technology for detecting HER2 metastatic breast cancer started. In December 2022, the company presented the interim results of its phase 1 study at the San Antonio Breast Cancer Symposium, highlighting the specificity and safety of MagSense® and in February 2023 announced the strategic shift to use of MRI as the detection method. Most recently, in March 2023, Imagion received positive feedback from FDA in relation to its proposed phase 2 trial design, based on which the company is planning to conduct a multi-site phase 2 clinical trial in the US.

Imagion envisages filing the IND submission by Q4 2023 or Q1 2024.

Imagion envisages filing the IND submission by Q4 2023 or Q1 2024. It is likely that the company will be able to commence the trial in the following months. The company is on solid footing to progress to the next stage of MagSense's clinical development. We expect that the company's progress will not only create value for shareholders but also make a solid contribution to the field of medical imaging.

A new leadership structure and new CEO

In late April, Imagion announced that it would separate the role of chair and CEO. Bob Proulx, who occupied both roles, opted to retire from the role of CEO once a replacement was found, while remaining as Chair. On 19 June 2023, after a process that involved the screening of more than 60 candidates, the company announced that it had appointed Dr Issac Bright as CEO, effective the following day.

Dr Bright brings over 20 years' experience as a health industry executive and venture capitalist in medical technology, biopharmaceuticals and oncology-based molecular diagnostics. He most recently served as an executive on several clinical stage biotechs - most recently as Co-Founder, CEO, and Chairman of RubrYc Therapeutics before its trade sale to iBio, Inc. in September 2022. He holds a bachelor's degree in biochemistry from Pepperdine University, a medical degree from the Stanford University School of Medicine and earnt his MBA from the Wharton School at the University of Pennsylvania as a Howard E. Mitchell Fellow. He will be based in San Diego and will provide hands-on leadership on Imagion's US team. It is positive for

the company to have someone of his skills and credentials as it enters this pivotal phase of its existence.

Valuing Imagion

We value Imagion at $83.1m in our base case and $127.6m in our optimistic case

As outlined in our initiation report, we value Imagion at $83.1m in our base case and $127.6m in our optimistic case, using a DCF valuation assuming certain levels of market penetration in relation to the indications being targeted. Our valuation equates to 3.6c per share and 5.4c per share taking into account our assumptions of capital raised up until FY27, but is 7.2c per share in our base case and 11.3c per share in our bull case using the current number of shares.

We assumed that the company partners with a major healthcare company in a deal involving milestone payments (to cover R&D coasts) upon the passage of Phase II and III clinical trials and the beginning of sales all adding up to ~$50m over the next five years, in return for a 50% share of revenues from commercial sales.

We used a WACC of 10.5%, based on a 3.2% risk free rate of return (the rate of the 10-year government bond), an 8% equity premium and a 1.16 beta (based on the industry average for Healthcare Product Companies)[1]. We modelled a soft commercial launch for HER2 breast cancer in FY27. This is followed by launch of prostate and ovarian cancer solutions by FY29, and brain cancer solutions by FY31.

The two key differences between our base case and bull case assumptions pertain to market penetration and product pricing. Please see Figure 3 for our valuation and Figure 4 for a table that outlines the sensitivity of our share price to various WACCs.

Figure 3: DCF valuation for Imagion

Valuation (A$m)	Base case	Bull case
Present value of FCF	4.7	13.2
Present value of Terminal FCF	77.0	112.1
Enterprise Value	**81.8**	**125.3**
Net debt (cash)	(1.4)	(1.4)
Equity value	**83.1**	**126.7**
Share outstanding (FY 2027E)	2,303.7	2,303.7
Implied price (A$ cents)	**3.6**	**5.5**
Adjusted Current price (A$ cents)	1.5	1.5
Upside (%)	*140.0%*	*266.7%*

Source: Pitt Street Research

[1] https://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/Betas.html

Figure 4: DCF value in A$ cents using various WACCs (base case)

Sensitivity						
WACC	**10.6%**					
Terminal Growth	**2.00%**					
Implied Price		*11.5%*	*12.5%*	*13.5%*	*14.5%*	*15.5%*
Change in Terminal Growth Rate	*1.25%*	5.2	4.2	3.4	2.9	2.5
	1.50%	5.3	4.3	3.5	2.9	2.5
	1.75%	5.4	4.3	3.5	3.1	2.5
	2.00%	5.4	4.3	**3.6**	3.0	2.5
	2.25%	5.4	4.5	3.7	3.3	2.6
	2.50%	5.4	4.5	3.8	3.5	2.6
	2.75%	5.5	4.6	3.8	3.5	2.6

Source: Pitt Street Research

Catalysts for a re-rating

We believe the following factors can contribute to the re-rating of Imagion in the direction of our valuation range:

- Completion of its Phase 1 study and receipt of official trial results.
- Successful results from phase 2 clinical trial in the US for patients with HER2-positive breast cancer.
- Meeting commercialisation milestones in relation to HER2-positive breast cancer in a timely manner.
- Encouraging results from studies and trials supporting the use of the MagSense technology for diagnosing prostate and ovarian cancers.
- Strategic collaboration or licensing agreement with any of the major medical technology players for Imagion's technology.

Key risks facing Imagion

We see four major risks for Imagion as a company and as a listed stock:

- **Funding risk**. Imagion currently has a funding commitment of ~A$18m that will help support the initial commercialisation activities. However, we estimate that the company will require further capital for commercialisation and R&D activities necessary for commercialisation. In case there is a delay in arranging further funding, it might impact the company's prospects and stock's valuation.
- **Execution risk**. There could be unexpected delays in the commercialisation process. Moreover, even after commercialisation, the company may not be able to penetrate the potential market at expected levels. Such setbacks will impact the cash flows and thus, valuation of the stock.
- **Clinical risk**. There is the risk that Imagion's clinical work with MagSense may not yield promising results for other oncology indications such as prostate, ovarian and brain.
- **Technology risk**. There is the risk that newer technologies with a superior cost profile in the personalised oncology space can emerge before Imagion has fully realised the commercial potential of MagSense.

Appendix I – Analyst 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, and numerous other 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. 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.

General advice warning, Disclaimer & Disclosures

Terms & Conditions

The information contained herein ("Content") has been prepared and issued by Pitt Street Research Pty Ltd ACN 626365615 ("Pitt Street Research"), an Authorised Representative (no: 1265112) of BR Securities Australia Pty Ltd. ABN 92 168 734 530, AFSL 456663. All intellectual property relating to the Content vests with Pitt Street Research unless otherwise noted.

Disclaimer

Pitt Street Research provides this financial advice as an honest and reasonable opinion held at a point in time about an investment's risk profile and merit and the information is provided by the Pitt Street Research in good faith. The views of the adviser(s) do not necessarily reflect the views of the AFS Licensee. Pitt Street Research has no obligation to update the opinion unless Pitt Street Research is currently contracted to provide such an updated opinion.

Pitt Street Research does not warrant the accuracy of any information it sources from others. All statements as to future matters are not guaranteed to be accurate and any statements as to past performance do not represent future performance. Assessment of risk can be subjective. Portfolios of equity investments need to be well diversified and the risk appropriate for the investor. Equity investments in a listed or unlisted company yet to achieve a profit or with an equity value less than $50 million should collectively be a small component of an individual investor's equity portfolio, with smaller individual investment sizes than otherwise. Investors are responsible for their own investment decisions, unless a contract stipulates otherwise. Pitt Street Research does not stand behind the capital value or performance of any investment.

Subject to any terms implied by law and which cannot be excluded, Pitt Street Research shall not be liable for any errors, omissions, defects or misrepresentations in the information (including by reasons of negligence, negligent misstatement or otherwise) or for any loss or damage (whether direct or indirect) suffered by persons who use or rely on the information. If any law prohibits the exclusion of such liability, Pitt Street Research limits its liability to the re-supply of the Information, provided that such limitation is permitted by law and is fair and reasonable.

General Advice Warning

The Content has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) personal advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances; ensure you obtain, read and understand any applicable offer document.

Disclosures

Pitt Street Research has been commissioned to prepare the Content. From time to time, Pitt Street Research representatives or associates may hold interests, transact or hold directorships in, or perform paid services for, companies mentioned herein. Pitt Street Research and its associates, officers, directors and employees, may, from time to time hold securities in the companies referred to herein and may trade in those securities as principal, and in a manner which may be contrary to recommendations mentioned in this document.

Pitt Street Research receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where Pitt Street Research has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.