PITT STREET RESEARCH

Imagion Biosystems

Strong financing in place to support execution strategy

Share Price: A$0.028

ASX: IBX

Sector: Health Care Equipment & Services

30 June 2020

An innovative medical device company

Imagion Biosystems (ASX: IBX) is an Australian medical device company whose MagSense diagnostic imaging technology, currently in early-stage development, can potentially improve on PET and MRI imaging modalities. Imagion is currently in preclinical development, with the first human pilot studies of the technology targeted for 2020. The FDA granted MagSense a Breakthrough Device designation in July 2019.

Imagion to commence Phase I clinic study in late FY20

Imagion intends to undertake a first-in-human study of the MagSense technology initially in HER2-positive breast cancer in Q4 FY20, to be followed later in prostate cancer and ovarian cancer. With HER2-positive breast cancer, the goal will be to establish a non-invasive method of detection of cancer in the lymph nodes, compared with the conventional biopsy of the sentinel lymph nodes. Imagion intends to sell MagSense on a 'printer and ink' model, where a low sales price for the SQUID equipment (US$0.5m at a 50% gross margin) is matched by a higher selling price for the nanoparticles (US$1,500 per test at an 80% gross margin). We estimate Imagion can potentially look to make its commercial launch in 2022 or 2023.

Imagion signs deal with Siemens Healthineers

In May 2020, Imagion signed a collaboration agreement with a leading medical technology firm Siemens Healthineers to explore the use of Imagion's MagSense nanoparticles as an MRI contrast agent for patients with HER2 metastatic breast cancer. The deal will also pave the path for Imagion to further explore MRI as a commercialisation strategy.

Funding raised through multiple avenues

In April 2020, Imagion raised A$2.5m through a renounceable rights issue, exceeding its initial goal of A$2m. Furthermore, Imagion generated funds through sale of nanoparticles formulation to other medical equipment manufacturers (A$0.56m) and R&D tax incentives worth A$4.2m. This was further supported by an improvement in cash flow generation on account of prudent fiscal management in 2019.

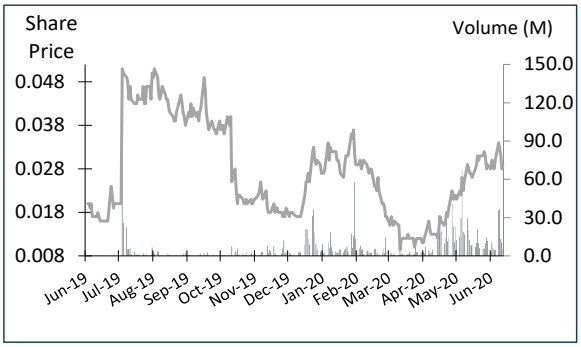
Imagion is undervalued based on our numbers

We value Imagion at 12 cents base case and 26 cents optimistic case on a risk-weighted DCF basis. We see Imagion being re-rated closer to our valuation range on the back of improved sentiment towards MagSense as a Breakthrough Device, as the company takes the device to clinic.

Market Cap. (A$ m)	22.1
# shares outstanding (m)	761.8
# shares fully diluted	877.5
Market Cap Ful. Dil. (A$ m)	24.6
Free Float	77.7%
52-week high/low (A$)	0.07 / 0.01
Avg. 12M daily volume (m)	6.4
Website	imagionbiosystems.com

Source: Company, Pitt Street Research

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



Source: Refinitiv, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.12–0.26
WACC	13.6%
Assumed terminal growth rate	3-5%

Source: Pitt Street Research

Analyst: Stuart Roberts

Tel: +61 (0)447 247 909

Stuart.Roberts@pittstreetresearch.com

Table of Contents

On track with commercialisation plans

First Australian clinical study to commence in Q4 FY20

Imagion to commence first Australian clinical trial in Q4 FY20

On 22 June 2020, Imagion announced its plans to conduct its first Australian in-human clinical study by Q4 FY20, which will involve the use of the company's MagSense diagnostic imaging technology. As part of the clinical study, Imagion also intends to explore the utility of its nanoparticles as a potential MRI contrast agent.

The Phase I study will allow Imagion to evaluate the company's MagSense HER2 nanoparticle test reagent for safety and initial effectiveness for lymph nodal metastases in HER2 breast cancer. It is expected to enrol 15 – 20 patients, subject to Human Research Ethics Committee (HREC) approval.

We see the initiation of a first-in-human clinical study as a significant milestone for Imagion as it will allow the company to demonstrate the safeness of nanoparticles and their effectiveness in detecting the presence and spread of HER2 breast cancer.

Manufacturing partner begins production of nanoparticle formulation

In February 2020, Imagion announced that it has started manufacturing its nanoparticle formulation, which is to be used in its first in-human study. Production will be carried out by contract manufacturing partners that have already been vetted by Imagion. The company has ensured that partners are in compliance with the Good Manufacturing Practice (GMP) standards.

First phase of manufacturing of the MagSense HER2 nanoparticle formulation has been completed on time

In May 2020, Imagion reported that the first phase of manufacturing of the MagSense HER2 nanoparticle formulation under GMP conditions has been completed on time. The company is now proceeding with completing the second phase of manufacturing the nanoparticle material. Meanwhile, Imagion is also monitoring the potential impact of COVID-19 and working on getting the clinical sites ready for its first-in-human study.

Receives patent approval in India

A US patent was granted in March 2019 under "Methods and Apparatuses for the localisation and treatment of disease such as cancer". The patent extends Imagion's core technology to therapeutic applications. In November 2019, the company received a patent in India for its core intellectual property related to detection, measurement and imaging using targeted magnetic nanoparticles. The number of people diagnosed with cancer in India stood at 1.15 million in 2018 and is expected to reach 1.41 million by 2026. According to Indian Cancer and Medical Research (ICMR), breast and lung cancer are the most common cancer types in the country. Imagion's early-detection, non-invasive technology will be critical in India, where 60% of breast cancer patients are diagnosed in late stages.

All cashed up to power through the execution strategy

Imagion secures deal with Siemens Healthineers to advance MagSense technology in breast cancer patients

Imagion inks deal with Siemens Healthineers, a leading medical technology firm, to advance its MagSense technology in breast cancer patients

In May 2020, Imagion signed a collaboration agreement with a leading medical technology firm Siemens Healthineers to explore the use of Imagion's MagSense nanoparticles as an MRI contrast agent for patients with HER2 metastatic breast cancer. This collaboration deal will see Imagion work together with Siemens Healthineers on identifying the most appropriate MRI scanning protocols for MagSense nanoparticles targeting HER2, which is a crucial development for breast cancer patients.

Imagion landed this deal with Siemens Healthineers following its World Molecular Imaging Conference in September 2019 where it demonstrated the potential application of its MagSense nanoparticles as an MRI contrast agent. The deal with Siemens Healthineers will help to pave the path for Imagion to further explore MRI as a commercial pathway. Given the large global installed base of existing MRI scanners, we think there is a material upside to the company if it becomes successful in proving the effectiveness and usefulness of its MagSense nanoparticles as an MRI contrast agent.

Renounceable rights issue raises A$2.5m for first human study

Imagion set out to raise A$2.5m via a renounceable rights issue in April 2020. The offer was oversubscribed (A$3.3m raised), but only additional A$0.45m could be placed. The aim of the rights issue was to fund R&D expenses, particularly the cost related to producing and testing nanoparticle formulations, along with clinical trials for the first human study. The investors' response towards the rights issue is a positive signal for the company's future prospects.

Tax incentives and compensation cut support expenses

Tax rebate of A$4.2m from the Australian Taxation Office have been received under the R&D Tax Incentive Program to strengthen balance sheet position

The company received a total tax rebate of A$4.2m from the Australian Taxation Office under the Research and Development Tax Incentive Program. The refund was split in two payments of A$2m in July 2019 and A$2.2m in April 2020. In response to the COVID-19 crisis, the Directors have elected to waive their fees for the current quarter, and the Executive Chairman and CEO, BOB Proulx, will take an equivalent salary reduction.

Order placed for Imagion's nanoparticle technology

NewPhase Ltd., an Israeli biotechnology company developing cancer treatment, has placed an order worth A$300,000 for Imagion's proprietary nanoparticles. NewPhase is developing a cancer therapy based on hyperthermia, the principle of killing cancer cells with heat, and plans to leverage Imagion's nanoparticles technology. The deal will bolster revenue generation capabilities and presents complementary product opportunities.

Improved profitability in 2019

Net loss of Imagion decreased 60% YoY from A$8.3m to A$3.4m in 2019, due to stricter expense control and benefit from the ~A$2mn R&D tax rebate. Prudent fiscal control and workforce reduction helped lower the net operating cash outflow by 36% to A$4.6m. Further, the company generated A$0.56m from the sale of nanoparticles to third parties researching biomedical applications.

Ten reasons to look at Imagion

1) MagSense is an important improvement on the standard of care, allowing more sensitive, specific and safe detection of cancer at a much earlier stage of development than competing modalities such as CT and MRI scans.

2) MagSense achieved Breakthrough Device designation. The July 2019 Breakthrough Device designation by the FDA for MagSense in HER2-positive breast cancer was an important development for Imagion. It not only allows expedited dialogue with the Agency but also recognises that MagSense is more than 'just another device'.

3) The business opportunity for Imagion with MagSense is large, given that cancer diagnostic tools represent a US$100bn market globally, and the largest share of that market is held by diagnostic imaging.

4) The market opportunity for HER2-positive breast cancer is particularly significant, as the use of MagSense in this cancer can eliminate lymphadenectomy in possibly 50% of patients, as well as remove uncertainties related to mammograms. There are ~50,000 new cases of HER2-postive breast cancer in the US annually.

5) MagSense goes to the clinic soon, with the first-in-human study of the product expected to commence in 2020, potentially allowing the first pivotal study to commence by late 2021.

6) MagSense has secured a collaboration agreement with Siemens Healthineers. In May 2020, Imagion signed a collaboration agreement with a leading medical technology firm Siemens Healthineers to explore the use of Imagion's MagSense nanoparticles as an MRI contrast agent for patients with HER2 metastatic breast cancer. The deal will also pave the path for Imagion to further explore MRI as a commercialisation strategy.

7) The business plan for Imagion is compelling, with Imagion proposing to sell MagSense on a 'printer and ink' model, where a low sales price for the equipment is matched with a higher selling price for the nanoparticles. This approach has been the basis of success for many medical equipment companies and should allow rapid sales growth, so long as the clinical data validates MagSense approach.

Imagion has a strong and capable leadership team, combining decades of extensive experience in the pharmaceutical, diagnostics and medical technology industries

8) Imagion has a strong leadership team. Imagion's Executive Chairman is Bob Proulx, whose background in medical devices includes a stint as President of Silicon Biosystems, developer of a liquid biopsy diagnostic system. Imagion's Vice President of Clinical & Regulatory Affairs is Dr. Oliver Steinbach, whose background includes 20 years of experience in the pharmaceutical, diagnostics and medical technology industries including 12 years at PHILIPS in MRI. The other directors of Imagion are Mike Harsh (long-time head of diagnostic imaging engineering at GE), David Ludvigson (an American life sciences entrepreneur), Jovanka Naumoska (an Australian corporate lawyer), Mark Van Asten (an Australian diagnostic entrepreneur) and Dianne Angus. Imagion's CFO, Brian Conn, has a long track record of working on the financial side of small biotech and medical device companies. VP of R&D, Dr. Marie Zhang, brings chemistry expertise of over 25 years. Imagion also created a Scientific Advisory Board with reputable oncology expertise from both Australia and US.

9) Imagion has had success in fund raising. Imagion raised A$12m at IPO and another A$4.3m in a 2018 rights issue. Further capital was raised through a renounceable rights issue in April 2020, and the response was overwhelming as the company ended up raising more than its initial target. Additionally,

through its Australian parent, Imagion is eligible for R&D tax credits and has received A$4.2m so far.

10) Imagion is undervalued based on our numbers. We value Imagion at 12 cents base case and 26 cents optimistic case on a risk-weighted DCF basis. We see Imagion being re-rated closer to our valuation range on the back of improved sentiment towards MagSense as a Breakthrough Device, as the company takes the device to clinic.

MagSense bridging gap between traditional imaging and newer screening technologies

Imagion plans to expand the applications of the technology, such as delivering therapeutics to targeted cells or diagnosing diseases other than cancer

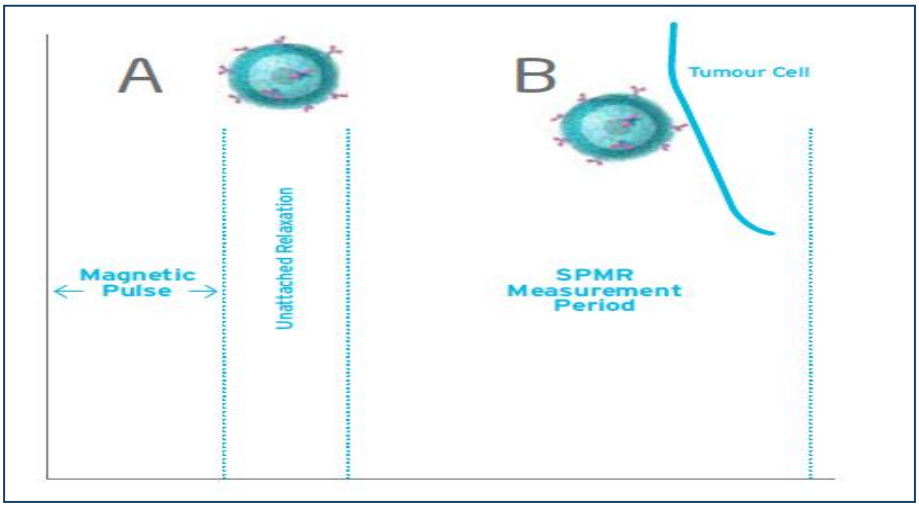
The MagSense technology is being developed with the objective of bridging the gap between existing medical imaging technologies, which lack the ability to identify the molecular makeup of the region of interest, and newer screening technologies – such as liquid biopsy – which have limited ability to precisely locate the target cells. The technology is being developed to provide a high-level overview of cancer cells, i.e., location of tumour, size of tumour and details such as molecular specificity. Imagion plans to expand the applications of the technology to other areas, such as delivering therapeutics to targeted cells or diagnosing diseases other than cancer. In February 2019, Imagion received an important US patent (No. 10,194,825) to include both detection and treatment.

Currently, the MagSense technology is being investigated for the detection and diagnosis of solid cancerous cells, such as those present in breasts, prostate or lungs. We believe that the technology can be further expanded to other indications once the proof-of-concept is established.

Technology involves delivery of payloads attached to nanoparticles to locate/quantify tumour cells

MagSense technology leverages the unique properties of specialised nanoparticles to locate and quantify diseased areas, such as cancer, present in the human body based on their distinct cell features. These nanoparticles are conjugated with antibodies or small molecules to enable them to bind with specific antigens present on the surface of target cells. Upon binding, the nanoparticles exhibit a unique magnetic signature, which is not exhibited by any other structure in the human body (including unbound nanoparticles). As can be seen in Figure 1, nanoparticles (particle B) that are attached to tumour cells relax from the magnetised state at a slower rate than particles that are unbound (particle A).

Figure 1: Magnetising particles and measuring relaxation time in few seconds



Source: Company

The detection of a magnetic signature allows the identification and quantification of targeted cells (e.g., cancer cells) without interference from any other substance/tissue in the human body. The physics and principles of magnetic relaxation of bounded nanoparticles are well characterised by and described within the research community as superparamagnetic relaxometry (SRPM), which is being employed by the company for detecting different types of tumours, including prostate, ovarian and breast tumour cells.

Breakthrough Device designation, a critical milestone in de-risking Imagion's clinical programme

In July 2019, Imagion received the Breakthrough Device designation from the Centre for Devices and Radiological Health (CDRH) of the United States Food and Drug Administration (USFDA). Granting of the Breakthrough Device designation to Imagion's MagSense system and its test for HER2-positive breast cancer staging represents a significant achievement for Imagion, as this designation is granted only to devices that are anticipated to provide an effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.

HER2-positive indication is the initial indication for which Imagion received Breakthrough Device designation

The designation granted to MagSense system and associated test for HER2 breast cancer is a clear indicator of a transformative opportunity in healthcare. In addition, it validates MagSense's ability to improve the standard of care for staging HER2-positive breast cancer. Imagion's device aims to eliminate unnecessary surgeries and concomitant morbidities that result from the current standard-of-care biopsy procedures. The device is expected to emerge as a non-invasive and non-radioactive procedure, which will be used for detecting the presence and progression of HER2-positive breast cancer.

Unlike current biopsy procedures, Imagion's MagSense system would not require the removal of tissue from the patient; rather, it will non-invasively detect/monitor the progression of HER2-positive breast cancer by delivering targeted nanoparticles to tumour cells.

Apart from fast-tracking the approval process for MagSense system, the grant of Breakthrough Device designation is expected to improve communication between the device manufacturer – Imagion – and the agency (USFDA) during device development and the review process of MagSense system and associated tests.

Valuing Imagion

We reiterate our valuation for Imagion at 12 cents per share base case and 26 cents per share optimistic case (Figure 2), using a DCF-based approach. We assumed that the company will not partner for MagSense and build its own distribution system for the product. We have retained our main assumptions related to WACC, launch date, peak sales, margins, etc., similar to the initiation report.

Figure 2: Our valuation of Imagion

	Base	Optim.
MagSense (A$m)	91.9	215.3
Value of tax losses	9.7	9.7
Underlying R&D cost	-24.0	-24.0
Cash now (A$m)	1.1	1.1
Cash from options and cash to be raised (A$m)	22.8	22.8
Total value (A$m)	101.5	225.0
Total diluted shares (million)	877.5	877.5
Value per share	$0.12	$0.26
Valuation midpoint	$0.19	
Share price now (A$ per share)	$0.039	
Upside to midpoint	377.0%	

Source: Pitt Street Research

Re-rating Imagion

We see the following factors contributing to the re-rating of Imagion in the direction of our valuation range:

- Successful completion of its first-in-human study in patients with HER2-positive breast cancer.
- Positive 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.

Please see https://www.pittstreetresearch.com/ for our initiating coverage on Imagion.

Appendix I – 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.

CT– The term "computed tomography", or CT, refers to a computerized x-ray imaging procedure, producing signals that are processed by the machine's computer to generate cross-sectional images—or "slices"—of the body.

GMP – Short for Good Manufacturing Practice; the set of standards laid down by regulators such as the FDA for the production of 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.

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.

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

MRI – Magnetic Resonance Imaging (MRI) uses a strong magnetic field and radio waves to create detailed images of the organs and tissues within the body.

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

PET – A positron emission tomography scan is a type of imaging test. It uses a radioactive substance called a tracer to look for disease in the body.

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

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

Appendix II – Analyst Qualifications

Stuart Roberts, lead analyst on this report, has been covering the Life Sciences sector as an 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 specialty 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 in 2015 and 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 Science 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 Science companies.

Appendix III– Risks related to Imagion

Risks specific to Imagion. We see four major risks for Imagion as a company and as a listed stock.

- **Funding risk**. More capital will likely be needed to continue clinical and commercial development of MagSense.
- **Engineering risk**. There is the risk that the device currently being developed by the company will take longer than expected to perfect.
- **Clinical risk**. There is the risk that Imagion's clinical work with MagSense will yield equivocal results.
- **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.

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.
- 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.

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, and 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.