



MEDICAL TECHNOLOGIES

19th July 2024

Market Announcements Office  
ASX Limited  
Exchange Centre  
20 Bridge Street  
Sydney NSW 2000

Dear Sir/Madam

**Allegra Medical Technologies Limited (AMT) – First Supplementary Target’s Statement**

We refer to Allegra Innovations Pty Ltd’s (**Allegra Innovations**) takeover offer of AMT. Pursuant to section 647(3)(b) of the Corporations Act 2001(Cth) as inserted by virtue of ASIC Corporations (Replacement Bidder’s and Target’s Statements) Instrument 2023/688, we attach by way of service a copy of the First Supplementary Target’s Statement of AMT dated 19 July 2024.

We have caused the First Supplementary Target’s Statement to be lodged with ASIC and served on the Bidder.

Kind Regards,

A handwritten signature in black ink, appearing to read "Patricia Vanni".

**Patricia Vanni**  
Company Secretary

**Allegra Medical Technologies Limited**

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## Allegra Medical Technologies Limited (ACN 066 281 132) First Supplementary Target's Statement in relation to the Allegra Innovations Offer

This document is a supplementary target's statement under section 644 of the Corporations Act 2001 (Cth). It is the first supplementary target's statement (**First Supplementary Target's Statement**) issued by Allegra Medical Technologies Limited (ACN 066 281 132) (**AMT**) in relation to the off-market takeover bid made by Allegra Innovations Pty Ltd (ACN 670 616 127) to purchase all of the ordinary shares in AMT. This document supplements, and should be read together with, AMT's target's statement dated 4 July 2024 (**Target's Statement**).

This First Supplementary Target's Statement has been prepared for the purpose of informing AMT Shareholders of additional information reasonably relevant to making an informed assessment of whether to accept the Allegra Innovations Offer.

Unless otherwise specified, capitalised terms used but not defined in this First Supplementary Target's Statement have the same meaning given to them in the Target's Statement. This First Supplementary Target's Statement prevails to the extent of any inconsistency with the Target's Statement.

A copy of this First Supplementary Target's Statement is being lodged with ASIC today. Neither ASIC nor any of its officers take any responsibility for its contents. A copy of this First Supplementary Target's Statement has also been provided to the ASX. Neither the ASX nor any of its officers takes any responsibility for the contents of this document.

### 1. Interests and dealings in AMT Shares

As at the date of both the Target's Statement and this First Supplementary Target's Statement, the AMT Directors had the following Relevant Interests in AMT Shares (excluding any acceptances under the Allegra Innovations Offer):

DIRECTOR NAME	CURRENT HOLDING	% OF IC	LAST ASX NOTICE
Nicholas Hartnell	52,257,354*	44.21	9 November 2023
Peter Kazacos	1,241,912**	1.05	9 November 2023
Sean Mulhearn	888,888***	0.38	9 November 2023

\* 51,033,264 held indirectly under the holder's name Robinwood Investments Pty Ltd.

\*\* 1,131,062 shares Indirectly held under the holder's name Destin Pty Ltd.

\*\*\* 444,444 shares Indirectly held under the holder's name Sean & Kirsten Pty Ltd. <Two S/F A/C>

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Allegra Innovations currently has a Relevant Interest in 60.17% of AMT Shares taking into account acceptances of the Allegra Innovations Offer as announced on the company announcements platform of the ASX as the date of this First Supplementary Target’s Statement.

**2. Dealings in AMT Shares**

In the 4-month period ending on the date immediately before the date of the Target’s Statement no AMT Director has acquired or disposed of a Relevant Interest in any AMT Shares, other than having agreed to enter into a deed to cancel their options over AMT Shares as set out in section 2.1 of the Target’s Statement (**Option Cancellation Deed**).

Additionally, on 6 September 2023, the AMT Directors and their Related Entities each took up entitlements under the Rights Issue under the Entitlement Offer (Offer Booklet dated 19 July 2023) as set out in the table below:

DIRECTOR NAME	ENTITLEMENTS	ASX NOTICE
Nicholas Hartnell	12,758,316	6 September 2023
Peter Kazacos	46,148	6 September 2023
Sean Mulhearn	222,222	6 September 2023

**3. Interests in Allegra Innovations shares**

As at the date of this First Supplementary Target’s Statement, no AMT Director had a Relevant Interest in Allegra Innovations shares other than Dr Nicholas Hartnell who owns 87% of all the issued shares in Allegra Innovations (being 870 of the 1,000 issued shares in Allegra Innovations), via his Related Entity, Robinwood. Robinwood acquired this interest in Allegra Innovations shares on 18 August 2023, being the incorporation date of Allegra Innovations.

Other than set out above, none of the AMT Directors acquired or disposed of a Relevant Interest in any Allegra Innovations shares in the 4-month period ending on the date immediately before the date of the Target’s Statement.

**4. Agreements by AMT Directors**

There are no agreements made between any AMT Director and any other person or entity in connection with, or conditional upon, the outcome of the Allegra Innovations Offer, other than as set out in section 10.7 of the Target’s Statement.

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As set out in section 10.7 of the Target's Statement, each Independent Director has entered into deeds releasing AMT from any claims they may have against AMT for any amounts due to them arising from their employment or engagement as a director of AMT. This release takes effect from the date the Allegra Innovations Offer is declared unconditional both in respect to the conditions of the Allegra Innovations Offer and as to acceptances.

Neither Mr Peter Kazacos nor Mr Sean Mulhearn has received any remuneration in connection with being a Director of AMT since July 2022.

Further, none of the AMT Directors (including Dr Nicholas Hartnell) will be seeking reimbursement of expenses reasonably incurred by them in connection with the Allegra Innovations Offer as they may be entitled to seek under section 642 of the Corporations Act.

#### **5. Benefits from Allegra Innovations**

None of the Independent Directors have agreed to receive, or are entitled to receive, any benefit from Allegra Innovations or any Related Entities of Allegra Innovations, other than in their capacity as the holder of AMT Shares.

None of the Independent Directors has any interest in any contract entered into by Allegra Innovations other than the Option Cancellation Deed.

Other than set out herein, none of the Independent Directors have any interest to and in Allegra Innovations.

#### **6. Costs**

Given the poor financial condition of AMT, the incurring of additional expenses associated with the Allegra Innovations Offer is likely to adversely impact AMT's cashflows and financial position, given that AMT is presently reliant upon existing debt facilities to meet its ongoing expenses.

#### **7. IER Report**

AMT appointed Stantons as the Independent Expert to give an independent opinion as to whether the Allegra Innovations Offer is fair and reasonable to AMT Shareholders not associated with Allegra Innovations. Stantons also appointed Acuity to provide the Valuation Report.

The Independent Expert's Report did not attach the Valuation Report. Stantons has since determined that the Valuation Report in full should form part of their Independent Expert's Report and has updated the Independent's Expert Report to both include the Valuation Report as an annexure and to make some further changes (**Updated Independent Expert's Report**). We note

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that the Independent Expert's opinion that the Allegra Innovations Offer is both **FAIR** and **REASONABLE** remains unchanged.

The Updated Independent Expert's Report (including the Valuation Report) is set out behind Attachment 1 to this First Supplementary Target's Statement.

## **8. Historical Share Trading Activity**

On 21 February 2024, AMT Shares went into a trading halt (**Trading Halt Date**). On 23 February 2024, AMT Shares went into suspension.

The following table sets out AMT Share trading information, including VWAP calculations and the Total volume traded, for the various periods up to the Trading Halt Date:

### **Allegra ASX Trading History**

Trading days	Low price (\$)	High price (\$)	VWAP (\$)	Cumulative volume traded	Percentage of total shares (%)	Annual equivalent (%)	Percentage of free float (%)	Annual equivalent (%)
1 Day	-	-	-	-	-	-	-	-
10 Days	0.022	0.029	0.0253	14,980	0.01%	0.32%	0.06%	1.54%
30 Days	0.022	0.044	0.0361	386,220	0.32%	2.74%	1.57%	13.21%
60 Days	0.022	0.058	0.0422	703,100	0.59%	2.50%	2.80%	11.76%
90 Days	0.022	0.058	0.0430	867,020	0.72%	2.05%	3.42%	9.55%
180 Days	0.022	0.075	0.0537	2,572,660	2.25%	3.18%	10.46%	14.53%
1 Year (255 trading days)	0.022	0.075	0.0547	2,760,950	2.48%	2.48%	11.36%	11.36%

*Source: Independent Expert's Report*

The Independent Expert has stated: "Trading in AMT Shares represents a low level of liquidity and is therefore not considered to be a reliable valuation measure".

Although the various AMT Share VWAP calculations set out in the table above demonstrate a price of AMT Shares higher than the Offer Consideration, the Independent Directors agree with the opinion of the Independent Expert that given the low level of liquidity in AMT Shares over the periods set out in the table above, the VWAP of AMT Shares is not considered to be a reliable valuation measure.

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## **9. Consents**

- (a) Stantons Corporate Finance Pty Ltd has given and has not before the date of this First Supplementary Target's Statement withdrawn its written consent to be named as the Independent Expert in this First Supplementary Target's Statement and to the inclusion in this First Supplementary Target's Statement of the Updated Independent Expert's Report behind Attachment 1 and the references to the Updated Independent Expert's Report elsewhere in this First Supplementary Target's Statement, in each case in the form and context in which they are included.
- (b) Acuity Technology Management Pty Ltd has given and has not before the date of this First Supplementary Target's Statement withdrawn its written consent to be named as the valuer who provided the valuation which is included in the Updated Independent Expert's Report behind Attachment 1 of this First Supplementary Target's Statement and the references to the valuation elsewhere in the Updated Independent Expert's Report and First Supplementary Target's Statement, in each case in the form and context in which they are included.
- (c) Each of the AMT Directors has given and not withdrawn their consent to:
  - a. be named in the Target's Statement and this First Supplementary Target's Statement in the form and context in which they are named; and
  - b. statements attributable to them being included in the Target's Statement and this First Supplementary Target's Statement in the form and context in which they appear.
- (d) Ms Jenny Swain, CEO of AMT, has given and not withdrawn her consent to:
  - a. be named in the Target's Statement and this First Supplementary Target's Statement in the form and context in which it appears; and
  - b. statements attributable to her being included in the Target's Statement and this First Supplementary Target's Statement in the form and context in which they appear.
- (e) Dr Nicholas Hartnell and Robinwood have given and not withdrawn their consent to:
  - a. be named in the Target's Statement and this First Supplementary Target's Statement in the form and context in which they appear; and
  - b. statements attributable to them being included in the Target's Statement and this First Supplementary Target's Statement in the form and context in which they appear.
- (f) Each person named in this section as having given its consent to the inclusion of a statement or to being named in this First Supplementary Target's Statement:
  - a. does not make, or purport to make, any statement in this First Supplementary Target's Statement or any statement on which a statement in this First Supplementary Target's Statement is based other than, in the case of a person referred to above as having given their consent to the inclusion of a statement, a statement included in this First Supplementary Target's Statement with the consent of that person; and
  - b. to the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this First Supplementary Target's Statement, other than a reference to its name and, in the case of a person referred to above as having given their consent to the inclusion of a statement, any statement or report which has been included in this First Supplementary Target's Statement with the consent of that party.

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**10. Authorisation**

This First Supplementary Target's Statement has been approved by the board of AMT by way a resolution passed by the Independent Directors. All Independent Directors voted in favour of that resolution. Dr Nicholas Hartnell was, for reasons set out in Section 1.3 of the Target's Statement, absent from the meeting during which the resolution was passed.

Signed by Peter Kazacos, a director of AMT duly authorised by resolution of the directors on AMT



Signature \_\_\_\_\_

Dated: 19 July 2024

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**Attachment 1**

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18 July 2024

The Independent Directors  
Allegra Medical Technologies Limited  
Level 8, 18-20 Orion Road  
Lane Cove West NSW 2066

Dear Independent Directors,

## Supplementary Independent Expert's Report Relating to the Takeover Offer

### 1 Executive Summary

#### Opinion

- 1.1 In our opinion, the proposed transaction outlined in the Target Statement ("**Target Statement**") relating to the proposed takeover offer of Allegra Medical Technologies Limited ("**Allegra**" or the "**Company**") by Allegra Innovation Pty Ltd ("**AI**"), is considered **FAIR** and **REASONABLE** to the Allegra shareholders not associated with AI ("**Non-Associated Shareholders**") as at the date of this report.

#### Introduction

- 1.2 Stantons Corporate Finance Pty Ltd ("**Stantons**") was engaged by the independent directors of Allegra to prepare an Independent Expert's Report ("**IER**") on the fairness and reasonableness of a proposal involving the acquisition of the Company by AI. An earlier version of this IER was released as part of the Target Statement on 4 July 2024.
- 1.3 Allegra is an Australian public company listed on the Australian Securities Exchange ("**ASX**") that develops orthopaedic devices. The Company's main product is the Sr-HT-Gahnite Spinal Cage Device ("**Spinal Cage Device**"). The Company has been suspended from trading on the ASX since 21 February 2024 pending an announcement regarding its funding arrangements and the proposed sale of all intellectual property relating to Sr-HT-Gahnite (the "**IP**").
- 1.4 The Company announced on 24 May 2024 that it had entered into a Bid Implementation Agreement (the "**Agreement**") with AI. Under the Agreement, AI proposes to acquire all of the outstanding capital of the Company by way of an off-market takeover pursuant to Chapter 6 of the Corporations Act 2001 (the "**Corporations Act**") for consideration of \$0.004 per ordinary share of Allegra (the "**Transaction**").

#### Purpose

- 1.5 Section 640 of the Corporations Act ("**s640**") specifies that the target of a takeover bid must commission an expert report when the bidder's voting power in the target is at least 30% of the target or when the bidder and the target have common directors.
- 1.6 AI is a wholly owned subsidiary of Robinwood Investments Pty Ltd ("**RIPL**"), an entity controlled by an Allegra director, Mr Nick Hartnell. RIPL holds an interest of 42.67% in the ordinary shares of Allegra, and accordingly AI has voting power in excess of 30%. Mr Nick Hartnell is also a director of both Allegra and AI.

- 1.7 The independent directors of Allegra have recommended that Shareholders accept the offer in the absence of a superior proposal, subject to an independent expert concluding that the Transaction is either fair and reasonable, or not fair but reasonable.
- 1.8 Accordingly, Allegra has commissioned Stantons to prepare an Independent Expert Report on the Transaction.
- 1.9 The proposed Transaction is described in the Target Statement to be forwarded to the Non-Associated Shareholders of Allegra. This IER provides an opinion on the fairness and reasonableness of the Transaction for Non-Associated Shareholders.

### *Basis of Evaluation*

- 1.10 With regard to the Australian Securities and Investments Commission (“ASIC”) Regulatory Guide 111: Content of Expert Reports (“RG111”), the Transaction is considered a control transaction, and we have assessed it as:
- fair if the value of the consideration offered is equal to or greater than the value of an Allegra share, on a control basis; and
  - reasonable if it is fair, or if despite not being fair there are sufficient reasons for Non-Associated Shareholders to accept the offer.

## Valuations

### *Allegra Share Value*

- 1.11 We engaged an independent specialist, Acuity Technology Management Pty Ltd (“Acuity”) to provide a valuation of the intellectual property owned by Allegra based on the commercial potential of the Company’s patented biomaterial, the Sr-HT-Gahnite Spinal Cage Device. The valuation was contained in the report titled “Independent Valuation of Intellectual Property – Allegra Medical Technologies Limited” prepared by Acuity and dated 4 July 2024 (the “Acuity Report”) attached as Appendix E. We have relied on the Acuity Report valuations in forming our opinion.
- 1.12 We assessed the fair market value of an Allegra ordinary share using a Net Asset on a realisation based approach (“Net Assets”) as our primary methodology, as follows.

**Table 1. Valuation of Allegra Shares**

	Ref	Low	Preferred	High
IP (\$)	Table 14	-	1,100,000	2,900,000
Other net assets (\$)	Table 8	(1,951,790)	(1,951,790)	(1,951,790)
Convertible Loan value eliminated (\$)	Table 8	1,279,721	1,279,721	1,279,721
<b>Pre-Transaction net assets (\$)</b>		<b>(672,069)</b>	<b>427,931</b>	<b>2,227,931</b>
Less: options value (\$)	Table 15	-	-	-
<b>Value attributable to ordinary shareholders</b>		<b>(672,069)</b>	<b>427,931</b>	<b>2,227,931</b>
Number of ordinary shares on issue	Table 9	152,666,206	152,666,206	152,666,206
<b>Value per ordinary share (\$) (control)</b>		<b>(0.0044)</b>	<b>0.0028</b>	<b>0.0146</b>
<b>Assessed value per ordinary share (\$) (control)</b>		<b>nil</b>	<b>0.0028</b>	<b>0.0146</b>

Source: Stantons analysis

- 1.13 Accordingly, we assessed the fair value of an Allegra ordinary share on a control basis to be between \$nil and \$0.0146, with a preferred value of \$0.0028.
- 1.14 We have assessed the Transaction under an alternative assumption regarding the treatment of a convertible loan from RIPL (refer to paragraphs 6.12 to 6.14). We note that under that scenario, the assessed value of an Allegra share is nil in the low and preferred cases, and lower than the above valuation in the high scenario.

### Value of Consideration

1.15 The consideration offered by AI is a cash offer of \$0.004 per share.

### Fairness Assessment

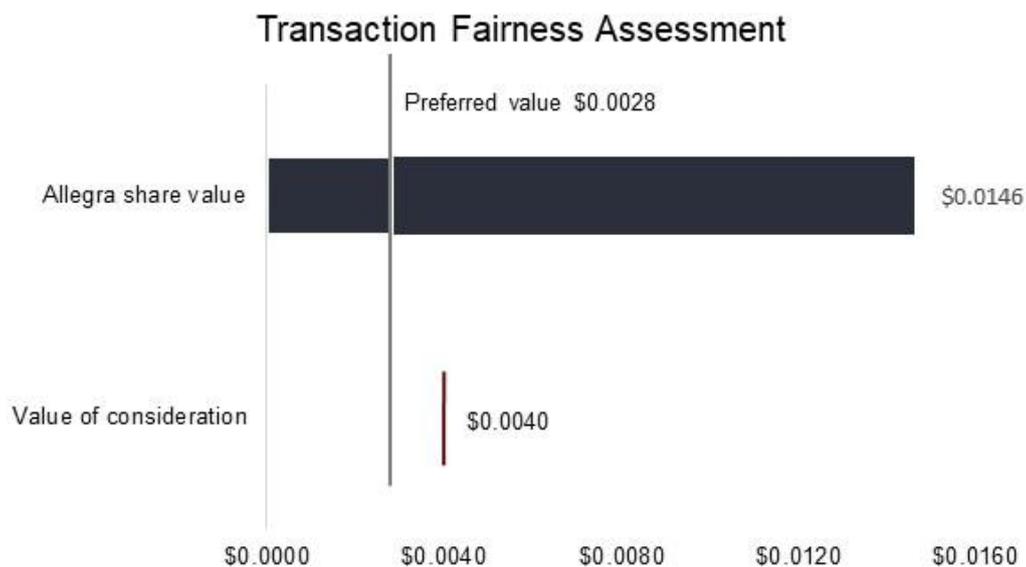
1.16 Our fairness assessment of the Transaction is set out below.

**Table 2. Fairness Assessment**

	Ref	Low	Preferred	High
Allegra share value (control) (\$)	Table 20	-	0.0028	0.0146
Consideration value (\$)	7.3	0.0040	0.0040	0.0040
<b>Fairness assessment</b>		<b>Fair</b>	<b>Fair</b>	<b>Not Fair</b>

Source: Stantons analysis

**Figure 1. Fairness Assessment**



1.17 We consider the Transaction to be **FAIR** to the Non-Associated Shareholders of Allegra.

### Reasonableness Assessment

1.18 As the Transaction is considered fair pursuant to RG111.12, it is also considered reasonable. For informative purposes, we considered the following advantages and disadvantages of the proposed Transaction to Shareholders.

**Table 3. Reasonableness Assessment of the Transaction**

Advantages	Disadvantages
<ul style="list-style-type: none"> <li>▪ The Transaction is fair</li> <li>▪ Provides liquidity</li> <li>▪ The Company's access to funding is uncertain</li> <li>▪ Certain cash outcome</li> <li>▪ No superior offers</li> <li>▪ No brokerage charges</li> </ul>	<ul style="list-style-type: none"> <li>▪ Offer price is below recent market prices</li> <li>▪ No exposure to potential future value of Allegra</li> </ul>
Other Factors	
<ul style="list-style-type: none"> <li>▪ May trigger a capital gains tax event</li> <li>▪ Tax loss benefits may be available</li> </ul>	

*Source: Stantons analysis*

### Conclusion

- 1.19 In our opinion, the Transaction proposal is **FAIR** and **REASONABLE** to the Non-Associated Shareholders of Allegra.
- 1.20 This opinion must be read in conjunction with the more detailed analysis included in this report, together with the disclosures, Financial Services Guide, and appendices to this report.

## Financial Services Guide

Dated 18 July 2024

### Stantons Corporate Finance Pty Ltd

Stantons Corporate Finance Pty Ltd (ABN 42 128 908 289 and AFSL Licence No 448697) ("**Stantons**" or "**we**" or "**us**" or "**ours**" as appropriate) has been engaged to issue general financial product advice in the form of a report to be provided to you.

### Financial Services Guide

In the above circumstances, we are required to issue to you, as a retail client, a Financial Services Guide ("**FSG**"). This FSG is designed to help retail clients decide as to their use of the general financial product advice and to ensure that we comply with our obligations as financial services licensees.

This FSG includes information about:

- a) who we are and how we can be contacted;
- b) the services we are authorized to provide under our **Australian Financial Services Licence, Licence No: 448697**;
- c) remuneration that we and/or our staff and any associates receive in connection with the general financial product advice;
- d) any relevant associations or relationships we have; and
- e) our complaints handling procedures and how you may access them.

### Financial services we are licensed to provide

We hold an Australian Financial Services Licence which authorises us to provide financial product advice in relation to:

- Securities (such as shares, options and debt instruments)

We provide financial product advice by virtue of an engagement to issue a report in connection with a financial product of another person. Our report will include a description of the circumstances of our engagement and identify the person who has engaged us. You will not have engaged us directly but will be provided with a copy of the report as a retail client because of your connection to the matters in respect of which we have been engaged to report.

Any report we provide is provided on our own behalf as a financial services licensee authorised to provide the financial product advice contained in the report.

### General Financial Product Advice

In our report, we provide general financial product advice, not personal financial product advice, because it has been prepared without considering your personal objectives, financial situation or needs. You should consider the appropriateness of this general advice having regard to your own objectives, financial situation and needs before you act on the advice. Where the advice relates to the acquisition or possible acquisition of a financial product, you should also obtain a product disclosure statement relating to the product and consider that statement before making any decision about whether to acquire the product. Where you do not understand the matters contained in the Independent Expert's Report, you should seek advice from a registered financial adviser.

### Benefits that we may receive

We charge fees for providing reports. These fees will be agreed with, and paid by, the person who engages us to provide the report. Fees will be agreed on either a fixed fee or time cost basis. Our fee for preparing this report is expected to be up to A\$20,000 exclusive of GST.

You have a right to request for further information in relation to the remuneration, the range of amounts or rates of remuneration and you can contact us for this information.

Except for the fees referred to above, neither Stantons nor any of its directors, employees or related entities, receive any pecuniary benefit or other benefit, directly or indirectly, for or in connection with the provision of the report.

## **Remuneration or other benefits received by our employees**

Stantons employees and contractors are eligible for bonuses based on overall productivity but not directly in connection with any engagement for the provision of a report.

## **Referrals**

We do not pay commissions or provide any other benefits to any person for referring customers to us in connection with the reports that we are licensed to provide.

## **Associations and relationships**

Stantons is ultimately a wholly owned subsidiary of Stantons International Audit and Consulting Pty Ltd, a professional advisory and accounting practice. From time to time, Stantons and Stantons International Audit and Consulting Pty Ltd (that trades as Stantons International) and/or their related entities may provide professional services, including audit, accounting and financial advisory services, to financial product issuers in the ordinary course of its business.

## **Complaints resolution**

### *Internal complaints resolution process*

As the holder of an Australian Financial Services Licence, we are required to have a system for handling complaints from persons to whom we provide financial product advice. All complaints must be in writing, addressed to:

The Complaints Officer  
Stantons Corporate Finance Pty Ltd  
Level 2  
40 Kings Park Road  
WEST PERTH WA 6005

When we receive a written complaint, we will record the complaint, acknowledge receipt of the complaint within 10 days and investigate the issues raised. As soon as practical, and not more than 45 days after receiving the written complaint, we will advise the complainant in writing of our determination.

### *Referral to External Dispute Resolution Scheme*

A complainant not satisfied with the outcome of the above process, or our determination, has the right to refer the matter to the Australian Financial Complaints Authority ("**AFCA**"). AFCA has been established to provide free advice and assistance to consumers to help in resolving complaints relating to the financial services industry.

Further details about AFCA are available at the AFCA website [www.afca.org.au](http://www.afca.org.au) or by contacting them directly via the details set out below.

Australian Financial Complaints Authority Limited  
GPO Box 3  
MELBOURNE VIC 3001

Telephone: 1800 931 678

Stantons confirms that it has arrangements in place to ensure it continues to maintain professional indemnity insurance in accordance with s.912B of the TCA 2001 (as amended). In particular our Professional Indemnity insurance, subject to its terms and conditions, provides indemnity up to the sum

insured for Stantons and our authorised representatives / representatives / employees in respect of our authorisations and obligations under our Australian Financial Services Licence. This insurance will continue to provide such coverage for any authorised representative / representative / employee who has ceased work with Stantons for work done whilst engaged with us.

**Contact details**

You may contact us using the details set out at above or by phoning (08) 9481 3188 or faxing (08) 9321 1204.

**Table of Contents**

<b>1</b>	<b>Executive Summary.....</b>	<b>1</b>
<b>2</b>	<b>Summary of Transaction.....</b>	<b>9</b>
<b>3</b>	<b>Scope.....</b>	<b>10</b>
<b>4</b>	<b>Profile of Allegra.....</b>	<b>12</b>
<b>5</b>	<b>Valuation Methodology .....</b>	<b>19</b>
<b>6</b>	<b>Valuation of Allegra Shares.....</b>	<b>20</b>
<b>7</b>	<b>Fairness Evaluation.....</b>	<b>27</b>
<b>8</b>	<b>Reasonableness Evaluation .....</b>	<b>28</b>
<b>9</b>	<b>Conclusion .....</b>	<b>30</b>

## 2 Summary of Transaction

### Background

2.1 Allegra was suspended from trading on ASX on 21 February 2024 pending an announcement regarding its funding arrangements and the proposed sale of all intellectual property relating to Sr-HT-Gahnite. On 24 May 2024, the Company announced it had entered into the Agreement with AI regarding the Transaction. A Bidders Statement prepared by AI was released via ASX on 21 June 2024.

### Transaction Details

2.2 The key components of the Transaction are:

- i) AI will acquire 100% of the outstanding ordinary shares of Allegra via a takeover bid to be implemented in accordance with Chapter 6 of the Corporations Act; and
- ii) Allegra shareholders will receive consideration of \$0.004 per ordinary share.

2.3 The offer is subject to the following conditions:

- i) the offer must be accepted by holders of at least 90% of Allegra shares on issue;
- ii) no material acquisitions, disposals or commitments are made in any property or other assets of Allegra or its subsidiaries;
- iii) no prescribed occurrences<sup>1</sup> occur between the date the Transaction is announced and the end of the offer period;
- iv) between the announcement date and end of the offer period, Allegra does not take certain actions with regard to the conduct of its business<sup>2</sup>;
- v) no regulatory action is taken against the Company to restrain, prohibit or impede the Transaction;
- vi) non-existence or exercise of certain rights<sup>3</sup>; and
- vii) Allegra enters into a deed with each holder of options over Allegra shares to cancel those options for an amount agreed by Allegra, AI and the option holder.

2.4 We note that based on the indicative timeline in the Agreement, the offer period is expected to close on 12 July 2024 unless extended.

2.5 The Company has 119,611,028 ordinary shares on issue, and accordingly the Transaction values the ordinary shares of the Company at \$478,444 in aggregate.

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<sup>1</sup> Prescribed occurrences are detailed in Appendix 1 of the Transaction announcement made via ASX on 24 May 2024

<sup>2</sup> Refer to Appendix 1(e) of the Transaction announcement released on 24 May 2024

<sup>3</sup> Refer to Appendix 1(g) of the Transaction announcement released on 24 May 2024

### 3 Scope

#### Purpose of the Report

##### *Chapter 6 s640*

- 3.1 s640 of the Corporations Act specifies that the target of a takeover bid must commission an expert report when the bidder's voting power in the target is at least 30% of the target or when the bidder and the target have common directors.
- 3.2 AI is a wholly owned subsidiary of RIPL, an entity controlled by the Allegra director, Mr Nick Hartnell. RIPL holds an interest of 42.67% in the ordinary shares of Allegra, and accordingly AI has voting power of above 30%. Mr Nick Hartnell is also a director of both Allegra and AI.

##### *Purpose*

- 3.3 Allegra intends to issue a Target Statement to its shareholders explaining the proposed Transaction. Based on the above, it is a requirement under s640 of the Corporations Act that an IER is commissioned by the Company.
- 3.4 The independent directors of Allegra have recommended that shareholders accept the offer in the absence of a superior proposal and subject to an independent expert concluding that the Transaction is either fair and reasonable, or not fair but reasonable.
- 3.5 Accordingly, Allegra has engaged Stantons to prepare an IER to assess the fairness and reasonableness of the proposal to accompany the Target Statement.

#### Basis of Evaluation

- 3.6 In determining the fairness and reasonableness of the Transaction, we have had regard to the guidelines set out by ASIC's RG111.
- 3.7 RG111 requires a separate assessment of whether a transaction is "fair" and whether it is "reasonable".
- 3.8 We therefore considered the concepts of "fairness" and "reasonableness" separately. The basis of assessment selected and the reasons for that basis are discussed below.

##### *Fairness*

- 3.9 As per RG111, the Transaction is considered to be a control transaction.
- 3.10 Accordingly, to assess whether the proposed Transaction is fair in accordance with RG111, we compared:
- the fair market value of an ordinary share in Allegra on a control basis; with
  - the fair market value of the consideration.
- 3.11 The value of an Allegra ordinary share is assessed at fair market value, which is defined by the International Glossary of Business Valuation Terms as:
- "The price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts."*
- 3.12 While RG111 contains no explicit definition of value, we believe the above definition of fair market value is consistent with RG111.11 and common market practice.

***Reasonableness***

- 3.13 In accordance with RG111.12, we have defined the proposed Transaction as being reasonable if it is fair, or if despite not being fair we believe that there are sufficient reasons for the Non-Associated Shareholders to accept the proposal.
- 3.14 In order to determine whether there are sufficient reasons for Non-Associated Shareholders to accept the proposal despite the Transaction not being fair, we compared the advantages and disadvantages to Non-Associated Shareholders of accepting the offer.

**Individual Circumstances**

- 3.15 We have evaluated the proposed Transaction for Non-Associated Shareholders generically. We have not considered the effect on the circumstances of individual investors. Due to their personal circumstances, individual investors may place different emphasis on various aspects of the proposed Transaction from those adopted in this report. Accordingly, individuals may reach a different conclusion to ours on whether the proposed Transaction is fair and reasonable. If in doubt, investors should consult an independent financial adviser about the impact of the proposed Transaction on their specific financial circumstances.

## 4 Profile of Allegra

### Company Profile and History

- 4.1 Allegra is an Australian public company listed on ASX that develops orthopaedic devices. The Company's main product is the Sr-HT-Gahnite Spinal Cage Device. The Company has been suspended from trading on ASX since 21 February 2024.
- 4.2 The Company completed the sale of its orthopaedics division to RIPL, the Company's major shareholder and an entity associated with Mr Nick Hartnell, on 28 August 2023. The orthopaedics division buys and sells orthopaedics medical equipment and earns income from selling certain medical devices on behalf of the manufacturer. The Company received cash consideration of \$1,000,000.
- 4.3 On 19 July 2023, the Company announced a 1 for 3 entitlement offer at an issue price of \$0.09 per share, to raise up to \$3,133,776 (before costs) with the intention to fund the commercialisation of the Spinal Cage Device. The offer closed on 28 August 2023, with the Company raising \$1,363,663 (before costs) via the issue of 15,151,825 new ordinary shares. 12,758,316 shares were issued to RIPL through part settlement of \$1,148,248 of outstanding loans (refer to paragraph 4.16 for the loan terms). Accordingly, the entitlement offer raised \$215,415 (before costs) of additional cash and had a shortfall of 19,668,108 shares.
- 4.4 The Company submitted a 501(k) application for the Spinal Cage Device to the United States Food and Drug Administration ("FDA") on 31 March 2023. After reviewing the application, the FDA requested additional supporting information, which related to the chemical characterisation and toxicology risk assessment, animal performance testing, and sterilisation, packaging and self-life validations. After an informal submission, the Company elected to withdraw its application due to the costs to provide the additional required supporting information. The Company subsequently assessed its options and elected to seek a sale of the IP associated with the Spinal Cage Device.
- 4.5 We note the attempts to sell or license the intellectual property was detailed in the Acuity Report as follows.

*"AMT has sought to sell its IP both through direct approaches to companies with an interest in orthopaedic products and to potential investors, as well as hiring the services of a company skilled in identifying collaborators. We were provided with a list of contacts made and some of their responses. In general, excluding those stating that the product did not fit their current portfolio of focus, these organisations expressed the view that they would only be interested once the product or material has been approved for clinical use. One contact raised an issue related to the mechanical properties."*

- 4.6 The Company's group structure is as set out below.

**Table 4. Allegra Group Structure**

Entity	Percentage owned by Allegra
Allegra	Parent entity
Allegra Orthopaedics Holding Pty Ltd	100% owned subsidiary
Advanced Surgical Design & Manufacture (UK) Limited <sup>4</sup>	100% owned subsidiary

Source: Allegra 2023 Annual Report

<sup>4</sup> This entity is dormant

## Board of Directors

4.7 The current board of directors of Allegra, as at 18 July 2024, is as follows.

**Table 5. Allegra Board of Directors**

Director	Position	Date Appointed	Details
Peter Kazacos	Non-Executive Chairman	11 May 2006	Mr Kazacos has over 40 years' experience in the IT industry. He founded KAZ in 1988, guiding it from a small IT services company in NSW to one of Asia Pacific's leading IT services and business process outsourcing service providers with over 4,000 employees, as a fully owned subsidiary of Telstra. He also founded Anittel Ltd, building it into one of Australia's leading IT&C service providers outside major metropolitan areas. Prior to founding KAZ and Anittel, he held a number of senior technical positions in the Australian IT industry.
Sean Mulhearn	Non-Executive Director	19 November 2015	Mr Mulhearn has been involved in financial markets for over 30 years' with experience in Asia, Europe and the Americas. He has particular expertise in risk management. He founded Jacaranda Capital Partners, a boutique advisory and markets training business with offices in Singapore and Australia.
Nick Hartnell	Non-Executive Director	9 March 2018	Mr Hartnell is an orthopaedic surgeon. Since 1995, he has been focused on orthopaedic training and specialisation and has many years of experience in all facets of orthopaedic care. He set up his practice in Bowral in the Southern Highlands, NSW, and has since expanded his surgical practice into the Goulbourn and Camden/Campbelltown areas.

Source: Allegra 2023 Annual Report

## Financial Performance

4.8 Allegra's audited Statements of Profit or Loss and Other Comprehensive Income for the years ended 30 June 2022 and 30 June 2023 and reviewed for the six-months to 31 December 2023 are set out below. We note that the financial statements for the half year to 31 December 2023 were prepared on a realisation basis and accordingly all revenue and expenses were considered to be from discontinued operations.

**Table 6. Allegra Statement of Profit or Loss and Other Comprehensive Income**

	Audited 12 months to 30 June 2022 (\$)	Audited 12 months to 30 June 2023 (\$)	Reviewed 6 months to 31 December 2023 (\$)
Revenue from contracts with customers	-	-	484,235
Other income	947,774	691,291	214,252
Interest revenue calculated using effective interest method	8	134	3,144
Cost of sales and purchases of consumables	5,295	(13,916)	(243,737)
Corporate and administration expenses	(1,101,941)	(1,092,817)	(659,843)
Quality and research and development expenses	(1,732,375)	(1,369,962)	(455,421)
Finance costs	(134,442)	(301,040)	(100,088)
Sales and marketing expenses	-	-	(118,859)
Impairment of assets	-	-	(567,854)
<b>Loss before income tax from continuing operations</b>	<b>(2,015,681)</b>	<b>(2,086,310)</b>	-
Income tax expense	-	-	-
<b>Loss after income tax from continuing operations</b>	<b>(2,015,681)</b>	<b>(2,086,310)</b>	-
Loss after income tax from discontinued operations	(519,647)	(1,561,427)	(1,444,171)
<b>Loss after income tax</b>	<b>(2,535,328)</b>	<b>(3,647,737)</b>	<b>(1,444,171)</b>
Other comprehensive income, net of tax	-	-	-
<b>Total comprehensive income/(loss)</b>	<b>(2,535,328)</b>	<b>(3,647,737)</b>	<b>(1,444,171)</b>

Source: Allegra Annual Report for the year ended 30 June 2023 and half year report for the period ended 31 December 2023

4.9 We note that the \$484,235 of revenue from contracts with customers were generated from the Orthopaedics division, which was disposed of on 28 August 2023. Revenues for the financial years ended 30 June 2022 and 30 June 2023 were \$2,932,844 and \$3,236,096, respectively, which are included in loss after income tax from discontinued operations.

4.10 Other income relates to government grants and research and development tax offsets.

### **Financial Position**

4.11 Set out below is Allegra's audited Statement of Financial Position as at 30 June 2022 and 30 June 2023 and reviewed as at 31 December 2023, prepared on a consolidated basis.

4.12 We note that the financial statements for the half year to 31 December 2023 were prepared on a realisation basis rather than a going concern basis. As described in the half year report:

*“Under the realisation basis of accounting, assets are written down to their estimated net realisable value, where relevant, and liabilities are stated at their estimated settlement amounts and relevant estimates are reviewed and adjusted as appropriate. All assets and liabilities are presented as current.”*

**Table 7. Allegra Statement of Financial Position**

	Audited as at 30 June 2022 (\$)	Audited as at 30 June 2023 (\$)	Reviewed as at 31 December 2023 (\$)
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	206,332	1,406	153,711
Trade and other receivables	1,197,529	1,138,257	232,777
Inventories	2,845,763	-	-
Prepayments	130,857	113,967	54,022
	4,380,481	1,253,630	440,510
Assets of disposal groups held for sale	-	942,800	-
<b>Total current assets</b>	<b>4,380,481</b>	<b>2,196,430</b>	<b>440,510</b>
<b>Non-current assets</b>			
Property plant and equipment	446,006	49,872	-
Right of use assets	135,614	266,167	-
Intangible assets	541,246	400,764	-
Security deposits	105,615	-	-
<b>Total non-current assets</b>	<b>1,228,481</b>	<b>716,803</b>	<b>-</b>
<b>Total assets</b>	<b>5,608,962</b>	<b>2,913,233</b>	<b>440,510</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	(914,273)	(1,046,373)	(541,295)
Borrowings	(326,395)	(311,464)	(1,265,294)
Lease liabilities	(136,268)	(138,350)	(189,088)
Employee benefits	(198,687)	(155,784)	(47,420)
Provisions	-	-	(10,000)
	(1,575,623)	(1,651,971)	(2,053,097)
Liabilities directly associated with assets classified as held for sale	-	(62,800)	-
<b>Total current liabilities</b>	<b>(1,575,623)</b>	<b>(1,714,771)</b>	<b>(2,053,097)</b>
<b>Non-current liabilities</b>			
Borrowings	(1,869,316)	(2,548,440)	-
Lease liabilities	-	(129,103)	-
Employee benefits	(21,717)	-	-
Provisions	(10,000)	(20,000)	-
<b>Total non-current liabilities</b>	<b>(1,901,033)</b>	<b>(2,697,543)</b>	<b>-</b>
<b>Total liabilities</b>	<b>(3,476,656)</b>	<b>(4,412,314)</b>	<b>(2,053,097)</b>
<b>Total net assets/(liabilities)</b>	<b>2,132,306</b>	<b>(1,499,081)</b>	<b>(1,612,587)</b>
<b>Equity</b>			
Issued capital	15,366,235	15,366,235	16,688,725
Share based payment reserve	858,453	874,803	882,978
Accumulated losses	(14,092,382)	(17,740,119)	(19,184,290)
<b>Total equity</b>	<b>2,132,306</b>	<b>(1,499,081)</b>	<b>(1,612,587)</b>

Source: Allegra Annual Report for the year ended 30 June 2023 and half year report for the period ended 31 December 2023

## Commentary on Financial Position

- 4.13 As at 30 June 2023, assets of disposal groups held for sale and liabilities directly associated with assets classified as held for sale relate to the Company's Orthopaedics division, which was sold to RIPL for consideration of \$1,000,000 cash on 28 August 2023.
- 4.14 As described above, the financial position as at 31 December 2023 is presented on a realisation basis. As a result, impairments were made against property, plant, and equipment, right of use assets and intangible assets to their estimated net realisable values, being nil. All non-current assets were reclassified as current assets and assessed at their expected settlement amounts.

### *RIPL Loan*

- 4.15 Borrowings include related party loans to RIPL (the "**Convertible Loan**"), an entity associated with Mr Nicholas Hartnell. As at 31 December 2023, the balance owing on the Convertible Loan was \$1,249,721.
- 4.16 We have been advised by the Company that the key terms of the loan agreement with RIPL are:
- the maximum loan amount is \$2,000,000 (plus interest, fees, costs and expenses);
  - the maturity date of the loan is 31 December 2024 (the "**Maturity Date**");
  - interest is payable at 13% p.a., accrued daily and paid monthly in arrears;
  - if prior to the repayment date, Allegra undertakes a capital raising<sup>5</sup>, at the Company's election, RIPL may be offered the right to convert any or all of the balance to equity, at the same price that shares are offered under the capital raising;
  - if not converted prior, at the Maturity Date, the Company has the right to convert all or some of the Convertible Loan balance at a 10% discount to the 90-day volume weighted average price ("**VWAP**") of the Company's shares<sup>6</sup>;
  - if not converted, the balance of the Convertible Loan must be repaid on the Maturity Date;
  - in an event of default, RIPL may make the Convertible Loan immediately due and payable;
  - until the loan is repaid in full, the Company must not incur any financial indebtedness over \$250,000 without the borrower's consent; and
  - until the loan is repaid in full, the Company must not pay any distributions to shareholders.
- 4.17 We note that as detailed at paragraph 4.3, an amount of \$1,148,248 of the Convertible Loan (the "**Rights Issue Amount**") was settled via the issue of shares under an entitlement offer on 28 August 2023 on the basis that the Rights Issue Amount could be redrawn by the Company under the Convertible Loan. To give effect to this, RIPL and the Company entered into a Deed of Amendment on 28 August 2023.
- 4.18 We note the ability of Allegra of drawdown further amounts under the Convertible Loan facility is subject to various legal clauses contained in the facility agreement (as amended) and interpretations of such clauses, including the satisfaction of certain conditions precedent (as outlined in section 10.2 of the Target Statement). We note the Company's ability to satisfy some or all of those conditions precedent in the future is uncertain.

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<sup>5</sup> Defined in the Loan Agreement as any form of public or private offer or placement of shares or any form of rights issue

<sup>6</sup> We note the legal definition of this clause is arguably ambiguous, however the Company has advised this is the understanding of the parties

### Updated Position

- 4.19 We have received management accounts presenting the Company's financial position as at 30 April 2024 and have separately been informed of the cash balance as at 31 May 2024<sup>7</sup>. In accordance with this information, the Company's estimated Net Asset position (excluding intangibles) as at 1 June 2024 is as set out below.

**Table 8. Allegra Adjusted Net Asset Position as at 1 June 2024**

	Reviewed as at 31 December 2023 (\$)	Adjustments (\$)	Adjusted as at 1 June 2024 (\$)
<b>Assets</b>			
Cash and cash equivalents	153,711	(127,610)	26,101
Trade and other receivables	232,777	53,358	286,135
Prepayments	54,022	(31,154)	22,868
<b>Total assets</b>	<b>440,510</b>	<b>(105,406)</b>	<b>335,104</b>
<b>Liabilities</b>			
Trade and other payables	(541,295)	(259,387)	(800,682)
Convertible Loan	(1,249,721)	(30,000)	(1,279,721)
Other loans	(15,573)	(65,002)	(80,575)
Lease liabilities	(189,088)	73,172	(115,916)
Employee benefits	(47,420)	47,420	-
Provisions	(10,000)	-	(10,000)
<b>Total liabilities</b>	<b>(2,053,097)</b>	<b>(233,797)</b>	<b>(2,286,894)</b>
<b>Total Net Assets</b>	<b>(1,612,587)</b>	<b>(339,203)</b>	<b>(1,951,790)</b>

Source: Allegra Management Accounts

- 4.20 We note that AI has agreed to fund the Company's required creditor payments on a month-by-month basis while it implements the takeover offer, though has made no ongoing commitment for general expenses. From 1 January 2024 to 20 June 2024, various customers of the orthopaedics business, which was sold by Allegra to AI, paid money owing to AI into the Allegra bank account, totalling \$74,237. Between 1 April 2024 and 1 June 2024, AI provided the Company with additional direct contributions of \$80,000. We understand these amounts, totalling \$154,237, are agreed by AI and the Company to be loans, however as at the date of this report, the exact loan terms have not yet been agreed.
- 4.21 We have been advised that the Company expects to receive a Research and Development tax incentive. It intends to make a claim for approximately \$160,000, however this claim has not yet been lodged, and any amount received will be subject to assessment by the Australian Taxation Office. We have not included this amount in our adjustments given the claim has not yet been lodged and the amount to be received is uncertain.

<sup>7</sup> We note the Target Statement declares a cash balance of \$2,191.23 as at 2 July 2024

## Capital Structure

### Ordinary Shares

4.22 As at 4 July 2024, Allegra had 119,611,028 ordinary shares on issue, with the top 20 holders being as follows.

**Table 9. Top 20 Shareholders**

Shareholder	Number held	Percentage (%)
RIPL	51,033,264	42.67%
Netwealth Investments Ltd <Wrap Services A/C>	12,279,615	10.27%
Welsh Superannuation Pty Ltd	6,600,000	5.52%
The University of Sydney	6,408,000	5.36%
Marie and Dawson Caroll	5,636,285	4.71%
BNP Paribas Nominees Pty Ltd <Clearstream>	4,958,074	4.15%
Andrew and Skye Leicester <Leicester Super Fund A/C>	3,353,123	2.80%
Dugal Diagnostics Pty Ltd <The Dugal Family A/C>	3,000,000	2.51%
Andrew and Sky Leicester	2,272,270	1.90%
Richard and Wendy Ulrich <Ulrich Super Fund A/C>	1,841,168	1.54%
Chew Investments Pty Ltd <Chew Investments A/C>	1,333,333	1.11%
Nicholas Hartnell	1,225,090	1.02%
Kenneth Campbell	1,000,000	0.84%
Thomas Carroll	1,000,000	0.84%
Destin Pty Ltd	946,470	0.79%
Misty Hills Nominees Pty Ltd	892,857	0.75%
Mergin Investments Pty Ltd <M & V Cross Super Fund>	627,490	0.52%
Fenton Healy <Cheeky Monkey A/C>	545,000	0.46%
Desmond J Bokor Pty Ltd <Kooringa Super Fund A/C>	510,000	0.43%
Raymond Hall	500,001	0.42%
<b>Total Top 20</b>	<b>105,962,040</b>	<b>88.59%</b>
Non-top 20 shareholders	13,648,988	11.41%
<b>Total Shares (as at 4 July 2024)</b>	<b>119,611,028</b>	<b>100.00%</b>

Source: Allegra register of shareholders

4.23 We note RIPL is an entity associated with Nicholas Hartnell.

### Options

As at 18 July 2024, the Company had the following options on issue.

**Table 10. Allegra Options**

Option	Number	Exercise Price (\$)	Expiry date
Unlisted Options 1	3,000,000	0.15	10 November 2024
Unlisted Options 2	1,500,000	0.16	31 January 2026

Source: ASX announcements

## 5 Valuation Methodology

### Available Methodologies

5.1 In assessing the value of Allegra, we considered a range of common market practice valuation methodologies in accordance with RG111, including those listed below.

- Capitalisation of future maintainable earnings ("**FME**")
- Discounted future cash flows ("**DCF**")
- Asset-based methods ("**Net Assets**")
- Quoted market prices or analysis of traded share prices
- Common industry rule-based methodologies

5.2 Each of these methods is appropriate in certain circumstances and often more than one approach is applied. The choice of methods depends on several factors such as the nature of the business being valued, the return on the assets employed in the business, the valuation methodologies usually applied to value such businesses and the availability of required information. A detailed description of these methods and when they are appropriate is provided in Appendix B.

### Selected Methodology

#### *Valuation methodology*

5.3 Our primary valuation methodology to value Allegra's shares is a Net Assets on a realisation based approach.

5.4 In selecting an appropriate valuation methodology to value the shares of Allegra, we considered the following factors:

- Allegra is currently loss-making and has limited revenue generating activities. As such FME methodology is not considered appropriate.
- Trading in Allegra's shares represents a low level of liquidity and is therefore not a reliable valuation measure. However as the VWAP of the Company's share price is a key term of the Convertible Loan, which is relevant to the capital structure of the Company, we have provided analysis of the Company's historical quoted market prices.
- Allegra's assets are predominantly comprised of IP assets related to its Sr-HT-Gahnite patents, which have been valued by a technical specialist. Accordingly, a Net Assets based approach is the most suitable for a valuation assessment.

## 6 Valuation of Allegra Shares

### Net Assets Valuation of Allegra Shares

6.1 To assess the value of an Allegra ordinary share, we used a realisable Net Assets approach, which sums the market values of Allegra's assets and liabilities to arrive at a net value of the Company.

6.2 In relation to our approach, we note the following:

- The Net Assets approach assumes a 100% control interest in the company.
- The valuation date is 1 June 2024.
- The IP of Allegra has been valued by an independent specialist, Acuity. A summary of Acuity's valuation is provided below from paragraph 6.6, and the Acuity Report is appended as Appendix E.
- All other net assets are assessed at their adjusted book values as set out in Table 8. We note that these values were based on a realisation basis.
- We note the Convertible Loan is considered a liability in the accounts, though contains a conversion option (refer to paragraph 4.16). The Company currently does not have the funds to repay the Convertible Loan and has been unsuccessful in attempts to raise further capital. For the valuation purpose, we have assumed the Company, acting rationally, would elect to convert the amount outstanding on the Convertible Loan.
- The Company is currently suspended from trading. The most recent 90-day VWAP of the Company's shares on ASX prior to suspension from trading on 21 February 2024 was \$0.0430, which we have assumed as the VWAP as at conversion for the valuation purpose. Accordingly, the number of shares that would be issued to RIPL on conversion would be as follows.

**Table 11. Number of shares on conversion of Convertible Loan (current balance)**

Convertible Loan face value (\$)	1,279,721
90-day VWAP (\$) (refer Table 18)	0.0430
Discount	10%
Conversion price (\$)	0.0387
<b>Number of shares issued</b>	<b>33,055,178</b>

*Source: Stantons analysis*

- Accordingly, the number of ordinary shares on issue following conversion of the Convertible Loan is as follows.

**Table 12. Post conversion number of shares outstanding**

Current ordinary shares	119,611,028
Shares issued on conversion of Convertible Loan	33,055,178
<b>Number of shares issued</b>	<b>152,666,206</b>

*Source: Stantons analysis*

- 6.3 The valuation of an ordinary share under the conversion scenario based on the current amount outstanding on the Convertible Loan is set out below.

**Table 13. Allegra Share Valuation (Conversion Scenario)**

	Ref	Low	Preferred	High
IP (\$)	Table 14	-	1,100,000	2,900,000
Other net assets (\$)	Table 8	(1,951,790)	(1,951,790)	(1,951,790)
Convertible Loan liabilities – eliminated on conversion (\$)	Table 8	1,279,721	1,279,721	1,279,721
<b>Pre-Transaction net assets (\$)</b>		<b>(672,069)</b>	<b>427,931</b>	<b>2,227,931</b>
Less: options value (\$)	Table 15	-	-	-
<b>Value attributable to ordinary shareholders</b>		<b>(672,069)</b>	<b>427,931</b>	<b>2,227,931</b>
Number of ordinary shares on issue	Table 12	152,666,206	152,666,206	152,666,206
<b>Value per ordinary share (\$) (control)</b>		<b>(0.0044)</b>	<b>0.0028</b>	<b>0.0146</b>
<b>Assessed value per ordinary share (\$) (control)</b>		<b>nil</b>	<b>0.0028</b>	<b>0.0146</b>

Source: Stantons analysis

- 6.4 Based on the assumptions outlined in paragraph 6.2, the Net Asset value of an Allegra ordinary share, on a control basis, is negative in the low case. As Allegra shares are issued on a limited liability basis, the assessed values in this case is nil. Accordingly, the assessed value of an Allegra ordinary share on a control basis is between nil and \$0.0146, with a preferred value of \$0.0028.

## Acuity Report

### Engagement of Acuity

- 6.5 Stantons engaged Acuity as a technical specialist to undertake a market valuation of the Company's IP. We have used and relied on the Acuity Report and note Acuity has declared that:
- Acuity is a suitably qualified consulting firm and has relevant experience in assessing the merits and preparing valuations of intellectual property and knowledge based intangible assets. The principal author of the Acuity Report, Dr David Randerson, is also suitably qualified and experienced; and
  - Acuity is independent of all parties involved in the Transaction.

### Acuity Report Valuation Summary

- 6.6 The Acuity Report provides a valuation of the IP held by Allegra as at a valuation date of 1 June 2024.
- 6.7 The valuation of Allegra's IP assets determined by Acuity is as follows. Full details of the valuation assumptions and methodology are located in Section 5 of the Acuity Report.

**Table 14. Acuity Report Valuation Summary of Allegra's Intellectual Property**

	Low (\$)	Preferred (\$)	High (\$)
Intellectual Property	-	1,100,000	2,900,000

Source: Acuity Report

### *Acuity Valuation Summary*

- 6.8 The Acuity Report valued Allegra's Intellectual Property to be between \$nil and \$2,900,000, with a preferred value of \$1,100,000.
- 6.9 The Acuity Report used a risk-adjusted DCF model to value the Intellectual Property Assets of Allegra. The valuation estimates cash flows, based on Acuity's industry experience, for the period to the end of the patent, plus an additional 3 years to account for the potential of an extension. The assumptions include a 5% market penetration. The valuation considers 2 scenarios:
- where 510(k) approval is obtained without trials but with trials conducted after US entry for purposes of post-market surveillance, to generate marketing information and to satisfy non-US compliance; and
  - where clinical trials are required as part of a 510(k) submission.
- 6.10 We note the valuation model assumes funding is available at a discount rate of 15% for the funding requirements of the product through to commercialisation. Acuity is of the view that *"trials are likely to be mandated due to the fact deficiencies have already been noted in the studies to date and the novel material has never been implanted into a human"* and accordingly it is not considered likely that the high scenario would occur. The Acuity Report also notes that *"our DCF analysis assumes funding for development and commercialisation is available, which, in the better scenario of no clinical requirement, could exceed \$5 million"*. Acuity notes that the Company has sought a sale or licencing arrangement for the IP and has not been able to obtain funding. Without this funding, Acuity believes that the IP may have no value.

### *Options Valuation*

- 6.11 We derived a value for the existing options in accordance with *AASB 2: Share Based Payments*, using the Black Scholes option methodology. We used an underlying spot price consistent with our preferred Net Asset value of nil, and accordingly the options are considered to have nil value. We note the circularity between the calculation of the Net Asset value and the option valuation. As the options have exercise prices of \$0.15 and \$0.16, the options would be well out of the money and have negligible value regardless of our assumed spot price.

**Table 15. Option Values**

Option	Number	Total value (\$)
Unlisted options 1	3,000,000	-
Unlisted options 2	1,500,000	-
	<b>4,500,000</b>	-

Source: Stantons analysis

### **Scenario Analysis**

- 6.12 For information purposes, we have assessed the value of an ordinary share in Allegra under alternative scenario where the Convertible Loan are repaid.

#### *Repayment Scenario*

- 6.13 We note that the financial statements of Allegra treat the Convertible Loan as a liability. We have interpreted the loan agreement as providing the Company with the right to convert the balance of the Convertible Loan at the Maturity Date, though note there may be different interpretations if Allegra shares remain in suspension and a VWAP is unable to be obtained to calculate the conversion price. Accordingly, we have also presented the scenario in which Allegra is required to repay the amount outstanding on the Convertible Loan.

- 6.14 Our Net Assets based valuation of an Allegra share assuming the Company elects to repay the Convertible Loan amount is as set out below.

**Table 16. Valuation of Allegra Shares**

	Ref	Low	Preferred	High
IP (\$)	Table 14	-	1,100,000	2,900,000
Other net assets (\$)	Table 8	(1,951,790)	(1,951,790)	(1,951,790)
<b>Net assets (\$)</b>		<b>(1,951,790)</b>	<b>(851,790)</b>	<b>948,210</b>
Less: options value (\$)	Table 15	-	-	-
<b>Value attributable to ordinary shareholders</b>		<b>(1,951,790)</b>	<b>(851,790)</b>	<b>948,210</b>
Number of ordinary shares on issue	Table 9	119,611,028	119,611,028	119,611,028
<b>Net Assets per ordinary share (\$) (control)</b>		<b>(0.0163)</b>	<b>(0.0071)</b>	<b>0.0079</b>
<b>Assessed value per ordinary share (\$) (control)</b>		<b>nil</b>	<b>nil</b>	<b>0.0079</b>

Source: Stantons analysis

### Analysis of Trading History

- 6.15 We considered the recent trading history of Allegra shares on the ASX prior to the suspension of trading pending the announcement of the Transaction. As outlined in paragraphs 4.16 and 6.2, the VWAP of the Company's share price is a key input component into the Convertible Loan legal agreement which determines the conversion price.
- 6.16 Allegra was suspended from trading on ASX on 21 February 2024. The trading history of Allegra on ASX for the two-year period to 21 February 2024 is set out below.

**Figure 2. Allegra ASX Trading History to 21 February 2024**



Source: S&P Capital IQ

- 6.17 The key announcements made by the Company over the past 12 months up to the Transaction are as follows.

**Table 17. Key Allegra ASX Announcements**

Date	Announcement details
27 May 2024	Announcement of cash takeover offer by AI
11 March 2024	Release of half year accounts as at 31 December 2023
23 February 2024	Company's shares suspended from trading pending an announcement regarding funding arrangements and the sale process relating to the Sr-HT-Gahnite Spinal Cage Device
21 February 2024	Company's shares enter trading halt
6 February 2024	The Company has withdrawn the Spinal Cage submission with the FDA, due to additional costs associated with obtaining supporting data. The Company has assessed its options and will seek to sell all Intellectual Property associated with the project
5 December 2023	The Company has submitted an informal response to the FDA, with a formal submission due on 4 February 2024
4 September 2023	The Company provided details the of additional information requested by FDA
31 August 2023	Annual Report for the year ended 30 June 2023 released
30 August 2023	Pro rata entitlement offer raised \$1,363,663 (before costs). Approximately \$215,000 was cash raised, as \$1,148,248 was through the part settlement of Convertible Loan with RIPL
28 August 2023	The Company completed the sale of its orthopaedics division to RIPL
16 August 2023	The FDA are reviewing the Spinal Cage device under the 510(k) pathway and have requested additional information
19 July 2023	The Company announced a 1 for 3 non-renounceable entitlement offer at an issue price of \$0.09 per share
2 May 2023	The Company enters into binding agreement for the sale of the Orthopaedics division to RIPL for \$1 million cash. The Company also announced it will undertake a capital raising in the near future. RIPL has agreed to underwrite the capital raising up to \$1.2 million
31 March 2023	The Company submitted the 501(k) for the Spinal Cage device to the FDA

Source: ASX announcements

- 6.18 As at 21 February 2024, the Company had an undiluted market capitalisation of approximately \$3,468,720.
- 6.19 Further details of Allegra's trading history as at 21 February 2024 are set out below.

**Table 18. Allegra ASX Trading History**

Trading days	Low price (\$)	High price (\$)	VWAP (\$)	Cumulative volume traded	Percentage of total shares (%)	Annual equivalent (%)	Percentage of free float (%)	Annual equivalent (%)
1 Day	-	-	-	-	-	-	-	-
10 Days	0.022	0.029	0.0253	14,980	0.01%	0.32%	0.06%	1.54%
30 Days	0.022	0.044	0.0361	386,220	0.32%	2.74%	1.57%	13.21%
60 Days	0.022	0.058	0.0422	703,100	0.59%	2.50%	2.80%	11.76%
90 Days	0.022	0.058	0.0430	867,020	0.72%	2.05%	3.42%	9.55%
180 Days	0.022	0.075	0.0537	2,572,660	2.25%	3.18%	10.46%	14.53%
1 Year (255 trading days)	0.022	0.075	0.0547	2,760,950	2.48%	2.48%	11.36%	11.36%

Source: S&P Capital IQ, Stantons analysis

- 6.20 Generally, the market is a fair indicator of what a share is worth, however for a quoted market price to be a reliable indicator of a company's value, the company's share must trade in a "liquid and active" market. We consider that a liquid and active market would typically be characterised by:
- regular trading in the company's securities;
  - trading of at least 1% of a company's securities on a weekly basis;
  - the spread of a company's shares must not be so great that a single minority trade can significantly affect the market capitalisation of the company; and
  - no significant but unexplained movements in the share price.
- 6.21 Allegra's shares have historically demonstrated trading volumes below 1% per week, with 11.36% of the outstanding shares being traded in the twelve-month period before being suspended from trading due to announcement of the Transaction.
- 6.22 We note Allegra undertook a 1 for 3 entitlement offer at \$0.09 per share that completed on 30 August 2023. The Company issued 15,151,825 new ordinary shares, of which 12,758,316 were issued to RIPL paid through settlement of part of the Convertible Loan. Cash raised was \$215,416 before costs. The entitlement offer had a significant shortfall of 19,668,108 shares.
- 6.23 As required by RG111.58/111.32, we have also considered the volatility of the market price of Allegra shares. The historical volatility of Allegra shares to 21 February 2024 over various periods is shown below.

**Table 19. Volatility**

Period	Low (\$)	High (\$)	Volatility (%)
1 year	0.022	0.075	73.56
2 year	0.022	0.190	65.43
3 year	0.022	0.410	67.87

*Source: S&P Capital IQ, Stantons analysis*

- 6.24 We note that the volatility is consistent with that expected for a pre-commercialisation biotechnology company.
- 6.25 Other key considerations for assessing traded prices of Allegra shares include:
- Allegra shares typically demonstrate a relatively high bid-ask spread, due to the ASX minimum tick size of \$0.001 representing a large percentage of the current market price.
  - Early-stage biotechnology company valuations are typically highly subjective and therefore investors may hold a wide range of opinions on the value of the shares.
  - Trading in early-stage biotechnology company shares such as Allegra may be driven by technical chartist traders, market sentiment, the involvement of key individuals and/or expectation/speculation of corporate activity.
  - Allegra is not covered by any major research analysts.
  - Allegra is not included in any indices.
- 6.26 Due to the low levels of liquidity of Allegra shares and the fact that the Company has been suspended from trading since 21 February 2024, we do not consider the above analysis to be sufficiently reliable as a primary valuation methodology for the Company's shares. However, we note that the VWAP of Allegra shares is an important assumption in our primary valuation assessment which determines the conversion price of the Convertible Loans (refer to paragraph 6.2 above).

## Valuation Summary

6.27 Based on the above analysis, our valuation of an Allegra share on a control basis is as follows.

**Table 20. Valuation Summary**

	Low value (\$)	Preferred value (\$)	High value (\$)
Net Assets valuation	-	0.0028	0.0146
<b>Adopted value</b>	-	<b>0.0028</b>	<b>0.0146</b>

*Source: Stantons analysis*

6.28 Our adopted minority interest value of an Allegra share is between \$nil and \$0.0146, with a preferred value of \$0.0028.

## 7 Fairness Evaluation

### Fairness Methodology

- 7.1 In determining the fairness of the Transaction, we have had regard to the guidelines set out by ASIC's RG111.
- 7.2 As per RG111, we consider the Transaction outlined in the Target Statement to be fair if:
- the value of the consideration offered; is equal to or greater than
  - the value of an Allegra share on a control basis.

### Value of Consideration

- 7.3 The consideration offered by AI is a cash offer of \$0.004 per share.

### Fairness Assessment

- 7.4 Our assessment of the fairness of the Transaction is set out below.

**Table 21. Fairness Assessment**

	Ref	Low	Preferred	High
Allegra share value (control) (\$)	Table 13	-	0.0028	0.0146
Value of consideration (\$)	7.4	0.0040	0.0040	0.0040
<b>Fairness Assessment</b>		<b>Fair</b>	<b>Fair</b>	<b>Not Fair</b>

*Source: Stantons analysis*

### Conclusion

- 7.5 As the value of an Allegra ordinary share is less than the value of the consideration offered in the low and preferred scenarios, we consider the Transaction to be **FAIR** to the Non-Associated Shareholders of Allegra.
- 7.6 The Transaction is considered not fair in the high scenario. We note that Acuity's high end IP value which drives this scenario, is based on a set of hypothetical assumptions which Acuity considers to be unlikely. These assumptions include that the FDA process does not require additional trials and the IP is fully funded through to commercialisation. These assumptions contrast with the Company's recent unsuccessful attempts to raise funding for the project. Further discussion of this is contained in our reasonableness assessment.
- 7.7 We note that the value per share is lower in the event that the Convertible Loan is repaid rather than converted into shares, accordingly our fairness opinion would be unchanged should that scenario eventuate.

## 8 Reasonableness Evaluation

8.1 Under RG111, a transaction is considered "reasonable" if it is "fair", or if despite not being "fair" there are sufficient reasons to accept the proposal.

8.2 As the Transaction is considered fair, it is also considered **REASONABLE**.

8.3 For information purposes, we have considered the following advantages, disadvantages and other factors in assessing the reasonableness of the Transaction.

### **Advantages**

#### *The Transaction is fair*

8.4 As detailed in our assessment in Section 7, the Transaction is considered fair to Non-Associated Shareholders.

#### *Provides liquidity*

8.5 The Company is currently suspended from trading on ASX, and there is no guarantee that it will be reinstated. Accepting the offer allows Non-Associated Shareholders to dispose of their shares, which they are currently unable to do on a listed exchange.

#### *The Company's access to funding is uncertain*

8.6 The Company requires additional funding for the Spinal Cage Device through the FDA approval process. The Company has attempted to raise funds via an entitlement offer and has tested the market via a sale process without having success. The Company is currently reliant on support from AI to meet its expense requirements, though this agreement is on a month-by-month basis and is only committed for the duration of the sale process.

8.7 If the Transaction doesn't proceed, then the Company's continued access to funding remains uncertain.

#### *Certain cash outcome*

8.8 Non-Associated Shareholders will receive a certain cash outcome of \$0.004 per share, as opposed to continuing to hold shares in a Company with uncertain prospects. Shareholders will no longer be exposed to risks associated with holding shares in Allegra.

#### *No other superior offers*

8.9 The Company has undertaken a sale process for the IP and did not receive any other offers.

#### *No brokerage charges*

8.10 Non-Associated Shareholders will not be required to pay any brokerage charges on accepting the offer, which they may be exposed to if they were to attempt to sell their shares on the ASX.

### **Disadvantages**

#### *Cash consideration is below recent market prices*

8.11 The Company's trading prices on ASX were higher than the cash offer of \$0.004. However, the Company's shares had low levels of liquidity and are currently suspended from trading.

#### *No exposure to potential future value of Allegra*

8.12 If the offer is accepted, Non-Associated Shareholders will no longer hold an interest in the shares of the Company. However, we note that the Company requires funding to commercialise its IP and has been unable to find a superior offer.

**Other Factors***Tax implications*

- 8.13 Accepting the offer may trigger a capital gains or loss event for taxation purposes. We have evaluated the transaction generically and do not comment on the specific situation of individual shareholders.

*Tax losses*

- 8.14 The Company has accumulated tax losses that may provide benefits to the Company in the future, though it is uncertain whether any benefits would be available to Non-Associated Shareholders. Stantons is not providing any tax advice on this matter.

## 9 Conclusion

### Opinions

- 9.1 The proposed Transaction, as described in the Target Statement, is considered **FAIR** and **REASONABLE** to the Non-Associated Shareholders of Allegra as at the date of this report.

### Shareholders Decision

- 9.2 Stantons was engaged to prepare an IER setting out whether in its opinion the proposed Transaction is fair and reasonable to the Non-Associated Shareholders and to state reasons for that opinion. Stantons has not been engaged to provide a recommendation to Non-Associated Shareholders as to whether to accept the offer.
- 9.3 The decision whether to accept the offer from AI is a matter for individual shareholders based on each shareholder's views as to the value, their expectations about future market conditions and their particular circumstances, including risk profile, liquidity preference, investment strategy, portfolio structure, and tax position. If in any doubt as to the action they should take in relation to the proposed offer, shareholders should consult their professional advisor.
- 9.4 Similarly, it is a matter for individual shareholders as to whether to buy, hold or sell shares in Allegra. This is an investment decision upon which Stantons does not offer an opinion. Shareholders should consult their own professional advisor in this regard.

### Source Information

- 9.5 In making our assessment as to whether the proposed Transaction is fair and reasonable to Non-Associated Shareholders, we reviewed published available information and other unpublished information of the Company that is relevant to the current circumstances. Statements and opinions contained in this report are given in good faith, but in the preparation of this report, we have relied in part on information provided by the directors and management of Allegra.
- 9.6 Information we have received includes, but is not limited to:
- Drafts of the Target Statement to 3 July 2024
  - The Bidders Statement released on 19 June 2024
  - The Acuity Report dated 4 July 2024
  - Allegra ASX announcements to 18 July 2024
  - Allegra's Annual Reports for the financial years ended 30 June 2022 and 30 June 2023
  - Allegra's Interim Financial Report for the half year ended 31 December 2023
  - Allegra's unaudited management accounts as at 30 April 2024
  - Register of Allegra shareholders as at 31 May 2024
  - The Bid Implementation Agreement between Allegra and AI dated 24 May 2024
  - The Loan Agreement between Allegra and RIPL executed on 21 February 2021
  - The Amendment to the Loan Agreement dated 28 August 2023
- 9.7 Our report includes the appendices, our declarations, and our Financial Services Guide.

Yours Faithfully

**STANTONS CORPORATE FINANCE PTY LTD**



**James Turnbull, CFA**  
**Authorised Representative**

## APPENDIX A

### GLOSSARY

	Definition
<b>Acuity</b>	Acuity Technology Management Pty Ltd
<b>Acuity Report</b>	"Independent Valuation of Intellectual Property – Allegra Medical Technologies Limited" prepared by Acuity and dated 4 July 2024
<b>AFCA</b>	Australian Financial Complaints Authority
<b>Agreement</b>	The Bid Implementation Agreement entered between Allegra and AI date 24 May 2024
<b>AI</b>	Allegra Innovation Pty Ltd
<b>Allegra</b>	Allegra Medical Technologies Limited
<b>ASIC</b>	Australian Securities and Investments Commission
<b>ASX</b>	Australian Securities Exchange
<b>Company</b>	Allegra Medical Technologies Limited
<b>Convertible Loan</b>	The loan received by Allegra from RIPL described at paragraphs 4.15 and 4.16
<b>Corporations Act</b>	The Corporations Act 2001
<b>DCF</b>	Discounted future cash flows valuation methodology
<b>ES</b>	Explanatory Statement
<b>FDA</b>	United States Food and Drug Administration
<b>FME</b>	Capitalisation of future maintainable earnings valuation methodology
<b>FSG</b>	Financial Services Guide
<b>IER</b>	Independent Expert's Report
<b>IP</b>	The intellectual property related to the Spinal Cage Device
<b>Loan Agreement</b>	The Loan Agreement between Allegra and RIPL executed on 21 February 2021
<b>Maturity Date</b>	31 December 2024
<b>Net Assets</b>	Asset-based valuation methodologies
<b>Non-Associated Shareholders</b>	Allegra shareholders who are not associated with Mr Nick Hartnell
<b>RG74</b>	ASIC Regulatory Guide 74: Acquisitions Approved by Members
<b>RG111</b>	ASIC Regulatory Guide 111: Content of Expert Reports
<b>Rights Issue Amount</b>	\$1,148,248 of the amount owed on the Convertible Loan that was settled on 28 August 2023 under an entitlement offer
<b>RIPL</b>	Robinwood Investments Pty Ltd
<b>s640</b>	Section 640 of the Corporations Act
<b>Spinal Cage Device</b>	Sr-HT-Gahnite Spinal Cage Device
<b>Stantons</b>	Stantons Corporate Finance Pty Ltd
<b>Target Statement</b>	The Target Statement released by Allegra
<b>Transaction</b>	The offer by AI to acquire 100% of the outstanding capital of Allegra for \$0.004 per share
<b>VWAP</b>	Volume Weighted Average Price

## APPENDIX B

### VALUATION METHODOLOGIES

#### Introduction

In preparing this report we have considered several valuation approaches and methods. These approaches and methods are consistent with:

- Market practice
- The methods recommended by the Australian Securities and Investments Commission in Regulatory Guide 111
- The International Valuation Standards
- The International Glossary of Business Valuation Terms

A valuation approach is a general way of determining an estimate of the value of a business, business ownership interest, security or intangible asset. Within each valuation approach, there are a number of specific valuation methods, which are specific ways to determine an estimate of value.

There are three general valuation approaches as follows:

#### i) **Income Approaches**

Indicates value by converting future cash flows to a single present value. Examples of an income approach are:

- The discounted cash flow method ("**DCF**")
- The capitalisation of future maintainable earnings method ("**FME**")

#### ii) **Asset/Cost Approaches**

Indicates value using the economic principle that a buyer will pay no more for an asset than the cost to obtain an asset of equal utility, whether by purchase or construction.

#### iii) **Market Approaches**

Indicates value by comparing the subject asset with identical or similar assets for which price information is available. The main examples of the market approach are:

- Analysis of recent trading
- Industry rules of thumb

#### 1. **Discounted Cash Flow Method**

Of the various methods noted above, the DCF method has the strongest theoretical basis. The DCF method estimates the value of a business by discounting expected future cash flows to a present value using an appropriate discount rate. A DCF valuation requires:

- A forecast of expected future cash flows
- An appropriate discount rate
- An estimate of terminal value

It is necessary to project cash flows over a suitable period (generally regarded as being at least five years) to arrive at the net cash flow in each period. For a finite-life project or asset, this would need to be done for the life of the project. This can be a difficult exercise requiring a significant number of assumptions such as revenue and cost drivers, capital expenditure requirements, working capital movements and taxation.

The discount rate used represents the risk of achieving the projected future cash flows and the time value of money. The projected future cash flows are then valued in current-day terms using the discount rate selected.

A terminal value reflects the value of cash flows that will arise beyond the explicit forecast period. This is commonly estimated using either a constant growth assumption or a multiple of earnings (as described under FME below). This terminal value is then discounted to current-day terms and added to the net present value of the forecast cash flows to provide an estimate for the overall value of the business.

The DCF method is often sensitive to a number of key assumptions such as revenue growth, future margins, capital investment, terminal growth and the discount rate. All these assumptions can be highly subjective, sometimes leading to a valuation conclusion presented that is too wide to be useful.

A DCF approach is usually preferred when valuing:

- Early-stage companies or projects
- Limited life assets such as a mine or toll concession
- Companies where significant growth is expected in future cash flows
- Projects with volatile earnings

It may also be preferred if other methods are not suitable, for example, if there is a lack of reliable evidence to support an FME approach. However, it may not be appropriate if:

- Reliable forecasts of cash flow are not available and cannot be determined
- There is an inadequate return on investment, in which case a higher value may be realised by liquidating the assets than through continuing the business

A DCF approach is not recommended when assets are expected to earn below the cost of capital. Also, when valuing a minority interest in a company, care needs to be taken if a DCF based on earnings for the whole business is prepared, as the holder of a minority interest would not have access to, or control of, those cash flows.

## 2. Capitalisation of Future Maintainable Earnings Method

The FME method is a commonly used valuation methodology that involves determining a future maintainable earnings figure for a business and multiplying that figure by an appropriate capitalisation multiple. This methodology is generally considered a short form of a DCF, where a single representative earnings figure is capitalised, rather than a stream of individual cash flows being discounted. The FME methodology involves the determination of:

- A level of future maintainable earnings
- An appropriate capitalisation rate or multiple

Any of the following measures of earnings can be used:

**Revenue** – mostly used for early-stage, fast-growing companies that do not make a positive EBITDA or as a cross-check of a valuation conclusion derived using another method.

**EBITDA** – most appropriate where depreciation distorts earnings, for example in a company that has a significant level of depreciating assets but little ongoing capital expenditure requirement.

**EBITA** – in most cases EBITA will be more reliable than EBITDA as it takes account of the capital intensity of the business

**EBIT** – whilst commonly used in practice, multiples of EBITA are usually more reliable as they remove the impact of amortisation which is a non-cash accounting entry that does not reflect a need for future capital investment (unlike depreciation)

**NPAT** – relevant in valuing businesses where interest is a major part of the overall earnings of the group (e.g., financial services businesses such as banks).

Multiples of EBITDA, EBITA and EBIT are commonly used to value whole businesses for acquisition purposes where gearing is in the control of the acquirer. In contrast, NPAT (or P/E) multiples are often used for valuing minority interests in a company as the investor has no control over the level of debt.

A normalised level of maintainable earnings needs to be determined for the selected earnings measure. This excludes the impact of any gains or losses that are not expected to reoccur and allows for the full-year impact of any changes (such as acquisitions or disposals) made partway through a given financial year.

The selected multiple to apply to maintainable earnings reflects expectations about future growth, risk and the time value of money captured in a single number. Multiples can be derived from three main sources.

- Using the comparable trading multiples, market multiples are derived from the trading prices of stocks of companies that are engaged in the same or similar lines of business that are actively traded on a free and open market, such as the ASX
- The comparable transactions method is a method whereby multiples are derived from transactions of significant interests in companies engaged in the same or similar lines of business.
- It is also possible to build a multiple from first principles based on an appropriate discount rate and growth expectations.

It is important to use the same earnings periods (historical, current or forecast) for calculating comparable multiples, as the period used for determining FME. For example, a multiple based on historical earnings of comparable companies should be applied to historical earnings of the subject of the valuation and not to forecast earnings.

The capitalisation of earnings method is widely used in practice. It is particularly appropriate for valuing companies with a relatively stable historical earnings pattern which is expected to continue. The method is less appropriate for valuing companies or assets if:

- There are no (or very few) suitable alternative listed companies or transaction benchmarks for comparison
- The asset has a limited life
- Future earnings or cash flows are expected to be volatile
- There are negative earnings, or the earnings of a business are insufficient to justify a value exceeding the underlying net assets
- Working capital requirements are not expected to remain stable

### **3. Asset or Cost Approaches**

The asset approach to value assumes that the current value of all assets (tangible and intangible) less the current value of the liabilities should equate to the current value of the entity. Specifically, an asset approach is defined as a general way of determining a value indication of a business, business ownership interest, or security using one or more methods based on the value of the assets net of liabilities. A cost approach is defined as a general way of determining a value indication of an individual asset by quantifying the amount of money required to replace the future service capability of that asset.

The asset-based valuation methods estimate the value of a company based on the realisable value of its net assets, less its liabilities. There are a number of asset-based methods including:

- Orderly realization
- Forced liquidation
- Net assets on a going concern

The orderly realisation of assets method estimates fair market value by determining the amounts that would be distributed to shareholders, after payments of all liabilities including realisation costs and taxation charges that arise, assuming the company is wound up in an orderly manner. The forced liquidation method is similar to the orderly realisation of assets except the liquidation method assumes the assets are sold in a shorter time frame. Since wind-up or liquidation of the company may not be contemplated, these methods in their strictest form may not necessarily be appropriate. The net assets on a going concern basis method estimates the fair market values of the net assets of a company but does not take account of realisation costs.

The asset/cost approach is generally used when the value of the business' assets exceeds the present value of the cash flows expected to be derived from the ongoing business operations, or the nature of the business is to hold or invest in assets. It is important to note that the asset approach may still be the relevant approach even if an asset is making a profit. If an asset is making less than the economic rate of return and there is no realistic prospect of it making an economic return in the foreseeable future, an asset/cost approach will be the most appropriate method.

An asset-based approach is a suitable method of valuation when:

- An enterprise is loss-making and not expected to become profitable in the foreseeable future
- Assets are employed profitably but earn less than the cost of capital
- A significant portion of the company's assets are composed of liquid assets or other investments (such as marketable securities and real estate investments)
- It is relatively easy to enter the industry (e.g., small machine shops and retail establishments)

Asset-based methods are not appropriate if:

- The ownership interest being valued is not a controlling interest, has no ability to cause the sale of the company's assets and the major holders are not planning to sell the company's assets
- A business has (or is expected to have) an adequate return on capital, such that the value of its future income stream exceeds the value of its assets

An asset-based approach is often considered as a floor value for a business assuming the business has the option to realise all its assets and liabilities.

#### **4. Analysis of Recent Trading**

The most recent share trading history provides evidence of the fair market value of the shares in a company where they are publicly traded in an informed and liquid market. There should also be some similarity between the size of the parcel of shares being valued and those being traded. Where a company's shares are publicly traded then an analysis of recent trading prices should be considered, at least as a cross-check to other valuation methods.

#### **5. Industry Specific Rule of Thumb**

Industry specific rules of thumb are used in certain industries. These methods typically involve a multiple of an operating figure such as traffic for internet businesses or the number of beds for a nursing home. These methods are typically fairly crude and therefore only appropriate as a cross-check to a valuation determined by an alternative method.

#### **Selecting an Appropriate Valuation Approach and Method**

The choice of an appropriate valuation approach and methodology is subjective and depends on several factors such as whether a methodology is prescribed, the company's historical and projected financial performance, stage of maturity, the nature of the company's operations and availability of information. The selection of an appropriate valuation method should be guided by the actual practices adopted by potential acquirers of the company involved and the information available.

## APPENDIX C

### CONTROL PREMIUM

#### Background

The difference between a control value and a minority value is described as a control premium. The opposite of a control premium is a minority discount (also known as a discount for lack of control). A control premium is said to exist because the holder of a controlling stake has several rights that a minority holder does not enjoy (subject to shareholders' agreements and other legal constraints), including to:

- Appoint or change operational management
- Appoint or change members of the board
- Determine management compensation
- Determine owner's remuneration, including remuneration to related party employees
- Determine the size and timing of dividends
- Control the dissemination of information about the company
- Set the strategic focus of the organisation, including acquisitions, divestments, and restructuring
- Set the financial structure of the company (debt/equity mix)
- Block any or all the above actions

The most common approach to quantifying a control premium is to analyse the size of premiums implied from prices paid in corporate takeovers. Another method is the comparison between the prices of voting and non-voting shares in the same company. We note that the size of the control premium should generally be an outcome of a valuation and not an input into one, as there is significant judgement involved.

Based on historical takeover premia that have been paid in Australian acquisitions in the period 2005-2015, the majority of takeovers have included a premium in the range of 20-50%, with 30% being the most commonly occurring. This is in line with standard industry practice, which tends to use a 30% premium for control as a standard.

#### Intermediate Levels of Ownership

There are several intermediate levels of ownership between a portfolio interest and 100% ownership. Different levels of ownership/strategic stakes will confer different degrees of control and rights as shown below.

- 90% - can compulsorily purchase remaining shares if certain conditions are satisfied
- 75% - the power to pass special resolutions
- <50% - gives control depending on the structure of other interests (but not absolute control)
- <25% - ability to block a special resolution
- <20% - power to elect directors, generally gives significant influence, depending on other shareholding blocks
- < 20% generally has only limited influence

Conceptually, the value of each of these interests lies somewhere between the portfolio value (liquid minority value) and the value of a 100% interest (control value). Each of these levels confers different degrees of control and therefore different levels of control premium or minority discount.

## APPENDIX D

### AUTHOR INDEPENDENCE AND INDEMNITY

This annexure forms part of and should be read in conjunction with the report of Stantons Corporate Finance Pty Ltd trading as Stantons Corporate Finance dated 18 July 2024, relating to the proposed Transaction.

At the date of this report, Stantons Corporate Finance does not have any interest in the outcome of the proposal. There are no relationships with Allegra other than Stantons Corporate Finance acting as an independent expert for the purposes of this report. Stantons Corporate Finance Pty Ltd undertook an independence assessment and considered that there are no existing relationships between Stantons Corporate Finance and the parties participating in the Transaction detailed in this report which would affect our ability to provide an independent opinion. The fee (excluding disbursements) to be received for the preparation of this report is based on time spent at normal professional rates plus out-of-pocket expenses. Our fee for preparing this report is expected to be up to A\$20,000 exclusive of GST. The fee is payable regardless of the outcome. Except for that fee, neither Stantons Corporate Finance Pty Ltd nor Mr James Turnbull has received, nor will or may they receive any pecuniary or other benefits, whether directly or indirectly for or in connection with the preparation of this report.

Stantons Corporate Finance Pty Ltd does not hold any securities in Allegra. There are no pecuniary or other interests of Stantons Corporate Finance Pty Ltd that could be reasonably argued as affecting its ability to give an unbiased and independent opinion in relation to the proposal. Stantons Corporate Finance and Mr James Turnbull have consented to the inclusion of this report in the form and context in which it is included as an annexure to the Target Statement.

### QUALIFICATIONS

We advise Stantons Corporate Finance Pty Ltd is the holder of an Australian Financial Services License (No 448697) under the Corporations Act 2001 relating to advice and reporting on mergers, takeovers and acquisitions involving securities. Stantons Corporate Finance Pty Ltd has extensive experience in providing advice pertaining to mergers, acquisitions and strategic financial planning for both listed and unlisted businesses.

Mr James Turnbull, the person with overall responsibility for this report, has experience in the preparation of valuations for companies, particularly in the context of listed company corporate transactions, including the fairness and reasonableness of such transactions. The professionals employed in the research, analysis and evaluation leading to the formulation of opinions contained in this report, have qualifications and experience appropriate to the tasks they have performed.

### DECLARATION

This report has been prepared at the request of Allegra to assist Shareholders of Allegra to assess the merits of the Transaction to which this report relates. This report has been prepared for the benefit of Allegra shareholders and those persons only who are entitled to receive a copy for the purposes under the Corporations Act 2001 and does not provide a general expression of Stantons Corporate Finance's opinion as to the longer-term value of Allegra, its subsidiaries and/or assets. Stantons Corporate Finance does not imply, and it should not be construed, that it has carried out any form of audit on the accounting or other records of Allegra or their subsidiaries, businesses, other assets and liabilities. Neither the whole, nor any part of this report, nor any reference thereto, may be included in or with or attached to any document, circular, resolution, letter or statement, without the prior written consent of Stantons Corporate Finance Pty Ltd to the form and context in which it appears.

### DISCLAIMER

This report has been prepared by Stantons Corporate Finance Pty Ltd with due care and diligence. However, except for those responsibilities which by law cannot be excluded, no responsibility arising in any way whatsoever for errors or omission (including responsibility to any person for negligence) is assumed by Stantons Corporate Finance Pty Ltd (and Stantons International Audit and Consulting Pty Ltd ("**SIAC**"), the parent company of Stantons Corporate Finance, its directors, employees or consultants) for the preparation of this report.

**DECLARATION AND INDEMNITY**

Recognising that Stantons Corporate Finance may rely on information provided by Allegra and its officers (save whether it would not be reasonable to rely on the information having regard to Stantons Corporate Finance's experience and qualifications), Allegra has agreed:

- (a) to make no claim by it or its officers against Stantons Corporate Finance Pty Ltd (and SIAC) to recover any loss or damage which Allegra may suffer as a result of reasonable reliance by Stantons Corporate Finance Pty Ltd on the information provided by Allegra; and
- (b) to indemnify Stantons Corporate Finance Pty Ltd against any claim arising (wholly or in part) from Allegra, or any of its officers, providing Stantons Corporate Finance Pty Ltd with any false or misleading information or in the failure of Allegra or its officers in providing material information, except where the claim has arisen as a result of wilful misconduct or negligence by Stantons Corporate Finance Pty Ltd.

A final draft of this report was presented to Allegra for a review of factual information contained in the report. Comments received relating to factual matters were considered, however, the valuation methodologies and conclusions did not change as a result of any feedback from Allegra.

**APPENDIX E – ALLEGRA MEDICAL TECHNOLOGIES PTY LTD INDEPENDENT  
VALUATION OF INTELLECTUAL PROPERTY PREPARED BY ACUITY  
TECHNOLOGY MANAGEMENT PTY LTD**

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4 July 2024

Mr James Turnbull  
Authorised Representative  
Stantons Corporate Finance Pty. Ltd.  
Level 2, 40 Kings Park Road  
West Perth, WA 6005

Dear James

## Allegra Medical Technologies Pty. Ltd. - Independent Valuation of Intellectual Property

### Executive Summary

We have pleasure in providing a valuation of the intellectual property (“**IP**”) owned by Allegra Medical Technologies Ltd. (“**AMT**” or the “**Company**”) based on the commercial potential of the Company’s patented biomaterial, Sr-HT-Gahnite. The valuation has been requested by Stanton Corporate Finance Pty. Ltd. (“**Stantons**”) and is to be used by Stantons to prepare an Independent Expert’s Report (“**IER**”) in relation to a takeover bid for the Company (“**Proposed Offer**”).

The Proposed Offer has been made by a party, or parties, associated with AMT. Stantons has been retained by AMT to prepare an IER in which it will advise existing shareholders as to whether the Proposed Offer is reasonable and fair in accordance with Chapter 6 of the Corporations Act 2001. Given the technical nature of the IP and markets for products, Stantons require a specialist to assist with their opinion. This report, prepared by Acuity Technology Management Pty. Ltd. (“**Acuity**”) is based on review of the Company’s research to date and attempts to commercialize and, more recently, sell the IP, along with examination of markets and competition in the medical devices area which the Company is targeting.

The most advanced product that may derive from the Sr-HT-Gahnite IP, and the one assessed for the current valuation, is an interbody cage for cervical spine fusion. A prototype product has been extensively tested in laboratory (*in vitro*) studies under the appropriate testing conditions and standards for implantable devices, and *in vivo* in animal studies aiming to demonstrate both safety and utility in the specific surgical setting. The Company has sought to have the product approved for human use in the United States (“**US**”) in accordance with a recognized regulatory route that would allow marketing approval on the basis of substantial equivalence to a previously cleared device, referred to as the 510(k) pathway. The US regulator, the Food and Drug Administration (“**FDA**”) recently advised the Company of concerns associated with the studies done to date and requested further work be undertaken while providing no assurance that the 510(k) pathway would be accepted. Following consideration of the costs that would be incurred to continue development and meet FDA requirements, the Company withdrew its application and has undergone a search for parties interested in licensing or acquiring the IP. This, largely unsuccessful search, led to the current Proposed Offer.

The Company has not sought to include human trials in the short-term development program and hoped that the animal studies would be adequate to prove substantial equivalence. Human clinical studies are not commonly mandated for regulatory clearance of interbody cages and other orthopaedic devices under the 510(k) pathway. However, many companies have chosen to do human studies for marketing purposes after regulatory clearance with the objective of demonstrating better performance or cost-effectiveness. In Europe, the regulatory clearance procedures were changed in May 2021 and, while there is a transitional period before they are applied, it is likely that human clinical studies will be required prior to marketing approval.

Sr-HT-Gahnite was originally developed by materials scientists and biomedical engineers at The University of Sydney (“**University**”) to provide a novel, high strength material for implants with potentially exceptional bone regeneration ability. An international patent application was filed by the University in 2012, providing protection to mid-2032, although an extension of up to five years is possible. It has been granted in the US and Australia while pending elsewhere. The patent was assigned to the Company in 2020 and there are no ongoing financial obligations to the University. The Company has full ownership of all experimental data generated by its studies.

### *Summary Valuation*

The method chosen to value the IP is a risk adjusted discounted cash flow (“**DCF**”) in which Acuity undertook an assessment of markets for the targeted product and generated projected cash flows. We considered development times and budgets with regards to the FDA’s request for additional studies and budgets for these studies as estimated by AMT. We also applied our own knowledge and experience in the development of medical devices to the analysis and considered the possibility of additional research, particularly a human study, to the development program.

**Our analysis, which is presented herein, suggests a current after-tax valuation of the IP of \$1.1 million with a range from nil to US\$2.9 million.** The estimate is based on the sales potential of the cervical interbody cage in major healthcare markets. Inclusion of products for other applications and other countries have the potential to increase this value.

The DCF analysis utilizes revenues and expenses as estimated by Acuity for the US, European and Japanese markets. Development expenses, other than for clinical trials, have been provided by AMT, and the post-approval costs of production and sales, general and administrative (“**SG&A**”) expenses are based on an analysis of expenses reported by internationally operating orthopaedic implant companies. A risk adjustment to cash flows has been included because further research is required and regulatory approvals have yet to be obtained. A premium has been added to the estimated Capital Assets Pricing Model (“**CAPM**”) for the Company and used as the discount rate for future cash flows, with the premium accounting for the lack of surety in revenue projections in the form of forward contracts or extrapolation of historic sales, and anticipated overheads. One of the commercial risks is the fact that there is considerable competition from interbody cages already in the marketplace. The strengths of the Sr-HT-Gahnite cage are its osteointegration and bone regenerative potential. These, however, need to be proven in the clinical setting.

Two critical factors influence the valuation. The first, as discussed, is the possible requirement for clinical studies as part of the 510(k) process rather than subsequent to US marketing approval. The second factor impacting the valuation is the declining residual life of the patent. If trials are mandated, there is only a short period of market monopoly before generic competition enters the market.

Our searches failed to identify any acquisitions of technology, IP or company, that we consider appropriate for use in a comparables analysis – the criterion being pre-market, single product or platform orthopaedic implant or biomaterial developers, and, most importantly, with limited patent protection for discoveries. We did identify a number of early-stage orthopaedic companies, but these are mostly private with no publicly available financial information. Similarly, we located few acquisitions that are relevant to the valuation of AMT.

Acuity specialises in the appraisal and valuation of IP and knowledge-based intangible assets, including in-process R&D (“**IPR&D**”). The company has experience in valuing medical devices, diagnostic systems, pharmaceuticals, genetic and recombinant DNA technologies, stem cell therapies and complementary and alternative medicines. Further details can be found in Section 9 of this report and at [www.acuitytechnology.com.au](http://www.acuitytechnology.com.au).

In presenting this valuation report, Acuity recognizes that Stanton's will rely on our assessment and conclusions and, at their discretion, may append a copy of our report to their IER. We have prepared this report with regards to guidelines issued by the Australian Securities and Investments Commission ("ASIC"), including: Regulator Guides RG111 *Content of experts reports* and RG112 *Independence of experts*. We point out that Acuity does not hold an Australian Financial Services Licence and, consequently, does not provide a comment on the benefits or otherwise of Proposed Offer to AMT shareholders.

## Table of Contents

Executive Summary	1
1. Background	6
1.1 The Company and its Technology	6
1.2 Intellectual Property	7
1.3 Studies Conducted by the Company	7
1.4 Discourse with the US FDA	9
1.5 Manufacturing Cost and Pricing	10
1.6 The Need for Clinical Trials	10
1.7 Attempts to Sell or License the IP	11
2. Orthopaedic Implants Markets	11
2.1 Spinal Surgery	11
2.2 Incidence of Surgery	12
2.3 Spinal Fusion Markets	13
3. AMT’s Strengths and Risks	13
4. Valuation Methods	14
4.1 Cost Based Methods	14
4.2 Market Based Methods	15
4.3 Methods Based on Future Prospects	15
5. IP Valuation	16
5.1 Comparable Companies and Licensing Deals	16
5.2 Future Benefits Analysis	16
6. Conclusions	19
7. Sources of Information	20
8. Disclaimer	20
9. Qualifications & Experience	20

## Glossary

ACDF	Anterior Cervical Discectomy and Fusion
Acuity	Acuity Technology Management Pty. Ltd.
AHRQ	Agency for Healthcare Research and Quality (US)
AMT	Allegra Medical Technologies Ltd.
ASP	Average Selling Price
ASIC	Australian Securities and Investment Commission
CAGR	Compound Average Growth Rate
CAPM	Capital Assets Pricing Model
CCSR	Clinical Classification Software Refined
COGS	Cost of Goods Sold
CRO	Contract Research Organisation
CT	Computed Tomography
DCF	Discounted Cash Flow
EV	Enterprise Value
FDA	Food and Drug Administration (US)
GLP	Good Laboratory Practices
HCUPnet	Healthcare Cost and Utilization Project
IDE	Investigational Device Exemption
IER	Independent Expert's Report
IP	Intellectual Property
IPO	Initial Public Offer
IPR&D	In-process Research and Development
NPV	Net Present Value
PCDF	Posterior Cervical Discectomy and Fusion
PLIF	Posterior Lumbar Interbody Fusion
PMA	Premarket Approval Application
PEEK	Polyetheretherketone
rNPV	Risk Adjusted NPV
SG&A	Sales General and Administrative
Stantons	Stanton Corporate Finance Pty. Ltd.
University	The University of Sydney
US	United States of America
WACC	Weighted Average Cost of Capital

## 1. Background

### 1.1 The Company and its Technology

AMT is a Sydney-based, ASX-listed company with a recent focus on the commercialization of orthopaedic implants based on a novel biocompatible material developed by researchers at The University of Sydney. On 2 November 2023 the Company changed its name from Allegra Orthopaedics Limited to Allegra Medical Technologies Limited following the sales of its distribution business.

The Company licenced the rights to the IP underpinning Sr-HT-Gahnite and associated biomaterial formulations from the University in 2014, and in 2020 acquired all the registered patents and application for patents held by the University. The management and Directors of AMT believe that Sr-HT-Gahnite has the potential to meet an unmet clinical need by achieving the critical combination of mechanical strength required for load-bearing orthopaedic application and bioactivity (osteoconductivity and osteoinductivity) required for bone regeneration.

Features of the novel material include:

- The ceramic material can be used to create any shape using additive manufacturing. As such, products could be customized for an individual's anatomy or clinical condition;
- Sr-HT-Gahnite releases ions into surrounding bone that are believed to regenerate bone growth;
- Safety and freedom from toxicity have been demonstrated in extensive laboratory and animal experiments, many conducted in accordance with the required testing standards;
- Products made of Sr-HT-Gahnite have shown adequate strength for orthopaedic use;
- The ability to manufacture a product of defined shape using 3D printing and in compliance with the standards establish for a comparable use material have been proven;
- Sr-HT-Gahnite represents a platform technology that can be applied to fixed orthopaedic implants as well as surface coatings of other implantable devices.

The initial product selected for development using the biomaterial is an interbody cage as used in fusion of upper vertebrae of the spine, the cervical spine. The design of the cage is generic and as such does not require proof of its utility from a regulatory perspective. The Company has self-funded the design and testing of the cage to the point that it considered it met the requirements for marketing approval in the US. Based on the fact that there are many interbody cage products for cervical fusion used clinically in the US, it was reasonable for the Company to assume that its product could be approved as a Class II device (moderate to high level risk) on the basis of substantial equivalence thereby obviating the need for costly clinical trials.

The Company sought to introduce the product into the US using the FDA's 510(k)<sup>1</sup> clearance pathway. The pathway requires proof that the device is substantially equivalent to a legally marketed device, *viz.* that it has the same intended use and the same technological characteristics as the predicate device, or that any different technological characteristics do not raise different questions of safety and effectiveness. Applicants must compare their device to one or more similar marketed devices and make and support their equivalence claims. The 510(k) approach reduces the onus on the developers to provide scientific evidence that the possible benefits to health from the intended use of a device outweigh the possible risks and that the device will significantly help a large portion of the target population.<sup>2</sup>

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<sup>1</sup> 510(k) refers to the section of the US Food, Drug and Cosmetic Act and codified into Title 21, Chapter 9 of the US Code. A 510(k), also called Premarket Notification, is based on the concept of substantial equivalence to a legally marketed device, referred to as a predicate. Substantial equivalence means that the new device is as safe and effective as the predicate and applicants are required to submit data that compares their device to one or more predicate devices.

<sup>2</sup> While most 510(k)s rely on non-clinical data, data suggests that the FDA may require clinical studies for approximately 10% to 15% of submissions.

The Company announced that a 510(k) submission had been filed with the FDA in March 2023.<sup>3</sup> In February 2024, AMT advised shareholders that the Directors had taken the decision to not proceed with its formal submission with written notification of the withdrawal having been received from the FDA.<sup>4</sup> The decision was taken following feedback from the FDA requesting additional supporting information prior to approving the product. The Company stated that its preferred option is to go to the market to seek a buyer for all of the IP relating to Sr-HT-Gahnite.

Prior to the FDA's response, future development focused on manufacturing scale-up, product launch in the USA, and R&D for new devices manufactured with the proprietary technology. It was anticipated by the Company that clinical trials would not be required for the US but only for the European, Australian and possibly other, markets, which trials could be done subsequent to the US approval.

The Sr-HT-Gahnite technology is applicable to other orthopaedic applications, including as a surface coating material to other substrates, although not currently evaluated and optimised for such uses. The potential for these applications is not considered in the current valuation.

## 1.2 Intellectual Property

The University filed one international patent application on Sr-HT-Gahnite claiming composition and uses. Published as WO2012/162753 and titled: *Biocompatible material and uses thereof*, it was filed on 1 June 2012. Granted in the USA and Australia, it will expire, in the absence of an extension, on 1 June 2032. Patent extensions, generally for up to five years, are possible where it can be demonstrated that regulatory approval processes delayed market introduction.

The patent claims a biocompatible composite material, comprising a first phase of doped Hardystonite ( $\text{Ca}_2\text{ZnSi}_2\text{O}_7$ ) and a second metal oxide phase belonging to the spinel group of minerals. Hardystonite is doped with at least one of strontium, barium and/or magnesium. The metal oxide is Gahnite ( $\text{ZnAl}_2\text{O}_4$ ), or other materials and combinations. The material is, it is claimed, suitable for implants and particularly suited for the regeneration of bone and other tissue, or for resurfacing arthritic joints to promote the growth of articular cartilage, or for the development of 3D scaffolds which promote migration, proliferation and differentiation of bone and endothelial cells. These uses include orthopaedic and maxillofacial surgical implants and load bearing parts, or use in supporting bone tissue regeneration or formation and vascularisation, for scaffolds for osteochondral defects, or as a coating on currently-used orthopaedic and dental implants.

The IP which the Company has developed and made available for sale includes the extensive laboratory and animal studies and their results, as well as guidance from the bodies responsible for approving the marketing of medical technologies. Some of this is presented in the following sections.

## 1.3 Studies Conducted by the Company

AMT has undertaken a number of studies over the past decade to both assess the biocompatibility and physical attributes of Sr-HT-Gahnite, to validate the manufacturing process and to evaluate the *in vivo* potential of its 3D printed cage. Many of the earlier studies have been published in peer review journals.

A description of the microstructural properties and initial *in vivo* studies were published as far back as 2013.<sup>5</sup> That study, by University researchers, presents details on the high level of porosity to facilitate bone ingrowth and shows the material has strength adequate and competitive with other implant materials. Studies with primary human osteoblast cultures confirmed the bioactivity of the scaffolds and, when implanted in rabbits, regeneration of critical-sized bone defects. The studies demonstrated that the material induces new bone defect bridging, with clear evidence of regeneration.

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<sup>3</sup> Allegra Orthopaedics Ltd. ASX Media Release 31 March 2023. AMT Submits 510(k) for Spinal Cage FDA Clearance/

<sup>4</sup> Allegra Medical Technologies Ltd. ASX Announcement. Spinal Cage FDA Submission Update. 6 February 2024.

<sup>5</sup> Roohani-Esfahani SI, *et al.* Unique microstructural design of ceramic scaffolds for bone regeneration under load. *Acta Biomater* 9(6):7014, 2013.

In a 2016 publication, the researchers reported that 3D printing obtained strength up to 150 times greater than values reported for polymeric and composite scaffolds and five times greater than reported values for ceramic and glass scaffolds at similar porosity.<sup>6</sup> In 2019, the first study in a large animal was reported with Sr-HT-Gahnite implanted into the tibia (shin bone) of sheep for up to 12 months.<sup>7</sup> The scaffolds, it was reported, induce substantial bone formation and defect bridging at 12 months, as indicated by X-ray, micro-computed tomography, and histological and biomechanical analyses.

The rabbit and initial sheep studies were not conducted in accordance with accepted laboratory practices and, while producing worthwhile knowledge and guiding future studies, would not be accepted as part of a regulatory submission aiming to obtain marketing approval. The first *in vivo* sheep study performed under good laboratory practices (“GLP”) conditions, aiming to demonstrate systemic safety in accordance with FDA guidelines, assessed a spinal fusion device over 26 weeks. Results were published in 2022.<sup>8</sup> The results show that no major changes in blood haematology or biochemistry parameters are observed, no systemic distribution of strontium to the blood and wool occurred, and that there were no macroscopic or histopathological abnormalities in the distant organs when Sr-HT-Gahnite was implanted. The conclusion is that the findings support the systemic safety of the Sr-HT-Gahnite interbody fusion device.

As a result of the unexpected failure of the porous design, AMT redesigned the Sr-HT-Gahnite cage. The new hollow spinal cage prototype was reassessed in a new large animal model. This activity was undertaken to evaluate the local and distant tissue effects and performance of a strontium-containing cervical fusion cage made from Sr-HT-Gahnite after sheep anterior cervical discectomy and fusion surgery. The test article was compared to a marketed control article (Valeo C®, by CTL Amedica, Inc.) in a sheep cervical spinal fusion model at 13- and 26-weeks post-implantation. AMT received the final results from the large animal study in February 2023 and these formed part of the 510(k) submission.

Based on all of the evaluations conducted by AMT and the University, the Company reports that available data support that the risk of systemic toxicity (acute, subacute, sub-chronic, and chronic), genotoxicity, carcinogenicity, and reproductive toxicity from potential exposure to the extracted constituents is low, and the device meets the requirements of GSPR 10.4.1 (per the European Medical Device Regulation standards).<sup>9</sup>

AMT has also conducted experiments to validate the manufacturing process. As there are no existing material standards for Sr-HT-Gahnite powder, being a new material, studies were conducted in accordance with requirements for the raw material hydroxylapatite powder (the relevant standard being ISO 13779-6:2015). As a result, the Company was able to define the physical properties of its printed spinal cage. The ability to sterilize the product post-manufacturing has also been achieved.

Additionally, the cervical fusion cage was tested under static and dynamic loading to assess the mechanical strength of the device after initial manufacture in accordance with the global standard of test methods for intervertebral body fusion devices. After receiving acceptable results, the Company conducted accelerated shelf-life testing to assess the performance of the devices over surrogate five- and ten-year intervals. The outcome of the accelerated shelf testing demonstrated that at ‘five’ years devices met the acceptance criteria for visual inspection. A decrease in mechanical strength was observed in compression shear load while meeting acceptance criteria when compared against the data for FDA-cleared cervical body fusion devices. The expiry date of five years was conditionally validated.

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<sup>6</sup> Roohani-Esfahani S-I, *et al.* Design and Fabrication of 3D printed Scaffolds with a Mechanical Strength Comparable to Cortical Bone to Repair Large Bone Defects. *Sci Reports* 6:19468, 2016.

<sup>7</sup> Li JJ, *et al.* A Novel Bone Substitute with High Bioreactivity, Strength, and Porosity for Repairing Large and Load Bearing Bone Defects. *Adv Healthcare Mat* 8(8):1801298, 2019.

<sup>8</sup> Newsom ET, *at al.* Design and evaluation of 3D-printed Sr-HT-Gahnite bioceramic for FDA regulatory submission: A Good Laboratory Practice sheep study. *Acta Biomater* 1(156):214, 2023 ([https://doi: 10.1016/j.actbio.2022.01.035](https://doi.org/10.1016/j.actbio.2022.01.035)).

<sup>9</sup> GSPR 10.4 is a requirement of medical devices. It mandates that devices should be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles that may be released from the device.

## 1.4 Discourse with Regulatory Authorities

The US FDA does not currently require a clinical trial for an interbody cage, classified as a Class II device, prior to market approval. However, for implants made of newer materials, the regulator has signalled an intention to require more and deeper pre-market tests and the possible requirement for post-market studies and up-classifying devices to allow more stringent regulation.<sup>10, 11</sup> An up-classification of the Sr-HT-Gahnite cage to class III, if mandated, will require a clinical trial.

AMT made its 510(k) submission to the FDA in early-2023, in which it included the extensive laboratory and pre-clinical investigations, as well as the positive results from the completed large animal GLP studies.

In its response to the submission, the FDA noted specific safety and effectiveness concerns relating to the strength of the device over time as well as biological effects of the device as reported from sheep studies. Additional information requested included reassessment of animal study deficiencies related to systemic toxicity, additional data collection timepoints, strontium evaluation, systemic and local histologic findings, imaging reports, device fracture, and fusion rates. The authority advised that evaluation of systemic toxicity in six animals is not sufficient to generate reliable data and support device safety and recommended evaluation of strontium levels at additional long-term timepoints after 26 weeks or until strontium levels reach steady-state or start decreasing.

The FDA noted that imaging and histology evaluations in animal studies reported incidents of device fracture. Histologic evaluation also identified possible degradation and migration of test article material. These data, in the words of the FDA examiner, are insufficient to demonstrate that the safety of the device is substantially equivalent to the predicate, which remained intact in both studies and showed no evidence of degradation. In addition, according to the FDA, the presence of the test article in the surrounding tissues and in the lymph node raises concerns about the possibility of material migration outside of its intended implantation space.

To address these concerns, the Company should provide *in vivo* data evaluating the safety and effectiveness of the device at later timepoints and that these include imaging, histology, histomorphometry, and biomechanical testing in the assessments. If the animal study data shows persistence and/or progression of device fracture over time, and/or there is evidence of device degradation, additional later timepoints may be indicated.

The FDA also requested more data on sterilisation, packaging, and shelf-life validations.<sup>12</sup>

Importantly, the FDA stated that in the future, “Clinical data may need to be used to further demonstrate long-term safety of the subject device.”

The Company prepared an updated development plan following the FDA’s comments. These budgets, which exclude staff and corporate costs, totalled \$1.35 million and involved approximately 3.5 years. The work included 28 months for additional animal studies. The potential need for human studies has not been addressed by the Company.

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<sup>10</sup> Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on efforts to evaluate materials in medical devices to address potential safety questions. March 15, 2019.

<sup>11</sup> The FDA has, for example, strengthened the regulation of metal-on-metal total hip replacement devices requiring that manufacturers submit premarket approval applications (“PMA”) following safety concerns associated with adverse biological reactions to metal wear particles and ions generated by the metal ball rubbing the metal socket joint during everyday use. The PMA pathway requires demonstration of safety and effectiveness through “adequate and well-controlled” clinical trials. The required trials are done under FDA supervision in the form of an investigational device exemption (“IDE”) in which the study design, outcome measures, etc., are approved by the FDA prior to initiation of the study.

<sup>12</sup> Allegra Orthopaedics Ltd. ASX Media Release 4 August 2023. Spinal Cage FDA Submission Update – Supplementary Announcement.

In Europe and Australia, the cage will be classified as a Class IIb device (medium to high risk installed in the body for periods greater than 30 days) and, as such, may require clinical evaluation. The Company, to our knowledge, has not instigated discussion with the European or Australian regulatory authorities as its main focus has been on accessing the US market.

### 1.5 Manufacturing Cost and Pricing

As part of our evaluation, AMT was able to provide a manufacturing cost estimate for the cervical cage. They have not proposed a selling price though it is likely that the Company would seek a premium on the basis of better biocompatibility and bone regenerative properties.

In Australia, the Prescribed List of Medical Devices, issued by the Department of Health and Aged Care, lists 41 devices as available in Australia.<sup>13</sup> It lists the amount that private health insurers must pay to the patients who have appropriate insurance policies, the amount for all cervical interbody cages being \$4,162.

An economic analysis of cervical cages commonly used in the US found that the average price for commonly available polyetheretherketone (“PEEK”) implants in 2020 was US\$2,961 (16 devices, with a range from US\$1,121 to US\$8,500) and titanium, US\$5,678 (n = 9, US\$1,121 to US\$9,095).<sup>14</sup> Nassr also confirmed a trend to increasing pricing as products evolve from allograft (natural bone) spacers to simple PEEK or titanium products, to titanium coated PEEK, 3D printed titanium and PEEK, to all in one fixation systems (with screws and plates) and nano surface coated implants. The higher prices often involve more complex designs, combination materials, and textured or porous surface modifications, some with pricing exceeding US\$11,000 per unit. At least six of the titanium products assessed by Nassr are 3D printed. More complex products, such as those with integrated screws or with integrated allografts were more highly priced.

### 1.6 The Need for Clinical Trials

AMT had not planned human clinical trials for its cervical cage working on the assumption that, in the US, it would be approved through the 510(k) mechanism because of substantial equivalence to one or more of the many cages currently on the market.

It is true that a 510(k) does not routinely require clinical trials, one estimate suggesting 10% to 15% of approvals, but that applies to common designs of implants and accepted materials, such as titanium and PEEK, and even silicon nitride, which have a history of use in implants. It appears that most companies initiate studies after the product has been launched seeking to demonstrate superiority in comparison to existing products, thus providing a marketing edge. These studies investigate pain and disability improvement, and the fusion status by X-ray and computed tomography (“CT”) scan over an extended period of time. Such studies recruit 100 or more (some up to 300) patients including those receiving a comparator device, over a one or two year period (see for example Amedica’s evaluation of its silicon nitride Valeo OL® device relative to a PEEK plastic implant, NCT01557829).<sup>15</sup>

St-HT-Gahnite is a new material which, to our knowledge, has never been implanted in a human and the FDA has noted some matters of concern with structural integrity and biological effects in the sheep studies. Although future animal studies will address these concerns there will always remain questions as to why the initial studies identified flaws.

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<sup>13</sup> Australian Government. Department of Health and Aged Care. Prescribed List of Medical Devices and Human Tissue Products. Last updated 19 March 2024 (<https://www.health.gov.au/resources/publications/prescribed-list-of-medical-devices-and-human-tissue-products?language=en>, accessed 21 May 2024).

<sup>14</sup> Nassr A. The Cost of Interbody Cages in Cervical Spine Surgery. Forty-eighth Annual Meeting of the Cervical Spine Research Society, Instructional Course, December 2<sup>nd</sup>, 2020. YouTube ([https://www.youtube.com/watch?v=UsT8Bibpc\\_I](https://www.youtube.com/watch?v=UsT8Bibpc_I), accessed 23 May 2024).

<sup>15</sup> The NCT is the number given to a clinical study in the US National Institutes of Health clinical trial database ClinicalTrials.gov (<https://clinicaltrials.gov>).

Under recent guidelines, the European Union and Australia, have made clinical studies a requirement for approval of novel Class IIb devices. The US may well follow in the coming years and there is a reasonable chance that AMT has missed the window. In any event, given that the design of the cage is not unique, AMT will want to demonstrate the product's advantages relative to existing materials in the clinical setting if it is to seek premium pricing.

Of relevance to the question of clinical trials, we do note that in March 2024, the FDA granted breakthrough device designation to RemeOs® Spinal Interbody Cage implant developed by Bioretec Ltd. The new RemeOs® product line is based on a magnesium alloy and hybrid composite, defined as a new range of strong biodegradable materials for enhanced surgical outcomes. The RemeOs® implants are absorbed and replaced by bone, which eliminates the need for removal surgery while facilitating fracture healing. Prior to this approval, the RemeOs® material had been evaluated in clinical trials as an ankle implant.

### 1.7 Attempts to Sell or License the IP

AMT has sought to sell its IP both through direct approaches to companies with an interest in orthopaedic products and to potential investors, as well as hiring the services of a company skilled in identifying collaborators. We were provided with a list of contacts made and some of their responses. In general, excluding those stating that the product did not fit their current portfolio or commercial focus, these organisations expressed the view that they would only be interested once the product or material has been approved for clinical use. One contact raised an issue related to the mechanical properties of the material.

## 2. Orthopaedic Implants and Markets

### 2.1 Spinal Surgery

Spinal fusion is a surgical procedure that connects two or more bones in the spine to correct or stabilize alignment and reduce pain. In performing spinal fusion surgery for neck (cervical) or lower back (lumber) pain, surgeons often insert interbody cages. These cages serve as space holders between adjacent vertebrae, allowing bone to grow through them and eventually become part of the spine. The cages can be made of materials like titanium or PEEK and are often filled with bone-growth promoting material, such as beta-tricalcium phosphate or the patient's own bone (autograft) taken from the hip. The cages have a hollow centre for placement of the growth promoting material. Depending on the number of spinal segments being fused, surgeons may place more than one cage in the spine. It is estimated that 70% to 95% of cervical fusions involve the use of cages.

First utilized in spinal fusion in the 1990s, titanium cages provide a low density, corrosion-resistant scaffolding for vertebral fusion. The surface of titanium cages can be modified to assist in osteointegration and bone adhesion. Introduced a decade later, PEEK cages are radiolucent, bioinert, magnetic resonance imaging compatible and display an elastic modulus that approximates that of bone. Studies comparing the performance of PEEK and titanium have failed to show one or other material is superior. Ceramic implants, specifically silicon nitride, are being introduced as new cage materials.

A disadvantage of metal cages is that they obstruct X-rays and therefore do not allow for good postoperative assessment of the effectiveness of the surgery. Although there are now many radiolucent cages available (PEEK) which allow X-rays and provide postoperative assessment, they do not provide as good fixation as metallic cages and may need to be supplemented by posterior pedicle screws or combination with titanium.

One significant development in spinal implants is the use of 3D printing. Personalized 3D printed implants enable increasing minimally invasive approaches for complex deformities and reduce patient risks. The advantages of 3D printed technology will improve the safety and efficiency of spine surgery, as it permits surgeons to pre-plan surgery based on preoperative imaging. It is this feature that is, in part, driving AMT's development program.

Recently approved 3D printed products include:

- Orthofix Medical, Inc. 3D printed FORZA Ti® PLIF Spacer System, designed for posterior lumbar interbody fusion (“**PLIF**”) surgeries and the Construx Mini Ti spacer system for anterior cervical discectomy and fusion (“**ACDF**”) procedures;
- In April 2023, ZSFab Inc. reported their release of a 3D printed titanium implant with a minimal lattice structure for ACDF. Positive results were demonstrated in two US clinical cases. In 2021, the system received 510(k) clearance; and
- In 2022, Aurora Spine, Inc. received 510(k) clearance for its Dexasolo-L® spinal fusion system, which is designed and personalized using the patient’s bone density and quality.

Medical Expo, a site where companies may exhibit their products, includes a section on cervical interbody cages.<sup>16</sup> The site lists 64 companies with 125 products while not including the products of several market leaders such as Biomet, Medtronic, NuVasive and DuPey/Synthes. Of those listed 77 are PEEK, 38 titanium and three allograft products. Acuity, through its own searches, identified at least 90 companies active in the field, with products on the market or in development.

## 2.2 Incidence of Surgery

In the US, numbers of fusion surgeries during the 1980s and early 1990s generally showed a steady but modest increase, until the introduction of interbody cages was approved for use in lumbar spine surgery in 1996, resulting in a 220% increment of lumbar spine surgery over the subsequent decade.

According to data published on the US Agency for Healthcare Research and Quality (“**AHRQ**”) website, Healthcare Cost and Utilization Project (“**HCUPnet**”), under Clinical Classification Software Refined (“**CCSR**”) for Spinal Fusion discharges, the total number of fusions in 2016 was 489,400, but this had declined to 386,370 in 2021. About one third of fusions are to the cervical region of the spine.

One study in New York state found that over the study period, 1997 to 2012, the population-adjusted annual cervical spine fusion rate increased from 23.7 to 50.6 per 100,000 population.<sup>17</sup> Fusions for both cervical and lumbar spine may be anterior (or the front of the body) or posterior (from behind). Another study reported that the number anterior or ACDF procedures is expected to increase from 153,288 in 2020 (46.2 per 100,000) to 173,699 in 2040, and over the same period, 29,260 to 35,335 for the posterior procedure (“**PCDF**”).<sup>18</sup>

It is less easy to obtain data in Europe and other parts of the world. Eurostat, for example, does not breakdown spine procedures but records hospital discharges as Deforming Dorsopathies and Spondylopathies totalling 428,314 in 2019 for incomplete national data and, with inclusion of the most recently presented data for other countries, 763,353 discharges. The US has by far the highest utilization rate for spine surgery. Kim, *et al.*, based on a literature search, determined that, when compared with the US as 100%, incidence of spinal surgery was 33% for Sweden, 44% for Australia, 49% for Ontario Canada and Norway, 56% for Finland, and 64% for Denmark.<sup>19</sup>

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<sup>16</sup> Medical Expo. Cervical interbody fusion cages (<https://www.medicalexpo.com/medical-manufacturer/cervical-interbody-fusion-cage-28428.html>, accessed 21 May 2024).

<sup>17</sup> Salzmann SN, *et al.* Cervical Spinal Fusion: 16-Year Trends in Epidemiology, Indications, and In-Hospital Outcomes by Surgical Approach. *World Neurosurg* 113:e280, 2018 (<https://doi.org/10.1016/j.wneu.2018.02.004>).

<sup>18</sup> Neifert SN, *et al.* Predicting Trends in Cervical Spinal Surgery in the United States from 2020 to 2040. *World Neurosurg* 141:e175, 2020 (<https://doi.org/10.1016/j.wneu.2020.05.055>).

<sup>19</sup> Kim P, *et al.* Technical Advancements and Utilization of Spine Surgery —International Disparities in Trend-Dynamics Between Japan, Korea, and the USA. *Neurol Med Chir (Tokyo)* 50:853, 2010.

### 2.3 Spinal Fusion Markets

The market for spinal implants and devices is large. In the US alone, the spine industry was estimated by Orthopedic Design and Technology, to have grown 5% between 2015 and 2016 to US\$7.8 billion in sales to US hospitals.<sup>20</sup> This is reported as the highest year-to-year growth in the market since 2010 and reflects the growth in specific sub-segments of the spine market. The US market for spinal implants and devices used in spinal surgery now exceed both the size and growth of the US hip and knee market.

As estimated by Grand View Research, the global spinal implants and devices market size was estimated at US\$13.3 billion in 2023 and projected to grow at a compound average growth rate (“CAGR”) of 5.4% from 2024 to 2030 to reach US\$19.0 billion.<sup>21</sup> The spinal fusion devices segment accounted for the largest market share of 58.4% in 2023. North America spinal implants and devices market dominated the overall global market and accounted for the 48.3% revenue share in 2023.

According to Insight Partners, the global spinal fusion devices market has experienced annual growth averaging 5.8% over the past decade with the sector’s overall value reaching US\$12.99 billion by 2030 (up from \$8.27 billion in 2022).<sup>22</sup> The analysts attribute the market’s growth to technological advancements and increasing numbers of spinal fusion procedures. Global interbody fusion device revenues are forecast to expand 6.5% annually over the next six years due to developments in interbody fusion device design and manufacture.

## 3. AMT’s Strengths and Risks

The underlying strength of Sr-HT-Gahnite and the Company’s interbody cage (see also Section 1) include:

- Granted patents;
- Excellent biocompatibility – not rejected by the body;
- Animal studies to 26 weeks demonstrating good biological and mechanical properties;
- 3D printing with the potential for customization;
- Prototyping completed and manufacturing process shown to be compliant with standards for other implantable materials, with cost of production reasonably determined;
- Load bearing being stronger than synthetic bone substitutes;
- Useful as a bone graft material, eliminating donor site complications associated with autograft surgeries; and
- Many applications of the technology across the orthopaedics industry.

Having said that a strength is the granted patents, at least in the US, the remaining life of the patent is limited and will be severely impacted by the need for additional studies. This will be particularly acute if there is a requirement to undertake clinical trials.

The main risk facing AMT, or an acquirer, is that the SR-HT-Gahnite is a new implantable material and has no history of human use. Although *in vitro* and *in vivo* testing to date has been positive there are a number of inadequacies as elucidated by the FDA. Once evaluated in the human setting the product may not perform clinically to expectation.

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<sup>20</sup> Orthopedics Design & Technology. 15 March 2017. First U.S. Cases Using One-Step-Insertion of Pedicle ‘Smart Screws’ ([https://www.odtmag.com/contents/view\\_videos/2017-03-15/first-us-cases-using-one-step-insertion-of-pedicle-smart-screws](https://www.odtmag.com/contents/view_videos/2017-03-15/first-us-cases-using-one-step-insertion-of-pedicle-smart-screws)).

<sup>21</sup> Grand View Research. Spinal Implants and Devices Market Size Report, 2024 – 2030. Report ID: GVR-1-68038-031-6 (abstract at <https://www.grandviewresearch.com>).

<sup>22</sup> Barbella M. Solid Growth Predicted for Spinal Fusion Devices market. Orthopedic Design & Technology 1 May 2024 ([https://www.odtmag.com/contents/view\\_breaking-news/2024-01-05/solid-growth-predicted-for-spinal-fusion-devices-market](https://www.odtmag.com/contents/view_breaking-news/2024-01-05/solid-growth-predicted-for-spinal-fusion-devices-market), accessed 28 May 2024).

AMT will face the usual business risks associated with economic uncertainty which are outside the control of the Company. Start-up companies in the sector face additional issues with funding as device evaluation programs and promotional costs are high and, to some extent, regulations are evolving.

The medtech industry and the development of implant materials and devices carry their own industry-specific risks. Several of the leading orthopaedic suppliers are already marketing or are developing enhanced interbody devices and AMT will compete against major healthcare companies to gain market share. Competition from innovative start-up companies, of which there are many in the orthopaedics area, are an additional risk to the Company's success. The development and marketing of medical devices and orthopaedic hardware are the realm of large and specialised companies. Many have substantial capital and other resources and are able to expend more funds and effort than AMT on brand-awareness and promotion. Competitors may develop more effective, more affordable or more convenient products. These competing products may render AMT's product candidate obsolete or non-competitive.

If one or more of the raw material suppliers or a contract research organisation ("CRO") used by the Company or the IP acquirer, where they are used, does not perform as expected or ceases their cooperative efforts with the Company, this will adversely impact sales progress. There is also a risk that if the Company cannot replace a supplier, sales will be affected and earnings below expectation.

The knowledge developed by the Company and its collaborators, including the University, may not be readily transferrable to an acquirer of the IP. In the event one or more key employees does not migrate to the new owners or no longer participates in the development, or that documentation is inadequate and incomplete, there is a risk that further learning will be required resulting in delays to product launch.

## 4. Valuation Methods

For the purpose of our valuation opinion, current market value is defined as the amount at which the IP assets could be expected to change hands in a hypothetical transaction between a knowledgeable willing, but not anxious, buyer and a knowledgeable willing, but not anxious, seller acting at arm's length.

Techniques used for valuing intangible assets, including IPR&D, generally fall into three main categories:

1. Cost Based;
2. Market Based; and
3. Revenue Based.

We examined several approaches, many of which were considered not applicable to the current valuation. These are briefly discussed in the following sections. The preferred valuation method, that relying on a risk adjusted net present value ("rNPV") of projected net benefit, is presented in further detail in Section 4.3.

### 4.1 Cost Based Methods

There are several cost approach valuation methods, the most common being the reproduction cost and the replacement cost methods. Often these may be based on the historical costs incurred by the original developer. Generally, however, patents provide a market monopoly for the originator's inventions and it would be very difficult for a third party to replicate the technology with equivalent utility, specificity and activity without infringing those patents.

Although the development of novel medical technologies is extremely costly, future benefits are considered to be worthy of the investment and deals to acquire promising R&D-stage programs may be an order of magnitude higher than the past expenditure. Patents, research results and regulatory approvals are the key assets underpinning inter-industry acquisitions and represent more than a cost-to-replicate the technology. Expedited time to market, realized through an asset's acquisition as opposed to its reproduction, is also a consideration in purchase price.

We consider that cost-based methods are not applicable in the present circumstance.

## 4.2 Market Based Methods

Valuation techniques based on analysis of transactions between companies to acquire or license IP, and equity valuations or capitalisations of companies with comparable IP and where the IP is the major asset, have considerable merit in the healthcare sector. There are also many fund raisings, both private placements and Initial Public Offerings (“**IPO**”), which may be used as analogies.

A market analysis should realistically be undertaken by comparing technology companies or transactions where the IP is at a similar stage of development, i.e., discovery, pre-clinical or laboratory evaluation, or clinical stage. In valuing a company or its IP, the comparable company or transaction should have common purpose and/or be technically equivalent to the subject company or IP. Such criteria are often difficult to meet and comparable analyses are usually used only to support the values derived with other methodologies or to provide a “ball park” estimate.

Further comment is provided in Section 5.1.

## 4.3 Methods Based on Future Prospects

A technique suitable for valuing a business, IP or a project, such as IPR&D, with strong and relatively predictable future prospects is based on a DCF analysis. To assume any level of credibility, the DCF must be based on sound cash flow predictions, with justifiable assumptions regarding sales estimates, expenses and revenue timings. These are then valued to present day using a discount rate, often following probability adjustment, that recognises the time value of money and risks involved in achieving the forecast cash flows.<sup>23</sup> The preferred approach is to use expected cash flows arrived at using decision analysis techniques and probability analysis.<sup>24</sup> The resulting cash flows may then be discounted at a rate close to the cost of capital as the risks are deemed to have been dealt with in the probability analysis. The explicit assessment of the probabilities associated with the possible cash flow outcomes provides computational transparency compared with selecting a discount rate purportedly commensurate with the risks. The procedure explicitly recognises the time profile of the risk by probability adjusting the cash flow using literature- or experience-based probabilities and applying these at the time points at which the risk has been resolved.

The usual discount rate in an rNPV analysis is based on a company’s Weighted Average Cost of Capital (“**WACC**”) which reduces to the Capital Assets Pricing Model (“**CAPM**”) in the absence of debt.

The CAPM for AMT may be determined using the following formula:

$$\text{CAPM} = R_f + \beta \times (R_m - R_f)$$

Where:

$R_f$  is the Risk Free Rate of Return. To estimate the risk-free rate, the US Ten-Year treasury yield of 4.5% is used, a rate of 2.2% after adjusting for inflation (the US being the initial and major market for products).

$R_m$  is the Expected Market Return and  $(R_m - R_f)$  the Risk Premium being the premium over the risk-free rate that an investor requires to invest in the market portfolio. The current Expected Market Return for investors is around 6.0% to 7.0%.

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<sup>23</sup> Bogdan B & Villager R. Valuation in Life Sciences: A Practical Guide. Springer Verlag (Berlin), 2007.

<sup>24</sup> Aaron AV, Bitton VR (co-chairs), *et al.* Assets Acquired to Be Used in Research and Development Activities - Accounting and Valuation Guide. AICPA, New Jersey, 2013.

Beta ( $\beta$ ) of a particular investment is a reflection of its risk expressed as a percentage of the volatility to that of a market portfolio, ie. a portfolio of stocks sufficiently diversified to reflect average market movements. Examination of a basket of listed early-stage medtech and orthopaedics companies suggests a suitable beta of between 1.4 and 1.6 as relevant to AMT.

To the CAPM may be added a risk premium that arises because of deficiencies in information underpinning cash flow forecasts. This is a metric that also considers market and general economic uncertainty. We suggest that a premium of 2% to 4% may be reasonable resulting in a real discount rate for AMT (following probability adjustment of development risks) of around 14% to 16%.

## 5. IP Valuation

### 5.1 Comparable Companies and Licensing Deals

Accepting that the enterprise value (“EV”) of an early-stage, pre-revenues company is dictated by the value of its IP, we searched finance databases for suitable analogies. Our searches failed to identify any acquisition of technology, IP or company, that we consider appropriate for use in a comparables analysis – the criterion being pre-market and pre-clinical, orthopaedic implant or materials IP, and limited residual patent life. We did identify a number of early-stage orthopaedic companies which are listed on a stock exchange but none of these were developing technologies with attributes sufficiently close to AMT’s development program. In any event, AMT has suffered a set back in its planned development program and the EVs of apparently well performing start-ups is hardly comparable.

### 5.2 Future Benefits Analysis

Acuity’s preferred valuation methodology is to use a risk adjusted discounted cash flow. This involves the generation of financial models that include estimates of the potential sales of products, based on addressable market, penetration and selling price; and expenses including development costs, cost of goods sold (“COGS”) and general and administrative costs. In present valuing the cash flows, adjustments are made for both developmental and commercial risks.

The valuation date is 1 June 2024 and the cash flows are estimated for 12 monthly periods commencing 1 June each year for the term of the current patent plus a patent extension. Such extensions are commonly for a maximum of five years, provided that delays by the FDA led to a loss of the patent owner’s ability to exercise their patent rights. As there is no assurance that the extension will be available, we have assumed three years, effectively assuming a 60% likelihood that the full extension will be granted.

Financial models are developed in US dollars, being the initial target market, and the valuation converted to Australian currency at the current exchange rate (\$1.00 equals US\$0.66).

We have considered sales in the US, Europe (the five main markets of France, Germany, Italy, Spain and the United Kingdom) and Japan only. Product is sold directly to hospitals/end users and through distributors with revenues deriving from a per device cost. We have estimated sales revenue for the following scenarios:

- 510(k) approval without trials but with trials conducted after US entry for purposes of post-market surveillance, to generate marketing information, and satisfy non-US compliance; and
- Clinical trials required as part of the US 510(k) submission.

We have assumed a manufacturers average selling price (“ASP”) of US\$3,800 based on the average price of cervical interbody cages in the US.

Projected revenues are based on the estimated numbers of cervical fusion procedures performed in each of the designated countries. We have assumed a single cage per procedure (not all fusions involve a cage while others utilize two or more). Market penetration assumes 5% of the market, based on procedure numbers, at peak. The addressable market is summarised in the following table.

**Table 1: Estimated Procedure Numbers (2024) and Pricing for Sr-HT-Gahnite Cages**

	USA	EU/UK	Japan
Procedures (thou)	168	80.5	18.5
Annual Growth	2.0%	2.0%	1.0%
Market Share	5.0%	5.0%	5.0%
ASP (US\$ per device)	\$3,800	\$3,800	\$3,800
Potential Revenues (US\$'mil)	\$32.0	\$15.3	\$3.5

We have applied the following development times and costs to our analyses:

**Table 2: Development Timings and Likelihoods**

	Clinical Trials as Part of 510(k)			Clinical Trials Post 510(k)		
	Duration (years)	Cost (US\$'000)	Likelihood	Duration (years)	Cost (US\$'000)	Likelihood
Laboratory Studies	1	66	100%	1	66	100%
Animal Studies	3	800	80%	3	800	80%
Clinical Study	2	6,000	60%	3	6,000	
Regulatory Review	1	30	90%	(post MA) 1	30	54%
<b>Totals (to US MA)</b>	<b>7</b>	<b>6,896</b>	<b>43.2%</b>	<b>5</b>	<b>896</b>	<b>43.2%</b>
Launch Year USA	2031			2029		
Launch Year EU/UK	2032			2032		
Launch Year Japan	2033			2033		

We have assumed a clinical trial of 50 subjects at US\$120,000 per subject in both scenarios.

In addition to the above study costs, the models include company overheads as fixed amounts up until product is launched in the US in line with AMT's historical management costs. Following product launch in the US, cost of sales is determined as 34.4% of revenues and sales, general and administrative costs as 42.7% of revenues. These ratios have been determined through an analysis of the reported financials of eight publicly listed, internationally operating orthopaedic device companies (analysis not presented).<sup>25</sup> It should be noted that these companies also report R&D at an average of 7.7% which we have not included in the AMT analysis as it is not relevant to an IP valuation. The cost of sales as a percentage of revenues is significantly higher than the COGS estimated by the Company but the companies examined are likely to include losses due to manufacturing rejects, returns, presentation and ancillary supplies, and other costs not considered by the Company.

A pre-launch advertising and promotion cost of 50% of the first year's sales is included in the year prior to launch.

<sup>25</sup> The companies used in our analysis are: Zimmer Biomet, Smith & Nephew, Stryker Corporation, Medtronic, NuVasive, Globus Medical, Alphatec Holdings and CONMED Corporation.

We have probability adjusted the cash flows based on our reading of the studies conducted to date, experience and knowledge in the development of medical devices, and our understanding of the response provided by the FDA. Risk adjustments are applied at the time points where they impact cash flows.<sup>26</sup>

We have assumed a corporate tax rate of 25% being the Australian rate for companies with turnover of less than \$50 million. Losses accumulated by the Company are not included while those incurred following the valuation date are carried forward to profitability.

The following table presents revenues and expenses for the case in which clinical trials are not required prior to US approval.

**Table 3: Estimated Revenues and Expenses without Clinical Trials (US\$'mil)**

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034
<b>Revenues</b>	0	0	0	0	0	8,837	18,027	27,581	41,993	48,363	54,953
COGS	0	0	0	0	0	3,041	6,204	9,493	14,453	16,645	18,913
<b>GM</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,795</b>	<b>11,823</b>	<b>18,089</b>	<b>27,540</b>	<b>31,718</b>	<b>36,040</b>
<b>Expenses</b>											
R&D	76	411	411	10	10	2,000	2,000	2,000	0	0	0
SG&A	550	605	666	732	5,254	886	974	11,778	17,932	20,652	23,466
<b>Total Exp.</b>	<b>626</b>	<b>1,016</b>	<b>1,076</b>	<b>742</b>	<b>5,264</b>	<b>2,886</b>	<b>2,974</b>	<b>13,778</b>	<b>17,932</b>	<b>20,652</b>	<b>23,466</b>
<b>EBIT</b>	<b>-626</b>	<b>-1,016</b>	<b>-1,076</b>	<b>-742</b>	<b>-5,264</b>	<b>2,910</b>	<b>8,848</b>	<b>4,311</b>	<b>9,608</b>	<b>11,066</b>	<b>36,040</b>
Risk Adj CF	-626	-813	-861	-356	-2,527	1,257	3,822	1,862	4,151	4,781	5,432

Discounting the probability adjusted cash flows at 15% suggests a valuation of \$2.89 million.

In the event that the FDA does require a clinical trial as part of the 510(k) process, the following cash flows have been determined:

**Table 4: Estimated Revenues and Expenses with Clinical Trials (US\$'mil)**

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034
<b>Revenues</b>	0	0	0	0	0	0	0	9,194	23,238	38,798	54,953
COGS	0	0	0	0	0	0	0	3,164	7,998	13,353	18,913
<b>GM</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>6,030</b>	<b>15,240</b>	<b>25,445</b>	<b>36,040</b>
<b>Expenses</b>											
R&D	76	277	277	277	3,010	3,010	40	0	0	0	0
SG&A	550	605	666	732	805	886	5,601	3,926	9,923	16,568	23,466
<b>Total Exp.</b>	<b>626</b>	<b>882</b>	<b>943</b>	<b>1,009</b>	<b>3,815</b>	<b>3,896</b>	<b>5,641</b>	<b>3,926</b>	<b>9,923</b>	<b>16,568</b>	<b>23,466</b>
<b>EBIT</b>	<b>-626</b>	<b>-882</b>	<b>-943</b>	<b>-1,009</b>	<b>-3,815</b>	<b>-3,896</b>	<b>-5,641</b>	<b>2,104</b>	<b>5,317</b>	<b>8,877</b>	<b>12,574</b>
Risk Adj CF	-626	-706	-754	-807	-1,831	-1,870	-2,693	909	2,297	3,835	5,432

The discounted cash flow at 15% results in a negative NPV and valuation, i.e., the investment does not justify the continued development of the product.

<sup>26</sup> Bogdan B & Villiger R. Valuation in Life Sciences: A Practical Guide. Springer 2010.

The valuation remains negative even if the cost of the clinical trial is removed due to the extended duration to product approval which cuts significantly into the available life of the patent. Use of a lower discount rate of 13%; a five year, rather than three year, patent extension; and no major launch cost have no impact on the outcome.

Our models do not include income from grants and R&D tax incentives.

## 6. Conclusions

Based on a risk adjusted DCF analysis, using projections of sales based on current and anticipated procedure numbers that may utilise the Sr-HT-Gahnite cage, we have determined that the IP has no or negligible value, should the FDA require a clinical trial, to under \$3.0 million if the minimum studies requested by the FDA leads to an approval. The primary factor in determining the low valuation is the short remaining life of the patent. If trials are mandated, then the time to recover the investment may be too short. We have proposed a trial involving 50 patients at a cost of US\$120,000 per patient, totalling US\$6.0 million, and taking two years to complete and evaluate. As discussed in Section 1.6, there could be a need for significantly more patients and a longer assessment period. The cost could be far higher if extended and where more interim and sophisticated analyses are required.

We are of the opinion that trials are likely to be required due to the facts that deficiencies have already been noted in studies to date and the novel material has never been implanted into a human. Nonetheless, we have considered the scenario where such trials are undertaken after the US approval as post-marketing surveillance or simply to generate marketing information. Such trials will most likely be required by European regulators. Their inclusion, at \$6.0 million and post the US marketing approval, suggest a positive valuation at around \$2.9 million. We note that this is considerably less than has spent by the Company on development so far and it largely arises because of the decay in patent life.

The Company's sale process did not attract a buyer. This fact alone mitigates against a sizeable valuation.

Assuming a 60% likelihood that early trials will be required with a valuation of nil, and a 40% likelihood that no trials will be required for US approval meaning the Company can bring its product to market in the shortest possible time, we propose a valuation of \$1.16 million in the range of nil to \$2.89 million.

It should also be pointed out that our DCF analysis assumes funding for development and commercialization is available which, in the better scenario of no clinical requirement, could exceed \$5.0 million not including promotional costs at launch, and without these funds the IP may have no value

Factors that would increase the valuation are a higher price for the proposed product, but we are of the opinion that demonstration of significant clinical advantages will be required before achieving a better than average price; greater penetration of the market, also requiring demonstration of superior performance, in the face of significant competition from more-than-adequate products; and the development and introduction of other products, such as a thoracic cage or Sr-HT-Gahnite coated PEEK cage. While additional cage types can greatly expand the market, we have difficulty in seeing how they can be introduced to the market until all issues with the material biosafety have been resolved and clinical utility demonstrated.

Additional patents will, of course, assist in extending the market monopoly, but at this stage none are mooted, and this valuation relates solely to the current IP.

While realising that the IP has value even when the patent has expired, if the product has significant advantages relative to PEEK and titanium, and none have been proven to date, competition will be able to replicate the product during the period of patent extension. This is a crowded market and we believe that the product will need to demonstrate significant clinical and cost advantage in order to capture reasonable market share and the only way to demonstrate this is with clinical trials, irrespective of the FDA's stance with the 510(k).

A valuation in the hands of a well-resourced acquirer may be higher because risks are lower, and skills and infrastructure may be better. Studies could be expedited by a well-resourced company.

## 7. Sources of Information

In preparing this report we have held discussions with Ms Jenny Swain, CEO of AMT and undertaken independent searches of the scientific, commercial and patent databases, and relied on the following information provided by the Company:

- AMT Pty Ltd. Financial Statements for the year ended 30 June 2023 and the six months to 31 December 2023;
- Cost Estimate for the Sr-HT-Gahnite cervical cage prepared by AMT; and
- Extracted responses from the draft review by V. Dwivedi, Intracolumnar Spinal Device Team, of the Office of Product Evaluation and Quality, Centre for Devices and Radiological Health, US Food and Drug Administration to NAMSAs dated 2 February 2024.

We assessed the markets for products and competition from publicly available sources including publications, and reviewed patent status and similar technological developments through the World Intellectual Property Organization Index (<https://patentscope.wipo.int>).

## 8. Disclaimer

The valuations make certain assumptions in relation to the revenue prospects. In preparing this report we have relied on information provided by AMT, complemented by our own experience in drug and medical technology development and independent searches of the literature. We can provide no assurance that material provided by the Company was complete and accurate although we have no reason to suspect that this was not the case. We have exercised all due care in verifying the information provided and found no reason to doubt its reliability.

A draft of this report was supplied to AMT to confirm factual accuracy and some changes were made to reflect their comments.

Acuity does not guarantee that the outcomes described in this report will actually occur because of possible changes in the markets and the Company's or IP acquirer's own actions, which are beyond our ability to forecast.

Acuity has acted independently in preparing this report and neither its Director nor staff have any pecuniary or other interest in AMT, their related entities or associates that could reasonably be regarded as affecting its ability to give an unbiased opinion. Acuity will receive normal professional fees, estimated at \$18,500, for the preparation of this report and, with the exception of these fees, will not receive any other direct or indirect benefits.

Acuity does not hold an Australian Financial Services Licence and provides no opinions or recommendations relating to the suitability of AMT as an investment, acquisition, or the merits of the Proposed Transaction.

## 9. Qualifications & Experience

Acuity provides management consulting to technology-based companies. The company is skilled in the development of business plans and the technical, commercial and financial analyses of engineering and science-based projects. An area of special interest is the provision of advice to investors and financial institutions on the funding of high technology R&D and the exploitation of outcomes.

The current valuation was undertaken by Acuity's Managing Director, David Randerson. Dr Randerson specializes in the valuation of intangible assets, and business entities whose main assets are intangibles, with particular expertise in IP and IPR&D. Valuations have been performed for purposes of licensing, capital raising and investment, sale, depreciation and amortization, impairment, purchase price allocation, consolidation, mergers, acquisitions, stock options and goodwill.

Dr Randerson has a Bachelor of Chemical Engineering (Monash University), Master of Science in Applied Science (UNSW) and a Doctorate of Philosophy (UNSW) with a thesis in artificial internal organs. He is a Fellow of the Australian Institute of Company Directors and a member of the Institution of Chemical Engineers. He has worked in academia at the University of Munich (LMU Klinikum, Großhadern) and The University of Queensland, and in industry with Rio Tinto Australia, Union Carbide Australia and Johnson & Johnson Extracorporeal Division (Philadelphia, USA). He was founder and managing director of one of Australia's first publicly listed biotechnology companies, specializing in the GMP production of therapeutic monoclonal antibodies and recombinant proteins. More recently David was CEO and Director of the Cooperative Research Centre for Biomarker Translation, a developer of therapeutic monoclonal antibodies, centred at La Trobe University, Melbourne.

Yours sincerely

A handwritten signature in blue ink, consisting of a stylized, cursive 'D' followed by a horizontal line extending to the right.

Dr David Randerson, BE, PhD  
Managing Director