



# PROSPECTUS

## **Tissue Repair Ltd**

ACN 158 411 566

For the Offer of 19.1 million Shares  
at an issue price of \$1.15 per Share  
to raise \$22 million

Lead Managers



Legal Adviser



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# Important Notices

## General

The Offer contained in this Prospectus is an invitation to apply to acquire Shares in Tissue Repair Ltd (ACN 158 411 566) (the **Company**).

This Prospectus is dated 7 October 2021 (**Prospectus Date**). A copy of this Prospectus was lodged with ASIC on that date.

The Company will apply to ASX within seven days of the date of this Prospectus for admission of the Company to the Official List and for quotation of its Shares on the ASX.

Neither ASIC nor ASX takes any responsibility for the contents of this Prospectus or the merits of the investment to which this Prospectus relates. No Shares will be allotted on the basis of this Prospectus after the Expiry Date. This Prospectus expires on the date that is 13 months after the Prospectus Date.

## Note to Applicants

This Prospectus provides information for investors to decide if they wish to invest in the Company.

The Offer does not take into account the investment objectives, financial situation or needs of particular investors. This Prospectus should not be construed as financial, taxation, legal or other advice. The Company is not licensed to provide financial product advice in respect of its securities or any other financial products.

This Prospectus is important and should be read in its entirety prior to deciding whether to invest in Shares. There are risks associated with an investment in Shares and the key risks are set out in Section 5. You should carefully consider these risks in light of your personal circumstances (including financial and tax issues) and seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest in Shares. There may also be risks in addition to these that should be considered in light of your personal circumstances.

Except as required by law and only to the extent so required, no person named in this Prospectus warrants or guarantees the Company's performance, the repayment of capital by the Company or any return on investment made under this Prospectus.

No person is authorised to give any information or to make any representation in connection with the Offer, other than as is contained in this Prospectus. Any information or representation not contained in this Prospectus should not be relied on as having been made or authorised by the Company, the Directors, the Lead Managers or any other person in connection with the Offer. You should rely only on the information in this Prospectus.

## Speculative investment

The Shares offered under this Prospectus should be considered highly speculative. There is no guarantee that the Shares offered under this Prospectus will make a return on the capital invested, that dividends will be paid on the Shares or that there will be an increase in the value of the Shares in the future.

Prospective investors should carefully consider whether the Shares offered under this Prospectus are an appropriate investment for them in light of their personal circumstances, including their financial and taxation position. Refer to Section 5 for details relating to the key risks applicable to an investment in the Shares.

## Forward looking statements

Various statements in this Prospectus may be in the nature of forward looking statements, including statements of current intentions, statements of opinion and predictions as to future events. Forward looking statements are identified by words such as 'may', 'could', 'believes', 'estimates', 'expects', 'intends', 'considers' and other similar words that involve risks and uncertainties. You should be aware that such statements are not statements of fact and there can be no certainty of outcome in relation to the matters to which the statements relate.

Forward looking statements are subject to various inherent risks and uncertainties (many of which are outside the Company's control) that could cause the Company's actual results to differ materially from the results expressed or anticipated in these statements. As a result, forward looking statements should be read in conjunction with risk factors as set out in Section 5 and other information in this Prospectus.

The Company does not intend to update or revise forward looking statements, regardless of whether new information, future events or any other factors affect the information contained in this Prospectus, except where required by law.

## Past Performance

This Prospectus includes information regarding the past performance of the Company. Investors should be aware that past performance should not be relied upon as being indicative of future performance.

## International offer restrictions

This Prospectus does not constitute an offer in any place outside Australia where, or to any person to whom, it would not be lawful to make such an offer. No action has been taken to register or qualify the Shares or the Offer, or to otherwise permit a public offer of the Shares, in any jurisdiction outside Australia. The distribution of this Prospectus outside Australia may be restricted by law and persons who come into possession of this Prospectus should observe any such restrictions. Any failure to comply with such restrictions could constitute a violation of applicable securities laws. See Section 7.10 for more details on the selling restrictions that apply to the Offer outside Australia.

This Prospectus must not be distributed in the United States. The Shares have not been, and will not be, registered under the US Securities Act of 1933, as amended (**US Securities Act**), and will not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and any applicable US state securities laws.

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## Defined terms and abbreviations

Defined terms and abbreviations used in this Prospectus are explained in Section 12. Unless otherwise stated or implied, references to times in this Prospectus are to the time in Sydney, Australia.

## Cooling off rights

Cooling off rights do not apply to an investment in Shares acquired under the Prospectus. This means that, in most circumstances, you cannot withdraw your Application to acquire Shares under this Prospectus once the Application has been accepted.

## Electronic prospectus

This Prospectus is available electronically at [www.tissuerepair.com.au](http://www.tissuerepair.com.au). The Application Form attached to the electronic version of this Prospectus must be used within Australia. Electronic versions of this Prospectus should be downloaded and read in their entirety. Obtain a paper copy of the Prospectus (free of charge) by telephoning 1300 288 664 (toll free within Australia) or +61 2 9698 5414 (outside Australia) from 9am until 5pm. Applications for Shares may only be made on the Application Form attached to this Prospectus or in its paper copy form downloaded in its entirety from [www.tissuerepair.com.au](http://www.tissuerepair.com.au).

## Exposure period

Under the Corporations Act the Company must not process Application Forms during the seven day period after the date of lodgement of this Prospectus with ASIC. This period may be extended by ASIC for up to a further seven days. This exposure period enables the Prospectus to be examined by market participants. Application Forms received during the exposure period will not be processed until after the expiry of that period. No preference will be given to Application Forms received during the exposure period.

## Contract summaries

Summaries of contracts detailed in this Prospectus are included for the information of potential investors but do not purport to be complete and are qualified by the text of the contracts themselves.

## Privacy

By completing an Application Form, you are providing personal information to the Company, and the Share Registry, which is contracted by the Company to manage Applications. The Company, and the Share Registry on their behalf, collect, hold and use that personal information to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included in the Company's public register. The information must continue to be included in the Company's public register if you cease to be a Shareholder. If you do not provide all the information requested, your Application Form may not be able to be processed. The Company, and the Share Registry may disclose your personal information for purposes related to your investment to their agents and service providers as disclosed in the Company's Privacy Policy or as otherwise authorised under the *Privacy Act 1988* (Cth).

You may request access to your personal information held by or on behalf of the Company. You can request access to your personal information or obtain further information about the Company's privacy practices by contacting the Share Registry or the Company. The Company aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact the Company or the Share Registry if any of the details you have provided change.

In accordance with the requirements of the Corporations Act, information on the Shareholder register will be accessible by members of the public.

## Currency

Monetary amounts shown in this Prospectus are expressed in Australian dollars unless otherwise stated.

## Photographs and diagrams

Photographs used in this Prospectus which do not have descriptions are for illustration only and should not be interpreted to mean that any person endorses this Prospectus or that assets shown in the photographs are owned by the Company.

Diagrams used in this Prospectus are illustrative only and may not be drawn to scale.

## Third party publications

The Industry Overview in Section 2 of this Prospectus includes attributed statements from books, journals and comparable publications that are not specific to, and have no connection with, the Company. Except where indicated otherwise, the authors of these books, journals and comparable publications have not provided their consent for these statements to be included in this Prospectus, and the Company is relying upon ASIC Corporations (Consents to Statements) Instrument 2016/72 for the inclusion of these statements in this Prospectus without that consent having been obtained.

**This document is important and should be read in its entirety.**

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# Key Dates and Key Offer Details

Key Event	Date
Prospectus Date	Thursday 7 October 2021
Broker Firm Offer opening date	Friday 22 October 2021
Broker Firm Offer closing date	5pm Friday 29 October 2021
Settlement of the Offer	Monday 15 November 2021
Allotment of Shares (Completion of the Offer)	Tuesday 16 November 2021
Expected dispatch of holding statements	Wednesday 17 November 2021
Expected commencement of trading of Shares on ASX on a normal settlement basis	Thursday 18 November 2021

The timetable above is indicative only. The Company, in consultation with the Lead Managers, reserves the right to amend any or all of these dates subject to the Corporations Act, the ASX Listing Rules and other applicable laws, including closing the Offer early, extending the Offer, deferring completion of the Offer or accepting late Applications either generally or in particular cases, allotting Shares at different times to investors, or to withdrawing the Offer, all without prior notice. The Official Quotation and commencement of trading of the Shares on ASX remains subject to confirmation from ASX.

## Key Offer details

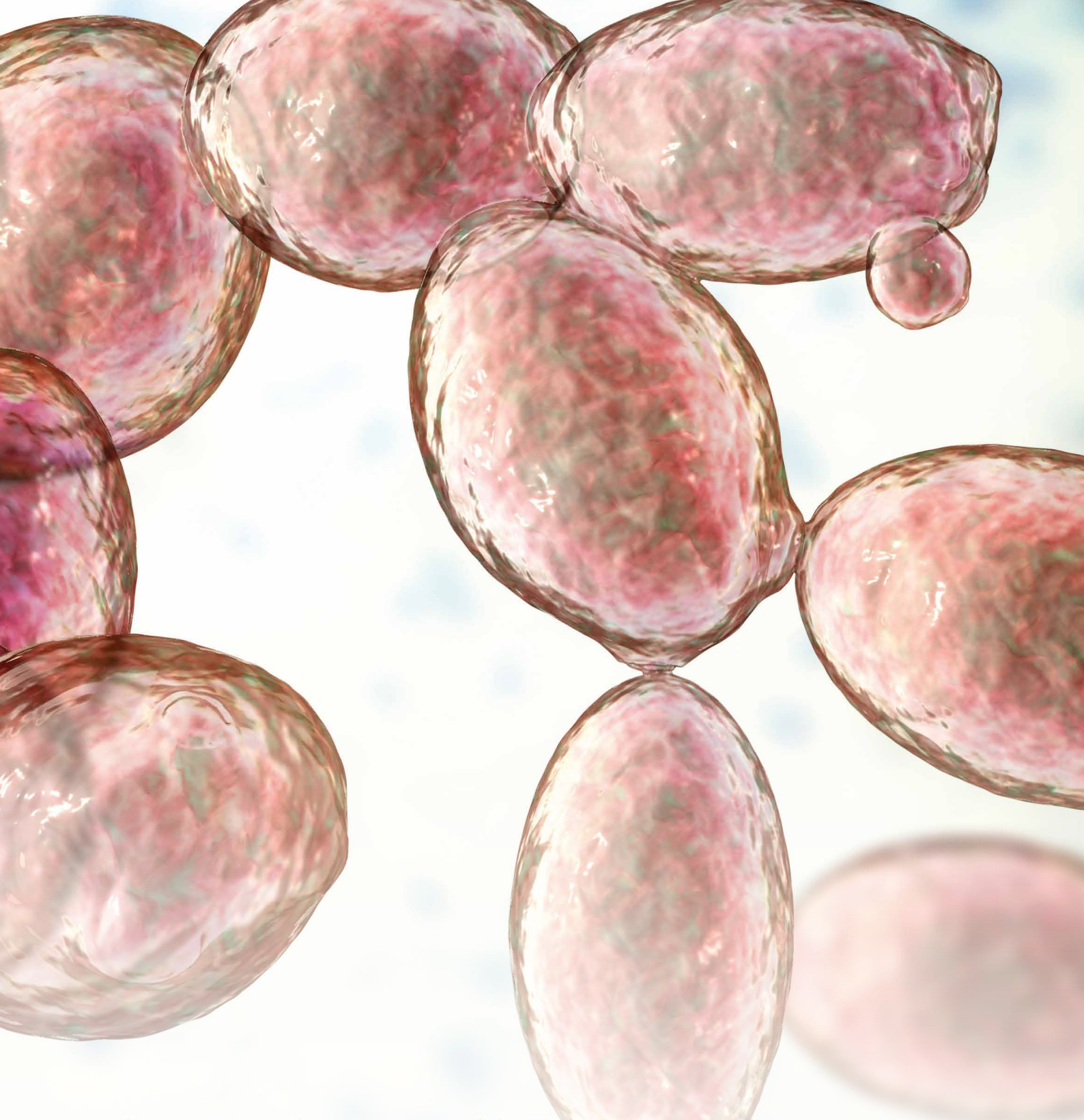
Company making the Offer	Tissue Repair Ltd
Proposed ASX code	TRP
Offer Price	\$1.15
Number of Shares available under the Offer	19,130,440
Gross proceeds from the Offer	Minimum Subscription Amount of \$22 million
Total number of Shares on issue at Listing, excluding the Shares available under the Offer	41,334,403
Total number of Options on issue at Listing	22,470,580
Total number of Shares on issue at Listing (on an undiluted basis)	60,464,843
Total number of Shares on issue at Listing (on a fully diluted basis)	82,935,423
Indicative market capitalisation at listing (on an undiluted basis) <sup>1</sup>	\$69.5 million
Pro forma net cash <sup>2</sup>	\$27.1 million
Enterprise value at the Offer Price <sup>3</sup>	\$42.4 million

1. Indicative market capitalisation at listing (on an undiluted basis) equals the Offer Price multiplied by the Total number of Shares on issue at Listing (on an undiluted basis).

2. Pro forma net cash is calculated as cash and cash equivalents as at 30 June 2021, plus gross Offer proceeds, less Offer costs, less net losses to mid September 2021.

3. Enterprise value at the Offer Price is defined as the Indicative market capitalisation at listing (on an undiluted basis), less the pro forma net cash.





Tissue Repair has a positive signal of efficacy from its Phase II clinical trials and is pursuing a drug classification in the active wound care market, which is currently dominated by medical devices.

**(+R)** TISSUE REPAIR

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# Chairman's Letter

Dear Investor,

On behalf of the Board of Directors, I am delighted to invite you to become a shareholder of the Company. Tissue Repair is a clinical stage biopharmaceutical company developing an advanced wound healing technology targeting applications in the chronic wound and cosmetic procedure markets.

In 2020, Tissue Repair completed the core clinical work and end of study statistical analysis on its Phase IIB chronic wound trial achieving a positive signal of efficacy that the Company believes warrants progression to Phase III clinical trials. The Company is aiming to prove in-use superiority of its drug candidate to current therapies. If successful, Tissue Repair could make a significant difference to the lives of many people currently living with debilitating chronic wound conditions and is aiming to become the first company in over 20 years to achieve a drug label with therapeutic claims in a chronic wound indication, in a market currently dominated by medical devices.

Tissue Repair has developed a unique active ingredient that is designed for wound healing and delivered topically. The biologically active pharmaceutical ingredient (**API**) behaves like a decoy cell and simulates a yeast infection resulting in the stimulation of the body's own wound repair pathways. This active ingredient also provides a platform for the opportunity to develop a range of products that have the potential to treat a broad range of conditions across the wound care market.

Tissue Repair is in the final stages of completing its Phase II program after completing Phase IIB clinical trial work and end of study statistical analysis for its chronic wound product, TR-987. The Phase IIB trial program was on two indications: chronic wounds and aesthetic dermatology. Tissue Repair is planning to commence pivotal Phase III trials in 2022 on a chronic wound indication, subject to approval by the FDA.

We are excited about the technology given its relatively advanced stage of clinical development and the opportunity to pursue a drug label in a chronic wound indication which has significant unmet needs. Therapeutic claims in a chronic wound (if achieved at the end of Phase III) provide a platform for growth and reimbursement differentiating Tissue Repair's product from competitor products. Over 240 patients (across different indications) have been studied clinically across Phase I, Phase IIA and Phase IIB trials with TR-987. Over 200 of these patients were within randomised, double-blind and placebo-controlled studies. Tissue Repair's planned Phase III clinical studies (subject to FDA approval) will seek to validate its unique active ingredient, Glucoprime, in providing patients dual benefits of enhancing and accelerating wound healing.

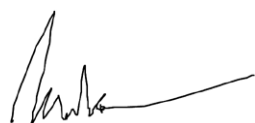
In the longer term (and if the required drug regulatory approvals are achieved), Tissue Repair's technology could have the potential to be employed to develop a family of products that promote and accelerate wound healing and tissue repair across a range of medical and surgical applications.

The core focus of Tissue Repair is the clinical development and commercialisation of its advanced wound healing gel, TR-987, however, Tissue Repair also hopes to commercialise its aesthetic dermatology gel, TR Pro+. Positive clinical data from aesthetic dermatology trials has laid the foundation for Tissue Repair's commercialisation plan for its cosmeceutical product, TR Pro+, as a post-procedure gel to be used following certain minimally invasive cosmetic procedures, with an Australian market launch currently planned in 2022.

We have assembled a high-quality team of scientific, medical, venture and pharmaceutical executives in Australia and the USA to support Tissue Repair in the pursuit of its objectives. To support our commercialisation strategy, including undertaking a Phase III trial as well as commercialising our cosmeceutical product, TR Pro+, the Company is seeking to raise \$22 million under the Offer and to list its Shares on the Australian Securities Exchange (**ASX**).

The Offer represents an opportunity to participate in the development of an advanced wound care technology with a Phase IIB clinical program supporting a positive signal of efficacy in two segments of large global markets, however, an investment in Tissue Repair must be considered highly speculative.

We encourage you to read the Prospectus carefully and in its entirety before making an investment decision. On behalf of my fellow Directors, we look forward to welcoming you as a Shareholder of Tissue Repair.



**Jack Lowenstein**  
Non-Executive Chair



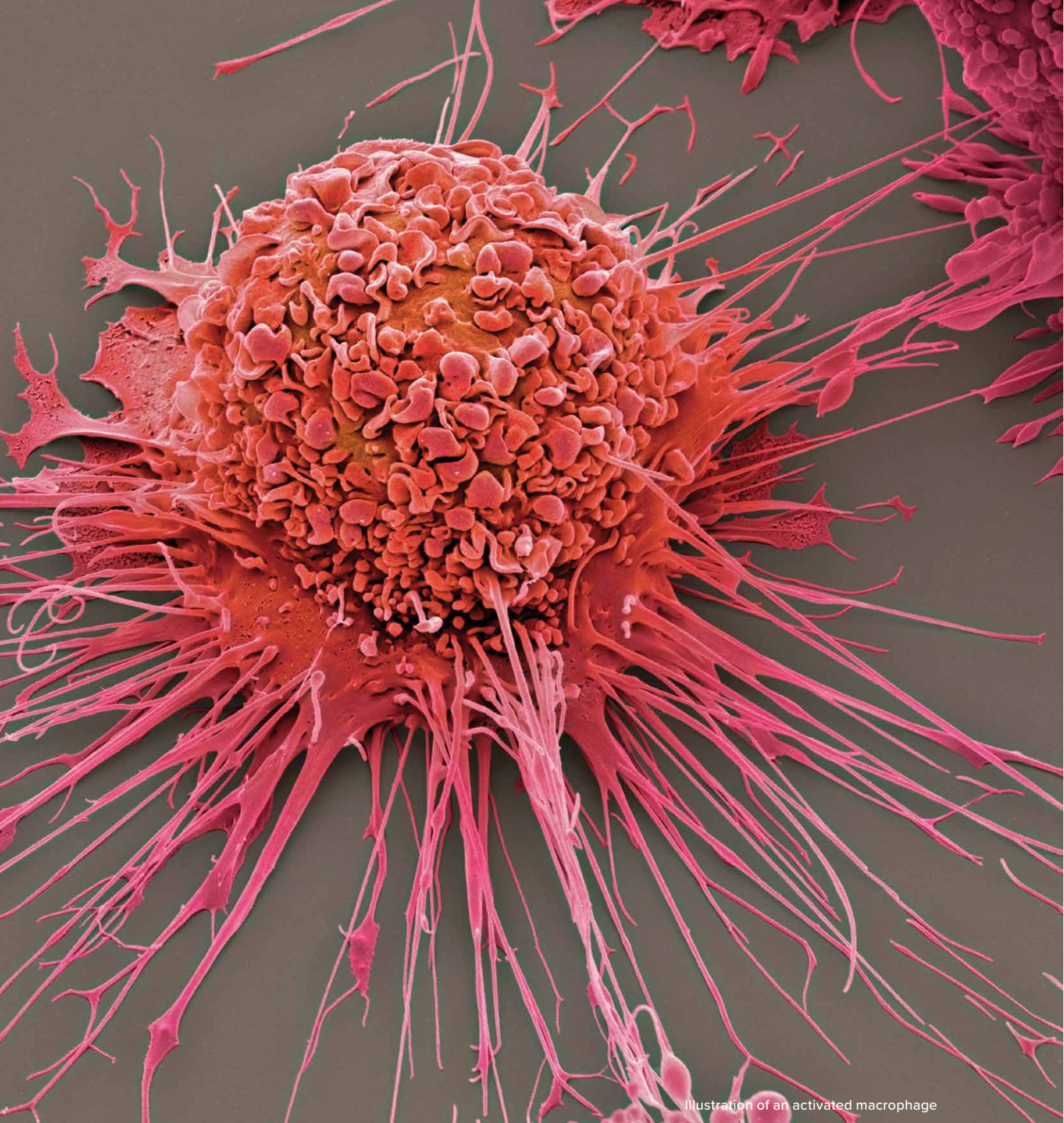


Illustration of an activated macrophage

## 1. Investment Overview





# 1. Investment Overview

The information set out in this Section is intended to be a summary only and should be read in conjunction with the more detailed information appearing elsewhere in this Prospectus. In deciding whether to apply for Shares under the Offer, you should read this Prospectus carefully and in its entirety. If you are in doubt as to the course you should follow, please consult your stockbroker, solicitor, accountant, financial adviser or other professional adviser.

## 1.1 Company Overview

Question	Answer	Location in this Prospectus
Who is Tissue Repair?	Tissue Repair is a clinical stage biopharmaceutical company developing advanced wound healing products targeting applications in the chronic wound and cosmetic procedure aftercare markets, with the potential for further development of related technologies.	Section 3.1
What is the Company's history?	<p>In 2012, the Company and its wholly owned US subsidiary, TR Therapeutics, Inc., were established to acquire the advanced wound care assets, intellectual property and technology of Novogen Research Pty Ltd and Glycotex, Inc.</p> <p>Since founding Tissue Repair in 2012, a team of dedicated venture capital and scientific founders have focused on obtaining further data and additional clinical evidence through undertaking a Phase IIB clinical trial program to confirm the early efficacy signals of the core technology. Additional work has also been undertaken on analytical identification and manufacturing of its active ingredient candidate.</p>	Section 3.2
What industry does Tissue Repair operate in?	The Company's core focus is part of the chronic wound market which, in the USA alone, is estimated to cost the federal healthcare system up to US\$50bn <sup>4</sup> (for both primary and secondary diagnosis, including the cost of infections and all costs associated with care including but not limited to hospital and medical costs). Tissue Repair is initially targeting the US\$1.5bn <sup>5</sup> market of active wound care products (biologics) used to treat these conditions in the USA. Tissue Repair is also targeting the market for aftercare of minimally invasive cosmetic procedures.	Section 2.2
What is Tissue Repair's unique technology?	<p>Tissue Repair has developed a unique immunogenic active ingredient, referred to as Glucoprime, which activates the body's own macrophages and stimulates an immune response that leads to accelerated wound healing.</p> <p>TR-987 is a drug candidate that has been designed to activate immune cells developed to defend against pathogenic microorganisms. Using the principle of biologic pattern recognition, the TR-987 gel utilises a purified insoluble biological polysaccharide (<math>\beta</math>-glucan) "skeleton" of a yeast cell that is used as a decoy to attract macrophages to the wound site.</p> <p>In the longer term (subject to regulatory approvals), Tissue Repair's technology could have the potential to be employed to develop a family of products that promote and accelerate wound healing and tissue repair across a range of medical and surgical applications.</p>	Sections 3.3 and 3.4

4. Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 21(1), 27-32.

5. SmartTRAK Business Intelligence.

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# 1. Investment Overview Continued

Question	Answer	Location in this Prospectus
What clinical stage is Tissue Repair at?	<p>Tissue Repair is in the final stages of closing its Phase II program having completed Phase IIB clinical trial work and end of study statistical analysis in 2020 for its chronic wound product, TR-987. It is planning to commence pivotal Phase III trials for its chronic wound product in 2022, subject to FDA approval. Tissue Repair is also preparing to launch its cosmeceutical product (TR Pro+) in the Australian market in 2022, a post-procedure gel to be used following some minimally invasive cosmetic procedures.</p> <p>Tissue Repair is in the process of undertaking the requisite planning, analytical identification and manufacturing work required to commence Phase III clinical trials for its chronic wound care product.</p>	Sections 3.1-3.6
What is Tissue Repair's product pipeline and what are they used for?	<p><b>Tissue Repair's products include:</b></p> <p><i>Chronic wound product</i></p> <p>Tissue Repair's primary objective is to achieve a drug label in a chronic wound indication. The US\$1.7bn global advanced active wound care (biologics) market (approximately US\$1.5bn in the USA alone)<sup>6</sup> predominantly treats chronic wounds and is currently dominated by medical devices, scaffolds and human derived placenta products.</p> <p>A key differentiator for Tissue Repair's lead drug product, TR-987, is its topical gel format and its immunogenic mechanism of action. The drug promotes an immune response to stimulate the body's own immune system and to help initiate wound repair. The drug is not a patch or scaffold and does not require any complicated application by a clinician or surgeon, providing caregiver and in-home application advantages over competitor products.</p> <p><i>Cosmeceutical product</i></p> <p>A secondary focus is the medium-term commercialisation of the technology as a cosmeceutical gel for use following certain minimally invasive (nonsurgical) cosmetic procedures.</p> <p><i>Other potential future products</i></p> <p>Subject to the collection of appropriate clinical data, Tissue Repair's platform technology potentially has relevance to a range of applications in a variety of other wound care markets such as burns, over-the-counter/pharmacy wound products, atopic dermatitis, or new bandage and scaffold products impregnated with Tissue Repair's API. The technology also has potential for animal use in veterinary applications. These alternate indications are future opportunities, and not currently being pursued by Tissue Repair in its existing program of work.</p>	Section 3.1

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6. SmartTRAK Business Intelligence.

Question	Answer	Location in this Prospectus
Who manufactures Tissue Repair's products?	Tissue Repair has engaged contract manufacturers for the manufacture of its API (Glucoprime), the finished drug product (TR-987) and the finished cosmeceutical product (TR Pro+).	Section 3.8
What are Tissue Repair's key costs?	<p><b>Operating expenses</b> relating to all indirect expenditure that is not attributable to the Company's research and development activities. These expenses include general office overheads, management and board costs, legal fees, corporate advisory costs, indirect employee costs, administration, travel, occupancy, and patent costs (application for patents as well as patent protection).</p> <p><b>Research and development expenses</b> representing costs for employees, contractors, materials and other expenditure associated with the Company's research and development programs. Included here are the costs of undertaking clinical trials, manufacturing and analytical and development work, regulatory costs and regulatory legal advice.</p> <p><b>Share based payments</b> representing the non-cash expense attributed to vested Options and the expenses to date for Options that have not yet vested (as the expense is spread over the vesting period). The Options have been issued to key management personnel, employees and non-employees of Tissue Repair as well as advisers.</p>	Section 4
Why are there no financial forecasts in the Prospectus?	The Company is in the development phase and has not begun selling its products in any market, and there are significant material uncertainties associated with forecasting any future revenues and expenses. On this basis, the Directors believe that there is no reasonable basis for the inclusion of financial forecasts in this Prospectus.	N/A
What is Tissue Repair's dividend policy?	Tissue Repair is currently in the development phase of operations and expects to incur significant expenditure to execute the Company's business plans. Accordingly, the Company does not expect to declare any dividends for the foreseeable future. The Company's ability to earn any significant free cashflow from which to pay a dividend is materially uncertain.	Section 4.12

# 1. Investment Overview Continued

## 1.2 Key features of industry in which Tissue Repair operates

Topic	Summary		Location in this Prospectus
Chronic wounds	<b>Description</b>	<b>Spending in the USA</b>	Section 2.2
	<p>Wounds with impaired healing that haven't healed within 4 weeks, including:</p> <ul style="list-style-type: none"> <li>• Venous ulcers (current clinical trial focus)</li> <li>• Diabetic foot ulcers</li> <li>• Pressure ulcers</li> <li>• Arterial ulcers</li> </ul>	<p><b>Over US\$50bn cost to treat, with approximately US\$1.5bn spent on active wound care products (biologics)</b></p> <p>Estimated USA Medicare cost of over US\$50bn to treat chronic wounds via both primary and secondary diagnosis, including cost of infections and all costs associated with care including but not limited to hospital and medical costs<sup>7</sup>, excluding costs incurred by the non-Medicare population</p> <p>It is estimated that 75% of chronic wounds occur in the Medicare population<sup>8</sup></p> <p>Tissue Repair is initially targeting the US\$1.5bn<sup>9</sup> market of active wound care products (biologics) used to treat these conditions in the USA</p>	
Aftercare of minimally invasive cosmetic procedures	<b>Description</b>	<b>Spending in the USA</b>	Section 2.2
	<p>Aftercare of a targeted segment of nonsurgical treatments administered by surgeons/physicians designed to improve the appearance of the skin (aesthetic dermatological procedures), including:</p> <ul style="list-style-type: none"> <li>• Laser skin resurfacing (initial and core focus of Tissue Repair)</li> <li>• Other potential segments include: <ul style="list-style-type: none"> <li>– Chemical peels</li> <li>– IPL treatment</li> <li>– Microdermabrasion</li> <li>– Needling</li> <li>– Laser hair removal</li> <li>– Laser tattoo removal</li> </ul> </li> </ul>	<p><b>Approximately US\$3.4bn annual spend on related procedures</b></p> <p>Almost 4.7m aesthetic dermatological procedures in 2019 with estimated total spend on these procedures of almost US\$3.4b (Australia had over 361,000 procedures worth an estimated A\$341m)<sup>10</sup></p> <p>Estimated spend does not include spending on aftercare products</p>	

7. Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 21(1), 27-32.

8. SmartTRAK Business Intelligence.

9. SmartTRAK Business Intelligence.

10. Frost & Sullivan Market Report.



Topic	Summary	Location in this Prospectus
Future markets (subject to the development of products future preclinical and clinical data and regulatory approval)	<b>Description</b>	Section 2.2
	<ul style="list-style-type: none"> <li>• Burns</li> <li>• Surgical wounds</li> <li>• Trauma wounds</li> <li>• After sun care</li> <li>• Other complex and/or healing impaired wounds</li> <li>• Veterinary</li> </ul>	
What are the Company's regulatory pathways?	<p>To be able to sell a drug product with therapeutic claims, Tissue Repair requires regulatory approval and market clearance in each respective jurisdiction in which it seeks to sell its products, with each country and region differing in its regulatory framework.</p> <p>Tissue Repair's therapeutic drug product, TR-987, is in the final stages of Phase II (having completed Phase IIB clinical trial work and end of study statistical analysis in 2020). The Company has commenced requisite preparatory and planning work for Phase III (subject to FDA approval) required to support regulatory approval as a drug in the USA and Australia.</p> <p>The potential regulatory and approval processes for Tissue Repair's therapeutic drug candidate, TR-987, in its preliminary target markets (the USA and Australia) are outlined in Section 2 of this Prospectus.</p> <p>Tissue Repair's cosmeceutical product, TR Pro+, may presently be classified and marketed as a cosmetic in Australia and the USA, although no therapeutic claims can be made. Tissue Repair plans to undertake market research in 2021 to determine the optimal launch pathway for TR Pro+ which is planned for 2022.</p>	Section 2.7

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# 1. Investment Overview Continued

## 1.3 Financial information

Question	Answer	Location in this Prospectus
What is Tissue Repair's historical financial performance?	The Company's historical results have been set out in detail in Section 4.5.	Section 4.5
How does Tissue Repair expect to fund its operations?	<p>The Company's expenditure program sets out its use of funds from the Offer and existing funds, with which the Company will have sufficient working capital at the time of its ASX admission to meet its stated objectives for at least the next 24 months.</p> <p>Tissue Repair does not expect to generate meaningful revenue in the short term.</p>	Section 7.1.2
What is Tissue Repair's forecast financial performance?	The Directors have considered the requirements of ASIC Regulatory Guide 170 <i>Prospective financial information</i> (RG170) to determine if prospective financial information should be included in this Prospectus. The Directors have determined that, as at the date of this Prospectus, Tissue Repair does not have reasonable basis to reliably forecast future earnings and accordingly forecast financial information is not included in this Prospectus. There is uncertainty in relation to the quantum and timing of Tissue Repair's future revenue given the status of its research, resulting in a level of unpredictability in the timing, quantum and recognition of future receipts.	Section 4.2

## 1.4 Board and management

Topic	Summary	Location in this Prospectus
Who are the directors of Tissue Repair?	<p><b>Mr Tony Charara</b> <i>Co-Founder, Executive Director</i></p> <p><b>Mr Jack Lowenstein</b> <i>Independent, Non-Executive Chair</i></p> <p><b>Mr Max Johnston</b> <i>Independent, Non-Executive Director</i></p> <p><b>A/Prof. Craig Stamp</b> <i>Independent, Non-Executive Director</i></p> <p><b>Mr Bryan Gray</b> <i>Independent, Non-Executive Director</i></p>	Section 6.1
Who are the management of Tissue Repair?	<p><b>Mr Tony Charara</b> <i>Co-Founder, Executive Director</i></p> <p><b>Dr Darryl Reed</b> <i>Chief Operations Officer (COO)</i></p> <p><b>Dr Pramod Nednoor</b> <i>Vice President of Chemistry and Controls</i></p> <p><b>Mr William Bost</b> <i>Vice President of Manufacturing</i></p> <p><b>Mr Mark Waring</b> <i>Vice President of Clinical and Regulatory Affairs</i></p> <p><b>Mr Cameron Jones</b> <i>Chief Financial Officer (CFO)</i></p>	Section 6.2

## 1.5 Significant interests of key people and related party transactions

Topic	Summary	Location in this Prospectus																
Who are the substantial shareholders and what will their interests be at Listing?	<p>On the Listing Date, it is anticipated that the following Shareholders (including the interests of their associates) will hold greater than 5% of the share capital in the Company:</p> <table> <tr> <th>Shareholder</th> <th>Shares</th> <th>Percentage interest of shares on issue<sup>1</sup></th> <th>Options</th> </tr> <tr> <td>Selene Holdings Limited<sup>2</sup></td> <td>5,955,980</td> <td>9.9%</td> <td>Nil</td> </tr> <tr> <td>Spark Capital Pty Limited (Mr Tony Charara)<sup>3</sup></td> <td>4,822,260</td> <td>8.0%</td> <td>13,640,000</td> </tr> <tr> <td>Creight Investments Pty Ltd (Mr Peter Scutt)<sup>4</sup></td> <td>4,022,260</td> <td>6.7%</td> <td>2,500,000</td> </tr> </table> <p>Notes:</p> <ol style="list-style-type: none"> <li>1. The percentage interest in shares on issue above is calculated on an undiluted basis.</li> <li>2. Selene Holdings Limited is an early investor in Tissue Repair.</li> <li>3. Spark Capital Pty Limited is an entity controlled by Tony Charara, a co-founder and Executive Director of the Company.</li> <li>4. Creight Investments Pty Ltd is an entity controlled by Peter Scutt, a co-founder and former Director of the Company.</li> </ol> <p>The above assumes no additional participation by these Shareholders in the Offer.</p> <p>Final holdings of all Substantial Shareholders will be notified to the ASX on the Company's Listing.</p>	Shareholder	Shares	Percentage interest of shares on issue <sup>1</sup>	Options	Selene Holdings Limited <sup>2</sup>	5,955,980	9.9%	Nil	Spark Capital Pty Limited (Mr Tony Charara) <sup>3</sup>	4,822,260	8.0%	13,640,000	Creight Investments Pty Ltd (Mr Peter Scutt) <sup>4</sup>	4,022,260	6.7%	2,500,000	Section 7.1.4
Shareholder	Shares	Percentage interest of shares on issue <sup>1</sup>	Options															
Selene Holdings Limited <sup>2</sup>	5,955,980	9.9%	Nil															
Spark Capital Pty Limited (Mr Tony Charara) <sup>3</sup>	4,822,260	8.0%	13,640,000															
Creight Investments Pty Ltd (Mr Peter Scutt) <sup>4</sup>	4,022,260	6.7%	2,500,000															

# 1. Investment Overview Continued

Topic	Summary	Location in this Prospectus
What significant benefits are payable to Directors and other persons connected with the Company or the Offer and what significant interests do they hold?	Directors are entitled to remuneration and fees as disclosed in Section 6.4.	Section 6.4
	Set out below are details of the interests of Directors in the Shares and other securities of the Company immediately prior to lodgement of the Prospectus with ASIC and on the Listing Date.	
	Shares at “Prospectus Date” numbers are expressed before the Share Split described in Section 11.3.	



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## 1.6 Key investment risks

Question	Answer	Location in this Prospectus
<b>Products not yet launched and the therapeutic product is not yet approved for commercial sale</b>	<p>Tissue Repair's ability to achieve profitability is dependent on a number of factors, including, for its therapeutic product, its ability to commence and complete successful Phase III clinical trials and obtain regulatory approval in the USA and Australia (at a minimum), and Tissue Repair's ability to successfully commercialise either or both of its cosmeceutical or therapeutic products. There is no guarantee that Tissue Repair's products (either or both its cosmeceutical and therapeutic product/s) will be commercially successful. Tissue Repair does not currently generate revenue from product sales, and any such revenue would first be from its cosmeceutical product, which has not yet been launched. Revenue from Tissue Repair's therapeutic drug product will not be possible until FDA approval is granted in the USA and the product is successfully launched. Clinical trials for Tissue Repair's therapeutic product may also be suspended for safety or efficacy reasons, following development it may prove difficult or impossible to replicate and manufacture any of Tissue Repair's products on a large scale, or, during the period of development, competitors (including those with greater resources) may emerge with competing or alternative treatments or technologies.</p>	Section 5.2.1
<b>Product acceptance</b>	<p>Tissue Repair's growth and the commercial success of Tissue Repair's current and future products is reliant on the acceptance of Tissue Repair's products by healthcare professionals, including the relevant medical and wound care specialists.</p> <p>The degree of market acceptance and continued adoption of Tissue Repair's products will depend on a number of factors, including:</p> <ul style="list-style-type: none"><li>• the potential and perceived advantages of Tissue Repair's products over competitor products and the preference by healthcare professionals of competitor's products due to familiarity with those products or for other reasons;</li><li>• Tissue Repair's products performing to expected standards of care and quality;</li><li>• Tissue Repair's ability to successfully market its products by providing clinical and economic data that show the safety, clinical efficacy, cost effectiveness and patient benefits from Tissue Repair's products; and</li><li>• Tissue Repair's ability to deliver consistent clinical results for indications when approved.</li></ul> <p>The acceptance of Tissue Repair's products may gain acceptance slower than planned or may not gain broad market acceptance by healthcare professionals which, should this arise, would impact Tissue Repair's operating and financial performance and viability.</p>	Section 5.2.2

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# 1. Investment Overview Continued

Question	Answer	Location in this Prospectus
<b>Clinical trial risk for therapeutic product</b>	<p>Tissue Repair may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to commence or conduct Phase III clinical trials for its therapeutic product. As a new manufacturing site is being established, it is possible that the FDA does not accept there is equivalence of the API used in prior stage clinical trials. The FDA could require bridging studies on the API produced at the new site or that prior stage clinical trials are repeated on the API produced by the new manufacturing site.</p> <p>There is also no guarantee that Tissue Repair's technology will prove to be safe and efficacious in the Phase III clinical trials, or that the regulatory approval to manufacture and market its therapeutic products will be received. The clinical trials could be put on hold or terminated, which will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its technology.</p>	Section 5.2.3
<b>Manufacturing risk</b>	<p>There is a risk that Tissue Repair may not be able to reproduce its API material and/or drug product that is consistent with what was used in clinical trials historically (i.e. it is not consistent with the IND specifications currently on file with the FDA), delaying or impeding Tissue Repair's ability to proceed to Phase III clinical trials. Should this risk occur, the FDA could require additional bridging studies or require that earlier stage clinical trials are repeated.</p> <p>Tissue Repair may face potential scale-up challenges as it seeks to increase the output of its manufacturing for commercialisation of its products and may have difficulty reproducing the API material and/or drug product and producing it in large quantities.</p> <p>The Company expects to be dependent on one or more Contract Manufacturing Companies (CMC), exposing it to additional risks through these counterparties.</p>	Section 5.2.4
<b>Regulatory and reimbursement approvals</b>	<p>The research, development, manufacture, marketing and sale of products using Tissue Repair's technology are subject to varying degrees of regulation by government authorities in Australia, USA, Europe and Asia. Products developed using Tissue Repair's technology must undergo a comprehensive and highly regulated development and review process.</p> <p>For Tissue Repair's therapeutic product that process also includes the requirement to receive regulatory approval to be able to sell and market the Company's drug product. This additional process includes the provision of clinical data relating to the quality, safety and efficacy of the therapeutic product for its proposed use, and therapeutic products may also need to be submitted for reimbursement approval. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of therapeutic products in some jurisdictions.</p> <p>Any of the products utilising Tissue Repair's technology may be shown to be unsafe, non-efficacious, difficult or impossible to manufacture on a large scale, uneconomical to market, unable to compete with superior products marketed by third parties or not be as attractive as alternative treatments or technologies.</p>	Section 5.2.5

Question	Answer	Location in this Prospectus
<b>Commercialisation of products, revenue and expenditure</b>	<p>Tissue Repair has not yet commercialised its technology and, as yet, has no revenues. Tissue Repair is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales (to fund sufficient revenues for continued operations and growth) may not be achieved.</p> <p>Tissue Repair may experience delay or adverse outcomes in achieving a number of critical milestones, including securing commercial partners, completion of clinical trials for its therapeutic products, obtaining regulatory approvals, manufacturing, pre-launch market research, product launch and sales. Any material delays may impact Tissue Repair adversely, including the timing of any revenues.</p> <p>The Directors believe the funds raised through the Offer will be sufficient for the Company's short-to-medium term objectives, however the Company may require substantial additional financing in the future to sufficiently fund its operations, commercialisation, and development. Unforeseen expenditure may not have been considered in the preparation of this Prospectus. Although the Company is not aware of any such additional expenditure requirements, if subsequently incurred they may adversely affect the expected use of funds of the Company as set out in this Prospectus.</p> <p>Without revenue from commercialisation, the Company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the Company is unsuccessful in obtaining funds when they are required, Tissue Repair may need to delay or scale down its operations.</p> <p>While the Company will be subject to the constraints of the ASX Listing Rules regarding the percentage of its capital that it is able to issue within a 12-month period without Shareholder approval (other than where exceptions apply), Shareholders may be diluted as a result of any issues and fundraisings.</p>	Section 5.2.6
<b>Intellectual property</b>	<p>Tissue Repair's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or Tissue Repair may incur substantial costs in asserting or defending its intellectual property rights. This includes the Company's ability to obtain commercially valuable patent claims.</p> <p>If relevant patents which have been filed or trademarks are not granted to Tissue Repair, then the value of the intellectual property rights may be significantly diminished. Further, any information contained in patent applications will become part of the public domain, and so will not be protected as confidential information.</p>	Section 5.2.7

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# 1. Investment Overview Continued

Question	Answer	Location in this Prospectus
<b>Dependence on key personnel, and growth management</b>	<p>Tissue Repair depends on the talent and experience of its personnel (employees and consultants) as its primary asset. There may be a negative impact on Tissue Repair if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel who leave to work for a competitor may adversely impact Tissue Repair. There is a corresponding risk that Tissue Repair may be unable to manage its future growth successfully. The ability to hire and retain skilled personnel as outlined above may be a significant obstacle to growth.</p>	Section 5.2.8
<b>Arrangements with contract manufacturers and third-party collaborators</b>	<p>Tissue Repair itself has not produced active pharmaceutical ingredient (API) material and has appointed a contract manufacturer to undertake manufacture of engineering and production batches of its unique active ingredient, named Glucoprime. There is no guarantee Tissue Repair will be able to produce the active ingredient and finished drug products of a consistent specification of previous batches used in the Phase IIA and Phase IIB trial programs. Any contract manufacturers will need to comply with quality expectations and applicable regulatory requirements and may not be able to be established in a timely manner.</p> <p>The service provided by contracted parties to Tissue Repair may be disrupted or terminated for a variety of reasons which may result in manufacturing disruptions or an inability to manufacture and produce its products for some time. This has the potential to limit, delay or prevent supply of Tissue Repair's products and have an adverse impact on the availability of Tissue Repair's products to customers.</p> <p>Tissue Repair may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of its products. These collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals, or product marketing. There is no assurance that the technology will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals.</p>	Section 5.2.9
<b>Competition</b>	<p>The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Other companies, both in Australia and abroad, may be pursuing the development of products that target the same medical conditions or markets that Tissue Repair is targeting. Tissue Repair's products may compete with existing alternative treatments or technologies that are already available to customers. Some of these companies may have, or develop, technologies superior to Tissue Repair's own technology. Tissue Repair may face competition from parties who have substantially greater resources than the Company.</p>	Section 5.2.10

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Question	Answer	Location in this Prospectus
<b>Product liability</b>	<p>Any defects in Tissue Repair's products may harm Tissue Repair and its customers' reputation and business. Tissue Repair may also be subject to warranty and liability claims for damages related to defects in its products. In addition, the products may be subject to a recall, withdrawal, or other regulatory action. This risk exists even if a product is cleared or approved for commercial sale by the TGA, FDA or other regulatory authorities and is manufactured in appropriately licensed and regulated facilities.</p> <p>There may also be adverse events reported from the use, misuse or defect of Tissue Repair's products which could expose Tissue Repair to product liability claims or litigation. Tissue Repair may be subject to product liability claims if its products cause, or merely appear to have caused, patient injury or death. The industry in which Tissue Repair operates has historically been subject to extensive litigation over product liability claims, especially in the USA market. Product liability claims may result in substantial litigation costs, product recalls or market withdrawals, suppressed demand for Tissue Repair products and damage to Tissue Repair's reputation, regardless of merit or eventual outcome. If this were to occur, it would adversely impact Tissue Repair's operating and financial performance.</p>	Section 5.2.11
<b>Country/region specific risks</b>	<p>Tissue Repair has operations in the USA and must comply with a range of different USA legal and regulatory regimes. As Tissue Repair expands the sales of its products geographically into new international jurisdictions, it is subject to the risks associated with conducting business in those new international jurisdictions, which include adapting to, and complying with, the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries, developing and managing foreign relationships and operations and being subject to the political and economic climate of the various countries. A breach of any of these areas could result in fines or penalties, the payment of compensation or the cancellation or suspension of Tissue Repair's ability to carry on certain activities or product offerings. It could also interrupt or adversely affect parts of Tissue Repair's business and may have an adverse effect on Tissue Repair's operating and financial performance.</p>	Section 5.2.12
<b>Currency risk</b>	<p>A significant proportion of Tissue Repair's costs are incurred in the USA. There is a risk that unfavourable exchange rate movements may cause higher than expected costs. Tissue Repair does hedge some of its USD foreign exchange rate exposure by holding some cash in a USD bank account, however other hedging arrangements may be considered closer to product launch and bulk manufacturing.</p>	Section 5.2.13
<b>COVID-19 global pandemic</b>	<p>Uncertainties relating to the ongoing COVID-19 global pandemic in jurisdictions within which Tissue Repair is operating may affect the Company's ability to achieve any of its objectives outlined in this Prospectus, including requisite preparatory Phase III operations and deliverables required by the FDA, its ability to conduct a Phase III trial and commercialisation plans (including its ability to generate revenue from its cosmeceutical product, TR Pro+).</p>	Section 5.3.11

# 1. Investment Overview Continued

## 1.7 Overview of the Offer

Topic	Summary	Location in this Prospectus																								
Who is the issuer of this Prospectus?	Tissue Repair Ltd ACN 158 411 566.	N/A																								
What is the Offer?	<p>This Prospectus relates to an initial public offering of 19,130,440 Shares at the Offer Price of \$1.15 per Share. The Shares offered under this Prospectus will represent approximately 32% of the Shares on issue at Listing.</p> <p>The Offer is expected to raise \$22 million. The total number of Shares on issue at Listing will be approximately 60,464,843 and all Shares once issued will rank equally with each other.</p>	Section 7																								
Why is the Offer being conducted?	<p>The purpose of the Offer is to:</p> <ul style="list-style-type: none"><li>• provide funding to prepare for and undertake the required Phase III clinical program;</li><li>• provide funding to undertake marketing and commercialisation efforts on its cosmeceutical product;</li><li>• provide funding and financial flexibility to support the Company’s growth strategy and future growth opportunities; and</li><li>• provide the Company with the benefits of an increased brand profile that may arise from being a publicly listed entity.</li></ul>	Section 7.1.2																								
What are the sources and uses of the proceeds of the Offer?	<table><tr><th>Sources of funds</th><th>A\$m</th><th>Uses of funds</th><th>A\$m</th></tr><tr><td>Cash proceeds received by the Company under the Offer from the issue of Shares</td><td>22.0</td><td>Phase III clinical trials</td><td>13.6</td></tr><tr><td></td><td></td><td>Market testing and initial commercialisation of cosmeceutical product (TR Pro+)</td><td>2.1</td></tr><tr><td></td><td></td><td>Development of chronic wound drug (TR-987)</td><td>3.7</td></tr><tr><td></td><td></td><td>Working capital and offer costs</td><td>2.6</td></tr><tr><td>Total sources</td><td>22.0</td><td>Total uses</td><td>22.0</td></tr></table>	Sources of funds	A\$m	Uses of funds	A\$m	Cash proceeds received by the Company under the Offer from the issue of Shares	22.0	Phase III clinical trials	13.6			Market testing and initial commercialisation of cosmeceutical product (TR Pro+)	2.1			Development of chronic wound drug (TR-987)	3.7			Working capital and offer costs	2.6	Total sources	22.0	Total uses	22.0	Section 7.1.2
Sources of funds	A\$m	Uses of funds	A\$m																							
Cash proceeds received by the Company under the Offer from the issue of Shares	22.0	Phase III clinical trials	13.6																							
		Market testing and initial commercialisation of cosmeceutical product (TR Pro+)	2.1																							
		Development of chronic wound drug (TR-987)	3.7																							
		Working capital and offer costs	2.6																							
Total sources	22.0	Total uses	22.0																							

Topic	Summary	Location in this Prospectus																																																																																								
What is the capital structure?	<table><tr><th rowspan="4">Shareholder</th><th colspan="5">Prospectus Date<sup>1</sup></th><th colspan="4">On Listing Date<sup>2</sup></th></tr><tr><th colspan="2">Shares</th><th colspan="2">Options</th><th>Convertible Notes</th><th colspan="2">Shares</th><th colspan="2">Options</th></tr><tr><th>No.</th><th>%</th><th>No.</th><th>%</th><th>No.</th><th>No.</th><th>%</th><th>No.</th><th>%</th></tr><tr><td>Existing Shareholders<sup>3</sup></td><td>1,652,465</td><td>100%</td><td>821,750</td><td>100%</td><td></td><td>33,049,300</td><td>55%</td><td>16,435,000</td><td>73%</td></tr><tr><td>Convertible Note Holders<sup>4,5</sup></td><td></td><td></td><td></td><td></td><td>7,500,000</td><td>8,152,123</td><td>13%</td><td></td><td>0%</td></tr><tr><td>New Investors under the Offer</td><td></td><td></td><td></td><td></td><td></td><td>19,130,440</td><td>32%</td><td></td><td>0%</td></tr><tr><td>Shares issued on Listing<sup>6</sup></td><td></td><td></td><td></td><td></td><td></td><td>132,980</td><td>0%</td><td></td><td>0%</td></tr><tr><td>Options issued on Listing</td><td></td><td></td><td></td><td></td><td></td><td></td><td>0%</td><td>6,035,580</td><td>27%</td></tr><tr><td>Total</td><td>1,652,465</td><td>100%</td><td>821,750</td><td>100%</td><td>7,500,000</td><td>60,464,843</td><td>100%</td><td>22,470,580</td><td>100%</td></tr></table> <p>Notes:</p> <ol style="list-style-type: none"><li>Shares at “Prospectus Date” numbers are expressed before the Share Split described in Section 11.3.</li><li>Following the changes to the capital structure as described in Section 11.3 including the Share Split of Existing Shares.</li><li>No Existing Shares will be sold under the Offer.</li><li>Convertible Notes will not be on issue as at Completion, having been converted into Shares.</li><li>Convertible Notes will be converted into Shares prior to Completion as described in Section 10.4.</li><li>Includes 132,980 Shares and 6,035,580 Options to be issued on Listing as described in 11.3.</li></ol> <p>Refer to Sections 7.1.3 and 11.3 for further detail.</p>	Shareholder	Prospectus Date <sup>1</sup>					On Listing Date <sup>2</sup>				Shares		Options		Convertible Notes	Shares		Options		No.	%	No.	%	No.	No.	%	No.	%	Existing Shareholders <sup>3</sup>	1,652,465	100%	821,750	100%		33,049,300	55%	16,435,000	73%	Convertible Note Holders <sup>4,5</sup>					7,500,000	8,152,123	13%		0%	New Investors under the Offer						19,130,440	32%		0%	Shares issued on Listing <sup>6</sup>						132,980	0%		0%	Options issued on Listing							0%	6,035,580	27%	Total	1,652,465	100%	821,750	100%	7,500,000	60,464,843	100%	22,470,580	100%	Section 7.1.3
Shareholder	Prospectus Date <sup>1</sup>					On Listing Date <sup>2</sup>																																																																																				
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Total	1,652,465	100%	821,750	100%	7,500,000	60,464,843	100%	22,470,580	100%																																																																																	
What is the consideration payable for the Shares?	Successful Applicants under the Offer will pay the Offer Price of \$1.15 per Share.	Section 7.1																																																																																								
Will the Shares be quoted on ASX?	<p>The Company will apply to the ASX within seven days after the Prospectus Date for admission to the Official List and quotation of Shares on the ASX (which is expected to be under the code TRP). Completion is conditional on ASX approving this application.</p> <p>If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn, and all application monies received will be refunded (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.</p> <p>The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that the ASX may admit the Company to the Official List is not to be taken as an indication of the merits of an investment in the Company.</p>	Section 7.8.1																																																																																								

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# 1. Investment Overview Continued

Topic	Summary	Location in this Prospectus
How is the Offer structured?	<p>The Offer comprises:</p> <ul style="list-style-type: none"><li>• the Broker Firm Offer, which is open to Australian retail clients of Brokers who have received a firm allocation from their Broker; and</li><li>• the Institutional Offer, which consisted of an invitation to bid for Shares made to Institutional Investors in Australia and certain other eligible jurisdictions.</li></ul> <p>No general public offer of Shares will be made under the Offer. Shares offered under the Offer are offered and issued with disclosure under this Prospectus.</p>	Section 7.1.1
What is the allocation policy?	<p>The allocation of Shares among bidders in the Institutional Offer has been determined by agreement between the Lead Managers and the Company. The Company and the Lead Managers have absolute discretion regarding the basis of allocation of Shares among Institutional Investors.</p> <p>The allocation policy was influenced, but not constrained, by the following factors:</p> <ul style="list-style-type: none"><li>• number of Shares bid for by particular Applicants;</li><li>• the timeliness of the bid by particular Applicants;</li><li>• the Company's desire for an informed and active trading market following Listing;</li><li>• the Company's desire to establish a wide spread of institutional Shareholders;</li><li>• overall level of demand under the Broker Firm Offer and Institutional Offer;</li><li>• the size and type of funds under management of particular Applicants;</li><li>• the likelihood that particular Applicants will be long-term Shareholders; and</li><li>• any other factors that the Company and the Lead Managers considered appropriate.</li></ul> <p>The allocation of Shares to the Broker Firm Offer, and the identity and level of participation of Brokers participating in the Broker Firm Offer, has been determined by agreement between the Lead Managers and the Company.</p>	Sections 7.3.4 and 7.4.2

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Topic	Summary	Location in this Prospectus
<b>Is there any brokerage, commission, stamp duty payable by Applicants?</b>	No brokerage, commission or stamp duty is payable by Applicants on the acquisition of Shares under the Offer.  Refer to Sections 6.5 and 11.8 for details of the fees payable by the Company to the Lead Managers.	Sections 6.5, 7.2 and 11.8
<b>Are there any tax considerations for Australian investors?</b>	The tax consequences of any investment in the Shares will depend upon an investor's particular circumstances. Applicants should obtain their own tax advice prior to deciding whether to invest.	Sections 7.2 and 11.12
<b>When will I receive confirmation that my Application has been successful?</b>	It is expected that initial holding statements will be dispatched by standard post on 17 November 2021.  Refunds (without interest) to Applicants who make an application and receive an allocation of Shares, the value of which is smaller than the amount of the application monies they have paid, will be made as soon as practicable after Completion.	Section 7.2
<b>How can I apply?</b>	If you have received an allocation of Shares from your Broker and wish to apply for those Shares under the Broker Firm Offer, you should contact your Broker for information about how to submit your Broker Firm Offer Application Form and for payment instructions. Applicants under the Broker Firm Offer must not send their Application Forms or payment to the Share Registry.	Section 7.3.2

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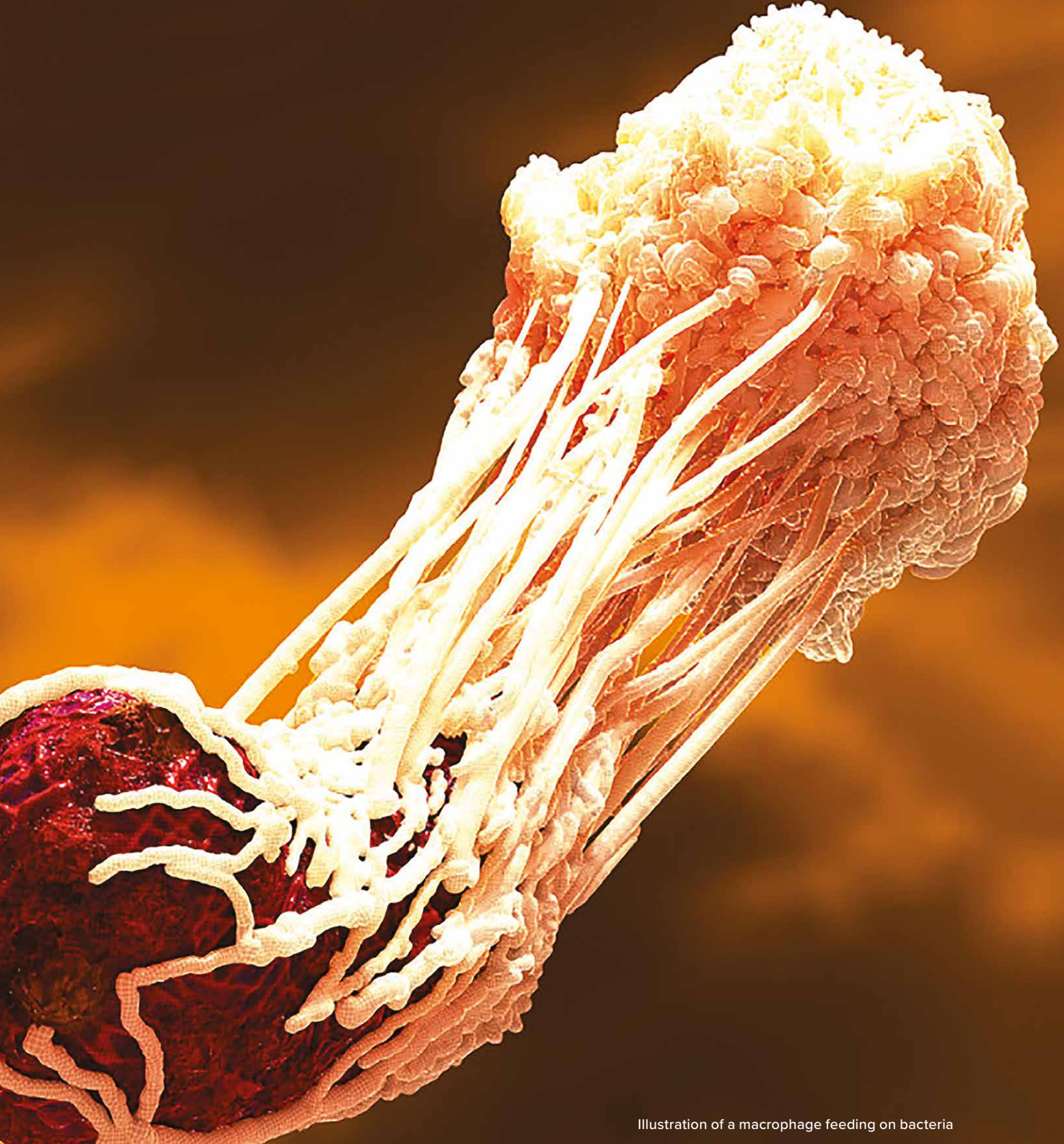


Illustration of a macrophage feeding on bacteria

## 2. Industry Overview



## 2. Industry Overview

### 2.1 Introduction

Tissue Repair is a clinical stage biopharmaceutical company developing advanced wound healing products targeting applications in the chronic wound (venous leg ulcers) and cosmetic procedure markets, with the potential for further development of related technologies. Subject to FDA approval, it is planning to commence Phase III clinical trials for its chronic wound product in 2022.

Tissue Repair has developed a unique active ingredient that is designed for wound healing and which is delivered topically. The biologically active pharmaceutical ingredient (**API**) behaves like a decoy cell that simulates a yeast infection, resulting in the stimulation of the body's own wound repair pathways. This unique active ingredient provides Tissue Repair with a platform with which to develop a number of products that have the potential to treat a broad range of conditions across the wound care and cosmetic procedure aftercare markets.

Tissue Repair is in the final stages of completing its Phase II program for its chronic wound product, TR-987, having completed the field activity and preliminary analysis of Phase IIB clinical trials in 2020. Tissue Repair is planning to commence pivotal Phase III trials for TR-987 in 2022, subject to FDA approval. Tissue Repair is also planning to launch its cosmeceutical product, TR Pro+, in the Australian market in 2022. TR Pro+ is a cosmeceutical post-procedure gel to be used following certain minimally invasive cosmetic procedures.

### 2.2 Markets in which Tissue Repair operates

Exhibit 2.1 below outlines the key markets for Tissue Repair's products. The Company's core focus is the chronic wound market which, in the USA, is estimated to cost the federal healthcare system up to US\$50bn<sup>11</sup> (for both primary and secondary diagnosis, including the cost of infections and all costs associated with care including but not limited to hospital and medical costs). Tissue Repair is initially targeting the US\$1.5bn<sup>12</sup> market of active wound care products (biologics) used to treat these conditions in the USA. Tissue Repair is also targeting the market for aftercare of minimally invasive cosmetic procedures. In 2019, there were an estimated 4.7m aesthetic dermatological procedures in the USA and over 361,000 in Australia (relevant procedures outlined in Exhibit 1 below).

**Exhibit 2.1: Market opportunity for Tissue Repair**

Market Opportunity	Description	Spending in the USA
Chronic wounds	Wounds with impaired healing that haven't healed within 4 weeks, including: <ul style="list-style-type: none"><li>• Venous ulcers (current clinical trial focus)</li><li>• Diabetic foot ulcers</li><li>• Pressure ulcers</li><li>• Arterial ulcers</li></ul>	<p><b>Over US\$50bn cost to treat, with approximately US\$1.5bn spent on active wound care products (biologics)</b></p> <p>Estimated USA Medicare cost of over US\$50bn to treat chronic wounds via both primary and secondary diagnosis, including cost of infections and all costs associated with care including but not limited to hospital and medical costs<sup>13</sup>, excluding costs incurred by the non-Medicare population</p> <p>It is estimated that 75% of chronic wounds occur in the Medicare population<sup>14</sup></p> <p>Tissue Repair is initially targeting the US\$1.5bn<sup>15</sup> market of active wound care products (biologics) used to treat these conditions in the USA (US\$1.7bn globally)</p>

11. Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 21(1), 27-32.

12. SmartTRAK Business Intelligence.

13. Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 21(1), 27-32.

14. SmartTRAK Business Intelligence.

15. SmartTRAK Business Intelligence.

## 2. Industry Overview Continued

Market Opportunity	Description	Spending in the USA
Aftercare of minimally invasive cosmetic procedures	<p>Aftercare of a targeted segment of nonsurgical treatments administered by surgeons/physicians designed to improve the appearance of the skin (aesthetic dermatological procedures), including laser skin resurfacing (secondary focus of Tissue Repair).</p> <p>Other potential segments include:</p> <ul style="list-style-type: none"> <li>• Chemical peels</li> <li>• Needling</li> <li>• Microdermabrasion</li> <li>• IPL treatment</li> <li>• Laser hair removal</li> <li>• Laser tattoo removal</li> </ul>	<p><b>Approximately US\$3.4bn annual spend on related procedures</b></p> <p>Almost 4.7m aesthetic dermatological procedures in 2019 with estimated total spend on these procedures of almost US\$3.4bn (Australia had over 361,000 procedures worth an estimated A\$341m)<sup>16</sup></p> <p>This estimated spend on the underlying procedure does not include an estimate of the spend on aftercare products (of the like Tissue Repair is planning to provide)</p>
Future markets (subject to the development of future preclinical and clinical data and regulatory approval)	<ul style="list-style-type: none"> <li>• Burns</li> <li>• Surgical wounds</li> <li>• Trauma wounds</li> <li>• After sun care</li> <li>• Other complex and/or healing impaired wounds</li> <li>• Veterinary</li> </ul>	

### 2.3 Types of wound conditions

Wound care products are used to treat a variety of wounds in hospital, and at home. Tissue Repair's clinical studies have so far focused on the treatment of chronic wounds (specifically, venous leg ulcers) and laser ablations (used in cosmetic procedures) however, given the underlying mechanism of Tissue Repair's platform technology, it is feasible that the product could be used in the treatment or management of other wounds, subject to appropriate clinical investigation.

#### 2.3.1 Chronic wounds

Wounds are typically classified as chronic after four weeks of non-healing. Chronic wounds occur when the normal healing process is impaired, stalling in the inflammatory or proliferation phase of healing.

An ageing population together with an increasing prevalence of obesity and diabetes are driving an increase in the incidence of chronic, non-healing wounds that are resistant to traditional standard of care treatments.<sup>17</sup> In 2019, approximately 463 million adults (20-79 years), or 9.3% of the global population, were living with diabetes. By 2045, this is expected to rise to 700 million, or 10.9% of the global population.<sup>18</sup>

16. Frost & Sullivan Market Report.

17. Pharma Intelligence – Wound Care: Tissue-Engineered Skin Replacements and Active Wound Repair Modulators 2020.

18. International Diabetes Federation (IDF) Diabetes Atlas – Ninth edition 2019.



These factors contribute to an increasing number of patients requiring advanced chronic wound treatment and represent a significant cost burden on the healthcare system. In the USA, chronic wounds affect approximately 6.5 million individuals<sup>19</sup> and have an estimated USA Medicare cost of up to US\$50 billion per annum (treating chronic wounds via both primary and secondary diagnosis, including cost of infections and all costs associated with care including but not limited to hospital and medical costs).<sup>20</sup>

Key categories of chronic wounds include<sup>21</sup>:

Wound	Description	2020 Prevalence <sup>22</sup>
<b>Venous ulcers</b>	<ul style="list-style-type: none"> <li>• Venous ulceration is a significant clinical problem, affecting approximately 1% of the population and 3% of people over 80 years of age in westernised countries<sup>23</sup></li> <li>• Primarily occur in the legs and are caused by improper function of valves in the veins that prevent blood from returning to the heart. The blood collects in the lower legs causing oedema and ischemia, damaging tissue and causing potential ulceration</li> <li>• In a study of 84 patients by Ma et al (2014) the mean total cost of treating venous ulcers during the follow up period was US\$15,732. Patients who had recurrence had additional costs of US\$12,760 and if inpatient admissions were required, total costs increased to US\$33,629<sup>24</sup></li> </ul>	Approximately 1.1m in the USA (approximately 560,000 are non-healing)
<b>Diabetic foot ulcers</b>	<ul style="list-style-type: none"> <li>• Occur on the feet of individuals with type I or type II diabetes because of poor blood circulation and neuropathy (inability to feel pain, heat and cold). As a result, calluses and sores may develop which become difficult to heal and lead to ulceration</li> <li>• The average cost to treat a diabetic foot ulcer is US\$13,179, with a range from US\$1,892 to the more severe at US\$27,721; 77% of these costs are associated with inpatient care<sup>25</sup></li> </ul>	Approximately 1.7m in the USA (approximately 1.0m are non-healing)
<b>Pressure (decubitus) ulcer</b>	<ul style="list-style-type: none"> <li>• Pressure ulcers occur as a result of tissue damage that develops after soft connective tissue is damaged through prolonged pressure being applied to a bony protrusion and an external surface. The pressure occludes the blood supply, resulting in damaged tissue causing ulceration</li> </ul>	Approximately 3.4m in the USA (approximately 1.3m are severe <sup>26</sup> )
<b>Vascular (arterial) ulcer</b>	<ul style="list-style-type: none"> <li>• Vascular ulcers occur as a result of atherosclerosis (narrowing of the arteries) which results in poor oxygenated blood flow to peripheral tissue, often a result of prolonged diabetes and/or cardiovascular disease<sup>27</sup></li> </ul>	Approximately 280,000 in the USA

19. SmartTRAK Business Intelligence.

20. Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. *Value Health*, 21(1), 27-32.

21. SmartTRAK Business Intelligence.

22. SmartTRAK Business Intelligence.

23. Franks PJ, Barker J, Collier M, Gethin G, Haesler E, Jawien A, Laeuchli S, Mosti G, Probst S, Weller C. Management of Patients With Venous Leg Ulcers: Challenges and Current Best Practice. *J Wound Care*. 2016 Jun;25 Suppl 6:S1-S67. doi: 10.12968/jowc.2016.25.Sup6.S1. PMID: 27292202; Posnett, J., Gottrup, F., Lundgren, H., Saal, G. The resource impact of wounds on health-care providers in Europe. *J Wound Care* 2009;18: 4,154–61.

24. Ma H, O'Donnell TF Jr, Rosen NA, Iafrafi MD. The real cost of treating venous ulcers in a contemporary vascular practice. *J Vasc Surg Venous Lymphat Disord*. 2014 Oct;2(4):355-61. doi: 10.1016/j.jvsv.2014.04.006. Epub 2014 Jun 24. PMID: 26993537.

25. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team. *J Am Podiatr Med Assoc*. 2010 Sep-Oct;100(5):335-41. doi: 10.7547/1000335. PMID: 20847346.

26. Classified as severe if Stage 3 (skin has craterlike sore with damage to the underlying tissue) or Stage 4 (a deep ulceration exists with underlying muscle and possibly bone tissue damage).

27. SmartTRAK Business Intelligence.

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## 2. Industry Overview Continued

### 2.3.1.1 Current standard of care in chronic wounds

Traditional dressings such as bandages, gauzes, and ointments, along with treatment of active infection and debridement, currently represent the “standard of care” for treating chronic wounds such as diabetic foot ulcers and venous ulcers.

Wound healing rates with the current standard of care remain low, often due to the underlying health issues of a patient.

If, after four weeks of standard of care therapy, the wound has not responded appropriately or improved, clinical research has shown that advanced therapy can be beneficial as part of the patient’s treatment plan.<sup>28</sup>

However, in many cases advanced therapies are not employed due to current treatment guidelines, product access, or medical education around the clinical and economic benefits of active wound care products. Tissue Repair believes this represents a significant opportunity for the market to grow.

### 2.3.2 Other challenging wounds

Advanced wound care products may also be used to treat a variety of other challenging wounds.

Wound	2020 Prevalence <sup>29</sup>
Burns	An estimated 493,000+ burns received medical treatment in the USA in 2020 (almost 41,000 requiring hospitalisation)
Surgical wounds	Almost 7.7m major surgical wounds in the USA
Trauma wounds	An estimated 432,000+ trauma wounds in the USA were considered hard to heal and resulted in the use of biologics/skin substitute application(s), with the majority requiring hospitalisation

#### 2.3.2.1 Current standard of care in treatment of other wounds

Treatment for these wounds typically begins with a recommended “standard of care” therapy that depends on the type of wound.

While there is currently limited clinical evidence, the presumed mechanism of action of Tissue Repair’s platform technology suggests that these wounds could benefit from future clinical evaluation.

##### *(i) Burns*

Tissue Repair’s 2019 Phase IIB trial was undertaken following a fractionated laser procedure which may be considered a controlled burn. In that trial TR-987 demonstrated close to double the incidence of improved skin quality at day 28 versus placebo.

For burns requiring medical treatment, treatment costs vary widely based on the need for grafting. A small surface area burn can often heal in three weeks on its own. Treatment of severe burns requires initial coverage of the burn followed by skin grafts. There were over 490,000 severe burns receiving medical treatment in the USA in 2020.<sup>30</sup>

##### *(ii) Surgical wounds*

Appropriate, post-operative surgical wound care is essential in preventing potential complications, such as surgical-site infections (also known as SSIs), wound dehiscence and haematomas.

The aim of post-operative wound care is to allow the wound to heal rapidly without complications, and with the best functional and aesthetic results.<sup>31</sup>

The current standard of care for surgical wounds typically consists of passive dressings (including bandages, hydrocolloids, hydrogels) without an active ingredient, unless there are complications or if the wound heals by secondary intention (i.e. there is a significant loss of tissue or is extensive and edges can’t be brought together).

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28.SmartTRAK Business Intelligence, Market Overview.

29.SmartTRAK Business Intelligence.

30.SmartTRAK Business Intelligence.

31. Singer AJ, Dagum AB. Current management of acute cutaneous wounds. NEJM 2008;359:1037–46.



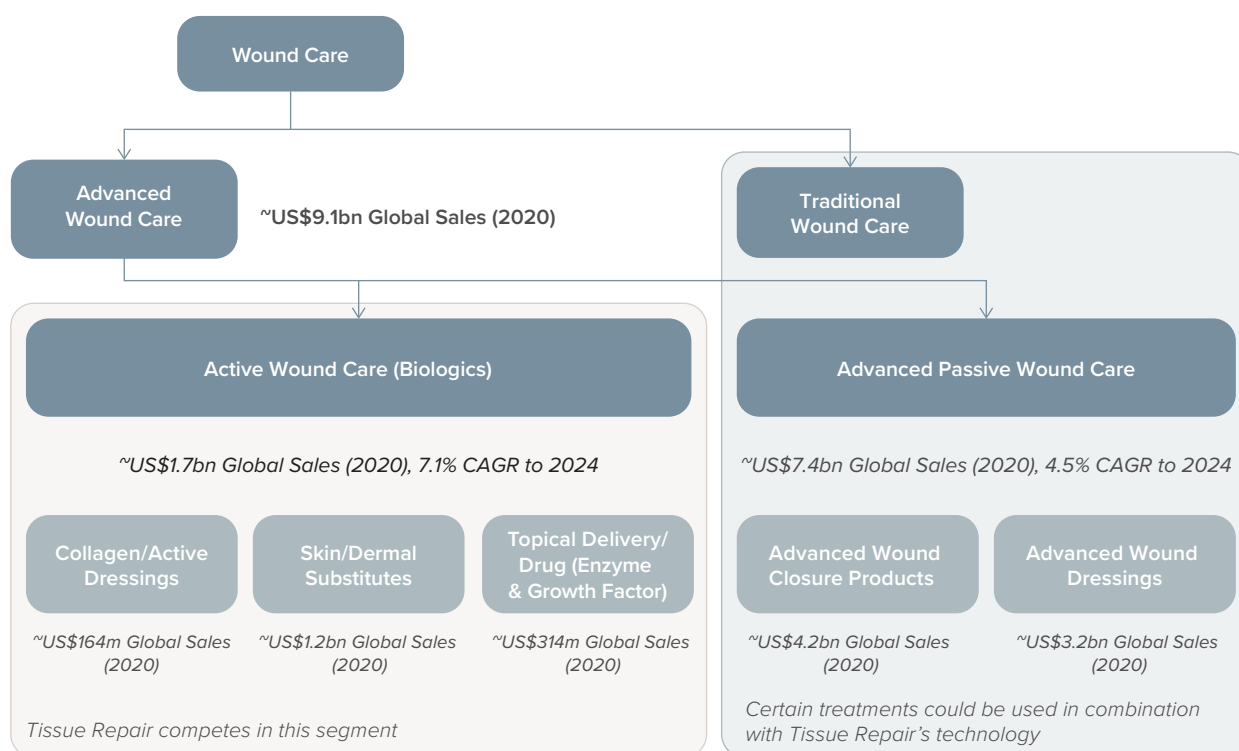
## 2.4 Commercial markets in wound care

The wound care market can be segmented into traditional and advanced products:

- **Advanced wound care:** includes both passive and active wound care technologies (also known as biologics),
- **Traditional wound care:** includes traditional materials used to maintain a clean wound healing environment, typically gauze based.

Tissue Repair's active wound care technology is designed to participate in the advanced wound care market while potentially being used in combination with passive and traditional wound care treatments to enhance wound healing outcomes for patients.

**Exhibit 2.2: The global wound care market<sup>32</sup>**



The advanced wound care market is defined by reference to revenue from the sale of advanced wound care products, including advanced wound dressings, advanced wound closure products and active wound care products (also named biologics). In 2020, global sales of advanced wound care products totalled approximately US\$9.1 billion.<sup>33</sup>

The advanced wound care market is expected to grow at a compound annual growth rate of 5.0% from 2020 to 2024, driven by the active wound care (biologics) category growing at a compound annual growth rate of 7.1%.<sup>34</sup>

32. SmartTRAK Business Intelligence, 30 June 2021; Informa Pharma, Wound Care, Advanced Dressings and Closure Products, November 2020.

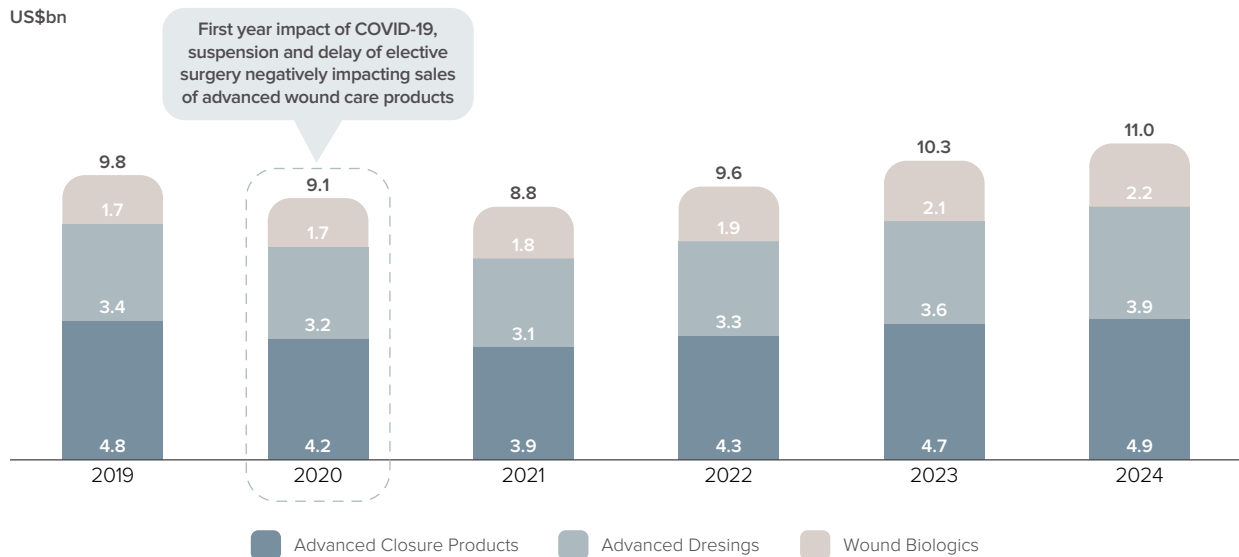
33. SmartTRAK Business Intelligence, 30 June 2021; Informa Pharma, Wound Care, Advanced Dressings and Closure Products, November 2020.

34. SmartTRAK Business Intelligence; Informa Pharma, Wound Care, Advanced Dressings and Closure Products, November 2020.

## 2. Industry Overview Continued

Exhibit 2.3 below illustrates the outlook for the advanced wound care market.

**Exhibit 2.3: Estimated global sales of advanced wound care products<sup>35,36</sup>**



Note: Excludes diagnostic aids (Circulation Measurement, Wound Measurement, Tissue Imaging, Biomarkers, Tissue Parameters, Prevention)

### 2.4.1 Active wound care (biologics)

Active wound care products are being used more frequently, as they may improve the effectiveness of wound healing, limit the risk of infection, and help to prevent more serious health problems. Overall, this helps to reduce hospitalisation periods and the cost of treatment. Active wound care products have also been found to reduce scarring, alleviating associated functional and aesthetic concerns of patients. Physicians' increasing familiarity and confidence in active wound care products is increasing usage, especially as a first-line treatment.

Active wound care product categories include:<sup>37</sup>

1. collagen/active dressings;
2. skin/dermal substitutes; and
3. topical drugs,

and each of these are considered in turn below.

A successful future drug approval may provide Tissue Repair a platform to compete in the active wound care market.

35. SmartTRAK Business Intelligence.

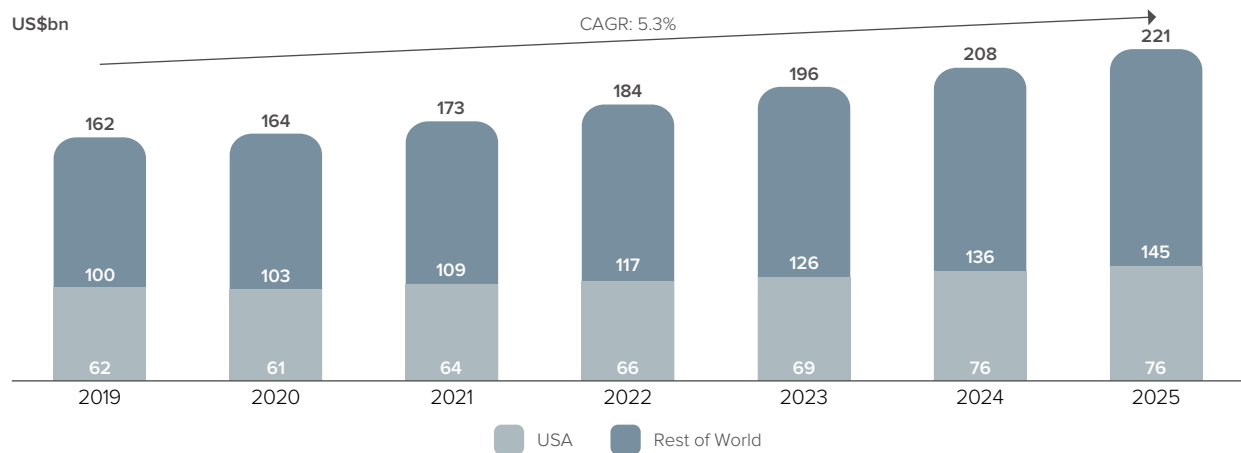
36. Informa Pharma, Wound Care, Advanced Dressings and Closure Products, November 2020.

37. SmartTRAK Business Intelligence.

#### 2.4.1.1 Collagen/active dressings

Active dressings seek to provide the functionalities of passive dressings, as well as added biologic factors that can trigger and enhance the body's natural healing process. Active dressings are commonly used to treat full thickness wounds, third degree burns, and severe chronic wounds and ulcers (diabetic, pressure, and venous). Due to their high costs compared to traditional dressings, active dressing usage is generally restricted to severe, hard to treat wounds.

**Exhibit 2.4: Global collagen/active dressings revenue<sup>38</sup>**



#### 2.4.1.2 Skin/dermal substitutes

Skin/dermal substitute products (also referred to as cell and tissue products or CTPs) typically aid in the closure of wounds and severe burns, replacing the function of the skin (temporarily or permanently).<sup>39</sup>

Skin substitute products include:

- **Autografts:** provided by the patient's own skin.
- **Allografts:** come from either amniotic-based tissue (from human placental tissue) or human skin (harvested from cadavers).
- **Cell-based/bioengineered:** contain living cells derived from neonatal foreskin tissue.
- **Xenografts:** derived from animal (equine, bovine, porcine or ovine), piscine (fish) or plant tissue. Acellular biodegradable tissue provides a scaffold for the patient's cells to migrate and to proliferate, allowing the wound to advance to closure.

While these products are commonly used in treatment of burns and chronic wounds, there may be some challenges in using skin grafts for chronic wound healing as obtaining the graft material involves the creation of another wound which may also be challenging to heal.<sup>40</sup>

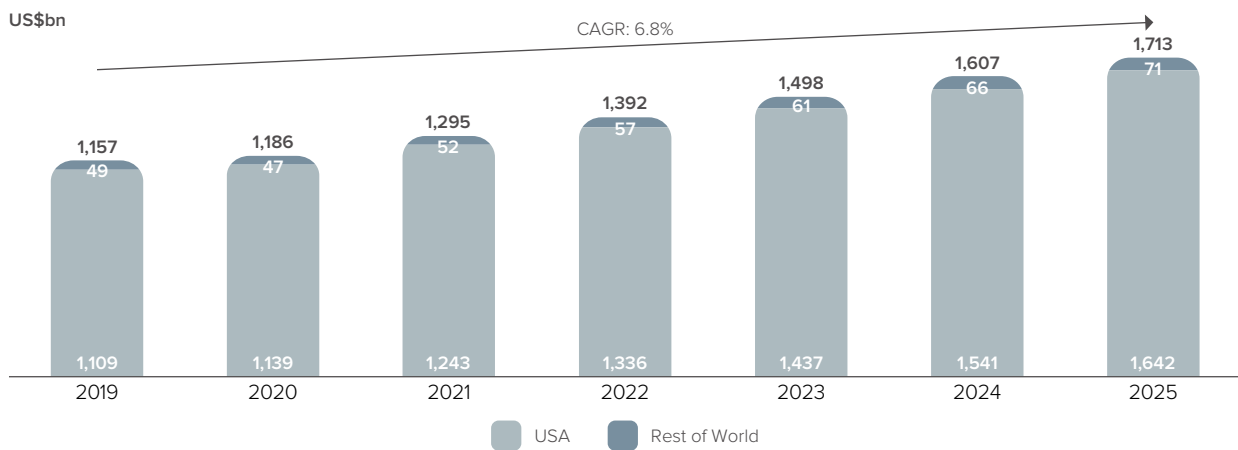
38.SmartTRAK Business Intelligence, 30 June 2021.

39.SmartTRAK Business Intelligence, 30 June 2021.

40.SmartTRAK Business Intelligence, 30 June 2021.

## 2. Industry Overview Continued

**Exhibit 2.5: Global Skin/Dermal Substitute Revenue<sup>41</sup>**



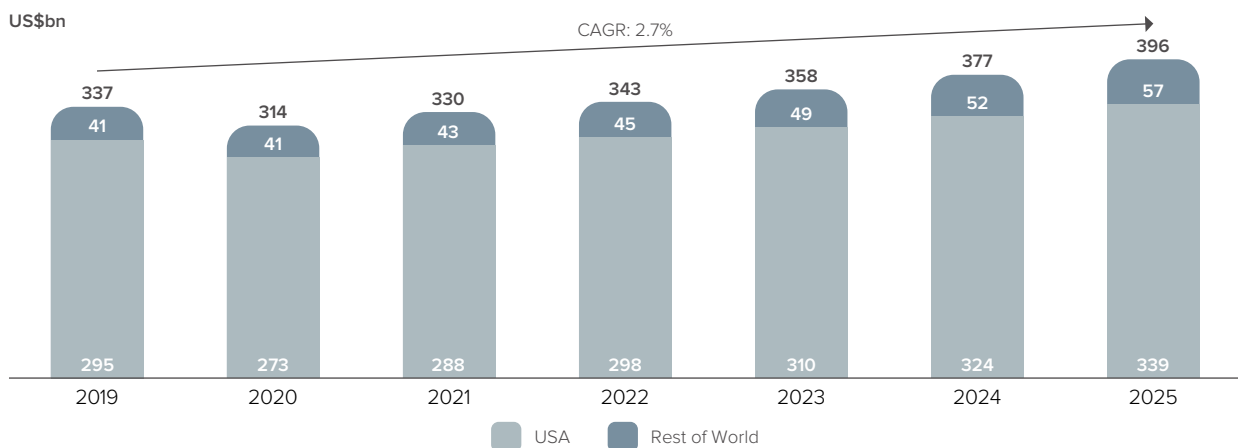
### 2.4.1.3 Topical delivery/drugs

Drug products with topical delivery involve the inclusion of an active ingredient to aid the wound healing process.

Drug products delivered topically are currently divided between two categories:

- **Growth factors:** stimulate the body's innate wound healing response to transition a chronic wound from stalled to healing.
- **Enzymes:** debridement aids, intended to assist in the removal of necrotic tissue to allow the wound to heal.

**Exhibit 2.6: Global topical delivery/drugs revenue<sup>42</sup>**



In the USA, there appear to be only two topical wound care drugs approved by the FDA under a Biologics License Application (BLA), both owned by Smith & Nephew Plc: Collagenase SANTYL® Ointment; and REGRANEX® Gel. SANTYL® (an active enzymatic debridement agent) constitutes approximately 93% of the topical delivery/drug market in the USA.<sup>43</sup>

A soluble  $\beta$ -glucan based topical wound healing gel called Woulgan®, historically received device regulatory approval in the EU, but has since been discontinued. Tissue Repair's products are based on a different, insoluble and unique active form of  $\beta$ -glucan.

41. SmartTRAK Business Intelligence, 30 June 2021.

42. SmartTRAK Business Intelligence, 30 June 2021.

43. SmartTRAK Business Intelligence.

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### 2.4.2 Advanced passive wound care

Advanced passive dressings are designed to maintain moisture levels in the wound (exudate management), as well as including products with anti-microbial agents to reduce infection. Moist wound dressings include semi-occlusive products, which are primarily used for exudate management.

Wound closure products include wound closure technologies providing an alternative to conventional methods, such as suturing by hand.

Technologies in this category include:

Moist wound dressings	Antimicrobial dressings	Wound closure products
<ul style="list-style-type: none"><li>• Alginates</li><li>• Hydrogels</li><li>• Hydrocolloid</li><li>• Foams</li><li>• Films</li></ul>	<ul style="list-style-type: none"><li>• Silver</li><li>• Non-silver agents (e.g. iodine)</li></ul>	<ul style="list-style-type: none"><li>• Surgical sealants and glues</li><li>• Energy-based wound closure devices</li><li>• Automated suturing devices</li><li>• Negative pressure wound therapy</li></ul>

### 2.4.3 Traditional wound care

Traditional wound care products include gauze, bandages, cotton and tape which provide cover and protection to the wound, but do not maintain moisture levels and have no anti-microbial or biologic agents to restrict infection and promote healing. They are generally indicated for the treatment of clean and dry wounds with mild exudate levels or used as secondary dressings.

## 2.5 Minimally invasive cosmetic procedures

Tissue Repair is also pursuing commercialisation of TR Pro+ as a cosmeceutical post-procedure topical gel designed to help improve skin quality, following certain minimally invasive cosmetic procedures.

Laser ablation (which is similar to a controlled, first-degree burn used in cosmetic laser resurfacing procedures) has been one of the two indications investigated by Tissue Repair in Phase II clinical trials.

Exhibit 2.7 provides an overview of minimally invasive cosmetic procedures that could serve as potential markets for TR Pro+, noting that clinical data have only been gathered for laser ablative procedures.

## 2. Industry Overview Continued

The indicative market size presented in Exhibit 2.7 relates to the cost of the underlying procedures and does not include the cost of post procedure topicals, dressings or other cosmeceuticals or drugs used by the patient to enhance or accelerate healing.

**Exhibit 2.7: Cosmetic Dermatology Procedures<sup>44</sup>**

	Indicative procedure cost \$/\$\$	Number of Procedures		Indicative Market Size	
		USA '000	AU '000	USA US\$m	AU A\$m
Chemical peel	\$	1,388	107	928	94
IPL treatment	\$	928	72	363	37
Laser hair removal	\$	1,055	82	301	31
Laser skin resurfacing	\$\$	1,088	84	1,668	170
<i>Ablative</i>	\$\$	457	35	946	96
<i>Non-ablative</i>	\$\$	631	49	722	73
Laser tattoo removal	\$	216	17	94	10
<b>Total</b>		<b>4,675</b>	<b>361</b>	<b>3,355</b>	<b>341</b>

Note: Initial focus of Tissue Repair's cosmeceutical product strategy

## 2.6 Competitors

Tissue Repair's primary competitors in the active wound care market are USA and NZ based research-intensive biotech companies focused on developing novel technologies.

The exception is the large global wound care company Smith & Nephew Plc, which also acquired an active wound care company, Osiris Therapeutics, in 2019.

**Exhibit 2.8: Main Industry Participants in Active Wound Care, Global, 2020<sup>45</sup>**

Company	Headquarters	Product Focus	Revenue
Integra LifeSciences Holdings Corporation	USA	Collagen/skin substitutes	Orthopaedics and tissue technologies revenue US\$477 million (2020)
MiMedx Group	USA	Skin allografts made from placental tissue	US\$248 million revenue (2020)
Organogenesis Holdings Inc.	USA	Skin substitutes	US\$338 million revenue (2020)
Smith & Nephew Plc (also including Osiris Therapeutics)	UK	Diversified	2020 advanced wound care product revenue of US\$647m 2020 advanced wound bioactives product revenue of US\$431m
Aroa Biosurgery Ltd	NZ	Skin substitutes and collagen dressings	NZ\$22 million revenue (financial year ending March 2021)

44.Frost & Sullivan Market Report.

45.Company filings and annual reports.



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The majority of active wound care technologies have been approved by the FDA through the 510(k)-clearance pathway as Class II medical devices, which require a lower evidentiary threshold for approval than a new drug or biologic. Tissue Repair, however, is seeking a New Drug Application (**NDA**), which would permit therapeutic claims relating to its technology's novel mechanism of action. This requires a higher evidentiary threshold (and therefore requires a higher level of clinical evidence) than many products currently on the market (particularly skin/dermal substitutes).

Tissue Repair's active wound care drug product candidate, TR-987, will be seeking to compete in this segment, with the aim of offering a more cost-effective alternative to leading therapies with comparable (or potentially superior) efficacy.

## 2.7 Regulatory approval pathways

Tissue Repair requires regulatory approval and market clearance in each respective jurisdiction in which it seeks to sell its products, with each country and region differing in its regulatory framework.

Tissue Repair's therapeutic drug product, TR-987, is in the final stages of completing its Phase II program having completed Phase IIB clinical studies in 2020 and end of study analysis. The Company has commenced the requisite preparatory work required prior to Phase III clinical studies and is planning to commence a Phase III clinical trial in 2022 subject to FDA approval. This work is required to support regulatory approval as a drug in the USA and Australia.

The potential regulatory and approval processes for Tissue Repair's therapeutic drug product, TR-987, in its preliminary target markets (the USA and Australia) are outlined in the Sections below.

Tissue Repair's cosmeceutical product (TR Pro+) may presently be classified and marketed as a cosmetic in Australia and the USA, although no therapeutic claims can be made under this cosmetic classification. Tissue Repair plans to conduct market research in 2021 to determine the optimal launch pathway for TR Pro+, currently planned for 2022.

### 2.7.1 United States of America (USA)

Within the USA, the relevant regulatory body for pharmaceuticals, biologics and medical devices including wound care products is the Food and Drug Administration (**FDA**).

There are typically three pathways to achieve regulatory approval that are taken by active wound care products, set out below.

## 2. Industry Overview Continued

Exhibit 2.9: FDA Approval Pathways

	Approval Pathway	Description
Medical Devices	Premarket Notification 510(k)	<p>Clearance for medical devices that prove substantial equivalence to existing products on the market. Must illustrate how the device is different from predecessors, that it maintains the same levels of safety and effectiveness, as well as the same intended use. Requires documented laboratory testing, however <b>human data is typically not required</b>.</p> <p>Typically includes:</p> <ul style="list-style-type: none"> <li>• Xenografts and collagen-based dressings</li> <li>• Synthetics</li> </ul>
	Pre-Market Approval (PMA)	<p>Applies to Class III medical devices (considered “high risk”) or that are not substantially equivalent to an existing medical device.</p> <p>Wound products designated with a PMA pathway require a randomised clinical trial to demonstrate safety and efficacy.</p>
	Human Cell and Tissue Products (HCT/Ps)	<p>Allografts (human tissue) are regulated as HCT/Ps and when minimally manipulated implanted for homologous use, they are not subject to 510(k) clearance or Pre-Market Approval (PMA) by the FDA. These products may contain uncharacterised growth factors.</p> <p>Typically includes:</p> <ul style="list-style-type: none"> <li>• Allografts (human tissue)</li> <li>• Stem cell products (provided not composed from allogenic sources)</li> </ul>
Drug Products	Biologics License Approval (BLA)	<p>BLA require a multi-step approval process similar to a New Drug Application (NDA). Definition expanded in 2017 to include Cell-based Bioengineered Skin Substitutes.</p> <p>Typically include:</p> <ul style="list-style-type: none"> <li>• Growth factors (if recombinant, i.e. formed by laboratory methods of recombination)</li> <li>• Enzymes used for the debridement of wounds</li> <li>• Stem cell products composed from allogenic sources (can be approved as either a biologic via a BLA or as a drug via an IND)</li> </ul>
	New Drug Application (NDA)	<p>Active wound care drug products pursuing this path tend to be clinical or preclinical stage, filing an Investigational New Drug Application (IND) required for authorisation to administration investigational drug to humans required for clinical trials.</p>

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## Reimbursement

Reimbursement from health insurers and payors for advanced wound care products sold in the USA depends on the product type:

- **Collagen/active dressings:** For an average wound size, reimbursement is approximately US\$24/application.<sup>46</sup> Reimbursement bundled into the payment for providers during a patient's USA Medicare covered stay, otherwise claimed by the durable medical equipment supplier of at home care.
- **Skin/dermal substitutes:** Each product is allocated its own medical code. In the USA, the average reimbursement of high-cost codes is US\$2,167 per application and the average reimbursement of low-cost codes is US\$822 per application.<sup>47</sup>
- **Topical delivery/drug:** There appear to be only two products on the market today in the USA that have successfully completed clinical trials and are Biologics License Application (BLA) approved products for wound care: Smith & Nephew's SANTYL® Collagenase and REGRANEX® Gel<sup>48</sup>. The cost of REGRANEX® Gel is around US\$1,250 for a 15g tube.<sup>49</sup>

Approximately 75% of all health care spending in the USA is from health insurance from public and private payers. Whether a drug product is covered, and at what price, is determined by each payer's coverage, coding and payment criteria (which consider both economic and patient outcomes).

Tissue Repair's aim is to obtain regulatory approval and be listed for reimbursement as a topical drug with a superior economic health outcome to competing therapies.

### 2.7.2 Australia

In Australia, the Therapeutic Goods Administration (**TGA**) is the relevant regulatory authority. The TGA is responsible for regulating the supply, import, export, manufacture, and advertising of therapeutic goods in Australia.

The TGA takes a 'risk-based' approach to regulating therapeutic goods designed to ensure that regulation is only used where absolutely needed. The identified level of risk determines the amount and type of information required for review, the degree of scrutiny necessary before the product can be made available in Australia, and the level of safety monitoring once it is available.

The focus of Tissue Repair's initial investigations are on qualifying as a Registered or Listed Medicine, noting that the range of possible regulatory options for wound care products include:

#### Registered medicines

Registered medicines are considered to be of higher risk and accordingly detailed evaluations are required before they can be approved for use in Australia. The data submitted in support of a new registered medicine should satisfactorily establish the quality, safety and efficacy of the proposed product for the purpose for which it is to be used (indication). Data fall into three main categories being quality control, safety, and efficacy. Those applications that include active ingredients with a long history of safe use are not required to be assessed to the same level as a new entity. Despite the lengthy evaluation process, this route is attractive because where the data are supportive, stronger claims can be made about conditions that are more serious. This route also presents a higher barrier to entry for competitors and offers the potential for data exclusivity and possible PBS (Pharmaceutical Benefits Scheme) reimbursement.

#### Listed medicines

Listed medicines are considered to be of lower risk and include vitamins, minerals, sunscreens and herbal complementary medicines. These receive a lesser degree of initial assessment, than higher risk medicines. These products are listed on the Australian Register of Therapeutic Goods (ARTG) provided certain conditions are met. The listing process for complementary medicines is based on an applicant certifying that the claims made about the effectiveness of their product are accurate, that the relevant quality and labelling and packaging standards have been followed, that the medicine contains only approved ingredients and that the manufacturing facilities and processes have been assessed for compliance with standards of good manufacturing practice (GMP).

46.SmartTRAK Business Intelligence, June 2021.

47. SmartTRAK Business Intelligence, June 2021.

48.SmartTRAK Business Intelligence, June 2021.

49.Sourced from independent medicine information website, [www.drugs.com](http://www.drugs.com).

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## 2. Industry Overview Continued

Unlike registered medicines, the TGA doesn't individually evaluate lower risk 'listed' medicines before they can be available for use in Australia. However, they cannot claim to treat serious diseases or conditions and can be removed from the market if the claims made for the products are inappropriate or any of those certifications are not correct. This route is attractive because of the low cost and short approval time which enables speed to market. Where ingredients are well supported and recognised there is no need for extensive evaluation, and this route permits flexibility around changing formulations, analytical methods and site of manufacture.

### **Medical devices**

Medical devices differ from medicines as they generally have a physical or mechanical effect on the body or are used to measure (or monitor) the body and its functions.

The way in which the TGA assesses medical devices (including the type of information required) is different than that used for medicines, but the risk-based approach is similar. The higher the potential risks of a medical device, the more examination and monitoring is required. Lower risk devices (such as bandages) rely on the applicant's certification of compliance with regulatory requirements (in a similar way to complementary medicines), whereas higher risk devices (such as pacemakers) involve a direct evaluation of the available evidence by TGA officers. Class I and IIa devices are analogous to a listed medicine in offering a quick entry to market at a low cost, but do not permit claims around serious conditions. Class IIb and III devices require a more rigorous assessment similar to registered medicines.

### **Biologicals**

Biologicals are a distinct group of therapeutic goods which are made from, or contain, human cells or human tissue. The regulation of biologicals also uses a risk-based approach and utilises a comprehensive system of assessment and controls that must be completed before products can be marketed in Australia.

The nature of biologicals means that they can pose risks that do not arise with other therapeutic goods, such as the risk of infectious disease transmission, or other unforeseen biological reactions. Unlike a medicine which can be immediately discontinued if serious adverse events occur, it is often not feasible to discontinue therapy with a biological, if for example the therapy has involved implantation of living cells into a patient.



Macrophages ingesting Glucoprime  
API under an electron microscope

### 3. Company Overview



## 3. Company Overview

### 3.1 Introduction

Tissue Repair is a clinical stage biopharmaceutical company developing advanced wound healing products targeting applications in the chronic wound (venous leg ulcers) and cosmetic procedure markets, with the potential for further development of related technologies. Subject to FDA approval, it is planning to commence Phase III clinical trials in 2022.

Tissue Repair has developed a unique active ingredient that is designed for wound healing and which is delivered topically. The biologically active pharmaceutical ingredient (**API**) behaves like a decoy cell that simulates a yeast infection, resulting in the stimulation of the body's own wound repair pathways. This unique active ingredient provides Tissue Repair with a platform with which to develop a number of products that have the potential to treat a broad range of conditions across the wound care and cosmetic procedure aftercare markets.

Tissue Repair is in the final stages of completing its Phase II program for its chronic wound product, TR-987, having completed the field activity and analysis of Phase IIB clinical trials in 2020. Tissue Repair is planning to commence pivotal Phase III trials for TR-987 in 2022, subject to FDA approval. Tissue Repair is also planning to launch its cosmeceutical product, TR Pro+, in the Australian market in 2022. TR Pro+ is a cosmeceutical post-procedure gel to be used following certain minimally invasive cosmetic procedures.

Key company highlights are set out in Exhibit 10 below.

#### Exhibit 10: Key company highlights

<b>Unique platform technology</b> <i>The API, Glucoprime, potentially has a range of uses</i>	<b>Phase IIB data demonstrating a positive signal of efficacy</b> <i>2020 Phase IIB data readout across two trials.</i> <i>Tested on over 240 patients across 20 years of research</i>	<b>Chronic wound product: Entering a Phase III clinical trial program targeting a superior in-use outcome to current treatments</b> <i>Venous leg ulcer indication a significant market opportunity</i>	<b>Cosmeceutical product: Medium-term commercialisation</b> <i>Opportunity to commercialise as a topical gel following minimally invasive cosmetic procedures</i>
<p>The technology platform is a unique immunogenic active ingredient that aims to stimulate wound healing.</p> <p>The immune-stimulating mechanism of action would suit a variety of different indications. A range of possible applications could be realised by modifying the product form in which the active pharmaceutical ingredient is applied to the tissue, along with applying with co-treatments, which would modify the desired end points.</p> <p>In the USA, Glucoprime may be considered a new chemical entity which could allow 5 years of data exclusivity (or 12 years if classified as a biologic).</p> <p>In Europe, Glucoprime could be eligible for 10 years data exclusivity.</p> <p>Patent has been lodged on the active ingredient – which could, if granted, provide 21 years of exclusivity from the date on which the provisional patent application was filed.</p> <p>Significant know-how and trade secrets from a multi-step manufacturing process.</p>	<p>All Phase II trials have been conducted under FDA approved protocols (double blind and placebo controlled) with the exception of a Phase IIA VLU trial conducted under the TGA in Australia.</p> <p>Tested on chronic wounds (venous leg ulcers) – promising trial results:<sup>50</sup></p> <ul style="list-style-type: none"> <li>• 27.37% difference in incidence of complete closure (p=0.1029) (per protocol cohort)</li> <li>• close to double the percentage wound area reduction, 90.5% TR-987 vs 46.6% placebo (p=0.035)<sup>51</sup> (per protocol cohort)</li> </ul> <p>Tested following cosmetic procedures – close to double the incidence of improved skin quality post laser ablation at day 28:<sup>51</sup></p> <ul style="list-style-type: none"> <li>• Elastosis: 75% active vs 35% placebo (p=0.011; MITT<sup>2</sup> cohort)</li> <li>• Wrinkling improvement: 85% active vs 50% placebo (p=0.041; MITT cohort)</li> </ul>	<p>The proposed Phase III study seeks to replicate the results of the Phase IIB trial with a larger patient cohort.</p> <p>Significant potential commercial opportunity if a drug label achieved around the incidence of complete wound closure in venous leg ulcers.</p>	<p>The Phase IIB trial post laser skin ablation showed that TR-987 almost doubled the skin quality compared to placebo at 28 days.</p> <p>Planning to launch TR Pro+ in 2022 as a high-end post procedure topical.</p>

50. 2020 Phase IIB FDA VLU trial (per protocol group) (adjusted difference based on logistic regression analysis, controlling for factors known to affect healing).

51. 2019 Phase IIB FDA aesthetic laser ablation trial, proportion of patients achieving a 33% improvement in elastosis in active vs placebo (chi square test).



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Notes:

1. While final drug approvals are at FDA discretion, the statistical methods used to evaluate Tissue Repair's clinical trial results to date are consistent with accepted practice and are within the thresholds the FDA would typically consider when evaluating clinical trial results.  
  
The p-value is a statistical measure that indicates whether or not an effect is statistically significant. For example, if a study comparing two treatments found that one seems to be more effective than the other, the p-value is the probability of obtaining these results by chance. By convention, if the p-value is below 0.05 (that is, there is less than a 5% probability that the results occurred by chance), it is therefore considered that there is probably a real difference between treatments.
2. "MITT" refers to the Modified Intention To Treat group which excluded two patients who were lost to follow up.

## Platform technology

Tissue Repair's proposed Phase III clinical studies will seek to validate its unique active ingredient, Glucoprime, in proving dual benefits of enhancing and accelerating wound healing, and further promoting closure of wounds where normal healing has become impaired or stalled. Tissue Repair completed Phase IIB clinical study field work in 2020 with final data analysis in March 2021 and will be filing an end of clinical study report with the FDA in 2021. Subject to final approval from the FDA following an end of Phase II meeting, Tissue Repair plans to commence Phase III trials in the second half of 2022, ultimately aiming to obtain regulatory approvals as a topical drug for the treatment of chronic wounds such as venous leg ulcers.

In the longer term, and subject to Tissue Repair achieving the necessary drug regulatory approvals, Tissue Repair's technology could potentially be used to develop a family of products that promote and accelerate wound healing and tissue repair across a range of medical and surgical applications.

## Chronic wound product

Tissue Repair's primary objective is to achieve a drug label in chronic wound treatment. In the USA, chronic wounds affect approximately 6.5 million individuals<sup>52</sup> and have an estimated USA Medicare cost of up to US\$50 billion per annum (treating chronic wounds via both primary and secondary diagnosis, including cost of infections and all costs associated with care including but not limited to hospital and medical costs)<sup>53</sup>. The US\$1.7bn global advanced active wound care (biologics) market (approximately US\$1.5bn in the USA alone)<sup>54</sup> predominantly treats chronic wounds and is dominated by medical devices, scaffolds and human derived placenta products. An approved drug label for Tissue Repair would be supported by the clinical and scientific rigour of drug development and would strongly position Tissue Repair with clinical data, in a market currently dominated by medical devices.

Tissue Repair's strategy differentiates it from competitor products and will, if successful, afford the ability for Tissue Repair to make approved therapeutic claims, supporting the potential for broad-based reimbursement and broader clinical validation, providing a robust foundation for sales growth.

In recent years, there has been a range of technologies introduced seeking to treat chronic wounds which may have a lower evidentiary threshold than a new drug application. Tissue Repair believes there is significant opportunity for a topical drug such as the technology Tissue Repair is developing, to provide an alternative treatment with superior in-use outcomes when compared to active wound care technologies (especially skin/dermal substitutes).

A key differentiator for Tissue Repair's lead drug product, TR-987, is its topical gel format and its immunogenic mechanism of action. The product promotes an immune response to stimulate the body's own immune system and to help initiate wound repair. The drug is not a patch or scaffold, and does not require any complicated application by a clinician or surgeon, providing significant caregiver and in-home application advantages over competitor products.

## Cosmeceutical product

A secondary focus is the medium-term commercialisation of the technology as a cosmeceutical gel for use following certain minimally invasive (nonsurgical) cosmetic procedures.

## Other potential products

Subject to the collection of appropriate clinical data, Tissue Repair's platform technology potentially has relevance to a range of other applications in a variety of other wound care settings such as treatment of burns, over-the-counter/pharmacy wound products, or new bandage and scaffold products impregnated with Tissue Repair's API, and veterinary products.

52.SmartTRAK Business Intelligence.

53.Nussbaum et al. (2018). An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. *Value Health*, 21(1), 27-32.

54.SmartTRAK Business Intelligence.

## 3. Company Overview Continued

### Company strategy

Tissue Repair's core focus is on realising value from its Glucoprime technology through the regulatory approval of its chronic wound product, TR-987, to treat chronic wounds, with a secondary focus on its post-procedure cosmeceutical gel, TR Pro+. As detailed in Exhibit 11 below, Tissue Repair's aim is to commercialise TR Pro+ in the medium term as a post-procedure gel for use following certain minimally invasive cosmetic procedures.

**Exhibit 11: Strategic Priorities**

	Strategic Focus	Description	Strategy
CORE FOCUS	1 Chronic wound treatment	Achieve FDA and TGA approval as a topical drug for use in venous leg ulcers.  Obtain reimbursement approvals in the USA and Australia.	Achieve Phase III approval targeting a 10-15% differential in incidence of complete healing.  Apply for approval as a drug with the FDA and TGA based on the data package assembled by Tissue Repair.  Seek reimbursement codes in the USA and Australia by proving compelling health economic outcomes.  Launch direct sales model; employ internal sales reps and sell to health care professionals (targeting hospitals, specialist wound clinics and other relevant specialist clinics).  Potentially explore distribution partnership opportunities following Phase III.
	2 Post-procedure cosmeceutical	Commercialise first product as a next generation post-procedure topical for minimally invasive cosmetic procedures.	Launch in Australia to test and refine go-to-market strategy ahead of expanding to other international markets.  Potentially explore distribution partnerships with dermatology and cosmetic companies.  Employ internal sales representatives targeting cosmetic surgeries, clinics and potentially beauticians.
	3 Additional products and indications	Invest in the research and development of additional products and build clinical evidence for a broader range of indications.  Other potential applications of Glucoprime technology could include the treatment of burns, an over-the-counter/pharmacy wound product, new bandage and scaffold products impregnated with Tissue Repair's API, veterinary products, etc.	

### 3.2 Company history

In 2012, the Company and its wholly owned US subsidiary, TR Therapeutics, Inc., were established to acquire the advanced wound care assets, intellectual property and technology of Novogen Research Pty Ltd and Glycotex, Inc. TR Therapeutics acquired these assets and has been responsible for conducting clinical research and trials in the USA since establishment.

Since founding Tissue Repair in 2012, a team of dedicated venture capital and scientific founders have been focused on obtaining further data and additional clinical evidence through undertaking a Phase IIB clinical trial program to confirm the early efficacy signals of the core technology. This Phase IIB clinical study was completed by Tissue Repair in November 2020, with data analysis finalised in March 2021. The Company is aiming to submit its end of study reports to the FDA in 2021. Additional work has since been undertaken on the analytical identification and manufacturing of its active ingredient candidate.

## Exhibit 12: Timeline of key events

1989	The technology that now forms the basis of Tissue Repair's product development program commences as a research project at the Department of Surgery, the University of Sydney, under the direction of Professor Graham Kelly.
1990s	Early preclinical, manufacturing chemistry and control work undertaken at the University of Sydney and then at Novogen Limited ( <b>Novogen</b> ) (the company formed to commercialise the technology).
Early 2000s	<p>Phase I/II clinical trials completed in venous leg ulcer indications demonstrating a safety and efficacy signal. Development of Glucoprime and Glucocol™:</p> <ul style="list-style-type: none"><li>• Glucoprime is a high molecular weight, micro-particulate glucan with a high degree of side branching. This compound is intended for trophic ulcer repair. Glucoprime is the active ingredient in Tissue Repair's lead product candidate, TR-987, for the treatment of venous ulcers.</li><li>• Glucocol™ is a low molecular weight, colloidal glucan with a lower degree of side-branching consistent with its higher solubility. This compound is intended to be used to accelerate healing of surgical incisions that are at risk of dehiscence, or wound breakdown. Glucocol™ is not currently being actively developed, with Tissue Repair's current focus on Glucoprime.</li></ul>
2006	FDA IND (Investigational New Drug Application) lodged. Obtained approval to conduct human clinical trials.
2006-2007	Phase IIA trial; 58 patient dose finding study completed in venous leg ulcers demonstrating safety and a signal of efficacy across percent wound area reduction.
2007	Application submitted by Novogen to list Glycotex, Inc on the Nasdaq to raise capital to conduct Phase III trials. Withdrawn by Novogen at the time, announcing intention to undertake further in-house development.
2008-2010	Preparatory work on the use of TR-987 as a post-procedure cosmeceutical treatment. Animal studies and Phase IIA trials on the use of TR-987 following fractionated CO <sub>2</sub> laser resurfacing procedures demonstrates safety and efficacy.
2012	Tissue Repair Pty Ltd and TR Therapeutics incorporated to acquire the advanced wound care assets, intellectual property and technology of the Novogen group and fund additional Phase IIB clinical trials, analytical development and manufacturing of the drug product with an existing inventory of API.
2012-2014	Additional manufacturing work undertaken, including formulation of gel products and analytical testing to ensure clearance/approval to undertake a Phase IIB clinical trial program.
2016	<p>Commencement of Phase IIB clinical trial program, consisting of double-blind placebo-controlled trials in two separate indications:</p> <ul style="list-style-type: none"><li>• <b>Chronic Wounds:</b> 82-patient double blind placebo-controlled trials evaluating the use of TR-987 gel for nonhealing venous leg ulcers vs. a placebo gel on wound healing</li><li>• <b>Aesthetic Dermatology:</b> 42-patient double blind placebo controlled studies evaluating the effects of TR-987 post fractionated CO<sub>2</sub> laser resurfacing on wound healing and skin quality</li></ul>
2019	Completion of 42 patient aesthetic dermatology Phase IIB trials providing evidence of safety and efficacy, with close to double the improvement in skin quality as measured by elastosis and wrinkling at day 28 for the TR-987 cohort over a placebo gel. An end of study report is anticipated to be filed with the FDA in 2021.
2020	Completion of 82 venous leg ulcer patient trial demonstrating safety and a positive signal of efficiency on the FDA approved endpoint of incidence of complete closure. The study showed a clinically significant adjusted difference of approximately 20% in incidence of wound closure following 12 weeks of treatment between the TR-987 group and a placebo group. An end of study report is anticipated to be submitted to the FDA in 2021.
2021	<p>Raised \$7.5m in May 2021 to progress to next stage of business development (including preparations for the Offer) and commence preparations required in advance of Phase III clinical trials.</p> <p>Partnered and executed an agreement with contract manufacturer on process development and manufacturing of API for Phase III clinical use and beyond.</p> <p>Preparations with a USA laboratory on further analytical characterisation work required prior to commencement of a Phase III trial.</p> <p>Commenced preliminary market research and business planning on a launch of TR Pro+.</p>

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## 3. Company Overview Continued

### 3.3 Overview of the technology

Tissue Repair has isolated a unique immunogenic active ingredient, referred to as Glucoprime, which aims to activate the body's own macrophages and stimulate an immune response that leads to accelerated wound healing.

TR-987 is the drug candidate incorporating Glucoprime that has been designed to activate immune cells which act to defend the body against pathogenic microorganisms. Using the principle of biologic pattern recognition, the TR-987 gel utilises a highly purified insoluble biological polysaccharide ( $\beta$ -glucan) "skeleton" of a yeast cell (composed of micro-particulate, insoluble glucan polymers) that is used as a decoy to attract macrophages to the wound site.

Macrophages are critical cells in the healing process, producing a range of cytokines and growth factors that initiate various components of the healing cascade, and ensuring that the process proceeds in a co-ordinated and integrated manner.

Although the evolutionary purpose of these mechanisms is to defend against a pathogenic threat, they may also be leveraged as powerful stimuli for tissue repair and regeneration, leading to enhanced wound healing.

The repair process within a dermal wound involves a complex set of biological responses that progressively results in the removal of damaged tissue, angiogenesis (formation of new blood vessels), fibrosis (thickening or scarring of the tissue) and epithelialisation (creating a new barrier between wound and environment). Under normal circumstances this complex interplay between many different biological responses involving a variety of tissue types occurs in a well-coordinated manner, ending in a remodelling process that results in minimal scar formation and a return to a fully functioning dermis.

In fresh wounds in healthy individuals, the influx of macrophages into the wound space can normally be expected to occur in a timely manner and at levels that will ensure that the repair process proceeds without interruption to a normal completion.

There are, however, other types of wounds where the local environment is averse to macrophages and discourages their presence and activity. Those wounds typically have delayed healing, and are inclined to remain chronic and harden the soft tissue, sometimes never healing over the life of the individual. Examples of such wounds include pressure (decubitus) ulcers, venous ulcers and diabetic ulcers.

Tissue Repair's unique technology seeks to trigger the healing process and offers the potential for accelerated healing. This in turn may provide superior cosmetic outcomes for wounds that would ordinarily heal, as well as the potential to re-initiate healing and lower treatment costs for chronic wounds that are failing to heal.

The way in which TR-987 works to achieve immune stimulation is supported by independent research on the active ingredient and this complements the abundance of published literature that describes the mode of action of  $\beta$ -glucans in general. Prior to this research, molecules similar to Glucoprime were thought to be too inflammatory and potentially deleterious to wound healing.

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A key component of the Glucoprime technology is understanding the structure of its unique molecules and their interaction with target cells in the wound. Tissue Repair has developed significant expertise with respect to identifying, analysing, characterising and producing the optimal forms of these molecules, which are highly purified and sterile, for use in wound healing.

The unique mechanism of action of TR-987 is designed to activate macrophages and seeks to offer important clinical benefits to patients undergoing treatment for acute or chronic wounds including:

- accelerating wound healing;
- restarting healing and closure for wounds which have stalled and become chronic;
- aiming to lower cost of hospitalisation and medical treatment;
- improving cosmetic outcomes; and
- enhancing patient quality of life.

### **Technology mechanism of action**

Glucoprime is TR-987's active pharmaceutical ingredient (or API) and is based on mimicking a microbial threat (i.e. yeast infection) that triggers pattern recognition receptors (Dectin-1 and TLR2 Receptors) on the surface of macrophage cells in proximity to the wound.

By engaging with these receptors, Glucoprime is able to stimulate the body's immune system, leading to initiation of tissue regeneration, wound healing, collagen production and improved cosmetic outcomes. Specifically, Glucoprime works by activating the NF-KB pathway in macrophages leading to the synthesis and release of multiple cytokines (agents that modulate or alter the immune response) including TNF- $\alpha$ .<sup>55</sup>

Tissue regeneration and wound healing requires both an inflammatory phase and an anti-inflammatory phase. Macrophages normally respond to clues in the wound and upon activation produce growth factors that work to generate new tissue, collagen and elastin. As this process proceeds, the role of macrophages becomes less important and an anti-inflammatory/healing phase begins.

In chronic wounds, the activity of macrophages is impaired. An independent study by Ohio State University's Comprehensive Wound Center (Roy et al)<sup>56</sup> showed that when applied topically to a wound, TR-987 was able to activate macrophages which led to wound closure indicating that the inflammation initiated by TR-987 was indeed transitory.

TR-987's active ingredient, Glucoprime, is a macro group of molecules isolated via a sophisticated, multistep process and is expected to be cost effective in its final configuration as a finished product.

55.S. Roy et al., Wound Repair Regen. 2011 May; 19(3):411-419.

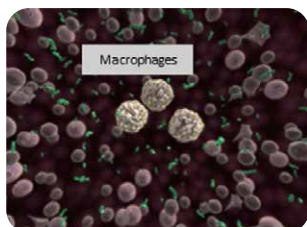
56.S. Roy et al., Wound Repair Regen. 2011 May; 19(3):411-419.

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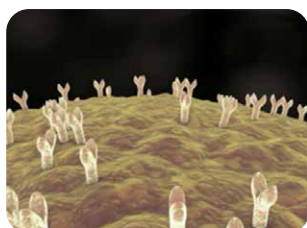
## 3. Company Overview Continued

### Exhibit 13: Macrophages and Glucoprime's Mechanism of Action

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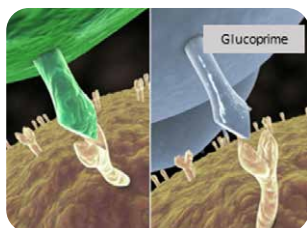
- Macrophages play a key role in wounds:
  - engulfing and digesting cellular debris and pathogens
  - stimulating other immune cells (e.g. neutrophils, mast cells, T-lymphocytes, dendritic cells)



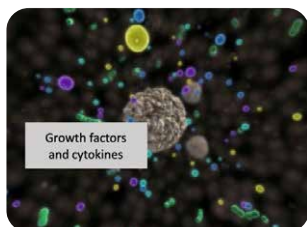
- Macrophages need to be activated by stimulating receptors in the cell wall to trigger expression of genes that enable phagocytosis, protein synthesis and cytokine release.



- Fungal cell walls are powerful stimulators of macrophages.
- $\beta$ -glucan is a bioactive found naturally in the cell walls of fungi.
- The immune system has learned to respond to these as threats.
- $\beta$ -glucans activate macrophages by binding to the Dectin-1 receptor and promote an immune response.



- Glucoprime is an insoluble non-infective particulate,  $\beta$ -glucan containing product isolated from yeast cells.
- Glucoprime is designed to activate macrophages without the toxic side effects seen with infections of living fungi.



- In laboratory and clinical studies TR-987 has been shown to promote wound healing by activating the genes in macrophages.
  - Cytokines are released which attract helper cells like fibroblasts, monocytes and additional macrophages which assist in wound repair.
  - Macrophage plays a key role in re-modelling by releasing growth factors that aid in tissue repair and angiogenesis.
-

## Independent support for the science and mechanism of action

A number of studies and peer reviewed articles have validated the science on which Tissue Repair's technology is based, namely, to deliver efficient acceleration of wound closure. Independent research published in the journal Nature (2011) confirms that only particulate  $\beta$ -glucans (such as Glucoprime, being distinct from soluble glucans) initiate the sequence of events needed for wound healing<sup>57</sup>.

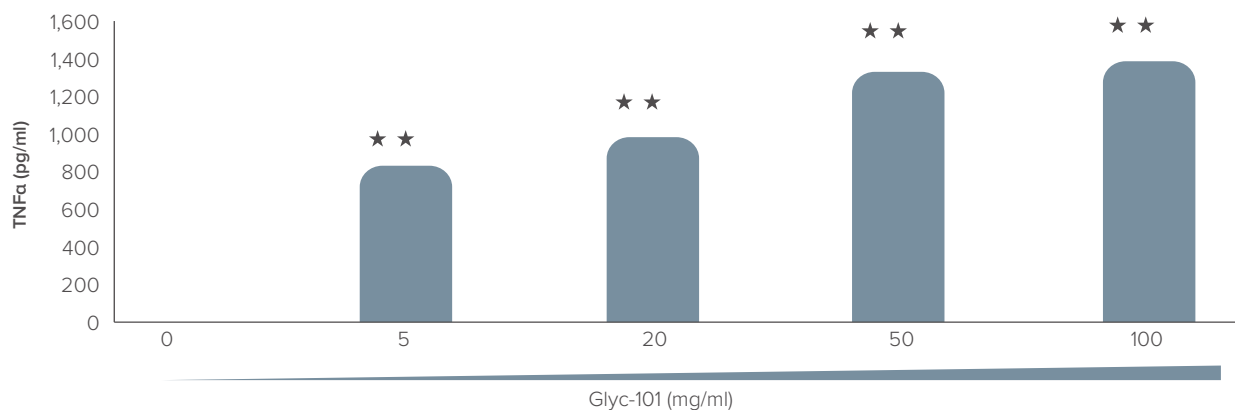
### Ohio State University Comprehensive Wound Center

A peer reviewed publication of a preclinical animal study based on TR-987 ("a novel  $\beta$ -glucan"), previously referred to as Glyc-101. The paper noted:

*"In this study, the hypothesis that Glyc101 [renamed TR-987 by Tissue Repair] regulates wound macrophage function was tested."*

*[The study found that] "Activation of wound macrophages by Glyc101 [renamed TR-987 by Tissue Repair] represents one of the potential mechanisms by which this  $\beta$ -glucan may benefit chronic wounds where inefficient inflammatory response is one of the underlying causes of impaired healing."*

#### Exhibit 14: Glyc-101 (renamed TR-987) induced TNF $\alpha$ production in human blood monocyte-derived macrophages (HBMM)



*Effect of treatment of varying dosages of Glyc-101 for 24 hours in human blood monocyte-derived macrophages TNF $\alpha$  production. Data are mean  $\pm$  SD (n=5). \*\*  $p < 0.001$  compared with control cells.*

*\*\*  $p < 0.001$  compared with control cells.*

## 3.4 Platform technology

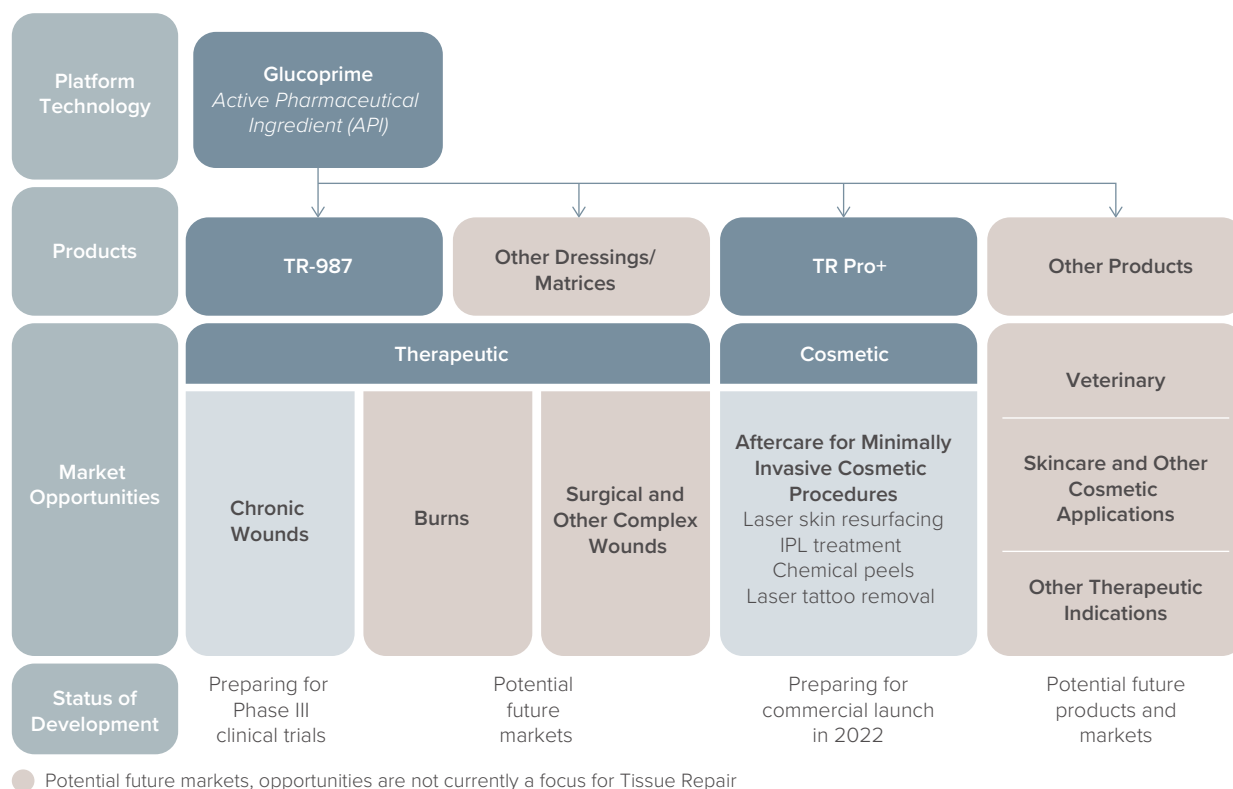
In the longer term, pending approval by the respective regulatory agencies, Tissue Repair's technology could have the potential to develop a family of products that promote and accelerate wound healing and tissue repair across a range of medical and surgical applications.

57. Nature magazine (Goodrich et al, 2011).



### 3. Company Overview Continued

**Exhibit 15: Overview of Tissue Repair potential products and applications**



### 3.5 Value proposition of Tissue Repair's wound care technology

The table below sets out several benefits of Tissue Repair's technology over existing active wound care products.

<b>Evidence of efficacy and robust clinical data in chronic wounds to Phase IIB</b>	<ul style="list-style-type: none"> <li>No drug or biologic appears to have been approved in chronic wounds since REGRANEX Gel was approved in 1997, as such, a drug label is highly prized driving cost reimbursement through high quality clinical data</li> <li>Clinically significant wound healing (including on key FDA accepted endpoints) demonstrated in clinical trials (TR-987 has been tested on over 240 patients across two indications in Phase I, IIA and IIB trials, the majority being randomised, double-blind and placebo-controlled)</li> <li>Validated multifaceted mechanism of action seeks to generate one of the highest immune responses when compared to any drug currently available for wound healing</li> <li>Independent scientific validation of the family of molecules to which Glucoprime belongs have demonstrated strong immunogenic properties and enhanced wound healing in animals, humans and in in vivo studies</li> </ul>
<b>Aiming to prove superior in-use outcomes to current therapies</b>	<ul style="list-style-type: none"> <li>Existing therapies can be expensive. Many active wound care products (biologics) are harvested from human placental tissue, which is the treatment of choice for chronic wounds in the USA (although approved as wound coverings, many are considered to have regenerative properties)</li> <li>However, human placental tissue has clinical limitations due to high cost and limited sizes. Tissue Repair aims to provide a superior in-use alternative to these therapies, without reliance on harvesting human tissue and with the ease of a topical gel in contrast to a complicated patch</li> </ul>

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<b>Evidenced patient safety</b>	<ul style="list-style-type: none"><li>• TR-987 has been tested across different indications on over 240 patients across two indications with no significant adverse events attributable to the drug product</li><li>• Limited evidence of negative effects of inflammation, despite the underlying pro-inflammatory API</li><li>• No evidence of higher infection rates attributable to the drug product</li><li>• TR-987 has a robust safety profile across its clinical program to date</li></ul>
<b>Ease of use as a topical gel</b>	<ul style="list-style-type: none"><li>• Administered topically directly onto the wound – no complicated bandages or patches</li><li>• Can be used in combination with standard of care products, including compression bandaging</li><li>• Capable of being administered by a nurse/caregiver or in the home directly by the patient</li></ul>
<b>Strong stability and long shelf life</b>	<ul style="list-style-type: none"><li>• TR-987 has stability testing which suggests a five-year shelf life at room temperature, no refrigeration or freezing required</li><li>• This contrasts with some biologics, which can come with ultra-cold storage requirements creating supply chain and storage complexities</li></ul>
<b>Intellectual property (IP)</b>	<ul style="list-style-type: none"><li>• If approved as a drug by the FDA, TR-987 may be eligible for 5 years of data exclusivity in the USA from the date of marketing approval and 10 years in Europe</li><li>• Recently lodged composition patent on Tissue Repair's unique active ingredient, Glucoprime, which, if granted, provides a potential 21 years of protection from the date on which the provisional patent application was filed</li></ul>
<b>Platform technology</b>	<ul style="list-style-type: none"><li>• Tissue Repair's unique active ingredient which stimulates an immune response could potentially be used across a variety of applications and the technology provides a platform for the development of a number of different products across indications such as diabetic ulcers, pressure ulcers, surgical wounds, burns (incl. sunburn) and veterinary applications</li><li>• A multi-step extraction process and batch record is on file with the FDA</li><li>• The Company has recently appointed a contract manufacturing organisation to replicate and produce API for the Phase III clinical trial program and for further commercial use</li></ul>

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### 3.6 Clinical Development Program

Over 240 patients across two indications have been studied across Phase I, Phase IIA and Phase IIB clinical studies with TR-987. Most studies (involving over 200 subjects) were randomised, double-blind and placebo-controlled. The majority of the study patients recruited have been in the USA under an Investigational New Drug (IND) Application, with the remainder having been recruited as part of studies undertaken in Australia.

Tissue Repair is in the final stages of completing its Phase II program, having recently completed Phase IIB clinical study data collection and statistical analysis across two indications: chronic wounds and aesthetic dermatology. The Company is planning to file end of study reports for its two Phase IIB trials with the FDA in 2021.

### 3. Company Overview Continued

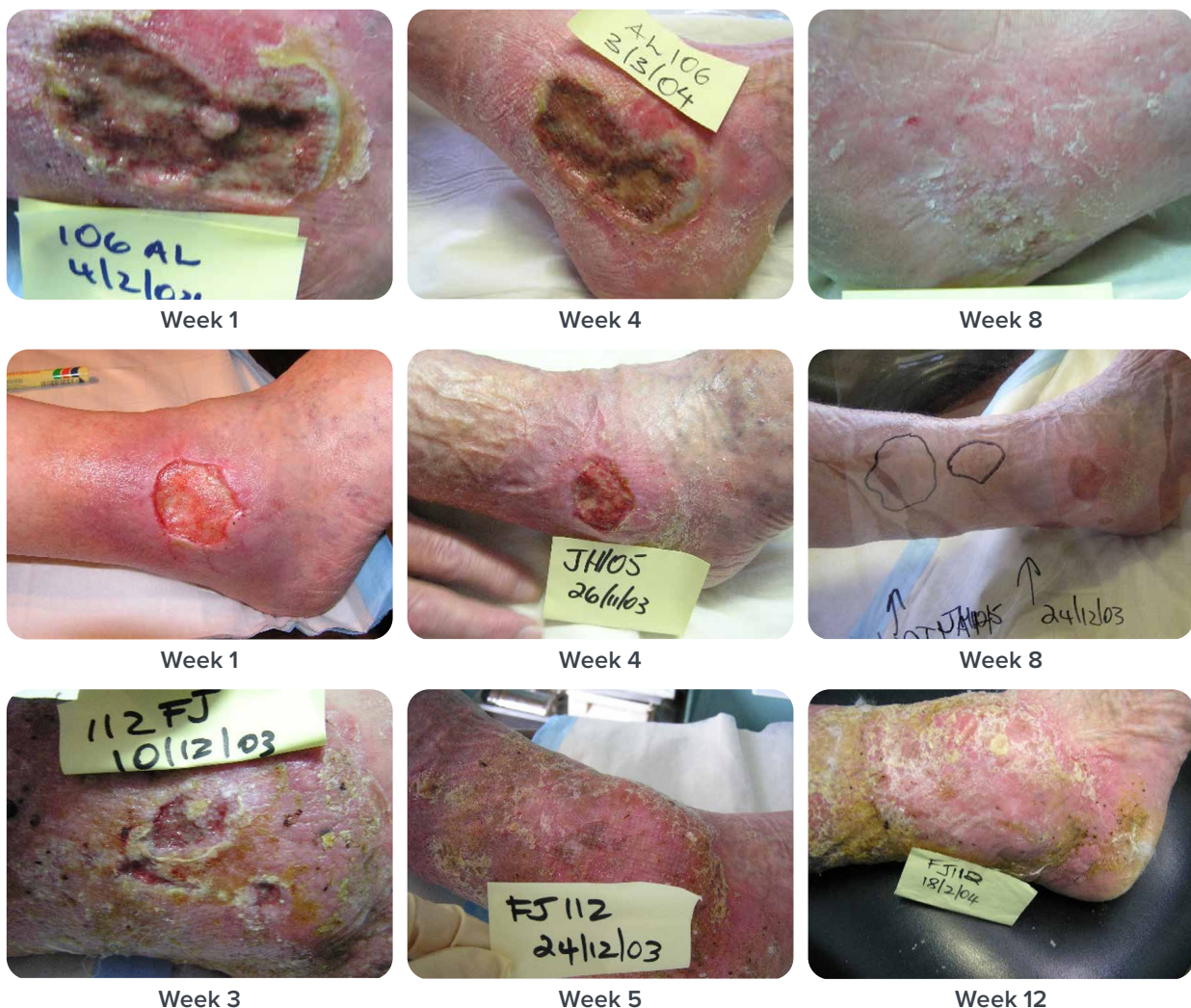
All Phase II trials have been undertaken employing FDA-approved protocols:

- **Randomised:** Trial subjects assigned to treatment or control groups using an element of chance to reduce selection and/or allocation bias.
- **Double-blind:** Neither the participants nor the administrators know if they are being administered the placebo or trial treatment. Information which may influence the participants in the experiment is withheld.
- **Placebo-controlled:** Control group receive a non-effective “placebo” treatment specifically designed to have no real effect in order to benchmark against the treatment being trialled.

In a trial, patients can fall into two cohorts:

- **Intention-To-Treat (ITT):** Defined as patients that were randomised and recorded one observation. By way of example, if a patient withdrew in week 4 of a 12-week treatment period, they would still be included in the ITT group.
- **Per Protocol (PP) or Completer Cohort:** Defined as those patients that received the full course of treatment and the full dosage of TR-987, representing those patients that adhered to the approved trial protocol.

**Exhibit 16: Examples of patients receiving TR-987 in the Australian Venus Ulcer Trial**



Atypical example of wound size reduction of a venous ulcer wound in the Australian Venus Ulcer trial for TR-987. Across the 58 patients in the completer cohort a statistically significant reduction of 45% was evidenced over 12 weeks ( $p < 0.008$ ) for patients receiving Tissue Repair's active was observed.

Exhibit 17: Examples of patients receiving TR-987 in the Phase IIB Venus Ulcer Trial



## 3. Company Overview Continued

### 3.6.1 Chronic wounds: Completed trials

Phase I and II studies confirmed the ability of Glucoprime to stimulate and further initiate healing within chronic trophic ulcers.

The Phase IIA study sought to identify the optimal formulation (i.e. concentration of Glucoprime) of TR-987 gel that yielded the greatest efficacy.

Phase IIB was focused on further demonstrating the efficacy and safety of TR-987 against standard of care combined with a placebo gel.

The drug product has been well tolerated by patients across all clinical trials confirming a strong safety profile.

The completion of Phase II will be marked by an end of Phase II meeting with the FDA whereby Tissue Repair will share its findings from the Phase II patient trials and propose plans for a Phase III clinical study.

Exhibit 18 below shows a summary of the clinical validation to date.

#### Exhibit 18: Summary of clinical trials in chronic wound (venous leg ulcer) indication

Indication	Phase	Country	Patients	Protocol Design	Results
Venous leg ulcers	Phase I/II	AU	6	Open, observational	• Reduction in wound area surface vs. baseline in all patients by 55%
			18	Double-blind, randomised, placebo-controlled	• Reduction in wound surface area of 36.7% (mean) after four weeks of treatment
	Phase IIA	AU	58	Double-blind, randomised, placebo-controlled	• Statistically significant (p=0.008) 43% reduction in wound surface area after 85 days of treatment vs. baseline in “completer cohort”
	Phase IIB	USA/AU	82	Double-blind, randomised, placebo-controlled, FDA approved	<ul style="list-style-type: none"><li>• 82 patients randomised</li><li>• Achieved robust signals of efficacy</li><li>• TR-987 achieves 27.37% adjusted difference in incidence of complete closure over placebo in the per protocol group p=0.1029 (ulcers 2-12cm<sup>2</sup>)</li><li>• TR-987 achieves 20.6% adjusted difference in incidence of complete closure vs. placebo in the ITT group (p=0.1239) (ulcers 2-12cm<sup>2</sup>)</li><li>• Phase III powering analysis suggests statistical significance achieved at n=300-400 patients</li></ul>



## Summary of historical nonclinical experience

In vivo studies looking at incisional wounds in mice, rats, guinea pigs and mini pigs have all confirmed clinical efficacy of Glucoprime (the Active Pharmaceutical Ingredient (API) of TR-987) and its precursors.<sup>58</sup>

The primary effects of the Glucoprime therapy were enhanced migration of macrophages and neutrophils into the wound space, followed by earlier onset of all aspects of the healing cascade.

### Phase I

Glucoprime was studied in six patients with lower limb ulcers due to chronic deep venous insufficiency (CDVI) disease. Patients were selected on the basis of the long-standing nature of their ulcers and failure to respond satisfactorily to standard wound management. The test article was applied every 2-3 days for 4 weeks, and the ulcers were assessed weekly for response and signs of toxicity. The ulcer area was determined by planimetry.

No significant intolerances or toxicities were observed or reported in association with the use of the test article. A healing response was observed in all 6 patients, with an average reduction of 55% in wound surface area, measured over a 56-day period.

### Phase I/II

The efficacy of Glucoprime was studied in a single-centre, randomised, double-blind, placebo-controlled trial in 18 patients with CDVI ulcers that had become refractory to standard wound management therapies. Glucoprime was compared to another form of glucan (Glucodine) with a lower molecular weight range and a smaller proportion of (1→6)-β-glucan side-branching, and to the placebo (control). Patients were randomly assigned to the three treatment groups (two active groups and one placebo control group), with 6 patients per group. Treatment was 3 times weekly for 4 weeks. No intolerances or toxicities were observed or reported in association with the use of either of the active test articles or placebo control. Efficacy was assessed by planimetry, measuring the surface area of the wound. The primary efficacy parameter was the improvement in ulcer surface area from baseline (visit 1) to the end of the trial (visit 6). The mean rates of improvement over 4 weeks were as follows:

#### Exhibit 19: Summary mean rates of ulcer improvement over 4 weeks

Treatment	Percent reduction in wound surface area after 4 weeks of treatment (a minus value indicates wound worsening)
Glucoprime (high molecular weight API)	36.7%
Glucodine (low molecular weight API)	-17.3%
Placebo (control)	4.4%

Ulcer healing was improved in patients in the Glucoprime group compared to placebo, and the results of this study were used to plan further studies using a larger number of patients over a longer treatment period.

### Phase IIA

This was a 58 patient, Phase II, double-blind, placebo-controlled study with patients assigned to one of the three treatment groups on a randomised basis using a computer-generated allocation sequence. There were two active treatment arms (0.1% and 1.0% active ingredient respectively) in order to assess the dose-response effect of Glucoprime and a control arm of gel base with no active ingredient. The study was intended to provide a statistical assessment of the efficacy and safety of TR-987 in patients with chronic venous insufficiency ulcers of the leg. It was anticipated that the outcomes from this study would contribute towards the planning of a pivotal Phase III trial.

58. Leibovich SJ, Danon D. *Promotion of wound repair in mice by application of glucan*. J. Reticuloendothel. Soc. 27, 1-11 (1980); Wolk M, Danon D. *Promotion of wound healing by yeast glucan evaluated on single animals*. Med Biol. 63, 73080 (1985); Browder W, Williams DL, Lucor P, Pretus H, Jones EL, McNamee R. *Effect of enhanced macrophage function on early wound healing*. Surgery 104, 224-230 (1988); Liu W-G. MM Thesis. University of Sydney (1993)

### 3. Company Overview Continued

A subset of the Intention-To-Treat population, in which all subjects had measurements at both baseline and Day 85, was created and called the 'Completer' population for further analysis of efficacy (n = 14 in the high dose (1.0% TR-987) group and n = 15 in each of the low dose (0.1% TR-987) and placebo groups). For the data analysis, non-parametric Wilcoxon rank sum tests with the Normal approximation were performed on the difference between placebo and each of the active treatment groups in the change in ulcer area from baseline to Day 85 for the Completer population. Statistically significant differences were found in the change in ulcer area from baseline to Day 85 for the high dose (1.0% TR-987) group compared with placebo (p = 0.022), and for the low dose (0.1% TR-987) group compared with placebo (p = 0.008).

Secondary analyses were carried out on the percent change from baseline to Day 85 for both populations using Wilcoxon ranked sum tests with the Normal approximation. There appeared to be a greater percent reduction in the low and high TR-987 dose groups than in placebo. While these apparent differences provided a positive indication of efficacy, they were not statistically significant, possibly due to the large variability in the data and to the relatively low sample sizes.

#### Percent change in ulcer area from baseline

Treatment	Intention-To-Treat Group (n=55)		Completer Group (n=44) (all subjects had measurements at both baseline and Day 85)	
	Median change in ulcer area	p-value	Median change in ulcer area	p-value
High Dose (1.0%)	-55.9%	0.598	-55.9%	0.432
Low Dose (0.1%)	-59.0%	0.301	-66.7%	0.115
Placebo	-35.7%		-35.7%	

There was no evidence of any significant toxicity in any of the three treatment groups. Therefore, the safety profile for both the high and low dose formulations of TR-987 gel, as well as for the gel base, was considered to be acceptable.

#### Phase IIB

This study was an 82 patient, multi-centre, randomised, double-blind, placebo-controlled study to evaluate the effectiveness of TR-987 gel on venous leg ulcers. It included a two-arm design with one group having received twice-weekly applications of 0.1% TR-987 in a gel base plus standard of care (SoC) for the first 4 weeks. The other group received twice-weekly applications of placebo gel base plus SoC for the same period. After 4 weeks, both groups received once weekly applications of their assigned treatment for the remaining 8 weeks of the trial.

Preliminary analysis of the trial has been conducted by Tissue Repair, with the final study report expected to be lodged with the FDA in 2021.

Statistical analysis was undertaken on both Intention-To-Treat (n=67) and Per Protocol (n=49) cohorts for the intended indication range of 2-12cm<sup>2</sup> and indicated that the primary objective of time to heal showed no difference between any of the groups. A key secondary objective of proportion of wounds healed, however demonstrated a positive signal of efficacy which is notable given wound closure is considered the gold standard FDA endpoint for wound healing.

The Phase IIB trial provided additional data and confirmed a target indication wound size of 2-12cm<sup>2</sup> for the forthcoming Phase III trial.

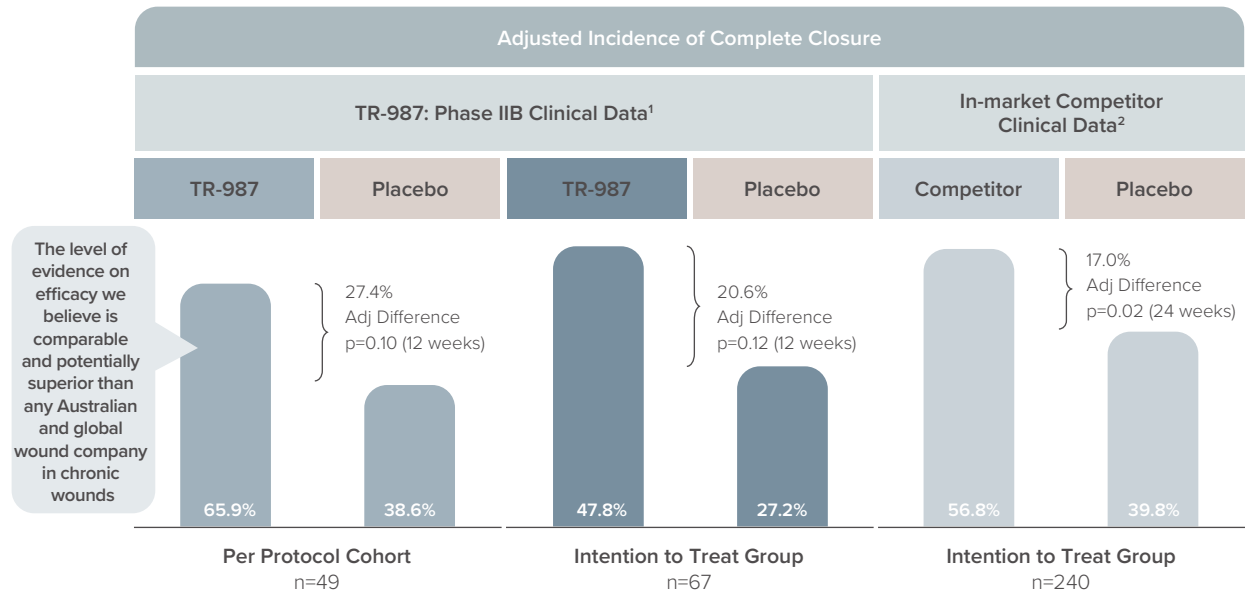
Key findings from the preliminary analysis include the following:

- 20.6% adjusted improvement<sup>59</sup> in incidence of complete closure (p=0.12) for the Intention-To-Treat Group (n=67) for 2-12 cm<sup>2</sup> ulcers (logistic regression analysis)
- 27.37% improvement in incidence of complete closure (p=0.1029) for the Per Protocol group (n=49) 2-12 cm<sup>2</sup> ulcers (logistic regression analysis)
- Almost double the percentage wound area reduction in chronic venous leg ulcers 90.5% TR-987 vs 46.6% placebo for the per protocol group (p=0.035); 2-12cm<sup>2</sup> ulcers

59. Adjusted difference based on logistic regression analysis, controlling for factors known to affect healing.



**Exhibit 20: Adjusted incidence of complete closure (TR-987 vs. competitor vs. placebo)**



Notes:

1. TR-987 2020 Phase IIB FDA VLU trial per protocol and ITT groups (adjusted difference based on logistic regression analysis, controlling for factors known to affect healing).
2. Competitor adjusted data based on Cox regression including factors known to affect healing (logistic regression also showed similar results for the competitor albeit with higher p value p=0.05).

#### Graph Legend

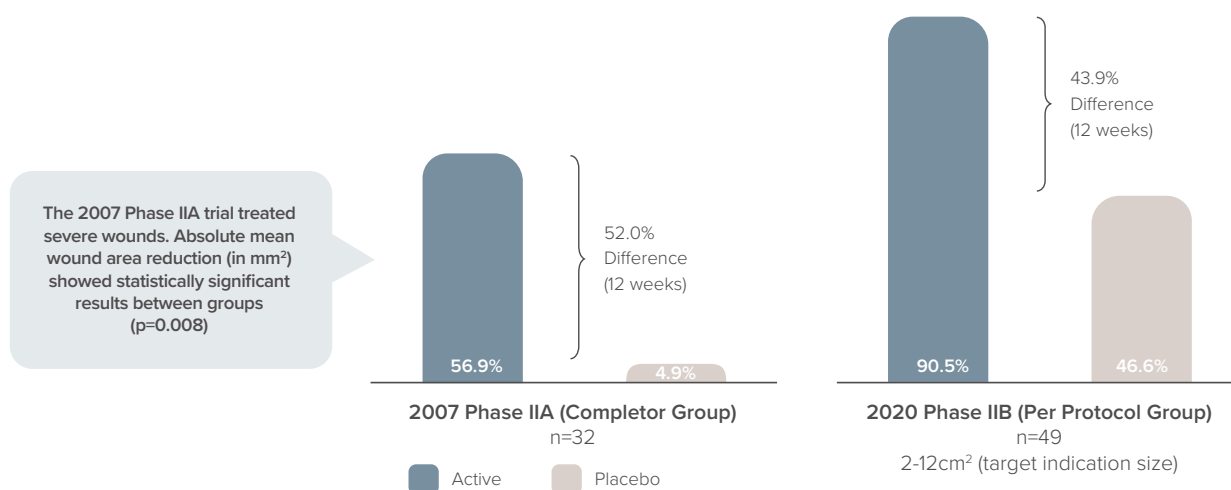
- The graph above shows the difference in the incidence of complete closure between placebo and active groups for TR-987 vs Phase IIB data from a current in-market competitor standard of care. The competitor standard of care is arguably the gold standard for venous leg ulcer closure, physician office reimbursement rates for the product being over US\$30 per sq cm (over US\$365 for a 12 sq cm wound), with weekly applications required for as long as the wound continues to respond
- TR-987 per protocol group from the Phase IIB trial are those patients that completed the trial and received the full drug dosage over the 12-week period
- Intention-To-Treat group includes all patients randomised including all withdrawals
- A clinically meaningful difference is generally considered to be +10% difference of absolute closure
- TR-987 achieved 20.6% adjusted difference in incidence of complete closure vs adjusted incidence of complete closure for the current competitor standard of care of 17%. Meaningful differences for the Intention-To-Treat group and Per Protocol groups are recorded
- Adjusted data is based on logistic regression (TR-987) and Cox regression (current standard of care) controlling for factors known to affect healing between the groups (e.g. base line ulcer size)

Results **are not** strictly comparable given differences in trial design (including blinding) inclusion and exclusion criteria but provide a data point of comparable efficacy for TR-987

### 3. Company Overview Continued

When comparing the endpoint of average percentage of wound area reduction, the Phase IIB trial demonstrated a similar robust efficacy signal to the 2007 Phase IIA trial as shown below.

**Exhibit 21: Comparison of Phase IIA and Phase IIB completor and per protocol groups – percent wound area reduction endpoint**



#### Graph Legend

- 2007 Phase IIA FDA VLU trial, mean percent wound area reduction for the completer group, low dose vs placebo. Note absolute mean wound area reduction showed statistically significant results (reduction of 1428mm<sup>2</sup> in low dose at day 85 vs 1084mm<sup>2</sup> in placebo; p=0.008).
- 2020 Phase IIB FDA VLU trial mean percent wound area reduction for the 2-12cm<sup>2</sup> ulcer range per protocol group (the company's target indication range).

#### 3.6.2 Chronic wounds: Planning for Phase III trial

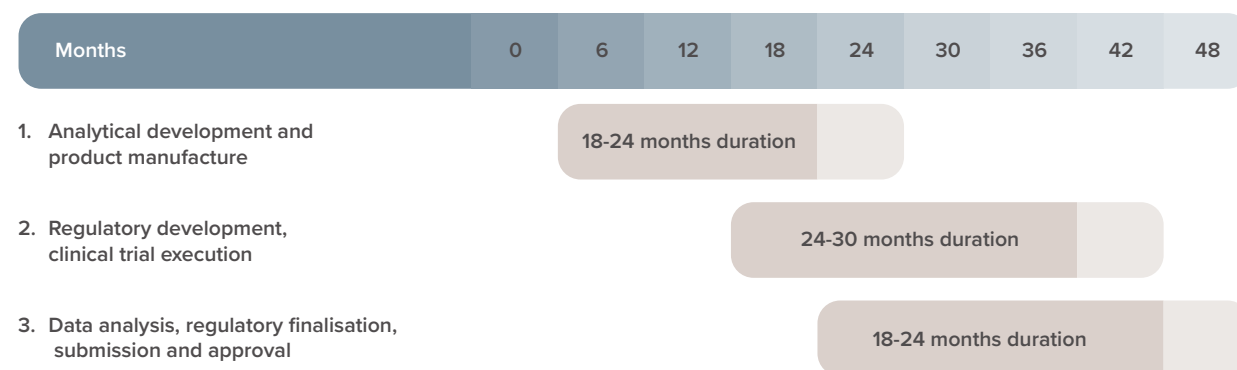
Tissue Repair has commenced preparatory work for the TR-987 Phase III clinical trial on venous leg ulcers and is expecting the study to take an estimated 36 months to complete, assuming no delays in patient recruitment, or onerous FDA requests in relation to the characterisation of the active ingredient, Glucoprime.

The Phase III clinical trial is being designed in accordance with FDA requirements to allow Tissue Repair to pursue regulatory approval in the USA. If successful, TR-987 may be the only topical drug approved for wound care in the USA since 1997 and as such, may represent a valuable asset with a significant market opportunity.

The key work streams required to successfully commence, and complete Phase III trials include:

<b>A</b>	<b>Analytical development and product manufacture</b>	<ul style="list-style-type: none"> <li>• Validation of commercial technical specifications and analytical characterisation of the API and drug candidate</li> <li>• Reproduce API and appropriately characterise the API and demonstrate equivalence with the API reference material used in the Phase IIB trial</li> <li>• Manufacture of three commercial quantities of API and drug product for clinical trial and generation of manufacturing data required by the FDA</li> </ul>
<b>B</b>	<b>Regulatory</b>	<ul style="list-style-type: none"> <li>• Preparation for an end of Phase II meeting with the FDA</li> <li>• Fulfilment of FDA CMC requirements prior to commencement of clinical trial</li> <li>• Agreement on clinical trial design with the FDA for a Phase III trial</li> <li>• Approval to conduct the clinical trial</li> </ul>
<b>C</b>	<b>Phase III trial</b>	<ul style="list-style-type: none"> <li>• Confirmation of clinical trial research partners and contract research organisations, and other preparatory requirements</li> <li>• Participant enrolment and clinical trial execution in accordance with the approved FDA protocols</li> <li>• Execution of 300-400 patient clinical trial in accordance with approved protocols</li> </ul>

#### Exhibit 22: Illustrative Timetable for Clinical Trials and Regulatory Approval



The timetable is indicative only, and may vary based on the following factors and risks:

- ability to recruit patients in a timely manner and in sufficient numbers
- FDA approvals (including protocol approvals and approvals in relation to chemistry, manufacturing and controls (CMC) required prior to Phase III
- ability to manufacture API consistent with batches manufactured in historical trials
- completing FDA requirements in relation to analytical development and characterising its unique active ingredient prior to commencement of Phase III to FDA requirements

Upon FDA review and marketing approval, should the Phase III trial be successful, Tissue Repair intends to manufacture commercial quantities of its TR-987 drug product to support market launch in the USA (and eventually other regions).

### 3.6.3 Aesthetic dermatology: Completed trials

The Phase IIB double-blind randomised placebo-controlled trial on aesthetic dermatology post a fractionated CO<sub>2</sub> laser ablation of the chest, showed an improvement in skin quality at 28 days post the procedure which was close to double that of a placebo gel. An end of clinical study report for the Phase IIB trial is planned to be submitted to the FDA in 2021.

### 3. Company Overview Continued

**Exhibit 23: Summary of Clinical Trials in Aesthetic (Laser Ablation) Indication**

Indication	Phase	Country	Patients	Design	Results
Laser ablation	Phase IIA	AU	Pilot – 12 Main – 26	Double-blind, randomised, placebo controlled	<ul style="list-style-type: none"> <li>• Safety and feasibility established</li> <li>• Statistically significant reduction in time to complete wound closure vs. placebo (p=0.0062); acceleration of wound closure by approx. 30% (mean) vs. placebo 10.9 days (Glucoprime 0.1% concentration) vs. 16.3 days (placebo)</li> </ul>
	Phase IIB	USA	42 (across two studies with the same protocol)	Double-blind, randomised, placebo controlled FDA approved	<ul style="list-style-type: none"> <li>• 35% improvement in wrinkling versus placebo group (p=0.041) at 28 days</li> <li>• 40% improvement in elastosis versus placebo group (p=0.011) at 28 days</li> </ul>

#### *Phase IIA*

The study evaluated the safety and efficacy of two concentrations of TR-987 gel (low and high Glucoprime dosages) compared to placebo (gel base), in promoting wound healing on the lower eyelid skin of 26 subjects undergoing fractionated CO<sub>2</sub> laser skin resurfacing for cosmetic purposes (wrinkle reduction). Overall, when compared to placebo, treatment with TR-987 (high Glucoprime dosage) or TR-987 (low Glucoprime dosage) was safe and well tolerated.

The comparison of each TR-987 arm to placebo with respect to the primary endpoint (mean time to complete wound closure/epithelialisation) showed positive results when considering the full subject dataset from all treatment combinations. Specifically, the efficacy outcome of time to complete wound closure was 20-30% shorter for TR-987 at 1.0% and 0.1% (13.1 days and 10.9 days, respectively) compared to placebo (16.3 days; p = 0.0062 and 0.0331, respectively).

#### *Phase IIB*

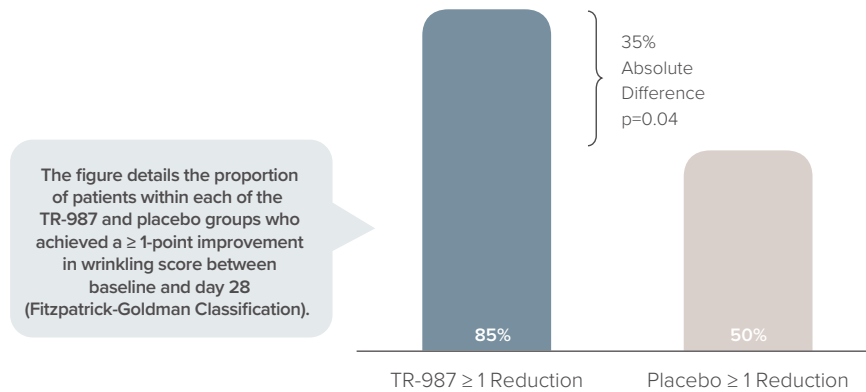
This study examined the efficacy of TR-987 in wound healing (epithelialisation) and improving skin quality following CO<sub>2</sub> ablative laser treatment of the chest. The trial, which was done at a single site in San Diego, USA, and was randomised, double-blind, and placebo-controlled. The trial initially involved 22 patients and was later extended to include a further 20 patients (under two protocols which were materially identical). The data from both studies (n=42) was pooled and analysed. Two patients were lost to follow up (one each from the active and placebo groups) and an Intention-To-Treat (ITT) analysis was done on 42 patients together with a Modified Intention-To-Treat (MITT) analysis on the 40 patients who completed the trial.

The validated 3- and 9-point Fitzpatrick-Goldman Wrinkle and Elastosis Scale (respectively) was used to evaluate the effectiveness of the TR-987 0.1% gel in promoting post-procedure healing most notably as it affected skin quality of the underlying procedure as compared to control. Both test and control regimens promoted safe and effective healing of the chest skin after the procedure.

#### **Wrinkling**

For the MITT group, 85% of responders achieved a wrinkling score of 1 or greater (i.e. 33% improvement) for the active group compared to the placebo group (where only 50% of responders achieved a wrinkling score of 1 or greater). The absolute difference of 35.0% is statistically significant (p = 0.041).

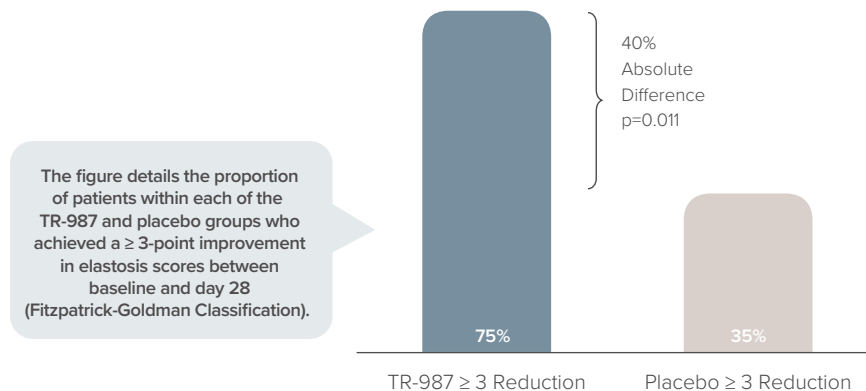
**Exhibit 24: Proportion of patients with a 33% improvement in Wrinkling**



### Elastosis

For the MITT group, 75% of responders achieved an improvement score of 3 or greater in elastosis (i.e. 33% improvement) for the active group compared to the placebo group where only 35% of responders achieved the same level of improvement. The absolute difference of 40.0% is statistically significant ( $p = 0.011$ ).

**Exhibit 25: Proportion of patients with a 33% improvement in Elastosis**



The study investigators confirmed TR-987 to be an efficacious topical treatment following laser ablation in regard to improving skin quality as measured by elastosis and wrinkling.

**Exhibit 26: Wrinkling improvement and elastosis repair**



A final clinical study report for the Phase IIB trial is planned to be submitted to the FDA in 2021.

## 3. Company Overview Continued

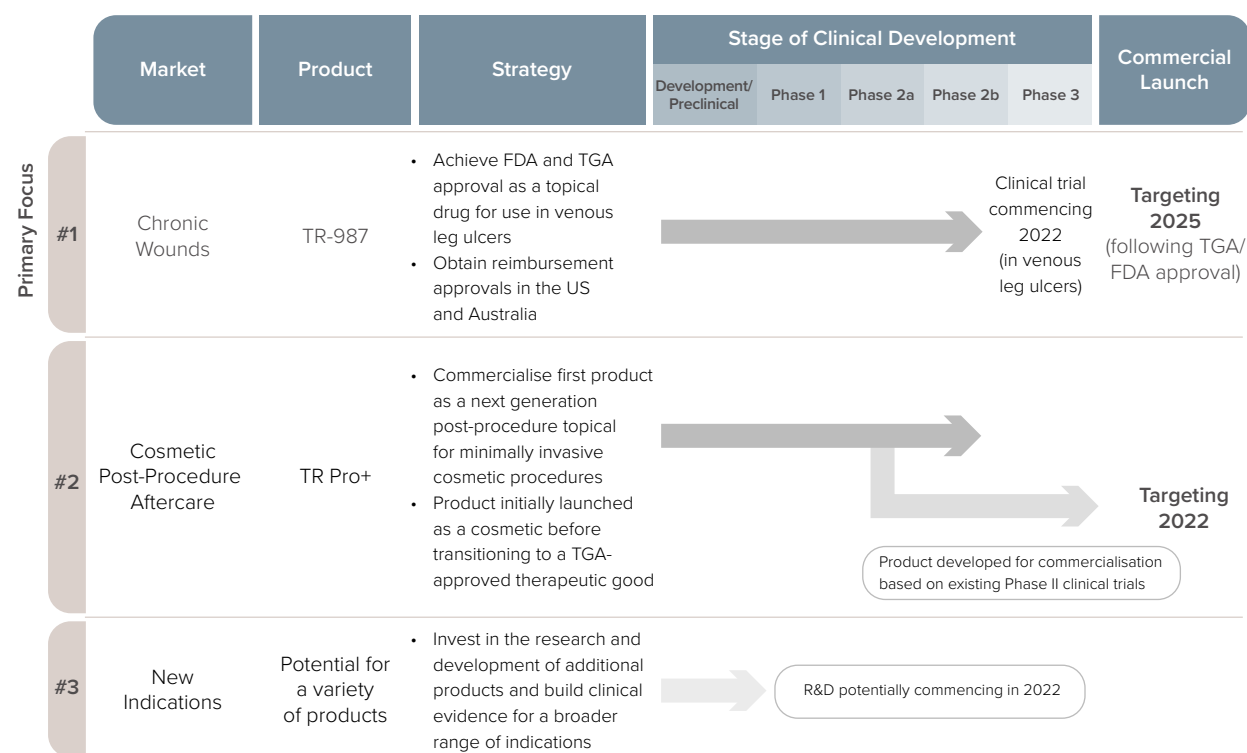
### 3.7 Commercialisation strategy

Tissue Repair's strategy is to develop topical, non-absorbable treatments using its platform technology for the regeneration and rejuvenation of tissues in both chronic wound and cosmetic applications.

This strategy includes developing uses compatible with existing treatment protocols and generally accepted best-practice treatments for various wound types. The markets for human wound healing and tissue repair products in regenerative medicine are large and growing. As outlined in Section 2, there are several trends that continue to drive market expansion including the ageing of the general population, the increasing rates of obesity, a heightened interest by the medical community in advanced dressings, increased pressure by hospitals and healthcare providers to discharge patients earlier, and the growth in incidence and prevalence of diabetes.

Although Tissue Repair's technology platform may prove beneficial for several indications, the Company is initially focusing on drug approval of its chronic wound product, with a secondary focus on commercialising a cosmeceutical product for use following certain minimally invasive cosmetic procedures.

**Exhibit 27: Commercialisation pathway**



#### Core focus: chronic wound drug product (TR-987)

Topical drug candidate intended to treat chronic wounds such as venous leg ulcers, pressure ulcers and diabetic foot ulcers.

In 2020, Tissue Repair undertook the final stages of its Phase II program, having completed the clinical study and statistical analysis of an 82-patient Phase IIB double-blind randomised placebo-controlled trial in venous leg ulcers with TR-987. The clinical study report for this study is expected to be filed with the FDA in 2021. In summary, the trial demonstrated a positive signal of efficacy in the target indication size of 2-12cm<sup>2</sup> on a key clinical endpoint of incidence of complete closure (i.e. proportion of patients achieving complete wound closure). After 12 weeks, 48% of the patients who received the active TR-987 gel achieved complete healing compared to only 27% of the patients who received the placebo gel (ITT; p=0.12). This difference is considered to be clinically significant and comparable to existing therapies based on publicly available information.

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Phase III clinical data is required before Tissue Repair can apply for regulatory approval for use as a therapeutic product to treat chronic wounds.

Tissue Repair is not expecting to generate any revenue from TR-987 until it is successfully approved by the FDA or TGA.

### **Secondary focus: aesthetic dermatology cosmeceutical product (TR Pro+)**

Tissue Repair plans to use Glucoprime to create a cosmeceutical product to sell under a separate brand, for use as a post-procedure topical treatment following nonsurgical cosmetic procedures (such as laser skin resurfacing).

This follows clinical evidence obtained in two Phase IIB trials with a combined 42-patients which used TR-987 to treat patients having undergone an ablative laser skin resurfacing procedure. The trial initially involved 22 patients and was later extended to include a further 20 patients (under two separate Phase IIB protocols which were materially identical, both randomised, double-blind and placebo-controlled). These trials demonstrated close to double the improvement of skin quality, as measured by elastosis and wrinkling using a validated graded scale, with the use of TR-987 in comparison to a placebo gel at 28 days. The results provided a statistically significant outcome regarding improved skin quality with the use of the gel over placebo. An end of clinical study report is planned to be filed with the FDA in 2021.

Ablative fractionated laser procedures have been chosen as the initial primary target indication for the cosmeceutical product. Ablative fractionated lasers have been increasingly utilised in recent years to improve the appearance of UV-induced photo-damage, skin wrinkles and scarring. The procedure involves using a laser with an intense controlled wavelength to destroy the top layer of skin and heat up lower layers which effectively causes many micro-wounds. Post-operative skin care is critical in promoting optimal wound healing after therapy, however there is currently no gold standard post-procedural agent. Tissue Repair's clinical trials demonstrate that TR-987 fills out wrinkles and fine lines more quickly than the placebo, presumably due to additional collagen production and fibrosis.

Sales are expected to be achieved through healthcare providers including but not limited to dermatology, plastic/cosmetic surgeons and targeted skin clinics.

Tissue Repair intends to commercialise this product, TR Pro+, as a cosmeceutical with a potential launch planned for late 2022.

## **3.8 Chemistry, Manufacturing and Controls (CMC)**

Tissue Repair's key components for manufacturing include:

- *Active Pharmaceutical Ingredient (API) – Glucoprime*
  - Extracted from a cell wall of a unique strain of the *Saccharomyces cerevisiae* yeast by a unique multi-step process
- *Drug Product – TR-987*
  - A formulation of Glucoprime in a topical hydrogel which will be submitted to regulatory authorities for drug designation
- *Cosmeceutical Product – TR Pro+*
  - A branded version of TR-987 for use as a cosmeceutical

Tissue Repair engages contract manufacturers for the manufacture of its Active Pharmaceutical Ingredient (Glucoprime), the finished drug product (TR-987) and the finished cosmeceutical product (TR Pro+).

The development is proceeding as planned in relation to production processes that deliver efficacy, purity and consistency of its API and finished products at a commercial scale.

## **3.9 Intellectual property**

Tissue Repair is seeking to protect its intellectual property through a combination of patent applications, eligibility for data exclusivity in certain jurisdictions, trade secrets, proprietary know-how in combination with assignments and confidentiality agreements with inventors, employees, partners, consultants, and other parties. The following exhibit provides an overview of the key protections over Tissue Repair's intellectual property.



### 3. Company Overview Continued

	Protection	Description
<b>Data Exclusivity</b>	<p>USA: At least 5 years from regulatory approval</p> <p>Europe: 10 years from regulatory approval</p>	<p>Glucoprime meets the FDA published criteria of A New Chemical Entity (<b>NCE</b>). There appears to be no drug substance currently approved globally for any indication based on Tissue Repair's unique active ingredient.</p> <ul style="list-style-type: none"> <li>• <b>USA:</b> The FDA defines a new chemical entity as “a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Act.” The FDA grants data exclusivity for NCEs. This exclusivity provides protection for the licence holder of an approved new drug application by preventing the submission of an application for any new active ingredient that relies on the data included in the Glucoprime marketing application from competition.</li> <li>• <b>Europe:</b> A chemical active substance that is not previously authorised in a medicinal product for human use in the European Union and that is from a chemical structure point of view not related to any other authorised substances should be considered as a NAS (“New Active Substance”).</li> </ul> <p>If Glucoprime was ultimately classified as a biologic by the FDA (rather than the planned drug pathway), it may be eligible to increase data exclusivity from 5 to 12 years in the USA. Whilst the focus for TR-987 is as a potential drug approval, the company may also discuss and consider the classification of Glucoprime with the FDA as a biologic.</p>
<b>Patents</b>	<p>Characterisation patent</p> <p>Additional patentable areas post Listing</p> <p>21 years should the patent be successfully granted</p>	<p>The Company has lodged a patent claiming its active ingredient, Glucoprime, as described by a number of specifications including its bioassay, and nuclear magnetic resonance analysis of the active ingredient and its use in wound healing and cosmetic applications. This patent application may allow the Company to achieve 21 years of patent protection on its active ingredient from the date on which the provisional patent application was filed.</p> <p>Identification and analytical characterisation is an area of specific know-how and potential intellectual property. Currently, there is a limited suite of tests globally that can effectively identify and characterise the active ingredient to achieve FDA advised requirements. Analytics around the active is a potential barrier for competitors in attempting to obtain drug approval for a new product.</p>
<b>Trademarks</b>	<p>Trademark applications in USA and Australia</p>	<p>Tissue Repair has lodged trademark applications in the USA and Australia for Glucoprime, TR-987, TR Pro+ and a selection of other names that may be used by the Company in the future.</p>
<b>Proprietary knowledge and trade secrets</b>	<p>Proprietary multi-step extraction process</p>	<p>Tissue Repair has trade secrets in manufacturing its API with a number of trade secret steps in its manufacturing process. Without this know-how, it would be difficult for a competitor to replicate the API and show chemical and clinical equivalence. To prove substantial equivalence, a competitor would likely be required to undertake its own trials recommencing at Phase I and would require a significant amount of supporting data.</p>

See Section 9 for further details on Tissue Repair's intellectual property arrangements.



## 4. Financial Information



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## 4. Financial Information

### 4.1 Introduction

Section 4 contains a summary of the historical financial information prepared by the Directors of Tissue Repair for the financial years ended 30 June 2019 (**FY19**), 30 June 2020 (**FY20**) and 30 June 2021 (**FY21**) as set out below:

- The historical financial information for Tissue Repair comprising:
  - Statutory historical statements of profit or loss for FY19, FY20 and FY21 (the **Historical Results**);
  - Statutory historical statements of cash flows for FY19, FY20 and FY21 (the **Historical Statements of Cash Flow**);
  - Statutory historical statement of financial position as at 30 June 2021 (the **Historical Statement of Financial Position**);(together, the **Historical Financial Information**);
- The pro forma historical financial information for Tissue Repair comprising pro forma historical statement of financial position as at 30 June 2021 (the **Pro Forma Historical Statement of Financial Position**), and supporting notes which includes the pro forma transactions, material subsequent events and capital raising.

The statutory and pro forma historical financial information is referred to in this Section 4 collectively as **Financial Information**.

Also summarised in this Section 4 are:

- the basis of preparation and presentation of the Financial Information (Section 4.2);
- the application of new accounting standards to the Financial Information and areas of critical judgements and estimates (Sections 4.10 and 4.11);
- information regarding certain non-IFRS measures (Section 4.4);
- a description of the pro forma adjustments to the Historical Statement of Financial Position, and reconciliations to the Pro Forma Historical Statement of Financial Position (Section 4.7);
- commentary on the liquidity of, and the sources of capital available to Tissue Repair (Section 4.8);
- management's discussion and analysis of the Historical Financial Information (Section 4.9); and
- details of Tissue Repair's proposed dividend policy (Section 4.12).

The information in this Section 4 should be read in conjunction with the Company Overview set out in Section 3, Risk Factors set out in Section 5 and other information contained in this Prospectus.

All amounts disclosed in the tables are presented in Australian dollars and, unless otherwise noted, are rounded to the nearest \$1,000. Rounding of figures provided in the Financial Information may result in some immaterial differences between the sum of components and the totals outlined within tables and percentage calculation.

### 4.2 Basis of preparation and presentation of the Financial Information

The Financial Information included in this Prospectus is intended to present potential investors with information to assist them in understanding the underlying historical financial performance, cash flows and financial position of Tissue Repair. The Directors of Tissue Repair are responsible for the preparation and presentation of the Financial Information.

The Historical Financial Information has been prepared and presented in accordance with the recognition and measurement principles of Australian Accounting Standards (**AAS**) issued by the Australian Accounting Standards Board (**AASB**), which are consistent with International Financial Reporting Standards (**IFRS**) and interpretations issued by the International Accounting Standards Board (**IASB**).

The Pro Forma Historical Statement of Financial Position has been prepared in accordance with the recognition and measurement principles of AAS, other than that it includes certain adjustments which have been prepared in a manner consistent with AAS in order to illustrate their effect as if they had occurred on or before 30 June 2021.

The Financial Information is presented in an abbreviated format and does not contain all of the disclosures required by the AAS and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act.

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## Forecast financial information

The Directors have considered the requirements of ASIC Regulatory Guide 170 *Prospective financial information* (RG170) to determine if prospective financial information should be included in this Prospectus. The Directors have determined that, as at the date of this Prospectus, Tissue Repair does not have a reasonable basis to reliably forecast future earnings and accordingly forecast financial information is not included in this Prospectus. There is uncertainty in relation to the quantum and timing of Tissue Repair's future revenue given the status of its research, resulting in a level of unpredictability in the timing, quantum and recognition of future results.

## Independent Limited Assurance Report

The Financial Information presented in this Prospectus has been reviewed by Pitcher Partners as the Investigating Accountant in accordance with the *Australian Standard on Assurance Engagements ASAE 3450 Assurance Engagements involving Corporate Fundraising and/or Prospective Financial Information* as stated in its Independent Limited Assurance Report set out in Section 8. Investors should note the scope and limitations of the Independent Limited Assurance Report.

## 4.3 Preparation of Historical and Pro Forma Historical Financial Information

The Historical Financial Information has been extracted from the audited financial statements of Tissue Repair for FY19, FY20 and FY21.

The financial statements of the Company for FY19, FY20 and FY21 were audited by Pitcher Partners Sydney Partnership in accordance with Australian Auditing Standards. The audit opinion issued for FY19, FY20 and FY21 were unmodified.

The Pro Forma Historical Statement of Financial Position has been prepared for the purpose of inclusion in this Prospectus. The Pro Forma Historical Statement of Financial Position has been derived from the Historical Financial Information, with pro forma adjustments being made to reflect:

- the impact of the conversion of convertible notes;
- issue of pre-IPO shares;
- cash expenditure to mid September; and
- the impact of the Offer.

Refer to Section 4.7 for a reconciliation between the Historical Statement of Financial Position and the Pro Forma Historical Statement of Financial Position.

In preparing the Financial Information, the Company's accounting policies have been consistently applied throughout the periods presented.

Investors should note that past results are not a guarantee of future performance.

## Going Concern

The Financial Information for FY19, FY20 and FY21 has been prepared on a going concern basis, which contemplates continuity of normal business activities and realisation of assets and discharge of liabilities in the normal course of business.

The Directors believe that there are reasonable grounds that the Company will be able to continue as a going concern as a result of the proceeds raised from the Offer.

## 4. Financial Information Continued

### 4.4 Explanation of certain non-IFRS financial measures

Tissue Repair uses certain measures to manage and report on its business that are not recognised under AAS, nor under IFRS. These measures are collectively referred in this Section 4 and under ASIC Regulatory Guide 230 *Disclosing Non-IFRS Financial Information* published by ASIC as “non-IFRS financial measures”. The principal ones used in this Prospectus are as follows:

- EBITDA is earnings before interest, taxation, depreciation, and amortisation;
- Operating cash flow is calculated as EBITDA, less non-cash items in EBITDA (e.g. share based payment expenses), plus or minus changes in Working Capital; and
- Working Capital is the aggregate of receivables less trade and other payables, and employee benefits.

Certain financial data included in Section 4 is also non-IFRS financial information.

Although Tissue Repair believe that these measures provide useful information about the financial performance of Tissue Repair, they should be considered as supplements to the statement of profit and loss and statement of cash flow measures that have been presented in accordance with the AAS and not as a replacement for them. Because these non-IFRS financial measures are not based on AAS, they do not have standard definitions, and the way Tissue Repair calculated these measures may differ from similarly titled measures used by other companies. Investors should therefore not place undue reliance on these non-IFRS financial measures.

### 4.5 Historical Results

#### 4.5.1 Statutory Historical Results

Table 4.1 below sets out the Historical Results for FY19, FY20 and FY21. Investors are referred to Section 4.9 which provides a description and management discussion of the profit and loss categories.

**Table 4.1: Historical Results for FY19, FY20 and FY21**

\$'000	Historical Statutory Results		
	FY19	FY20	FY21
<b>Income</b>			
Foreign exchange	–	–	26
Interest income	2	–	1
<b>Total income</b>	2	–	28
<b>Expenses</b>			
Finance costs	–	–	390
Medical trials	424	325	409
Professional fees	33	51	112
Share based payments	–	23	39
Consulting fees	55	4	32
General and administration	11	37	27
Employee benefits expense	–	–	21
Occupancy	9	9	–
Other expenses	24	52	66
<b>Total Expenses</b>	<b>557</b>	<b>501</b>	<b>1,095</b>
<b>Net Loss Before Income Tax</b>	<b>(555)</b>	<b>(501)</b>	<b>(1,068)</b>
<b>Income Tax Benefit</b>	<b>198</b>	<b>149</b>	<b>153</b>
<b>Net Loss After Tax</b>	<b>(357)</b>	<b>(352)</b>	<b>(915)</b>

Notes:

1. Income tax benefit relates to R&D tax incentive

## 4.6 Historical Statements of Cash Flow

### 4.6.1 Statutory Historical Statements of Cash Flow

Table 4.2 sets out Tissue Repair's Statutory Historical Statements of Cash Flow for FY19, FY20 and FY21. Investors are referred to Section 4.9, which provides a management discussion and analysis of the cash flow line items.

**Table 4.2: Statutory Historical Statement of Cash Flow**

	Statutory Historical Statements of Cash Flow		
\$'000	FY19	FY20	FY21
<b>Operating Cash Flows</b>			
Receipts from operations	9	–	5
Payments to suppliers and employees	(624)	(848)	(854)
Research and development tax refund	558	198	–
Interest received	2	–	1
<b>Net Cash Flows from Operating Activities</b>	<b>(56)</b>	<b>(650)</b>	<b>(848)</b>
<b>Financing Cash Flows</b>			
Proceeds from convertible note issue	–	–	7,500
Proceeds from share issue	–	1,200	–
Payments for cost of capital raising	–	–	(35)
<b>Net Cash Flows from Financing Activities</b>	<b>–</b>	<b>1,200</b>	<b>7,465</b>
<b>Cash and Cash Equivalents</b>			
Cash and cash equivalents at beginning of period	652	597	1,147
Net change in cash for period	(56)	550	6,617
<b>Cash and cash equivalents at end of period</b>	<b>597</b>	<b>1,147</b>	<b>7,764</b>

## 4. Financial Information Continued

### 4.7 Statutory and Pro Forma Historical Statement of Financial Position

Table 4.3 below sets out the pro forma adjustments that have been made to the audited Historical Statement of Financial Position for Tissue Repair as at 30 June 2021 in order to prepare the Pro Forma Historical Statement of Financial Position for Tissue Repair. These adjustments reflect certain pro forma adjustments including the Offer proceeds, transaction expenses, the conversion of convertible notes into ordinary equity, operating losses to mid September 2021, and the impact of the operating and capital structure that will be in place following Completion of the Offer as if it had occurred or were in place as at 30 June 2021.

**Table 4.3: Statutory and Pro Forma Historical Consolidated Statements of Financial Position as at 30 June 2021**

\$'000	Statutory	Subsequent Events	Pro forma Adjustments	Pro forma Offer
<b>ASSETS</b>				
<b>Current Assets</b>				
Cash and cash equivalents	7,764	(347)	19,694	27,111
Trade and other receivables	54		–	54
Tax receivables	301		138	439
Other assets	5		–	5
<b>Total Current Assets</b>	<b>8,124</b>		<b>19,832</b>	<b>27,609</b>
<b>Non-Current Assets</b>				
Plant and equipment	–		–	–
Intangible assets	–		–	–
<b>Total Non-Current Assets</b>	<b>–</b>		<b>–</b>	<b>–</b>
<b>Total Assets</b>	<b>8,124</b>		<b>19,832</b>	<b>27,609</b>
<b>LIABILITIES</b>				
<b>Current Liabilities</b>				
Trade and other payables	534		–	534
Provisions	2		–	2
<b>Total Current Liabilities</b>	<b>536</b>		<b>–</b>	<b>536</b>
<b>Non-Current Liabilities</b>				
Convertible notes	7,500	(7,500)	–	–
<b>Total Non-Current Liabilities</b>	<b>7,500</b>	<b>(7,500)</b>	<b>–</b>	<b>–</b>
<b>Total Liabilities</b>	<b>8,036</b>	<b>(7,500)</b>	<b>–</b>	<b>536</b>
<b>Net Assets</b>	<b>88</b>	<b>(7,153)</b>	<b>19,832</b>	<b>27,073</b>
<b>EQUITY</b>				
Contributed equity	3,819	7,991	21,253	33,063
Reserves	61	–	–	61
Accumulated losses	(3,792)	(838)	(1,421)	(6,051)
<b>Total Equity</b>	<b>88</b>	<b>7,153</b>	<b>19,832</b>	<b>27,073</b>



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#### **4.7.1 Subsequent events and Pro Forma Adjustments**

Subsequent to 30 June 2021, events have occurred which have changed the Shares on issue. These changes have been reflected in the Pro Forma Statement of Financial Position. These transactions are detailed in Section 4.7.2.

With the exception of the subsequent events and pro forma transactions noted below no other material transactions have occurred between 30 June 2021 and the date of this Prospectus which the Directors consider require disclosure.

This Prospectus contemplates transactions subsequent to 30 June 2021 which are to take place on or before the completion of the Offer. These transactions are reflected in the pro forma statement of financial position and are explained in Section 4.7.3.

#### **4.7.2 Subsequent Events**

##### **(a) Conversion of Notes**

The convertible note liability and equity adjustment of \$7.5 million relates to the conversion of convertible notes to equity which will complete one business day prior to the Allotment Date.

##### **(b) YTD Financial Performance**

The net cash expenditure for the period since 30 June 2021 to mid September 2021 is approximately \$347,000, after capitalisation of Offer related costs discussed in sections 4.7.3(b). The loss largely relates to professional fees (\$111,000), consultancy fees (\$76,000), employee benefit expenses (\$69,000) and medical trial costs (\$59,000). The impact of financial performance to mid September 2021 has been adjusted as a subsequent event in the pro forma Statement of Financial Position against cash (\$347,000) and accumulated losses.

##### **(c) Issue of Shares**

In addition to cash expenditure since 30 June 2021, the Company has issued 419,460 shares on a post share split basis for services rendered to the company and expensed to the amount of \$491,000, including medical trials (\$187,500), director fees (\$105,000), consultancy (\$108,000) and Offer costs (\$70,000).

#### **4.7.3 Pro forma transactions**

##### **(a) The Offer**

The issue of 19,130,440 shares amounting to \$22 million Offer proceeds.

##### **(b) Offer Costs**

Total expenses associated with the Offer are estimated to be \$2.3 million to be paid in cash. Those costs which directly related to the issue of new shares totalling \$0.8 million have been capitalised, hence netted against the amount of capital raised, while the remaining costs totalling \$1.5 million have been expensed.

##### **(c) Issue of Options**

The Company has issued to employees, consultants and the board 6,035,580 Options on a post share split basis which will be issued on the successful completion of the Offer. These share based payments will be expensed over their vesting periods in accordance with AAS. No expense has been included in the Pro Forma statement of financial position.

## 4. Financial Information Continued

### 4.7.4 Pro forma cash and cash equivalents

The reviewed pro forma cash and cash equivalents have been set out below:

<b>\$'000</b>	<b>Reference</b>	<b>Pro forma amount</b>
<b>Statutory cash and cash equivalents as at 30 June 2021</b>		<b>7,764</b>
<b>Subsequent events</b>		
Conversion of convertible notes to ordinary shares	4.7.2 (a)	–
YTD Financial Performance	4.7.2(b)	(347)
<b>Pro forma transactions</b>		
Proceeds from Shares issued under the Offer	4.7.3 (a)	22,000
Payment of the costs relating to the Offer	4.7.3 (b)	(2,306)
<b>Pro forma cash and cash equivalents</b>		<b>27,111</b>

Except for the adjustment described in Section 4.7.2(b), the pro forma cash and cash equivalents does not reflect the change in cash position between mid September 2021 and Completion, which will occur as a result of ongoing R&D spend and other cash requirements of the business over this period.

### 4.7.5 Share Capital

The reviewed pro forma share capital has been set out below:

	<b>Reference</b>	<b>Amount (\$'000)</b>	<b>No. of issued shares ('000)</b>
<b>Statutory share capital as at 30 June 2021</b>		<b>3,819</b>	<b>1,638</b>
<b>Subsequent events</b>			
Conversion of notes issued	4.7.2 (a)	7,500	408
Pre-IPO shares issued		491	21
<b>Pro forma share capital before share split</b>		<b>11,810</b>	<b>2,067</b>
<b>Pro forma transactions</b>			
Share split	Note 1	–	39,268
Shares issued pursuant to the Offer	4.7.3 (c)	22,000	19,130
Offer costs	4.7.3 (b)	(747)	–
<b>Pro forma share capital</b>		<b>33,063</b>	<b>60,465</b>

Note:

- Each fully paid ordinary share in Tissue Repair will be split into 20 shares before the Listing Date.

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## 4.8 Liquidity and Capital Resources

Following Completion, Tissue Repair's principal sources of funds are expected to be cash on hand. Until commercialisation is achieved, Tissue Repair's operating cash flows are expected to be negative (outflows). Net cash raised from the Offer will be used to fund Working Capital, clinical development, intellectual property management and regulatory management (refer to Section 7.1.2). Following Completion, Tissue Repair expects that it will have sufficient cash to meet its operational and Working Capital requirements and stated business objectives for at least the next 24 months.

## 4.9 Management discussion and analysis

### 4.9.1 General factors affecting the operating results of Historical Financial Information

This section discusses the general factors that affected Tissue Repair's operations and relative financial performance in FY19, FY20 and FY21 and which Tissue Repair expects may continue to affect it in the future.

The discussion of these general factors is intended to provide a summary only and does not detail all factors that affected Tissue Repair's historical operating and financial performance, nor everything that may affect Tissue Repair's operations and financial performance in the future.

Unless otherwise stated, all metrics and financial information presented in this section, and the related commentary are on a pro forma basis.

#### FY19

Tissue Repair's total revenue was \$2,197, consisting entirely of interest.

Medical trials expenditure represented \$424,200 (76%) of the operating cost base, consulting fees represented \$55,100 (10%), professional fees was \$32,789 (6%), and administration and other costs amounted to \$45,254 (8%).

Net loss after income tax benefit totalled \$357,193.

The net decrease in cash and cash equivalents of \$55,598 relate entirely to operating activities.

#### FY20

Tissue Repair's total revenue was \$156, consisting almost entirely of interest.

Medical trials expenditure represented \$325,074 (65%) of the operating cost base, professional fees represented \$50,975 (10%), general and administration expenses amounted to \$37,155 (7%), share-based payments amounted to \$22,611 (5%), and other costs amounted to \$65,206 (13%).

Net loss after income tax benefit totalled \$352,214.

The net increase in cash and cash equivalents of \$550,016 is a combination of operating losses for the year net of proceeds of share issuance of \$1,200,000.

#### FY21

Tissue Repair's total revenue was \$27,576, consisting of foreign currency gains of \$26,393 (96%) and interest of \$1,183 (4%).

Medical trials represented \$409,138 (37%) of the operating cost base, finance costs represented \$389,893 (36%), professional fees amounted to \$111,585 (10%), share-based payments totalled to \$38,760 (4%) and other costs amounted to \$146,063 (13%).

Net loss after income tax benefit totalled \$915,227.

The net increase in cash and cash equivalents of \$6,617,041 is primarily a combination of operating losses for the year net of proceeds from convertible note issuance of \$7,500,000.

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## 4. Financial Information Continued

### 4.9.2 Research & development costs and incentives

Tissue Repair undertakes research and development (**R&D**) activities to generate new capabilities in its core technology and progress its clinical applications. The research projects address the development and commercialisation of wound healing products targeting applications in the chronic wound (venous leg ulcers) and cosmetic procedure aftercare markets. Tissue Repair has developed a unique active ingredient (Glucoprime) that is designed for wound healing and which is delivered topically.

Primary components of Tissue Repair's R&D activity include testing and manufacturing its chronic wound product, TR-987, the analytical development and management of its active pharmaceutical ingredient (**API**) (Glucoprime) and clinical trials involving TR-987. Tissue Repair undertakes this work both in Australia and overseas and has received a certificate for overseas finding under section 28A of the Industry Research and Development Act 1986 for these projects and for associated work required to be undertaken overseas. The finding allows Tissue Repair's eligible R&D expenses on these projects overseas to be counted towards its R&D tax incentive from the Australian Government. The income tax benefits set out in table 4.1 for FY19, FY20 and FY21 represent the funding claimed through the R&D rebate for the R&D expenditure incurred in those years.

Expenditure during the research phase of a project is recognised as an expense when incurred. Development costs would only be capitalised when technical feasibility studies identify that the projects will deliver future economic benefits and these benefits can be measured reliably. These high measurement hurdles are established by the AAS and IFRS accounting standards and Tissue Repair applies a conservative approach to assessing potential future benefits that can be measured reliably and, consequently, has historically expensed all its R&D costs.

The capitalisation of any development costs would also defer the timing by which Tissue Repair would be able to access certain tax incentives and grants available to it in association with those costs.

To date, Tissue Repair has been able to fund its R&D activity through successfully applying for grants from Australian government agencies and from investors. This includes R&D activities on projects that it has committed to continue over the next few years. To the extent that new R&D projects are unable to attract such funding support, the level of R&D expenditures would most likely be reduced.

R&D costs includes costs for employees, contractors, materials and other expenditure associated with the Company's R&D programs. Included here are the costs of undertaking clinical trials, manufacturing, development and analytical characterisation of its API (Glucoprime), regulatory costs and regulatory legal advice.

### 4.10 Application of new accounting standards to the Financial Information

The significant accounting policies applied consistently in the preparation of the Financial Information are set out in Section 13. Tissue Repair adopted AASB 9 Financial Instruments and AASB 15 *Revenue from Contracts with Customers* from 1 July 2018 and AASB 16 *Leases* from 1 July 2020 which had no impact on Tissue Repair's financial statements.

The adoption of AASB 9 and AASB 15 did not materially impact Tissue Repair's financial performance or cash flows, and accordingly no pro forma adjustments have been retrospectively applied to reflect these standards.

### 4.11 Critical accounting judgements and estimates

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events, management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results. The judgements, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities (refer to the respective notes) within the next financial year are discussed below.

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#### **(i) Research and development expenditure**

The Company has expensed research and development expenditure incurred during the year, where applicable, as the costs relate to the initial expenditure for research and development of biopharmaceutical products where generation of future economic benefits are not considered certain. It was considered appropriate to expense these research and development costs as they did not meet the criteria to be capitalised under AASB 138 Intangible assets.

#### **(ii) Share based payment transactions**

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using the Black-Scholes model taking into account the terms and conditions upon which the instruments are granted. The accounting estimates and assumptions relating to equity-settled shares-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity. Judgment is required in relation to the non-market vesting conditions.

### **4.12 Dividend policy**

Tissue Repair is currently in the development phase of operations and therefore expects to incur significant expenditure to execute the Company's business plans. These activities are expected to dominate the period following the date of this Prospectus. Accordingly, the Company does not expect to declare any dividends for the foreseeable future.

Any future determination as to the payment of dividends by Tissue Repair, if any, will be at the discretion of the Directors and will depend on the availability of distributed earnings and operating results and financial condition of the Company, future capital requirements and general business and other factors considered relevant by the Directors. No assurance in relation to the payment of dividends or franking credits attaching to dividends can be given by the Company.





Glucoprime API under a microscope

## 5. Key Risks



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## 5. Key Risks

### 5.1 Introduction

Tissue Repair is subject to various risk factors. Some of these are specific to Tissue Repair's business activities. Others are of a more general nature. Individually, or in combination, these risk factors may affect the future operating and financial performance of the Company, its investment returns, and the value of an investment in the Shares. Each of the risks set out in this Section, if they eventuate, could have a material adverse impact on Tissue Repair's business, financial condition, and results of operations.

Investors should be aware that this Section does not purport to list every risk that may be associated with an investment in the Shares or the industry in which Tissue Repair operates now or in the future. The occurrence or consequences of some of the risks described in this Section are partially or completely outside of the control of the Company, its Directors, and its management team. This Section should be read in conjunction with other information disclosed in this Prospectus. There can be no guarantee that the Company will achieve its stated objectives or that any forward-looking statements will be realised or otherwise eventuate.

The selection of risks has been based on the assessment of a combination of the probability of the risk occurring, the ability to mitigate the risk and the impact of the risk if it did occur. That assessment is based on the knowledge of the Directors at the Prospectus Date, but there is no guarantee or assurance that the importance of different risks will not change or that other risks will not emerge.

Before applying for Shares, investors should satisfy themselves that they have a sufficient understanding of these matters and should consider whether Shares are a suitable investment for them, having regard to their own investment objectives, financial circumstances, and taxation position. If investors are unclear in relation to any of the risks outlined in this Section or are uncertain as to whether the Company is a suitable investment for them, they should seek professional guidance from their solicitor, stockbroker, accountant or other independent and qualified professional adviser before deciding whether to invest.

Shares to be issued under this Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares. Investment in the Company must be regarded as highly speculative and neither the Company nor any of its Directors or any other party associated with the preparation of this Prospectus guarantees that any specific objectives of the Company will be achieved or that any particular performance of the Company or of the Shares, including those offered by this Prospectus, will be achieved.

Investors should consult their professional advisers before deciding whether to apply for Shares.

### 5.2 Business risks associated with Tissue Repair

#### 5.2.1 Products not yet launched and the therapeutic product is not yet approved for commercial sale

Tissue Repair's ability to achieve profitability is dependent on a number of factors, including, for its therapeutic product, its ability to commence and complete successful Phase III clinical trials and obtain regulatory approval in the USA and Australia (at a minimum), and Tissue Repair's ability to successfully commercialise either or both of its cosmeceutical or therapeutic products. There is no guarantee that Tissue Repair's products (either or both its cosmeceutical or therapeutic product/s) will be commercially successful. Tissue Repair does not currently generate revenue from product sales, and any such revenue would first be from its cosmeceutical product, which has not yet been launched. Revenue from Tissue Repair's therapeutic product will not be possible until FDA approval is granted in the USA and the product is successfully launched. Clinical trials for Tissue Repair's therapeutic product may also be suspended for safety or efficacy reasons, following development it may prove difficult or impossible to replicate and manufacture any of Tissue Repair's products on a large scale, or, during the period of development, competitors (including those with greater resources) may emerge with competing or alternative treatments or technologies.



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## 5. Key Risks Continued

### 5.2.2 Product acceptance

Tissue Repair's growth and the commercial success of Tissue Repair's current and future products is reliant on the acceptance of Tissue Repair's products by healthcare professionals, including the relevant medical and wound care specialists.

The degree of market acceptance and continued adoption of Tissue Repair's products will depend on a number of factors, including:

- the potential and perceived advantages of Tissue Repair's products over competitor products and the preference by healthcare professionals of competitor's products due to familiarity with those products or for other reasons;
- Tissue Repair's products performing to expected standards of care and quality;
- Tissue Repair's ability to successfully market its products by providing clinical and economic data that show the safety, clinical efficacy, cost effectiveness and patient benefits from Tissue Repair's products; and
- Tissue Repair's ability to deliver consistent clinical results for indications when approved.

The acceptance of Tissue Repair's products may be slower than planned, or the products may not gain broad market acceptance by healthcare professionals which, should it arise, would impact Tissue Repair's operating and financial performance and viability.

### 5.2.3 Clinical trial risk for therapeutic product

Tissue Repair may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to commence or conduct Phase III clinical trials for its therapeutic product. As a new manufacturing site is being established, it is possible that the FDA does not accept there is equivalence of the API used in prior stage clinical trials. The FDA could require bridging studies on the API produced at the new site or that prior stage clinical trials are repeated on the API produced by the new manufacturing site. The FDA may also require two Phase III trials (rather than one) as part of its approval to conduct Phase III trials.

There is no guarantee that Tissue Repair's technology will prove to be safe and efficacious in the Phase III clinical trials, or that the regulatory approval to manufacture and market its therapeutic products will be received. The clinical trials could be put on hold or terminated, which will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its technology.

### 5.2.4 Manufacturing risk

There is a risk that Tissue Repair may not be able to reproduce its API material and/or drug product consistently with what was used in clinical trials to date (i.e. it is not consistent with the IND specifications currently on file with the FDA), delaying or impeding Tissue Repair's ability to proceed to Phase III clinical trials. Should this risk occur, the FDA could require additional bridging studies or require that earlier stage clinical trials are repeated.

Tissue Repair may face potential scale-up challenges as it seeks to increase the output of its manufacturing for commercialisation of its products and may have difficulty reproducing the API material and/or drug product and producing it in large quantities.

The Company expects to be dependent on one or more Contract Manufacturing Companies (CMC), exposing it to additional risks through these counterparties (see section 5.2.9).

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### 5.2.5 Regulatory and reimbursement approvals

The research, development, manufacture, marketing and sale of products using Tissue Repair's technology are subject to varying degrees of regulation by government authorities in Australia, USA, Europe and Asia. Products developed using Tissue Repair's technology must undergo a comprehensive and highly regulated development and review process.

For Tissue Repair's therapeutic product, that process also includes the requirement to obtain regulatory approval for marketing. This additional process includes the provision of clinical data relating to the quality, safety and efficacy of the therapeutic product for its proposed use, and therapeutic products may also need to be submitted for reimbursement approval. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of therapeutic products in some jurisdictions.

Any of the products utilising Tissue Repair's technology may be shown to be unsafe, non-efficacious, difficult or impossible to manufacture on a large scale, uneconomical to market, compete with superior products marketed by third parties or not be as attractive as alternative treatments or technologies.

### 5.2.6 Commercialisation of products, revenue, and expenditure

Tissue Repair has not yet commercialised its technology and, as yet, has no revenues. Tissue Repair is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales (to fund sufficient revenues for continued operations and growth) may not be achieved.

Tissue Repair may experience delay or adverse outcomes in achieving a number of critical milestones, including securing commercial partners, completion of clinical trials for its therapeutic products, obtaining regulatory approvals, manufacturing, pre-launch market research, product launch and sales. Any material delays may impact Tissue Repair adversely, including the timing of any revenues.

The Directors believe the funds raised through the Offer will be sufficient for the Company's short-to-medium term objectives, however the Company may require substantial additional financing in the future to sufficiently fund its operations, commercialisation, and development. Unforeseen expenditure may not have been considered in the preparation of this Prospectus. Although the Company is not aware of any such additional expenditure requirements, if subsequently incurred they may adversely affect the expected use of funds of the Company as set out in this Prospectus.

Without revenue from commercialisation, the Company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the Company is unsuccessful in obtaining funds when they are required, Tissue Repair may need to delay or scale down its operations.

While the Company will be subject to the constraints of the ASX Listing Rules regarding the percentage of its capital that it is able to issue within a 12-month period without Shareholder approval (other than where exceptions apply), Shareholders may be diluted as a result of any issues and fundraisings.

### 5.2.7 Intellectual property

Tissue Repair's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or Tissue Repair may incur substantial costs in asserting or defending its intellectual property rights. This includes the Company's ability to obtain commercially valuable patent claims.

If relevant patents or trademarks are not granted to Tissue Repair, then the value of the intellectual property rights may be significantly diminished. Further, any information contained in patent applications will become part of the public domain, and so will not be protected as confidential information.

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## 5. Key Risks Continued

### 5.2.8 Dependence upon key personnel, and growth management

Tissue Repair depends on the talent and experience of its personnel (employees and consultants) as its primary asset. There may be a negative impact on Tissue Repair if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel who leave to work for a competitor may adversely impact Tissue Repair. There is a corresponding risk that Tissue Repair may be unable to manage its future growth successfully. The ability to hire and retain skilled personnel as outlined above may be a significant obstacle to growth.

### 5.2.9 Arrangements with contract manufacturers and third-party collaborators

Tissue Repair itself has not produced active pharmaceutical ingredient (API) material and has appointed a contract manufacturer to undertake manufacture of engineering and production batches of its unique active ingredient, named Glucoprime. There is no guarantee Tissue Repair will be able to produce the active ingredient and finished drug products of a consistent specification of previous batches used in the Phase IIA and Phase IIB trial programs. Any contract manufacturers will need to comply with quality expectations and applicable regulatory requirements and may not be able to be established in a timely manner.

The service provided by contracted parties to Tissue Repair may be disrupted or terminated for a variety of reasons which may result in manufacturing disruptions or an inability to manufacture and produce its products for some time. This has the potential to limit, delay or prevent supply of Tissue Repair's products and have an adverse impact on the availability of Tissue Repair's products to customers.

Tissue Repair may pursue collaborative arrangements with pharmaceutical and life science companies, academic institutions or other partners to complete the development and commercialisation of its products. These collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals, or product marketing. There is no assurance that the technology will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals.

### 5.2.10 Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Other companies, both in Australia and abroad, may be pursuing the development of products that target the same medical conditions or markets that Tissue Repair is targeting. Tissue Repair's products may compete with existing alternative treatments or technologies that are already available to customers. Some of these companies may have, or develop, technologies superior to Tissue Repair's own technology. Tissue Repair may face competition from parties who have substantially greater resources than the Company.

### 5.2.11 Product liability

Any defects in Tissue Repair's products may harm Tissue Repair and its customers' reputation and business. Tissue Repair may also be subject to warranty and liability claims for damages related to defects in its products. In addition, the products may be subject to a recall, withdrawal, or other regulatory action. This risk exists even if a product is cleared or approved for commercial sale by the TGA, FDA or other regulatory authorities and is manufactured in appropriately licensed and regulated facilities.

There may also be adverse events reported from the use, misuse or defect of Tissue Repair's products which could expose Tissue Repair to product liability claims or litigation. Tissue Repair may be subject to product liability claims if its products cause, or merely appear to have caused, patient injury or death. The industry in which Tissue Repair operates has historically been subject to extensive litigation over product liability claims, especially in the USA market. Product liability claims may result in substantial litigation costs, product recalls or market withdrawals, suppressed demand for Tissue Repair products and damage to Tissue Repair's reputation, regardless of merit or eventual outcome. If this were to occur, it would adversely impact Tissue Repair's operating and financial performance.

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### **5.2.12 Country/region specific risks**

Tissue Repair has operations in the USA and must comply with a range of different USA legal and regulatory regimes. As Tissue Repair expands the sales of its products geographically into new international jurisdictions, it is subject to the risks associated with conducting business in those new international jurisdictions, which include adapting to, and complying with, the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries, developing and managing foreign relationships and operations and being subject to the political and economic climate of the various countries. A breach of any of these areas could result in fines or penalties, the payment of compensation or the cancellation or suspension of Tissue Repair's ability to carry on certain activities or product offerings. It could also interrupt or adversely affect parts of Tissue Repair's business and may have an adverse effect on Tissue Repair's operating and financial performance.

### **5.2.13 Currency risk**

A significant proportion of Tissue Repair's costs are incurred in the USA. There is a risk that unfavourable exchange rate movements may cause higher than expected costs. Tissue Repair does hedge some of its USD foreign exchange rate exposure by holding some cash in a USD bank account, however other hedging arrangements may be considered closer to product launch and bulk manufacturing.

## **5.3 General risks**

In addition to the specific risks outlined above, there are a number of general risk factors including those set out below. Many of the general risks discussed below are outside the control of the Company and the Directors and cannot be mitigated. These factors, and others not specifically referred to below, may in the future materially affect the financial performance of the Company and the value of the Shares offered.

These risks should be carefully considered, together with the information contained elsewhere in this Prospectus, before deciding to apply for Shares. It is not an exhaustive list of the risks faced by Tissue Repair or by investors in the Company.

### **5.3.1 Counterparty risk**

As a party to many contracts, Tissue Repair has various contractual rights in the event of non-compliance by a counterparty. However, no assurance can be given that all contracts will be fully performed by all contracting parties and that Tissue Repair will be successful in securing compliance with the terms of each contract by the counterparties to its contracts.

Tissue Repair's material contracts contain provisions providing for early termination of the contracts, on giving notice and paying a termination amount (which varies between the contracts). The early termination of any of these contracts, for any reason, may mean that Tissue Repair will not realise the full value of the contract, which is likely to adversely affect the growth prospects, operating results, and financial performance of the Company.

### **5.3.2 Data management and security risk**

Tissue Repair engages third party software suppliers and service providers which employ independent data security protections. However, advances in computer capabilities, increasingly sophisticated tools and methods used by hackers and cyber terrorists, new discoveries in the field of cryptography and other developments may result in Tissue Repair's software failing to or being unable to adequately protect its sensitive information.

### **5.3.3 Litigation, claims and disputes**

Tissue Repair may be subject to litigation and other claims and disputes, including contractual disputes with suppliers or customers, employment disputes, indemnity claims, and occupational and other claims. There is a risk that any such litigation, claim or dispute could materially adversely impact Tissue Repair's operating and financial performance due to the significant cost and time invested by management in investigating, commencing, defending and/or settling such matters. Any claim against Tissue Repair, if proven, may also have a sustained negative impact on its operations, financial performance, financial position, and reputation.

The Company is not currently engaged in litigation and, as at the date of this Prospectus, the Directors are not aware of any legal proceedings pending or threatened against, or any material legal proceedings affecting, the Company.

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## 5. Key Risks Continued

### 5.3.4 Changes in laws and regulations

The operation of Tissue Repair's business in the biotechnology and pharmaceutical industries is governed by a variety of laws, regulations and guidelines. While to the knowledge of management, Tissue Repair is currently in compliance with all current laws, changes to laws and regulations due to matters beyond the control of Tissue Repair may cause adverse effects to its operations. The introduction of new legislation or amendments to existing legislation by governments, or the respective interpretation of the legal requirements in any of the legal jurisdictions which govern Tissue Repair's operations or contractual obligations, could impact adversely on the assets, operations and, ultimately, the financial position and financial performance of the Company and its Shares. In addition, there is a risk that legal action may be taken against Tissue Repair in relation to commercial, legal, regulatory or other matters.

### 5.3.5 Market for Shares

Prior to the Offer there has been no public market for the Shares. Once the Shares are quoted on ASX, their price might rise or fall, and they might trade at prices below or above the Offer Price. No assurance can be given that an active market will develop in the Shares or that the Shares will trade at or above the Offer Price in the future.

Share market conditions may affect the value of the Company's quoted securities regardless of the Company's operating performance. Share market conditions can be affected by many market factors including:

- general economic outlook;
- interest rates and inflation rates;
- currency fluctuations;
- changes in investor sentiment towards equities or particular market sectors;
- political instability;
- short selling and other trading activities;
- the demand for, and supply of, capital; and
- force majeure events.

The market price of the Shares can fall as well as rise and may be subject to varied and unpredictable influences on the share market. The trading price of the Shares at any given time may be higher or lower than the price paid under the Offer. Further, you may be unable to sell or realise your investment because the market for Shares may be illiquid.

### 5.3.6 Taxation

There are tax implications arising from buying and selling Shares, the receipt of dividends (both franked and unfranked) (if any) from the Company and participation in any on-market Share buy-back. The tax treatment of an investment in Shares will differ depending on each investor's personal circumstances. Investors should seek their own independent taxation advice before applying for Shares.

### 5.3.7 Insurance risks

Although Tissue Repair maintains insurance, no assurance can be given that adequate insurance will continue to be available to Tissue Repair in the future on commercially acceptable terms.

### 5.3.8 Unforeseen delays and expenses

The proposed expenditure on Tissue Repair's projects may be adversely affected by any unforeseen expenses which arise in the future and which have not been considered in this Prospectus, including delays to commencement or completion of clinical trials, preparatory Phase III work, reimbursement submissions, and others.

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### **5.3.9 Litigation**

The Company is not currently involved in any material contractual disputes or litigation, arbitration or government prosecution matters. There is a risk that the Company may in the future have disputes with third parties (including payment disputes) and this may have an adverse impact on the Company's growth prospects, operating results and financial performance.

### **5.3.10 General economic conditions**

General economic conditions, introduction of tax reform, new legislation, movements in interest and inflation rates and currency exchange rates may have an adverse effect on Tissue Repair's research and development programs, clinical trials, as well as on its ability to fund those programs. The general economic climate may affect Tissue Repair's performance, including the general level of international and domestic economic activity, inflation, and interest rates.

### **5.3.11 COVID-19 global pandemic**

Uncertainties relating to the ongoing COVID-19 global pandemic in jurisdictions within which Tissue Repair is operating may affect the Company's ability to achieve any of its objectives outlined in this Prospectus, including requisite preparatory Phase III operations and deliverables required by the FDA, its ability to actually conduct a Phase III trial and commercialisation plans, including but not limited to its ability to generate revenue from its cosmeceutical product, TR Pro+.



Illustration of yeast cells

## 6. Key Individuals and Corporate Governance





## 6. Key Individuals and Corporate Governance

### 6.1 Board of directors

The Directors bring to the Board relevant experience and skills, including industry and business knowledge, financial management and corporate governance experience.

#### Director & experience



##### **Mr Tony Charara**

##### *Co-Founder, Executive Director*

Tony is a co-founder of Tissue Repair. He has been actively involved in the Company's clinical development program, across its two-Phase IIB trials, commercialisation strategy and overall operations. Tony is an investment banker by background and has extensive experience across early-stage venture assets and in advising technology companies at ANZ Investment Bank, Ord Minnett Securities and JPMorgan in their respective investment banking teams. Tony is also a co-founder of Mable Technologies, an online marketplace and health technology platform operating in the aged care and disability sectors. Mable was named Australian growth technology company of the year in 2020. It was also listed in the Top 10 Deloitte Technology Fast 50 in 2020.

As Tony is a co-founder and has been a Director of Tissue Repair since the Company's incorporation, he is considered by the Board not to be an independent director.

On Listing, Tony will hold a relevant interest in 4,822,260 Shares and 13,640,000 Options in the Company.



##### **Mr Jack Lowenstein**

##### *Independent, Non-Executive Chair*

Jack has over 25 years of senior management experience in financial services and was a pioneer in developing Australian ESG investment, first at Hunter Hall Investment Management from 1997 to 2011, and then from 2012 to 2019 at Morpheic Asset Management. Both companies specialised in investing in ethically screened global mid-cap equities. Morpheic was acquired in 2019 by Ellerston Capital and he remains a non-executive director of the company.

He was also a co-founder of Fiji's first investment bank, Kontiki Capital which he chaired from its inception in 1998 to 2017, and remains a director of Kinetic Growth Fund, which is listed on the South Pacific Stock Exchange.

Jack has been a director of several Australian ASX listed public companies, including Hunter Hall International, Hunter Hall Global Value, Kresta Holdings, Reinsurance Australia and Calliden Group. He is currently a director of Morpheic Ethical Equities and Fiji Kava.

Jack has an MA (Oxon) and completed the Owner/President Management Course at Harvard Business School in 2009.

Jack is considered by the Board to be an independent director.

On Listing, Jack will hold a relevant interest in 26,080 Shares and 366,060 Options in the Company.

## 6. Key Individuals and Corporate Governance Continued

### Director & experience



#### **Mr Max Johnston**

##### *Independent, Non-Executive Director*

Max held the position of President and Chief Executive Officer (CEO) of Johnson & Johnson Pacific, a division of one of the world's largest medical, pharmaceutical and consumer healthcare company for 11 years. Prior to joining Johnson & Johnson, Max's career also included senior roles with Diageo and Unilever in Europe. He has also held several prominent industry roles as a past President of ACCORD Australasia Limited, a former Vice Chairman of the Australian Food and Grocery Council and a former member of the board of the Australian Skills Management Institute.

Max is currently Non-Executive Chairperson of AusCann Group Holdings Limited and a Non-Executive Director of Medical Developments International Ltd and BARD1 Life Sciences Ltd. Former board roles include Non-Executive Director of PolyNovo Ltd and Enero Group Limited, as well as Non-Executive Chairperson of Probiotec.

Max is considered by the Board to be an independent director.

On Listing, Max will hold a relevant interest in 26,080 Shares and 366,060 Options in the Company.



#### **A/Prof Craig Stamp**

##### *Independent, Non-Executive Director*

Craig has over 25 years of senior management experience in pharmaceuticals, healthcare and medical devices in Australia and Asia, previously holding senior positions at Allergan (Director Sales and Marketing) and Bausch & Lomb (Managing Director and VP Commercial Operations, Asia-Pacific). He has had considerable public company experience having served as CEO and Managing Director at Vision Group Holdings Ltd, a former ASX listed company (now privately held). Craig was also Executive General Manager at Device Technologies between 2014 and 2020, the largest independent medical technology supplier in Australia and New Zealand. Craig is Chair of the School of Optometry and Vision Science (SOVS) Visiting Committee and is an Adjunct Associate Professor of the SOVS, Faculty of Medicine and Health, UNSW. Craig was a former Director of the Medical Technology Association of Australia (MTAA) and was Chair of the MTAA Finance Committee.

Craig is considered by the Board to be an independent director.

On Listing, Craig will hold a relevant interest in 26,080 Shares and 366,060 Options in the Company.



#### **Mr Bryan Gray**

##### *Independent, Non-Executive Director*

Bryan has over 35 years' experience in Banking and Financial services in Australia and New Zealand. He spent 20 years at J.P Morgan in the Corporate and Investment Bank, the last 12 years as a Managing Director. Prior to that he held senior roles at State Street Bank and had a Chartered Accounting background in New Zealand working with Deloitte. He holds a Bachelor of Commerce and Administration from Victoria University of Wellington, New Zealand and is a member of the Australian Institute of Company Directors. He is currently a non-executive director of RFBI a not-for-profit business operating in the Residential Aged Care and Retirement sector.

Bryan is considered by the Board to be an independent director.

On Listing, Bryan will hold a relevant interest in 13,040 Shares and 366,060 Options in the Company.

The Board has determined that the independent directors listed above are free from any business or other relationship that could materially interfere with, or reasonably be perceived to materially interfere with their independent exercise of judgement. The determination of what would materially affect a Director's independence is based on principle 2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations.

## 6.2 Management

### Management team & experience



#### **Mr Tony Charara**

*Co-Founder, Executive Director*

See Section 6.1 above.



#### **Dr Darryl Reed**

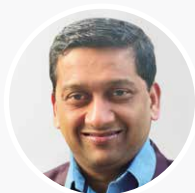
*Chief Operating Officer (COO)*

*B.Sc (Hons); Ph.D Molecular Genetics; M. Medical Science (Drug Development); M. Business Management*

With over 25 years' experience in the pharmaceutical industry, Dr Darryl Reed has worked across research, Government and the private sector. At the completion of his melanoma research fellowship in Lausanne, Switzerland, Dr Reed relocated back to Australia where he joined the Therapeutic Goods Administration (Dept. of Health) and represented the Government on several joint industry committees. Moving to the private sector, Darryl has worked in a variety of senior roles with both Roche and Bayer, spanning regulatory and scientific affairs, medical and clinical support, product development, and sales and marketing.

Dr Reed headed up the Medical teams for Roche and Bayer Consumer Health divisions before moving into dedicated commercial roles, Dr Reed has a 19-year history with Bayer, he has extensive experience in leading strong product portfolios and heading up internal sales teams selling to health care professionals.

On Listing, Dr Reed will hold 1,027,880 Options in the Company.



#### **Dr Pramod Nednoor**

*Vice President of Chemistry and Controls*

*PhD Analytical Chemistry, member of AAPS, CPHI*

Dr Pramod Nednoor is a strategic and technical CMC (chemistry, manufacturing and controls) leader with a track record in directing numerous pharmaceutical projects (including injectables) to FDA approval and commercialisation.

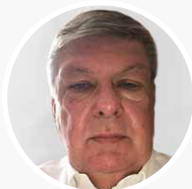
Dr Nednoor has held leadership roles at a number of pharmaceutical companies undertaking drug development and manufacturing activities. He has extensive experience assisting small and medium size pharma companies in identifying, evaluating and selecting CDMOs, and contract analytical and microbiology labs to support drug development for IND/NDA/ANDA submissions. Dr. Nednoor also has expertise in creating and maintaining detailed CMC project plans, timelines, budget and managing multiple CMC programs.

Dr Nednoor played a key role in the development, production and quality control testing of Tissue Repair's TR-987 gel product to support the Phase IIB clinical study. He is currently leading the CMC activities to support Phase III clinical studies. He is also actively involved in the preparation of CMC documentation to the FDA.

On Listing, Dr Nednoor will hold 700,000 Options in the Company.

## 6. Key Individuals and Corporate Governance Continued

### Management team & experience



#### **Mr William Bost**

*Vice President of Manufacturing*

*BEng (University of Cincinnati, Fenn College of Cleveland State University)*

Bill is a chemical operations and process specialist with extensive experience advising pharmaceutical manufacturers in drug development and manufacture, with a focus on topicals. Bill has direct specific experience in a topical drug approved for chronic wounds.

Bill has held roles varying from leading technical manufacturing transfer, process development and scale up, product development and launch for product manufacturers including in relation to Smith + Nephew's sterile diabetic ulcer gel product REGRANEX® and debridement product SANTYL®, Coppertone's spray sunscreens, Purell's hand sanitiser and McNeil's liquid Tylenol products.

On Listing, Bill will hold 765,000 Options in the Company.



#### **Mr Mark Waring**

*Vice President Clinical and Regulatory Affairs*

*BSc (Hons) Pharmacology & Biochemistry ASQ C.PGMP, PMP*

Mark is an executive level project manager, researcher and consultant. He has over 30 years' experience in Research and Development of Pharmaceutical products and Medical Devices. His early career was spent at the University of Sydney and Royal Prince Alfred Hospital (RPAH). As part of his work there he worked with Dr Graham Kelly to describe many new biologically active isoflavones and the early development of the TR-987 technology for wound healing (Tissue Repair's proprietary technology). He moved to the U.S. in 1998 to head the Clinical Research and Technical affairs program for a growing biotech firm. Mark has held roles of increasing responsibility since, including Deloitte Consulting and Quintiles IMS (IQVIA), advising both large and small clients in clinical research, product approval and launch.

On Listing, Mark will hold 630,000 Options in the Company.



#### **Mr Cameron Jones**

*Chief Financial Officer (CFO)*

*CA, B.Bus, GIA (Cert)*

Cameron is the Managing Director of Bio101, a financial services firm providing accounting, tax and company secretarial services specialising in the healthcare and life science sectors. A qualified Chartered Accountant and registered tax agent, Cameron acts as CFO and Company Secretary for a number of ASX listed life science companies and venture capital investee companies. In his role at Bio101 Cameron has assisted clients in the initial public offer process.

Cameron is a Director and Treasurer of registered charities Cystic Fibrosis Community Care Ltd and BioAutism Ltd.

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## Management team & experience



### **Alistair McKeough**

*Company Secretary*

*BA, LLB, LLM*

Alistair has practised as a solicitor for about 20 years, as a partner or principal for the past 15.

Alistair has held roles at Freehills, then boutique practice specialising in commercial law, property and litigation, where he then became the Managing Partner. In 2010 Alistair founded, and was Managing Director of, the law firm that has been known as Automic Legal since it merged with the Automic Group in 2018. As Head of Professional Services at Automic, Alistair oversees Automic's legal and company secretarial businesses.

Alistair has extensive experience in most aspects of corporate and commercial law (both transactional and litigious), regulatory compliance and corporate governance.

Alistair's listed company secretarial experience spans over a decade and includes serving as secretary to ASX listed companies in sectors such as resources, technology (software and hardware), pharmaceuticals and professional services. Alistair also has extensive experience working with charities and not for profits.

On Listing, Alistair will hold 43,460 Options in the Company.

## 6.3 Scientific Advisory Board

A number of scientific and medical professionals have joined Tissue Repair's scientific advisory board to provide feedback on Tissue Repair's clinical development program and potential applications for its technology.



### **Prof Graham Kelly**

*B.Sc (Hons), B.VSc (Hons), Ph.D*

Dr Kelly was the inventor of Tissue Repair's technology and has a 28-year background in medical research, principally in transplantation immunology and cancer research. As Head of the Transplantation Laboratories of the Department of Surgery, The University of Sydney, Dr Kelly led a research team investigating the issue of impaired wound healing in immunosuppressed transplant recipients. That work led to the finding that yeast-derived, micro-particulate  $\beta$ - (1-3)(1-6) glucan optimally restores normal rates of healing in incisional wounds in animals where the repair process is inhibited by immunosuppressive therapy. Dr Kelly currently is CEO of Noxopharm limited a cancer drug development company. He has been awarded an Adjunct Professorship by the University of Sydney.

On Listing, Dr Kelly will hold 793,940 Shares indirectly through an entity that he controls.

## 6. Key Individuals and Corporate Governance Continued



### **Dr Thomas E. Serena**

*MD, FACS, FACHM, MAPWCA*

Dr. Serena is the Founder and Medical Director of The SerenaGroup®, a family of wound, hyperbaric and research companies, and is a graduate of The College of William and Mary and Penn State Medical School.

He completed his residency in Surgery at The Milton S. Hershey Medical Center and maintains board certification in Surgery.

To date he has opened and operates advanced wound care centres across the United States and globally. Dr. Serena has been the lead or principal investigator in over 100 clinical trials, including gene therapy, antimicrobial dressings, growth factors, topical and parenteral antibiotics and CTP therapy.

Dr Serena is recognised in the USA and internationally as an expert in the field of wound healing and holds numerous patents on wound care devices and dressings: he has more than 200 published papers and has given more than 1,500 invited lectures throughout the world.

On Listing, Dr Serena will hold 52,140 Shares indirectly, through an entity that he controls.



### **A/Prof Michael Woodward**

*MB, BS, MD, FRACP*

Dr Woodward is an expert in wound management, rehabilitation, geriatric medicine, dementia and cognitive disorders and quality use of medications. He is currently Director of Aged Care Research and heads the Wound Clinic at one of Melbourne's large metropolitan teaching hospitals. His previous roles include President of the Australian Wound Management Association and Editor of Wound Practice and Research and of the Geriatric Therapeutics section of the Journal of Pharmacy Practice and Research.



### **Dr Vaclav Vetvicka**

*Ph.D*

Vaclav Vetvicka, Ph.D., is a Professor of Pathology at the Department of Pathology of the University of Louisville in Kentucky, USA. He graduated from Charles University in Prague, Czech Republic with an advanced degree in biology and obtained his Ph.D. from the Czechoslovak Academy of Sciences. His postgraduate training included a stay at the Oklahoma Medical Research Foundation, Oklahoma City, OK, and at the Institute of Microbiology, Prague, Czech Republic.

His main area of research interest focuses on the development of natural immunomodulators. In addition to the glucan research, Dr. Vetvicka helped to launch glucan in several countries including USA, France, Brazil, Turkey, South Korea, Australia and Czech Republic.

Dr. Vetvicka is author and co-author of more than 360 peer-reviewed publications, ten books and nine international patents. He has presented over 80 invited lectures at the universities and research institutes all around the world.

## 6.4 Directors' shareholding qualifications, remuneration and interests

Directors are not required under the Company's Constitution to hold any Shares.

The Company engaged Craig Stamp, through an entity that he controls, to provide consulting services prior to and in connection with the Offer. Mr Stamp will be paid \$30,000 (excl GST) in relation to those services.

Except as disclosed above and elsewhere in this Prospectus, no Director or proposed Director of the Company, or firm in which a Director or proposed Director is a partner, has any interest, nor has had any interest for registration, or has received or is entitled to receive any sum for services rendered by either them or the firm to induce them to become or qualify them as a Director, or otherwise in connection with the promotion or formation of the Company or in the property proposed to be acquired by the Company in connection with its promotion or formation.

### 6.4.1 Directors' remuneration

Under the Constitution, the total aggregate amount to be paid to the Directors (excluding any Executive Director) is \$500,000. Under the ASX Listing Rules, any increase to that aggregate annual amount will need to be approved by the Shareholders. The Company does not utilise that full amount based on its current Board of Directors.

The annual remuneration of the Board of Directors to be paid by the Company following admission to the ASX is as follows:

Director	Annual board fees (inclusive of serving on any committee)
Tony Charara, Executive Director	\$50,000 <sup>1</sup>
Jack Lowenstein, Non-Executive Chair	\$80,000
Max Johnston, Non-Executive Director	\$50,000
Craig Stamp, Non-Executive Director	\$50,000
Bryan Gray, Non-Executive Director	\$50,000

Note:

1. Tony Charara will be paid \$50,000 per annum for his role as a Director. See Section 10.6 for the details of his Executive Contract.

In addition to their annual remuneration, the Directors may also be reimbursed for expenses properly incurred by the Directors in connection with the affairs of the Company including travel and other expenses. There are no retirement benefit schemes for Non-Executive Directors.

### 6.4.2 Directors' deeds of indemnity

The Company has entered into deeds of indemnity with each Director (the **Deeds**). In accordance with the Constitution, under the Deeds the Company indemnifies each Director on a full indemnity basis (to the extent permitted by law) against:

- (a) any liability incurred by the Director as a director of a group company (being the Company and its related bodies corporate); and
- (b) all liabilities incurred by the Director in relation to a claim by the Director against third parties in order to protect the Director's interests or reputation. This indemnity includes a liability for reasonable legal costs.

Subject to the terms of the Deed, the Company must also pay or indemnify the Director on a full indemnity basis for any defence costs.

The Directors are indemnified under the Deeds for the entirety of their term as Director and for 7 years from the date of the Director's retirement or removal or ceasing to hold office.

Under the Constitution, the Company may purchase and maintain insurance, or pay or agree to pay a premium for insurance, for any person who is or has been a director, secretary or executive officer of the Company or its related bodies corporate against any liability incurred by that person as such an officer, including, but not limited to, a liability for negligence and for legal costs.



## 6. Key Individuals and Corporate Governance Continued

### 6.4.3 Directors' interests in securities

Set out below are details of the interests of the Directors in the Shares and other securities of the Company immediately prior to lodgement of the Prospectus with ASIC and as at the Listing Date. Interests include those held directly by Directors in their own names and indirectly by their associates and/or entities that they control.

Name	Position	As at Prospectus Date			On Listing Date		
		Shares	Options	Option exercise price	Shares <sup>1</sup>	Options <sup>1</sup>	Option exercise price <sup>1</sup>
Tony Charara <sup>2</sup>	Executive Director	241,113	477,000	\$4.11	4,822,260	9,540,000	\$0.2055
			125,000	\$7.43		2,500,000	\$0.3715
						1,600,000	\$1.15
Jack Lowenstein	Non-Executive Chair				26,080	366,060	\$1.15
Max Johnston	Non-Executive Director				26,080	366,060	\$1.15
Craig Stamp	Non-Executive Director				26,080	366,060	\$1.15
Bryan Gray	Non-Executive Director				13,040	366,060	\$1.15

Notes:

1. Following changes to the capital structure as described in Section 7.1.3.
2. Tony Charara has a relevant interest in Shares through Spark Capital Pty Limited, an entity that he controls.

### 6.5 Interests of advisers

On successful completion of the Offer, the Lead Managers will receive 6% of the gross amount raised under the Offer.

Other than as set out above and disclosed in this Prospectus, no person named in this Prospectus as providing professional or advisory services in connection with the preparation of this Prospectus or any firm in which any such person is a partner:

- has or had at any time during the two years preceding the date of the Prospectus, any interest in the formation or promotion of the Company, or in any property acquired or proposed to be acquired by the Company or the Offer; or
- has been paid or agreed to be paid any amount or given or agreed to be given any other benefit for services.

### 6.6 Related party transactions

Other than as set out below or elsewhere in this Prospectus, there are no existing agreements or arrangements nor any currently proposed transactions in which the Company was, or is to be, a participant and in which any related party of the Company has or will have a direct or indirect material interest in the Company or the Offer:

- the compensation arrangements with Directors which are described in Section 6.4.1; and
- the indemnification arrangements with Directors which are described in Section 6.4.2.

The Company's Audit and Risk Committee is responsible for reviewing, monitoring and making recommendations to the Board in relation to decisions on related party transactions and investments involving the Company and its Directors and senior executives. If a Director considers that they may be in a position where there is a reasonable possibility of a conflict of interest, they must fully and frankly inform the Board and abstain from voting from deliberations relating to the matter, unless the Board otherwise determines.

The Board will only approve those related party transactions that are determined to be in, or are not inconsistent with, the best interests of the Company and its Shareholders, after taking into account all available facts and circumstances as the Board determines in good faith to be necessary. Transactions with related parties will also be subject to Shareholder approval to the extent required by the Corporations Act and the ASX Listing Rules.

## 6.7 Options on issue

On Listing, the Company will have 22,470,580 Options on issue. The key terms of the incentive plans under which those Options have been issued are set out at Sections 6.8 to 6.10 below. A summary of the terms key terms attaching to the Options, other than as provided for in the relevant plans are set out in the table below:

	Tranche 1	Tranche 2	Tranche 3
Plan applicable to Options	Former Plan (Section 6.8)	Former Plan (Section 6.8)	Current Incentive Plan (Section 6.9)
Total number of Options issued (one Option being exercisable for one ordinary share)	11,240,000	5,195,000	6,035,580
Option holders and number of Options held	Mr Tony Charara – 9,540,000 Options <sup>1</sup> Creight Investments Pty Ltd – 1,700,000 Options <sup>2</sup>	Mr Tony Charara – 2,500,000 Options <sup>1</sup> The estate of Mr Mark Deacon-Shaw – 1,100,000 Options Creight Investments Pty Ltd – 800,000 Options <sup>2</sup> Mr Mark Waring – 330,000 Options Ms Jayne Shaw – 300,000 Options Mr William Bost – 165,000 Options	See Section 6.9.1
Issue dates	30-Dec-18	30-Aug-19 and 1-Oct-19	On or about the Listing Date
Vesting period (months)	48	48	48
Expiry date	15 years from the date of issue	15 years from the date of issue	15 years from the date of issue
Vesting Conditions	No performance conditions 25% vests in 12 months from the issue date, then vests monthly pro rata over remaining 36 months	No performance conditions 25% vests in 12 months from the issue date, then vests monthly pro rata over remaining 36 months	No performance conditions 25% vests in 12 months from the issue date, then vests monthly pro rata over remaining 36 months
Exercise Price	\$0.2055	\$0.3715	Offer price
Other terms	Must remain engaged by the company (as an employee, consultant or director) for the Options to vest. The Options cease to vest during any unpaid leave of absence. The holder cannot dispose of the Options without the prior written consent of the Company.	Must remain engaged by the company (as an employee, consultant or director) for the Options to vest. The Options cease to vest during any unpaid leave of absence. The holder cannot dispose of the Options without the prior written consent of the Company.	Must remain engaged by the company (as an employee or director) for the Options to vest.

Notes:

1. Tony Charara (Co-Founder, Executive Director) has a relevant interest in Options through Spark Capital Pty Limited, an entity that he controls.
2. Creight Investments Pty Ltd is an entity controlled by Peter Scutt, a co-founder and former Director of the Company.

## 6. Key Individuals and Corporate Governance Continued

### 6.8 Former Employee Option Plan

#### 6.8.1 Background

On 1 January 2019, the Company adopted an Employee Option Plan (**Former Plan**) to enable the Board, at its sole discretion, to offer Options to selected participants. Those eligible to participate are employees, contractors and directors (or prospective employees, contractors or directors) of one or more Group members selected by the Board to participate in the Former Plan (**Eligible Persons**).

#### 6.8.2 Maximum number of Options to be issued

Options issued under the Former Plan are set out in the table below.

Option holder	Number of Options held	Exercise price	Number of Options unvested as at Listing Date	Last exercise date
Creight Investments Pty Ltd	1,700,000	\$0.2055	476,944	29-Dec-33
	800,000	\$0.3715	357,778	29-Aug-34
Mr Tony Charara	9,540,000	\$0.2055	2,676,500	29-Dec-33
	2,500,000	\$0.3715	1,118,056	29-Aug-34
Mr Mark Waring	330,000	\$0.3715	147,583	29-Aug-34
Ms Jayne Shaw	300,000	\$0.3715	134,167	29-Aug-34
Mr William Bost	165,000	\$0.3715	77,344	30-Sep-34
The estate of Mr Mark Deacon-Shaw	1,100,000	\$0.3715	515,625	30-Sep-34
<b>Total</b>	<b>16,435,000</b>		<b>5,503,997</b>	

For details relating to the vesting period of the Options, please refer to the table at Section 6.7.

As set out below, the Former Plan was terminated on 7 October 2021. At the time of termination, the Directors resolved that the Options issued under the Former Plan that had not been exercised would continue to be governed by the Former Plan. However, as no new Options will be issued under the Former Plan, the maximum number of equity securities under the Former Plan is as set out in the table above.

#### 6.8.3 Key Terms

The key terms of the Former Plan are summarised below.

##### 6.8.3.1 Administration

The Former Plan is administered by the Board, which may delegate some or all of its powers in administering the plan to a sub-committee of the Board. The Board (or any sub-committee, as the case may be) has the power to:

- (a) select the persons to participate in the plan;
- (b) determine the terms and conditions of any offer;
- (c) amend any offer related to an Option;
- (d) determine appropriate procedures, regulations and guidelines for the administration of the plan; and
- (e) take advice in relation to the exercise of any of its powers or discretions under the rules.

##### 6.8.3.2 Rights attaching to Option shares

If an Option holder exercises vested Options, the Company must issue the number of fully paid ordinary shares which corresponds with the number of Options exercised, free of any security interest. The shares issued rank equally in all respects with the other Shares on issue in the Company as at the date of issue and are subject to the terms of the Constitution.

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#### **6.8.3.3 Vesting and exercise**

An offer to an Eligible Person may specify vesting conditions or other vesting events which must be satisfied before an Option vests. The Board has the discretion to determine or vary any vesting conditions or other vesting events.

The Former Plan provides for standard vesting conditions that apply if an offer does not specify any vesting conditions. In this case Options will only vest while an Eligible Person remains employed, provides consulting services or acts as a director of a Group member, and Options cease to vest for the duration of any unpaid leave of absence. Options vest, in respect of 25% of the Options the subject of an offer, one year from the date of issue, and the remaining 75% vest on a quarterly basis over the following three year period. An Option will only vest on the occurrence or satisfaction of the condition or other vesting events specified in respect of the Option.

An Option holder may exercise an outstanding Option during its exercise period by giving the Company a signed exercise notice and paying the exercise price.

#### **6.8.3.4 Leavers**

If an Option holder ceases to be employed by the Company or ceases to be a contractor or director of the Company, the Board may exercise any combination of the following rights:

- (a) give notice advising the person that all or some of their unvested Options have lapsed;
- (b) give notice requiring the person to sell some or all of their unvested Options to any person nominated by the Board at fair market value; or
- (c) allow the person to retain some or all of their Options.

#### **6.8.3.5 Exit**

On or prior to an exit event, which includes an initial public offering and admission to the official list of ASX (or any other recognised stock exchange), a business sale or share sale, the Board may do any of the following:

- (a) in the case of a reconstruction, provide for the grant of new Options in substitution for some or all of the Options on a like for like basis, by the new holding entity (or related body corporate) or arrange for some or all of the Options to be acquired for fair market value by the new holding entity;
- (b) buyback or cancel some or all of the Options (whether vested or not) in exchange for their fair market value; or
- (c) notify an Option holder of the number of Options that will vest on an exit event, ensure that the Options can be exercised and use reasonable endeavours to ensure that the Option shares issued at or about the time of the exit event are accorded the same rights and receive the same benefits in relation to the exit event as pre-existing ordinary shares.

The Company may require Options to be exercised or otherwise lapse if they are not exercised if an exit event is to occur.

The Former Plan also provides for drag along provisions where in connection with an exit event, the Board must, if requested by the majority shareholders of the Company issue a notice to the Company and each Eligible Person and Option holder stating that they want the Eligible Persons and Option holders to sell all of their Option shares to:

- (a) third party buyer, in connection with a share sale;
- (b) an initial public offering entity, in connection with a listing;
- (c) a new holding entity in connection with a share sale or asset sale.

#### **6.8.3.6 Reorganisation of share capital**

In the event that a reorganisation of share capital occurs prior to all Options capable of vesting in favour of an Option holder have vested, the Company will procure that the terms of the Former Plan are varied in such a way as to neither disadvantage or advantage that Option holder nor adversely affect the rights of the other holders of shares, to account for the effect of the reorganisation.

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## 6. Key Individuals and Corporate Governance Continued

### 6.8.3.7 Disposal restrictions

Unless otherwise consented to by the Board, an Option may not be disposed of until after:

- (a) where a listing occurs, the earlier of the date that is 180 days following the listing, and the expiration of any underwriter imposed lock-up in connection with the listing; and
- (b) in the case of any other exit event, the occurrence of that exit event.

Unless an Option holder disposes of an Option or an Option share under an arrangement which satisfies the requirements in section 83A-130 of the *Income Tax Assessment Act 1997* (Cth) (**Tax Act**), a legal or beneficial interest in an Option or an Option share must not be disposed of until the earlier of:

- (a) 3 years after the issue of the Option or such earlier time as the Commissioner of Taxation allows in accordance with section 83A-45(5) of the Tax Act; and
- (b) where the Option holder becomes ceases to be an employee, consultant or director of the Company or a Group member.

In addition to the restrictions specified in the plan, an offer may specify restrictions on disposal of any Option.

### 6.8.3.8 Rights of Option holders

An Option does not confer on an Eligible Person or an Option holder:

- (a) any voting rights in respect of Shares or any other equity security of the Company;
- (b) the right to participate in any new issues of Shares or other equity securities of the Company;
- (c) the right to attend or vote at any general meeting or other meeting of holder of any Shares or other equity securities of the Company;
- (d) the right to receive any dividends or other distributions or receive or participate in any returns of capital from the Company; or
- (e) the right to participate in a liquidation or winding up of the Company.

### 6.8.3.9 Compliance with ASX Listing Rules

The Board has resolved that the terms of the Options issued under the Former Plan allow for the rights of an Option holder to be changed to the extent necessary in order to comply with the ASX Listing Rules applying to a reorganisation of capital at the time of the reorganisation.

## 6.9 Current Incentive Plan

### 6.9.1 Background

On 7 October 2021, the Board resolved to terminate the Former Plan with effect from the date of the resolution, and has now adopted a long term incentive plan (**Current Incentive Plan**).

The Company has adopted the Current Incentive Plan in order to provide long term incentives to persons who have been selected by the Board to participate (referred to in this Section 6.9 as **Eligible Participants**). The Current Incentive Plan is designed to assist in the reward, retention and motivation of Eligible Participants, link the reward of Eligible Participants to shareholder value creation and align the interests of Eligible Participants with Shareholders by providing an opportunity to receive equity in the Company. Under the Current Incentive Plan, Eligible Participants may be invited by the Board to participate in a grant of Options. The extent to which Directors have received Options under the Current Incentive Plan is set out below. It is not currently expected that Non-Executive Directors will participate any further in the Current Incentive Plan.

Options that have been agreed to be issued under the Current Incentive Plan are set out in the table below.

Option holder	Number of Options held	Exercise price	Number of Options unvested as at Listing Date	Last exercise date
Mr Tony Charara <sup>1</sup>	1,600,000	\$1.15	1,600,000	15-Nov-36
Mr Max Johnston	366,060	\$1.15	366,060	15-Nov-36
A/Prof. Craig Stamp	366,060	\$1.15	366,060	15-Nov-36
Mr Jack Lowenstein	366,060	\$1.15	366,060	15-Nov-36
Mr Bryan Gray	366,060	\$1.15	366,060	15-Nov-36
Dr Darryl Reed	1,027,880	\$1.15	1,027,880	15-Nov-36
Dr Pramod Nednoor	700,000	\$1.15	700,000	15-Nov-36
Mr William Boost	600,000	\$1.15	600,000	15-Nov-36
Mr Mark Waring	300,000	\$1.15	300,000	15-Nov-36
Mr Alistair McKeough	43,460	\$1.15	43,460	15-Nov-36
Service providers and consultants	100,000	\$1.15	100,000	15-Nov-36

Note:

1. Tony Charara (Co-Founder, Executive Director) has a relevant interest in Options through Spark Capital Pty Limited, an entity that he controls.

For details relating to the vesting period of the Options, please refer to the table at Section 6.7.

## 6.9.2 Key terms

The key terms of the Company's Current Incentive Plan (which replaces the Former Plan) are summarised below.

### 6.9.2.1 Invitation

Under the Current Incentive Plan, the Company may, at the Board's discretion invite an Eligible Participant to participate in a grant of Options by issue of an invitation letter. Acceptance of an invitation must be made by the Eligible Participant on an application form in accordance with instructions provided by the Company. An Eligible Participant may nominate an affiliate to receive the Options the subject of an invitation.

### 6.9.2.2 No dealing in Options

Dealing in respect of an Option, including by sale, transfer or other alienation or any hedging or transaction intended to limit the economic risk associated with holding an Option, is prohibited, except:

- (a) in the event of the participant's death, to their legal personal representative; and
- (b) in the event of a transaction that meets the requirements in section 83A-130 of the *Income Tax Assessment Act 1997* (Cth).

If a participant deals with an Option other than in the circumstances above, the Option is forfeited immediately.

### 6.9.2.3 Listing

Unless otherwise determined by the Board in its absolute discretion, an Option granted under the Current Incentive Plan will not be quoted on ASX.

### 6.9.2.4 Vesting

An Option that is subject to vesting conditions as set out in any invitation, will only vest where each vesting condition and all other relevant conditions advised to the participant, have been satisfied or waived, and a vesting notice is given to the participant. A vesting condition for an Option may, subject to applicable laws, be waived by the Board by written notice.

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## 6. Key Individuals and Corporate Governance Continued

### 6.9.2.5 Exercise of vested Options

Following receipt of a vesting notice, a participant is entitled to exercise an Option that has vested by delivering a signed exercise notice to the Company, accompanied by payment of the aggregate exercise price for all Options being exercised.

Following the occurrence of a liquidity event (including an initial public offer, a sale of all of the Company's shares or a sale of all or a substantial proportion of the Company's assets), where a participant ceases to be employed or engaged by a member of the Group, all vested Options held by the participant may be exercised within 90 days (or such other period as determined by the Board at its absolute discretion).

At the discretion of the Board, at the time of a liquidity event, the Board may give notice to a participant, requiring them to exercise all of their vested Options or they will lapse.

### 6.9.2.6 Rights attaching to shares

The following rights attach to shares issued or transferred pursuant to the Current Incentive Plan (**Plan Shares**):

- (a) all Plan Shares rank equally in all respects with the shares on issue of the same class, except for any rights attaching to shares by reference to a record date prior to the date of issue or transfer of the Plan Shares;
- (b) if Plan Shares are in the same class as shares which are listed on ASX or any other recognised securities exchange, the Company will apply for quotation of the Plan Shares;
- (c) a participant will be entitled to any dividends declared and distributed by the Company on the Plan Shares which are held by the participant at the closing date for determining entitlement to such dividends;
- (d) a participant may participate in any dividend reinvestment plan operated by the Company in respect of their Plan Shares;
- (e) a participant may exercise any voting rights attaching to Plan Shares held by the participant;
- (f) other than as permitted by the Current Incentive Plan, dealing in Plan Shares by a participant is prohibited and unless otherwise permitted, the dealing will not be recognised by the Company.

A participant may not deal with Plan Shares without the written consent of the Board until the earlier of:

- (a) a transaction occurring that meets the requirements in section 83A-130 of the Tax Act;
- (b) three years from the grant date of the Options;
- (c) such earlier time as the Commissioner of Taxation allows in accordance with section 83A-45(5) of the Tax Act; and
- (d) when the participant ceases to be employed or engaged by a Group member.

### 6.9.2.7 Forfeiture of Options or Plan Shares

If a participant ceases to be employed or engaged by the Group, all unvested Options held by the participant will be forfeited for no consideration, unless the Board determines otherwise.

If a participant ceases to be employed or engaged by a member of the Group prior to a liquidity event, all vested Options held by the participant may (at the discretion of the Board) be bought back or cancelled by the Company in exchange for their fair market value and all Plan Shares (if any) held by the participant may (at the discretion of the Board) be compulsorily transferred to a nominee nominated by the Board in exchange for their fair market value.

In order to prevent inappropriate benefits, in certain circumstances, such as where a participant has acted fraudulently, dishonestly or negligently or has breached their duties to the Company, or where the Company becomes aware of a material misstatement or omission in its financial statements (amongst other circumstances), the Board may determine that any vested or unvested Options held by a participant are forfeited for no consideration will be compulsorily transferred to a nominee nominated by the Board for no consideration.

An Option will automatically lapse upon the earliest to occur of a forfeiture, and a failure to meet a vesting condition or other condition within the prescribed period.

The Board however may decide that some or all of the participant's Options will not be forfeited at that time, but will be forfeited or transferred (as the case may be) at the time and subject to the conditions it may specify by written notice to the participant.

A participant may by written notice to the Company voluntarily forfeit their Options or transfer their Plan Shares to a nominee nominated by the Board for no consideration.



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#### 6.9.2.8 Change of control

If a change of control event occurs, or the Board determines that such an event is likely to occur, all Options will vest in a manner that allows the participant to participate in and/or benefit from any transaction arising from, or in connection with the change of control event, and the Board may determine the manner in which any or all of the participant's Options will be dealt with, including determining that they become immediately exercisable immediately prior to the change of control event and/or reducing or waiving any of the vesting conditions attaching to the unvested Options.

#### 6.9.2.9 Adjustment of Options

In the event of a reorganisation of the issued share capital of the Company, the rights of each participant holding Options will be changed as necessary to comply with the ASX Listing Rules.

If Shares are issued by the Company pro rata to Shareholders generally by way of bonus issue, the holder of Options is entitled, upon exercise of the Options, to receive, in addition to the Plan Shares in respect of which the Options are exercised and without payment, an allotment of as many additional Plan Shares as would have been issued to a Shareholder who, on the date for determining entitlements under the bonus issue, held Shares equal in number to the Plan Shares in respect of which the Options are exercised.

A holder of Options (prior to the exercise of such Options), does not generally have the right to participate in any new issue of Shares in the Company as a result of holding Options.

#### 6.9.2.10 Non-exclusivity

The Current Incentive Plan is not necessarily the sole means by which all members of the Group intend to provide incentives to Eligible Participants, but no member of the Group is under any obligation to provide any other such incentives to Eligible Participants. Participation in the Current Incentive Plan does not affect, and is not affected by, participation in any other incentive or other scheme operated by any member of the Group (unless the terms of that scheme provide otherwise).

### 6.10 2022 equity incentive plan

#### 6.10.1 Background

On 7 October 2021, the Board resolved adopt a new equity incentive plan to take effect on 1 July 2022 (**2022 Plan**).

Adoption of the 2022 Plan is in order to assist in the attraction, motivation and retention of current and prospective Company employees, Directors and advisors, consultants and contractors. The 2022 Plan is designed to align the interests of eligible participants more closely with the interests of the Company by providing an opportunity for eligible participants to receive an equity interest in the Company. Under the 2022 Plan, eligible participants may be offered rights, Options, performance share awards or share awards, which may be subject to vesting and exercise conditions set by the Board.

The 2022 Plan applies to eligible participants who are any permanent full time or part time employee of the Company, a Director, or an employee, consultant, advisor or contractor who works a pro-rata equivalent of at least 40% of a comparable full time position (referred to in this Section 6.10 as **Eligible Participants**).

As the 2022 Plan does not come into effect until 1 July 2022, no awards have been made under the plan as at the Prospectus Date. It is not currently expected that Non-Executive Directors will participate in the 2022 Plan.

#### 6.10.2 Key terms

The key terms of the 2022 Plan are summarised below.

##### 6.10.2.1 Employee Awards

Under the 2022 Plan, the Company may, at the Board's discretion, offer or issue to Eligible Participants, the following awards:

- Options: a right to acquire a share upon satisfaction of any applicable performance hurdles, service conditions and exercise conditions (including payment of the exercise price, if any) in accordance with the terms set out in the 2022 Plan and the invitation to participate;
- Performance Share Award: a Share granted under the 2022 Plan, which is subject to performance hurdles and/or service conditions and/or exercise conditions in accordance with the terms set out in the 2022 Plan and the invitation;

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## 6. Key Individuals and Corporate Governance Continued

- Share Award: being –
  - an exempt share award: a Share issued for no consideration or at a purchase price which is a discount to the then market price of the Share with the intention that up to \$1,000 (or such other amount which is exempted from tax under the *Income Tax Assessment Act 1997* (Cth) and any other applicable law) of the total value or discount received by each participant and which is taxed upfront will be exempt from tax;
  - a salary sacrifice share award; or
  - a Directors' fee sacrifice share award;
- Right: a right to acquire a Share upon satisfaction of any applicable performance hurdles, service conditions and exercise conditions (other than the payment of an exercise price) in accordance with the terms set out in the 2022 Plan and the invitation.

### 6.10.2.2 Price

The exercise price for a Right is nil, unless otherwise determined by the Board. For an Option, the exercise price is the amount payable (if any) as specified in the invitation.

### 6.10.2.3 Vesting and exercise of Awards

Awards will vest in an Eligible Participant upon the satisfaction of any performance hurdles and/or service conditions specified and become exercisable upon the satisfaction of any exercise conditions specified and before the last exercise date. performance hurdles, service conditions and exercise conditions may be waived at the discretion of the Board.

### 6.10.2.4 Ranking

Each Eligible Participant's Share issued will rank equally in all respects with all Existing Shares from the date of issue.

### 6.10.2.5 Change of control

Where:

- a takeover bid is made for the Company and the Board recommends acceptance of that bid by the Company's shareholders;
- a Court orders that a meeting of shareholders of the Company be held to consider a scheme of arrangement between the Company and its shareholders; or
- the Board determines that some other transaction has occurred, or is likely to occur, which involves a change of control of the Company,

the Board may determine that any Right, Option or Performance Share Award that has not vested will vest on, and may be exercised on and from, the date determined by the Board.

### 6.10.2.6 Holding lock

Any security granted to a participant may be subject to a holding lock up to a maximum of 15 years from the grant date, at the Board's absolute discretion. A holding lock prevents the participant from dealing with or transferring their Shares or creating a security interest over their Shares. The holding lock may be removed at the Board's discretion in certain circumstances.

### 6.10.2.7 Lapsing and forfeiture

Eligible Participants are subject to lapsing and forfeiture events, unless the Board determines otherwise in its absolute discretion. These events include Rights, Performance Share Awards and/or Options held by an Eligible Participant which have not vested by the last vesting date and in the case of breach, fraud or dishonesty.

### 6.10.2.8 Clawback

The Board may take action to adjust or recover/clawback unvested 'at risk' remuneration where there is reasonable evidence that an Eligible Participant has materially contributed to, or been materially responsible for, the need for the restatement of financial results.

### 6.10.2.9 Variation of Share capital

In the event of a reorganisation of the Company's share capital, the Board will review and modify the terms of the awards if required by, and in accordance with, the ASX Listing Rules.

## 6.11 Director disclosures

### 6.11.1 No legal or disciplinary action

No Director (or company that the Director was a director of at the relevant time) has, in the 10 year period ending on the date of this Prospectus, had any legal or disciplinary action against the Director that is relevant to the Director's role in the Company and a potential investor's decision to apply for Shares.

### 6.11.2 Insolvent companies

No Director has been an officer of a company that entered into a form of external administration because of insolvency while the Director was an officer of the company or within 12 months of the Director ceasing to be an officer of the company.

## 6.12 Corporate Governance

The Directors are responsible for the strategic direction of the Company, the identification and implementation of corporate policies and goals, and monitoring of the business and affairs of the Company on behalf of its members.

The Company has adopted charters in respect of its Board and committees as well as key policies in relation corporate governance, copies of which are available at [www.tissuerepair.com.au](http://www.tissuerepair.com.au).

## 6.13 Compliance with ASX corporate governance principles and recommendations

The Company is seeking to list on the ASX. The ASX Corporate Governance Council has developed and released its Corporate Governance Principles and Recommendations (4th Edition) (**ASX Recommendations**) for entities listed on the ASX in order to promote investor confidence and to assist companies to meet shareholders' expectations.

The ASX Recommendations are not mandatory, but guidelines. However, under the ASX Listing Rules, the Company will be required to provide a statement in its annual report or on its website and also in an Appendix 4G that it must lodge with ASX at the time it lodges its annual report, disclosing the extent to which it has followed the ASX Recommendations. The Company must identify the recommendations that have not been followed and give reasons for not following them.

The Directors have assessed the Company's current practice against the ASX Recommendations and outlines its assessment below:

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Principle 1 – Lay solid foundations for management and oversight</b>		
1.1 A listed entity should have and disclose a board charter setting out:	The Board is responsible for the overall corporate governance and decision-making of the Company.	Complies
(a) the respective roles and responsibilities of its board and management; and	The Board has adopted a Board charter that formalises its roles and responsibilities and defines the matters that are reserved for Board approval and specific matters that are delegated to management.	
(b) those matters expressly reserved to the board and those delegated to management.	The members of the Board and their qualifications and experience are disclosed on the Company's website. The Board Charter is also available on the website.	

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<p>1.2 A listed entity should:</p> <p>(a) undertake appropriate checks before appointing a director or senior executive or putting someone forward for election as a director; and</p> <p>(b) provide security holders with all material information in its possession relevant to a decision on whether or not to elect or re-elect a director.</p>	<p>The Remuneration and Nominations Committee, being a sub-committee of the Board, will monitor that character and background checks of proposed Directors are undertaken prior to putting a person forward for election as a Director. The Remuneration and Nominations Committee will identify and assess the skills, knowledge, experience, diversity, independence and time commitment of proposed directors, before recommending suitable candidates to the Board.</p> <p>The Company will conduct police checks, solvency and banned director searches in relation to all prospective Directors or senior executives. The Company will also make appropriate inquiries into the experience and education of prospective directors and senior executives.</p> <p>The Remuneration and Nominations Committee will provide security holders with all material information in the Company's possession relevant to the decision on whether to elect or re-elect a Director. This includes biographical details, other directorships held, Board statement of support and reasons why, and for new Directors, confirmation and detail of appropriate background checks, conflicts of interest and level of independence, and for re-elected Directors, current term of office and level of independence.</p>	Complies
<p>1.3 A listed entity should have a written agreement with each director and senior executive setting out the terms of their appointment.</p>	<p>The Company has written agreements with each Director and senior executive setting out the terms of their appointment.</p> <p>The Board is responsible for ensuring that the Company enters into written employment or consultancy agreements with Directors and senior executives.</p> <p>Each executive Director enters into a service contract with the Company setting out their duties, responsibilities, rights and termination conditions. Each Non-Executive Director will be engaged by a letter of appointment setting out the terms and conditions of their appointment. Any consulting or other services rendered to the Company by Non-Executive Directors requires Board approval.</p>	Complies
<p>1.4 The company secretary of a listed entity should be accountable directly to the board, through the chair, on all matters to do with the proper functioning of the board.</p>	<p>Under the Board Charter, the company secretary is responsible for all matters to do with the proper functioning of the Board and is accountable directly to the Board through the Chair. The company secretary's responsibilities include all of those included in recommendation 1.4. Specifically, they are required to help organise and facilitate the induction and professional development of Directors as the secretary of the Remuneration and Nominations Committee.</p> <p>The Board approves the appointment of the company secretary. The company secretary is responsible for ensuring each Director has access to the company secretary.</p>	Complies

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
1.5 A listed entity should:	The Company has a Diversity and Inclusion Policy, which is publicly disclosed on its website.	Partially complies
(a) have and disclose a diversity policy;	Due to the size and structure of the Company, the Board and Remuneration and Nominations Committee have not yet determined a fixed percentage target of women at any given level within the Company, so no measurable objectives have been set at this time. The Company expects to be able to set more specific, numerical targets once its human resources grow to a number that allows these targets to be set. The Board and Remuneration and Nominations Committee are jointly responsible under the Diversity and Inclusion Policy to assess, on an annual basis and more frequently if required, the need to set measurable objectives for achieving diversity in the composition of the Board, senior executives and the workforce generally.	
(b) through its board or a committee of the board set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally; and		
(c) disclose in relation to each reporting period:		
(1) the measurable objectives set for that period to achieve gender diversity;		
(2) the entity's progress towards achieving those objectives; and	The Company is not required to comply with the 'Gender Equality Indicators' as it does not qualify as a 'relevant employer' under the Workplace Gender Equality Act, since it is not likely to have 100 or more employees in Australia. As and when it does qualify as a 'relevant employer', it will have regard to those requirements under that Act.	
(3) either:		
(A) the respective proportions of men and women on the board, in senior executive positions and across the whole workforce (including how the entity has defined "senior executive" for these purposes); or	In accordance with recommendation 1.5, the Company's Diversity and Inclusion Policy seeks to consider gender as well as other facets of diversity.	
(B) if the entity is a "relevant employer" under the Workplace Gender Equality Act, the entity's most recent "Gender Equality Indicators", as defined in and published under that Act.		

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
1.6 A listed entity should: <ul style="list-style-type: none"> <li>(a) have and disclose a process for periodically evaluating the performance of the board, its committees and individual directors; and</li> <li>(b) disclose for each reporting period whether a performance evaluation has been undertaken in accordance with that process during or in respect of that period.</li> </ul>	<p>Under the Board Charter, the Board, with assistance from the Remuneration and Nominations Committee, is responsible for annually evaluating the performance of the Board, its committees and individual Directors.</p> <p>The Chair has responsibility to assess each Director standing for re-election following mandatory retirement in accordance with the Company's constitution and the ASX Listing Rules. The Board (aside from the Director involved) will then determine whether to recommend the re-election of that Director to the Shareholders.</p> <p>Under the Board Charter, the Board is required to disclose in the Company's annual report whether a performance evaluation has been taken in respect of any particular Director during the relevant period.</p>	Complies
<b>Principle 2 – Structure the board to be effective and add value</b>		
2.1 The board of a listed entity should: <ul style="list-style-type: none"> <li>(a) have a nomination committee which:               <ul style="list-style-type: none"> <li>(1) has at least three members, a majority of whom are independent directors; and</li> <li>(2) is chaired by an independent director, and disclose:</li> <li>(3) the charter of the committee;</li> <li>(4) the members of the committee; and</li> <li>(5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or</li> <li>(6) if it does not have a nomination committee, disclose that fact and the processes it employs to address board succession issues and to ensure that the board has the appropriate balance of skills, knowledge, experience, independence and diversity to enable it to discharge its duties and responsibilities effectively.</li> </ul> </li> </ul>	<p>The Board has a combined Remuneration and Nominations Committee established with its own charter. The members are:</p> <ul style="list-style-type: none"> <li>• Max Johnston (Chair)</li> <li>• Craig Stamp</li> <li>• Jack Lowenstein</li> <li>• Bryan Gray</li> </ul> <p>Under the Remuneration and Nominations Committee Charter, the Committee must have at least three members, a majority of whom are independent Directors and the chair must be an independent Non-Executive Director. Currently, the members of the Committee are all of the Non-Executive Directors, all of whom are independent.</p> <p>The members of the Remuneration and Nominations Committee and their qualifications and experience are disclosed on the Company's website. The charter of the committee is also available on that website.</p> <p>The number of times the committee meets during a given reporting period and individual attendances of the members at those meetings will be included in the annual reports provided to investors.</p> <p>The Remuneration and Nominations Committee is also responsible for developing succession plans for the Board to ensure an appropriate mix of skills, knowledge, experience, independence and diversity within the Board, and for overseeing the ongoing process of succession planning for the role of the Chair and CEO (if one is appointed).</p>	Complies

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
2.2 A listed entity should have and disclose a board skills matrix setting out the mix of skills that the board currently has or is looking to achieve in its membership.	The Remuneration and Nominations Committee is required to maintain and disclose a board skills matrix updated on a regular basis, setting out the appropriate mix of skills, knowledge, experience, diversity and independence that the Board and its committees are seeking to achieve, and the time commitment required from Non-Executive Directors.	Complies
2.3 A listed entity should disclose: (a) the names of the directors considered by the board to be independent directors; (b) if a director has an interest, position or relationship of the type described in Box 2.3 but the board is of the opinion that it does not compromise the independence of the director, the nature of the interest, position or relationship in question and an explanation of why the board is of that opinion; and (c) the length of service of each director.	<p>The Board considers Tony Charara (appointed 17 May 2012), an Executive Director, to not be independent as he is a founding and substantial shareholder of the Company.</p> <p>The Board considers Jack Lowenstein (Chair) (appointed 13 August 2021), Max Johnston (appointed on 7 October 2021), Craig Stamp (appointed on 7 October 2021), and Bryan Gray (appointed on 7 October 2021), all Non-Executive Directors, to be independent.</p> <p>Under the Board Charter, the Board will continue to monitor whether a Director should be considered independent in accordance with the ASX Recommendations, as well as whether any services arrangement has evolved such that a Director should be considered an Executive Director.</p>	Complies
2.4 A majority of the board of a listed entity should be independent directors.	<p>On Listing, four of the five Directors are independent, making the Board majority independent.</p> <p>The Board considers its present composition to be appropriate. The size of the Board reflects the size of the Company's operations, and takes into account the degree of contribution of the non-independent director to date. The Board will monitor this composition and, if deemed appropriate, recruit further directors.</p>	Complies
2.5 The chair of the board of a listed entity should be an independent director and, in particular, should not be the same person as the CEO of the entity.	<p>The Chair of the Board is Jack Lowenstein, who is an independent Director.</p> <p>Mr Charara is the Company's Executive Director. On Listing, the Company will not have appointed a CEO given the relative size and current complexity of operations. It has appointed within its senior executive team Dr Darryl Reed as Chief Operating Officer who in this capacity will support the leadership of the founder and Executive Director Mr Charara.</p>	Complies



## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
2.6 A listed entity should have a program for inducting new directors and for periodically reviewing whether there is a need for existing directors to undertake professional development to maintain the skills and knowledge needed to perform their role as directors effectively.	<p>Under the Board Charter, new Directors are expected to participate in induction or orientation programs. Directors are expected to participate in any continuing education or training arranged at the Company's expense.</p> <p>The Remuneration and Nominations Committee is responsible for assisting the Board in relation to director induction and continuing professional development.</p> <p>The induction program must sufficiently allow new Directors to gain an understanding of the Company, its operations and values, financial, strategic and risk management, and the rights, duties and responsibilities of the Board, its committees and senior executive management team. The Remuneration and Nominations Committee must ensure the Directors have access to professional development at the Company's expense to the extent that the Committee considers it necessary and appropriate, assessing against the board skills matrix that it is required to maintain.</p>	Complies
<b>Principle 3 – Instil a culture of acting lawfully, ethically and responsibly</b>		
3.1 A listed entity should articulate and disclose its values.	<p>The Company is committed to acting lawfully, ethically and responsibly, which is reflected in its Code of Conduct. The Code of Conduct is designed to be followed by all officers, employees, consultants and contractors – in short, anyone who can be seen to be a representative of the Company.</p> <p>The Code of Conduct includes a statement of the Company's values, which include a number of the suggestions for the content of a code of conduct in Box 3.2 of the ASX Recommendations.</p>	Complies
3.2 A listed entity should:	<p>The Company has adopted the Code of Conduct which applies to all Directors, senior executives and employees. The Code sets out the Company's values as a framework for the Company's representatives to follow in the performance of their duties and responsibilities. The Code ensures a set of behavioural standards is made known and followed by representatives, in pursuit of best practice corporate governance.</p> <p>Any breaches of the Code are to be reported to the Chair, and any material breaches of the Code will be directly reported to the Board to ensure proper accountability and action.</p> <p>The Code of Conduct is disclosed to the public on the Company's website.</p>	Complies
(a) have and disclose a code of conduct for its directors, senior executives and employees; and		
(b) ensure that the board or a committee of the board is informed of any material breaches of that code.		

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<p>3.3 A listed entity should:</p> <ul style="list-style-type: none"> <li>(a) have and disclose a whistleblower policy; and</li> <li>(b) ensure that the board or a committee of the board is informed of any material incidents reported under that policy.</li> </ul>	<p>The Company has adopted a Whistleblower Policy which encourages the reporting of any suspected unethical, illegal, fraudulent or undesirable conduct involving the Company's businesses, and specifies the processes and protections available to those reporting. The Whistleblower Policy has been prepared on the basis of ASIC Regulatory Guide 270 and section 1317AI of the Corporations Act and is consistent with Box 3.3 'Suggestions for the content of a whistleblower policy' of the ASX Recommendations.</p> <p>The Eligible Recipients of whistleblower incident reports (as identified under the <i>Corporations Act 2001</i> (Cth) and <i>Taxation Administration Act 1953</i> (Cth)) must report at least annually to the Board on the number and type of reports (with anonymity preserved). The Board will receive copies of all whistleblower reports (anonymised) and Eligible Recipients must consider immediately referring serious or material Disclosable Matters to the Chair.</p> <p>The Whistleblower Policy is disclosed to the public on the Company's website.</p>	Complies
<p>3.4 A listed entity should:</p> <ul style="list-style-type: none"> <li>(a) have and disclose an anti-bribery and corruption policy; and</li> <li>(b) ensure that the board or a committee of the board is informed of any material breaches of that policy.</li> </ul>	<p>The Company has adopted an Anti-Bribery and Corruption Policy. The Anti-Bribery and Corruption Policy complies with Box 3.4 'Suggestions for the content of an anti-bribery and corruption policy' of the ASX Recommendations.</p> <p>All material breaches of the Anti-Bribery and Corruption Policy are to be reported to the Board. The CEO (and if one is not appointed, the Executive Director) has primary and day-to-day responsibility for implementing the policy. The Board will monitor the effectiveness and review the implementation of the policy by periodically considering its suitability, adequacy and effectiveness.</p> <p>The Anti-Bribery and Corruption Policy is disclosed to the public on the Company's website.</p>	Complies

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Principle 4 – Safeguard the integrity of corporate reports</b>		
4.1 The board of a listed entity should:	The Company has established a combined Audit and Risk Management Committee operating in accordance with its own charter. The members are:	Complies
(a) have an audit committee which:		
(1) has at least three members, all of whom are non-executive directors and a majority of whom are independent directors; and	<ul style="list-style-type: none"> <li>• Bryan Gray (Chair)</li> <li>• Max Johnston</li> <li>• Craig Stamp</li> <li>• Jack Lowenstein</li> </ul>	
(2) is chaired by an independent director, who is not the chair of the board, and disclose:	Under its Charter, the Audit and Risk Management Committee must comprise at least three members, all of whom must be Non-Executive Directors and a majority of whom must be independent. Currently, the members of the Committee are all of the Non-Executive Directors, all of whom are independent.	
(3) the charter of the committee;		
(4) the relevant qualifications and experience of the members of the committee; and	The Chair of the committee is a Non-Executive Director who is independent and is not the Chair of the Board. If the independent Non-Executive Directors are not eligible or available to serve as chair, a Non-Executive Director who is not independent will be appointed as the Chair. This will be unlikely at present given that all Non-Executive Directors are independent, but is included in case any Non-Executive Directors are considered non-independent at a later point in time, due to the size of the Board and the practicality of having an appropriate appointee as chair.	
(5) in relation to each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or		
(6) if it does not have an audit committee, disclose that fact and the processes it employs that independently verify and safeguard the integrity of its corporate reporting, including the processes for the appointment and removal of the external auditor and the rotation of the audit engagement partner.	<p>The members of the Audit and Risk Management Committee and their qualifications and experience are disclosed on the Company's website. The charter of the committee is also available on the website.</p> <p>The number of times the committee met during a given reporting period and individual attendances of the members at those meetings will be included in the annual reports provided to investors.</p>	

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
4.2 The board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.	Under the Audit and Risk Management Committee Charter, the Audit and Risk Management Committee will, prior to providing approval of financial statements for a financial period, receive from the CEO (if one is appointed) and CFO a declaration in accordance with this recommendation 4.2.	Complies
4.3 A listed entity should disclose its process to verify the integrity of any periodic corporate report it releases to the market that is not audited or reviewed by an external auditor.	The Audit and Risk Management Committee Charter sets out the process to verify the integrity of periodic corporate reports released to market that are not audited or review by an external auditor, namely, that the Audit and Risk Management Committee must first review the draft report in accordance with the standards in its charter and once it is comfortable with it, present it to the Board for consideration and approval prior to release to market.	Complies
<b>Principle 5 – Make timely and balanced disclosure</b>		
5.1 A listed entity should have and disclose a written policy for complying with its continuous disclosure obligations under ASX Listing Rule 3.1.	<p>The Company has adopted a Continuous Disclosure Policy to ensure prompt and complete disclosure of price sensitive information in compliance with ASX Listing Rule 3.1.</p> <p>The Continuous Disclosure Policy complies with Box 5.1 'Suggestions for the content of a continuous disclosure policy' of the ASX Recommendations.</p> <p>The Continuous Disclosure Policy is disclosed to the public on the Company's website.</p>	Complies
5.2 A listed entity should ensure that its board receives copies of all material market announcements promptly after they have been made.	Under the Continuous Disclosure Policy, each member of the Board must receive a copy of all material market announcements promptly after their release.	Complies
5.3 A listed entity that gives a new and substantive investor or analyst presentation should release a copy of the presentation materials on the ASX Market Announcements Platform ahead of the presentation.	All new investor and analyst presentations must be approved by the Disclosure Committee (which is established under the Continuous Disclosure Policy). A copy of the presentation materials, once approved by the Disclosure Committee, are released on the ASX Market Announcements Platform ahead of the presentation.	Complies

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Principle 6 – Respect the rights of security holders</b>		
6.1 A listed entity should provide information about itself and its governance to investors via its website.	Under the Shareholder Communications Policy, the Company will use its website <a href="http://www.tissuerepair.com.au">www.tissuerepair.com.au</a> to communicate with investors. The 'Investor Centre' section of the Company's website contains information relevant to shareholders and stakeholders, including certain key documents lodged with the ASX, Board and committee charters and corporate governance policies and other material relevant to shareholders.	Partially complies
6.2 A listed entity should have an investor relations program that facilitates effective two-way communication with investors.	The Company's Continuous Disclosure Policy and Shareholder Communications Policy provide that the Company will use its website, half year and annual reports, market announcements and media disclosures to communicate with its shareholders, as well as encourage participation at general meetings.  The policies also allow for briefings for analysts and institutional investors to engage existing and potential investors.	Complies
6.3 A listed entity should disclose how it facilitates and encourages participation at meetings of security holders.	Under the Shareholder Communications Policy, shareholders are encouraged to express to the Company's representatives at the AGM any matters of concern or interest to the shareholder group. Shareholders who are unable to attend the AGM are given the opportunity to provide questions or comments beforehand and where appropriate, these questions or comments are addressed at the AGM.  The Company may also facilitate participation in the AGM via technology to ensure participation and voting in the meeting.	Complies
6.4 A listed entity should ensure that all substantive resolutions at a meeting of security holders are decided by a poll rather than by a show of hands.	The Shareholder Communications Policy provides that all substantive resolutions at a meeting of shareholders are decided by poll rather than by a show of hands, to enable the chair of the meeting to ascertain the true will and voting of the shareholders attending, whether in person, electronically, by proxy or other representative.	Complies
6.5 A listed entity should give security holders the option to receive communications from, and send communications to, the entity and its security registry electronically.	Under the Shareholder Communications Policy, the Company encourages shareholders to receive information and communications from, and send communications to, the Company and its share registry, electronically. The policy sets out the specific process, being that shareholders may elect to send and receive communications electronically by registering their email addresses online with the Company's share registry. Shareholders are directed to the share registry to obtain further information about this process.	Complies

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Principle 7 – Recognise and manage risk</b>		
7.1 The board of a listed entity should:	The Company has a combined Audit and Risk Management Committee. See 4.1 above.	Complies
(a) have a committee or committees to oversee risk, each of which: <ol style="list-style-type: none"> <li>(1) has at least three members, a majority of whom are independent directors; and</li> <li>(2) is chaired by an independent director,</li> </ol> and disclose: <ol style="list-style-type: none"> <li>(3) the charter of the committee;</li> <li>(4) the members of the committee; and</li> <li>(5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or</li> <li>(6) if it does not have a risk committee or committees that satisfy (a) above, disclose that fact and the processes it employs for overseeing the entity's risk management framework.</li> </ol>		
7.2 The board or a committee of the board should:	In accordance with the Audit and Risk Management Committee Charter, the committee must review the Company's risk management framework at least annually and report the results to the Board. The risk management review is with reference to the risk appetite of the Company as set by the Board and includes assessment of the management's performance against the risk management framework, examines new and emerging sources and risk and mitigation processes of existing and new risks.	Complies
(a) review the entity's risk management framework at least annually to satisfy itself that it continues to be sound and that the entity is operating with due regard to the risk appetite set by the board; and		
(b) disclose, in relation to each reporting period, whether such a review has taken place.	The Company is required to disclose in each reporting period whether the above reviews have taken place.	

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<p>7.3 A listed entity should disclose:</p> <p>(a) if it has an internal audit function, how the function is structured and what role it performs; or</p> <p>(b) if it does not have an internal audit function, that fact and the processes it employs for evaluating and continually improving the effectiveness of its governance, risk management and internal control processes.</p>	<p>The Company does not have an internal audit function as at the date of the Prospectus. This is disclosed in the Audit and Risk Management Committee Charter. Therefore, section 4.4 of the charter applies to specify the processes employed for the committee to review and report to the Board on the overall adequacy and effectiveness of internal control systems, controls and processes, legal and ethical compliance and insurance coverage. As a part of this process, the committee will review and report to the Board on any material threatened or actual claims or issues in relation to tax or legal matters, recommendations to changes to be made to the risk management framework or risk appetite, and any material incidents involving non-compliance with internal controls or breakdown of risk controls and 'lessons learned'. Minutes of each committee meeting will be circulated to all members of the Board to ensure proper communication of matters.</p> <p>For completeness, section 4.3 of the Audit and Risk Management Committee Charter sets out the responsibilities of the committee with respect to an internal auditor should they be engaged at any time.</p>	Complies
<p>7.4 A listed entity should disclose whether it has any material exposure to environmental or social risks and, if it does, how it manages or intends to manage those risks.</p>	<p>The Board does not believe that the Company has material exposure to any such risks. Under the Audit and Risk Management Committee Charter, the committee will consider, at least annually, whether the Company has any material exposure to environmental or social risks and provide a report to the Board on how it intends to manage those risks.</p>	Complies



Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Principle 8 – Remunerate fairly and responsibly</b>		
8.1 The board of a listed entity should:	The Company has a combined Remuneration and Nominations Committee. See 2.1 above.	Complies
<ul style="list-style-type: none"> <li>(a) have a remuneration committee which: <ul style="list-style-type: none"> <li>(1) has at least three members, a majority of whom are independent directors; and</li> <li>(2) is chaired by an independent director,</li> </ul> </li> <li>and disclose: <ul style="list-style-type: none"> <li>(3) the charter of the committee;</li> <li>(4) the members of the committee; and</li> <li>(5) as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or</li> <li>(6) if it does not have a remuneration committee, disclose that fact and the processes it employs for setting the level and composition of remuneration for directors and senior executives and ensuring that such remuneration is appropriate and not excessive.</li> </ul> </li> </ul>		
8.2 A listed entity should separately disclose its policies and practices regarding the remuneration of non-executive directors and the remuneration of executive directors and other senior executives.	The Company discloses its policies and practices of Non-Executive Directors, and remuneration of Executive Directors and other senior executives in the Prospectus and will continue to do so on an ongoing basis in remuneration reports forming part of the annual reports provided to investors.	Complies
8.3 A listed entity which has an equity-based remuneration scheme should: <ul style="list-style-type: none"> <li>(a) have a policy on whether participants are permitted to enter into transactions (whether through the use of derivatives or otherwise) which limit the economic risk of participating in the scheme; and</li> <li>(b) disclose that policy or a summary of it.</li> </ul>	In accordance with the Securities Trading Policy, the Company has the policy that participants in an equity-based remuneration scheme are only permitted to enter into transactions (whether through the use of derivatives or otherwise) which limit the economic risk of their participation in that scheme after they have received approval through the general trading clearance process specified in the Securities Trading Policy.	Complies

## 6. Key Individuals and Corporate Governance Continued

Principles and Recommendations	Compliance	Complies/partially complies/does not comply
<b>Additional compliance requirements from the ASX Listing Rules</b>		
ASX Listing Rule 1.1 Condition 13 requires a listed entity to appoint a person responsible for communication with ASX on ASX Listing Rule matters.	Under the Board Charter, the company secretary is responsible for ensuring compliance with the ASX Listing Rules and communication with the ASX on ASX Listing Rule matters and generally.	Complies
ASX Listing Rule 12.9 requires a listed entity to have a trading policy covering its directors and other key management personnel and regulating trading in its securities during certain “prohibited periods”.	The Securities Trading Policy applies to all Directors, employees, contractors and anyone with access to confidential information about the Company, and sets out prohibitions on insider trading as well as the restrictions on trading during certain prohibited periods (which are in relation to the release of quarterly, half year and full year results, or any other periods that the Board may set).	Complies
ASX Listing Rule 4.10.3 requires a listed entity to include in its annual report either a corporate governance statement that meets the requirements of that rule, or the URL of the page on its website where such a statement is located.  “Corporate governance statement” is defined in ASX Listing Rule 19.12 to mean the statement referred to in ASX Listing Rule 4.10.3 which discloses the extent to which an entity has followed the recommendations set by the ASX Corporate Governance Council during a particular reporting period.  ASX Listing Rule 4.7.4 provides that if an entity’s corporate governance statement is not included in its annual report, the entity must also give ASX a copy of its corporate governance statement at the same time as it gives its annual report to ASX.	In the Board Charter, the Company has stated that it will include in its annual report a corporate governance statement that complies with the requirements of the ASX Listing Rules.	Complies



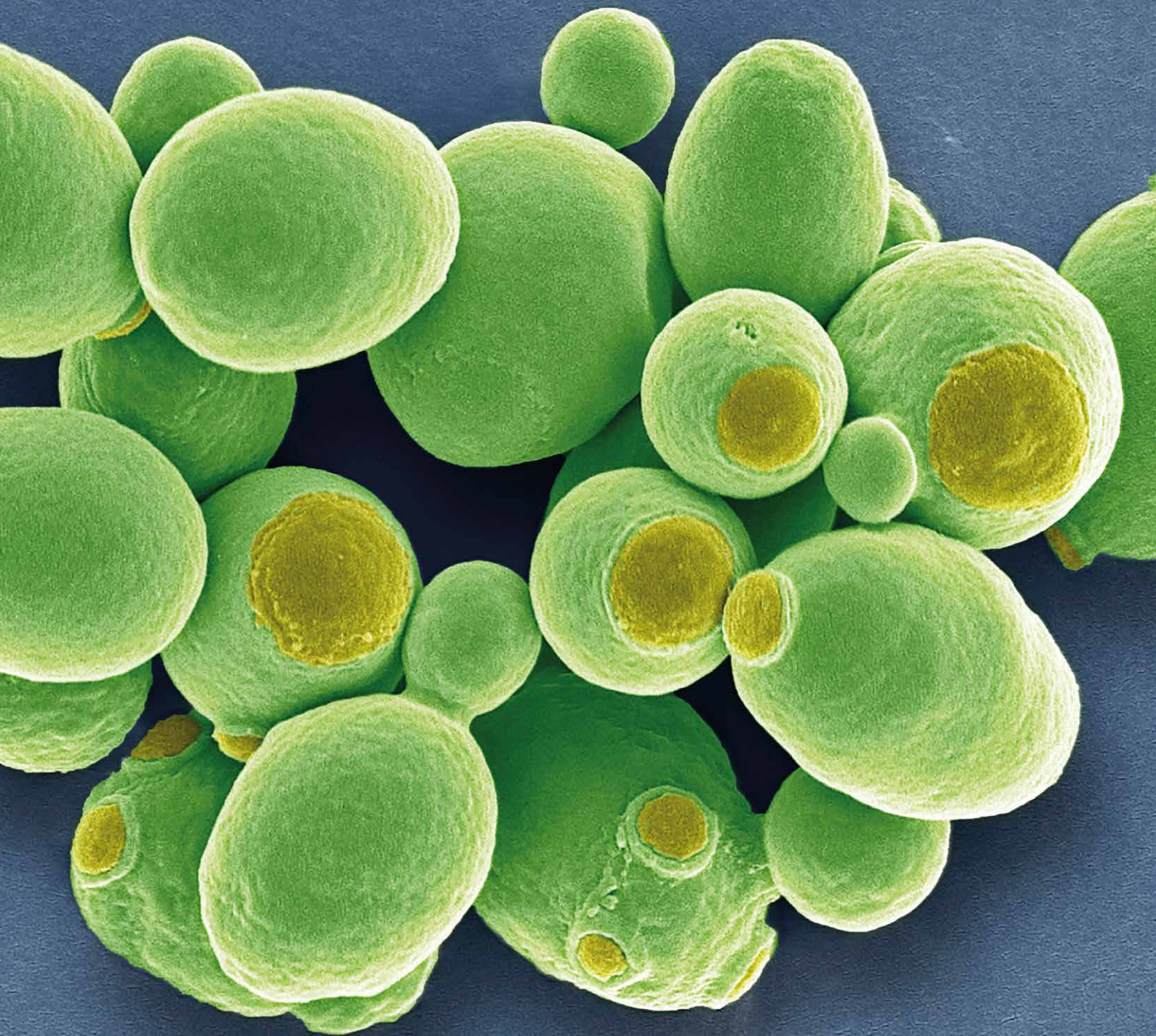


Illustration of yeast cells

## 7. Details of the Offer



## 7. Details of the Offer

### 7.1 The Offer

This Prospectus relates to an initial public offering of 19,130,440 Shares at the Offer Price of \$1.15 per Share. The Shares offered under this Prospectus will represent approximately 31.6% of the Shares on issue at the Listing Date.

The Offer is expected to raise \$22 million. The total number of Shares on issue at the Listing Date will be approximately 60,464,843 and all Shares once issued will rank equally with each other. A summary of the rights attaching to the Shares is set out in Section 11.4.

The Offer is made on the terms, and is subject to the conditions, set out in this Prospectus.

#### 7.1.1 Structure of the Offer

The Offer comprises:

- the Broker Firm Offer, which is open to Australian retail clients of Brokers who have received a firm allocation from their Broker; and
- the Institutional Offer, which consisted of an invitation to bid for Shares made to Institutional Investors in Australia and certain other eligible jurisdictions.

No general public offer of Shares will be made under the Offer. Shares offered under the Offer are offered and issued with disclosure under this Prospectus.

Details of the Broker Firm Offer and the allocation policy under it are described in Section 7.3.

Details of the Institutional Offer and the allocation policy under it are described in Section 7.4. The allocation of Shares between the Broker Firm Offer and the Institutional Offer was determined by the Lead Managers and the Company, having regard to the allocation policies outlined in Sections 7.3.4 and 7.4.2.

#### 7.1.2 Purpose of the Offer and use of funds

Historically, Tissue Repair's operations have been financed by investment from private investors.

The purpose of the Offer is to:

- provide funding to prepare for and undertake the required Phase III clinical program;
- provide funding to undertake marketing and commercialisation efforts on its cosmeceutical product;
- provide funding and financial flexibility to support the Company's growth strategy and future growth opportunities; and
- provide the Company with the benefits of an increased brand profile that may arise from being a publicly listed entity.

The Offer proceeds received by the Company will be applied as set out below.

**Figure 7.1: Sources and uses of funds**

Sources of funds	A\$m	Uses of funds	A\$m
Cash proceeds received by the Company under the Offer from the issue of Shares	22.0	Phase III clinical trials	13.6
		Market testing and initial commercialisation of cosmeceutical product (TR Pro+)	2.1
		Development of chronic wound drug (TR-987)	3.7
		Working capital and Offer costs	2.6
<b>Total sources</b>	<b>22.0</b>	<b>Total uses</b>	<b>22.0</b>



The Company's stated business objectives, which it will use cash reserves, cash flow from existing operations and the net proceeds of the Offer to fund, are described further in Section 3.

The Company does not expect to generate meaningful revenue in the short to medium term.

The Board retains the right to vary these uses of funds, acting in the best interests of the Company and as circumstances require.

### 7.1.3 Shareholding structure of the Company

Prospectus Date						On Listing Date				
Shareholder	Shares		Options		Conv- ertible Notes	Shares		Options		Fully diluted
	Number	%	Number	%		Number	%	Number	%	
Existing Shareholders <sup>3</sup>	1,652,465	100%	821,750	100%		33,049,300	55%	16,435,000	73%	59%
Convertible Note Holders <sup>4,5</sup>					7,500,000	8,152,123	13%		0%	10%
New Investors under the Offer						19,130,440	32%		0%	23%
Shares issued on Listing Date <sup>6</sup>						132,980	0%		0%	0%
Options issued on Listing Date							0%	6,035,580	27%	7%
<b>Total</b>	<b>1,652,465</b>	<b>100%</b>	<b>821,750</b>	<b>100%</b>	<b>7,500,000</b>	<b>60,464,843</b>	<b>100%</b>	<b>22,470,580</b>	<b>100%</b>	<b>100%</b>

Notes:

1. Shares at "Prospectus Date" numbers are expressed before the Share Split described in Section 11.3.
2. Following the changes to the capital structure as described in Section 11.3 including the Share Split of Existing Shares.
3. No Existing Shares will be sold under the Offer.
4. Convertible Notes will not be on issue as at Completion, having been converted into Shares.
5. Convertible Notes will be converted into Shares prior to Completion as described in Section 10.4.
6. Includes 132,980 Shares and 6,035,580 Options to be issued on Listing as described in 11.3.

### 7.1.4 Substantial Shareholders

It is expected that the following Shareholders will have a substantial holding in the Company following Listing:

Shareholder	Shares	Percentage interest of Shares on issue <sup>1</sup>
Selene Holdings Limited <sup>2</sup>	5,955,980	9.9%
Spark Capital Pty Limited <sup>3</sup>	4,822,260	8.0%
Creight Investments Pty Ltd <sup>4</sup>	4,022,260	6.7%

Notes:

1. The percentage interest in shares on issue above is calculated on an undiluted basis.
2. Selene Holdings Limited is an early investor in Tissue Repair.
3. Spark Capital Pty Limited is an entity controlled by Tony Charara, a co-founder and Executive Director of the Company.
4. Creight Investments Pty Ltd is an entity controlled by Peter Scutt, a co-founder and former Director of the Company.

The above assumes no additional participation by these Shareholders in the Offer.

Final holdings of all Substantial Shareholders will be notified to ASX on the Company's Listing.

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## 7. Details of the Offer Continued

### 7.1.5 Control implications of the Offer

On Completion, no Shareholder will have a controlling interest (as defined by section 50AA of the Corporations Act) in the Company.

### 7.1.6 Potential effect of the Offer on the future of the Company

The Company believes that from Completion it will have sufficient funds available from the proceeds of the Offer and from its operations to fulfil the purposes of the Offer and meet its stated business objectives.

## 7.2 Terms and conditions of the Offer

Topic	Summary
What is the type of security being offered?	Shares (being fully paid ordinary shares in the capital of the Company).
What are the rights and liabilities attached to the Shares being offered?	A description of the Shares, including the rights and liabilities attaching to them, is set out in Section 11.4.
What is the consideration payable for each Share being offered?	Successful Applicants under the Offer will pay the Offer Price, being \$1.15 per Share. Except as required by law, Applicants cannot withdraw or vary their application.
What is the Broker Firm Offer period?	The key dates, including details of the Offer Period, are set out in the Key dates and Key Offer details section of this Prospectus.  The Broker Firm Offer opens at 9.00am (Sydney time) on 22 October 2021 and will close at 5.00pm (Sydney time) on 29 October 2021.  No securities will be issued on the basis of this Prospectus later than the Expiry Date.  The timetable is indicative only and may change. Unless otherwise indicated, all times are stated as the time in Sydney, Australia. The Company in consultation with the Lead Managers, reserves the right to vary both of the above times and dates without notice (including, subject to the ASX Listing Rules and the Corporations Act, to close the Offer early, to extend the Closing Date, to accept late Applications or bids, either generally or in particular cases, or to cancel or withdraw the Offer before settlement, in each case without prior notice). Your Broker may also impose an earlier closing date. Applicants are therefore encouraged to submit their Applications as early as possible.  If the Offer is cancelled or withdrawn before the allocation of Shares, then all Application Monies will be refunded in full (without interest) as soon as possible in accordance with the requirements of the Corporations Act.
What are the cash proceeds to be raised?	Approximately \$22 million will be raised under the Offer.
What are the conditions to the Offer?	The Offer is conditional upon the Company raising the Minimum Subscription Amount and being granted conditional approval to list on the ASX. There is no guarantee that ASX will grant this approval.  If these conditions are not met the Offer will not proceed and investors' Application Monies will be returned (without interest).
Is the Offer underwritten?	The Offer is not underwritten.

Topic	Summary
<b>What is the minimum and maximum Application size under the Broker Firm Offer?</b>	<p>The minimum Application under the Broker Firm Offer is \$2,000 worth of Shares.</p> <p>There is no maximum value of Shares that may be applied for under the Broker Firm Offer.</p>
<b>What is the allocation policy?</b>	<p>The allocation of Shares between the Broker Firm Offer and the Institutional Offer was determined by the Lead Managers and the Company, having regard to the results of the Bookbuild and the allocation policies outlined in Sections 7.3.4 and 7.4.2 (as applicable).</p> <p>For Broker Firm Offer participants, the relevant Broker will decide as to how they allocate Shares among their retail clients.</p> <p>The Lead Managers and the Company have absolute discretion regarding the allocation of Shares to Applicants under the Offer and may reject an Application, or allocate a lesser number of Shares than applied for. The Lead Managers and the Company also reserve the right to aggregate any Applications that they believe may be multiple Applications from the same person.</p>
<b>When will I receive confirmation that my Application has been successful?</b>	<p>It is expected that initial holding statements will be dispatched by standard post on 17 November 2021.</p> <p>Refunds (without interest) to Applicants who make an application and receive an allocation of Shares, the value of which is smaller than the amount of the application monies they have paid, will be made as soon as practicable after Completion.</p>
<b>Will the Shares be quoted?</b>	<p>The Company will apply to the ASX within seven days after the Prospectus Date for admission to the Official List and quotation of Shares on the ASX (which is expected to be under the code TRP). Completion is conditional on ASX approving this application.</p> <p>If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all application monies received will be refunded (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.</p> <p>The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that the ASX may admit the Company to the Official List is not to be taken as an indication of the merits of an investment in the Company.</p>
<b>When are the Shares expected to commence trading?</b>	<p>It is expected that trading of the Shares on ASX will commence on or around 18 November 2021 on a normal settlement basis.</p> <p>It is expected that holding statements will be dispatched by standard post on or about 17 November 2021. It is the responsibility of each Applicant to confirm their holding before trading in Shares.</p> <p>If you sell Shares before receiving a holding statement, you do so at your own risk. The Company, the Share Registry and the Lead Managers disclaim all liability, whether in negligence or otherwise, if you sell Shares before receiving your holding statement, even if you received confirmation of your allocation from your Broker or otherwise.</p>
<b>Are there any escrow arrangements?</b>	<p>Yes. Details are provided in Section 7.5.</p>
<b>Are there any taxation considerations?</b>	<p>The tax consequences of any investment in the Shares will depend upon an investor's particular circumstances. Applicants should obtain their own tax advice prior to deciding whether to invest.</p> <p>Refer to Section 11.12 for general Australian taxation considerations.</p>



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## 7. Details of the Offer Continued

Topic	Summary
<b>Are there any brokerage, commission or stamp duty considerations?</b>	No brokerage, commission or stamp duty is payable by Applicants on the acquisition of Shares under the Offer.  Refer to Sections 6.5 and 11.8 for details of the fees payable by the Company to the Lead Managers.
<b>Where can enquiries be made?</b>	All enquiries in relation to this Prospectus and the Broker Firm Offer should be directed to your Broker.  If you are unclear in relation to any matter or are uncertain as to whether Shares are a suitable investment for you, you should seek professional guidance from your solicitor, stockbroker, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

### 7.3 Broker Firm Offer

#### 7.3.1 Who may apply

The Broker Firm Offer is open to persons who have received a firm allocation of Shares from their Broker and who have a registered address in Australia. If you have received a firm allocation of Shares from your Broker, you will be treated as a Broker Firm Offer Applicant in respect of that allocation. You should contact your Broker to determine whether you can receive an allocation of Shares from them under the Broker Firm Offer. The Broker Firm Offer is not open to persons in the United States.

#### 7.3.2 How to apply

If you have received an allocation of Shares from your Broker and wish to apply for those Shares under the Broker Firm Offer, you should contact your Broker for information about how to submit your Broker Firm Offer Application Form and for payment instructions. Applicants under the Broker Firm Offer must not send their Application Forms or payment to the Share Registry.

Applicants under the Broker Firm Offer should contact their Broker or the Share Registry by telephoning 1300 288 664 (toll free within Australia) or +61 2 9698 5414 (outside Australia) from 9.00am until 5.00pm to request a copy of this Prospectus and Application Form, or download a copy at [www.tissuerepair.com.au](http://www.tissuerepair.com.au). Your Broker will act as your agent and it is your Broker's responsibility to ensure that your Application Form and Application Monies are received before 5.00pm (Sydney time) on the Closing Date or any earlier closing date as determined by your Broker.

If you are an investor applying under the Broker Firm Offer, you should complete and lodge your Broker Firm Offer Application Form with the Broker from whom you received your firm allocation. Broker Firm Offer Application Forms must be completed in accordance with the instructions given to you by your Broker and the instructions set out on the reverse of the Application Form.

The minimum application size for investors in the Broker Firm Offer is 2,300 Shares (\$2,000 worth of Shares), rounded up to the value of the nearest Share). There is no maximum value of Shares that may be applied for under the Broker Firm Offer.

The Company and the Lead Managers reserve the right to aggregate any applications that they believe may be multiple applications from the same person or reject or scale back any applications in the Broker Firm Offer. The Company may determine a person to be eligible to participate in the Broker Firm Offer, and may amend or waive the Broker Firm Offer application procedures or requirements, at their discretion in compliance with applicable laws.

By making an Application, you declare that you were given access to this Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is attached to, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

The Company, the Lead Managers and the Share Registry take no responsibility for any acts or omissions committed by your Broker in connection with your Application.

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The Company and the Lead Managers may elect to close the Offer or any part of it early, extend the Offer or any part of it, or accept late Applications either generally or in particular cases. The Offer or any part of it may be closed at any earlier time and date, without further notice. Your Broker may also impose an earlier closing date. Applicants are therefore encouraged to submit their Applications as early as possible. Please contact your Broker for instructions.

### **7.3.3 Payment methods**

Applicants under the Broker Firm Offer must pay their Application Monies to their Broker in accordance with instructions provided by that Broker.

### **7.3.4 Allocation policy under the Broker Firm Offer**

The allocation of Shares to the Broker Firm Offer, and the identity and level of participation of Brokers participating in the Broker Firm Offer, has been determined by agreement between the Lead Managers and the Company.

Shares that are allocated to Brokers for allocation to their clients will be issued or transferred to the Applicants nominated by those Brokers (subject to the Company's right, and the right of the Lead Managers to reject, aggregate or scale back applications). It will be a matter for each Broker as to how they allocate Shares among their retail clients, and they (and not the Company or the Lead Managers) will be responsible for ensuring that retail clients who have received an allocation from them receive the relevant Shares.

Applicants will be able to confirm their allocations by contacting the Broker from whom they received their allocation.

If you sell Shares before receiving a holding statement, you do so at your own risk. The Company, the Lead Managers and the Share Registry, disclaim all liability, whether in negligence or otherwise, if you sell Shares before receiving your holding statement, even if you received confirmation of allocation from a Broker or otherwise.

### **7.3.5 Acceptance of Applications**

An Application in the Broker Firm Offer is an offer by you to the Company to apply for the number of Shares specified in the Application Form at the Offer Price on the terms and conditions set out in this Prospectus (including any supplementary or replacement document) and the Application Form. To the extent permitted by law, an Application by an Applicant under the Offer may not be varied and is irrevocable.

By making an Application, you declare that you were given access to this Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is attached to, or accompanied by, a paper copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

An Application may be accepted in respect of the full number of Shares specified in the Application Form or any lower number, without further notice to the Applicant. Acceptance of an Application will give rise to a binding contract on allocation of Shares to successful Applicants.

The Company and the Lead Managers reserve the right to reject any Application which is not correctly completed or which is submitted by a person who they believe is ineligible to participate in the Broker Firm Offer, or to waive or correct any errors made by an Applicant in completing their Application.

Successful Applicants in the Broker Firm Offer will be issued Shares at the Offer Price. Acceptance of an Application will give rise to a binding contract, conditional on settlement and quotation of Shares on the ASX.

### **7.3.6 Application monies**

Application Monies received under the Broker Firm Offer will be held in a special purpose account until Shares are issued or transferred to successful Applicants. Applicants under the Broker Firm Offer whose Applications are not accepted, or who are allocated a lesser number of Shares than the amount applied for, will be mailed a refund (without interest) of all or part of their Application Monies, as applicable. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any monies refunded and any interest earned on Application Monies pending the allocation or refund will be retained by the Company.

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## 7. Details of the Offer Continued

### 7.4 Institutional Offer

#### 7.4.1 Invitations to bid

The Company invites certain Institutional Investors in Australia and other eligible jurisdictions outside the United States to bid for an allocation of Shares at the Offer Price. The Lead Managers separately advised Institutional Investors of the application procedures for the Institutional Offer.

#### 7.4.2 Allocation policy under the Institutional Offer

The allocation of Shares among bidders in the Institutional Offer has been determined by agreement between the Lead Managers and the Company. The Company and the Lead Managers have absolute discretion regarding the basis of allocation of Shares among Institutional Investors.

The allocation policy was influenced, but not constrained, by the following factors:

- number of Shares bid for by particular Applicants;
- the timeliness of the bid by particular Applicants;
- the Company's desire for an informed and active trading market following Listing;
- the Company's desire to establish a wide spread of institutional Shareholders;
- overall level of demand under the Broker Firm Offer and Institutional Offer;
- the size and type of funds under management of particular Applicants;
- the likelihood that particular Applicants will be long-term Shareholders; and
- any other factors that the Company and the Lead Managers considered appropriate.

Participants in the Institutional Offer have been advised of their allocation of Shares, if any, by the Lead Managers.

### 7.5 Escrow arrangements

Upon Listing, approximately 33,182,280 Shares, being approximately 55% of the Shares on issue, will be subject to escrow arrangements.

In addition, 22,040,580 Options, being approximately 98% of the Options on issue, will be also subject to escrow arrangements.

Escrowed Securityholders have entered into voluntary escrow arrangements which prevent them from disposing of their Escrowed Securities during the relevant escrow period (subject to relevant exceptions). See Section 10.8 for a summary of the terms of the escrow arrangements and the limited exceptions that permit dealing in the Escrowed Securities during the relevant escrow period.

Certain Shares held by Existing Shareholders will be classified by the ASX as restricted securities and be subject to escrow restrictions for up to 24 months from the date of Official Quotation. For all Shares classified by ASX as restricted securities the Company will enter into escrow agreements with the holders of the restricted securities, in accordance with Chapter 9 of the ASX Listing Rules. Any mandatory escrow arrangements are subject to ASX discretion.

Prior to Shares commencing trading on ASX, the Company will announce to ASX full details of the Shares that have been classified as restricted securities, including the number of Escrowed Securities and the relevant periods of the escrow restrictions.

It is anticipated that at Listing, the free float of the Company will be approximately 45%.

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## 7.6 Acknowledgements

Each Applicant in the Broker Firm Offer and each person in Australia to whom the Institutional Offer is made under this Prospectus, will be taken to have represented, warranted, agreed and acknowledged as follows:

- it agrees to become a member of the Company and to be bound by the terms of the Constitution and the terms and conditions of the Offer;
- it acknowledges having personally received a printed or electronic copy of this Prospectus (and any supplementary or replacement prospectus) accompanying the Application Form and having read them all in full;
- declared that all details and statements in their Application Form are complete and accurate;
- declared that the Applicant(s), if a natural person, is/are over 18 years of age;
- acknowledged that, once the Company, the Share Registry or a Broker receives an Application Form (including electronically), it may not be withdrawn;
- applied for the number of Shares at the Australian dollar amount shown on the front of the Application Form;
- agreed to being allocated and issued the number of Shares applied for (or a lower number allocated in a way described in this Prospectus), or no Shares at all;
- authorised the Company and the Lead Managers and their respective officers or agents, to do anything on behalf of the Applicant(s) necessary for Shares to be allocated to the Applicant(s), including to act on instructions received by the Share Registry upon using the contact details in the Application Form;
- acknowledged that, in some circumstances, the Company may not pay dividends, or that any dividends paid may not be franked;
- acknowledged that the information contained in this Prospectus (or any supplementary or replacement prospectus) is not financial product advice or a recommendation that Shares are suitable for the Applicant(s), given the investment objectives, financial situation or particular needs (including financial and tax issues) of the Applicant(s);
- declared that the Applicant(s) is/are a resident of Australia (except as applicable to the Institutional Offer);
- acknowledged and agreed that the Offer may be withdrawn by the Company or may otherwise not proceed in the circumstances described in this Prospectus; and
- acknowledged and agreed that if Listing does not occur for any reason, the Offer will not proceed.

Each Applicant under the Institutional Offer will be required to make certain representations, warranties, acknowledgements and covenants set out in the confirmation of allocation letter distributed to it.

## 7.7 Discretion regarding the Offer

The Company may withdraw the Offer at any time before the issue of Shares to successful Applicants under the Offer. If the Offer, or any part of it, does not proceed, all relevant Application Monies will be refunded (without interest) as soon as possible.

The Lead Managers and the Company also reserve the right to, subject to the Corporations Act, extend the Offer or any part of it, accept late Applications or bids either generally or in particular cases, reject any Application or bid, or allocate to any Applicant or bidder fewer Shares than the amount applied or bid for.

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## 7. Details of the Offer Continued

### 7.8 ASX listing, registers and holding statements

#### 7.8.1 Application for ASX listing and quotation of Shares

The Company will apply to ASX within seven days of the Prospectus Date, for admission to the Official List and quotation of the Shares on ASX under the code 'TRP'.

The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that ASX may admit the Company to the Official List is not to be taken as an indication of the merits of the Company or the Shares offered for subscription.

If the Company does not apply to ASX for admission to the Official List and quotation of the Shares on ASX within seven days of the Prospectus Date or approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all Application Monies received will be refunded without interest, as soon as practicable in accordance with the requirements of the Corporations Act.

Upon Listing, the Company will be required to comply with the ASX Listing Rules, subject to any waivers obtained by the Company from time to time.

#### 7.8.2 CHESS and issuer sponsored holdings

The Company has applied to participate in ASX's Clearing House Electronic Subregister System (**CHESS**) and must comply with the ASX Listing Rules and ASX Settlement Operating Rules. CHESS is an electronic transfer and settlement system for transactions in securities quoted on ASX under which transfers are effected in an electronic form.

When the Shares become approved financial products (as defined in the ASX Settlement Operating Rules), holdings will be registered in one of two sub-registers, being an electronic CHESS sub-register or an issuer sponsored sub-register. For all successful Applicants, the Shares of a Shareholder who is a participant in CHESS or a Shareholder sponsored by a participant in CHESS will be registered on the CHESS sub-register. All other Shares will be registered on the issuer sponsored sub-register.

Following Completion, Shareholders will be sent a holding statement that sets out the number of Shares that have been allocated to them. This statement will also provide details of a Shareholder's Holder Identification Number (**HIN**) for CHESS holders or, where applicable, the Securityholder Reference Number (**SRN**) of issuer sponsored holders. Shareholders will subsequently receive statements showing any changes to their Shareholding. Certificates will not be issued.

Shareholders will receive subsequent statements during the first week of the following month if there has been a change to their holding on the register and as otherwise required under the ASX Listing Rules and the Corporations Act. Additional statements may be requested at any other time either directly through the Shareholder's sponsoring broker in the case of a holding on the CHESS sub-register or through the Share Registry in the case of a holding on the issuer sponsored sub-register. The Company and the Share Registry may charge a fee for these additional issuer sponsored statements.

### 7.9 Restrictions on distribution

No action has been taken to register or qualify this Prospectus, the Shares or the Offer or otherwise to permit a public offering of the Shares in any jurisdiction outside Australia.

This Prospectus does not constitute an offer or invitation to apply for Shares in any jurisdiction in which, or to any person to whom, it would not be lawful to make such an offer or invitation or issue under this Prospectus.

This Prospectus may not be released or distributed in the United States or elsewhere outside Australia, unless it has attached to it the selling restrictions applicable in the jurisdictions outside Australia, and may only be distributed to persons to whom the Institutional Offer may lawfully be made in accordance with the laws of any applicable jurisdiction.

The Shares have not been, and will not be, registered under the U.S. Securities Act or the securities laws of any state or other jurisdiction of the United States and may not be offered or sold, directly or indirectly, in the United States.

The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. This Prospectus may not be released or distributed in the United States.

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## 7.10 International offer restrictions

This document does not constitute an offer of Shares in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

### 7.10.1 Hong Kong

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the **SFO**). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the Shares offered under this Prospectus have not been and will not be offered or sold in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the Shares offered under this Prospectus has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares pursuant to this Prospectus may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

### 7.10.2 New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the *Financial Markets Conduct Act 2013* (the **FMC Act**). The Shares offered under this Prospectus are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

### 7.10.3 Cayman Islands

The Company is not licensed to conduct investment business in the Cayman Islands by the Cayman Islands Monetary Authority and this document does not constitute an offer of securities to the public in the Cayman Islands. No offer or invitation to subscribe for Shares under this Prospectus may be made to the public in the Cayman Islands or from within the Cayman Islands.



## 8. Investigating Accountant's Report





## 8. Investigating Accountant's Report



7 October 2021

The Directors  
Tissue Repair Limited  
Level 10,  
255 Pitt Street  
Sydney NSW 2000

Pitcher Partners Sydney Corporate  
Finance Pty Ltd

Level 16, Tower 2 Darling Park  
201 Sussex Street  
Sydney NSW 2000

Postal Address  
GPO Box 1615  
Sydney NSW 2001

p. +61 2 9221 2099  
e. [sydneypartners@pitcher.com.au](mailto:sydneypartners@pitcher.com.au)

Dear Directors,

### **PART 1: INDEPENDENT LIMITED ASSURANCE REPORT ON TISSUE REPAIR LIMITED HISTORICAL FINANCIAL INFORMATION AND PRO FORMA HISTORICAL FINANCIAL INFORMATION**

#### **8.1 INTRODUCTION**

The directors ("*Directors*") of Tissue Repair Limited (the "*Company*") have engaged Pitcher Partners Sydney Corporate Finance Pty Ltd ("*Pitcher Partners*") to report on the Historical Financial Information and Pro Forma Historical Financial Information of the Company to be included in the prospectus of the Company ("*Prospectus*") for the proposed initial public offering of new fully paid ordinary shares in the Company ("*Offer*") and listing on an Australian Securities Exchange ("*ASX*").

We have prepared this Independent Limited Assurance Report ("*Report*") to be included in a Prospectus dated on or around 7 October 2021 relating to the Offer.

The Offer is not underwritten.

Under the Offer, there will be no options attached to the Shares.

Unless stated otherwise, expressions defined in the Prospectus (in which this Report is included) have the same meaning in this Report and section references are to sections of the Prospectus.

The nature of this Report is such that it can only be issued by an entity which holds an Australian Financial Services License ("*AFSL*") under the Corporations Act. Pitcher Partners holds the appropriate AFSL authority under the Corporations Act. Refer to our Financial Services Guide included as Part 2 of this Report.

#### **8.2 SCOPE**

This Report deals with the financial information included in Section 4 of the Prospectus ("*Financial Information*"). The Financial Information consists of the Company's:

- Statutory historical Statement of Financial Position as at 30 June 2021, statutory historical Statements of Financial Performance, and statutory historical Statements of Cash Flows for the financial years ended 30 June 2019, 30 June 2020, 30 June 2021 ("*Historical Financial Information*");
- pro forma historical Statement of Financial Position as at 30 June 2021 ("*Pro Forma Historical Financial Information*");
- related notes as set out in Section 4 of the Prospectus.

As described in Section 4.2 of the Prospectus the stated basis of preparation is the recognition and measurement principles contained in Australian Accounting Standards and the Company's adopted accounting policies applied to the Historical Financial Information.

Adelaide Brisbane Melbourne Newcastle Perth Sydney

Pitcher Partners is an association of independent firms.

Pitcher Partners Sydney Corporate Finance Pty Ltd, ABN 77 122 561 184, AFSL 516413. Liability limited by a scheme approved under Professional Standards Legislation. Pitcher Partners is a member of the global network of Baker Tilly International Limited, the members of which are separate and independent legal entities.



NETWORK MEMBER

[pitcher.com.au](http://pitcher.com.au)

## 8. Investigating Accountant's Report Continued



The Historical Financial Information in Section 4 has been prepared for inclusion in the Prospectus and has been derived from the financial statements of the Company for the financial years ended 30 June 2019, 30 June 2020 and 30 June 2021 audited by Pitcher Partners in accordance with Australian Auditing Standards. The three audit opinions issued to the members of the Company relating to those financial reports were unmodified.

The Pro Forma Historical Financial Information in Section 4.7 has been prepared to illustrate the financial position of the Company as at completion of the Offer and has been derived from the statutory historical Statement of Financial Position as at 30 June 2021 and adjusted for the effects of the events to which the pro forma assumptions relate, as described in Sections 4.7.1, 4.7.2 and 4.7.3 of the Prospectus, as if those events had occurred as at 30 June 2021. Due to its nature, the Pro Forma Financial Information does not represent the Company's actual or prospective financial position.

The Financial Information is presented in the Prospectus in an abbreviated form insofar as it does not include all the presentation and disclosures required by Australian Accounting Standards and other mandatory professional reporting requirements applicable to the general purpose financial reports prepared in accordance with the Corporations Act 2001 (Cth).

### 8.3 DIRECTORS' RESPONSIBILITIES

The Directors of the Company are responsible for the preparation and presentation of the Historical Financial Information and Pro Forma Historical Financial Information, including its basis of preparation and the selection and determination of pro forma adjustments made to the statutory historical financial information and included in the Pro Forma Historical Financial Information.

This includes responsibility for its compliance with applicable laws and regulations and such internal controls as the Directors determine are necessary to enable the preparation of the Financial Information that is free from material misstatement, whether due to fraud or error.

### 8.4 OUR RESPONSIBILITIES

Our responsibility is to express a limited assurance conclusion on the Financial Information included in Section 4 of the Prospectus based on the procedures performed and the evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagement ASAE 3450 *Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information*.

A review consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the Financial Information of the Company.

Our engagement did not involve updating or re issuing any previously issued audit or review report on any Financial Information used as a source of the Financial Information.

### 8.5 CONCLUSION

#### Historical Financial Information

Based on our review, which is not an audit, nothing has come to our attention which causes us to believe that:

- the statutory historical Statements of Financial Performance for the financial years ended 30 June 2019, 30 June 2020 and 30 June 2021 as set out in Section 4.5 of the Prospectus;
- the statutory historical Statements of Cash Flows for the financial years ended 30 June 2019, 30 June 2020 and 30 June 2021 as set out in Section 4.6 of the Prospectus; and



- the statutory historical Statement of Financial Position as at 30 June 2021 as set out in Section 4.7 of the Prospectus;

are not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 4.3 of the Prospectus being the recognition and measurement principles described under Australian Accounting Standards and the Company adopted accounting policies applied to the Historical Financial Information.

#### **Pro Forma Historical Financial Information**

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Pro Forma Historical Financial Information, being the pro forma historical Statement of Financial Position as at 30 June 2021 as set out in Section 4.7 is not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Sections 4.7.1, 4.7.2 and 4.7.3 of the Prospectus, as if those events or transactions had occurred as at the date of the Pro Forma Historical Financial Information.

#### **8.6 RESTRICTION ON USE**

Without modifying our conclusions, we draw attention to Section 4.3 of the Prospectus, which describes the purpose of the Financial Information, being for inclusion in the Prospectus. As a result, the Financial Information may not be suitable for use for another purpose.

Investors should consider the risks factors set out in Section 5 of the Prospectus.

#### **8.7 LIABILITY**

Pitcher Partners has consented to the inclusion of this Report in the Prospectus in the form and context in which it is included. At the date of this Report, this consent has not been withdrawn.

The liability of Pitcher Partners is limited to the inclusion of this Report in the Prospectus. Pitcher Partners has not authorised the issue of the Prospectus. Accordingly, Pitcher Partners makes no representation regarding, and takes no responsibility for, any other statements or material in or omissions from, the Prospectus.

#### **8.8 INDEPENDENCE OR DISCLOSURE OF INTEREST**

Pitcher Partners has no financial or other interest that could reasonably be regarded as being capable of affecting its ability to give an unbiased conclusion on the matters that are subject of this Report for which normal professional fees will be received.

Pitcher Partner Sydney Partnership is the auditor of the Company and from time to time, associated entities may also provide the Company with certain other professional services (where independence requirements permit) for which normal professional fees are received.

#### **8.9 FINANCIAL SERVICES GUIDE**

We have included our Financial Services Guide as Part 2 of this Report. The Financial Services Guide is designed to assist retail investors in their use of any general financial product advice in our Report.

Yours faithfully

**Pitcher Partners Sydney Corporate Finance Pty Ltd**

A handwritten signature in dark ink, appearing to read "S Whiddett".

**Scott Whiddett**

Director

## 8. Investigating Accountant's Report Continued



### PART 2 - FINANCIAL SERVICES GUIDE

This Financial Services Guide was prepared on 17 September 2021.

#### 1. Pitcher Partners Sydney Corporate Finance Pty Ltd

Pitcher Partners Sydney Corporate Finance Pty Ltd ("Pitcher Partners") is licensed as an Australian Financial Services Licensee, Licence No. 516413.

Pitcher Partners may provide the following financial services to wholesale and retail clients:

- Financial product advice for the following classes of financial products:
  - (i) deposit and payment products including:
    - (a) basic deposit products;
    - (b) deposit products other than basic deposit products; and
    - (c) non-cash payment products;
  - (ii) debentures, stocks or bonds issued or proposed to be issued by a government;
  - (iii) interests in managed investment schemes excluding investor directed portfolio services; and
  - (iv) securities;(collectively "Authorised Financial Products") and
- Deal in a financial product by:
  - (i) arranging for another person to issue, acquire, vary or dispose of a financial product in respect of the following classes of financial products:
    - (a) interests in managed investment schemes excluding investor directed portfolio services; and
    - (b) securities; and
  - (ii) applying for, acquiring, varying or disposing of a financial product on behalf of another person in respect of the following classes of products:
    - (a) deposit and payment products including:
      - (1) basic deposit products;
      - (2) deposit products other than basic deposit products; and
      - (3) non-cash payment products;
    - (b) debentures, stocks or bonds issued or proposed to be issued by a government;
    - (c) interests in managed investment schemes excluding investor directed portfolio services; and
    - (d) securities.

#### 2. Financial Services Guide

The Corporations Act 2001 (Cth) requires Pitcher Partners to provide this Financial Services Guide ("FSG") in connection with its provision of an Independent Limited Assurance Report ("Report") which is included in the Prospectus issued by the Company.

#### 3. General Financial Product Advice

The financial product advice provided in our Report is known as "general advice" because it does not take into account your personal objectives, financial situation or needs. You should consider whether the general advice contained in our Report is appropriate for you, having regard to your own personal objectives, financial situation or needs. You may wish to obtain personal financial product advice from the holder of an Australian Financial Services Licence to assist you in this assessment.

#### 4. Remuneration

The fees we charge for preparing reports are usually determined on an hourly basis, however they may be a fixed amount or derived using another basis. We may also seek reimbursement of any out-of-pocket expenses incurred in providing the services.

Fee arrangements are agreed and confirmed in a letter of engagement with the party or parties who engage us. Neither Pitcher Partners, nor its directors or officers, nor any related bodies corporate and their directors and officers, receives any other fees, commissions or other benefits in connection with preparing and providing this report.

All of our employees receive a salary and while eligible for annual salary increases and bonuses based on overall performance they do not receive any commissions or other benefits arising directly as a result of the services provided to you. We do not pay commissions or provide any other benefits to any parties or person for referring customers to us in connection with the reports that we are licensed to provide.

Pitcher Partners' shareholders (including any shareholders of a related body corporate) will also receive a benefit based on Pitcher Partners' ongoing overall performance.

#### 5. Independence

Pitcher Partners is required to be independent of the Company.

Neither Pitcher Partners, any related entities, any Director thereof, nor any individual involved in the preparation of the Report have any financial interest in the outcome of the Company's Offer, other than a fee in connection with the preparation of our Report for which professional fees in the order of \$75,000 (excluding GST) will be received and audit fees agreed from time to time.

No pecuniary or other benefit, direct or indirect, has been received by Pitcher Partners, any related entities, their Directors or employees, or related bodies corporate for or in connection with the preparation of this Report.

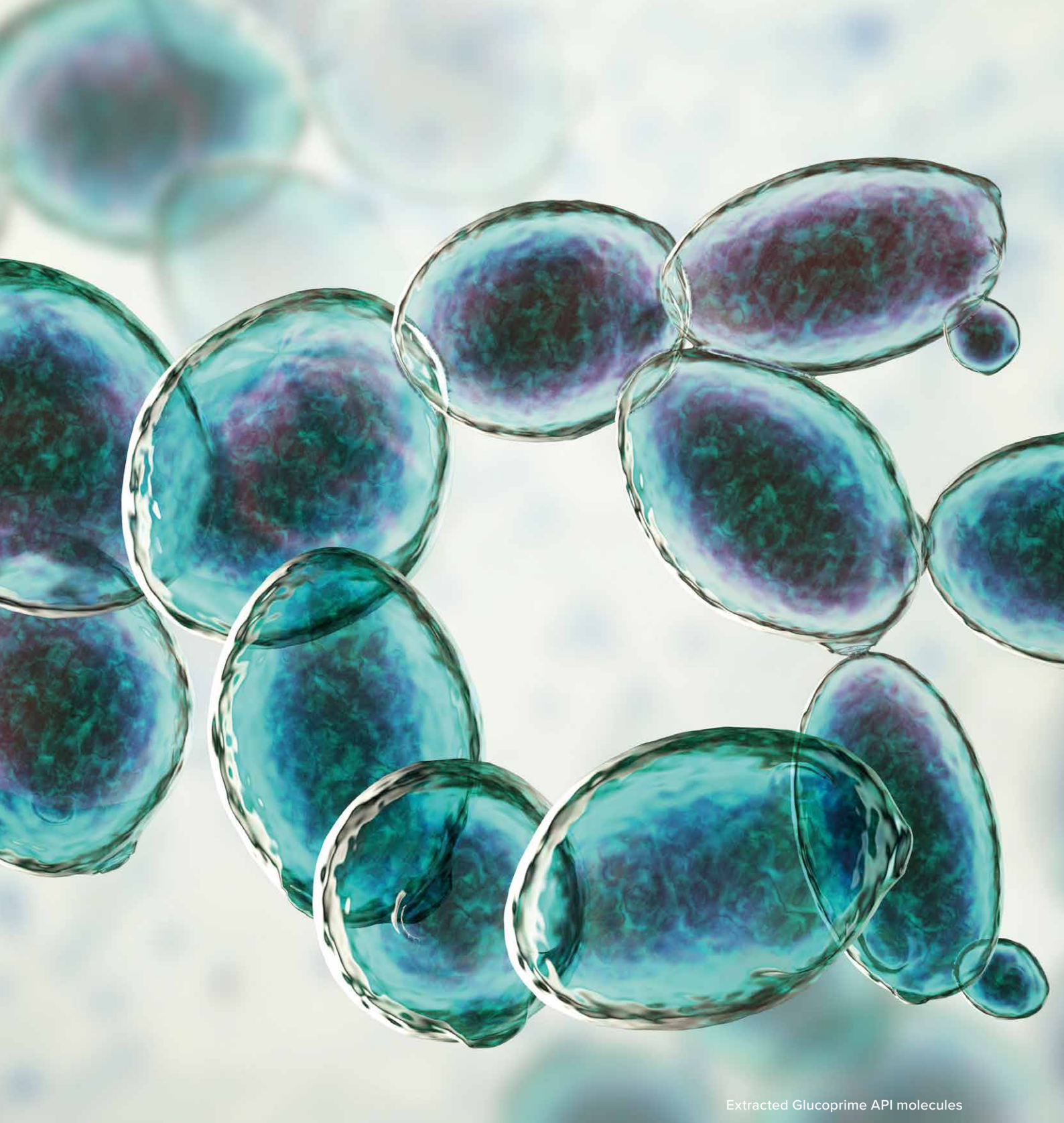
#### 6. Complaints Resolution

Pitcher Partners is only responsible for its Report and this FSG. Complaints or questions about the Prospectus should not be directed to Pitcher Partners which is not responsible for that document.

If you have a complaint about Pitcher Partners' Report or this FSG:

- You can contact the Complaints Manager of Pitcher Partners on (02) 9221 2099 or send a written complaint to GPO Box 1615, Sydney NSW 2001 or [sydneypartners@pitcher.com.au](mailto:sydneypartners@pitcher.com.au). We will try to resolve your complaint quickly, fairly and within prescribed timeframes.
- If you do not get a satisfactory outcome, you have the right to complain to the Australian Financial Complaints Authority at GPO Box 3 Melbourne VIC 3001, email at [info@afca.org.au](mailto:info@afca.org.au) or call on 1800 931 678 (free call). AFCA provides fair and independent financial services complaint resolution that is free to consumers.





Extracted Glucoprime API molecules

## 9. Intellectual Property Report



## 9. Intellectual Property Report



17 September 2021

**Mills Oakley**  
ABN: 51 493 069 734

Our ref: TMNS/TMNS/3521059

The Directors  
Tissue Repair Ltd  
Level 8  
20 Hunter Street  
SYDNEY NSW 2000

All correspondence to:  
PO Box H316  
AUSTRALIA SQUARE NSW 1215  
**DX 13025 Sydney Market Street**

**Partner**  
Dr Teresa Nicoletti +61 2 8035 7860  
Email: [tnicoletti@millsOakley.com.au](mailto:tnicoletti@millsOakley.com.au)

Dear Directors

### Intellectual Property Report

1. This Intellectual Property Report (**Report**) has been prepared by Mills Oakley Lawyers (**Mills Oakley**) for inclusion in a Prospectus to be issued by Tissue Repair Ltd (**Tissue Repair**).
2. The Report is directed to a patent application (**New Glucoprime Application**) filed on 31 July 2021 on behalf of Tissue Repair by Mr Robert Snoep, a registered patent attorney at CreateIP in New Zealand. The invention described in the patent application relates to an isolated biological polysaccharide compound and methods of use and manufacture thereof.
3. The Report considers the following:
  - a) In Section 1, an overview of the process for obtaining a patent and the requirements that must be met in order for a patent to be granted (**Overview of Patent Process**).
  - b) In Section 2, the ownership of the invention as claimed in the New Glucoprime Application (**Ownership of the Invention**).
  - c) In Section 3, an assessment on the patentability of the invention claimed in the New Glucoprime Application, having regard to reviews of the prior art conducted by a third-party reviewer and CreateIP (**Patentability Assessment**).
4. In preparing the Report, we have had regard to the following documents:
  - a) An Opportunity Assessment dated 31 October 2019 prepared by Dr Kristian Slack of InnovIQ, which reviewed the prior art in the form of public disclosure through journals, trade shows and the internet (**Opportunity Assessment**);
  - b) A Consulting Agreement between Mark Deacon Shaw and Tissue Repair executed on 12 August 2013 (**Consulting Agreement**);
  - c) A Confirmatory IP Assignment Deed executed by Anthony Charara on 16 September 2021 (**Charara Assignment Deed**);
  - d) A Confirmatory IP Assignment Deed executed by Tissue Repair and its subsidiary, TR Therapeutics, Inc. (**TR Therapeutics**), on 16 September 2021 (**Intercompany Assignment Deed**);
  - e) The New Glucoprime Application; and

- f) A letter from CreatelP (**CreatelP Letter**) dated 14 September 2021 concerning the prior art review completed in respect of the New Glucoprime Application.

## Section 1: Overview of Patent Process

### Patents and patentability

5. A patent protects novel, non-obvious and useful inventions by providing a statutory monopoly right that confers on the owner an exclusive right to exploit (use, manufacture or sell) the invention as claimed in the country or territory in which the patent has been granted. While there are many commonalities, patent laws, rules and requirements may differ in material respects from jurisdiction to jurisdiction. Further, while there are streamlined administrative processes for making patent applications in multiple jurisdictions, patents are not conferred automatically nor globally, and must be sought and obtained in each jurisdiction in which patent protection is desired.
6. A patent may be granted in respect of a wide range of subject matter, which may include new or improved products, new uses for products and new methods of manufacture. Other than innovation patents,<sup>1</sup> patents generally<sup>2</sup> provide protection for 20 years from the date of filing of the application, which establishes the 'priority date'. This is the date that applies for the purposes of assessing the invention against the prior art.
7. The key criteria for patentability are that an invention must be new (novel) and non-obvious (inventive) as at the priority date. An assessment of novelty and inventiveness requires an examination of the prior art, which includes all published material or information that was in existence before the priority date. Accordingly:
  - a) for an invention to be "novel", it must be different to the prior art; that is, it must be different to what was known or existed before the priority date, and it must not have previously been publicly available; and
  - b) for an invention to be non-obvious and involve an inventive step, it must be an improvement or advancement over the prior art, and it must not be an invention that would have been obvious to a person skilled in the art as at the priority date.
8. For novelty and inventiveness to be properly assessed, it is essential that the patent application fully disclose the invention in the patent specification, which generally contains a detailed description of the invention and the claims that define the scope of the invention.

### Ownership of an invention and patent

9. There are a number of rules relating to the concept of inventorship, but the general rule is that the inventor(s) of an invention is/are the person or persons who created or materially contributed to the invention as claimed.
10. The Australian *Patents Act 1990* provides that a patent for an invention may only be granted to a person who is the inventor, or to a person or entity to whom the invention, or the patent once granted, has been assigned by the inventor. This principle of 'entitlement' and the law to which it relates, generally applies in all jurisdictions. If a person other than the inventor, or a body corporate, wishes to claim ownership of an invention, then it is necessary to demonstrate that the legal title to that invention has been assigned by the inventor to that other person or body corporate. If there is more than one inventor, then assignment of the title to the invention must occur from each inventor in order for the assignee to be the sole person entitled to the patent.

<sup>1</sup> Innovation patents provide protection for 8 years.

<sup>2</sup> Certain pharmaceutical patent terms may be extended to allow for delays in marketing authorisation.



## 9. Intellectual Property Report Continued

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11. Establishing that the applicant for a patent is the lawful owner of the invention as claimed in the patent is a critical component of any intellectual property due diligence. Generally, a patent as granted should reflect the true inventor(s) and owners of the patent, and it is the true legal position that will always prevail regardless of what is stated on the patent or in the Patent Register in a particular country. In this regard, although in an application for a patent submitted to the Australian Patent Office (**APO**), the APO will generally accept the applicant's attestation as to the inventor and owner of the invention, it is possible for inventorship and ownership to be legally challenged at any time after the patent has been granted, by any person or entity in whose interests it is to do so. Accordingly, if the applicant for a patent is not the inventor of the invention claimed, they will need to demonstrate that they lawfully acquired the rights to the invention from the inventors, which could be by way of a valid assignment, through the provisions of an employment or consultancy agreement, or through another agreement.

### Obtaining a patent

12. For a patent to be granted, a patent application must be lodged in (or in respect of) each relevant national or regional jurisdiction setting out the claims that are specific to the invention. The application must ultimately be examined by the local Patent Office (in the case of a national application) or the Regional Patent Office (in the case of the regional application) to ensure that the requirements in the jurisdiction have been met and the patentable subject matter is adequately defined in the claims.
13. Patent protection in some countries can be obtained *via* regional protection. For example, in Europe, a regional European patent application may be lodged instead of separate national patent applications in multiple European countries.
14. An international patent application process commonly used to initiate patent applications in more than 140 member countries (including Australia, the US and countries in Europe) is through the Patent Cooperation Treaty (**PCT**), which is a treaty administered by the World Intellectual Property Organisation. PCT applications are not substantively examined before they 'enter the national phase' for a given jurisdiction and do not of themselves give rise to grant of a patent *per se*. Rather, they provide a mechanism to obtain deemed simultaneous filing in multiple jurisdictions for a given single, earliest priority date, to delay the lodgement of a national patent application for up to 30 months (more in some countries) from that priority date, and to obtain a non-binding preliminary view of patentability from a PCT Patent Examiner.
15. At the end of this "international phase" of 30 months, applicants must then enter the national or regional phase in the country or region where a patent is sought, which results in a family of separate national or regional patent applications. Each national or regional patent application must then be examined by local Patent Office authorities in order to meet local patentability requirements.
16. Successful progression through the examination process, either through a lack of objections raised by the examiner or by adequately addressing any objections raised by third parties (through oppositions), will result in the grant of the patent in the country or region in which it has been applied.
17. The grant of a patent in one jurisdiction does not guarantee that it will be granted in another jurisdiction or granted in the same form with the same scope of claims (which define the patentee's monopoly). It also does not necessarily guarantee its validity or enforceability, and patents are susceptible to challenge by third parties throughout their term. A successful challenge to a patent can invalidate some or all of the patent and, in the latter case, results in its subsequent removal from the relevant national or regional Patent Register. This can arise, for example, if it is established that some or all of the claims in a granted patent lack novelty and inventiveness when compared to prior art.

18. Once a patent is granted, the patentee may enforce its patent rights against any infringing third party. In turn, it is common, when a third party is sued for allegedly infringing a patent, for that third party to challenge the validity of the patent by way of a counterclaim.
19. In addition, the grant of a patent does not necessarily mean that the patent owner is immune from an infringement claim in respect of another granted patent, and it is possible for an invention that is *prima facie* protected by a granted patent to infringe the rights in another previously granted patent.

## Section 2: Ownership of the Invention

20. The inventors of the invention claimed in the New Glucoprime Application, and named in that application, are Mark Deacon Shaw (deceased) (**Shaw**) and Anthony Charara (**Charara**).
21. The designated applicant for the New Glucoprime Application, as recorded in the Application Data Sheet filed with the application on 31 July 2021, is Tissue Repair. Although we understand from Tissue Repair's U.S. patent attorney that the designation of Tissue Repair as the proposed applicant/assignee is "non-controlling" as to ownership, the naming of Tissue Repair as the proposed applicant indicates at least a present intention that Tissue Repair will be entitled to be recorded as the owner of the invention by the time any patent is issued on the New Glucoprime Application. It is necessary, therefore, to establish whether ownership of the invention lawfully resides with, or will lawfully reside with, Tissue Repair, either by way of a valid assignment of the invention to Tissue Repair by the inventors, or through the provisions of an employment or consultancy agreement, or through another agreement.
22. With respect to the assignment of the invention by Shaw to Tissue Repair, the Consulting Agreement provides the following:
  - a) That all "Developed Items" (which included, relevantly, all inventions, discoveries, developments, products, methods, processes and procedures) developed by Shaw during the Term of, and in the performance of services under, the Consulting Agreement were the property of Tissue Repair and its subsidiary, TR Therapeutics, both of which are referred to as '**the Client**' in the Consulting Agreement.
  - b) All title and interest therein, and to all services performed and products developed by Shaw vested in the Client.
  - c) To the extent that title to any Developed Items may not have, by operation of law, vested in the Client, all rights, title and interest therein throughout the world were irrevocably assigned by Shaw to the Client, and Shaw would do all things reasonably required by the Client to give effect to ownership or assignment of any Developed Items to the Client, including executing any document reasonably required by the Client to be executed.
23. Based on:
  - a) the terms of the Consulting Agreement; and
  - b) our instructions and the assumptions that the invention claimed in the New Glucoprime Application was developed by Shaw in conjunction with Charara during the Term of, and in the performance of services that Shaw performed under, the Consulting Agreement,

we are satisfied that, insofar as it derives from Shaw's inventorship, ownership of the invention claimed in the New Glucoprime Application vested in the Client.
24. In our view, although it is not entirely certain, the likely effect of the Consulting Agreement is that Shaw's entitlement as co-inventor of the invention claimed in the New Glucoprime

## 9. Intellectual Property Report Continued

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Application vested in both Tissue Repair and TR Therapeutics, with the result being that both Tissue Repair and TR Therapeutics were, by virtue of the Consulting Agreement, joint owners of the invention insofar as it derives from Shaw's inventorship.

25. However, the Intercompany Assignment Deed provides the following:
- a) That pursuant to the Consultancy Agreement, TR Therapeutics may have become joint owner with Tissue Repair of any Intellectual Property Rights created or developed by Shaw during the Term of, and in the performance of services under, the Consulting Agreement, including Shaw's right, title and interest in and to the inventions described in the New Glucoprime Application; and
  - b) To the extent to which TR Therapeutics held any right, title or interest in and to the Intellectual Property Rights created or developed by Shaw as described in paragraph 25.a) above, TR Therapeutics assigned all right, title and interest in and to those rights to Tissue Repair.
26. Based on:
- a) the matters described in paragraphs 23 and 24 above; and
  - b) the terms of the Intercompany Assignment Deed,
- we are satisfied that, insofar as it derives from Shaw's inventorship, ownership of the invention claimed in the New Glucoprime Application vests in Tissue Repair.
27. With respect to the assignment of the invention by Charara to Tissue Repair, we are instructed that:
- a) there was no formal written employment or other agreement between Charara and Tissue Repair (or TR Therapeutics) which contained terms dealing with the ownership of any Intellectual Property Rights created or developed by Charara during or in connection with his employment by, officeholding in and/or other relationship with, Tissue Repair and/or TR Therapeutics; and
  - b) except to the extent to which, by implication or otherwise by operation of law, it may have been a term of his employment by, officeholding in and/or other relationship with, Tissue Repair and/or TR Therapeutics that Tissue Repair and/or TR Therapeutics would own any Intellectual Property Rights created or developed by Charara during or in connection with that employment, officeholding or other relationship, Charara did not, prior to execution of the Charara Assignment Deed, assign or purport to assign any right, title or interest in or to such Intellectual Property Rights to any other person.
28. However, the Charara Assignment Deed provides the following:
- a) That it was unclear whether (pursuant to the relationship and arrangements between Charara, Tissue Repair and TR Therapeutics) Charara, Tissue Repair and/or TR Therapeutics would own, and owns, any Intellectual Property Rights created or developed by Charara during or in connection with his employment by, officeholding in and/or other relationship with, Tissue Repair and/or TR Therapeutics (which specifically include, in Schedule 1 of the Assignment Deed, Charara's right, title and interest in and to the inventions described in the New Glucoprime Application); and
  - b) To the extent to which Charara still held any right, title or interest in and to the Intellectual Property Rights created or developed by Charara as described in paragraph 28.a) above, Charara assigned all right, title and interest in and to those rights to Tissue Repair.
29. Further, the Intercompany Assignment Deed provides the following:

- a) That it was unclear whether, pursuant to the relationship and arrangements between Charara, Tissue Repair and TR Therapeutics, Charara, Tissue Repair and/or TR Therapeutics would own, and own, any Intellectual Property Rights created or developed by Charara during or in connection with his employment by, officeholding in and/or other relationship with, Tissue Repair and/or TR Therapeutics (which specifically include, in Schedule 1 of the Intercompany Assignment Deed, Charara's right, title and interest in and to the inventions described in the New Glucoprime Application); and
  - b) To the extent to which TR Therapeutics held any right, title or interest in and to the Intellectual Property Rights created or developed by Charara as described in paragraph 29.a) above, TR Therapeutics assigned all right, title and interest in and to those rights to Tissue Repair.
30. Based on:
- a) the terms of the Charara Assignment Deed;
  - b) the terms of the Intercompany Assignment Deed; and
  - c) our instructions and the assumptions that the invention claimed in the New Glucoprime Application was developed by Charara in conjunction with Shaw during the course of Charara's employment by, or other relationship with, Tissue Repair and/or TR Therapeutics (which is still current),
- we are satisfied that, insofar as it derives from Charara's inventorship, ownership of the invention claimed in the New Glucoprime Application vests in Tissue Repair.
31. Having regard to paragraphs 26 and 30 above, we are satisfied that the owner of the invention claimed in the New Glucoprime Application is Tissue Repair and that Tissue Repair is entitled to apply for the New Glucoprime Application in its name.

### Section 3. Patentability Assessment

32. The claims submitted in the pending New Glucoprime Application concern the following:
- a) An isolated biological polysaccharide compound (**Glucoprime**) with defined characteristics, including a novel structure with higher purity and molecular weight, and significantly higher amounts of side chains compared to prior art compounds, and the fact that, unlike similar prior art compounds reviewed and considered in the course of preparing the New Glucoprime Application, the Glucoprime compound is insoluble;
  - b) A method of manufacture of an isolated biological polysaccharide compound with the above characteristics, where the method includes novel water rinse (and other method) steps; and
  - c) Topical treatment methods using the above isolated biological polysaccharide compound and, in particular, the unexpected high efficacy exhibited in chronic wound and cosmetic applications.
33. Tissue Repair claims that the process for producing Glucoprime provides an improvement in yield over prior art (including that of the company's previously patented process) and has application as a topical get to accelerate skin quality benefits of laser ablative surgery.

### The Opportunity Assessment

34. The Opportunity Assessment prepared by InnoviQ involved a review of the prior art to examine the novelty, utility and inventiveness of the invention described in the New Glucoprime Application. InnoviQ reviewed the international patent database and identified

## 9. Intellectual Property Report Continued

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18 prior art patents which it regarded as relevant to an assessment of the patentability of the invention. These prior art patents were described as covering, variously:

- a) the use of a yeast cell membrane product for treating skin conditions;
- b) the process of making a micro-particulate insoluble beta glucan from *Saccharomyces Cerevisiae*;
- c) treatment of skin to improve elasticity and revitalization using a mechanically obtained lysate of *Saccharomyces Cerevisiae*;
- d) revitalizing skin using a topically applied yeast-derived particulate glucan;
- e) cereal-derived beta glucan for topical treatment of burns as a gel or cream;
- f) beta glucan for sunburn and improving elastosis and wrinkling;
- g) the preparation of small particle glucan using freeze drying;
- h) the process of extracting beta glucan using enzymes;
- i) using carboxymethyl beta glucan in a carrier to treat skin after laser or chemical peeling treatment;
- j) the topical application of microparticulate beta glucan for treating skin after laser or chemical peeling treatment; and
- k) a gel glucan product derived from *Saccharomyces Cerevisiae*.

- 35. In its review of the 18 prior art patents, InnovIQ noted the following:
  - a) The majority of the patents identified had expired, either because they were more than 20 years old or due to failure of the assignee to maintain them.
  - b) A small number of patents related to the production of microparticulate glucans and application of glucan-based topical treatments for wound healing, cosmetics and recovery following laser treatment.
- 36. However, InnovIQ's review stated that it did not identify any prior art patents that described key elements of the invention claimed in the New Glucoprime Application, including:
  - a) the improved process for increased yield of high purity, microparticulate glucan;
  - b) the use of microparticulate glucan to improve skin quality measured by elastosis; and
  - c) the use of microparticulate glucan to provide acceleration in skin quality benefits following laser ablative laser surgery.
- 37. InnovIQ concluded that these aspects of the invention claimed in the New Glucoprime Application may be considered novel and differentiated the invention from the prior art, and could therefore form the basis of patent claims for the invention.
- 38. However, a significant limitation we identified in the Opportunity Assessment is that InnovIQ's evaluation of the potential patentability of the invention omitted significant prior art from the review. This prior art comprised patents that were identified as assets acquired by Tissue Repair's subsidiary, TR Therapeutics, Inc., from Novogen Research Pty Ltd and Glycotex, Inc. on 26 July 2012 (**Novogen Patents**). These patents are relevant to the invention claimed in the New Glucoprime Application but do not appear to have been reviewed in the Opportunity Assessment. Moreover, because CreateIP was asked to rely on the Opportunity Assessment as representing an accurate evaluation of the relevant prior art for the purpose of drafting and filing the New Glucoprime Application, it was a limitation that needed to be addressed.

39. As a result of identifying this apparent omission in the Opportunity Assessment, we asked CreateIP to review the Novogen Patents and opine on the patentability of the New Glucoprime Application having regard to the Novogen Patents (and the prior art already reviewed as part of the Opportunity Assessment).

#### The CreateIP Letter

40. CreateIP's review of the Novogen Patents is summarised in the CreateIP Letter. CreateIP noted in that letter that, having not instructed nor completed the search carried out by InnovIQ to prepare the Opportunity Assessment, it could not guarantee that the InnovIQ search identified all of the relevant prior art. CreateIP noted, however, that the Opportunity Assessment had clearly considered *some* of the prior art and, on that basis, it was "*confident that the invention claimed is patentable based on the prior art noted in the InnovIQ report*".
41. The CreateIP Letter includes the following disclaimers:
- a) That no patent attorney or IP advisor could ever confidently say they have considered all of the relevant prior art, simply because patent searching is not an exact science and publications can be missed through no fault of the searcher.
  - b) That patents/applications are generally only published 18 months after filing hence no search would find unpublished filings filed within the 18 months before the relevant priority date which may become relevant in future.
42. While there was a time period between the InnovIQ search and filing of the application that passed where new publications could have occurred, the CreateIP Letter notes that a 'top up' search was undertaken on behalf of Tissue Repair, reported on 11 June 2021, looking for patent publications after 31 Oct 2019 (when InnovIQ produced their report). The author of the CreateIP Letter notes that although that 'top up' search was limited by a budget, he was confident that he had found the main results of interest (although these results were obscured by a large number of skincare/skin moisturiser/skin whitening composition patents that use beta glucan as one of many components).
43. Notwithstanding the disclaimers listed in paragraph 41 above, based on the Opportunity Assessment, the 'top up' search referred to in paragraph 42 above and a review of the Novogen Patents, the author of the CreateIP Letter concluded as follows:
- I have reviewed everything provided to me and conducted my own 'top-up' search and I am confident that the claims made in the New Glucoprime Application are novel and inventive over the prior art provided to me and identified in my own 'top-up' search.*
- I cannot however guarantee or rule out that an examiner or third party might find relevant prior art somewhere that may have some impact on the claims and my view is that it would be impossible to make such an assurance.*
44. The disclaimers in paragraph 41 above are standard, uncontroversial limitations arising in relation to any prior art search, and any report assessing the patentability of an invention must be understood in that context. Notwithstanding those limitations, CreateIP was confident in the novelty and inventiveness of the claims made in the New Glucoprime Application.
45. In order for us to independently draw conclusions about patentability, we would need to conduct searches of the prior art ourselves and review all of the relevant prior art identified in those searches. We note as well that there was a slight – perhaps practically inevitable – delay between the CreateIP 'top up' search (11 June 2021) and the date of filing of the New Glucoprime Application (31 July 2021), and therefore it is not known if

## 9. Intellectual Property Report Continued

Page 9 of 9

further relevant prior art published during that period (albeit short) may exist. The patentability of the New Glucoprime Application is therefore subject to that limitation (among others). However, assuming that:

- a) no such relevant prior art exists; and
- b) the Opportunity Assessment and CreateIP Letter can be relied upon as:
  - i. accurate identifications and reviews of the content of all relevant prior art; and
  - ii. accurate assessments of the patentability of the invention in light of that prior art,

(in both cases that prior art being read by the representative skilled person in the art), it is more likely than not that the New Glucoprime Application will be allowed and the patent granted.

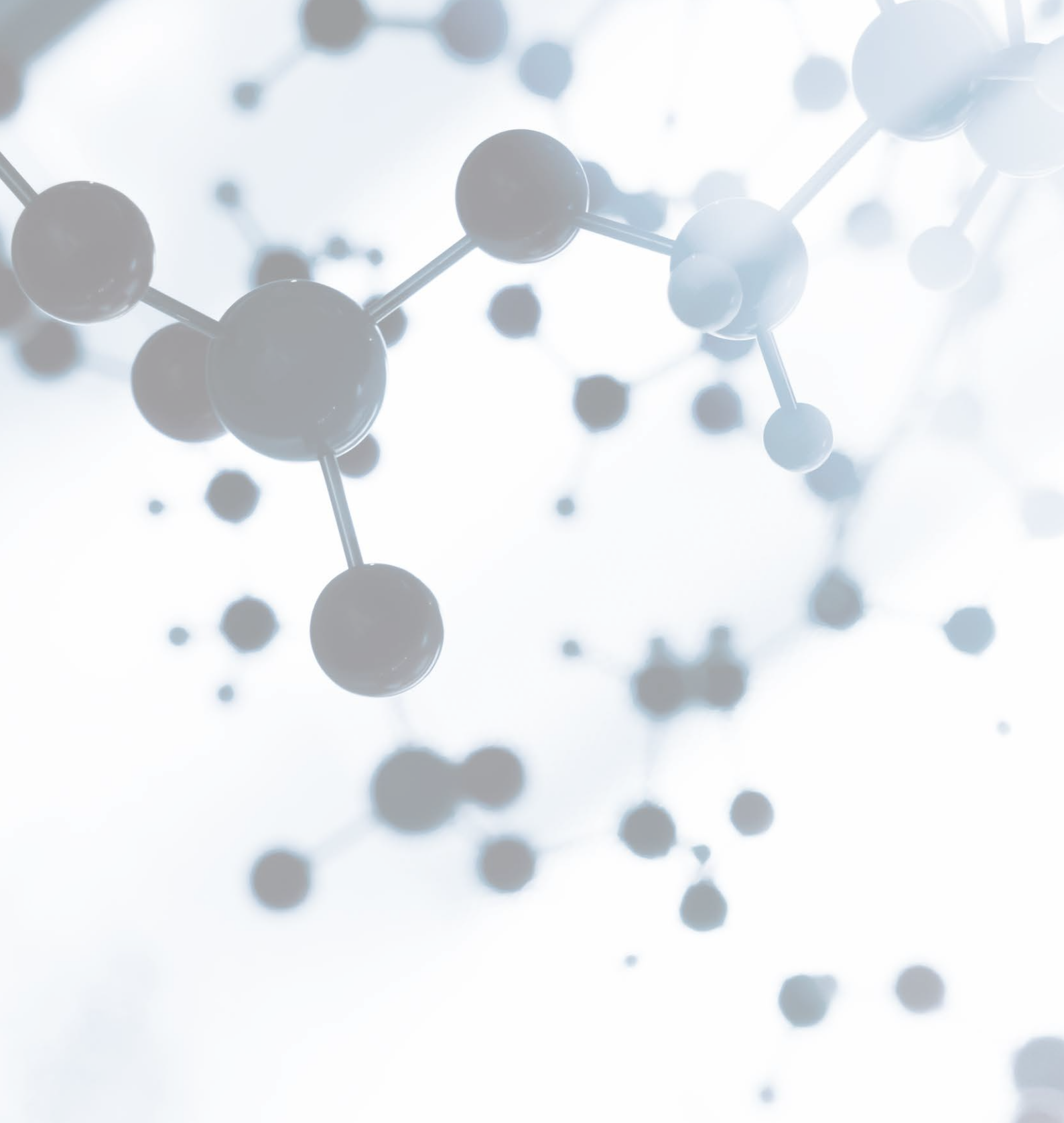
46. The opinion expressed in the preceding paragraph does not, however, constitute a guarantee that:
- a) a U.S. patent will be granted in respect of the New Glucoprime Application with specification content and claims the same as presently drafted and filed (for reasons which include that there may be objections based on considerations of patentability requirements other than novelty and inventive step);
  - b) any other patent will be granted in respect of the invention described and claimed in the New Glucoprime Application in any other jurisdiction, having particular claim scope or at all; or
  - c) any patent granted in the U.S. or any other jurisdiction in respect of the invention described and claimed in, or otherwise based on, the New Glucoprime Application will not be susceptible to challenge by a third party and subsequent invalidation and revocation in whole or part, whether due to lack of novelty, lack of inventive step, or failure to meet any other requirement of patentability in a given jurisdiction.

Yours sincerely



**DR TERESA NICOLETTI**  
**PARTNER**





## 10. Material Contracts



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## 10. Material Contracts

The Board considers that certain agreements relating to the Company are significant to the Offer, the operations of the Company, or may be relevant to investors. A description of material agreements or arrangements, together with a summary of the key details of each of these agreements is set out below.

### 10.1 SerenaGroup, Inc Master Clinical Study Agreement

TR Therapeutics and SerenaGroup, Inc (**Serena**) are parties to a Master Clinical Study Agreement dated 21 March 2016 under which Serena is engaged as a contract research organisation to facilitate, coordinate and perform clinical studies in relation to Tissue Repair's TR-987 product, through a network of affiliated practices (**Study Sites**). The material terms of the agreement are as follows:

- (a) **(Approvals)** TR Therapeutics is responsible for ensuring that the required approvals for a clinical trial of TR-987 are obtained;
- (b) **(Conduct of the study)** The study will be conducted under the supervision of Thomas E Serena, MD who is responsible for oversight of the study. Designated individual physicians are responsible for the oversight at their respective Study Sites (**Investigators**);
- (c) **(Personnel)** Serena and the Study Sites must arrange for qualified medical, technical, laboratory, clerical and other personnel necessary to support the study. Serena and Investigators must ensure that all personnel are bound to assign rights to inventions to TR Therapeutics for work performed under the agreement or protocol;
- (d) **(Institutional review board)** Serena and the Investigators will coordinate with Serena's institutional review board to obtain their written approval of the Investigators' conduct of the study at the Study Sites;
- (e) **(Notification)** In the event that there are any deviations from the protocol necessary to protect the safety, rights or welfare of subjects enrolled in the study, or any serious adverse event occurs in respect of a subject in the study, Serena has obligations to promptly notify TR Therapeutics;
- (f) **(Records)** Serena and the Investigators must maintain complete and accurate records of the status and progress of the study as required by the protocol and Investigators and Study Sites must create and maintain complete and up to date medical records of study subjects. TR Therapeutics will have access to all documentation, data and information relating to or resulting from the study;
- (g) **(Study drug)** TR Therapeutics must provide sufficient quantities of the study drug to the Study Sites at no charge. Serena, the Study Sites and the Investigators are only permitted to use the study drug to conduct the study;
- (h) **(Case report forms)** The Investigators must complete data collection forms required for all subjects enrolled in the study;
- (i) **(Confidentiality)** The agreement contains standard confidentiality provisions, which apply for the duration of the study and for a period of 10 years following completion of the study. In addition, the agreement permits Serena and the Investigators to use the study results for internal, non-commercial research purposes, and in connection with subject care;
- (j) **(Study data)** TR Therapeutics owns all study data generated by the study and has the sole right to use the study data for all commercial purposes. Serena has the right to use the study data for non-commercial purposes, including academic uses and publication (see publication requirements);
- (k) **(Publication)** Prior to public presentation or submission for publication, Serena and the Investigators agree to submit for review to TR Therapeutics, the content of any manuscript for publication, abstract or presentation containing data and results of the study generated under the agreement;
- (l) **(Intellectual Property)** All existing inventions and technologies of each party remain the separate property of the relevant party. Any new invention, development, improvement or discovery made or conceived by Serena, the Investigators or Study Site personnel resulting from the conduct of the study, performance of the protocol or use of the study drug or TR Therapeutics' confidential information (**Sponsor Inventions**) must be promptly disclosed in writing to TR Therapeutics. All of the Sponsor Inventions are owned by TR Therapeutics. Serena assigns all right, title and interest in the Sponsor Inventions to TR Therapeutics and agrees to execute all necessary documents to give effect to that assignment, and agrees to procure Study Sites and Investigators to do the same. Other than as set out in the agreement, none of TR Therapeutics, Investigators, Study Sites nor Serena transfer to the other any intellectual property;

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- (m) **(Term)** The agreement commenced on 21 March 2016 and continues until completion of all obligations established in the protocol, unless terminated earlier;
  - (n) **(Termination)** Serena may terminate the agreement in the event of TR Therapeutics' unremedied material breach. Serena may suspend the study if there are health or safety concerns. TR Therapeutics may suspend the study or terminate the agreement, with or without cause at any time, effective immediately upon written notice;
  - (o) **(Indemnification)** TR Therapeutics indemnifies, defends and holds harmless Serena, its trustees, officers, employees, staff, agents and any Study Site personnel from and against any liability arising by reason of personal injury or property damage which arises out of or in connection with the performance of the study or use of the study results or data, except in the case of failure to adhere to the protocol, breach of any applicable regulation and/or negligence or wilful misconduct. Serena indemnifies, defends and holds harmless TR Therapeutics, its trustees, officers, employees, staff and agents against any liability incurred by TR Therapeutics as a result of the negligence, wilful misconduct or material breach of the agreement by Serena or the Study Sites;
  - (p) **(Insurance)** The agreement requires each of the parties to have relevant insurance in place throughout the performance of the study;
  - (q) **(Subject injury)** TR Therapeutics is responsible for the cost of reasonable and customary medical treatment of any illness or injury sustained by a study subject as a result of injuries or adverse reactions caused by the study drug or directly related to the study or properly performed procedures in accordance with the protocol, except to the extent that those costs are covered by the subject's insurance or other third party coverage. TR Therapeutics is however not liable for expenses to the extent that adverse experiences arise out of or are related to any indemnified persons, a failure to follow certain regulations, wrongful or negligent acts or omissions or wilful misconduct or misuse of the study drug, failure to follow the protocols, or the subject's failure to follow instructions or any pre-existing medical condition;
  - (r) **(Governing law)** The agreement is governed by the laws of the Commonwealth of Massachusetts.

## 10.2 Research Development Services Agreement

In accordance with the Master Clinical Study Agreement with Serena set out above, TR Therapeutics has entered into a Research Development Services Agreement with Serena dated 21 March 2016 under which Serena agrees to assist TR Therapeutics in product development and research activities, including in relation to the development of a Phase IIB study for TR-987, to meet FDA standards. Under the agreement Serena agrees to develop the protocol and logistics for the study, contract with clinical sites to test TR-987, and engage with the institutional review board to ensure the objectivity of research and the protection of human subjects. The agreement terminates at the time that the Master Clinical Study Agreement terminates.

## 10.3 Master agreement for process development and scale up of $\beta$ -glucan drug substance for Phase III clinical trials with PCI Synthesis

The Company has entered into an agreement with PCI Synthesis, a contract manufacturing organisation, to conduct development and manufacturing activities in relation to the scale up of TR-987 production. This will facilitate the production of batches of the Company's product for use in its Phase III clinical trials. The material terms of the agreement are as follows:

- (a) **(Work orders)** The Company will engage PCI Synthesis for services described in work orders which will be appended to the master agreement. The work orders will specify the material terms for the project and may include the scope of work, services, timetables, milestones, quantities, budgets and other details;
- (b) **(Materials)** In the event that the Company provides any materials or requires PCI Synthesis to source any raw materials from a specific supplier, the Company is responsible for timely delivery of such materials and their conformity to the specification required;
- (c) **(Confidentiality)** The agreement contains standard confidentiality provisions for an agreement of this nature;

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## 10. Material Contracts Continued

- (d) **(Intellectual Property)** All rights in the Company's intellectual property remains vested in the Company and the Company grants a licence to PCI Synthesis to use any of its intellectual property communicated to PCI Synthesis in order for PCI Synthesis to undertake any work order. All rights to PCI Synthesis' intellectual property remains vested in PCI Synthesis. All improvements to the product resulting from PCI Synthesis' performance of a work order are assigned to the Company. In circumstances where the improvement relies on PCI Synthesis' intellectual property or background intellectual property, PCI Synthesis grants a non-exclusive worldwide, free of charge and perpetual licence to the Company for use of such intellectual property in the manufacture of the product. Each party retains its rights to its own background intellectual property;
- (e) **(Termination)** Either party may terminate the agreement or any work order that is pending by written notice to the other party in the event of insolvency, unremedied material breach and/or a force majeure event;
- (f) **(Expiration)** The agreement expires upon conclusion of services under all outstanding work orders;
- (g) **(Warranty)** PCI Synthesis warrants that the services will be performed with requisite care, skill and diligence, in accordance with applicable laws and industry standards, and by individuals who are appropriately qualified and trained;
- (h) **(Indemnification)** Each party indemnifies the other from any losses brought by a third party based on the use under the agreement of any intellectual property provided or licensed to it and used in its performance of its obligations under the agreement;
- (i) **(Limitation of liability)** Neither party is liable for any direct, special or consequential loss or damage. Except in cases of gross negligence and wilful misconduct causing personal injury or death, PCI Synthesis' liability in relation to the agreement is limited to the total amount paid by the Company under the relevant work order that gave rise to the claim. The limitations on liability do not apply to damages resulting from breaches by a party of its duty of confidentiality and the parties' indemnification obligations;
- (j) **(Governing law)** The agreement is governed by the laws of the Commonwealth of Massachusetts.

### 10.4 Convertible note deed poll

The Company issued 7,500,000 convertible notes at \$1.00 per note (**Convertible Notes**) to several investors (**Convertible Note Holders**) pursuant to a convertible note deed poll dated 30 April 2021 (**Convertible Note Deeds**), raising \$7,500,000 (**Note Subscription Amount**). The intended use of the Note Subscription Amount is primarily to provide capital to prepare for and complete the Offer, and to enable the Company to commence preparations in advance of its Phase III clinical trials.

The Convertible Notes issued under the terms of the Convertible Note Deed are unsecured obligations but are convertible to fully paid ordinary shares in the Company. The Convertible Notes will automatically convert to fully paid ordinary shares on the business day immediately prior to the Allotment Date.

The material terms of the Convertible Note Deeds are as follows. On successful Completion it is currently expected that the Conversion Price (defined below) will be the Offer Price less 20%, as contemplated in item (b) below:

- (a) **(Conversion)** the Convertible Notes automatically convert into fully paid ordinary shares on the earliest of:
  - (i) the maturity date, being 31 December 2022 (**Maturity Date**);
  - (ii) one business day immediately prior to the Allotment Date;
  - (iii) at least one business day prior to the completion of a trade sale, subject to conditions specified in the Convertible Note Deeds; and
  - (iv) an event of default (see 10.4(e) below).

At the election of a Convertible Note Holder, the Company will convert the Convertible Notes one business day prior to the allotment date of shares offered under an equity capital raising (other than the Offer).

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- (b) **(Conversion shares)** the number of conversion shares to be issued to the Convertible Note Holder upon conversion is calculated as follows:

$$A = B/C$$

Where:

A = number of Shares to be issued to the relevant Convertible Note Holder (rounded up to the nearest whole number);

B = the total subscription price paid by the Convertible Note Holder in respect of their Convertible Notes; and

C = Conversion Price, being the lower of:

- (i) in the case of:

- (A) an initial public offer, the Offer Price;
- (B) any other equity capital raising, the weighted average price at which shares are issued under that equity capital raising;
- (C) a trade sale by sale of Shares, the actual price per Share paid (on a fully diluted basis) by the purchaser;
- (D) a trade sale by sale of assets, the value attributable to each Share based on the amount available for distribution to Shareholders (on a fully diluted basis) assuming the total proceeds of the asset sale are distributed to Shareholders following conversion; and
- (E) conversion on the Maturity Date, the fair market value of each Share prior to the conversion, as determined by an independent accountant,

less:

- (F) 20% where the conversion event occurs prior to 28 February 2022;
- (G) 25% where the conversion event occurs after 28 February 2022 but prior to the Maturity Date; and
- (H) 30% where the conversion event occurs on the Maturity Date; and

- (ii) \$60,000,000 divided by the total number of Shares in the Company (on a fully diluted basis) on issue immediately prior to the conversion of the Convertible Notes.

- (c) **(Note terms)** each Convertible Note:

- (i) is issued with a face value of \$1.00 per note;
- (ii) bears no interest;
- (iii) is unsecured;
- (iv) is non-redeemable (except in specified circumstances arising as part of a trade sale).

- (d) **(Ranking)** the Convertible Notes:

- (i) rank equally in all respects with each other and among all other convertible notes issued on identical terms;
- (ii) rank above the equity securities on issue in the Company as at the completion date under the deed poll and any equity securities to be issued past that date; and
- (iii) will be subordinate to any existing third party debt of the Company in existence as at the completion date under the deed poll.

Shares issued upon conversion of the Convertible Notes will rank equally in all respects with other Shares on issue.

- (e) **(Event of default)**: an event of default occurs if:

- (i) an order is made or an effective resolution passed for winding up of the Company (other than for the purposes of or in the course of a solvent reorganisation, reconstruction or amalgamation previously approved by the Convertible Note Holder);
- (ii) any administration order has been made by a court of competent jurisdiction or any administrator has been appointed in respect of the Company; or

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## 10. Material Contracts Continued

- (iii) the Company (other than in the course of a trade sale, reorganisation, reconstruction, or amalgamation with another company) ceases or threatens to cease to carry on its business or a substantial part of its business;
  - (iv) the Company enters into an arrangement or composition with one or more of its creditors, or an assignment for the benefit of one or more of its creditors;
  - (v) the Company proposes a winding-up or dissolution or reorganisation, moratorium, deed of company arrangement or other administration involving one or more of its creditors; or
  - (vi) it is taken to have failed to comply with a statutory demand as a result of a section of 459F(1) of the Corporations Act;
- (f) **(Transfer):** Convertible Notes may not be transferred without the prior written approval of the Company.

### 10.5 Asset sale agreement

TR Therapeutics entered into an asset sale agreement dated 27 July 2012 with Novogen Research Pty Ltd, Glycotex, Inc (**Sellers**) and Novogen Limited in relation to Tissue Repair's purchase of the intellectual property and related assets of the Sellers, relating to the business of research and development, and commercialisation of glucan technology for therapeutic use.

### 10.6 Executive contracts

The Company has entered into:

- a service agreement dated 7 October 2021 with Tony Charara, under which Mr Charara has agreed to act as an Executive Director of the Company. As set out in section 6.4.1, Mr Charara will be paid \$50,000 per annum for his role as a Director, and may also be entitled to a cash bonus payment to be determined at the discretion of the Board.
- an employment agreement commencing 7 June 2021 with Dr Darryl Reed, under which Dr Reed has agreed to act as the Company's chief operating officer. Dr Reed will be paid \$273,750 (including superannuation). Dr Reed's employment agreement specifically provides for the issue of Options (see Section 6.7 for details) and contemplates the payment of annual cash bonuses at the discretion of the Board.

The agreements with key executives each contain standard terms and conditions for agreements of their nature, including in relation to confidentiality, restraint on competition and retention of intellectual property provisions. The agreements can be terminated by either the executive or the Company. Each executive is eligible to participate in any Company incentive plan.

### 10.7 Chief Financial Officer and Company Secretarial services

The Company has engaged:

- Bio101 Financial Advisory Pty Ltd (**Bio101**) to provide accounting and chief financial officer services to the Company. Under the terms of the agreement with the Company, Bio101 agrees to provide assistance and advice in relation to listing on ASX, basic bookkeeping functions, preparation of accounts, workpapers and the Company's annual report and financial statements, payroll services and assistance with insurance requirements. Bio101 provides the agreed services at hourly rates ranging from \$100-\$250. The agreement continues in force until it is terminated in accordance with its terms;
- Automic to provide company secretarial services to the Company, to be delivered by Alistair McKeough as the named company secretary. Under the terms of the agreement Automic will provide company secretarial advice and compliance, advice and assistance with ASIC and ASX requirements, provide support for board meetings and the annual general meeting and attend to other administrative matters. The services provided by Automic following the Offer will be on the basis of a \$4,800 monthly fee, with additional consulting work charged hourly, with rates ranging from \$300-\$600 per hour. The agreement continues for a minimum period of 36 months and will automatically renew for successive 12 month terms.

The agreements for outsourced services set out above contain terms consistent with similar arrangements, including provisions in respect of confidentiality and intellectual property.

## 10.8 Escrow

### 10.8.1 Mandatory escrow

It is expected that some or all of the Existing Shares may be classified by the ASX as restricted securities, applying the ASX Listing Rules and its discretion. In addition, certain Options on issue upon Listing, and Shares to be issued upon conversion of the Options and Convertible Notes may also be classified by the ASX as restricted securities.

ASX retains discretion as to the restrictions that it may impose on the Company's existing securities. The Company believes that the following escrow arrangements are likely to apply, subject to ASX's discretion.

Shareholder	Number of escrowed Shares	Escrow Period	Number of escrowed Options	Escrow Period
Selene Holdings Pty Limited	4,949,143	24 months from Official Quotation		
Spark Capital Pty Limited	4,656,830	24 months from Official Quotation	13,640,000	24 months from Official Quotation
Creight Investments Pty Ltd	3,926,395	24 months from Official Quotation	2,500,000	24 months from Official Quotation
Other Shareholders	3,770,440 225,640 41,700 152,120	Until 30 April 2022 Until 7 October 2022 12 months from Listing 24 months from Official Quotation	1,464,240	24 months from Official Quotation

### 10.8.2 Voluntary escrow

Each Escrowed Securityholder has agreed to enter into an Escrow Deed in respect of their Shareholding and/or Option holding commencing from Official Quotation in addition to any mandatory escrow, which prevents them from disposing of their respective Escrowed Securities for the applicable escrow period as described below.

Shareholder	Number of escrowed Shares	Escrow Period
Selene Holdings Limited	1,006,837	6 months from Official Quotation
Spark Capital Pty Limited	4,656,830	30 months from Official Quotation
Creight Investments Pty Ltd	95,865	6 months from Official Quotation
Other Shareholders	3,603,852 14,415,408	6 months from Official Quotation 24 months from Official Quotation

Option holder	Number of escrowed Options	Escrow Period
Spark Capital Pty Limited	13,640,000	30 months from Official Quotation
Other Existing Option Holders	887,268 3,549,072	6 months from Official Quotation 24 months from Official Quotation

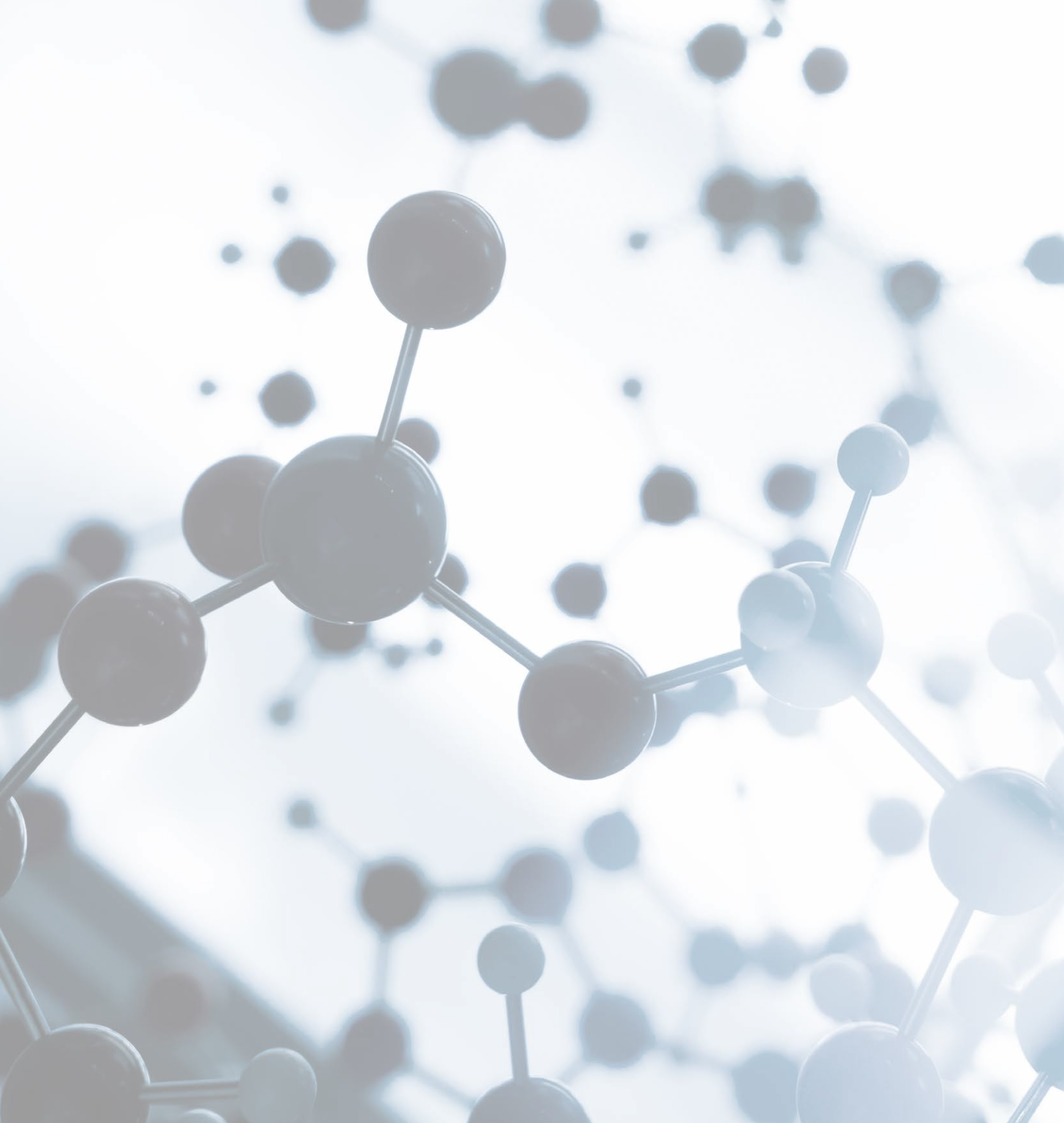


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## 10. Material Contracts Continued

The Escrow Deeds provide that:

- (a) Escrowed Securityholders must not:
  - (i) dispose of, or agree to offer to dispose of the Escrowed Securities;
  - (ii) create, or agree or offer to create, any security interest in the Escrowed Securities unless otherwise permitted under the Escrow Deed; or
  - (iii) do, or omit to do, any act if the act or omission would have the effect of transferring effective ownership or control of the Escrowed Securities;
- (b) the Company and Escrowed Securityholders agree to comply with chapter 9 of the ASX Listing Rules;
- (c) the Escrowed Securities will be registered and held by the Escrowed Securityholder on the issuer sponsored subregister and the Company may apply a holding lock to the Escrowed Securities during the relevant period;
- (d) the restrictions referred to under (a) above do not apply in certain circumstances, including:
  - (i) a takeover bid where the holders of at least 50% of the Shares that are not subject to escrow have accepted the offer, or proportional takeover bid approved by the Company in a general meeting;
  - (ii) a merger by way of scheme or arrangement under Part 5.1 of the Corporations Act;
  - (iii) a buy back or capital reduction, to the extent necessary to allow for any of the Escrowed Securities to be transferred or cancelled as part of any Share buyback or return of capital or other similar pro rata reorganisation or an acquisition of all Shares;
  - (iv) to the extent necessary to allow a reorganisation or change of trustee of the Escrowed Securityholder;
  - (v) where required by law;
  - (vi) in the event of a request by the Escrowed Securityholder, agreed to by the Company in writing; or
  - (vii) a transfer to a related body corporate or subsidiary where the transferee agrees to be bound by the same restrictions as the Escrowed Securityholder.



## 11. Additional Information



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# 11. Additional Information

## 11.1 Company information

The Company was incorporated on 17 May 2012 under the Corporations Act as a proprietary company limited by shares. On 13 August 2021, the Company converted to a public company limited by shares. The Company will be taxed as a public company and its statutory accounts will be made up to 30 June annually.

## 11.2 Corporate structure

The Company wholly owns TR Therapeutics, Inc., a US-based entity incorporated in Delaware with File Number: 5159694. TR Therapeutics is the operating subsidiary of the Company in the United States, and the Company's only subsidiary as at the date of this Prospectus. Refer to Section 3.2 for further detail.

## 11.3 Capital structure

The issued capital of the Company as at the Prospectus Date is set out at Section 7.1.3.

Prior to the Allotment Date, the following changes will occur to the capital structure of the Company, under the terms of the Convertible Notes and under the Share Split:

- Each Existing Share will be split into a larger number of shares (with each holding rounded to the nearest whole number) in accordance with the following ratio: 1:20;
- Each Option will be reconstructed to mirror the Share Split; and
- The Convertible Notes will convert into Shares in accordance with their terms as set out at 10.4.

On or around the Listing Date the Company will:

- issue Options under the Current Incentive Plan as set out in Section 6.9; and
- issue 132,980 Shares to Tissue Repair's Directors and other consultants and service providers.

The issued capital for the Company as at Listing is set out at Section 7.1.3

## 11.4 Company's Constitution: rights attaching to Shares

The Shares the subject of the Offer are fully paid ordinary shares in the capital of the Company. A summary of the rights, liabilities and obligations attaching to the Shares, and a description of other material provisions of the Constitution are set out below. This summary is not exhaustive and is qualified by the full terms of the Constitution, which is available from the Company on request free of charge.

This summary does not constitute a definitive statement of the rights and liabilities of the Shareholders, which can involve complex questions of law arising from the Constitution's interaction with statutory and common law requirements. Shareholders should seek legal advice in relation to any definitive assessment of the rights and liabilities attached to Shares in any specific circumstances.

### 11.4.1 Ranking

At the date of this Prospectus, the Company's only class of shares on issue is ordinary shares which rank equally in all respects. From their date of issue, the Shares offered under this Prospectus will rank equally with the Company's Existing Shares.

### 11.4.2 General meetings

Shareholders are entitled to be present in person, or by proxy, attorney or representative to attend and vote at general meetings of the Company. Shareholders may requisition general meetings in accordance with the Corporations Act and the Constitution.

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### **11.4.3 Voting**

At a general meeting of the Company, every Shareholder present in person, or by proxy, attorney or representative shall on a show of hands have one vote and upon a poll every Shareholder present in person or by proxy, attorney or representative has one vote for every Share held.

### **11.4.4 Winding up**

Shareholders will be entitled in a winding up to share in any surplus assets of the Company in proportion to the capital paid up on the Shares held.

### **11.4.5 Transfer of Shares**

Shares in the Company may be transferred by a written transfer instrument, in any other form approved by the Directors or, at the discretion of the Directors, by a computerised or electronic system for market settlement, securities transfer and registration conducted in accordance with the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules. The Directors may, subject to the ASX Listing Rules and the ASX Settlement Operating Rules, request an ASX approved clearing and settlement facility to apply a holding lock to prevent any transfer of Shares. The Directors may refuse to register a paper based transfer of a Share in particular circumstances.

### **11.4.6 Variation of class rights**

The rights attached to any class of shares may be varied or cancelled with the consent in writing of the holders of shares of that class who are entitled to at least 75% of the votes that may be cast in respect of the shares of that class or by special resolution passed at a meeting of the holders of the shares of that class.

### **11.4.7 Restricted securities**

If the ASX classifies any of the Company's share capital as restricted securities, then the restricted securities must not be disposed of, or agreed to be disposed of, during the escrow period and the Company must refuse to acknowledge a disposal of the restricted securities during the escrow period, except as permitted under the ASX Listing Rules or by the ASX.

### **11.4.8 Non-marketable parcels**

In accordance with the ASX Listing Rules, the Board may sell Shares which constitute less than a marketable parcel by following the procedures set out in the Constitution.

### **11.4.9 Dividends**

If the Directors determine that a final or interim dividend is payable, it is (subject to the terms of issue on any shares or class of shares) paid on all Shares proportionate to the amount paid up on each Share.

The Directors may set aside out of profits such amounts by way of reserves as they think appropriate to pay a dividend.

Subject to the ASX Listing Rules, the Directors may adopt and implement on the terms they think appropriate, one or more dividend reinvestment plans, under which a Shareholder may elect that the dividends payable by the Company be reinvested by a subscription for new Shares.

## **11.5 Legal proceedings**

There is no litigation of a material nature or threatened which may significantly affect the Company or its activities.

## **11.6 Directors responsibility statement**

The Directors of the Company state that for the purposes of section 731 of the Corporations Act, they have made all enquiries that were reasonable in the circumstances and have reasonable grounds to believe that any statements by them in this Prospectus are true and not misleading or deceptive, and that with respect to any other statements made in this Prospectus by persons other than the Directors, the Directors have made reasonable enquiries and have reasonable grounds to believe that persons making the statement or statements were competent to make such statements, those persons have given the consent required by section 716(2) of the Corporations Act and have not withdrawn that consent before lodgement of this Prospectus with ASIC.

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## 11. Additional Information Continued

This Prospectus is prepared on the basis that:

- certain matters may be reasonably expected to be known to professional advisers of the kind with whom Applicants may reasonably be expected to consult; and
- information is known to Applicants or their professional advisers by virtue of any legislation or laws of any State or Territory of Australia or the Commonwealth of Australia.

### 11.7 Consents and disclaimers

Chapter 6D of the Corporations Act imposes a liability regime on the Company (as the offeror of the Shares), the Directors of the Company, persons named in the Prospectus with their consent as proposed directors of the Company, any underwriters, persons named in the Prospectus with their consent as having made a statement in the Prospectus and persons involved in a contravention in relation to the Prospectus, with regard to misleading or deceptive statements made in the Prospectus. Although the Company bears the primary responsibility for the Prospectus, other parties involved in the preparation of the Prospectus can also be responsible for certain statements made in it.

In light of the above, each of the parties referred to below (each a consenting party), to the maximum extent permitted by law, expressly disclaims all liabilities in respect of, makes no representations with regard to, and takes no responsibility for, any statements in or omissions from this Prospectus, other than the reference to its name in the form and context in which it is named and a statement or report included in this Prospectus with its consent as specified below.

Each of the consenting parties has given and has not, before the lodgement of this Prospectus with ASIC, withdrawn its consent to be named in this Prospectus in the form and context in which it is named:

- Bell Potter Securities Limited
- Morgans Corporate Limited
- Mills Oakley
- Pitcher Partners Sydney Partnership
- Pitcher Partners Sydney Corporate Finance Pty Ltd
- Automic Pty Ltd
- Bio101 Financial Advisory Pty Ltd
- each of the management personnel in Section 6.2
- each of the members of the scientific advisory board in Section 6.3
- SerenaGroup Inc
- PCI Synthesis

Pitcher Partners has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named as the Investigating Accountant in the form and context in which it is named and to the inclusion in this Prospectus of its Independent Limited Assurance Report set out in Section 8.

Pitcher Partners Sydney Partnership has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named in this Prospectus as auditor in the form and context in which it is named. Pitcher Partners Sydney Partnership has not authorised or caused the issue of this Prospectus and does not make or purport to make any statement in the Prospectus.

Mills Oakley has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named as Australian legal adviser in the form and context in which it is named and to the inclusion in this Prospectus of its Intellectual Property Report set out in Section 9.

Automic Pty Ltd has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named as Share Registry in the form and context in which it is named. The Share Registry has had no involvement in the preparation of any part of the Prospectus other than being named as Share Registrar to the Company and has not authorised or caused the issue of, and expressly disclaims and takes no responsibility for, any part of the Prospectus.

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## 11.8 Interests of experts and advisers

The Company has engaged the following professional advisers in relation to the Offer:

- Bell Potter Securities Limited has acted as joint lead manager to the Offer and the fees payable to Bell Potter Securities Limited are described in Section 6.5;
- Morgans Corporate Limited has acted as joint lead manager to the Offer and the fees payable to Morgans Corporate Limited are described in Section 6.5;
- Mills Oakley has acted as Australian legal adviser to the Company in relation to the Offer and the Company has paid, or agreed to pay, approximately \$280,000 (excluding disbursements and GST) for the services up to the Prospectus Date. Further amounts may be paid to Mills Oakley in accordance with its normal time-based charges; and
- Pitcher Partners has acted as the Investigating Accountant on, and has performed work in relation to due diligence enquiries, the Financial Information in relation to the Offer and has performed work in relation to its Investigating Accountant's Report in Section 8. The Company has paid, or agreed to pay, approximately \$75,000 (excluding disbursements and GST) for these services up to the date of this Prospectus.
- Pitcher Partners Sydney Partnership has acted as the independent Auditor to the Company and will be paid an estimated fee of \$75,000 for the audit of the financial reports for the financial years ending 30 June 2019, 30 June 2020 and 30 June 2021.

These amounts, and other expenses of the Offer will be paid by the Company out of funds raised under the Offer or available cash. Further information on the use of proceeds and payment of expenses of the Offer is set out in Section 7.1.2.

## 11.9 Investor considerations

Before deciding to participate in this Offer, you should consider whether the Shares to be issued are a suitable investment for you. There are general risks associated with any investment in the stock market. The value of Shares listed on the ASX may rise or fall depending on a range of factors beyond the control of the Company. You should carefully read the key risks set out in Section 5. If you are in doubt as to the course you should follow, you should seek advice on the matters contained in this Prospectus from a stockbroker, solicitor, accountant or other professional adviser.

The potential tax effects relating to the Offer will vary between investors. Investors are urged to consider the possible tax consequences of participating in the Offer by consulting a professional tax adviser.

## 11.10 Expenses of the Offer

The total expenses of the Offer payable by the Company including ASX and ASIC fees, management fees, accounting fees, legal fees, share registry fees, printing costs, public relations costs and other miscellaneous expenses are estimated to be approximately \$2.3 million.

## 11.11 Electronic Prospectus

This Prospectus is available in electronic form at [www.tissuerepair.com.au](http://www.tissuerepair.com.au). Any person receiving this Prospectus electronically will, on request, be sent a paper copy of the Prospectus by the Company free of charge until the Closing Date.

Applications must be made by completing a paper copy of an Application Form. The Company does not accept Application Forms electronically.

An Application Form may only be distributed attached to a complete and unaltered copy of the Prospectus. An Application Form included with this Prospectus contains a declaration that the investor has personally received the complete and unaltered Prospectus before completing the relevant Application Form.

The Company will not accept a completed Application Form if it has reason to believe that the Applicant has not received a complete paper copy or electronic copy of the Prospectus or if it has reason to believe that the Application Form or electronic copy of the Prospectus has been altered or tampered with in any way.

While the Company believes that it is extremely unlikely that during the period of the Offer the electronic version of the Prospectus will be altered in any way, the Company cannot give any absolute assurance that this will not occur. Any investor in doubt about the validity or integrity of an electronic copy of the Prospectus should immediately request a paper copy of the Prospectus directly from the Company or a financial adviser.

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## 11. Additional Information Continued

### 11.12 Australian tax considerations

The comments below provide a general summary of Australian tax issues for Shareholders who are Australian residents for income tax purposes (**Australian tax resident Shareholders**) who acquire Shares under this Prospectus and hold their Shares on capital account. Different tax implications apply to non-resident Shareholders and Shareholders who hold their Shares on revenue account.

This summary does not purport to be a complete analysis of the tax laws of Australia or the potential tax consequences for Shareholders and is intended to be a general guide to the Australian tax implications only. It should not be a substitute for advice from a professional advisor and all Shareholders are strongly encouraged to obtain their own professional advice on the tax implications based on their own specific circumstances.

#### 11.12.1 Dividends paid on Shares

##### **Australian resident individuals and complying superannuation entities**

Dividends paid by the Company on a Share will constitute assessable income of an Australian tax resident Shareholder. Australian tax resident Shareholders who are individuals or complying superannuation entities should include the dividend in their assessable income in the year the dividend is paid, together with any franking credit attached to that dividend. Such Shareholders should be entitled to an income tax offset equal to the franking credit attached to the dividend, subject to being a “qualified person” (refer comments below). Where the income tax offset exceeds the tax payable on the investor’s taxable income, such Shareholders should be entitled to a tax refund.

To the extent that the dividend paid by the Company is unfranked, the investor will generally be taxed at their prevailing marginal rate on the dividend received with no income tax offset.

##### **Corporate Shareholders**

Shareholders that are corporations (**Corporate Shareholders**) are also required to include both the dividend and the associated franking credit in their assessable income. An income tax offset is then available up to the amount of the franking credit attached to the dividend. An Australian tax resident Corporate Shareholder should be entitled to a credit in its own franking account to the extent of the franking credit on the dividend received. This allows the Corporate Shareholder to pass on the benefit of the franking credits to their own shareholders on the payment of dividends. Any difference in the corporate tax rate and franking rate for the Company and a Corporate Shareholder may impact the return to the Corporate Shareholders’ own shareholders.

Excess franking credits received by Corporate Shareholders cannot give rise to a refund, however may be converted into carry forward income tax losses.

##### **Trusts and partnerships**

Shareholders who are trustees (other than trustees of complying superannuation entities) or partnerships should include the dividend and associated franking credit in determining the net income of the trust or partnership. There are special rules that apply in relation to the receipt of franked dividends through a trust or partnership, and subject to satisfying these rules, the relevant beneficiary or partner may be entitled to an income tax offset equal to the beneficiary or partner’s share of the franked dividend that was included in the net income of the trust or partnership.

##### **Qualified persons**

The benefit of franking credits can be denied where a Shareholder is not a “qualified person”, in which case the Shareholder will not need to include an amount for the franking credits in their assessable income and will not be entitled to an income tax offset.

Broadly, to be a qualified person, a Shareholder must satisfy the holding period rule and, if necessary, the related payment rule. The holding period rule requires a Shareholder to hold the Shares “at risk” for more than 45 days continuously, measured as the period commencing the day after the Shares were acquired and ending on the 45th day after the Shares become ex-dividend. The dates the Shares are acquired and disposed of are ignored for the purposes of determining the 45-day period. Any day on which a Shareholder has a materially diminished risk of loss or opportunity for gain (through transactions such as Options or warrants over Shares or entering into a contract to sell the Shares) will not be counted as a day where the Shareholder has held the Shares “at risk”.



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The holding period rule is subject to certain exceptions, including where the total franking offsets of an individual in a year of income do not exceed \$5,000. Special rules apply to trusts and beneficiaries.

Under the related payment rule, a different testing period applies where the Shareholder has made, or is under an obligation to make, a related payment in relation to the dividend paid by the Company. The related payment rule requires the Shareholder to have held the Shares at risk for the continuous 45-day period as above but within the period commencing on the 45th day before, and ending on the 45th day after the day the Shares become ex-dividend. Investors should seek professional advice to determine if these requirements, as they apply to them, have been satisfied.

### 11.12.2 Disposal of Shares

The disposal of a Share by a Shareholder will be a Capital Gains Tax (CGT) event. A capital gain will arise where the capital proceeds received on disposal exceeds the CGT cost base of the Share (broadly the amount paid to acquire the share plus any transaction/incidental costs). In the case of an arm's length on-market sale, the capital proceeds will generally be the cash proceeds received from the sale of Shares.

A capital loss will be incurred where the reduced cost base of the Shares exceeds the capital proceeds. Capital losses may only be offset against capital gains derived by the taxpayer in the same or future income years, subject to certain loss recoupment tests being satisfied. Capital losses cannot be offset against other assessable income.

A CGT discount may be available on the capital gain for Shareholders that are individuals, trustees or complying superannuation entities provided the particular Shares are held for more than 12 months prior to sale. Any current year or carry forward capital losses should offset the capital gain first before the CGT discount can be applied.

The CGT discount for individuals and trusts is 50% and for complying superannuation entities is 33.33%. In relation to trusts, the rules are complex, but this discount may flow up to beneficiaries of the trust.

A company is not entitled to a CGT discount.

### 11.12.3 Tax File Numbers

A Shareholder is not required to provide their Tax File Number (**TFN**) to the Company. However, if TFN or exemption details are not provided, Australian tax may be required to be deducted by the Company from distributions at the top marginal tax rate plus the Medicare levy.

A Shareholder that holds Shares as part of an enterprise may quote its Australian Business Number (**ABN**) rather than its TFN.

### 11.12.4 Australian Goods and Services Tax

Shareholders should not be liable for Australian Goods and Services Tax (**GST**) in respect of their acquisition or disposal of Shares.

An Australian resident Shareholder that is registered for GST may not be entitled to claim full input tax credits in respect of GST on expenses they incur that relate to the acquisition, redemption or disposal of the Shares. Shareholders should seek their own advice on the impact of GST in their own particular circumstances.

### 11.12.5 Stamp duty

No stamp duty should be payable by Shareholders on the acquisition of Shares in the Company.

Investors should seek their own advice as to the impact of stamp duty in their own particular circumstances.

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## 11. Additional Information Continued

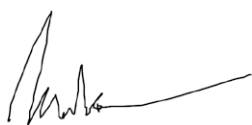
### 11.13 Governing Law

This Prospectus, the Offer and the contracts formed on acceptance of Applications under the Offer are governed by the laws in force in the state of New South Wales, Australia and each Applicant submits to the non-exclusive jurisdiction of the courts of New South Wales, Australia.

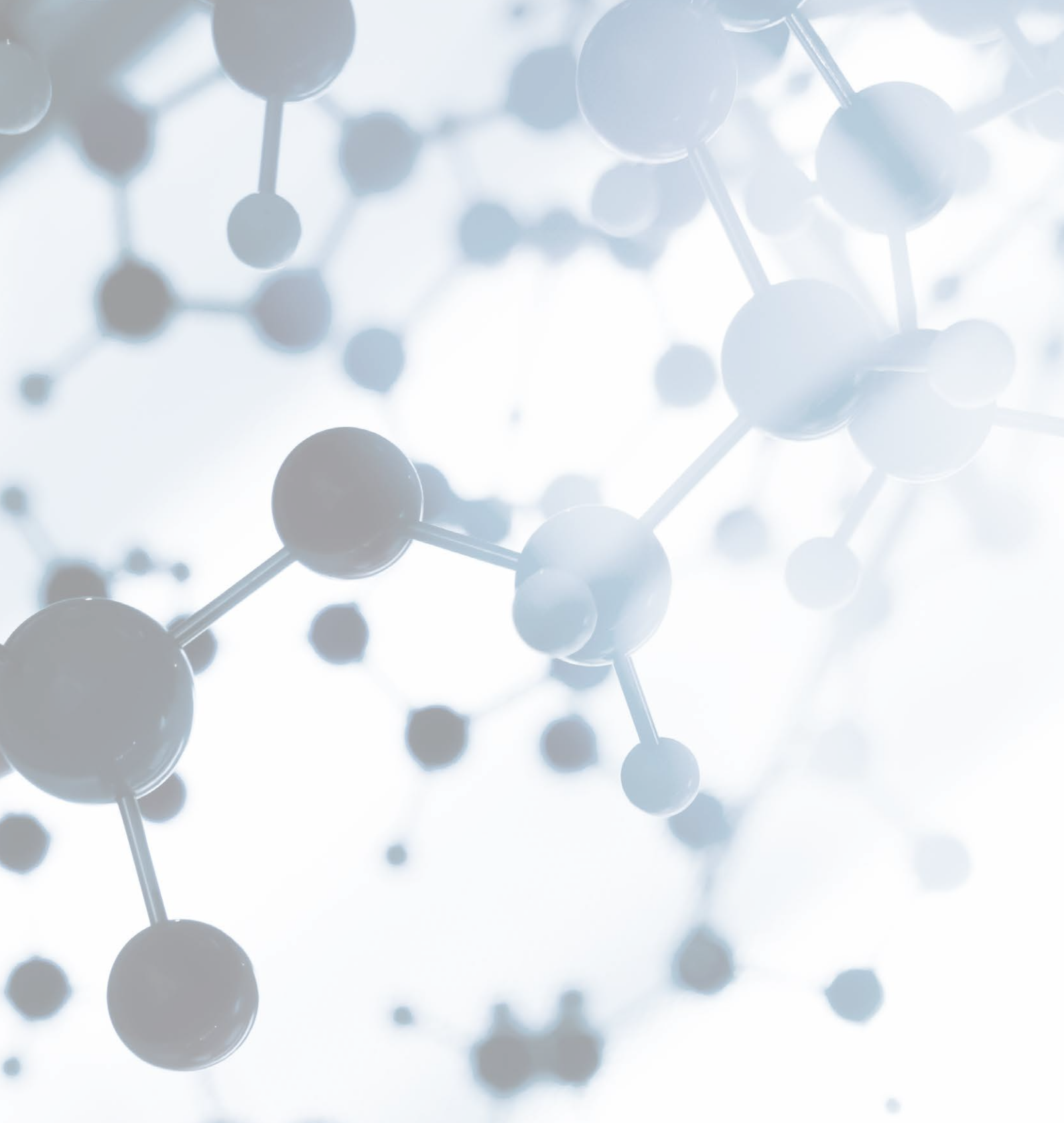
### 11.14 Authorisation

This Prospectus is issued by the Company. Each Director consented (and has not withdrawn their consent) to the lodgement of this Prospectus with ASIC.

Dated 7 October 2021

A handwritten signature in black ink, appearing to read 'Jack Lowenstein', with a long horizontal stroke extending to the right.

**Jack Lowenstein**  
Non-Executive Chair



## 12. Glossary



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## 12. Glossary

In this document:

<b>AAS</b>	means Australian Accounting Standards.
<b>AASB</b>	means Australian Accounting Standards Board.
<b>Allotment Date</b>	means the date the Company anticipates the Shares will be allotted and issued to Applicants.
<b>API</b>	means active pharmaceutical ingredient.
<b>Applicant</b>	means a person or entity who submits an Application Form.
<b>Application</b>	means an application to subscribe for Shares under this Prospectus.
<b>Application Form</b>	means an application form attached to this Prospectus.
<b>Application Money or Application Monies</b>	means the money received by the Company under the Offer, being the Offer Price multiplied by the number of Shares applied for.
<b>ASIC</b>	means Australian Securities and Investments Commission.
<b>ASX</b>	means ASX Limited ACN 008 624 691 or the securities exchange operated by it (as the case requires).
<b>ASX Listing Rules</b>	means the listing rules of the ASX.
<b>ASX Settlement</b>	means ASX Settlement Pty Ltd ACN 008 504 532.
<b>ASX Settlement Operating Rules</b>	means the ASX Settlement Operating Rules, being the operating rules of the Settlement Facility for the purposes of the Corporations Act.
<b>Board or Board of Directors</b>	means the board of directors of the Company.
<b>Bookbuild</b>	means the process through which Institutional Investors may be invited to bid under the Institutional Offer as described in Section 7.4.
<b>Broker</b>	means any ASX participating organisation appointed to act as a broker to the Offer.
<b>Broker Firm Offer</b>	means the offer of Shares under this Prospectus to eligible Australian resident retail clients of Brokers as described in Section 7.3.
<b>CHESS</b>	means Clearing House Electronic Subregister System, operated by ASX Settlement.

<b>Closing Date</b>	means the date on which the Offer closes, being Friday 29 October 2021, or another date nominated by the Company in consultation with the Lead Managers.
<b>Company</b>	means Tissue Repair Ltd ACN 158 411 566.
<b>Completion</b>	means the completion of the Offer, being the date on which Shares are issued or transferred to successful Applicants in accordance with the terms of the Offer.
<b>Constitution</b>	means the Company's constitution adopted on 13 August 2021.
<b>Convertible Notes</b>	has the meaning given in section 10.4.
<b>Corporations Act</b>	means the <i>Corporations Act 2001</i> (Cth), as in force from time to time.
<b>Director</b>	means director of the Company and Directors means all of them.
<b>Escrow Deeds</b>	means the escrow deeds entered into between the Company and the Escrowed Securityholders as described in Section 10.8.2.
<b>Escrowed Securityholders</b>	means the Shareholders and/or Option holders who are subject to restrictions on their ability to sell their Shares and/or Options as described in Section 10.8.2.
<b>Escrowed Securities</b>	means each of the Shares and/or Options held by the Escrowed Securityholders at Listing (other than any Shares issued in connection with the Offer).
<b>Existing Shareholders</b>	means the holders of Shares before the date of this Prospectus.
<b>Existing Shares</b>	means the Shares on issue before the date of this Prospectus.
<b>Expiry Date</b>	means the date that is 13 months after the Prospectus Date.
<b>FDA</b>	means the United States Food and Drug Administration.
<b>Glucoprime</b>	means Glucoprime™, Tissue Repair's unique active pharmaceutical ingredient.
<b>Group</b>	means the Company and its subsidiaries.
<b>IND</b>	means Investigational New Drug Application.
<b>Institutional Investors</b>	means the investors participating in the Institutional Offer.
<b>Institutional Offer</b>	means the offer of shares described in Section 7.4.

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## 12. Glossary Continued

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<b>Investigating Accountant's Report or Independent Limited Assurance Report</b>	means the report prepared by Pitcher Partners and provided at Section 8.
<b>Intellectual Property Report</b>	means the intellectual property report prepared by Mills Oakley and provided at Section 9.
<b>Lead Managers</b>	means Bell Potter Securities Limited ACN 006 390 722 and Morgans Corporate Limited ABN 32 010 539 607.
<b>Listing</b>	means the Company being admitted to the Official List.
<b>Listing Date</b>	means the date that the Company is admitted to the Official List.
<b>Mills Oakley</b>	means Mills Oakley ABN 51 493 069 734.
<b>Minimum Subscription Amount</b>	means \$22 million. This is also the total amount to be raised under the Offer.
<b>Offer</b>	means the offer of Shares under this Prospectus, as described in Section 7.
<b>Offer Period</b>	means the period expected to be from Friday 22 October 2021 to Friday 29 October 2021 during which investors may subscribe for Shares under the Offer.
<b>Offer Price</b>	means \$1.15 per Share.
<b>Official List</b>	means the official list of ASX.
<b>Official Quotation</b>	means official quotation of the Company's Shares by ASX.
<b>Options</b>	means options to acquire Shares.
<b>Pitcher Partners or Investigating Accountant</b>	means Pitcher Partners Sydney Corporate Finance Pty Limited ACN 122 561 184.
<b>Pitcher Partners Sydney Partnership or Auditor</b>	means Pitcher Partners Sydney ABN 17 795 780 962.
<b>Prospectus</b>	means this prospectus.
<b>Prospectus Date</b>	means 7 October 2021.
<b>Settlement Facility</b>	has the meaning specified in the ASX Settlement Operating Rules.
<b>Share Registry or Automic</b>	means Automic Pty Ltd (ACN 152 260 814).

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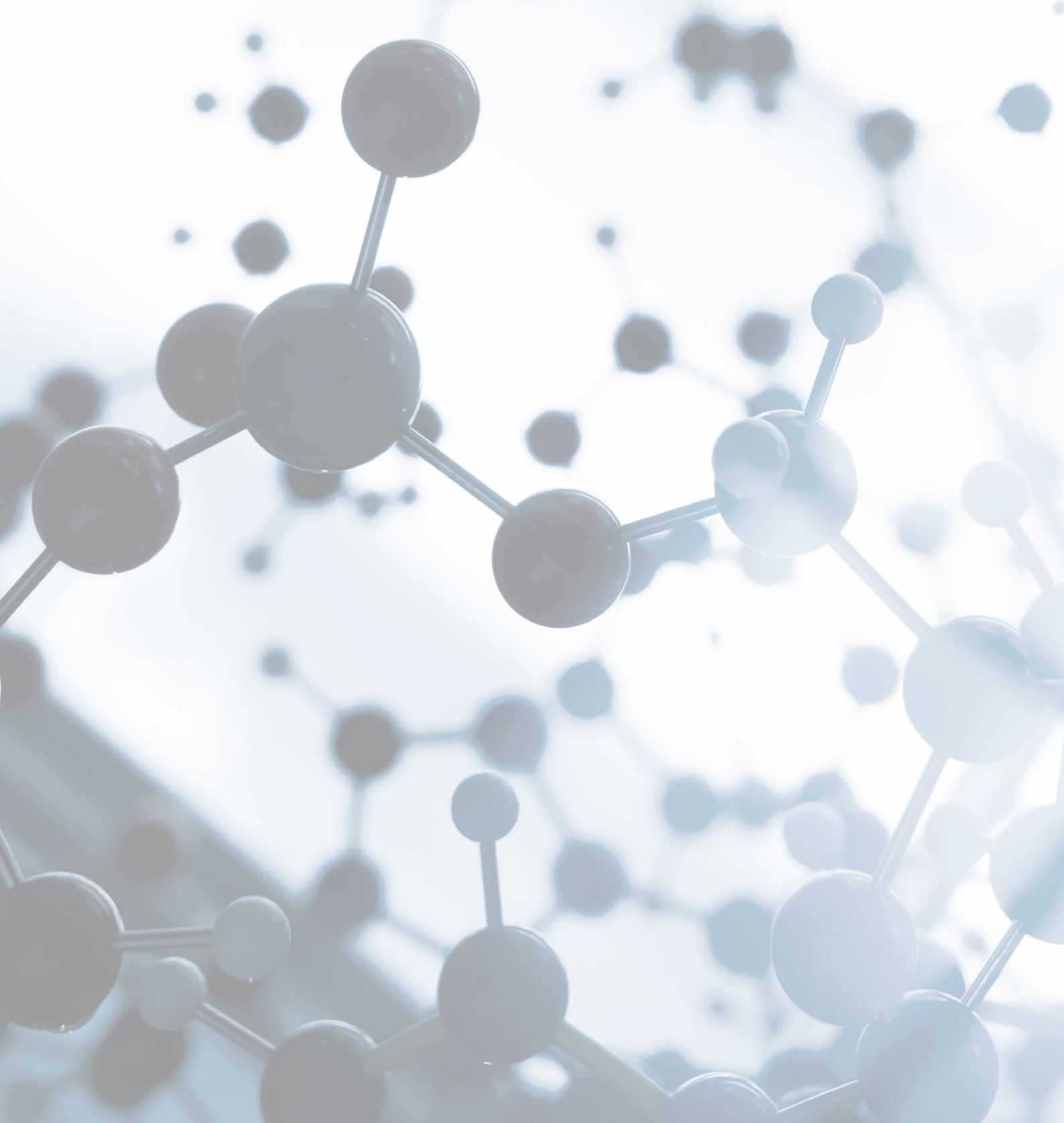
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<b>Share Split</b>	means the share subdivision approved by the Company's Shareholders on 1 July 2021.
<b>Shareholders</b>	means holders of shares in the Company.
<b>Shares</b>	means fully paid ordinary shares in the Company.
<b>TGA</b>	means the Therapeutic Goods Administration.
<b>Tissue Repair</b>	means the Company and/or TR Therapeutics, Inc, the Company's subsidiary, as the context requires.
<b>TR-987</b>	means Tissue Repair's chronic wound product.
<b>TR Pro+</b>	means Tissue Repair's aesthetic dermatology gel product.
<b>TR Therapeutics</b>	means TR Therapeutics, Inc, a US-based entity incorporated in Delaware with File Number: 5159694 and subsidiary of the Company.
<b>VLU</b>	means venous leg ulcer.
<b>You</b>	means the investors under this prospectus.

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## 13. Significant Accounting Policies



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## 13. Significant Accounting Policies

### (a) Basis of preparation

The Company's general purpose financial reports are prepared in accordance with Australian Accounting Standards, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standard Board and the *Corporations Act 2001*.

Australian Accounting Standards set out accounting policies that the AASB has concluded would result in a financial report containing relevant and reliable information about transactions, events and conditions. Compliance with Australian Accounting Standards ensures that the financial statements and notes also comply with International Financial Reporting Standards. Material accounting policies adopted in the preparation of this financial report are presented below. They have been consistently applied unless otherwise stated.

Except for cash flow information, the financial report has been prepared on an accruals basis and is based on historical costs, except for selected financial assets for which the fair value basis of accounting has been applied.

### Critical accounting estimates

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies.

### (b) Going concern

The financial statements have been prepared on a going concern basis which contemplates the realisation of assets and the settlement of liabilities in the normal course of business.

Following the proceeds from the IPO and based on the Company's cash flow forecast, the directors believe the Company should have sufficient funding for at least the next 24 months to undertake its stated business activities and to ensure the realisation of assets in the ordinary course of business and extinguishment of liabilities as and when they fall due.

### (c) Foreign currency translation

The functional and presentation currency of the Company is Australian dollars.

Foreign currency transactions are translated into the functional currency using the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the end of the reporting period. Foreign exchange gains and losses resulting from settling foreign currency transactions, as well as from restating foreign currency denominated monetary assets and liabilities, are recognised in profit or loss, except when they are deferred in other comprehensive income as qualifying cash flow hedges or where they relate to differences on foreign currency borrowings that provide a hedge against a net investment in a foreign entity.

Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when fair value was determined.

### (d) Revenue recognition

#### Revenue from contracts with customers

The Company currently has no revenue from the sale of goods or services.

#### Interest income

Interest income is recognised as interest accrues using the effective interest method. The effective interest method uses the effective interest rates which is the rate that exactly discounts the estimated future cash receipts over the expected future life of the financial asset.

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## 13. Significant Accounting Policies Continued

### **(e) Government grants**

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received, and the Company will comply with all attached conditions. Government grants relating to costs are deferred and recognised in the profit and loss over the period necessary to match them with the costs that they are intended to compensate.

### **(f) Income tax**

The income tax expense or revenue for the period is the tax payable on the current period's taxable income based on the income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences between the tax base of assets and liabilities and their carrying amounts in the financial statements, and to unused tax losses.

Deferred tax assets are only recognised to the extent that it is probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

### **(g) Contributed equity**

Costs directly attributable to the issue of new shares are shown as a deduction from the equity as a deduction proceeds net of any income tax benefit. Costs directly attributable to the issue of new shares or options associated with the acquisition of a business are included as part of the purchase consideration.

### **(h) Adoption of New and Revised Accounting Standards**

The Company has adopted all of the new, revised or amending Accounting Standard and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period. This includes AASB 16 Leases which had no impact on the Group's financial statements.

Any new, revised or amending Accounting Standards or Interpretations that are not yet mandatory have not been early adopted. There are no expected impacts of pending standards not yet mandatory.



## CORRECT FORMS OF REGISTRABLE TITLE

Type of Investor	Correct Form of Registration	Incorrect Form of Registration
Individual	Mr John Richard Sample	J R Sample
Joint Holdings	Mr John Richard Sample & Mrs Anne Sample	John Richard & Anne Sample
Company	ABC Pty Ltd	ABC P/L or ABC Co
Trusts	Mr John Richard Sample <Sample Family A/C>	John Sample Family Company
Superannuation Funds	Mr John Sample & Mrs Anne Sample <Sample Family Super A/C>	John & Anne Superannuation Fund
Partnerships	Mr John Sample & Mr Richard Sample <Sample & Son A/C>	John Sample & Son
Clubs/Unincorporated Bodies	Mr John Sample <Health Club A/C>	Health Club
Deceased Estates	Mr John Sample <Estate Late Anne Sample A/C>	Anne Sample (Deceased)

## INSTRUCTIONS FOR COMPLETING THE FORM

### YOU SHOULD READ THE PROSPECTUS CAREFULLY BEFORE COMPLETING THIS BROKER FIRM OFFER APPLICATION FORM.

This is an Application Form for fully paid ordinary Shares in Tissue Repair Ltd (ACN 158 411 566) (**Company**) made under the terms of the Broker Firm Offer set out in the Prospectus dated 7 October 2021.

The Broker Firm Offer is open to Australian resident retail clients of Brokers who have received a firm allocation to apply for Shares under the Broker Firm Offer. If you have been offered a firm allocation by a Broker, you will be treated as an Applicant under the Broker Firm Offer in respect of that allocation. You should contact your Broker to determine whether they may allocate Shares to you under the Broker Firm Offer.

Capitalised terms not otherwise defined in this document has the meaning given to them in the Prospectus. The Prospectus contains important information relevant to your decision to invest and you should read the entire Prospectus before applying for Shares. If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser. To meet the requirements of the Corporations Act, this Application Form must not be distributed unless included in, or accompanied by, the Prospectus and any supplementary Prospectus (if applicable). While the Prospectus is current, the Company will send paper copies of the Prospectus, and any supplementary Prospectus (if applicable) and an Application Form, on request and without charge.

- Shares Applied For & Payment Amount** - Enter the number of Shares & the amount of the application monies payable you wish to apply for. Applications must be for a minimum 2,300 Shares (\$2,000 worth of Shares), rounded up to the value of the nearest Share). There is no maximum value of Shares that may be applied for under the Broker Firm Offer.
- Applicant Name(s) and Postal Address** - ONLY legal entities can hold Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable by the Company. At least one full given name and surname is required for each natural person. Refer to the table above for the correct forms of registrable title(s). Applicants using the wrong form of names may be rejected. Next, enter your postal address for the registration of your holding and all correspondence. Only one address can be recorded against a holding.
- Contact Details** - Please provide your contact details for us to contact you between 9:00am and 5:00pm (AEST) should we need to speak to you about your application. In providing your email address you elect to receive electronic communications. You can change your communication preferences at any time by logging in to the Investor Portal accessible at <https://investor.automic.com.au/#/home>
- CHESS Holders** - If you are sponsored by a stockbroker or other participant and you wish to hold Shares allotted to you under this Application on the CHESS subregister, enter your CHESS HIN. Otherwise leave the section blank and on allotment you will be sponsored by the Company and a "Securityholder Reference Number" ('SRN') will be allocated to you.
- TFN/ABN/Exemption** - If you wish to have your Tax File Number, ABN or Exemption registered against your holding, please enter the details. Collection of TFN's is authorised by taxation laws but quotation is not compulsory, and it will not affect your Application.
- Payment** - Please complete the details of your cheque or bank draft in this section. The total amount of your cheque or bank draft should agree with the amount shown in section 1.  
If you receive a firm allocation of Shares from your Broker, make your cheque payable to your Broker in accordance with your instructions.

## DECLARATIONS

### BY SUBMITTING THIS APPLICATION FORM WITH THE APPLICATION MONIES, I/WE DECLARE THAT I/WE:

- Have received a copy of the Prospectus, either in printed or electronic form and have read the Prospectus in full;
- Have completed this Application Form in accordance with the instructions on the form and in the Prospectus;
- Declare that the Application Form and all details and statements made by me/us are complete and accurate;
- I/we agree to provide further information or personal details, including information related to tax-related requirements, and acknowledge that processing of my application may be delayed, or my application may be rejected if such required information has not been provided;
- Agree and consent to the Company collecting, holding, using and disclosing my/our personal information in accordance with the Prospectus; and
- Where I/we have been provided information about another individual, warrant that I/we have obtained that individual's consent to the transfer of their information to the Company;
- Acknowledge that once the Company accepts my/our Application Form, I/we may not withdraw it;
- Apply for the number of Shares that I/we apply for (or a lower number allocated in a manner allowed under the Prospectus);
- Acknowledge that my/our Application may be rejected by the Company in its absolute discretion;
- Authorise the Company and their agents to do anything on my/our behalf necessary (including the completion and execution of documents) to enable the Shares to be allocated;
- Am/are over 18 years of age;
- Agree to be bound by the Constitution of the Company; and
- Acknowledge that neither the Company nor any person or entity guarantees any particular rate of return of the Shares, nor do they guarantee the repayment of capital.

## LODGEMENT INSTRUCTIONS

The Broker Firm Offer opens on 22 October 2021 and is expected to close at on 29 October 2021. Tissue Repair Ltd in consultation with the Lead Manager may elect to extend the Broker Firm Offer.

If you have been contacted by your Broker regarding the Broker Firm Offer, you should ask your Broker for information about how and when to lodge this Application Form, and who to make your cheque payable to. Generally, you will lodge this Application Form and cheque payment with your Broker in accordance with their instructions. Do NOT lodge this Application form with the Share Registry.

Your Broker must receive your completed Application Form and Application Monies (if applicable) in time to arrange settlement on your behalf by the relevant Closing Date for the Broker Firm Offer.

## ASSISTANCE

Need help with your application, no problem. Please contact Automic on:



**PHONE:**  
1300 288 664 within Australia  
+61 (2) 9698 5414 from outside Australia



**LIVE WEBCHAT:**  
Go to [www.automicgroup.com.au](http://www.automicgroup.com.au)



**EMAIL:**  
[corporate.actions@automicgroup.com.au](mailto:corporate.actions@automicgroup.com.au)





# BROKER FIRM OFFER APPLICATION FORM

### Broker Code

**Adviser Code**

Applicants who received this Offer from their broker must return their Application Form and Application Monies back to their broker

This Application Form is important. If you are in doubt as to how to deal with it, please contact your stockbroker or professional advisor without delay. You should read the Tissue Repair Ltd Prospectus dated 7 October 2021 and any relevant supplementary Prospectus (if applicable), carefully before completing this Application Form. The Corporations Act prohibits any person from passing on this Application Form (whether in paper or electronic form) unless it is attached to or accompanies a complete and unaltered copy of the Prospectus and any relevant supplementary Prospectus (whether in paper or electronic form).

## Standard Application and Pay by Cheque

Enter your details below (clearly in capital letters using pen), attach cheque and return in accordance with the instructions on page 2 of the form.

### 1. Number of Shares applied for

**Application payment (multiply box 1 by \$1.15 per Share)**

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A\$ 

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Applications must be for a minimum of 2,300 Shares (\$2,000 worth of Shares), rounded up to the value of the nearest Share).

**2. Applicant name(s) and postal address (Refer to Naming Standards overleaf)**

Applicant name(s) and postal address (Refer to Naming Standards Overleaf)																								
																				Post Code:				

Post Code:

### 3. Contact details

Telephone Number

( )

Contact Name (PLEASE PRINT)

Email Address

By providing your email address, you elect to receive all communications despatched by the Company electronically (where legally permissible).

#### 4. CHESS Holders Only – Holder Identification Number (HIN)

[illegible]

Note: if the name and address details in section 2 does not match exactly with your registration details held at CHESS, any Shares issued as a result of your Application will be held on the Issuer Sponsored subregister.

## 5. TFN/ABN/Exemption Code

Applicant #1

### Applicant #2

### Applicant #3

[illegible]

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If NOT an individual TFN/ABN, please note the type in the box  
C = Company; P = Partnership; T = Trust; S = Super Fund

## 6. Cheque Payment details

Cheque or Bank Draft Number

BSB

Account Number

[illegible]

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Total Amount A\$   ,    ,    .

## YOUR PRIVACY

Automatic Pty Ltd (ACN 152 260 814) trading as Automic Group advises that Chapter 2C of the Corporation Act 2001 requires information about you as a securityholder (including your name, address and details of the Shares you hold) to be included in the public register of the entity in which you hold Shares. Primarily, your personal information is used in order to provide a service to you. We may also disclose the information that is related to the primary purpose and it is reasonable for you to expect the information to be disclosed. You have a right to access your personal information, subject to certain exceptions allowed by law and we ask that you provide your request for access in writing (for security reasons). Our privacy policy is available on our website – [www.automic.com.au](http://www.automic.com.au)



## CORRECT FORMS OF REGISTRABLE TITLE

Type of Investor	Correct Form of Registration	Incorrect Form of Registration
Individual	Mr John Richard Sample	J R Sample
Joint Holdings	Mr John Richard Sample & Mrs Anne Sample	John Richard & Anne Sample
Company	ABC Pty Ltd	ABC P/L or ABC Co
Trusts	Mr John Richard Sample <Sample Family A/C>	John Sample Family Company
Superannuation Funds	Mr John Sample & Mrs Anne Sample <Sample Family Super A/C>	John & Anne Superannuation Fund
Partnerships	Mr John Sample & Mr Richard Sample <Sample & Son A/C>	John Sample & Son
Clubs/Unincorporated Bodies	Mr John Sample <Health Club A/C>	Health Club
Deceased Estates	Mr John Sample <Estate Late Anne Sample A/C>	Anne Sample (Deceased)

## INSTRUCTIONS FOR COMPLETING THE FORM

### YOU SHOULD READ THE PROSPECTUS CAREFULLY BEFORE COMPLETING THIS BROKER FIRM OFFER APPLICATION FORM.

This is an Application Form for fully paid ordinary Shares in Tissue Repair Ltd (ACN 158 411 566) (**Company**) made under the terms of the Broker Firm Offer set out in the Prospectus dated 7 October 2021.

The Broker Firm Offer is open to Australian resident retail clients of Brokers who have received a firm allocation to apply for Shares under the Broker Firm Offer. If you have been offered a firm allocation by a Broker, you will be treated as an Applicant under the Broker Firm Offer in respect of that allocation. You should contact your Broker to determine whether they may allocate Shares to you under the Broker Firm Offer.

Capitalised terms not otherwise defined in this document has the meaning given to them in the Prospectus. The Prospectus contains important information relevant to your decision to invest and you should read the entire Prospectus before applying for Shares. If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser. To meet the requirements of the Corporations Act, this Application Form must not be distributed unless included in, or accompanied by, the Prospectus and any supplementary Prospectus (if applicable). While the Prospectus is current, the Company will send paper copies of the Prospectus, and any supplementary Prospectus (if applicable) and an Application Form, on request and without charge.

- Shares Applied For & Payment Amount** - Enter the number of Shares & the amount of the application monies payable you wish to apply for. Applications must be for a minimum 2,300 Shares (\$2,000 worth of Shares), rounded up to the value of the nearest Share). There is no maximum value of Shares that may be applied for under the Broker Firm Offer.
- Applicant Name(s) and Postal Address** - ONLY legal entities can hold Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable by the Company. At least one full given name and surname is required for each natural person. Refer to the table above for the correct forms of registrable title(s). Applicants using the wrong form of names may be rejected. Next, enter your postal address for the registration of your holding and all correspondence. Only one address can be recorded against a holding.
- Contact Details** - Please provide your contact details for us to contact you between 9:00am and 5:00pm (AEST) should we need to speak to you about your application. In providing your email address you elect to receive electronic communications. You can change your communication preferences at any time by logging in to the Investor Portal accessible at <https://investor.automic.com.au/#/home>
- CHESS Holders** - If you are sponsored by a stockbroker or other participant and you wish to hold Shares allotted to you under this Application on the CHESS subregister, enter your CHESS HIN. Otherwise leave the section blank and on allotment you will be sponsored by the Company and a "Securityholder Reference Number" ('SRN') will be allocated to you.
- TFN/ABN/Exemption** - If you wish to have your Tax File Number, ABN or Exemption registered against your holding, please enter the details. Collection of TFN's is authorised by taxation laws but quotation is not compulsory, and it will not affect your Application.
- Payment** - Please complete the details of your cheque or bank draft in this section. The total amount of your cheque or bank draft should agree with the amount shown in section 1.  
If you receive a firm allocation of Shares from your Broker, make your cheque payable to your Broker in accordance with your instructions.

## DECLARATIONS

### BY SUBMITTING THIS APPLICATION FORM WITH THE APPLICATION MONIES, I/WE DECLARE THAT I/WE:

- Have received a copy of the Prospectus, either in printed or electronic form and have read the Prospectus in full;
- Have completed this Application Form in accordance with the instructions on the form and in the Prospectus;
- Declare that the Application Form and all details and statements made by me/us are complete and accurate;
- I/we agree to provide further information or personal details, including information related to tax-related requirements, and acknowledge that processing of my application may be delayed, or my application may be rejected if such required information has not been provided;
- Agree and consent to the Company collecting, holding, using and disclosing my/our personal information in accordance with the Prospectus; and
- Where I/we have been provided information about another individual, warrant that I/we have obtained that individual's consent to the transfer of their information to the Company;
- Acknowledge that once the Company accepts my/our Application Form, I/we may not withdraw it;
- Apply for the number of Shares that I/we apply for (or a lower number allocated in a manner allowed under the Prospectus);
- Acknowledge that my/our Application may be rejected by the Company in its absolute discretion;
- Authorise the Company and their agents to do anything on my/our behalf necessary (including the completion and execution of documents) to enable the Shares to be allocated;
- Am/are over 18 years of age;
- Agree to be bound by the Constitution of the Company; and
- Acknowledge that neither the Company nor any person or entity guarantees any particular rate of return of the Shares, nor do they guarantee the repayment of capital.

## LODGEMENT INSTRUCTIONS

The Broker Firm Offer opens on 22 October 2021 and is expected to close at on 29 October 2021. Tissue Repair Ltd in consultation with the Lead Manager may elect to extend the Broker Firm Offer.

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**EMAIL:**  
[corporate.actions@automicgroup.com.au](mailto:corporate.actions@automicgroup.com.au)





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# Corporate Directory

## Company

### Tissue Repair Ltd

Level 10, 255 Pitt Street  
Sydney NSW 2000  
[www.tissuerepair.com.au](http://www.tissuerepair.com.au)

## Officeholders

### Directors

Tony Charara  
Jack Lowenstein  
Max Johnston  
Craig Stamp  
Bryan Gray

### Company Secretary

Alistair McKeough

## Share Registry

### Automic Pty Ltd

Deutsche Bank Tower  
Level 5/126 Phillip Street  
Sydney NSW 2000

## Registered Office

Level 10, 255 Pitt Street  
Sydney NSW 2000

## Lead Managers

### Bell Potter Securities Limited

Level 29, 101 Collins Street  
Melbourne VIC 3000  
[www.bellpotter.com.au](http://www.bellpotter.com.au)

### Morgans Corporate Limited

Level 29, Riverside Centre  
123 Eagle Street  
Brisbane QLD 4000  
[www.morgans.com.au](http://www.morgans.com.au)

## Legal Adviser

### Mills Oakley

Level 7, 151 Clarence Street  
Sydney NSW 2000  
[www.millsoakley.com.au](http://www.millsoakley.com.au)

## Investigating Accountant

### Pitcher Partners Sydney Corporate Finance Pty Limited

Level 16, Tower 2, Darling Park  
201 Sussex Street  
Sydney NSW 2000  
[www.pitcher.com.au](http://www.pitcher.com.au)

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