

Tissue Therapies Limited ABN 45 101 955 088

The Annual General Meeting of the Company will be held at McCullough Robertson Lawyers, Level 11, Central Plaza Two, 66 Eagle Street Brisbane QLD 4000, on the 12<sup>th</sup> of November 2012 at 10:30 am.

### **Corporate Headquarters**

GPO Box 1596, Brisbane, QLD 4001, Australia Level 19, 179 Turbot Street, Brisbane QLD 4000 Australia

Tel: +61 7 3334 3900 Fax: +61 7 3334 3999

### **European Operations**

Tissue Therapies Europe Limited Unit F34, Daresbury Innovation Centre, Keckwick Lane, Daresbury, Cheshire, WA4 4FS, United Kingdom

Tel: +44 75 4007 2628

www.tissuetherapies.com

#### Directors

Mr Roger Clarke Mr Mel Bridges Dr Cherrell Hirst Mr Iain Ross Dr Steven Mercer

### **Company Secretary**

Mr Drummond McKenzie

### **Chief Scientific Officer**

**Professor Zee Upton** 

### **Share Registry**

Link Market Services Level 15, 324 Queen Street Brisbane, QLD 4000 Australia

### Auditors

Lawler Hacketts Audit Level 3, 549 Queen Street Brisbane, QLD 4000 Australia

### Lawyers for the Company

McCullough Robertson Level 11, Central Plaza Two 66 Eagle Street Brisbane, QLD 4000 Australia

## **Contents**

Tissue Therapies Limited	iv
Tissue Therapies Limited ————————————————————————————————————	iv
Delivering "economic care" drives adoption ————————————————————————————————————	iv
Our Product: VitroGro® ECM	V
What is VitroGro® ECM	V
Clinical effectiveness	
European commercial readiness Future of the VitroGro® brand	vii
Future of the VitroGro® brand	vii
References	viii
Chairman and CEO's report	ix
The Board	х
References Chairman and CEO's report The Board The Tissue Therapies team	xi-xii
Corporate governance	xiii-xvi
Corporate governance Financial Report Shareholder information	xviii
Shareholder information	xix-xx

### **Tissue Therapies Limited**

Tissue Therapies Limited is a biomedical technology company that is developing significantly more effective treatments for acute and chronic wound healing applications, including chronic skin ulcers and burns.

Tissue Therapies Limited is commercialising VitroGro® ECM, a technology created by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation at the Queensland University of Technology (QUT). The Company is also developing treatments for psoriasis, scar prevention and various cancers including those of the breast, colon and prostate. Tissue Therapies Limited's shares are traded on the Australian, Berlin and Frankfurt stock exchanges.

### Our business opportunity

There is a significant need in wound care for improving the outcome of hard to heal wounds. Hard to heal wounds are defined as wounds that have not responded to standard therapy in an orderly and timely manner [1]. This type of delayed healing occurs in a variety of wound types (venous leg ulcers, arterial leg ulcers, mixed leg ulcers, diabetic foot ulcers and pressure ulcers) [2.3.4].

### Delivering "economic care" drives adoption

In todays economic climate companies must strive to develop healthcare products that reduce the cost associated with delivering improved outcomes to patients.

The cost of treating hard to heal wounds with current standard of care is considered a snowballing problem driven by increasing factors such as age of populations, diabetes and obesity. Hospitalisation due to infection, associated nursing time and low healing rates of wounds in the community care setting (where most ulcers are treated) all lead to increasing costs of treatment.

The longer any ulcer remains unhealed, the greater the risk of infection and the consequent morbidity and associated financial costs [5]

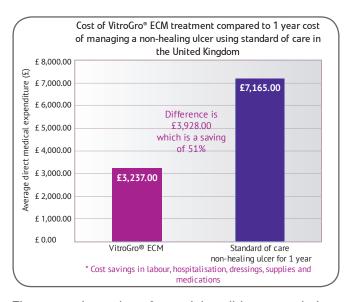
• Cost to the UK National Health Service (NHS) are estimated at £2-3 billion per year [6].

- In the USA, hard to heal wounds are estimated to cost in excess of US\$25 billion annually [7].
- In Germany, according to cautious estimates, approximately 3-4 million people suffer from hard to heal wounds and costs for just venous leg ulcers alone are on average € 8,600 per patient <sup>[8]</sup>.

Healing rates obtained outside of a clinical trial run at a specialised clinic are low; UK community centres showed that fewer than 10% of venous leg ulcers were healed in six months [9]

Initial health economic modelling for the United Kingdom shows a treatment cost reduction of 22% in the clinic setting and 32% in community care setting for a treatment period of 12 weeks. In clinical studies 43% of patients treated with VitroGro® ECM showed a greater than 90% reduction in wound size with 12 weeks.

Many ulcers take time to heal when managed using current standard of care treatment. Up to 50% of venous ulcers may be present for 7 to 9 months and between 8% and 34% may be present for more than 5 years [10, 11]. For this reason it is appropriate to show the cost comparison between using VitroGro® ECM and managing a non-healing ulcer with standard of care for a duration of one year. In this case a reduction of 51% in treatment costs is achievable.



These initial cost benefit models will be expanded on and applied to other European countries. Providing a cost benefit is key to reimbursement and wide usage of VitroGro® ECM.

## Our Product: VitroGro® ECM



### What is VitroGro® ECM

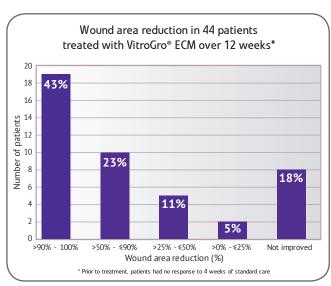
VitroGro® ECM is a topically applied, biomimetic scaffold, comprising a synthetic extracellular matrix protein for the treatment of hard to heal wounds such as venous leg ulcers.

How it works: In hard to heal wounds, a structure called the extracellular matrix (ECM) is defective. In normal wound healing, the ECM changes over time to guide the process of healing. Without a viable ECM skin cells are unable to migrate into the wound and restore damaged tissue. VitroGro® ECM replaces the degraded ECM of the hard to heal wound providing a physical structure (a scaffold) for cell attachment, which is a primary requirement for subsequent cell functions critical for healing, such as cell proliferation and migration.

An optimal scaffold: In hard to heal wounds the normal process of healing is stalled at an early stage and is characterised by prolonged inflammation and a degraded ECM. VitroGro® ECM is ideal as an ECM replacement since its structural and functional elements mimic those present in the ECM at the early stages of normal wound healing.

Designed for ease of use: VitroGro® ECM is a liquid that is applied to the surface of the wound which requires minimal clinical training making it easy to deploy to community based care where most ulcers are treated.

### Clinical effectiveness: 2011 European study



Improved wound healing: The clinical effectiveness data for VitroGro® ECM from the recent 2011 European certification trial is summarised below:

- Ulcers had not responded at all to standard of care during four weeks of treatment prior to study entry.
- Mean baseline ulcer duration 36 months, mean age of patients 74.2 years, mean baseline ulcer area 7.4cm<sup>2</sup>.
- 44 patients completed the study 12 week study.
- Of the patients that completed the study, 34% (15 patients) totally healed and 43% (19 patients) achieved greater than 90% wound area reduction. 64% (29 patients) achieved greater than 50% wound area reduction.

Improved wound care: In addition to reduction in wound size, the clinical study identified significant pain reduction in patients who reported pain at baseline.

The baseline pain characteristics for the patients involved in the EU study were;

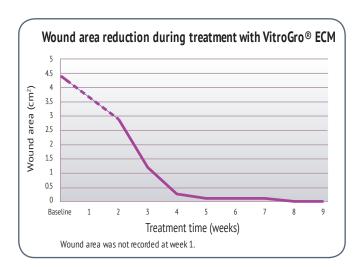
- 28 patients (52.8%) had pain at baseline;
- 15, 7 and 6 patients had mild, moderate or severe pain, respectively.

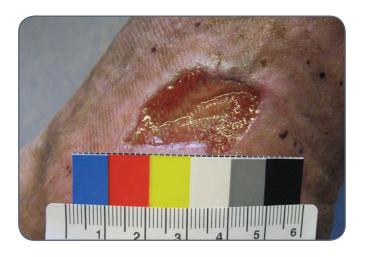
The pain analysis at the conclusion of the study was:

- 75.0% (n=21) of the 28 patients with pain at baseline had complete resolution of wound pain following treatment with VitroGro® ECM;
- All 6 patients with severe pain at baseline had no pain at their last assessment;
- Of the 28 patients with pain at baseline, 22 (78.6%) experienced a meaningful reduction in pain (> 33%);
- Of all 53 patients in the study, only 6 (11.3%) experienced worsened pain during the study

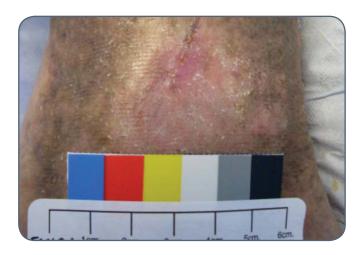
The reduction of pain is an important result because pain management in chronic wounds is a considerable source of expense to the healthcare community. Any reduction in pain not only benefits the patient physically and emotionally, but can also have significant effects on the health economic value of a wound management product such as VitroGro® ECM.

### VitroGro® ECM improves patient outcomes





### 84 months ulcer duration: 9 weeks to heal



Note: This patient had not responded to 4 weeks standard of care prior to treatment with VitroGro® ECM



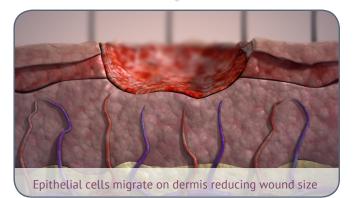
1



2



3



### **European commercial readiness**

- Manufacturing: The Manufacturing of VitroGro® ECM which was necessary for both sales and regulatory filing for CE Mark has been completed. Finished stock is currently stored at the main logistics hub in Holland and a smaller back-up facility in Belgium.
- Sales & Distribution: The sales and distribution network combining Tissue Therapies, Movianto (logistics & distribution) and Quintiles (sales staff) has been implemented and tested. This network involves many processes and people and is a key milestone in being able to get product to customers effectively and within the regulatory framework.
- Sales targeting: A comprehensive sales target list has been established for the United Kingdom and Germany.
- Reimbursement: A comprehensive reimbursement strategy is in place and ready for rollout coinciding with the launch of VitroGro® ECM. Reimbursement is key to driving long term sales in any healthcare market.
- © CE Mark approval: The CE Mark application for VitroGro® ECM has been referred by the notified body (British Standards Institute) to the UK health regulatory body, the MHRA (Medicines and Healthcare products Regulator Agency) to arbitrate which Medical Device Directive Rule is appropriate for the classification of VitroGro® ECM; Device Rule 8 or Device Rule 13. The Device Rule under which CE Mark is granted makes no commercial difference to Tissue Therapies. However, it is possible that the MHRA review may result in a further referral to the European Medicines Agency (EMA) for a review of the VitroGro® ECM manufacturing process. EMA is the European Union health regulatory agency.

### Future of the VitroGro® brand

VitroGro® is a "platform brand" for future products that utilise Tissue Therapies synthetic protein technologies. VitroGro® ECM is the first commercial product for the VitroGro® brand and is designed for the treatment of hard to heal wounds. Other products in development for the brand include burns products for both paediatric and adult use, surgical wound applications for at-risk patients and broad retail applications include dressings, creams, lotions, product range for burns, acute sunburn etc.

## References

- [1] White R "Delayed wound healing": In whom, what, when and why?" Primary Health Care 2008
- [2] Vowden P. Hard to heal wounds made easy. Wounds International 2011
- [3] Srinivasaiah N. et al. A point prevalence survey of wounds in the North East of England. J. Wound Care 2007.
- [4] Vowden KR. and Vowden P. The prevalence, management, equipment provision and outcomes for patients with pressure ulceration identified in a wound care survey with one English health care district. J. Tissue Viability 2009
- [5] Moffet C. et. al. European Wound Management Association Position document: Hard to heal wounds a holistic approach. 2008
- [6] Harding K. and Queen D. Chronic wounds and their management and prevention is a significant public health issue. Int. Wound J. 2010
- [7] Sen CK. et. al. Human skin wounds: a major and snowballing threat to public health and the economy Wound Repair Regen. 2009
- [8] Purwins S et al. Cost of illness of chronic leg ulcers in Germany Int. Wound J. 2010
- [9] Guest JF. et. al. Relative cost-effectiveness of a skin protectant in managing venous leg ulcers in the UK. J Wound Care. 2012
- [10] Barwell JR, Davies CE, Deacon J, et al Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. Lancet 363(9424). 2004
- [11] Rippon M, Davies P, White R, Bosanquet N. The economic impact of hard-to-heal leg ulcers. Wounds UK. 2007

## Chairman's and CEO's Report

On behalf of the Tissue Therapies Group, it gives us great pleasure to present the Company's Annual Report for the financial year ending 30 June 2012.

During the 2011-12 financial year, some of the most important final milestones necessary for the sales launch of VitroGro® ECM were successfully completed. These achievements were essential for both the start of sales in the EU as well as the global commercialisation plans of the Company and include:

- Successful larger scale commercial manufacturing of VitroGro® ECM, compliant with health regulatory requirements and delivering a lower cost of manufacturing;
- Design and volume manufacturing of final packaging for VitroGro® ECM;
- Successful formal FDA classification of VitroGro® ECM as a combination biologic / device, delivering significant commercial advantages in clinical trial flexibility, speed and simplicity of reimbursement;
- Strong EU clinical trial results in a group of very difficult-to-heal patients who had not responded to expert care for an average of 36 months;
- Finalisation of all customer service, logistics, financial, tax and other requirements for the sales launch of VitroGro® ECM in the EU;
- Compelling health economic data which demonstrates the cost effectiveness of VitroGro® ECM.

Since the end of the 2011-12 financial year, there has been the frustration of the unusual and unexpected delay in the granting of CE Mark. Despite this delay required for the determination by the UK Government Health Regulatory Body, the Medicines and Healthcare products Regulatory Agency (MHRA) as to which Medical Device Rule should apply to VitroGro® ECM, we remain confident in the data we have provided and that CE Mark will be granted.

While waiting for the MHRA response, the integrated sales launch program has continued to be fine-tuned and sales in the EU will begin literally on the first business day following the granting of CE Mark. This initial sales launch program in Germany, Switzerland, Austria, the UK and the Netherlands will by run by

existing Company staff, including the EU Head of Commercial Operations, International Product Manager and the CEO. It was always planned to implement the initial sales launch in this way, with the employment of dedicated sales staff only occurring once CE Mark is granted.

While waiting for CE Mark, work has also progressed on European reimbursement submissions, final preparation for submission of FDA clinical trial applications and global rollout plans.

#### **Financial Results**

During the 2011-12 financial year, the Tissue Therapies Group recorded an after-tax loss of \$6,769,382 in line with budget expectations. This loss includes non-cash expenses of \$694,651 relating to the write off of protein component inventory developed during the Group's research program.

Net assets decreased by \$6,566,545 to \$10,466,891 and at 30 June 2012 the Group had cash resources of \$5,158,393.

### Outlook

Despite the unusual delay in gaining CE Mark, Tissue Therapies is now well positioned for the start of sales in Europe where there is already significant and growing demand for VitroGro® ECM. We will continue to develop and vigorously pursue the global commercialisation plans we have in place, starting with FDA clinical trials, as well as applications for approval for sale in multiple global regions.

We are confident that VitroGro® ECM is a unique technology that offers the opportunity for strong commercial returns as well as the ability to transform the treatment of difficult to heal wounds with a cost effectiveness that is unprecedented. We look forward with great anticipation to the start of sales and the progress of the global commercialisation of VitroGro® ECM.

## The Board



#### Roger Clarke (Chairman)

Mr Clarke has over 30 years commercial experience, principally in the investment banking industry, with responsibilities in fund management, banking and corporate finance, and involvement in a significant number of initial public offerings, capital raisings and corporate transactions. He is Chairman of the Board of Advice of RBS Morgans Limited , Chairman of NextDC Limited, CoalBank Limited and MTQ Insurance Limited. Mr. Clarke is also a Director of Trojan Equity Limited and Maverick Drilling and Exploration Limited.

Bachelor of Commerce, Chartered Accountant.



#### **Mel Bridges**

Mr Bridges has extensive experience as a CEO and Company Director in healthcare, agricultural technology, drug development, pathology, diagnostics and medical devices. Mr Bridges has successfully raised in excess of \$300M investment capital in the healthcare/biotech sector and been directly involved in over \$1B in merger and acquisition and related transactions. Mr Bridges is Chairman of Alchemia Limited, Genetic Technologies Limited and Leaf Energy Limited and is also a Director of Benitec Biopharma Limited, ALS Limited (previously Campbell Brothers Limited) and ImpediMed Limited.

Bachelor of Science (Chemistry), Honorary Doctorate from Queensland University of Technology, Fellow of the Australian Institute of Company Directors.



#### **Dr Cherrell Hirst**

Dr. Hirst has had a distinguished clinical career in the detection and treatment of breast cancer and extensive and respected achievements as Director and Chair of multiple commercial, government and not-for-profit organisations. Dr. Hirst is Deputy Chair and CEO (part time) of QIC and a Director of Medibank Private Limited, Avant Mutual Group, Avant Insurance Limited, ImpediMed Limited and Xenome Limited.

Bachelor of Medicine, Bachelor of Surgery, Bachelor of Education Studies, Honorary Doctorates from Queensland University of Technology, Griffith University and Southern Cross University, Fellow of the Australian Institute of Company Directors.



#### **lain Ross**

Following a career with multi-national companies including Sandoz, Fisons Plc and Hoffman La Roche, Mr Ross was responsible for building Celltech Biologics, the contract manufacturing division. For the last 15 years he has undertaken a number of company turnarounds and start-ups as a board member on behalf of private equity groups and banks. Currently he is Executive Chairman of Ark Therapeutics Plc (LSE), Non-Executive Chairman of Biomer Technology Ltd and Pharminox Ltd, and is a Non-Executive Director of Benitec Biopharma Limited (ASX).

Bachelor of Science (Hons) Biochemistry, Chartered Director.

## The Tissue Therapies Team



**Dr Steven Mercer** (Chief Executive Officer & Managing Director)

Dr Mercer has been CEO of Tissue Therapies Ltd since late September 2004. During this time, Tissue Therapies has successfully developed multiple formulations of synthetic proteins and produced VitroGro® ECM for the treatment of hard to heal wounds to a commercial scale. The Company has conducted successful clinical trials, submitted an application for approval for sale in the EU (CE Mark) and applications to start US FDA clinical trials for the treatment of venous and diabetic ulcers are also planned for submission during 2012.

Bachelor of Medical Science, Bachelor of Medicine, Bachelor of Surgery, Fellow of the Australian Institute of Management, Fellow of the Australian Institute of Company Directors, Registered Medical Practitioner.



#### **Nigel Johnson** (Operations Director)

Mr Johnson has more than 17 years experience in the medical device and biologics industries, principally with responsibilities for development, manufacturing, quality management and regulatory affairs in Europe, Australia, Canada and the United States. Nigel has been instrumental in the development and manufacturing of VitroGro® ECM for commercial sale. Bachelor of Applied Science.



#### **Drummond McKenzie** (Chief Financial Officer)

Mr McKenzie, who has been involved with Tissue Therapies since its inception, has significant experience in senior financial management in a range of industries including mining, financial services, health and the accounting profession, in Australia and internationally.

Bachelor of Science, Fellow of the Institute of Chartered Accountants, Fellow of the Institute of Chartered Secretaries.



#### **Dr Hedie Meka** (Regulatory and Intellectual Property Manager)

Dr Meka has more than 6 years experience as a registered patent and trade marks attorney and prior to joining Tissue Therapies, was partly responsible for the management of Tissue Therapies' international patents and trademarks. Earlier in her career, Dr Meka worked as an interdisciplinary research scientist in molecular and cell biology, with experience at the University of Queensland, Imperial College, London and at Oxford University.

Bachelor of Applied Science, Masters of Industrial Property, PhD (Medical Science), Fellow of the Institute of Patent and Trade Mark Attorneys of Australia.



#### **Saskia Jo** (Corporate Accountant)

Saskia is an experienced corporate accountant with first-hand knowledge of implementing and modernising financial systems that are required in an evolving company such as Tissue Therapies.

Bachelors degree in Commerce, a Graduate Diploma of Applied finance and is a Certified Practicing Accountant.

## The Tissue Therapies Team



#### **Dr Brian Ziegelaar** (International Product Manager)

Dr Ziegelaar has extensive experience in the commercialisation of clinical devices in his former capacity as International Product and European Sales Manager for ImpediMed Limited. Dr Ziegelaar specialises in marketing, sales and commercial support. Earlier in his career, Dr Ziegelaar gained his PhD and pursued post-doctoral research in Europe in tissue engineering and cell biology.

Bachelor of Science, Master of Medical Science, PhD.



#### **Andrew Thelwell** (Managing Director, EU Commercial Operations)

Mr Thelwell has over twenty five years experience in the wound sector, working for Smith & Nephew and ConvaTec. Previous roles have included General Management within both the Benelux and the United Kingdom & Ireland regions, and leadership of global marketing functions.

Bachelor of Arts (Hons), Masters Business Administration.



#### **Dr Eva-Lisa Heinrichs** (Medical Director, Global Medical Affairs)

Dr Heinrichs has over 16 years of experience in the medical device industry including 4 years as Chief Medical Officer of Orteq Limited, a London-based privately owned orthobiologics company and 10 years as European Medical Director of ConvaTec Limited, an international wound care, skin care and stoma care devices company. Dr Heinrichs obtained her medical qualification from Helsinki University, Finland and has a postgraduate research doctorate of medicine degree from Cardiff University in the UK.

Bachelor of Medicine, PhD.



#### **Professor Zee Upton** (Chief Scientific Officer)

Professor Upton is the lead-inventor of VitroGro® and oversees the Company's R&D activities as its Consulting Chief Scientific Officer. Professor Upton is an expert in cellular technologies and is based at QUT.

Bachelor of Science, PhD, Professorial Chair at Queensland University of Technology.



#### **Dr Gary Shooter** (Director of Research and Development)

Dr Shooter is a Senior Research Fellow within the Tissue Repair and Regeneration program at QUT and has a diverse range of interests in structural biology and protein chemistry. Following his PhD, Dr Shooter has held several positions within industry and academia where he has developed a proven track record in the GMP production and characterisation of protein-based therapeutics. Dr Shooter is currently co-leader of program 1 of the Wound Management and Innovation Co-operative Research Centre (CRC), alongside Professor Zee Upton.

Bachelor of Science (Honours), PhD (Medical Science).

# **Corporate Governance**

Responsibility for the Company's proper corporate governance rests with the Board. The Board is committed to implementing the highest standards of corporate governance, and its guiding principle in meeting this responsibility is to act honestly, conscientiously and fairly, in accordance with the law, in the interests of Tissue Therapies' shareholders with a view to building sustainable value for them, for employees and those with whom the Company has dealings — residents, suppliers and the general community.

The Company has complied with the ASX Corporate Governance Council's Principles and Recommendations (2<sup>nd</sup> Edition, as amended at 30 June 2010). A more detailed assessment of Tissue Therapies' current corporate governance practice against the ASX Corporate Governance Council's Principles and Recommendations (2<sup>nd</sup> Edition) is provided later in this section.

Tissue Therapies' Corporate Governance Charter, Securities Trading Policy and Remuneration and Nomination Committee Charter can be viewed on the Company's website at www.tissuetherapies.com. The Company's Corporate Governance Charter includes the Board Charter, Code of Ethics, Rules of Committees and the Audit and Risk Management Committee Charter,

#### Scope of Responsibility of the Board

The Board's broad function is to:

- Chart strategy and set financial targets for the Company
- Monitor the implementation and execution of strategy and performance against financial targets
- Appoint and oversee the performance of executive management, and generally to take and fulfil an effective leadership role in relation to the Company.

Power and authority in certain areas is specifically reserved to the Board – consistent with its function as outlined above.

#### These areas include:

- Composition of the Board itself including the appointment and removal of Directors
- Oversight of the Company including its control and accountability systems

- Development, implementation and review of remuneration policy and practices
- Appointment and removal of senior management and the Company Secretary
- Reviewing and overseeing systems of risk management and internal compliance and control, codes of ethics and conduct, and legal and statutory compliance
- Monitoring senior management's performance and implementation of strategy, and approving and monitoring financial and other reporting and the operation of committees.

#### Composition of Board

The Board performs its role and function, consistent with the above statement of its overall corporate governance responsibility, in accordance with the following principles:

- The Board comprises five Directors, four Non-Executive Directors and one Executive Director.
- Details of each Directors' skills and experience are set out in the Directors' Report
- Directors (except for the Chief Executive Officer) are subject to re- election by rotation at each Annual General Meeting as stipulated in the Corporations Act and the Company's constitution. There are no maximum terms for Non-Executive Director appointments. Newly elected Directors must seek re- election at the first general meeting of shareholders following their appointment.
- The Board considers that the four Non-Executive Directors are independent. In reaching this conclusion the Directors have considered the following:
  - The Chairman, Roger Clarke, is considered independent. Roger Clarke (including his associates) was previously a substantial shareholder of the Company and deemed not to be independent. Roger Clarke ceased to be a substantial shareholder on 11 February 2010, as announced to the ASX.
  - Melvyn Bridges, Cherrell Hirst and lain Ross (appointed a Director on 25 May 2012) do not have any previous association with the Company or any other relationships that are relevant to their independence.

- Gregory Baynton (resigned as a Director 12 June 2012) previously provided management services to the Company as managing director of Orbit Capital. Orbit Capital no longer provides management services to the Company and the Board is satisfied that the previous arrangement does not affect his independence.
- Dr Steven Mercer is an Executive Director and CEO and is not considered independent.
- The Chairman of the Board, Roger Clarke, a Non-Executive Director, is independent. Mr Clarke chairs the Board in such a manner to facilitate the effective contribution of all Board members and management. This includes established meeting procedure, the timely despatch of detailed Board papers, and the timely issue of draft minutes. Directors with a potential conflict of interest in any matter exclude themselves from the discussion and any decision on the matter.
- The role of Chairman and Chief Executive Officer are exercised by different individuals providing for clear division of responsibility at the head of the Company. Their roles and responsibilities, and the division of responsibilities between them, are clearly understood and there is regular communication between them.
- The Board has established a Remuneration and Nomination Committee. The Remuneration and Nomination Committee Charter can be viewed on the Company's website at www.tissuetherapies.com
- The Corporate Governance Charter adopted by the Board requires individual performance review and evaluation to be conducted formally on an annual basis. External reviews and assessments of the Board's policies and procedures, and its effectiveness generally, may periodically be conducted by independent consultants. possibility (which would involve professional scrutiny and benchmarking against developing best market practice) will be kept under review by the Board for possible future implementation. The Board acknowledges that performance can always be enhanced and will continue to seek and consider ways of further enhancing performance both individually and collectively.

#### **Board Charter and Policy**

The Board's Charter (which is kept under review and will be amended from time to time as the Board

may consider appropriate) gives formal recognition to the matters outlined above. This Charter sets out various other matters that are important for effective corporate governance including the following:

- A detailed definition of 'independence'
- A framework for the identification of candidates for appointment to the Board and their selection
- A framework for individual performance review and evaluation
- Proper training to be made available to Directors both at the time of their appointment and on an ongoing basis
- Basic procedures for meetings of the Board and its committees – frequency, agenda, minutes and private discussion of management issues among Non-Executive Directors
- Ethical standards and values formalised in a detailed code of ethics and values.
- Dealings in securities formalised in a detailed code for securities transactions designed to ensure fair and transparent trading by Directors and senior management and their associates, and
- Communications with shareholders and the market.

These initiatives, together with the other matters provided for in the Board's Charter, are designed to 'institutionalise' good corporate governance and, generally, to build a culture of best practice both in Tissue Therapies' own internal practices and in its dealings with others, including shareholders, suppliers and the general community.

#### Audit and Risk Management Committee

The purpose of this Committee is to advise on the establishment and maintenance of a framework of internal control and appropriate ethical standards for the management of the Company. Its members during the financial year have been the following Directors:

- Melvyn Bridges (Chairman)
- Gregory Baynton (resigned as a Director on 12 June 2012 )
- lain Ross (appointed a Director on 25 May 2012)
- Roger Clarke

Roger Clarke, Melvyn Bridges, Gregory Baynton and lain Ross are considered independent.

The Committee performs a variety of functions relevant to risk management and internal and external reporting and reports to the Board following each meeting. Among the matters for which the Committee

is responsible are the following:

- Board and committee structure to facilitate a proper review function by the Board
- Internal control framework including management information systems
- Corporate risk assessment and compliance with internal controls
- Internal audit function and management processes supporting external reporting
- Review of financial statements and other financial information distributed externally
- Review of the effectiveness of the audit function
- Review of the performance and independence of the external auditors, including audit partner rotation
- Review of the external audit function to ensure prompt remedial action by management, where appropriate, in relation to any deficiency in or breakdown of controls
- Assessing the adequacy of external reporting for the needs of shareholders, and
- Monitoring compliance with the Company's code of ethics.

Meetings are held at least twice a year. The external auditors attend each of the committee's meetings.

#### Risk Management

The Board, together with the Audit and Risk Management Committee are responsible for ensuring that the Company's risk management systems are effective, and that:

- The principle strategic, operational and financial risks are identified
- Effective systems are in place to monitor and manage risk
- Reporting systems, internal controls and arrangements for monitoring compliance with legislation and regulations are adequate.

The Board acknowledges the Revised Supplementary Guidelines to Principle 7 issued by the ASX in June 2008 and has continued its proactive approach to risk management. The Board determines the Company's risk profile and is responsible for overseeing and approving risk management strategy, policies, internal compliance and internal control. The function is carried out by the Audit and Risk Management Committee and its findings are reported to, reviewed and discussed by the Board. The Company's Risk Management Policy can be viewed on the Company's website at

#### www.tissuetherapies.com

#### **Certifying Financial Reports**

The Chief Executive Officer and Chief Financial Officer certify in respect of the half yearly and the full year financial results that the Company's financial reports present a true and fair view, in all material respects, of the financial position and performance of the Company and are in accordance with the Corporations Act. As part of this certification, they are required to confirm that the risk management and internal control systems, to the extent that they relate to financial reporting, are operating effectively in all material respects based on the risk management model adopted by the Company.

#### **Best Practice Commitment**

The following are a tangible demonstration of the Company's corporate governance commitment:

- Independent professional advice: With the prior approval of the Chairman, which may not be unreasonably withheld or delayed, each Director has the right to seek independent legal and other professional advice concerning any aspect of the Company's operations or undertakings in order to fulfil their duties and responsibilities as Directors. Any costs incurred are borne by the Company.
- Code of ethics and values: The Company has developed and adopted a detailed Code of Ethics to guide Directors in the performance of their duties.
- Code of conduct for transactions in securities: The Company has developed and adopted a formal code to regulate dealings in securities by Directors and senior management and their associates. This is designed to ensure fair and transparent trading in accordance with both the law and best practice.
- Charter: The Code of Ethics and the Securities Trading Policy (referred to above) both form part of the Company's Corporate Governance Charter which has been formally adopted and can be inspected on its website at www.tissuetherapies.com

## Compliance with ASX Corporate Governance Guidelines and Best Practice Recommendations

The Board has assessed Tissue Therapies' current practice against the ASX Corporate Governance Council's Principles and Recommendations (2nd Edition as amended at 30 June 2010) "the Principles" and outlines its assessment below:

 Lay solid foundations for management and oversight: The role of the Board and delegation to management have been formalised as described

above. This will continue to be refined, in accordance with the Principles in light of practical experience gained in operating as a listed company. Tissue Therapies complies with the Principles in this area.

- Structure the Board to add value: The Directors have a broad range of experience, expertise, skills, qualifications and contacts relevant to the business of the Company. The Non-Executive Directors [Roger Clarke, Melvyn Bridges, Cherrell Hirst, Gregory Baynton (resigned 12 June 2012) and Iain Ross (appointed 25 May 2012)], are considered by the Board to be independent and comprise a majority of the Board. The Chairman of the Board, Roger Clarke, is considered independent. Tissue Therapies does comply with the Principles in this regard.
- Promote ethical and responsible decision-making: The Board has adopted a detailed code of ethics and a detailed code of conduct for transactions in securities. The purpose of these codes is to guide Directors in the performance of their duties and to define the circumstances in which both they and management, and their respective associates, are permitted to deal in securities. The Board ensures that restrictions on dealings in securities are strictly enforced. Both codes have been designed with a view to ensuring the highest ethical and professional standards, as well as compliance with legal obligations, and therefore comply with the Principles.

In June 2012 the Board adopted a Group Diversity Policy to ensure that the Company continues to benefit from a workforce which is diverse in respect of gender, ethnicity and age by:

- Reviewing and determining, as frequently as required, a Diversity profile that meets the particular needs of Tissue Therapies, including identifying the skill, experience and expertise requirements set for the Board and senior management necessary to effectively oversee its business and achieve its corporate goals;
- Through the Remuneration and Nomination Committee, seeking to ensure that the Diversity profile is a factor that is taken into account in the selection and appointment of qualified employees, senior management and Board candidates;
- Implementing initiatives focused on skills development, such as executive mentoring programs or more targeted practices relating to career advancement including

- those that develop skills and experience that prepare employees, in particular women, for senior management or Board positions;
- Establishing an effective measurement and reporting framework to enable the achievement of the objectives of the Group Diversity Policy.

The Company's Group Diversity Policy can be viewed on the Company's website at www.tissuetherapies.com

- Safeguard integrity in financial reporting: The Audit and Risk Management Committee (with its own charter) complies with the Guidelines. The Committee consists only of Non-Executive Directors and Melvyn Bridges (its Chairman), Roger Clarke, Gregory Baynton (resigned 12 June 2012) and lain Ross (appointed 25 May 2012) are considered independent. All members of the Committee are financially literate;
- Make timely and balanced disclosure: Current Tissue Therapies' practice on disclosure is consistent with the Guidelines. Policies and procedures for compliance with ASX Listing Rule disclosure requirements are included in the Company's Corporate Governance Charter. Compliance with the ASX Listing Rule Continuous Disclosure requirements is incorporated in the Company's Corporate Governance Charter and is a standing agenda item at each Board meeting;
- Respect the rights of shareholders: The Board recognises the importance of this principle and strives to communicate with shareholders both regularly and clearly both by electronic means and using more traditional communication methods. Shareholders are encouraged to attend and participate at general meetings. The Company's auditors attend the annual general meeting and are available to answer shareholders' questions. The Company's policies comply with the Principles in relation to the rights of shareholders;
- Recognise and manage risk: The Board, together with management, has constantly sought to identify, monitor and mitigate risk. Internal controls are monitored on a continuous basis and, wherever possible, improved. The whole issue of risk management is formalised in the Company's Corporate Governance Charter (which complies with the Principles in relation to risk management) and is kept under regular review. Review takes place at

both committee level (Audit and Risk Management Committee), with meetings at least two times each year, and at Board level;

Remunerate fairly and responsibly: Tissues Therapies' current practices in this area are reviewed regularly. Remuneration of Directors and executives are fully disclosed in this annual report. A clear distinction is made between Non-Executive Directors and executives in terms of the structure of their remuneration. The Board has established a Remuneration and Nomination Committee. The Remuneration and Nomination Committee Charter can be viewed on the Company's website at www.tissuetherapies.com.

# **Financial Report**

## **Contents**

Directors' report	1-10
Auditors' declaration	11
Financial statements	
Consolidated statement of comprehensive income	12
Consolidated statement of financial position	
Consolidated statement of changes in equity	14
Consolidated statement of cash flows	15
Notes to the financial statements	16-43
Directors' declaration	44
Independent auditors report	45-46



#### **DIRECTORS' REPORT**

Your Directors present their report on Tissue Therapies Limited ("the Company") and Controlled Entity, ("the Group") for the year ended 30 June 2012.

#### **Directors**

The names of Directors at any time during or since the end of the year, and their qualifications are detailed below:

Roger Clarke - Chairman (appointed 6 November 2003)

Qualifications — Bachelor of Commerce

**Chartered Accountant** 

Experience — Chairman of Board of Advice, RBS Morgans Limited

Chairman of NextDC Limited, Coalbank Limited (formerly Lodestone Energy Limited) and MTQ Insurance Ltd, Director of Trojan Equity Limited, and Maverick Drilling and

**Exploration Limited** 

Former ASX entity Directorships — PIPE Networks Limited (February 2005 to March 2010)

Special Responsibilities — Member of the Audit and Risk Management Committee, Member of Remuneration

Committee and Nomination Committee

Interest in Shares and Options — 5,200,000 Ordinary Shares

Melvyn Bridges - Director (appointed 12 March 2009)

Qualifications — Bachelor of Science (Chemistry)

Honorary Doctorate from Queensland University of Technology

Fellow of the Australian Institute of Company Directors

Experience — Extensive experience as a CEO and Company Director in Healthcare, Agricultural

Technology, Drug Development, Pathology, Diagnostics and Medical Devices. Related experience in Retail. Has successfully raised in excess of \$300M investment capital in the healthcare/biotech sector and been directly involved in over \$1B in M&A

and related transactions

Chairman of Alchemia Limited, Genetic Technologies Limited and Leaf Energy

Limited (formerly AquaCarotene Limited), Director of Benitec Biopharma Limited, Campbell

Brothers Limited and ImpediMed Limited.

Former ASX entity Directorships — Incitive Limited (November 2007 to June 2010), Peptech Limited (December 2002 to

October 2007) and Genera Biosystems Limited (December 2008 to November 2010)

Special Responsibilities — Chairman of the Audit and Risk Management Committee, Member of Remuneration

Committee and Nomination Committee

Interest in Shares and Options — 245,287 Ordinary Shares and options to acquire a further 250,000 Ordinary Shares

lain Ross - Director (appointed 25 May 2012)

Qualifications — Bachelor of Science (Hons) Biochemistry

**Chartered Director** 

Experience — Chairman of Ark Therapeutics Plc (LSE), Biomer Technology Limited, and Pharminox

Limited, Director of Benitec BioPharma Limited

Former ASX entity Directorships — None

Special Responsibilities — Member of the Audit and Risk Management Committee, Member of Remuneration

Committee and Nomination Committee

Interest in Shares and Options — None

Cherrell Hirst - Director (appointed 30 June 2009)

Qualifications — Bachelor of Medicine, Bachelor of Surgery

**Bachelor of Education Studies** 

Honorary Doctorates from Queensland University of Technology, Griffith University

and Southern Cross University

Fellow of the Australian Institute of Company Directors

Deputy Chair and CEO (part time) of QIC and a Director of Medibank Private Limited, Avant Mutual Group, Avant Insurance Limited, ImpediMed Limited and Xenome

Limited

Experience — Distinguished clinical career in the screening and diagnosis of breast cancer and

extensive and respected achievements as Director and Chair of multiple commercial,

government and not-for-profit organisations

Former ASX entity Directorships — Peplin Inc. (August 2000 to November 2009) and Suncorp-Metway Limited (February

2002 to April 2010)

Special Responsibilities — Member of the Remuneration Committee and Nomination Committee

Interest in Shares and Options — 281,250 Ordinary Shares

Gregory Baynton - Director (appointed 6 September 2002, resigned 12 June 2012)

Qualifications — Master of Business Administration

Master of Economic Studies

Post Graduate Diploma in Applied Finance and Investment

**Bachelor of Business** 

Fellow of the Australian Institute of Company Directors Fellow of the Financial Services Institute of Australia

Experience — Director of Coalbank Limited (formerly Lodestone Energy Limited), NextDC Limited

and Diversa Limited

Former ASX entity Directorships — PIPE Networks Limited (December 2004 to March 2010)

Special Responsibilities — Member of the Audit and Risk Management Committee, Member of Remuneration

Committee and Nomination Committee

Interest in Shares and Options — 764,780 Ordinary Shares are held by Orbit Capital, which is a related entity of

**Gregory Baynton** 

Steven Mercer – Chief Executive Officer and Executive Director (appointed 10 May 2006)

Qualifications — Bachelor of Medical Science

Bachelor of Medicine, Bachelor of Surgery
Fellow of the Australian Institute of Management
Fellow of the Australian Institute of Company Directors

Registered Medical Practitioner

Experience — Significant medical and commercial experience, most recently as Managing Director

of Mercy Tissue Engineering, a successful tissue engineering company. Significant international expertise prior to Tissue Therapies following a successful career with multinational companies, including six years with Smith & Nephew as General Manager, Smith & Nephew Surgical and seven years with IBM Health Industry Centre

in Australia and New York

Former ASX entity Directorships — Nil

Special Responsibilities — Chief Executive Officer, and appointed Executive Director on 10 May 2006

Interest in Shares and Options — 1,125,750 Ordinary Shares and options to acquire a further 480,000 Ordinary Shares

#### **Company Secretary**

The following person held the position of company secretary at the end of the financial year:

**Drummond McKenzie** – Company Secretary

Qualifications — Bachelor of Science (Economics) (Hons.)

Fellow of the Institute of Chartered Accountants
Fellow of the Institute of Chartered Secretaries

Experience — Over 15 years experience in the financial management and administration of public

companies

#### **Principal activities**

During the year the principal activities of the Group consisted of the research, development and commercialisation of the Group's exclusive international intellectual property in wound healing and tissue regeneration.

There were no significant changes in the nature of the Group's principal activities during the year.

#### Operating results

The loss of the Group after tax amounted to \$6,769,382 (2011: loss \$5,340,548).

#### **Dividends**

No dividends were paid or declared since the start of the financial year. No recommendation for payment of dividends has been made.

#### Review of operations

During the 2011-12 financial year:

Tissue Therapies recorded an after-tax loss of \$6,769,382 in line with budget expectations. This loss includes non-cash expenses of \$694,651 relating to the write off of protein component inventory developed during the Group's research programme.

Net assets decreased by \$6,566,545 to \$10,466,891 and at 30 June 2012 the Group had cash resources of \$5,158,393.

VitroGro® has been developed from a profound set of discoveries by the Chief Scientific Officer, Professor Zee Upton and her research group from the Institute of Health and Biomedical Innovation at the Queensland University of Technology.

VitroGro® ECM is a topically applied, biomimetic scaffold, comprising a synthetic extracellular matrix (ECM) protein.

**How it works:** VitroGro® ECM replaces the degraded matrix of a hard to heal wound. VitroGro® ECM binds to a prepared wound bed and provides a physical structure (a scaffold) for cell attachment, which is a primary requirement for subsequent cell functions critical for healing, such as cell proliferation and migration [1].

An optimal scaffold: One of the characteristics of hard to heal wounds is prolonged inflammation, which damages the native ECM that would normally guide the wound healing process [1,2,3,4]. Replacement of this damaged ECM is a beneficial strategy for treating hard to heal wounds [1]. VitroGro® ECM is ideal as an ECM replacement since its structural and functional elements mimic those present in the ECM at the early stages of normal wound healing.

Expert health economics modelling indicates that VitroGro® ECM offers the opportunity for substantially more cost effective treatment of wounds than the current standard of care.

- [1] Widgerow AD. Deconstructing the stalled wound. Wounds 2012
- [2] Schultz GS. Extracellular Matrix: review of its roles in acute and chronic wounds. World Wide Wounds. 2005
- [3] Moor AN. et al. Proteolytic activity in wound fluids and tissues derived from chronic venous leg ulcers. Wound Rep Reg. 2009
- [4] International consensus, Acellular matrices for treatment of wounds. Wounds Int. 2010

VitroGro® is protected by a family of international patent applications with patents already granted in the EU, US, China, Japan, South Korea, South Africa, Australia and New Zealand.

#### Highlights

During the 2011 - 2012 financial year the final phases of commercialisation of VitroGro® ECM necessary for approval for sale within the European Union (including the UK) were successfully completed and preparation for approval for sale in the United States and global rollout were started.

- Larger scale commercial manufacturing was successfully developed and tested. EU compliant final packaging was
  also completed and the first full scale commercial manufacturing batches of VitroGro® ECM were successfully
  completed, compliant with all required health product standards.
- 2. US Food & Drug Administration (FDA) gave a formal classification of the final VitroGro® ECM product as a combination biologic / device. This was a significant milestone for the Group since it confirmed that in the United State, VitroGro® ECM is not considered to be a pharmaceutical and this decision also gave certaintly about that the US reimbursement approval process.
- 3. The EU Notified Body, British Standards Institute (BSI) completed a formal audit of the Tissue Therapies quality management system and found zero non-conformities. This represented the successful completion of another important milestone for global commercialisation of VitroGro® ECM.

- 4. Strong clinical results were reported from the EU multicentre trial from 44 difficult-to-treat venous ulcer patients treated with VitroGro® ECM for only 12 weeks:
  - 34% (15 patients) were completely healed.
  - 1 of the patients who was completely healed within 12 weeks was 100 years of age.
  - 43% (19 patients) were more than 90% healed.
  - 82% (36 patients) were improved ie. were partially or completely healed
  - Average reduction in venous ulcer area was 56%
  - Average ulcer size at the start of the trial was 7.2 cm2
  - Average time the treated ulcers had not responded to expert care prior to VitroGro® ECM treatment was 36 months
  - Average age of the patients in this study was 74 years
- 5. Final commercial partnerships were agreed for multilingual customer service, logistics and dedicated, full time sales staff for the launch of sales in the EU, starting with the UK, Germany, Austria, Switzerland and the Netherlands. These sales arrangements provide Tissue Therapies with the advantages of minimising operational risk, limiting costs and optimising revenue while maximising flexibility and control.
- 6. A comprehensive Design Dossier was completed and submitted to BSI for approval for sale of VitroGro® ECM throughout the EU for the indicated use of "treatment of hard to heal wounds, particularly venous ulcers." Following this submission, additional information was provided by Tissue Therapies Ltd to BSI in response to BSI examiner questions. These queries were as expected and are routine during a Design Dossier review.

#### Significant Changes in State of Affairs

There were no siginificant changes in the state of affairs of the Group during the financial year.

#### Matters Subsequent to the End of the Financial Year

During July 2012 the Group was advised by BSI that VitroGro® ECM conforms to the essential requirements of the EU Medical Devices Directive. This meant that the examination of the Design Dossier was complete, that all examiner questions had been answered to the satisfaction of BSI and BSI advised that CE Mark would be granted shortly.

During August 2012, despite the earlier notification, BSI advised that it had referred the VitroGro® ECM application to the UK Government Health Regulatory Body, the Medicines and Healthcare products Regulatory Agency (MHRA) for a final decision as to which Medical Device Rule was appropriate for the classification of VitroGro® ECM: Device Rule 8 or Device Rule 13.

BSI further advised the Group that the review by MHRA would take up to 30 calendar days, plus any additional days necessary for questions to the Group and for Tissue Therapies' staff to reply to MHRA, but that there would be no additional charges for the MHRA review.

Once CE Mark is received, the Device Rule under which it is granted is of no practical or commercial importance to Tissue Therapies.

It is possible that the MHRA review may result in a further referral to the European Medicines Agency (EMA) for a review of the VitroGro® ECM manufacturing process. EMA is the European Union health regulatory agency.

Except for the above, no other matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

#### Future Developments, Prospects and Business Strategies

The planned developments in the operations of the Group in future financial years are as follows:

Key Achievement / Indicative Milestone	Target
FDA application for venous ulcer trial.	Q1 2013
FDA application for diabetic ulcer trial.	Q2 2013
Canada & Australia: application for accelerated approval for sale of VitroGro® ECM under the Mutual Recognition agreements with the EU.	6 months after CE Mark
Define requirements; regulatory approval, taz, local content, other requirements: India, Japan, China, rest of East Asia, Brazil, Argentina.	Q1 2013
Prioritise and lodge applications for approval for sale: global rollout	Q3 2013

#### **Workforce Diversity**

The Board recognises that workforce diversity is fundamental to the sustainability of our business. Our Group Diversity Policy ensures a strong culture of diversity is established where each employee is respected for who they are and valued for their skills and experience.

% of Women

	30 June 2012	30 June 2011
The Group		
Board <sup>1</sup>	25%	25%
Scientific Advisors	33%	33%
Executive and management	38%	-
Total	33%	20%

<sup>&</sup>lt;sup>1</sup> Non-executive Directors only

#### **Options**

At the date of this report, options over the un-issued shares of the Group are as follows:

Grant date	Date of Expiry	Exercise price	Number under op	otion
29/11/2007	2 years from each milestone achieved*	\$0.64	180,000	*
27/11/2008	2 years from each milestone achieved*	\$0.15	50,000	**
9/3/2010	31 October 2012	\$0.26	500,000	***
19/6/2012	4 July 2014	\$0.59	950,000	*v
			1,680,000	

<sup>\*</sup> Options issued to the CEO under the Company's Equity Option Plan in lieu of cash bonus. 400,000 options were originally issued which vest on the achievement of certain Key Events. As at 30 June 2012, 220,000 of the options issued had expired.

<sup>\*\*</sup> Options issued to the CEO under the Company's Equity Option Plan in lieu of cash bonus. 500,000 options were originally issued which vest on the achievement of certain Key Events. As at 30 June 2012, 350,000 of the options issued had expired and 100,000 had been exercised by 30 June 2012.

<sup>\*\*\*</sup> Options issued to Directors. 750,000 options were issued of which 250,000 had been exercised by 30 June 2012.

<sup>\*</sup>v Options issued to Key Personnel.

360,000 ordinary shares were issued on the exercise of options during the year ended 30 June 2012.

During the year 1,115,000 options expired.

Option holders do not have any rights to participate in any issues of ordinary shares or other interests in the Company or any other entity.

#### **Remuneration Report (Audited)**

This report outlines the remuneration arrangements in place for the Directors and executives of Tissue Therapies Limited.

The Company's Board of Directors is responsible for determining and reviewing compensation arrangements for the Directors, the Chief Executive Officer (CEO) and others involved in the operation of the Group.

The Board assesses the appropriateness of the nature and amount of remuneration of the Directors and senior managers on a periodic basis by reference to relevant market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high quality Board and executive team.

#### **Non-executive Director Remuneration**

Objective: The Board seeks to set aggregate remuneration at a level which provides the Group with the ability to attract and retain Directors of the highest calibre at a cost that is acceptable to shareholders.

Structure: The Constitution and the ASX Listing Rules specify that the aggregate remuneration of non-executive directors shall be determined from time to time by a general meeting. An amount not exceeding the amount determined is then divided between the Directors as agreed. The latest determination was at the Annual General Meeting held on 28 November 2011 when shareholders approved an aggregate remuneration of \$400,000 per year.

The amount of aggregate remuneration sought to be approved by shareholders and the manner in which it is apportioned among Directors is reviewed annually. Each Director receives an annual fee for being a Director of the Company. No incentive payments are included.

#### **Executive Director Remuneration**

Objective: The Company aims to reward the Executive Directors with remuneration commensurate with their position and responsibilities. The CEO, Dr Steven Mercer, does not receive additional remuneration above his CEO salary to act as an Executive Director.

Structure: The Executive Directors receive a fixed annual amount in remuneration plus incentive payments for achievment of specific objectives.

#### **Executive Remuneration**

#### Chief Executive Officer

Objective: The Company aims to reward the CEO with remuneration commensurate with his position and responsibilities.

Structure: The CEO, Dr Steven Mercer is employed under contract. The current contract commenced on 27 September 2004. Dr Mercer's employment contract with the Company encompasses a curent total remuneration package of \$299,750 per annum.

Dr Mercer was awarded 400,000 performance based options in 2007 in lieu of a cash bonus. These options vested on the achievement of a series of specific performance milestones and have an exercise price of 64c within two years of each tranche of options vesting, however 220,000 of these options had expired by the end of the financial year.

In 2008, in lieu of a cash bonus, Dr Mercer was awarded a further 500,000 performance based options. These options will also vest on the achievement of specific performance milestones and have an exercise price of 15c within two years of each tranche of options vesting, however 350,000 of these options had expired and 100,000 had been exercised by the end of the financial year.

During 2010 a futher 250,000 options were awared to Dr Mercer as part of the options issued at that time to key management personnel. These options are exercisable at \$0.26 and are included in the following section, "Key Management Personnel Remuneration".

During June 2011 Dr Mercer was awarded a performance based cash bonus of \$25,000. Achievement of this bonus is dependent on successful completion of the international multicentre venous ulcer trial, successful completion of larger scale manufacturing and successful classification by the FDA of VitroGro®.

#### Company Secretary

Objective: The Company aims to reward the Company Secretary with remuneration commensurate with his position and responsibilities.

Structure: The Company Secretary is employed under contract. The current contract commenced on 5 September 2011. Mr McKenzie's employment contract with the Company encompasses a current total remuneration package of \$218,000 per annum.

During 2010, 250,000 options at \$0.26 were awarded to the Company Secretary as part of the options issued at that time to key management personnel. These options had been exercised by the end of the financial year.

#### **Key Management Personnel Remuneration**

Details of the nature and amount of each element of the emoluments to Key Management Personnel of Tissue Therapies Limited for the year ended 30 June 2012 are set out as follows:

		Pri	mary	Post Employment	Share-based payment			
Key Manageme Personnel	nt	Cash Salary and fees	Bonus / Non- monetary benefits	Super- annuation	Equity	Options (a)	Total	Performance related
		\$	\$	\$	\$	\$	\$	%
Non-Executive Director	rs							
R. Clarke (Chairman)	2012	60,000	•	5,400	-	-	65,400	-
	2011	45,000	-	4,050	-	-	49,050	-
M. Bridges	2012	59,952	-	-	-	-	59,952	-
	2011	40,000	-	-	-	47,750	87,750	54.4%
I. Ross	2012	4,979	-	-	-	-	4,979	-
	2011	-	-	-	-	-	-	-
C. Hirst	2012	55,000	-	4,950	-	-	59,950	-
	2011	40,000	-	3,600	-	47,750	91,350	52.3%
G. Baynton	2012	57,454	-	-	-	-	57,454	-
	2011	40,000	-	-	-	-	40,000	-
Executive Directors								
Dr S. Mercer (CEO)	2012	275,000	22,936	26,814	-	-	324,750	
	2011	205,620	-	18,505	-	47,750	271,875	17.6%
Other Key Managemen Personnel	t							
D. McKenzie	2012	184,943	-	10,668	-	-	195,611	-
	2011	84,065	-	-	-	8,061	92,126	8.7%
Total	2012	728,831	-	48,603	-	-	777,434	
	2011	454,685	-	26,155	-	151,311	632,151	

#### (a) Options issued to Key Management Personnel

During the year 950,000 (2011: 750,000) options were issued under the Company's Equity Option Plan to Key Personnel. 360,000 options were exercised during the year.

The value of options issued to Key Personnel have been partly amortised during the year with \$6,333 (2011: \$183,393) being included in Administration expense in the statement of comprehensive income.

#### **Options Granted as Remuneration**

#### Terms and conditions for each grant

Key Management Personnel	Vested no.	Granted no.	Grant date	Value per option at grant date \$	Exercise price \$	First exercise date	Last exercise date
2011 M Bridges Dr C Hirst Dr S Mercer	250,000 250,000 250,000	250,000 250,000 250,000	9/3/2010 9/3/2010 9/3/2010	0.191 0.191 0.191	0.26 0.26 0.26	31/03/2011 31/03/2011 31/03/2011	31/10/2012 31/10/2012 31/10/2012

360,000 shares were issued on the exercise of options during the financial year.

#### Directors' and Officers' Indemnification

The Company has indemnified Directors and officers to the maximum extent permitted by law, against any liability incurred by them as, or by virtue of their holding office as and acting in the capacity of, an officer of the Company.

Insurance premiums have been paid during the year in respect of a contract insuring Directors and officers against legal costs incurred in defending proceedings against them. Details of the nature of liabilities covered or the amount of premiums paid are not disclosed as such disclosure is prohibited in terms of the contract.

#### **Directors' Meetings**

The number of meetings of Directors (including meetings of committees of Directors) held during the year and the number of meetings attended by each Director was as follows:

	Directors'	Directors' Meetings		Audit and Risk Management Committee		n Committee	Nomination	Committee
	Eligible to Attend	Attended	Eligible to Attend	Attended	Eligible to Attend	Attended	Eligible to Attend	Attended
R Clarke	9	9	3	3	1	1	1	1
M Bridges	9	9	3	3	1	1	1	1
l Ross	1	1	1	1	-	-	-	-
C Hirst	9	9	n/a	n/a	1	1	1	1
G Baynton	9	8	3	3	1	1	1	1
Dr S Mercer	9	9	n/a	n/a	n/a	n/a	n/a	n/a

#### **Environmental Regulation**

The Group's operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of a State or Territory.

#### **Proceedings on Behalf of the Company**

No proceedings have been brought, or intervened in, on behalf of the company with leave of the Court under S237 of the *Corporations Act 2001* 

#### **Auditor**

Lawler Hacketts Audit has been appointed as the Company's auditor.

There is no former partner or director of Lawler Hacketts Audit who is or was at any time during the year an officer of the Company.

#### **Non-audit Services**

The Board of Directors, in accordance with advice from the Audit and Risk Management Committee, is satisfied that the provision of the non-audit services during the year is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001*. The Directors are satisfied that the services disclosed below did not compromise the external auditor's independence for the following reasons:

- all non-audit services are reviewed and approved by the Audit and Risk Management Committee prior to commencement to ensure they do not adversely affect the integrity and objectivity of the auditor; and
- the nature of the services provided do not compromise the general principles relating to auditor independence in accordance with APES 110: Code of Ethics for Professional Accountants set by the Accounting Professional and Ethical Standards Board.

The following fees for non-audit services were paid / payable to the external auditors or related entities of the external auditors during the year ended 30 June 2012:

Non-audit services	30 June 2012 \$	30 June 2011 \$
Audit or review of regulatory returns and due diligence services	1,500	12,500

#### **Auditor's Declaration**

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is attached to this Directors' Report.

Signed in accordance with a resolution of the Board of Directors.

Roger Clarke Chairman

Brisbane, 21 August 2012

ull

Steven Mercer CEO & Director



## Auditor's Independence Declaration under Section 307C of the Corporations Act 2001 to the Directors of Tissue Therapies Limited and Controlled Entity

I declare that, to the best of my knowledge and belief, during the year ended 30 June 2012 there have been:

- (a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- (b) no contraventions of any applicable code of professional conduct in relation to the audit.

**Lawler Hacketts Audit** 

19

L J Murphy Partner

Brisbane, 21 August 2012

#### **FINANCIAL STATEMENTS**

# TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2012

		CONSO	LIDATED
	Note	30 June 2012 \$	30 June 2011 \$
Continuing operations			
Revenue	2(a)	336,637	232,024
Other income	2(b)	532,815	220,586
	<del>-</del>	869,452	452,610
Research and development expenses		(1,288,256)	(1,255,700)
Clinical trials expenses		(668,550)	(2,168,238)
Occupancy expenses		(102,903)	(21,847)
Marketing and business development		(294,759)	(9,470)
Regulatory approvals		(754,827)	-
Intellectual property		(324,908)	(349,148)
Sales and distribution		(182,266)	-
Transport and logistics		(58,433)	-
Inventory write down to net realisable value		(728,601)	(364,995)
Manufacturing expenses		(25,646)	-
Employment expenses		(1,443,517)	(574,030)
Consultants		(977,807)	(471,239)
Administration expenses		(878,843)	(723,592)
Depreciation and amortisation		(37,404)	(13,836)
Finance costs		(8,204)	(3,780)
Loss on foreign exchange		(165,864)	(48,883)
Other expenses		(135,890)	(93,439)
Loss before income tax benefit	3	(7,207,226)	(5,645,587)
Income tax benefit	4(a)	437,844	305,039
Loss from continuing operations after income tax benefit	-	(6,769,382)	(5,340,548)
Other comprehensive income items			
Other comprehensive income:			
- Foreign exchange translation reseve		(2,012)	-
Income tax relating to components of other comprehensive income items	_	-	-
Other comprehensive income after income tax benefit	-	(2,012)	-
Total comprehensive income for the year	-	(6,771,394)	(5,340,548)
Loss attributable to members of the Company		(6,769,382)	(5,340,548)
Total comprehensive income attributable to members of the Company	_	(6,771,394)	(5,340,548)
	-	Cents	Cents
Overall Operations			• • • • • • • • • • • • • • • • • • • •
Basic earnings per share	26	(4.01)	(3.79)
Diluted earnings per share	26	(4.01)	(3.79)
The accompanying notes form part of th	ese statements	, ,	, ,

# TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2012

CURRENT ASSETS           Current assets         5         5,158,393         15,416,321           Trade and other receivables         6(a)         122,391         125,689           Current tax assets         4(c)         393,730         217,845           Inventories         7(a)         5,983,541         574,651           Other assets         8(a)         254,372         545,695           TOTAL CURRENT ASSETS         11,912,427         16,880,201           NON-CURRENT ASSETS         7(b)         305,552         694,796           Property, plant and equipment         9         370,499         86,119           Intrangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         10,19,826         1,123,165           TOTAL ASSETS         10,19,826         1,123,165           TOTAL ASSETS         11         2,071,919         858,718           Current tax isabilities         4(e)         5,649         -           Current tax isabilities         4(e)         5,649         -           Current tax isabilities         12         168,934         111,212		CONSOLIDATED		
Cash and cash equivalents         5         5,158,393         15,416,321           Trade and other receivables         6(a)         122,391         125,689           Current Lax assets         4(c)         393,730         217,845           Inventories         7(a)         5,983,541         574,651           Other assets         8(a)         254,372         545,695           TOTAL CURRENT ASSETS         11,912,427         16,880,201           NON-CURRENT ASSETS         7(b)         305,552         694,796           Properly, plant and equipment         9         370,499         66,119           Intensible assets         10         342,250         342,250           Other assets         10         342,250         342,250           Other assets         10         342,250         342,250           Other assets         10         1,193,265         1,123,165           TOTAL ASSETS         10,198,266         1,123,165         1           TOTAL ASSETS         11         2,071,919         858,718           Turde and other payables         11         2,071,919         858,718           Trade and other payables         12         168,934         111,212           Financial liab		Note	30 June 2012	30 June 2011
Trade and other receivables         6(a)         122,391         125,689           Current tax assets         4(c)         333,730         217,845           Inventories         7(a)         5,983,541         574,651           Other assets         8(a)         254,372         545,695           TOTAL CURRENT ASSETS         11,912,427         16,880,201           NON-CURRENT ASSETS           Property, plant and equipment         9         370,499         66,119           Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL AON-CURRENT ASSETS         10,19,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES         12,971,919         858,718           Current tax liabilities         4(e)         5,549         -           Current tax liabilities         27         23,972         -           Financial liabilities         27         23,972         -           Financial liabilities         13         164,924         -           Financial liabilities         13         164,924	CURRENT ASSETS			
Current tax assets         4(c)         393,730         217,845           Inventories         7(a)         5,983,541         574,651           Other assets         8(a)         254,372         545,695           TOTAL CURRENT ASSETS         11,912,427         16,880,201           NON-CURRENT ASSETS         7(b)         305,552         694,796           Properly, plant and equipment         9         370,499         86,119           Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         1,019,826         1,123,165           CURRENT LIABILITIES         1         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILIT	Cash and cash equivalents	5	5,158,393	15,416,321
Trade and other payables   11   2,071,919   858,718   11,1212   11,213   11,212   11,212   11,213   11,212   11,213   11,212   11,213   11,212   11,213   11,212   11,213	Trade and other receivables	6(a)	122,391	125,689
Other assets         8(a)         254,372         545,695           TOTAL CURRENT ASSETS         111,912,427         16,880,201           NON-CURRENT ASSETS         111,912,427         16,880,201           Inventories         7(b)         305,552         694,796           Property, plant and equipment         9         370,499         86,119           Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         10,19,826         1,123,165         -           TOTAL ASSETS         10,19,826         1,23,165         -           TOTAL ASSETS         11         2,071,919         858,718           CURRENT LIABILITIES         12         168,934         111,212           Provisions         12         168,934         111,212           Provisions         12         168,934         111,212           Provisions         12         168,934         111,212           Provisions         12         168,934         111,212           Total CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           <	Current tax assets	4(c)	393,730	217,845
NON-CURRENT ASSETS         11,912,427         16,880,201           NON-CURRENT ASSETS         1         11,912,427         16,880,201           Property, plant and equipment land equipment land equipment land equipment land sissets         9         370,499         86,119           Intengible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         10,19,826         1,123,165           TOTAL ASSETS         10,19,826         1,123,165           CURRENT LIABILITIES         12,393,253         18,003,366           CURRENT Liabilities         4(e)         5,649         -           Provisions         12         168,934         111,1212           Financial liabilities         27         23,972         -           Other liabilities         27         23,972         -           TOTAL CURRENT LIABILITIES         164,924         -           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES	Inventories	7(a)	5,983,541	574,651
NON-CURRENT ASSETS   Inventories   7(b)   305,552   694,796   Property, plant and equipment   9   370,499   86,119   Intangible assets   10   342,250   342,250   Other assets   1,019,826   1,525   -	Other assets	8(a)	254,372	545,695
Inventories         7(b)         305,552         694,796           Property, plant and equipment         9         370,499         86,119           Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         3,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL SOLUTION CONTENT LIABILITIES         164,924         -	TOTAL CURRENT ASSETS	-	11,912,427	16,880,201
Property, plant and equipment         9         370,499         86,119           Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Re	NON-CURRENT ASSETS			
Intangible assets         10         342,250         342,250           Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,36	Inventories	7(b)	305,552	694,796
Other assets         8(b)         1,525         -           TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL SEETS         10,466,891         17,033,436           EQUITY         2,465,362         969,930           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986 </td <td>Property, plant and equipment</td> <td>9</td> <td>370,499</td> <td>86,119</td>	Property, plant and equipment	9	370,499	86,119
TOTAL NON-CURRENT ASSETS         1,019,826         1,123,165           TOTAL ASSETS         12,932,253         18,003,366           CURRENT LIABILITIES           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           EQUITY         10,466,891         17,033,436           EQUITY         10,466,891         17,033,436           EQUITY         20,000,000         15         121,986         356,799           Accumulated losses         129,395,426	Intangible assets	10	342,250	342,250
CURRENT LIABILITIES         12,932,253         18,003,366           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Other assets	8(b)	1,525	-
CURRENT LIABILITIES           Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	TOTAL NON-CURRENT ASSETS	<u>-</u>	1,019,826	1,123,165
Trade and other payables         11         2,071,919         858,718           Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	TOTAL ASSETS	-	12,932,253	18,003,366
Current tax liabilities         4(e)         5,649         -           Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	CURRENT LIABILITIES			
Provisions         12         168,934         111,212           Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Trade and other payables	11	2,071,919	858,718
Financial liabilities         27         23,972         -           Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Current tax liabilities	4(e)	5,649	-
Other liabilities         13         29,964         -           TOTAL CURRENT LIABILITIES         TOTAL INDIVIDUAL MON-CURRENT LIABILITIES           Other liabilities         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Provisions	12	168,934	111,212
TOTAL CURRENT LIABILITIES         2,300,438         969,930           NON-CURRENT LIABILITIES         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Financial liabilities	27	23,972	-
NON-CURRENT LIABILITIES           Other liabilities         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY           Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Other liabilities	13	29,964	-
Other liabilities         13         164,924         -           TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	TOTAL CURRENT LIABILITIES	- -	2,300,438	969,930
TOTAL NON-CURRENT LIABILITIES         164,924         -           TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	NON-CURRENT LIABILITIES			
TOTAL LIABILITIES         2,465,362         969,930           NET ASSETS         10,466,891         17,033,436           EQUITY         Value of the contributed equity         14(a)         39,740,331         39,525,004           Reserves         15         121,986         356,799           Accumulated losses         (29,395,426)         (22,848,367)	Other liabilities	13	164,924	-
NET ASSETS       10,466,891       17,033,436         EQUITY       Value of the contributed equity       14(a)       39,740,331       39,525,004         Reserves       15       121,986       356,799         Accumulated losses       (29,395,426)       (22,848,367)	TOTAL NON-CURRENT LIABILITIES	<del>-</del>	164,924	-
EQUITY         Contributed equity       14(a)       39,740,331       39,525,004         Reserves       15       121,986       356,799         Accumulated losses       (29,395,426)       (22,848,367)	TOTAL LIABILITIES	- -	2,465,362	969,930
Contributed equity       14(a)       39,740,331       39,525,004         Reserves       15       121,986       356,799         Accumulated losses       (29,395,426)       (22,848,367)	NET ASSETS	-	10,466,891	17,033,436
Reserves       15       121,986       356,799         Accumulated losses       (29,395,426)       (22,848,367)	EQUITY			
Accumulated losses (29,395,426) (22,848,367)	Contributed equity	14(a)	39,740,331	39,525,004
	Reserves	15	121,986	356,799
TOTAL EQUITY 10,466,891 17,033,436	Accumulated losses	_	(29,395,426)	(22,848,367)
	TOTAL EQUITY	-	10,466,891	17,033,436

The accompanying notes form part of these statements.

# TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2012

		Rese	ves			
	Share Capital	Option Reserve	Foreign Exchange Translation Reserve \$	Accumulated Losses \$	Total \$	
Total equity at 1 July 2010	25,276,808	173,406	-	(17,507,819)	7,942,395	
Total comprehensive income	-	-	-	(5,340,548)	(5,340,548)	
Transactions with owners in their capacity as owners:						
- Contributions of equity	15,177,873	-	-	-	15,177,873	
- Transaction costs	(929,677)	-	-	-	(929,677)	
- Employee share options	-	183,393	-	-	183,393	
Total transactions with owners	14,248,196	183,393	-	-	14,431,589	
Total equity at 30 June 2011	39,525,004	356,799	-	(22,848,367)	17,033,436	
Total comprehensive income	-	-	(2,012)	(6,769,382)	(6,771,394)	
Transactions with owners in their capacity as owners:						
- Contributions of equity	229,481	(16,811)	-	-	212,670	
- Transaction costs	(14,154)	-	-	-	(14,154)	
- Employee share options	-	6,333	-	-	6,333	
- Option reserve transferred	=	(222,323)	-	222,323	=	
Total transactions with owners	215,327	(232,802)	-	222,323	204,849	
Total equity at 30 June 2012	39,740,331	123,998	(2,012)	(29,395,426)	10,466,891	

The accompanying notes form part of these statements.

# TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2012

		CONSOLIDATED	
	Note	30 June 2012	30 June 2011
CASH FLOW FROM OPERATING ACTIVITIES			
Receipts from customers (inclusive of goods and services tax)		346,152	508,790
Payments for research, clinical trials and regulatory		(3,024,421)	(1,204,324)
Payments to suppliers and employees (inclusive of goods and services tax)		(8,356,405)	(4,056,285)
Interest received		551,219	187,709
Finance costs paid		(8,204)	(3,780)
Income tax rebate received	_	267,607	277,001
Net cash provided by (used in) operating activities	25(b)	(10,224,052)	(4,290,889)
CASH FLOW FROM INVESTING ACTIVITIES			
Payments for property, plant and equipment		(112,037)	-
Net cash provided by (used in) investing activities	-	(112,037)	-
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from share issues		93,600	15,177,873
Costs of share issue	_	(14,154)	(929,677)
Net cash provided by (used in) financing activities	-	79,446	14,248,196
Net increase / (decrease) in cash held		(10,256,643)	9,957,307
Cash at beginning of year		15,416,321	5,500,285
Effects of exchange rate fluctuations on cash held		(1,285)	(41,271)
Cash at end of year	25(a)	5,158,393	15,416,321

The accompanying notes form part of these statements.

### TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2012

#### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES

These consolidated financial statements and notes represent those of Tissue Therapies Limited (the "Company") and Controlled Entity (the "Consolidated Group" or "Group"). The company was incorporated and domiciled in Australia.

The separate financial statements of the parent entity, Tissue Therapies Limited, have not been presented within this financial report as permitted by the *Corporations Act 2001*.

The financial report was authorised for issue on 21 August 2012 by the Board of Directors.

#### Basis of preparation

The financial report is a general purpose financial report that has been prepared in accordance with Australian Accounting Standards, including Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

The Group is a for-profit entity for financial reporting purposes under Australian Accounting Standards.

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 to which they apply. Compliance with Australian Accounting Standards ensures that the financial statements and notes also comply with International Financial Reporting Standards. Significant accounting policies adopted in the preparation of this financial report are presented below. They have been consistently applied unless otherwise stated.

Except for cashflow information, the financial report has been prepared on an accrual basis, based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities.

#### **Accounting Policies**

#### a. Principles of Consolidation

The consolidated financial statements incorporate the assets, liabilities and results of entities controlled by Tissue Therapies Limited, a Listed Public Limited at the end of the reporting period. A controlled entity is any entity over which Tissue Therapies Limited has the ability and right to govern the financial and operating policies so as to obtain benefits from the entity's activities.

Where controlled entities have entered or left the Group during the year, the financial performance of those entities is included only for the period of the year that they were controlled. A list of controlled entities is contained in Note 30 to the financial statements.

In preparing the consolidated financial statements, all intragroup balances and transactions between entities in the consolidated group have been eliminated in full on consolidation.

Non-controlling interests, being the equity in a subsidiary not attributable, directly or indirectly, to a parent, are reported separately within the equity section of the consolidated statement of financial position and statement of comprehensive income. The non-controlling interests in the net assets comprise their interests at the date of the original business combination and their share of changes in equity since that date.

#### b. Income Tax

The income tax expense (revenue) for the year comprises current income tax expense (income) and deferred tax expense (income). Current income tax expense charged to the profit or loss is the tax payable on taxable income calculated using applicable income tax rates enacted, or substantially enacted, as at reporting date. Current tax liabilities (assets) are therefore measured at the amounts expected to be paid to (recovered from) the relevant taxation authority.

Deferred income tax expense reflects movements in deferred tax asset and deferred tax liability balances during the year as well unused tax losses.

Current and deferred income tax expense (income) is charged or credited directly to equity instead of the profit or loss when the tax relates to items that are credited or charged directly to equity.

### TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2012

#### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### b. Income Tax (Continued)

Deferred tax assets and liabilities are ascertained based on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred tax assets also result where amounts have been fully expensed but future tax deductions are available. No deferred income tax will be recognised from the initial recognition of an asset or liability, excluding a business combination, where there is no effect on accounting or taxable profit or loss.

Deferred tax assets and liabilities are calculated at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates enacted or substantively enacted at reporting date. Their measurement also reflects the manner in which management expects to recover or settle the carrying amount of the related asset or liability.

Deferred tax assets relating to temporary differences and unused tax losses are recognised only to the extent that it is probable that future taxable profit will be available against which the benefits of the deferred tax asset can be utilised.

#### c. Research and Development expenditure

Expenditure during the research phase of a project is recognised as an expense when incurred. Development costs are capitalised only when technical feasibility studies identify that the project will deliver future economic benefits and these benefits can be measured reliably.

#### d. Intangibles

Licenses and Patents

Licenses and patents are recognised at cost of acquisition. Licenses, patents and trademarks have a finite life and are carried at cost less any accumulated amortisation and any impairment losses. Licenses and patents are amortised over their useful life, which has been assessed as ten years from the date the intangible asset is in its intended use.

#### e. Employee benefits

Provision is made for the Company's liability for employee benefits arising from services rendered by employees to balance date. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled, plus related on-costs. Employee benefits payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits with consideration given to employees wages increases and the probability that the employees may satisfy vesting requirements.

Equity -settled Compensation

The Company operates equity-settled share-based payment employee share and option schemes. The fair value of the equity to which employees become entitled is measured at grant date and recognised as an expense over the vesting period, with a corresponding increase to an equity account. The fair value of shares is ascertained as the market bid price. The fair value of options is ascertained using a Black–Scholes pricing model which incorporates all market vesting conditions. The number of shares and options expected to vest is reviewed and adjusted at each reporting date such that the amount recognised for services received as consideration for the equity instruments granted shall be based on the number of equity instruments that eventually vest.

#### f. Cash and cash equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within short-term borrowings in current liabilities on the statement of financial position.

### TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2012

#### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### g. Revenue recognition

Revenues are recognised at fair value of the consideration received net of any applicable taxes.

Interest revenue is recognised as it accrues taking into account the interest rates applicable to the financial assets.

Government grants are recognised at fair value where there is reasonable assurance that the grant will be received and all grant conditions will be met. Grants relating to expense items are recognised as income over the periods necessary to match the grant to the costs they are compensating. Grants relating to assets are credited to deferred income at fair value and are credited to income over the expected useful life of the asset on a straight-line basis.

All revenue is stated net of the amount of goods and services tax.

#### h. Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Taxation Office. In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense. Receivables and payables in the statement of financial position are shown inclusive of GST.

Cash flows are presented in the statement of cash flows on a gross basis, except for the GST component of investing and financing activities, which are disclosed as operating cash flows.

#### i. Property, plant and equipment

Each class of property, plant and equipment is carried at cost or fair value less, where applicable, any accumulated depreciation and impairment losses.

#### Plant and equipment

Plant and equipment are initially measured on the cost basis.

The carrying amount of plant and equipment is reviewed annually by Directors to ensure it is not in excess of the recoverable amount from these assets. The recoverable amount is assessed on the basis of the expected net cash flows that will be received from the asset's employment and subsequent disposal. The expected net cash flows have been discounted to their present values in determining recoverable amounts.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Company and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the statement of comprehensive income during the financial period in which they are incurred.

#### Depreciation

The depreciable amount of all fixed assets including building and capitalised lease assets, but excluding freehold land, is depreciated on a straight-line basis over their useful lives to the Group commencing from the time the asset is held ready for use. The expected useful life for plant and equipment is 3 to 10 years.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains and losses are included in the statement of comprehensive income. When revalued assets are sold, amounts included in the revaluation reserve relating to that asset are transferred to retained earnings.

#### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### j. Inventory

Inventories are measured at the lower of cost and net realisable value. The cost of manufactured products includes direct materials, direct labour and an appropriate portion of variable and fixed overheads.

#### k. Trade and other creditors

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year and which are unpaid. The amounts are unsecured and usually paid within 30 days of recognition.

#### I. Leases

Lease payments for operating leases, where substantially all the risks and benefits remain with the lessor, are charged as expenses in the periods in which they are incurred.

Lease incentives under operating leases are recognised as a liability and amortised on a straight-line basis over the lease term.

### m. Impairment of assets

At each reporting date, the Group reviews the carrying values of its tangible and intangible assets to determine whether there is any indication that those assets have been impaired. If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Any excess of the asset's carrying value over its recoverable amount is expensed to the statement of comprehensive income. Impairment testing is performed annually for intangible assets with indefinite lives.

Where it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

#### n. Comparative figures

When required by Accounting Standards, comparative figures have been adjusted to conform to changes in presentation for the current financial year.

# o. Financial Instruments

Recognition and Initial Measurement

Financial assets and financial liabilities are recognised when the entity becomes a party to the contractual provisions to the instrument. For financial assets, this is equivalent to the date that the company commits itself to either the purchase or sale of the asset (ie trade date accounting is adopted).

Financial instruments are initially measured at fair value plus transaction costs, except where the instrument is classified "at fair value through profit or loss", in which case transaction costs are expensed to profit or loss immediately.

Classification and Subsequent Measurement

Financial instruments are subsequently measured at fair value, amortised cost using the effective interest method, or cost.

Amortised cost is calculated as the amount at which the financial asset or financial liability is measured at initial recognition less principal repayments and any reduction for impairment, and adjusted for any cumulative amortisation of the difference between that initial amount and the maturity amount calculated using the *effective interest method*.

Fair value is determined based on current bid prices for all quoted investments. Valuation techniques are applied to determine the fair value for all unlisted securities, including recent arm's length transactions, reference to similar instruments and option pricing models.

### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### o. Financial Instruments (Continued)

The effective interest method is used to allocate interest income or interest expense over the relevant period and is equivalent to the rate that discounts estimated future cash payments or receipts (including fees, transaction costs and other premiums or discounts) over the expected life (or when this cannot be reliably predicted, the contractual term) of the financial instrument to the net carrying amount of the financial asset or financial liability. Revisions to expected future net cash flows will necessitate an adjustment to the carrying amount with a consequential recognition of an income or expense item in profit or loss.

The Group does not designate any interests in subsidiaries, associates or joint venture entities as being subject to the requirements of Accounting Standards specifically applicable to financial instruments.

# (i) Financial assets at fair value through profit or loss

Financial assets are classified at "fair value through profit or loss" when they are held for trading for the purpose of short-term profit taking, derivatives not held for hedging purposes, or when they are designated as such to avoid an accounting mismatch or to enable performance evaluation where a Group of financial assets is managed by key management personnel on a fair value basis in accordance with a documented risk management or investment strategy. Such assets are subsequently measured at fair value with changes in carrying amount being included in profit or loss.

#### (ii) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are subsequently measured at amortised cost. Gains or losses are recognised in profit or loss through the amortisation process and when the financial asset is derecognised.

### (iii) Held-to-maturity investments

Held-to-maturity investments are non-derivative financial assets that have fixed maturities and fixed or determinable payments, and it is the Group's intention to hold these investments to maturity. They are subsequently measured at amortised cost. Gains or losses are recognised in profit or loss through the amortisation process and when the financial asset is derecognised.

### (iv) Available-for-sale investments

Available-for-sale investments are non-derivative financial assets that are either not capable of being classified into other categories of financial assets due to their nature or they are designated as such by management. They comprise investments in the equity of other entities where there is neither a fixed maturity nor fixed or determinable payments.

They are subsequently measured at fair value with any remeasurements other than impairment losses and foreign exchange gains and losses recognised in other comprehensive income. When the financial asset is derecognised, the cumulative gain or loss pertaining to that asset previously recognised in other comprehensive income is reclassified into profit or loss.

Available-for-sale financial assets are classified as non-current assets when they are expected to be sold after 12 months from the end of the reporting period. All other available-for-sale financial assets are classified as current assets.

## (v) Financial liabilities

Non-derivative financial liabilities other than financial guarantees are subsequently measured at amortised cost. Gains or losses are recognised in profit or loss through the amortisation process and when the financial liability is derecognised.

### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### o. Financial Instruments (Continued)

#### Impairment

At the end of each reporting period, the Group assesses whether there is objective evidence that a financial asset has been impaired. A financial asset or a group of financial assets is deemed to be impaired if, and only if, there is objective evidence of impairment as a result of one or more events (a "loss event") having occurred, which has an impact on the estimated future cash flows of the financial asset(s).

In the case of available-for-sale financial assets, a significant or prolonged decline in the market value of the instrument is considered to constitute a loss event. Impairment losses are recognised in profit or loss immediately. Also, any cumulative decline in fair value previously recognised in other comprehensive income is reclassified to profit or loss at this point.

In the case of financial assets carried at amortised cost, loss events may include: indications that the debtors or a group of debtors are experiencing significant financial difficulty, default or delinquency in interest or principal payments; indications that they will enter bankruptcy or other financial reorganisation; and changes in arrears or economic conditions that correlate with defaults.

For financial assets carried at amortised cost (including loans and receivables), a separate allowance account is used to reduce the carrying amount of financial assets impaired by credit losses. After having taken all possible measures of recovery, if management establishes that the carrying amount cannot be recovered by any means, at that point the written-off amounts are charged to the allowance account or the carrying amount of impaired financial assets is reduced directly if no impairment amount was previously recognised in the allowance account.

When the terms of financial assets that would otherwise have been past due or impaired have been renegotiated, the Group recognises the impairment for such financial assets by taking into account the original terms as if the terms have not been renegotiated so that the loss events that have occurred are duly considered.

### Financial Guarantees

Where material, financial guarantees issued that require the issuer to make specified payments to reimburse the holder for a loss it incurs because a specified debtor fails to make payment when due are recognised as a financial liability at fair value on initial recognition.

The fair value of financial guarantee contracts has been assessed using a probability-weighted discounted cash flow approach. The probability has been based on:

- the likelihood of the guaranteed party defaulting during the next reporting period;
- the proportion of the exposure that is not expected to be recovered due to the guaranteed party defaulting; and
- the maximum loss exposure if the guaranteed party were to default.

Financial guarantees are subsequently measured at the higher of the best estimate of the obligation in accordance with AASB 137: Provisions, Contingent Liabilities and Contingent Assets and the amount initially recognised less, when appropriate, cumulative amortisation in accordance with AASB 118: Revenue. Where the entity gives guarantees in exchange for a fee, revenue is recognised under AASB 118.

### Derecognition

Financial assets are derecognised when the contractual rights to receipt of cash flows expire or the asset is transferred to another party whereby the entity no longer has any significant continuing involvement in the risks and benefits associated with the asset. Financial liabilities are derecognised when the related obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability extinguished or transferred to another party and the fair value of consideration paid, including the transfer of non-cash assets or liabilities assumed, is recognised in profit or loss.

### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Foreign Currency Transactions and Balances

Functional and Presentation Currency

The functional currency of each of the Group's entities is measured using the currency of the primary economic environment in which that entity operates. The consolidated financial statements are presented in Australian dollars, which is the parent entity's functional currency.

Transactions and Balances

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the year-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined.

Exchange differences arising on the translation of monetary items are recognised in profit or loss, except where deferred in equity as a qualifying cash flow or net investment hedge.

Exchange differences arising on the translation of non-monetary items are recognised directly in other comprehensive income to the extent that the underlying gain or loss is recognised in other comprehensive income; otherwise the exchange difference is recognised in profit or loss.

**Group Companies** 

The financial results and position of foreign operations, whose functional currency is different from the Group's presentation currency, are translated as follows:

- assets and liabilities are translated at exchange rates prevailing at the end of the reporting period;
- income and expenses are translated at average exchange rates for the period; and
- retained earnings are translated at the exchange rates prevailing at the date of the transaction.

Exchange differences arising on translation of foreign operations with functional currencies other than Australian dollars are recognised in other comprehensive income and included in the foreign currency translation reserve in the statement of financial position. These differences are recognised in profit or loss in the period in which the operation is disposed of.

### q. Critical Accounting Estimates and Judgments

The Directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Group.

Key Estimates — Impairment

The Group assesses impairment at each reporting date by evaluating conditions specific to the Group that may lead to impairment of assets. Where an impairment trigger exists, the recoverable amount of the asset is determined.

No impairment has been recognised in respect of licenses and trademarks for the year ended 30 June 2012.

Key Judgements - Inventory

The Group assessed the valuation of protein inventory on hand at 30 June 2012. Based on the outcome of research and development activities to date and anticipated future events and use of protein on hand, the Group has written down the value of protein components on hand by \$728,601 (2011: \$364,995). This is shown in the statement of comprehensive income for the current year.

### NOTE 1: STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### r. Uncertainty regarding the Recoverability of VitroGro® ECM Inventory

Subsequent to 30 June 2012, the group was advised by the Notified Body, the British Standards Institute (BSI) that the product could be regulated as a Medical Device under an alternative Rule to that which was previously agreed. The United Kingdom regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) is currently arbitrating the matter. Depending upon the outcome, there is potential for a delay in commencement of sales while an additional regulatory review is undertaken as a result of the alternative Device Rule being applied. At 30 June 2012, the current shelf life of the inventory of VitroGro® ECM is 14 months which will expire in August 2013. Therefore, as a result of a potential delay in the sales of VitroGro® ECM and its shelf life there is uncertainty as to the recoverable value of the finished goods of VitroGro® ECM, unless a concession note to extend shelf life is obtained and the cost of relabeling of the finished goods can be absorbed by the available margin in the sales price.

In assessing the recoverable value of the inventory of VitroGro® ECM, Management recognises that a routine concession note process exists under the regulatory procedures allowing an extension to the shelf life for a period of time that can be supported by stability data available at the time. In this regard, at 30 June 2012, and based on stability analysis already undertaken which indicates a stable profile for the commercial lifetime of the product, Management has assessed that the inventory of VitroGro® ECM is not impaired and no impairment provisions has been raised.

Management is therefore confident that the carrying value of finished goods of VitroGro® ECM at 30 June 2012 is recoverable provided the following circumstances can be achieved:

- Successful resolution of the mediation to allow sales of product in line with forecast sales for 2013, or
  - The routine concession note process under the relevant regulatory procedures allows an extension to the shelf life of
- the March 2012 batch at the time it is requested, and;
  - The additional cost of relabeling the finished goods of VitroGro® ECM is absorbed by the available margin in the
- sales price.

The directors are confident of achieving the above and therefore believe that the carrying value of finished goods of VitroGro® ECM is recoverable.

No adjustments have therefore been made relating to the recoverability of recorded cost of finished goods of VitroGro® ECM.

	CONSO	LIDATED
	30 June 2012	30 June 2011
	\$	\$
NOTE 2: REVENUE / OTHER INCOME		
a) Revenue		
Research grants	336,637	220,461
Product sales		11,563
Total revenue	336,637	232,024

		CONSOLIDATED	
		30 June 2012 \$	30 June 2011 \$
NO	TE 2: REVENUE / OTHER INCOME (Continued)		
b) (	Other income		
	Interest received	532,815	220,586
	Total other income	532,815	220,586
NO	TE 3: LOSS FOR THE YEAR		
Ехр	enses		
	Research and development expenses	1,288,256	1,255,700
	Clinical trials expenses	668,550	2,168,238
	Inventory write down to net realisable value	728,601	364,995
	Loss on foreign exchange	165,864	48,883
	Finance costs – external	8,204	3,780
	Rental expense on operating leases – minimum lease payments	75,022	7,240
	Depreciation expenses	37,404	13,836
NO	TE 4: INCOME TAX		
a)	The components of income tax benefit comprises		
	Current tax	388,100	217,843
	Under provision in respect of prior years	49,744	87,196
	Total tax benefit	437,844	305,039
b)	The prima facie tax benefit on loss from ordinary activities before income tax is reconciled to the income tax benefit as follows		
	Tax benefit on loss from ordinary activities at 30% (2011 : 30%)	2,162,168	1,693,676
	Tax effect of:		
	R&D expenditure taken as a cash offset	(313,353)	(231,364)
	Other	(61,248)	(88,682)
	Tax losses available	1,787,567	1,373,630
	Tax losses utilised by:		
	Income tax benefit attributable to R&D tax offset receivable	393,730	217,843
	Income tax benefit attributable to R&D tax offset understated in prior year	49,744	87,196
	Income tax expense	(5,630)	,
	Income tax benefit relating to entity	437,844	305,039
	·	•	
	The applicable weighted average effective tax rates are as follows:	(6.1%)	(5.4%)

		CONSOLIDATED	
		30 June 2012 \$	30 June 2011 \$
NOT	E 4: INCOME TAX (Continued)		
c)	Current Tax Asset		
	Opening balance of R&D tax offset concession claimed	217,845	189,807
	Add- R&D tax offset understated in prior year	49,744	87,196
	Less- Income tax benefit attributable to R&D tax offset received	(267,589)	(277,001)
	Add - Income tax benefit attributable to R&D tax offset receivable	393,730	217,843
	Closing balance of research and development tax offset concession claimed	393,730	217,845
d)	Deferred Tax Asset  Deferred tax assets not brought to account, the benefits of which will only be realised if the conditions for deductibility set out in Note 1a occur:		
	Temporary differences	692,589	644,542
	Tax losses – operating losses	7,468,278	5,675,726
		8,160,867	6,320,268
e)	Current Tax Liabilities		
	Opening balance	-	-
	Income tax payable	5,649	-
	Closing balance of current tax liabilities	5,649	-
NOT	E 5: CASH AND CASH EQUIVALENTS		
Cash	at bank	56,166	581,539
Shor	term bank deposits - at call *	5,102,227	14,834,782
		5,158,393	15,416,321

 $<sup>^\</sup>star$  The deposits were in interest bearing floating rate accounts. Interest rates varied between 0.0% and 6.00% (2011 : 0.0% to 6.00%).

	CONSOLIDATED	
	30 June 2012	30 June 2011
	\$	\$
NOTE C. TRADE AND OTHER RECEIVANTES		
NOTE 6: TRADE AND OTHER RECEIVABLES		
a) Current assets		
GST/VAT receivable	103,523	92,804
Other receivables	18,868	32,885
	122,391	125,689
Current trade and term receivables are non-interest bearing loans and generally on 30 day terms. A provision for impairment is recognised when there is objective evidence that an individual trade or term receivable is impaired. There are no balances within trade debtors which are 'past due'.		
NOTE 7: INVENTORIES		
a) Current assets		
VitroGro® ECM – at cost	5,718,740	-
VitroGro® ECM – Work-in-progress – at cost	264,801	-
VitroGro® protein – at cost	_	574,651
	5,983,541	574,651

The inventory of finished goods of VitroGro® ECM is represented by a batch of VitroGro® ECM produced in March 2012 with a common shelf life of 18 months. At 30 June 2012, the current shelf life of the inventory of VitroGro® ECM is 14 months which will expire in August 2013. In assessing the recoverable value of the inventory of VitroGro® ECM, Management recognises that a routine concession note process exists under the relevant health regulatory procedures allowing an extension to the shelf life for a period of time that can be supported by stability data available at the time. In this regard, at 30 June 2012, and based on stability analysis already undertaken which indicates a stable profile for the commercial lifetime of the product, Management has assessed that the inventory of VitroGro® ECM is not impaired and no impairment provision has been raised.

### b) Non-current assets

VitroGro® production cells and reference protein – at net realisable value	305,552	-
VitroGro® Protein Components – at net realisable value	-	694,796
	305,552	694,796

Although the VitroGro® Protein Components were expensed during the year, it is expected that this material will be consumed during normal research and development activities.

	CONSOLIDATED		
	30 June 2012 \$	30 June 2011 \$	
NOTE 8: OTHER ASSETS			
a) Other current assets			
Prepayments			
- Clinical trials expenses	147,523	-	
- Inventory	-	491,912	
- Other	106,849	53,783	
	254,372	545,695	
b) Other non-current assets			
Other assets	1,525	-	
NOTE 9: PROPERTY, PLANT AND EQUIPMENT			
Plant and equipment – at cost	93,117	93,117	
Less: Accumulated depreciation	(20,930)	(15,745)	
	72,187	77,372	
Furniture and fixtures – at cost	80,033	29,453	
Less: Accumulated depreciation	(35,316)	(20,706)	
·	44,717	8,747	
Computer hardware and software – at cost	61,457	_	
Less: Accumulated depreciation	(2,750)	_	
•	58,707	-	
Fit out at cost	000 747		
Fit out – at cost	209,747	-	
Less: Accumulated depreciation	(14,859)	-	
	194,888	-	
Total property, plant and equipment	370,499	86,119	

# NOTE 9: PROPERTY, PLANT AND EQUIPMENT (Continued)

Reconciliations of the carrying amounts of each class of property, plant and equipment at the beginning and end of the current financial year are set out below.	Plant and equipment	Furniture and fixtures	Computer hardware and software	Fit out	Total
	\$	\$	\$	\$	\$
Carrying amount at 1July 2010	87,507	17,635	-	-	105,142
Additions	-	-	-	-	-
Disposals (written down value)	(5,187)	-	-	-	(5,187)
Depreciation expense	(4,948)	(8,888)	-	-	(13,836)
Carrying amount at 30 June 2011	77,372	8,747	-	-	86,119
Additions	-	50,580	61,457	209,747	112,037
Disposals (written down value)	-	-	-	-	-
Depreciation expense	(5,185)	(14,610)	(2,750)	(14,859)	(37,404)
Carrying amount at 30 June 2012	72,187	44,717	58,707	194,888	370,499

Based on the methodology applied in Note 1 to the financial statements, there were no impairment gains or losses recorded during the current financial year.

	CONSOLIDATED		
	30 June 2012 30 June	30 June 2011	
	\$	\$	
NOTE 10: INTANGIBLE ASSETS			
Licenses and patents - at cost	342,250	342,250	

Licences and patents are assessed to have finite useful lives. Amortisation will begin during the financial year ended 30 June 2013 when the Company commences commercial operations. There are no amortisation charges for licenses and patents for the current or prior financial periods.

# **NOTE 11: TRADE AND OTHER PAYABLES**

^	rrent			• • •
('111	rrant	ีเเว	nıı	ITIAC
Ou:	ICIII	. IIa	vII	เนธอ

Trade creditors	1,222,789	594,770
Other creditors and accruals	849,130	263,948
	2,071,919	858,718

	CONSOLIDATED		
	30 June 2012	30 June 2011	
	\$	\$	
NOTE 12: PROVISIONS			
Current provisions			
Provision for annual leave	168,934	111,212	
	_	_	
NOTE 13: OTHER LIABILITIES			
a) Current liabilities			
Deferred lease incentives	29,964	-	
b) Non-current liabilities			
Deferred lease incentives	164,924	-	
		_	
NOTE 14: ISSUED CAPITAL			
a) Share capital			
169,357,192 (2011: 168,739,422) fully paid ordinary shares	39,740,331	39,525,004	

# b) Fully paid ordinary shares

Ordinary shares participate in dividends and the proceeds on winding up of the Company in proportion to the number of shares held.

At shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands.

# **NOTE 14: ISSUED CAPITAL (Continued)**

# c) Movements in ordinary share capital

Date	Details	No. Shares	Issue price	\$
	Balance at 1 July 2010	138,201,447		25,276,808
	Ordinary shares issued on exercise of Options	100,000	15c	15,000
18/04/11	Ordinary shares issued on exercise of Options	250,000	26c	65,000
26/05/11	Ordinary shares issued by Placement	11,500,000	50c	5,750,000
26/05/11	Ordinary shares issued by Rights Issue	18,632,464	50c	9,316,232
21/06/11	Ordinary shares issued to consultant for consultancy services	55,511	57c	31,641
	Transaction costs arising from share issues			(929,677)
	Balance at 30 June 2011	168,739,422		39,525,004
02/12/11	Ordinary shares issued to consultant for consultancy services	115,712	52c	59,893
28/03/12	Ordinary shares issued on exercise of Options	320,000	31c	98,144
30/03/12	Ordinary shares issued on exercise of Options	40,000	31c	12,268
20/04/12	Ordinary shares issued to consultant for consultancy services	127,160	41c	51,840
20/06/12	Ordinary shares issued to consultant for consultancy services	14,898	49c	7,336
	Transaction costs arising from share issues			(14,154)
	Balance at 30 June 2012	169,357,192		39,740,331

# d) Options

For information relating to options issued, exercised and lapsed during the financial year and the options outstanding at year-end refer to Note 19: Share-based Payments.

### e) Capital Management

Management controls the capital of the Group in order to maintain an appropriate debt to equity ratio, and ensure that the Group can fund its operations and continue as a going concern. The Group's debt and capital includes ordinary share capital and financial liabilities, supported by financial assets. There are no externally imposed capital requirements.

Management effectively manages the Group's capital by assessing the Group's financial risks and adjusting its capital structure in response to changes in these risks and in the market. These responses include the management of debt levels, distributions to shareholders and share issues.

There have been no changes in the strategy adopted by management to control the capital of the Group since the prior year.

	CONSO	LIDATED
	30 June 2012 \$	30 June 2011 \$
NOTE 15: RESERVES		
Option reserve	123,998	356,799
Foreign exchange translation reserve	(2,012)	-
	121,986	356,799
a) Option Reserve		
The option reserve records items recognised as expenses on valuation of employee share options.		
Movement		
Balance at beginning of year	356,799	173,406
Amortisation of options granted during the year	6,333	183,393
Options exercised during the year	(16,811)	-
Transfer of amortisation relating to expired options to retained earnings	(222,323)	-
Balance at end of year	123,998	356,799
b) Foreign Exchange Translation Reserve		
Movement		
Balance at beginning of year	-	-
Movement during the year	(2,012)	-
Balance at end of year	(2,012)	-
NOTE 16: REMUNERATION OF AUDITORS		
Audit services – Lawler Hacketts Audit		
Audit and review of financial reports and other audit work under the Corporations Act 2001	39,000	35,463
Non-audit services		
Audit / review of regulatory returns and due diligence services – Hacketts Corporate		
Advisory	1,500	12,500
	40,500	47,963

### NOTE 17: FINANCIAL RISK MANAGEMENT

#### **Financial Risk Management Policies**

The Group's financial instruments consist mainly of deposits with banks, short-term investments, and accounts receivable and payable.

### a) Treasury Risk Management

The Board, at each of its meetings, analyses financial risk exposure and evaluates treasury management strategies in the context of the most recent economic conditions and forecasts. The Board's overall risk management strategy seeks to assist the Group in meeting its financial targets, whilst minimising potential adverse effects on financial performance. Risk management policies are approved and reviewed on a regular basis.

### b) Financial Risk Exposures and Management

The main risks the Group is exposed to through its financial instruments are credit risk, interest rate risk, liquidity risk and foreign currency risk.

### Credit risk exposures

Exposure to credit risk relating to financial assets arises from the potential non-performance by counterparties of contract obligations that could lead to a financial loss to the Group. The credit risk on financial assets of the Group which have been recognised on the statement of financial position is generally the carrying amount, net of any provisions for doubtful debts.

### Interest rate risk exposures

Exposure to interest rate risk arises on financial assets and financial liabilities recognised at the end of the reporting period whereby a future change in interest rates will affect future cash flows or the fair value of fixed rate financial instruments. The Group is also exposed to earnings volatility on floating rate instruments. The Group's exposure to interest rate risk and the effective weighted average interest rate is set out in the relevant note.

#### Liquidity risk

Liquidity risk arises from the possibility that the Group might encounter difficulty in settling its debts or otherwise meeting its obligations related to financial liabilities. The Group manages liquidity risk by monitoring forecast cash flows and ensuring that adequate facilities or financing options are maintained.

#### Foreign currency risk

Exposure to foreign currency risk may result in the fair value or future cash flows of a financial instrument fluctuating due to movement in foreign exchange rates of currencies in which the Group holds financial instruments which are other than the functional currency of the Group. The Group manages foreign currency risk by monitoring forecast foreign currency commitments and foreign exchange rates. The Group's exposure to foreign currency risk arises from the holding of cash balances  $\leqslant$ 3,662 (2011 :  $\leqslant$ 4,071),  $\leqslant$ 3,402 (2011:  $\leqslant$ 30,658) and CHF82.00 at exchange rates of 0.8080, 0.6507 and 0.9709 respectively.

# c) Net fair value of financial assets and liabilities

The net fair value of cash and cash equivalents and non-interest bearing monetary financial assets and the financial liabilities of the Group approximates their carrying amounts.

The net fair value of other monetary financial assets and financial liabilities is based upon market prices where a market exists or by discounting the expected future cash flows by the current interest rates for assets and liabilities with similar risk profiles.

#### d) Sensitivity Analysis

The Group has performed a sensitivity analysis relating to its exposure to interest rate and foreign currency exchange rate risks, to assess the effect on reported results and equity which could result from a change in these risks.

Management have determined that, at 30 June 2012, the effect on profit and equity as a result of changes in the interest rate by +100 basis points or -100 basis points would be \$51,022 (2011 : \$147,829) additional, or less, interest revenue.

Management have determined that, at 30 June 2012, the effect on profit and equity as a result of changes in foreign currency exchange rates by +100 basis points or -100 basis points would be \$135 (2011 : \$764) exposure to foreign currency exposure.

# NOTE 18: KEY MANAGEMENT PERSONNEL COMPENSATION

# a) Key Management Personnel

Names and positions held of the Company's key management personnel in office at any time during the financial year are:

Key Management Person	Position
Mr R Clarke	Chairman – Non-executive
Mr I Ross	Director - Non-executive (appointed 25 May 2012)
Mr G Baynton	Director – Non-executive (resigned 12 June 2012)
Mr M Bridges	Director – Non-executive
Dr C Hirst	Director – Non-executive
Dr S Mercer	Chief Executive Officer and Executive Director
Mr D McKenzie	Company Secretary

Key management personnel remuneration has been included in the Remuneration Report section of the Directors' Report.

# b) Option Holdings

Number of options held by Key Management Personnel:

Key Management Personnel	Balance 30.06.2011	Granted as compensation	Options exercised	Options expired	Balance 30.06.2012	Total Vested 30.06.2012	Total Exercisable 30.06.2012
Mr R Clarke	-	-	-	-	-	-	-
Mr G Baynton	-	-	-	-	-	-	-
Mr M Bridges	250,000	-	-	-	250,000	250,000	250,000
Dr C Hirst	-	-	-	-	-	-	-
Dr S Mercer	705,000	-	-	225,000	480,000	480,000	480,000
Mr D McKenzie	250,000	-	250,000	-	-	-	-
Total	1,205,000	-	250,000	225,000	730,000	730,000	730,000

# c) Share Holdings

Number of Shares held by Key Management Personnel:

Key Management Personnel	Balance 1.7.2011	Acquired in Rights Issue, Options Exercised and other purchases	Balance 30.06.2012
Mr R Clarke	5,200,000	-	5,200,000
Mr I Ross	-	-	-
Mr M Bridges	147,299	97,988	245,287
Dr C Hirst	281,250	-	281,250
Dr S Mercer	1,125,750	-	1,125,750
Mr D McKenzie	225,000	250,000	475,000
Total	6,979,299	347,988	7,327,287

#### **NOTE 19: SHARE-BASED PAYMENTS**

The following share-based payment arrangements existed at 30 June 2012:

- On 29 November 2007, 400,000 share options were granted to the CEO to take up ordinary shares at an exercise price of \$0.64 each. These options which remain exercisable will vest on the achievement of a series of specific performance milestones and are exercisable within two years of each tranche of options vesting. At 30 June 2012, 220,000 of these options had expired.
- On 27 November 2008, 500,000 share options were granted to the CEO to take up ordinary shares at an exercise price of \$0.15 each. These options which remain exercisable will vest on the achievement of a series of specific performance milestones and are exercisable within two years of each tranche of options vesting. At 30 June 2012, 350,000 of these options had expired and 100,000 had been exercised.
- On 9 March 2010, 1,250,000 share options were granted to Key Management Personnel, and research staff employed by the Queensland University of Technology, to take up ordinary shares at an exercise price of \$0.26 each. The options cannot be exercised unless the exercise price is less than the share price on the exercise date. At 30 June 2012, 890,000 of these options had expired and 360,000 had been exercised.
- On 13 October 2010, 750,000 options were granted to Directors on approval by shareholders at the Annual General Meeting, to take up ordinary shares at an exercise price of \$0.26 each. The options cannot be exercised unless the exercise price is less than the share price on the exercise date. The options expire on 31 October 2012. At 30 June 2011 250,000 of these options had been exercised.
- On 19 June 2012, 950,000 share options were granted to Key Personnel, to take up ordinary shares at an exercise price of \$0.59 each. These options cannot be exercised unless the exercise price is less than the share price on the exercise date. The options will vest on 15 June 2013 and expire on 4 July 2014. Total value of these options granted was \$152,000 which will be amortised during vesting period. Current year amortisation of \$6,333 have been included under Administration expense in the Statement of Comprehensive Income.

The options hold no voting or dividend rights and are not transferable.

	2012			2011
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
Outstanding at the beginning of the year	2,205,000	0.29	1,925,000	0.31
Granted	950,000	0.59	750,000	0.26
Forfeited	-	-	-	-
Exercised	(360,000)	0.26	(350,000)	0.23
Expired	(1,115,000)	0.26	(120,000)	0.64
Outstanding at year-end	1,680,000	0.33	2,205,000	0.29
Exercisable at year-end	730,000	0.35	1,890,000	0.29

There were 360,000 options exercised during the year ended 30 June 2012.

The options outstanding at 30 June 2012 had a weighted average exercise price of \$0.33 and a weighted average remaining contractual life of 1.3 (2011:0.8) years. Exercise prices range from \$0.15 to \$0.64 in respect of options outstanding at 30 June 2012.

Included under Administration expense in the Statement of Comprehensive Income is \$6,333 (2011 : \$183,393) which relates, in full, to equity-settled share-based payment transactions.

	CONSOLIDATED	
	30 June 2012	30 June 2011
	\$	\$
NOTE 20: COMMITMENTS FOR EXPENDITURES		
Commitments for rental lease and consultancy services contracted for at the reporting date but not recognised as liabilities payable:		
Within one year	1,153,537	531,415
Later than one year but not later than 5 years	820,341	184,140
Later than 5 years	328,731	-
	2,302,609	715,555

#### NOTE 21: CONTINGENT LIABILITIES AND CONTINGENT ASSETS

The Company has entered into a Deed of Assignment of Intellectual Property Rights with Queensland University of Technology ("QUT"), under which QUT will assign the Intellectual Property to the Company on the payment of \$100,000 by the Company and the satisfaction of certain preconditions regarding, among other things, its level of cash reserves, the Company's share price and a minimum level of expenditure under the R&D Agreement. The Directors are not able to reasonably determine at this point in time when the above pre-conditions are likely to be satisfied.

Directors are not aware of any other contingent liabilities or assets that are likely to have a material effect on the results of the Group as disclosed in these financial statements.

### **NOTE 22: RELATED PARTY TRANSACTIONS**

Transactions with related parties

Transactions between related parties are on normal commercial terms and conditions no more favourable than those available to other parties unless otherwise stated.

The following transactions occurred with related parties:

Key management personnel

The Company has incurred share issue transaction costs of \$9,091 (2011: \$791,378) to RBS Morgans Corporate Limited primarily for its part in the rights issue and share placement for previous financial year. Roger Clarke is associated with RBS Morgans Corporate Limited.

#### **NOTE 23: SEGMENT INFORMATION**

Operating segments are identified, and segment information disclosed, on the basis of internal reports that are regularly provided to, or reviewed by, the Company's chief operating decision maker which, for the Company, is the Board of Directors. In this regard, the Board of Directors confirms that the Company continues to operate in one operating segment, being biotechnology.

#### NOTE 24: EVENTS SUBSEQUENT TO REPORTING DATE

During July 2012 the Group was advised by BSI that VitroGro® ECM conforms to the essential requirements of the EU Medical Devices Directive. This meant that the examination of the Design Dossier was complete, that all examiner questions had been answered to the satisfaction of BSI and BSI advised that CE Mark would be granted shortly.

During August 2012, despite the earlier notification, BSI advised that it had referred the VitroGro® ECM application to the UK Government Health Regulatory Body, the Medicines and Healthcare products Regulatory Agency (MHRA) for a final decision as to which Medical Device Rule was appropriate for the classification of VitroGro® ECM: Device Rule 8 or Device Rule 13.

BSI further advised the Group that the review by MHRA would take up to 30 calendar days, plus any additional days necessary for questions to the Group and for Tissue Therapies' staff to reply to MHRA, but that there would be no additional charges for the MHRA review.

Once CE Mark is received, the Device Rule under which it is granted is of no practical or commercial importance to Tissue Therapies.

It is possible that the MHRA review may result in a further referral to the European Medicines Agency (EMA) for a review of the VitroGro® ECM manufacturing process. EMA is the European Union health regulatory agency.

Except for the above, no other matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years

CONSOL	IDATED
30 June 2012	30 June 2011
\$	\$

### **NOTE 25: CASH FLOW INFORMATION**

### a) Reconciliation of Cash

Cash at end of the financial year as shown in the statement of cash flows is reconciled to the related items in the statement of financial position as follows:

Cash and cash equivalents 5,158,393 15,416,321

	CONSOL	IDATED
	30 June 2012	30 June 2011
	\$	\$
NOTE 25: CASH FLOW INFORMATION (Continued)		
b) Reconciliation of Cash Flow from Operations with Loss after Income Tax		
Loss after income tax benefit	(6,769,382)	(5,340,548)
Non-cash flows in profit from ordinary activities	( , , , ,	( , , ,
Depreciation	37,270	13,836
Amortisation of deferred lease incentives	(14,859)	-
Unrealised exchange loss	23,972	41,271
Inventory write down to net realisable value	728,601	364,995
Loss on disposal of property, plant and equipment	, -	5,187
Non-cash consultant fees	119,070	-
Amortisation of option expenses	6,333	183,393
Changes in assets and liabilities		
(Increase)/ decrease in receivables	2,705	343,755
(Increase) / decrease in inventory	(5,483,446)	(255,909)
(Increase) / decrease in current tax assets	(175,885)	(28,038)
(Increase) / decrease in other assets	24,997	-
Increase / (decrease) in payables and provisions	1,270,923	381,169
Increase / (decrease) in current tax liabilities	5,649	-
Cash outflows from operations	(10,224,052)	(4,290,889)

	CONSOLIDATED		
	30 June 2012	30 June 2011	
	\$	\$	
NOTE 26: EARNINGS PER SHARE			
Loss after income tax benefit attributable to the Company	(6,769,382)	(5,340,548)	
Weighted average number of shares used as the denominator	No.	No.	
Weighted average number of ordinary shares outstanding during the year used in calculation of Basic EPS	168,925,642	140,884,769	
Weighed average number of options outstanding which are considered potentially dilutive	-	-	
Weighted average number of potential ordinary shares outstanding during the year used in calculation of Dilutive EPS	168,925,642	140,884,769	

The diluted EPS calculation includes that portion of these options considered to be potentially dilutive, weighted with reference to the date of conversion.

	Cents	Cents
Basic earnings per share	(4.01)	(3.79)
Diluted earnings per share	(4.01)	(3.79)

### NOTE 27: FINANCIAL ASSETS AND LIABILITIES

The Group's planned developments include the USA approval of VitroGro® for the treatment of venous ulcers. The expenditure associated with these developments will be incurred by the Group in USD currencies over the period to 30 June 2013. In accordance with the Group's Risk Management policy the Group has executed forward exchange contracts to mitigate the Group's exposure to foreign currency movements in these foreign currencies.

### Forward Exchange Contracts

The Group has open forward exchange contracts at the end of the reporting period relating to highly probable forecast transactions and recognised financial assets and liabilities. These forward exchange contracts commit the Group to buy and sell specified amounts of foreign currencies in the future as specified exchange rates.

The following table summarises the notional amounts of the Group's commitments in relation to forward exchange contracts. The notional amounts do not represent amounts exchanged by the transaction counterparties and are therefore not a measure of the exposure of the Group through the use of these contracts.

NOTE 27: FINANCIAL ASSETS AND LIABILITIES (Continued)

	<b>Notional Amount</b>		Average exc	verage exchange rate	
	2012	2011	2012	2011	
	\$	\$			
Buy USD / sell AUD					
Settlement – expire on 28 June 2013 (2011: 28 June 2012)					
- Buy USD with a variable asset value of AUD as at 30 June of	1,447,347	2,502,002	0.978	1.0445	
- Sell AUD for a fixed liability amount of	(1,471,319)	2,502,002	1.008	1.0445	
Net exposure	(23,972)	-			
Buy Euro / sell AUD					
Settlement – expire on (2011: 28 June 2012)					
- Buy EUR with a variable asset value of AUD as at 30 June of	-	2,302,566	-	0.7320	
- Sell AUD for a fixed liability amount of	-	(2,302,566)	-	0.7320	
Net exposure	-	-			
Net unrealised exposure at 30 June	(23,972)	-			

Prior period comparative figures for financial assets of \$4,804,568 and financial liabilities of \$4,804,568 relating to a Foreign Exchange Facility have been offset and presented on a net basis. This amendment to disclosure recognises management's intention to settle the foreign exchange facility on a net basis in accordance with the terms of the facility agreement.

#### **NOTE 28: CHANGE IN ACCOUNTING POLICY**

New Accounting Standards for Application in Future Periods

The AASB has issued a number of new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods, some of which are relevant to the Group. The Group has decided not to early adopt any of the new and amended pronouncements. The Group's assessment of the new and amended pronouncements that are relevant to the Group but applicable in future reporting periods is set out below:

AASB 9: Financial Instruments (December 2010) and AASB 2010–7: Amendments to Australian Accounting Standards arising from AASB 9 (December 2010) [AASB 1, 3, 4, 5, 7, 101, 102, 108, 112, 118, 120, 121, 127, 128, 131, 132, 136, 137, 139, 1023 & 1038 and Interpretations 2, 5, 10, 12, 19 & 127] (applicable for annual reporting periods commencing on or after 1 January 2013).

These Standards are applicable retrospectively and include revised requirements for the classification and measurement of financial instruments, as well as recognition and derecognition requirements for financial instruments.

The key changes made to accounting requirements include:

- simplifying the classifications of financial assets into those carried at amortised cost and those carried at fair value;
- simplifying the requirements for embedded derivatives;

#### NOTE 28: CHANGE IN ACCOUNTING POLICY (Continued)

- removing the tainting rules associated with held-to-maturity assets;
- removing the requirements to separate and fair value embedded derivatives for financial assets carried at amortised cost;
- allowing an irrevocable election on initial recognition to present gains and losses on investments in equity instruments that are not held for trading in other comprehensive income. Dividends in respect of these investments that are a return on investment can be recognised in profit or loss and there is no impairment or recycling on disposal of the instrument;
- requiring financial assets to be reclassified where there is a change in an entity's business model as they are initially classified based on: (a) the objective of the entity's business model for managing the financial assets; and (b) the characteristics of the contractual cash flows; and
- requiring an entity that chooses to measure a financial liability at fair value to present the portion of the change in its fair value due to changes in the entity's own credit risk in other comprehensive income, except when that would create an accounting mismatch. If such a mismatch would be created or enlarged, the entity is required to present all changes in fair value (including the effects of changes in the credit risk of the liability) in profit or loss.

The Group has not yet been able to reasonably estimate the impact of these pronouncements on its financial statements.

AASB 2010–8: Amendments to Australian Accounting Standards – Deferred Tax: Recovery of Underlying Assets [AASB 112] (applies to periods beginning on or after 1 January 2012).

This Standard makes amendments to AASB 112: Income Taxes and incorporates Interpretation 121: Income Taxes – Recovery of Revalued Non-Depreciable Assets into AASB 112.

Under the current AASB 112, the measurement of deferred tax liabilities and deferred tax assets depends on whether an entity expects to recover an asset by using it or by selling it. The amendments introduce a presumption that an investment property is recovered entirely through sale. This presumption is rebutted if the investment property is held within a business model whose objective is to consume substantially all of the economic benefits embodied in the investment property over time, rather than through sale.

The amendments are not expected to significantly impact the Group.

AASB 10: Consolidated Financial Statements, AASB 11: Joint Arrangements, AASB 12: Disclosure of Interests in Other Entities, AASB 127: Separate Financial Statements (August 2011), AASB 128: Investments in Associates and Joint Ventures (August 2011) and AASB 2011–7: Amendments to Australian Accounting Standards arising from the Consolidation and Joint Arrangements Standards [AASB 1, 2, 3, 5, 7, 9, 2009–11, 101, 107, 112, 118, 121, 124, 132, 133, 136, 138, 139, 1023 & 1038 and Interpretations 5, 9, 16 & 17] (applicable for annual reporting periods commencing on or after 1 January 2013).

AASB 10 replaces parts of AASB 127: Consolidated and Separate Financial Statements (March 2008, as amended) and Interpretation 112: Consolidation – Special Purpose Entities. AASB 10 provides a revised definition of control and additional application guidance so that a single control model will apply to all investees. The Group has not yet been able to reasonably estimate the impact of this Standard on its financial statements.

AASB 11 replaces AASB 131: Interests in Joint Ventures (July 2004, as amended). AASB 11 requires joint arrangements to be classified as either "joint operations" (where the parties that have joint control of the arrangement have rights to the assets and obligations for the liabilities) or "joint ventures" (where the parties that have joint control of the arrangement have rights to the net assets of the arrangement). Joint ventures are required to adopt the equity method of accounting (proportionate consolidation is no longer allowed).

AASB 12 contains the disclosure requirements applicable to entities that hold an interest in a subsidiary, joint venture, joint operation or associate. AASB 12 also introduces the concept of a "structured entity", replacing the "special purpose entity" concept currently used in Interpretation 112, and requires specific disclosures in respect of any investments in unconsolidated structured entities. This Standard will affect disclosures only and is not expected to significantly impact the Group.

To facilitate the application of AASBs 10, 11 and 12, revised versions of AASB 127 and AASB 128 have also been issued. These Standards are not expected to significantly impact the Group.

## NOTE 28: CHANGE IN ACCOUNTING POLICY (Continued)

AASB 13: Fair Value Measurement and AASB 2011–8: Amendments to Australian Accounting Standards arising from AASB 13 [AASB 1, 2, 3, 4, 5, 7, 9, 2009–11, 2010–7, 101, 102, 108, 110, 116, 17, 118, 119, 120, 121, 128, 131, 132, 133, 134, 136, 138, 139, 140, 141, 1004, 1023 & 1038 and Interpretations 2, 4, 12, 13, 14, 17, 19, 131 & 132] (applicable for annual reporting periods commencing on or after 1 January 2013).

AASB 13 defines fair value, sets out in a single Standard a framework for measuring fair value, and requires disclosures about fair value measurement.

#### AASB 13 requires:

- inputs to all fair value measurements to be categorised in accordance with a fair value hierarchy; and
- enhanced disclosures regarding all assets and liabilities (including, but not limited to, financial assets and financial liabilities) to be measured at fair value.

These Standards are not expected to significantly impact the Group.

 AASB 2011–9: Amendments to Australian Accounting Standards – Presentation of Items of Other Comprehensive Income [AASB 1, 5, 7, 101, 112, 120, 121, 132, 133, 134, 1039 & 1049] (applicable for annual reporting periods commencing on or after 1 July 2012).

The main change arising from this Standard is the requirement for entities to group items presented in other comprehensive income (OCI) on the basis of whether they are potentially reclassifiable to profit or loss subsequently.

This Standard affects presentation only and is therefore not expected to significantly impact the Group.

AASB 119: Employee Benefits (September 2011) and AASB 2011–10: Amendments to Australian Accounting Standards arising from AASB 119 (September 2011) [AASB 1, AASB 8, AASB101, AASB124, AASB134, AASB1049 & AASB 2011–8 and Interpretation 14] (applicable for annual reporting periods commencing on or after 1 January 2013).

These Standards introduce a number of changes to accounting and presentation of defined benefit plans. The Group does not have any defined benefit plans and so is not impacted by the amendment.

AASB 119 (September 2011) also includes changes to the accounting for termination benefits that require an entity to recognise an obligation for such benefits at the earlier of:

- (i) for an offer that may be withdrawn when the employee accepts;
- (ii) for an offer that cannot be withdrawn when the offer is communicated to affected employees; and
- (iii) where the termination is associated with a restructuring of activities under AASB 137: Provisions, Contingent Liabilities and Contingent Assets, and if earlier than the first two conditions when the related restructuring costs are recognised.

The Group has not yet been able to reasonably estimate the impact of these changes to AASB 119.

NOTE 29: PARENT INFORMATION		
The following information has been extracted from the books and records of the parand has been prepared in accordance with Australian Accounting Standards.	arent	
STATEMENT OF FINANCIAL POSITION		
ASSETS		
Current assets	11,889,001	16,880,201
Non-current assets	1,029,701	1,123,165
TOTAL ASSETS	12,918,702	18,003,366
LIABILITIES		
Current liabilities	2,310,008	969,930
Non-current liabilities	164,924	-
TOTAL LIABILITIES	2,474,932	969,930
NET ASSETS	10,443,770	17,033,436
EQUITY		
Contributed equity	39,740,331	39,525,004
Reserves	123,998	356,799
Accumulated losses	(29,420,559)	(22,848,367)
TOTAL EQUITY	10,443,770	17,033,436
STATEMENT OF COMPREHENSIVE INCOME		
Total losses after income tax benefit	(6,794,515)	(5,340,548)
Total comprehensive income	(6,794,515)	(5,340,548)
		\ , , , ,

30 June 2012

\$

30 June 2011

\$

### Guarantees

Tissue Therapies Limited has not entered into any guarantees, in the current or previous financial year, in relation to the debts of its subsidiary.

# Contingent Liabilities

For information relating to contingent liabilities, refer to Note 21: Contingent Liabilities and Contingent Assets.

# **Contractual Commitments**

For information relating to contractual commitments, refer to Note 20: Commitments for Expenditures.

# **NOTE 30: CONTROLLED ENTITY**

Tissue Therapies Europe Limited ("the Subsidiary"), a wholly owned subsidiary was formed on 23<sup>rd</sup> January 2012, based in United Kingdom, to provide administration support to Tissue Therapies Limited ("the Parent Entity).

# **NOTE 31: COMPANY DETAILS**

The registered office and the principal place of business of the Company is:

Tissue Therapies Limited Level 19 179 Turbot Street BRISBANE QLD 4000 Australia

# TISSUE THERAPIES LIMITED AND CONTROLLED ENTITY FOR THE YEAR ENDED 30 JUNE 2012

# **DIRECTORS' DECLARATION**

In accordance with a resolution of the directors of Tissue Therapies Limited declare that:

- 1. the financial statements and notes, as set out on pages 12 to 43, are in accordance with the Corporations Act 2001 and:
  - a. comply with Australian Accounting Standards, which, as stated in accounting policy Note 1 to the financial statements, constitutes compliance with International Financial Reporting Standards (IFRS); and
  - b. give a true and fair view of the financial position as at 30 June 2012 and of the performance for the year ended on that date of the consolidated group;
- 2. in the directors' opinion there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
- 3. the directors have been given the declarations required by s 295A of the *Corporations Act 2001* from the Chief Executive Officer and Chief Financial Officer.

Roger Clarke Chairman

Brisbane, 21 August 2012

estelle

Steven Mercer CEO & Director



# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TISSUE THERAPIES LIMITED

### Report on the Financial Report

We have audited the accompanying financial report of Tissue Therapies Limited which comprises the consolidated statement of financial position as at 30 June 2012, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the Directors' declaration of the consolidated entity comprising the company and the entity it controlled at the year's end or from time to time during the financial year.

#### Directors' Responsibility for the Financial Report

The Directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such internal control as the Directors determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error. In Note 1, the Directors also state, in accordance with Accounting Standard AASB 101; Presentation of Financial Statements, that the financial statements comply with International Financial Reporting Standards.

### Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Independence

In conducting our audit, we have complied with the independence requirements of the Corporations Act 2001.

#### Opinion

In our opinion:

- the financial report of Tissue Therapies Limited is in accordance with the Corporations Act 2001, including:
  - giving a true and fair view of the consolidated entity's financial position as at 30 June 2012 and of their i. performance for the year ended on that date; and
  - complying with Australian Accounting Standards and the Corporations Regulations 2001; and ii.
- the financial report also complies with International Financial Reporting Standards as disclosed in Note 1. b)

### Emphasis of Matter

Without qualification to the opinion expressed above, attention is drawn to the following matter. As a result of the matters described in Note 1(r) to the financial statements, there is uncertainty as to whether the carrying value of finished goods of VitroGro® ECM as at 30 June 2012 is recoverable.

Lawler Hacketts Audit ABN 33 873 151 348

Brisbane

Level 3, 549 Queen Street Brisbane QLD 4000 Australia

telephone 07 3839 9733 facsimile 07 3832 1407



# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TISSUE THERAPIES LIMITED (continued)

### Report on the Remuneration Report

We have audited the Remuneration Report included in pages 7 to 9 of the Directors' Report for the year ended 30 June 2012. The Directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with Section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

### Opinion

In our opinion the Remuneration Report of Tissue Therapies Limited for the year ended 30 June 2012, complies with section 300A of the *Corporations Act 2001*.

**Lawler Hacketts Audit** 

Lawler Horlett

Brisbane, 21 August 2012

L J Murphy Partner

19

# **Annual Report 2012**

# **Shareholder Information**

Information shown was current as of the 6th September 2012.

# Distribution of equity securities

Ranges	Number of Investors	Number of shares	% Issued Capital
1 to 1,000	299	82,984	0.05%
1,001 to 5,000	627	1,987,337	1.15%
5,001 to 10,000	465	3,815,273	2.21%
10,001 to 50,000	1,016	25,019,586	14.51%
50,001 to 100,000	233	17,542,838	10.18%
100,001 and over	265	123,934,174	71.89%
Total	2,905	172,382,192	100.00%

The number of security investors holding less than a marketable parcel of 1,031 securities (\$0.485 on 06/09/2012) is 300 and they hold 83,997 securities.

# Distribution of unquoted equity securities

Ranges	Number of Holders	Number of options on Issue	% Options Issued
1 to 1,000	-	-	_
1,001 to 5000	-	-	-
5,001 to 10,000	-	-	-
10,001 to 50,000	-	-	-
50,001 to 100,000	-	-	-
100,001 and over	7	1,615,000	100.00%
Total	7	1,615,000	100.00%

25,000 options are exercisable at \$0.15, 140,000 exercisable at \$0.64, 500,000 exercisable at \$0.26 and 950,000 exercisable at \$0.59

# **Substantial shareholders**

There is one substantial shareholder.

Name of Investor	Number of shares	% Issued Capital
Asia Union Investments Pty Limited	22,985,000	13.33%

# **Voting Rights**

The voting rights attaching to ordinary shares are set out below:

- On a show of hands every member present in person or by proxy shall have one vote;
- Upon a poll each share shall have one vote.

# **Annual Report 2012**

# Names of the twenty largest shareholders

Information shown was current as of the 6<sup>th</sup> September 2012.

Rank	Name of Investor	Number of shares	% Issued Capital
1	Asia Union Investments Pty Limited	22,985,000	13.33%
2	Queensland University of Technology	8,087,010	4.69%
3	Mr Roger Brian Clarke & Mrs Barbara Joan Clarke (Roger B Clarke Family A/C)	4,600,000	2.67%
4	ABN AMRO Clearing Sydney Nominees Pty Ltd (Custodian A/C)	4,278,629	2.48%
5	JP Morgan Nominees Australia Limited (Cash Income A/C)	3,954,358	2.29%
6	Mr Thai Quoc Tang	3,330,000	1.93%
7	Aslog Holding Ltd	3,000,000	1.74%
8	BERNE No 132 Nominees Pty Ltd (323731 A/C)	2,594,292	1.50%
9	Mr Thai Quoc Tang	1,910,000	1.11%
10	Mr Paul Robert Baster & Ms Catherine Bellemore (The Avenue S/F A/C)	1,700,000	0.99%
11	BERNE no 132 Nominees Pty Ltd (323723 A/C)	1,539,042	0.89%
12	HSBC Custody Nominees (Australia) Limited	1,501,694	0.87%
13	Mr Edward William Gallop & Ms Glenda Joy Gallop (Gallop Family S/F A/C)	1,431,190	0.83%
14	Mr Wayne Martin & Mrs Anthea Martin	1,250,000	0.73%
15	Mr Steven John Mercer (LJL Account)	1,150,750	0.67%
16	Mr David Frederick Oakley	1,150,000	0.67%
17	Dr Zee Upton	1,086,776	0.63%
18	UBS Wealth Management Australia Nominees Pty Ltd	1,067,250	0.62%
19	Mr Rohan John Armstrong	1,002,283	0.58%
20	Abercairney Pty Ltd (Simpson Family S/Fund A/C)	1,000,000	0.58%
Total		68,618,274	39.81%
There a	re 2,885 other investors out of a total of 2,905 investors		
Total shares held by other investors:		103,763,918	60.91%
Grand Total:		172,382,192	100.00%

