

# **Annual Report 2011**

**Tissue Therapies Limited** 





he 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 28<sup>th</sup> of November, 2011 at 10:30 am.

Tissue Therapies Limited ABN 45 101 955 088

#### Registered and Head Office

Level 11, Central Plaza 2 66 Eagle Street Brisbane Qld 4000 Tel: (07) 3839 9938 Fax: (07) 3839 1486 www.tissuetherapies.com

#### Postal Address

GPO Box 1596 Brisbane Old 4001

#### **Directors**

Mr Roger Brian Clarke (Chairman) Mr Mel Bridges Mr Gregory Alexander John Baynton Dr Cherrell Hirst Dr Steven John Mercer

#### Chief Scientific Officer

Professor Zee Upton

#### Independent Scientific Advisors to the Board

Professor Robert Baxter Professor Keith Harding

#### **Company Secretary**

Mr Drummond McKenzie

#### **Share Registry**

Link Market Services Level 15, 324 Queen Street Brisbane Qld 4000

#### **Auditors**

Lawler Hacketts Chartered Accountants Level 3, 549 Queen Street Brisbane Qld 4000

#### Lawyers for the Company

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







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### **About Tissue Therapies**

Tissue Therapies Limited is an Australian company developing biomedical technologies for wound healing, tissue repair, cell culture and other applications.

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT) for cell growth and migration. VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and other cell culture uses.

Based on its VitroGro® technology, Tissue Therapies is developing more effective treatments for acute and chronic wound healing applications including chronic skin ulcers and burns.

Tissue Therapies is also proceeding with the development of other commercial applications for various VitroGro® and other technologies for the treatment of psoriasis, scar prevention and potential treatments for various cancers including those of the breast, colon and prostate.

The Company holds the exclusive worldwide licence to commercialise the VitroGro® family of patents which includes "Skin Regeneration System", "Growth Factor Complex" and "Modulation of Cell Migration and Growth".

Patent applications have been filed in the USA, Canada, Europe, Australia, New Zealand, South Korea, China, Hong Kong, India, South Africa and Japan, with patents already granted in the USA, Europe, South Korea, Japan, South Africa, Australia and New Zealand.

### What is VitroGro® ECM

VitroGro® ECM is a mimetic scaffold that is sterile, acellular and flow-able. It is an artificially created matrix protein designed from parts of proteins that normally provide attachment sites in healthy dermal matrix which guide cells during wound healing. In chronic (non-healing) wounds cells are deprived of these attachment sites because the extracellular matrix (ECM) is degraded . VitroGro® ECM acts to restore normal wound healing by replacing the degraded ECM with a scaffold containing attachment sites that guide epithelial cell attachment, migration and proliferation. VitroGro® ECM is a provisional matrix that is designed to be replaced by cells through the normal process of tissue restoration and turnover. VitroGro® ECM consistently and conveniently restores healing in ulcers that have failed to respond to standard care.

Clinical data from human studies in Canada and Australia indicate that VitroGro® ECM applications will only be required once or twice per week. This is consistent with the results from more than eight years of published human live skin equivalent scientific data.

In human trials, VitroGro® ECM has demonstrated the consistent and convenient restoration of healing of venous and diabetic ulcers that have not responded to expert care with current state of the art treatments. VitroGro® ECM has the proven ability to restore healing in these chronic wounds alone, and in combination with other wound care technologies. It therefore has considerable commercial potential for use with existing and new medical products in these markets.





### Clinical Results 2010/11

During the 2010 - 2011 financial year strong clinical results were released from the Australian human trial of VitroGro® ECM for the treatment of chronic venous ulcers.

This clinical trial produced impressive results even though patients only received VitroGro® ECM twice per week for approximately three weeks.

### Average of 43% reduction of ulcer in 24 days

- Complete healing of 5 out of 30 ulcers or 16.7%.
- Only 1 patient did not completely or partially heal in 24 days increase in ulcer area of 2%.
- Average reduction of ulcer area of 43% in 24 days (p < 0.0001).
- VitroGro® ECM is safe and well tolerated in humans.
- These results were obtained in patients who had not healed despite expert compression therapy for up to 11 months. (Compression therapy is the current best practice treatment for venous ulcers).
- Average age of the patients was 71 years.
- Average duration of venous ulcer prior to VitroGro® ECM treatment was 11 months.
- Average time the venous ulcer was unresponsive to compression therapy prior to joining the VitroGro® ECM trial was 9 months.

These clinical results are in addition to the positive results achieved in the previously announced Canadian human VitroGro® ECM trial of 10 patients all of whom were extremely medically challenging and were in the most difficult hard-to heal category. (Please see ASX: TIS CEO AGM Presentation 18 November 2009.)

### **Further Strong Clinical Wound Healing Data: July 2011**

During July 2011 the Company received compelling new human trial data from the multi-centre international wound healing study led by key opinion leader Professor Keith Harding. (Please see ASX: TIS "Strong New Clinical Trial Data", 14 July 2011)

The data shows that for the 24 evaluated venous ulcer patients treated with VitroGro® ECM to date:

- 8 patients achieved complete healing and an additional 2 patients achieved ≥ 98% healing.
- Out of 24 evaluable patients, 22 (92%) were partially or completely healed in 12 weeks. (One patient was unchanged and 1 patient worsened).
- The average reduction in wound size was 65% with a median of 72% after 12 weeks of treatment.
- The average time venous ulcers had not responded to expert care before VitroGro® ECM treatment was 37 months with a median of 10 months.
- The average age of patients that have completed treatment so far is 71 years with a median of 73 years.

Unlike previous VitroGro® ECM human wound healing studies, these patients typically had a considerable history of recurrent ulceration and have complicated wounds that would not be expected to heal. They also have co-existing conditions in addition to the underlying disease in their arteries or veins, which together make this study a more challenging test.





The objective of this study was to recruit 40 evaluable patients. A total of 53 patients have been recruited, all of whom had not responded to expert care for at least 4 weeks, many for much longer. Final patients are now completing treatment and analysis of the data is well under way. The final report for the European (EU) study is expected at the end of October.

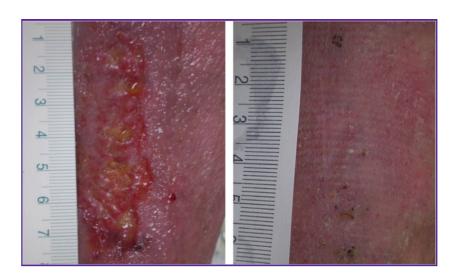
The EU regulatory consultant assisting Tissue Therapies is confident that the human trial data already announced is sufficient for approval for sale.

### Resistant to expert care for 7 years completely healed with VitroGro



**51 year old female** This recalcitrant ulcer of 7 years was completely healed.

### Complete healing in 5 weeks of treatment



**75** year old male

This ulcer of 2 months duration completely healed within 5 weeks.

The patient's pain level significantly improved in the first 2 weeks.







### **Commercial Update**

Commercial negotiations are proceeding well. The Company is confident that an announcement will be made during November 2011 and sales of VitroGro® ECM to treat chronic wounds are expected to start in the UK and Europe during the 2nd quarter of calendar 2012, as planned.

Current global economic conditions have made establishing an attractive commercial arrangement more difficult but negotiations are now well advanced and the planned November 2011 announcement will allow sufficient preparation time for the planned sales launch in the UK and Europe during the second quarter of 2012.

Manufacturing of VitroGro® ECM to the desired larger scale has been successfully completed to the Good Manufacturing Practice (GMP) standard required for human use. Final packaging design consistent with regulatory and commercial requirements is complete and packaging of ready-for-sale VitroGro® ECM is about to start.

All data indicates that VitroGro® ECM has the potential to transform the treatment of diabetic, venous and pressure ulcers

## Chronic wound care is currently a US\$14 billion market with annual compound growth of 25%. (1)

Clinical trial results from the earlier Canadian and Australian studies and now the EU results confirm that VitroGro® ECM can substantially increase the incidence of complete healing and reduce treatment time for diabetic and venous ulcers, as well as being potentially more cost effective than currently available treatments.

VitroGro® ECM is therefore an exceptional candidate for a new generation of wound healing and consumer products because it can be produced to therapeutic standard (already achieved by Tissue Therapies) and because all pre-clinical and human trial data consistently indicates a cost effectiveness that has not previously been available to patients and health care systems worldwide.

### VitroGro® ECM Device Classification

VitroGro®ECM, used as a topical wound healing treatment, has been classified as a device by Health Canada and also by an EU Notified Body. This means that it is only necessary for VitroGro® ECM to successfully complete a device clinical test regime instead of the Phase trials that apply to pharmaceutical candidates.

Only a single, small clinical trial of new formulation VitroGro® ECM should be required to gain approval for the sale of new VitroGro® ECM wound healing products in the EU and a single trial for each indication in the USA, under Food and Drug Administration (FDA) regulations.

Earlier this year, the Company took advantage of the opportunity for an expert consulting review of the USA FDA Request for Designation (RFD) application prior to its submission. This regulatory consulting group includes two former Directors of the FDA. These consultants are confident that the request for designation (RFD) will result in a successful device classification by the FDA.

Preparations for the FDA clinical trial of VitroGro® ECM for the treatment of venous ulcers are almost complete. The Chief Clinical Investigator and Clinical Research Organisation have been appointed, the protocol has been finalised, site selection is underway and patient recruitment is planned to start during December 2011.





### VitroGro®: Lead Product Addressing a Significant Un-met Medical Need

VitroGro® ECM has been designed to provide convenient, cost effective new treatments for diabetic, venous and pressure ulcers. This is backed by ten years of substantial laboratory and pre-clinical data, including multiple publications in peer-reviewed, scientific journals.

Current treatments for diabetic, venous and pressure ulcers are costly and tend to be only moderately effective. These treatments include compression dressings, moist wound healing products, vacuum dressings and antimicrobial dressings to limit infection.

Complete healing rates for diabetic, venous and pressure ulcers remain at approximately 25–50% following up to 20 weeks of treatment<sup>(2,3)</sup>. Our target is to substantially increase the incidence of complete healing and substantially reduce healing time with VitroGro® ECM.

Worldwide, it is estimated that patients suffering diabetic, venous and pressure ulcers spent US\$14 billion in 2010 on wound dressings, with a compound annual growth rate of 25%<sup>(1)</sup>. World market growth is being driven by an aging population, an increased incidence of venous disease and diabetes and the increasing afford-ability of health care in developing countries<sup>(2)</sup>. The potential for consumer, retail and acute wound care products offers an additional and substantially larger opportunity.

Up to 70% of all lower limb amputations in the world are related to diabetic ulcers. A lower limb is lost to diabetic ulcers every 30 seconds. This represents more than one million amputations globally each year<sup>(4)</sup>.

### References

- 1. Primary research, Frost & Sullivan and CanCare Consultancy Services.
- 2. Clinical Guide to Wound Care, 6th Ed. 2008, Hess CT, Lippincott, Williams & Wilkins.
- 3. Apelqvist J, Larsson J, Agardh CD. Long term prognosis for diabetic patients with foot ulcers. J Intern Med 1993; 233: 483-491.
- 4. Sorensen Tl. The changing lifestyle in the world. Body weight and what else? Diabetes Care 2000; 23 Suppl 2: B1-4.





### Chairman's and CEO's Report

On behalf of the Company, it gives us great pleasure to present the Company's annual report for the financial year ending 30 June 2011.

Since July 2010, Tissue Therapies has made substantial progress in satisfying the preconditions necessary for the start of sales of VitroGro® wound healing products.

### **Progress Since July 2010**

- Advancing commercial negotiations to the point where the Board is confident that an announcement will be made during November 2011 and sales of VitroGro® ECM to treat chronic wounds are expected to start in the UK and Europe during the second quarter of calendar 2012, as planned.
- The manufacturing of VitroGro® ECM to the desired larger scale has been successfully completed to the Good Manufacturing Practice (GMP) standard required for human use. Final packaging design consistent with regulatory and commercial requirements is complete and packaging of ready-for-sale VitroGro® ECM is about to start.
- The announcement of strong clinical trial results for the treatment of chronic wounds, particularly venous ulcers (see page iv of this document for details).
- The successful classification of VitroGro® ECM as a device by an EU Notified Body, following the earlier device classification by Health Canada and the submission of a formal Request for Designation (RFD) to the USA FDA.
- Preparations for the USA FDA clinical trial of VitroGro® ECM for the treatment of venous ulcers are almost complete. The Chief Clinical Investigator and Clinical Research Organisation have been appointed, the protocol has been finalised, site selection is underway and patient recruitment is planned to start during December 2011.
- Continuing to work within our low-cost approach to operations, largely due to working effectively with our major research partner, the Queensland University of Technology (QUT).

#### **Financial Results**

During the 2010-2011 financial year:

Tissue Therapies recorded an after-tax loss of \$5,340,548 line with budget expectations. This loss includes non-cash expenses of \$1,693,969 relating to usage of VitroGro® ECM during the year in clinical trials.

Net assets increased by \$9,091,041 to \$17,033,436 and at 30 June 2011 the Company had cash resources of \$15,416,321.

In April and May 2011 the Company conducted successful rights issue of 18,632,464 ordinary shares, and placements of 11,500,000 ordinary shares with institutional and sophisticated investors at \$0.50 per share to raise \$15,066,232 before issue costs.

The Company's contributed equity following the share issues and after transaction costs arising from the issues was \$39,525,004.





#### **Outlook**

The commercially significant progress of the last financial year has positioned Tissue Therapies well to capitalise on the opportunity to transform the lives of millions of people suffering from non-healing skin wounds and to

potentially provide shareholders with excellent returns.



From Development to Production (L to R: Mr Nigel Johnson, COO and Ms Jacqui Symonds, former Research Scientist.)

We look forward with great anticipation to the start of sales, particularly given the enthusiastic response we have received during recent meetings with more than twenty key wound care opinion leaders in the UK and Europe. They were unanimous in their praise of the careful, scientific approach we have taken in the development of VitroGro® ECM and are impatient to start using VitroGro® ECM to treat their patients.

We look forward to providing further updates on these activities and particularly future revenue streams from commercial products using VitroGro® ECM and other technologies.

Roger Clarke

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Chairman

Dr. Steven Mercer Chief Executive Officer

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### The Tissue Therapies Team

The Tissue Therapies team consists of a number of commercial and scientific experts, employed either directly by the Company or via contracting arrangements.

The Company's ongoing R&D is out-sourced to a group of more than 35 tissue engineering, cell biology and protein scientists at QUT's Institute of Health and Biomedical Innovation (IHBI). Under this arrangement, Tissue Therapies has the benefit of QUT's expertise, resources and facilities without the capital and personnel costs associated with setting up its own laboratory.

#### **Chief Executive Officer**



Dr. Steven Mercer

long-term healthcare commercialisation professional, Dr. Mercer leads the Company's commercial and strategic activities as Tissue Therapies' Chief Executive Officer. previous roles, Dr Mercer was former General Manager for Smith & Nephew Surgical (Australia & New Zealand)

and the former Managing Director of Mercy Tissue Engineering, a successful tissue engineering company operating in Singapore and Melbourne.

### **Chief Operations Officer**



Nigel Johnson

The Company's manufacturing programs and regulatory systems are managed by Nigel Johnson. Mr. Johnson has over 15 years experience in manufacturing bio-therapeutic goods. His previous roles in tissue banking and engineering were held with the Australian Red Cross Blood Service and Queensland Health.

#### **Chief Financial Officer**



**Drummond McKenzie** 

Mr McKenzie 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. Mr. McKenzie is a Fellow of the Institute of Chartered Accountants, a Fellow of the

Chartered Institute of Company Secretaries and has a Bachelor of Science (Economics) (Honours), (London) degree.

#### **Chief Scientific Officer**



Professor Zee Upton

Prof. Upton is the lead-inventor of VitroGro® and oversees the Company's research activities as its Consulting Chief Scientific Officer. Prof. Upton is an expert biochemist and tissue engineer who is nationally and internationally renowned for her research into extracellular matrix proteins and wound repair. She

is Assistant Dean (Research) in the Faculty of Health, QUT and Leader of the Tissue Repair and Regeneration Program within the QUT Institute of Health and Biomedical Innovation.



### **Independent Scientific Advisor**



**Professor Keith Harding** 

Prof. Harding graduated in medicine from the University of Birmingham before undertaking training in surgery and family medicine. In 1991 he became Director of the Wound Healing Research Unit at the University of Wales, College of Medicine in Cardiff. Prof. Harding is widely published and a prolific presenter

at scientific and clinical wound care conferences, and has devised and managed many clinical wound care product trials for large international health care companies.

### **Independent Scientific Advisor**



**Professor Robert Baxter** 

Prof. Baxter, Director of the Kolling Institute of Medical Research at the Royal North Shore Hospital in Sydney, advises the Board as its Independent Scientific Advisor. Prof. Baxter is also Head of Molecular Medicine at the University of Sydney and a leading expert in proteins that

regulate cell growth and metabolism, the insulin-like growth factors and their binding proteins. He was the first to identify several of these proteins and to devise methods of measuring them.

## Regulatory & Intellectual Property Manager



Dr. Hedie Meka

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 Tissue the management of Therapies' international VitroGro® patents and Earlier trademarks. 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.

### **International Product Manager**



Dr. Brian Ziegelaar

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. Earlier in his career, Dr. Ziegelaar gained his PhD. and pursued post-doctoral research in Europe in

tissue engineering and cell biology.





### **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 (2nd 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 (2nd 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, Standing 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 the 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 Clark ceased to be a substantial shareholder on 11 February 2010, as announced to ASX.
  - Gregory Baynton, as managing director of Orbit Capital, previously provided management services to the Company. Orbit Capital no longer provides management services to the Company and the Board is satisfied that the previous arrangement does not affect his independence.
  - Melvyn Bridges and Cherrell Hirst do not have any previous association with the Company or any other relationships that are relevant to their 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 procedures, 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. This 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 current members are the following Directors:

- Melvyn Bridges (Chairman)
- Gregory Baynton
- Roger Clarke
- Roger Clarke, Melvyn Bridges and Gregory Baynton 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 and values 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) "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. Four of the five Directors (Roger Clarke, Gregory Baynton, Melvyn Bridges and Cherrell Hirst) are considered by the Board to be independent and comprise a majority of the Board. Tissue Therapies complies with the Principles in this area. 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 values
  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.
- 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 and Gregory Baynton are considered independent. All three of its 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**



#### **DIRECTORS' REPORT**

Your Directors present their report on Tissue Therapies Limited ("the Company") for the year ended 30 June 2011.

#### **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

**Gregory Baynton** – Director (appointed 6 September 2002)

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** 

Melvyn Bridges – Director (appointed 12 March 2009)

Qualifications — Bachelor of Science (Chemistry)

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, ImpediMed Limited and Leaf Energy Limited (formerly AquaCarotene Limited), Director of Benitec Limited, Campbell Brothers Limited and

Genera Biosystems 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 — 147,299 Ordinary Shares and options to acquire a further 250,000 Ordinary Shares

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 Queensland Biocapital Funds 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

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 705,000 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 Company consisted of the research, development and commercialisation of the Company's exclusive international intellectual property in wound healing and tissue regeneration.

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

#### **Operating results**

The loss of the Company after tax amounted to \$5,340,548 (2010: loss \$3,486,399).

#### **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 2010-2011 financial year:

Tissue Therapies recorded an after-tax loss of \$5,340,548 in line with budget expectations. This loss includes non-cash expenses of \$1,693,969 relating to usage of VitroGro® during the year in clinical trials.

Net assets increased by \$9,091,041 to \$17,033,436 and at 30 June 2011 the Company had cash resources of \$15,416,321.

- In April and May 2011 the Company conducted successful rights issue of 18,632,464 ordinary shares, and placements
  of 11,500,000 ordinary shares with institutional and sophisticated investors at \$0.50 per share to raise \$15,066,232
  before issue costs.
- The Company's contributed equity following the share issues and after transaction costs arising from the issues were \$39,525,004.

VitroGro® has been developed from a profound set of discoveries by the Chief Scientific Officer, Professor Zee Upton, described in more than eight years of peer reviewed, published scientific papers. VitroGro® is a new type of wound care treatment, being a synthetic biomimetic fusion protein.

All current data including sophisticated health economics modelling indicates that VitroGro® may offer significant cost effectiveness, particularly in the treatment of venous ulcers which represent 70% of all chronic skin wounds.

Part of the cost effectiveness of VitroGro® for the treatment of diabetic, venous and pressure ulcers is due to the fact that it can be used easily, quickly, conveniently and consistently, as has been demonstrated in the human trials.

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**

1. During the 2010 - 2011 financial year strong clinical results were released from the Australian human trial of VitroGro® for the treatment of chronic venous ulcers.

This clinical trial produced exceptional results even though patients only received VitroGro® twice per week for 3 weeks. Some of the results from this 24-day VitroGro® human venous ulcer trial include:

- Complete healing of 5 out of 30 ulcers or 16.7%.
- Average reduction of ulcer area of 43% in 24 days (p < 0.0001).
- VitroGro® is safe and well tolerated in humans.
- These results were obtained in patients who had not healed despite expert compression therapy for up to 11 months. (Compression therapy is the current best practice treatment for venous ulcers).
- Average age of the patients was 71 years.
- Average duration of venous ulcer prior to VitroGro® treatment was 11 months.
- Average time the venous ulcer was unresponsive to compression therapy (the current gold standard of care) prior to joining the VitroGro® trial was 9 months.

These clinical results are in addition to the positive results achieved in the previously announced Canadian human VitroGro® trial of 10 patients all of whom were extremely medically challenging and were in the most difficult hard-to-heal category. (Please see ASX: TIS CEO AGM Presentation 18 November 2009.)

- 2. During the last financial year Tissue Therapies was also successful in achieving a medical device classification in the EU. VitroGro® was already classified as a medical device in Canada and the preparation for a USA FDA request for classification was also undertaken. A formal classification has not yet been received from the FDA but the American FDA consultants working on behalf of Tissue Therapies are confident that this will also be successful.
- 3. Lead product VitroGro® addresses a significant and growing unmet medical need:
  - VitroGro® has been designed to provide simple, cost effective new treatments for diabetic, venous and pressure
    ulcers. This is backed by ten years of substantial laboratory and preclinical data, including multiple publications
    in peer-reviewed, scientific journals.
  - Current treatments for diabetic, venous and pressure ulcers are costly and are only moderately effective. These include compression dressings, moist wound healing products, vacuum dressings and antimicrobial dressings to limit infection. Complete healing rates for diabetic, venous and pressure ulcers remain at approximately 25 50% following up to 20 weeks of treatment. (9, 10) Our target is to increase the incidence of complete healing and substantially reduce healing time with VitroGro®.
  - Up to 70% of all lower limb amputations in the world are related to diabetic ulcers. A lower limb is lost to diabetic ulcers every 30 seconds. This represents more than 1 million amputations globally each year. (5)

#### 4. Commercialisation Strategy

Tissue Therapies:

- Is using the exceptional clinical trial data in formal negotiations with identified potential healthcare partners.
- Is proceeding with regulatory approvals and reimbursement approvals in the Company's name, further enhancing Tissue Therapies' position in negotiations with potential commercial partners.
- Has successfully completed commercial scale GMP manufacturing and larger scale manufacturing is on schedule to deliver increased output late in 2011.
- Will proceed with application for approval for sale in the EU late in 2011.
- Is proceeding with development of other commercial applications for VitroGro® and other technologies for the treatment of psoriasis, scar prevention and treatment and potential treatments for various cancers including those of the breast, colon and prostate.

#### References:

- 1. Primary research, Frost & Sullivan and CanCare Consultancy Services
- 2. Clinical Guide to Wound Care, 6th Ed. 2008, Hess CT, Lippincott, Williams & Wilkins
- 3. Amos AF, McCarty DJ, Zimmet P. The rising global burden of diabetes and its complications: estimates and projections to the year 2010. Diabet Med 1997; 14 Suppl 5: S1-85
- 4. Sorenson TI. The changing lifestyle in the world. Body weight and what else? Diabetes Care 2000; 23 Suppl 2: B1-4
- 5. Diabetes in North America: millions of feet at risk of amputations. 65th Annual Sessions of the American Diabetes Association, International Diabetes Federation. San Diego, 11 June 2005
- Campbell LV, Graham AR, Kidd RM, Molloy HF, O'Rourke SR, Colagiuri S. Position statement of the Australian Diabetes Society. MJA 2000; 173: 369-372
- 7. Boyle JP, Honeycutt AA, Narayan KM, Hoerger TJ, Geiss LS, Chen H, et al. Projection of diabetes burden through 2050: impact of changing demography and disease prevalence in the U.S. Diabetes Care 2001; 24 (11): 1936-40
- 8. Apelqvist J, Larsson J, Agardh CD. Long term prognosis for diabetic patients with foot ulcers. J Intern Med 1993; 233: 483-491
- Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Healing diabetic neuropathic foot ulcers: are we getting better? Diabet Med. 2005; 22 (2): 172-176
- 10. Franks PJ, Moffatt CJ. Health related quality of life in patients with venous ulceration: use of the Nottingham health profile. Qual Life Res. 2001;10 (8): 693-700
- 11. Winter GD. Formation of the Scab and the Rate of Epithelialisation of Superficial Wounds in the Skin of the Young Domestic Pig. Nature Jan 1962; 193: 293-294
- 12. Stuart M. Advanced Wound Care: The Device Industry's New Billion Dollar Product Market. Start-Up, Nov 2007: 20-26
- 13. Chronic Wound Care. 4th Ed HMP Communications 2007. Co-editors; Krasner DL, Rodeheaver GT, Sibbald RG

#### Significant Changes in State of Affairs

As outlined above, in April and May 2011 the Company conducted successful rights issue of 18,632,464 ordinary shares, and placements of 11,500,000 ordinary shares with institutional and sophisticated investors at \$0.50 per share to raise \$15,066,232 before issue costs.

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

During July 2011 the Company received compelling new human trial data from the multi-centre international wound healing study led by key opinion leader Professor Keith Harding. (Please see ASX: TIS "Strong New Clinical Trial Data", 14 July 2011.)

The data shows that for the 24 evaluated venous ulcer patients treated with VitroGro® to date:

- 8 patients achieved complete healing and an additional 2 patients achieved ≥ 98% healing
- out of 24 evaluable patients, 22 (92%) were partially or completely healed in 12 weeks. (One patient was unchanged and 1 patient worsened.)
- The average reduction in wound size was 65% with a median of 72% after 12 weeks of treatment
- The average time venous ulcers had not responded to expert care before VitroGro® treatment was 37 months with a median of 10 months
- The average age of patients that have completed treatment so far is 71 years with a median of 73

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 Company, the results of those operations, or the state of affairs of the Company in future financial years.

#### **Future Developments, Prospects and Business Strategies**

The planned developments in the operations of the Company in future calendar years are as follows:

Key Achievement / Indicative Milestone	Target	Status
Completion of larger commercial scale GMP manufacture of VitroGro®.	Q3 2011	On schedule.
Strategic partnership for international sales of new VitroGro® wound care products.	Q3 2011	Negotiations progressing well with multiple international potential commercialisation partners.
Approval for sale of VitroGro® in the EU.	Q1 2012	Submission planned for late 2011 when manufacturing stability data available.
First sales of VitroGro® in EU.	Q2 2012	Planned.
US Approval of VitroGro® for the treatment of venous ulcers.	Q2 2013	Planned.
First sales of VitroGro® in USA for treatment of venous ulcers.	Q3 2013	Planned.

#### **Options**

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

Grant date	Date of Expiry	Exercise price Number under optic	
29/11/2007	2 years from each milestone achieved*	\$0.64	230,000 *
27/11/2008	2 years from each milestone achieved*	\$0.15	225,000 **
9/3/2010	31 March 2012	\$0.26	1,250,000 ***
9/3/2010	31 October 2012	\$0.26	500,000 *v
			2,205,000

<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 2011, 170,000 of the options issued had expired.

- \*\* 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 2011, 175,000 of the options issued had expired and 100,000 had been exercised by 30 June 2011.
- \*\*\* Options issued to Key Management Personnel and QUT Research Staff.
- \*v Options issued to Directors. 750,000 options were issued of which 250,000 had been exercised by 30 June 2011.

350,000 ordinary shares were issued on the exercise of options during the year ended 30 June 2011.

During the year 120,000 options expired.

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

#### **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 Company.

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 Company 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 a General Meeting of members held on 29 January 2004 when shareholders approved an aggregate remuneration of \$250,000 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. No incentive payments are included.

#### **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 current 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 will vest 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 170,000 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 175,000 of these options had expired and 100,000 had been exercised by the end of the financial year.

During 2010 a further 250,000 options were awarded 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 designation by the FDA of VitroGro® as appropriate for a device PMA approval process.

#### Company Secretary

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

Structure: The Company Secretary receives remuneration based on an hourly rate for his services. No incentive payments are included.

During 2010, 250,000 options were awarded to the Company Secretary 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".

#### **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 2011 are set out as follows:

		Pri	mary	Post Employment	Share-base	ed payment		
Key Management Personnel	ł	Cash Salary and fees	Bonus / Non- monetary benefits	Super- annuation	Equity	Options (a)	Total	Performance related
		\$	\$	\$	\$	\$	\$	%
Non-Executive Directors	i							
R. Clarke (Chairman)	2011	45,000	-	4,050	-	-	49,050	-
	2010	45,000	-	4,050	-	-	49,050	-
G. Baynton	2011	40,000	-	-	-	-	40,000	-
	2010	40,000	-	-	-	-	40,000	-
M.Bridges	2011	40,000	-	-	-	47,750	87,750	54.4%
	2010	40,000	-	-	-	-	40,000	-
C. Hirst	2011	40,000	-	3,600	-	47,750	91,350	52.3%
	2010	40,000	-	3,600	-	-	43,600	-
Executive Directors								
Dr S. Mercer (CEO)	2011	205,620	-	18,505	•	47,750	271,875	17.6%
	2010	198,857	-	17,606	-	2,256	218,719	1.0%
Other Key Management Personnel								
D. McKenzie	2011	84,065	-	•	-	8,061	92,126	8.7%
	2010	45,804	-	-	-	3,646	49,450	7.4%
Total	2011	454,685	-	26,155	-	151,311	632,151	
	2010	409,661	-	25,256	-	5,902	440,819	

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

During the year 750,000 (2010: 1,250,000) options were issued under the Company's Equity Option Plan, of which 250,000 (2010: 250,000) options were issued to Key Management Personnel. 350,000 options were exercised during the year.

The value of options issued to Key Management Personnel have been partly amortised during the year with \$183,393 (2010: \$20,488) 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	250,000	250,000	9/3/2010	0.191	0.26	31/03/2011	31/10/2012
Dr C Hirst	250,000	250,000	9/3/2010	0.191	0.26	31/03/2011	31/10/2012
Dr S Mercer	250,000	250,000	9/3/2010	0.191	0.26	31/03/2011	31/10/2012
2010 D McKenzie	-	250,000	9/3/2010	0.046	0.26	31/03/2011	31/3/2012

The total remuneration represented by options granted during the financial year:

Key Management Personnel	Options granted as part of remuneration \$	Total remuneration represented by options %
M Bridges	47,750	54.41
Dr C Hirst	47,750	52.27
Dr S Mercer	47,750	17.56
D McKenzie	8,061	8.75
	151,311	

350,000 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' Meetings			Audit and Risk Management Committee		Remuneration Committee		Committee
	Eligible to Attend	Attended	Eligible to Attend	Attended	Eligible to Attend	Attended	Eligible to Attend	Attended
R Clarke	10	9	3	3	1	1	1	1
G Baynton	10	8	3	3	1	1	1	1
M Bridges	10	10	3	3	1	1	1	1
C Hirst	10	10	n/a	n/a	1	1	1	1
Dr S Mercer	10	10	n/a	n/a	n/a	n/a	n/a	n/a

#### **Environmental Regulation**

The Company'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 (formerly Hacketts DFK) 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 2011:

Non-audit services	30 June 2011 \$	30 June 2010 \$
Audit or review of regulatory returns and due diligence services	12,500	-
Taxation compliance services	-	6,500
	12,500	6,500

#### **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.

estell

Roger Clarke

Chairman

Brisbane, 10 August 2011

Steven Mercer

**CEO & Director** 



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

As lead audit partner for the audit of the financial report of Tissue Therapies Limited for the year ended 30 June 2011, I declare that to the best of my knowledge and belief, there have been:

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

Yours faithfully

**Lawler Hacketts Audit** 

L J Murphy Partner

Brisbane, 10 August 2011

#### **FINANCIAL STATEMENTS**

#### TISSUE THERAPIES LIMITED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2011

	Note	30 June 2011 \$	30 June 2010 \$
Continuing operations			
Revenue	2(a)	232,024	229,484
Other income	2(b)	220,586	151,221
	<del>-</del>	452,610	380,705
Research and development expenses		(1,255,700)	(996,004)
Clinical trials expenses		(2,168,238)	(841,627)
Occupancy expenses		(21,847)	(18,902)
Administration expenses		(1,286,363)	(911,311)
Marketing, business development and patent protection		(369,877)	(285,062)
Laboratory expenses		-	(21,342)
Depreciation		(13,836)	(8,561)
Inventory write down to net realisable value		(364,995)	(348,209)
Finance costs		(3,780)	(7,178)
Loss on foreign exchange		(48,883)	(374,458)
Other expenses		(564,678)	(263,626)
Loss before income tax benefit	3	(5,645,587)	(3,695,575)
Income tax benefit	4(a)	305,039	209,176
Loss from continuing operations after income tax benefit	- -	(5,340,548)	(3,486,399)
Other comprehensive income/(loss) items			
Other comprehensive income items		-	-
Income tax relating to components of other comprehensive income items		-	-
Other comprehensive income/(loss) after income tax benefit	<u>-</u>	-	-
Total comprehensive income/(loss)	- -	(5,340,548)	(3,486,399)
Loss attributable to members of the Company		(5,340,548)	(3,486,399)
Total comprehensive income/(loss) attributable to member of the Company	-	(5,340,548)	(3,486,399)

		Cents	Cents
Overall Operations			
Basic earnings per share	23	(3.79)	(3.08)
Diluted earnings per share	23	(3.79)	(3.08)

#### TISSUE THERAPIES LIMITED STATEMENT OF FINANCIAL POSITION AS AT 30 JUNE 2011

	Note	30 June 2011	30 June 2010
CURRENT ASSETS		\$	\$
Cash and cash equivalents	5	15,416,321	5,500,285
Trade and other receivables	6(a)	125,689	242,564
Inventories	7(a)	574,651	335,528
Current tax assets	4(d)	217,845	189,807
Other current assets	6(b)	545,695	739,698
Financial assets	0(b) 24		739,090
	-	4,804,568	7,007,000
TOTAL CURRENT ASSETS	-	21,684,769	7,007,882
NON-CURRENT ASSETS			
Inventories	7(b)	694,796	1,043,005
Property, plant and equipment	8	86,119	105,142
Intangible assets	9	342,250	342,250
TOTAL NON-CURRENT ASSETS	-	1,123,165	1,490,397
TOTAL ASSETS	- -	22,807,934	8,498,279
CURRENT LIABILITIES			
Trade and other payables	10	969,930	555,884
Financial liabilities	24	4,804,568	-
TOTAL CURRENT LIABILITIES	<del>-</del>	5,774,498	555,884
TOTAL LIABILITIES	- -	5,774,498	555,884
NET ASSETS		17,033,436	7,942,395
EQUITY			
Contributed equity	11(a)	39,525,004	25,276,808
Reserves	12	356,799	173,406
Accumulated losses		(22,848,367)	(17,507,819)
TOTAL EQUITY	-	17,033,436	7,942,395

#### TISSUE THERAPIES LIMITED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011	30 June 2010
	\$	\$
CONTRIBUTED EQUITY		
Ordinary shares at beginning of period	25,276,808	17,556,691
Shares issued	15,177,873	8,164,828
Transaction costs	(929,677)	(444,711)
Dividend paid		<u>-</u>
Balance of issued capital at end of period	39,525,004	25,276,808
RESERVES		
Reserves at beginning of period	173,406	152,918
Share options expensed	183,393	20,488
Balance of options reserve at end of period	356,799	173,406
ACCUMULATED LOSSES		
Accumulated losses at beginning of period	(17,507,819)	(14,021,420)
Loss from continuing operations after income tax benefit	(5,340,548)	(3,486,399)
Other comprehensive income/(loss) after income tax benefit	-	-
Total comprehensive income/(loss)	(5,340,548)	(3,486,399)
Accumulated losses at end of period	(22,848,367)	(17,507,819)
Total equity at the end of the period	17,033,436	7,942,395

#### TISSUE THERAPIES LIMITED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2011

CASH FLOW FROM OPERATING ACTIVITIES           Receipts from customers (inclusive of goods and services tax)         508,790         299,367           Payments to research facilities         (1,204,324)         (1,337,381)           Payments to suppliers (inclusive of goods and services tax)         (4,056,285)         (2,059,894)           Interest received         187,709         151,221           Finance costs         (3,780)         (7,178)           Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           Net cash provided by (used in) investing activities         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net cash provided by (used in) financing activities         9,957,307         5,012,626           Cash at beginn		Note	30 June 2011 \$	30 June 2010 \$
Payments to research facilities         (1,204,324)         (1,337,381)           Payments to suppliers (inclusive of goods and services tax)         (4,056,285)         (2,059,894)           Interest received         187,709         151,221           Finance costs         (3,780)         (7,178)           Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	CASH FLOW FROM OPERATING ACTIVITIES			
Payments to suppliers (inclusive of goods and services tax)         (4,056,285)         (2,059,894)           Interest received         187,709         151,221           Finance costs         (3,780)         (7,178)           Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Receipts from customers (inclusive of goods and services tax)		508,790	299,367
Interest received         187,709         151,221           Finance costs         (3,780)         (7,178)           Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           Net cash provided by (used in) investing activities         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Payments to research facilities		(1,204,324)	(1,337,381)
Finance costs         (3,780)         (7,178)           Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           Net cash provided by (used in) investing activities         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Payments to suppliers (inclusive of goods and services tax)		(4,056,285)	(2,059,894)
Income tax rebate received         277,001         268,397           Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           Net cash provided by (used in) investing activities         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Interest received		187,709	151,221
Net cash provided by (used in) operating activities         22(b)         (4,290,889)         (2,685,468)           CASH FLOW FROM INVESTING ACTIVITIES           Payments for property, plant and equipment         -         (22,023)           Net cash provided by (used in) investing activities         -         (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Finance costs		(3,780)	(7,178)
CASH FLOW FROM INVESTING ACTIVITIES  Payments for property, plant and equipment  - (22,023)  Net cash provided by (used in) investing activities  - (22,023)  CASH FLOW FROM FINANCING ACTIVITIES  Proceeds from share issues  15,177,873 8,164,828  Costs of share issue  (929,677) (444,711)  Net cash provided by (used in) financing activities  14,248,196 7,720,117  Net increase in cash held  9,957,307 5,012,626  Cash at beginning of year  5,500,285 791,369  Unrealised foreign currency movement  (41,271) (303,710)	Income tax rebate received		277,001	268,397
Payments for property, plant and equipment         - (22,023)           Net cash provided by (used in) investing activities         - (22,023)           CASH FLOW FROM FINANCING ACTIVITIES           Proceeds from share issues         15,177,873         8,164,828           Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	Net cash provided by (used in) operating activities	22(b)	(4,290,889)	(2,685,468)
Net cash provided by (used in) investing activities  - (22,023)  CASH FLOW FROM FINANCING ACTIVITIES  Proceeds from share issues 15,177,873 8,164,828 Costs of share issue (929,677) (444,711)  Net cash provided by (used in) financing activities 14,248,196 7,720,117  Net increase in cash held 9,957,307 5,012,626 Cash at beginning of year 5,500,285 791,369 Unrealised foreign currency movement (41,271) (303,710)	CASH FLOW FROM INVESTING ACTIVITIES			
CASH FLOW FROM FINANCING ACTIVITIES         Proceeds from share issues       15,177,873       8,164,828         Costs of share issue       (929,677)       (444,711)         Net cash provided by (used in) financing activities       14,248,196       7,720,117         Net increase in cash held       9,957,307       5,012,626         Cash at beginning of year       5,500,285       791,369         Unrealised foreign currency movement       (41,271)       (303,710)	Payments for property, plant and equipment		-	(22,023)
Proceeds from share issues       15,177,873       8,164,828         Costs of share issue       (929,677)       (444,711)         Net cash provided by (used in) financing activities       14,248,196       7,720,117         Net increase in cash held       9,957,307       5,012,626         Cash at beginning of year       5,500,285       791,369         Unrealised foreign currency movement       (41,271)       (303,710)	Net cash provided by (used in) investing activities	<del>-</del>	-	(22,023)
Costs of share issue         (929,677)         (444,711)           Net cash provided by (used in) financing activities         14,248,196         7,720,117           Net increase in cash held         9,957,307         5,012,626           Cash at beginning of year         5,500,285         791,369           Unrealised foreign currency movement         (41,271)         (303,710)	CASH FLOW FROM FINANCING ACTIVITIES			
Net cash provided by (used in) financing activities 14,248,196 7,720,117  Net increase in cash held 9,957,307 5,012,626  Cash at beginning of year 5,500,285 791,369  Unrealised foreign currency movement (41,271) (303,710)	Proceeds from share issues		15,177,873	8,164,828
Net increase in cash held       9,957,307       5,012,626         Cash at beginning of year       5,500,285       791,369         Unrealised foreign currency movement       (41,271)       (303,710)	Costs of share issue		(929,677)	(444,711)
Cash at beginning of year 5,500,285 791,369 Unrealised foreign currency movement (41,271) (303,710)	Net cash provided by (used in) financing activities	<del>-</del>	14,248,196	7,720,117
Unrealised foreign currency movement (41,271) (303,710)	Net increase in cash held		9,957,307	5,012,626
	Cash at beginning of year		5,500,285	791,369
Cash at end of year 22(a) 15,416,321 5,500,285	Unrealised foreign currency movement		(41,271)	(303,710)
	Cash at end of year	22(a)	15,416,321	5,500,285

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

The financial report covers Tissue Therapies Limited, which is a listed public company, incorporated and domiciled in Australia.

The financial report was authorised for issue on 10 August 2011 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*.

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.

The financial report has been prepared on a going concern and 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. 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.

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.

#### b. 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.

#### c. 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.

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

#### d. 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.

#### e. 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.

#### f. 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.

#### g. 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.

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

#### h. 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 Company 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.

#### i. 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.

#### j. Trade and other creditors

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

#### k. 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.

#### I. Impairment of assets

At each reporting date, the Company 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 Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

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

#### m. Comparative figures

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

#### n. Financial Instruments

#### Recognition and Initial Measurement

Financial instruments, incorporating financial assets and financial liabilities, are recognised when the Company becomes a party to the contractual provisions of the instrument. Financial instruments are initially measured at fair value plus transactions costs where the instrument is not classified as at fair value through profit or loss. Transaction costs related to instruments classified as at fair value through profit or loss are expensed to profit or loss immediately. Financial instruments are classified and measured as set out below.

#### Derecognition

Financial liabilities are derecognised where the related obligations are either discharged, cancelled or expire. The difference between the carrying value 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.

#### Classification and Subsequent Measurement

Non-derivative financial liabilities (excluding financial guarantees) are subsequently measured at amortised cost using the effective interest rate method.

#### Impairment

At each reporting date, the Company assesses whether there is objective evidence that a financial instrument has been impaired. In the case of available-for-sale financial instruments, a prolonged decline in the value of the instrument is considered to determine whether an impairment has arisen. Impairment losses are recognised in the statement of comprehensive income.

#### o. Foreign Currency Transactions and Balances

#### Functional and Presentation Currency

The functional currency of the Company is measured using the currency of the primary economic environment in which the Company operates. The financial statements are presented in Australian dollars which is the Company's functional and presentation currency.

#### Transactions and Balances

Foreign currency transactions are translated into the Company's 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 the statement of comprehensive income, 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 equity to the extent that the gain or loss is directly recognised in equity, otherwise the exchange difference is recognised in the statement of comprehensive income.

# TISSUE THERAPIES LIMITED NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

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

# p. 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 Company.

# Key Estimates — Impairment

The Company assesses impairment at each reporting date by evaluating conditions specific to the Company 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 2011.

Key Judgements - Inventory

The Company assessed the valuation of protein inventory on hand at 30 June 2011. Based on the outcome of research and development activities to date and anticipated future events and use of protein on hand, the Company has written down the value of protein components on hand by \$364,995 (2010: \$348,209). This is shown in the statement of comprehensive income for the current year.

	30 June 2011	30 June 2010
	\$	\$
NOTE 2: REVENUE / OTHER INCOME		
a) Operating activities		
Research grants	220,461	229,484
Product sales	11,563	-
Total revenue from operating activities	232,024	229,484
b) Non operating activities		
,	000 500	151 001
Interest received	220,586	151,221
Total income from non operating activities	220,586	151,221
NOTE 3: LOSS FOR THE YEAR		
Expenses		
Research and development expenses	1,255,700	996,004
Clinical trials expenses	2,168,238	841,627
Inventory write down to net realisable value	364,995	348,209
Loss on foreign exchange	48,883	374,458
Finance costs – external	3,780	7,178
Rental expense on operating leases – minimum lease payments	7,240	5,292
Depreciation expense	13,836	8,561

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

		30 June 2011 \$	30 June 2010 \$
NO.	TE 4: INCOME TAX		
a)	The components of income tax benefit comprises		
	Current tax	217,843	189,806
	Under provision in respect of prior years	87,196	19,370
	Total tax benefit	305,039	209,176
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% (2010: 30%)	1,693,676	1,108,673
	Tax effect of:		
	R&D expenditure taken as a cash offset	(231,364)	(151,845)
	Other	(88,682)	(51,674)
	Tax losses available	1,373,630	905,154
	Tax losses utilised by:		
	Income tax benefit attributable to R&D tax offset receivable	305,039	209,176
	Income tax benefit attributable to R&D tax offset overstated in prior year	-	-
	Income tax benefit relating to entity	305,039	209,176
	The applicable weighted average effective tax rates are as follows:	(5.4%)	(5.6%)
c)	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	644,542	355,711
	Tax losses – operating losses	5,675,726	4,302,096
		6,320,268	4,657,807
d)	Current Tax Asset		
	Opening balance of R&D tax offset concession claimed	189,807	249,028
	Less - R&D tax offset understated / (overstated) in prior year	87,196	19,370
	Less - Income tax benefit attributable to R&D tax offset received	(277,001)	(268,397)
	Add - Income tax benefit attributable to R&D tax offset receivable	217,843	189,806
	Closing balance of research and development tax offset concession claimed	217,845	189,807

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011	30 June 2010
	\$	\$
NOTE 5: CASH AND CASH EQUIVALENTS		
Cash at bank	581,539	98,952
Short term bank deposits - at call *	14,834,782	5,401,333
	15,416,321	5,500,285
$^{\star}$ The deposits were in interest bearing floating rate accounts. Interest rates varied between 0.0% and 6.00% (2010: 0.0% to 6.02%).		
NOTE 6: TRADE AND OTHER RECEIVABLES & OTHER CURRENT ASSETS		
a) Trade and other receivable		
Trade debtors	32,885	129,427
GST receivable	92,804	113,137
	125,689	242,564
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'.		
b) Other current assets		
Prepayments -	545,695	739,698
NOTE 7: INVENTORIES		
a) Current assets		
VitroGro® protein – at cost	574,651	335,528
b) Non-current assets		
VitroGro® Protein Components – at net realisable value	694,796	1,043,005

Based on research and development activities to date and the timing of future expected events, the Directors are of the opinion that the classification of the protein components above as non-current is more appropriate. The Directors believe that the value of these proteins may not be recovered through further conversion or sale within 12 months. The amount of the write-down of these proteins to net realisable value during the year is shown in the statement of comprehensive income.

# TISSUE THERAPIES LIMITED NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June	2011	30 June 2010
	\$		\$
NOTE 8: PROPERTY, PLANT AND EQUIPMENT			
Plant and equipment – at cost	110	,181	136,830
Less: Accumulated depreciation	(36,	451)	(44,077)
	73	,730	92,753
Capital works in progress – at cost	12	,389	12,389
Total property, plant and equipment	86	,119	105,142
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	Capital works in progress	n Total
	\$	\$	\$
Carrying amount at 1July 2010	92,753	12,389	105,142
Additions	-		
Transfers	-		
Disposals (written down value)	(5,187)		- (5,187)
Depreciation expense	(13,836)		- (13,836)
Carrying amount at 30 June 2011	73,730	12,389	86,119

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

	30 June 2011 \$	30 June 2010 \$
NOTE 9: INTANGIBLE ASSETS		
Licenses and patents - at cost	342,250	342,250

Licences and patents are assessed to have finite useful lives. Amortisation shall begin when the asset is available for use, that is, when it is in the location and condition necessary for it to be capable of operating in the manner intended by management. There are no amortisation charges for licenses and patents for the current or prior financial periods.

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011 \$	30 June 2010 \$
NOTE 10: TRADE AND OTHER PAYABLES		
Trade creditors	594,770	36,608
Other creditors and accruals	375,160	519,276
	969,930	555,884
NOTE 11: ISSUED CAPITAL		
a) Share capital		
168,739,422 (2010: 138,201,447) fully paid ordinary shares	39,525,004	25,276,808

# 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.

# c) Movements in ordinary share capital

Date Details	No. Shares	Issue price	\$
01/07/10 Balance at beginning of year	138,201,447		25,276,808
09/11/10 Ordinary shares issued on exercise of Options	100,000	15 c	15,000
18/04/11 Ordinary shares issued on exercise of Options	250,000	26 c	65,000
26/05/11 Ordinary shares issued by Placement	11,500,000	50 c	5,750,000
26/05/11 Ordinary shares issued by Rights Issue	18,632,464	50 c	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)
30/06/11 Balance at end of year	168,739,422		39,525,004

# 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 16: Share-based Payments.

# e) Capital Management

Management controls the capital of the Company in order to maintain an appropriate debt to equity ratio, and ensure that the Company can fund its operations and continue as a going concern. The Company'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 Company's capital by assessing the Company'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 Company since the prior year.

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011	30 June 2010
	\$	\$
NOTE 12: RESERVES		
Option reserve	356,799	173,406
a) Option Reserve		
The option reserve records items recognised as expenses on valuation of employee share options.		
b) Movement		
Balance at beginning of year	173,406	152,918
Cost of options issued	183,393	20,488
Balance at end of year	356,799	173,406
NOTE 13: REMUNERATION OF AUDITORS		
Audit services – Lawler Hacketts Audit		
Audit and review of financial reports and other audit work under the Corporations Act 2001	35,463	30,025
Non-audit services		
Audit / review of regulatory returns and due diligence services – Hacketts Corporate Advisory	12,500	-
Taxation compliance services – Lawler Hacketts	-	6,500
	47,963	36,525

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

#### NOTE 14: FINANCIAL RISK MANAGEMENT

### **Financial Risk Management Policies**

The Company'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 Company 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 Company 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 Company. The credit risk on financial assets of the Company 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 Company is also exposed to earnings volatility on floating rate instruments. The Company'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 Company might encounter difficulty in settling its debts or otherwise meeting its obligations related to financial liabilities. The Company 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 Company holds financial instruments which are other than the functional currency of the Company. The Company manages foreign currency risk by monitoring forecast foreign currency commitments and foreign exchange rates. The Company's exposure to foreign currency risk arises from the holding of €4,071 (2010: €1,168,356) and £30,658 (2010: £148,185) at exchange rates of 0.7364 and 0.6616 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 Company 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 Company 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 2011, 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 \$147,829 (2010: \$54,013) additional, or less, interest revenue.

Management have determined that, at 30 June 2011, 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 \$764 (2010: \$27,886) exposure to foreign currency exposure.

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

# NOTE 15: 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 G Baynton	Director – Non-executive
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
Dr C Hirst Dr S Mercer	Director – Non-executive Chief Executive Officer and Executive Director

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 30.06.2010	Granted as compensation	Options exercised	Options expired	Balance 30.06.2011	Total Vested 30.06.2011	Total Exercisable 30.06.2011
Mr R Clarke	-	-	-	-	-	-	-
Mr G Baynton	-	-	-	-	-	-	-
Mr M Bridges	-	250,000	-	-	250,000	250,000	250,000
Dr C Hirst	-	250,000	250,000	-	-	-	-
Dr S Mercer	675,000	250,000	100,000	120,000	705,000	705,000	390,000
Mr D McKenzie	250,000	-	-	-	250,000	250,000	250,000
Total	925,000	750,000	350,000	120,000	1,205,000	1,205,000	890,000

# c) Share Holdings

Number of Shares held by Key Management Personnel:

Key Management Personnel	Balance 1.7.2010	Acquired in Rights Issue, Options Exercised and other purchases	Balance 30.06.2011
Mr R Clarke	5,058,000	142,000	5,200,000
Mr G Baynton [1]	612,500	152,280	764,780
Mr M Bridges	68,200	79,099	147,299
Dr C Hirst	-	281,250	281,250
Dr S Mercer	1,025,750	100,000	1,125,750
Mr D McKenzie	200,000	25,000	225,000
Total	6,964,450	779,629	7,744,079

<sup>[1]</sup> Orbit Capital, a related entity of Gregory Baynton holds 764,780 shares.

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

#### **NOTE 16: SHARE-BASED PAYMENTS**

The following share-based payment arrangements existed at 30 June 2011:

- 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 2011, 170,000 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 2011, 175,000 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. The options expire on 31 March 2012.
- 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.

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

	2011			2010
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
		\$		\$
Outstanding at the beginning of the year	1,925,000	0.40	1,130,000	0.55
Granted	750,000	0.26	1,250,000	0.26
Forfeited	-	-	-	-
Exercised	(350,000)	0.23	-	-
Expired	(120,000)	0.64	(455,000)	0.76
Outstanding at year-end	2,205,000	0.29	1,925,000	0.31
				_
Exercisable at year-end	1,890,000	0.29	675,000	0.40

There were 350,000 options exercised during the year ended 30 June 2011.

The options outstanding at 30 June 2010 had a weighted average exercise price of \$0.29 and a weighted average remaining contractual life of 0.8 (2010: 1.4) years. Exercise prices range from \$0.15 to \$0.64 in respect of options outstanding at 30 June 2011.

Included under Administration expense in the Statement of Comprehensive Income is \$183,393 (2010: \$20,488) which relates, in full, to equity-settled share-based payment transactions.

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011	30 June 2010	
	\$	\$	
NOTE 17: COMMITMENTS FOR EXPENDITURES			
Commitments for consultancy services contracted for at the reporting date but not recognised as liabilities payable:			
Within one year	531,415	587,995	
Later than one year but not later than 5 years	184,140	184,140	
Later than 5 years	-	-	
	715,555	772,135	

#### **NOTE 18: 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 Company as disclosed in these financial statements.

# **NOTE 19: RELATED PARTY TRANSACTIONS**

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

Key Management Personnel

The Company has incurred share issue transaction costs of \$791,378 (2010: \$365,080) to RBS Morgans Corporate Limited primarily for its part in the rights issue and share placement during the year. Roger Clarke is associated with RBS Morgans Corporate Limited.

#### **NOTE 20: 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, with its revenue being predominantly sourced in Australia.

# TISSUE THERAPIES LIMITED NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

#### NOTE 21: EVENTS SUBSEQUENT TO REPORTING DATE

During July 2011 the Company received compelling new human trial data from the multi-centre international wound healing study led by key opinion leader Professor Keith Harding. (Please see ASX: TIS "Strong New Clinical Trial Data", 14 July 2011.)

The data shows that for the 24 evaluated venous ulcer patients treated with VitroGro® to date:

- 8 patients achieved complete healing and an additional 2 patients achieved ≥ 98% healing
- out of 24 evaluable patients, 22 (92%) were partially or completely healed in 12 weeks. (One patient was unchanged and 1 patient worsened.)
- The average reduction in wound size was 65% with a median of 72% after 12 weeks of treatment
- The average time venous ulcers had not responded to expert care before VitroGro® treatment was 37 months with a median
  of 10 months
- The average age of patients that have completed treatment so far is 71 years with a median of 73

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 Company, the results of those operations, or the state of affairs of the Company in future financial years.

NOTE 22: CASH FLOW INFORMATION	30 June 2011 \$	30 June 2010 \$
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	15,416,321	5,500,285
	15,416,321	5,500,285

# NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

	30 June 2011 \$	30 June 2010 \$
NOTE 22: CASH FLOW INFORMATION (Continued)		
b) Reconciliation of Cash Flow from Operations with Loss after Income Tax		
Loss after income tax benefit	(5,340,548)	(3,486,399)
Non-cash flows in profit from ordinary activities		
Depreciation	13,836	8,561
Unrealised exchange loss	41,271	303,710
Inventory write down to net realisable value	364,995	348,209
Loss on disposal of property, plant and equipment	5,187	-
Share based payments	183,393	20,488
Finance costs for convertible notes converted to share capital, included in		
financing activities	-	-
Changes in assets and liabilities		
(Increase) / decrease in receivables and prepayments	343,755	(706,828)
(Increase) / decrease in inventory	(255,909)	659,915
(Increase) / decrease in tax recoverable	(28,038)	59,221
Increase / (decrease) in payables and provisions	381,169	107,655
Cash outflows from operations	(4,290,889)	(2,685,468)
NOTE 23: EARNINGS PER SHARE		
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	140,884,769	112,982,362
Weighed average number of options outstanding which are considered potentially dilutive	<u>-</u>	
Weighted average number of potential ordinary shares outstanding during the year used in calculation of Dilutive EPS	140,884,769	112,982,362

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

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

#### **NOTE 24: FINANCIAL ASSETS AND LIABILITIES**

The Company's planned developments include the commercial scale GMP manufacture of VitroGro® and the USA approval of VitroGro® for the treatment of venous ulcers. The expenditure associated with these developments will be incurred by the Company in Euro and USD currencies over the period to 30 June 2012. In accordance with the Company's Risk Management policy the Company has executed forward exchange contracts to mitigate the Company's exposure to foreign currency movements in these foreign currencies.

# **Forward Exchange Contracts**

The Company 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 Company to buy and sell specified amounts of foreign currencies in the future as specified exchange rates.

The following table summarises the Company's commitment in relation to forward exchange contracts:

		Exposure		Average exchange rate	
		2011	2010	2011	2010
		\$	\$		
Buy USD / sell AUD					
Settlement	- less than 6 months	-	-	-	-
	- 6 months to 1 year	2,502,002	-	1.0445	-
Buy Euro / sell AUD					
Settlement	- less than 6 months	-	-		-
	- 6 months to 1 year	2,302,566	-	0.7320	-
		4,804,568	-		

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

#### **NOTE 25: CHANGE IN ACCOUNTING POLICY**

New Accounting Standards for application in future periods

The AASB has issued new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods. The Company has decided against early adoption of these Accounting Standards and Interpretations. A discussion of those future requirements and their impact on the Company is as follows:

(a) AASB 9: Financial Instruments (December 2010) (applicable for annual reporting periods commencing on or after 1 January 2013).

This standard is applicable retrospectively and includes revised requirements for the classification and measurement of financial instruments, as well as recognition and derecognition requirements for financial instruments. The Company has not yet determined the potential impact on the financial statements.

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;
- 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 classified 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.
- (b) AASB 1053: Application of Tiers of Australian Accounting Standards and AASB 2010-2: Amendments to Australian Accounting Standards arising from Reduced Disclosure Requirements [AASB 1, 2, 3, 5, 7, 8, 101, 102, 107, 108, 110, 111, 112, 116, 117, 119, 121, 123, 124, 127, 128, 131, 133, 134, 136, 137, 138, 140, 141, 1050 and 1052 and Interpretations 2, 4, 5, 15, 17, 127, 129, and 1052] (applicable for annual reporting periods commencing on or after 1 July 2013).

AASB 1053 establishes a revised differential financial reporting framework consisting of two tiers of financial reporting requirements for those entities preparing general purpose financial statements:

- Tier 1: Australian Accounting Standards; and
- Tier 2: Australian Accounting Standards Reduced Disclosure Requirements.

Tier 2 of the framework comprises the recognition, measurement and presentation requirements of Tier 1, but contains significantly fewer disclosure requirements.

The following entities are required to apply Tier 1 reporting requirements (i.e. full IFRS):

- for-profit private sector entities that have public accountability; and
- the Australian Government and state, territory and local governments.

Since the Company is a for-profit private sector entity that has public accountability, it does not qualify for the reduced disclosure requirements for Tier 2 entities.

#### NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

## NOTE 25: CHANGE IN ACCOUNTING POLICY (Continued)

- (c) AASB 2010–2 makes amendments to Australian Accounting Standards and Interpretations to give effect to the reduced disclosure requirements for Tier 2 entities. It achieves this by specifying the disclosure paragraph that a Tier 2 entity need not comply with as well as adding specific "RDR" disclosures.
- (d) AASB 2010–4: Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 1, 7, 101 and 134 and Interpretation 13] (applicable for annual reporting periods commencing on or after 1 January 2011).

This Standard details numerous non-urgent but necessary changes to Accounting Standards arising from the IASB's annual improvements project. Key changes include:

- clarifying the application of AASB 108 prior to an entity's first Australian Accounting Standards financial statements;
- adding an explicit statement to AASB 7 that qualitative disclosures should be made in the context of the quantitative disclosures to better enable users to evaluate an entity's exposure to risks arising from financial instruments;
- amending AASB 101 to the effect that disaggregation of changes in each component of equity arising from transactions recognized in other comprehensive income is required to be presented, but is permitted to be presented in the statement of changes in equity or in the notes;
- adding a number of examples to the list of events or transactions that require disclosure under AASB 134; and
- making sundry editorial amendments to various Standards and Interpretations.

This Standard is not expected to impact the Company.

- (e) AASB 2010–5: Amendments to Australian Accounting Standards [AASB 1, 3, 4, 5, 101, 107, 112, 118, 119, 121, 132, 133, 134, 137, 139, 140, 1023 and 1038 and Interpretations 112, 115, 127, 132 and 1042] (applicable for annual reporting periods beginning on or after 1 January 2011).
  - This Standard makes numerous editorial amendments to a range of Australian Accounting Standards and Interpretations, including amendments to reflect changes made to the text of IFRSs by the IASB. However, there editorial amendments have no major impact on the requirements of the respective amended pronouncements.
- (f) AASB 2010–6: Amendments to Australian Accounting Standards Disclosures on Transfers of Financial Assets [AASB 1 and 7] (applicable for annual reporting periods beginning on or after 1 July 2011).
  - This Standard adds and amends disclosure requirements about transfers of financial assets, expecially those in respect of the nature of the financial assets involved and the risks associated with them. Accordingly, this Standard makes amendments to AASB 1: First-time Adoption of Australian Accounting Standards, and AASB 7: Financial Instruments: Disclosures, establishing additional disclosure requirements in relation to transfers if financial assets.
  - This Standard is not expected to impact the Company.
- (g) 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 and 1038 and Interpretations 2, 5, 10, 12, 19 and 127] (applies to periods beginning on or after 1 January 2013).

This Standard makes amendments to a range of Australian Accounting Standards and Interpretations, as a consequence of the issuance of AASB 9: Financial Instruments in December 2010. Accordingly, these amendments will only apply when the Company adopts AASB 9.

As noted above, the Company has not yet determined any potential impact on the financial statements from adopting AASB 9.

# TISSUE THERAPIES LIMITED NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2011

# **NOTE 26: COMPANY DETAILS**

The registered office of the Company is:

Tissue Therapies Limited c/o McCullough Robertson Lawyers Level 11 Central Plaza Two 66 Eagle Street BRISBANE QLD 4000 Australia

The principal place of business of the Company is:

Tissue Therapies Limited 6th Floor Institute of Health and Biomedical Innovation 60 Musk Avenue KELVIN GROVE QLD 4059 Australia

# **DIRECTORS' DECLARATION**

The Directors of the Company declare that:

- 1. the financial statements and notes, as set out on pages 11 to 34, are in accordance with the Corporations Act 2001; and
  - a. comply with Accounting Standards; and
  - b. give a true and fair view of the Company's financial position as at 30 June 2011 and of its performance for the year ended on that date.
- 2. the Chief Executive Officer and Chief Finance Officer have each declared that:
  - a. the financial records of the Company for the financial year have been properly maintained in accordance with section 286 of the *Corporations Act 2001*;
  - b. the financial statements and notes for the financial year comply with the Accounting Standards; and
  - c. the financial statements and notes for the financial year give a true and fair view;
- 3. in the Directors' opinions there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.

**Roger Clarke** 

Chairman

Brisbane, 10 August 2011

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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 ("the Company") which comprises the statement of financial position as at 30 June 2011, and the statement of comprehensive income, statement of changes in equity and 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 Company.

# 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 gives a true and fair view and 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 judament, 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 company's preparation of the financial report that gives a true and fair view 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 company'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 Company's financial position as at 30 June 2011 and of its performance for the year ended on that date; and
  - ii. complying with Australian Accounting Standards and the Corporations Regulations 2001; and
- the financial report also complies with International Financial Reporting Standards as disclosed in Note 1.

telephone 07 3839 9733 facsimile 07 3832 1407 advice@lawlerhacketts.com.au



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

# **Report on the Remuneration Report**

Lawler Hochett

We have audited the Remuneration Report included in pages 6 to 8 of the Directors' Report for the year ended 30 June 2011. 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 2011, complies with section 300A of the *Corporations Act 2001*.

**Lawler Hacketts Audit** 

Brisbane, 10 August 2011

L J Murphy Partner

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# **Shareholder Information**

Additional information required by the Australian Stock Exchange Ltd and not shown elsewhere in this report is as follows.

The information is current as at 3rd October 2011.

# 1(a). Distribution of equity securities

The number of shareholders, by size of holding, in each class of shares is:

Range	Number of investors	Number of shares	% Issued Capital
1-1,000	294	87,258	0.05%
1,001-5,000	585	1,870,354	1.11%
5,001-10,000	433	3,561,299	2.11%
10,001-100,000	1,114	37,779,323	22.39%
100,001 and over	234	125,441,188	74.34%
Total	2,660	168,739,422	100.00%

<sup>1(</sup>b) There were 298 holders of less than a marketable parcel of securities.

# 2. Names of the twenty largest holders of quoted shares

	Name of Holders	Number of Shares	% of Ordinary shares
1	Asia Union Investments Pty Ltd	21,010,000	12.45%
2	National Nominees Limited	13,618,050	8.07%
3	Queensland University of Technology	8,087,010	4.79%
4	JP Morgan Nominees Australia Limited <cash a="" c="" income=""></cash>	6,531,302	3.87%
5	Citicorp Nominees Pty Limited	5,989,545	3.55%
6	Mr Roger Brian Clarke + Mrs Barbara Joan Clarke <roger a="" b="" c="" clarke="" family=""></roger>	4,600,000	2.73%
7	Mr Thai Quoc Tang	3,330,000	1.97%
8	Berne No 132 Nominees Pty Ltd <323731 A/C >	2,594,292	1.54%
9	HSBC Custody Nominees (Australia) Limited	1,760,000	1.04%
10	Mr Thai Quoc Tang	1,684,000	1.00%
11	Mr Paul Robert Baster + Ms Catherine Bellemore <the a="" avenue="" c="" f="" s=""></the>	1,600,000	0.95%
12	Berne No 132 Nominees Pty Ltd <323723 A/C>	1,539,042	0.91%
13	Mr Edward William Gallop + Ms Glenda Joy Gallop <gallop a="" c="" f="" family="" s=""></gallop>	1,461,500	0.87%
14	Mr Wayne Martin + Mrs Anthea Martin	1,250,000	0.74%
15	Dr Zee Upton	1,185,776	0.70%
16	Dr Steven John Mercer <ljl account=""></ljl>	1,125,750	0.67%
17	Abercairney Pty Ltd <simpson a="" c="" family="" fund="" s=""></simpson>	1,000,000	0.59%
18	Mr David Frederick Oakley	882,905	0.52%
19	Berne No 132 Nominees Pty Ltd <224266 A/C >	786,095	0.47%
20	Ms Wai Kwan Chan	715,000	0.42%
Total fo	or top 20 holders	80,750,267	47.86%



# 3. Substantial Shareholders

Substantial shareholders in the Company are set out below:

Name	Number	Percentage
Asia Union Investments Pty Ltd	21,010,000	12.45%
National Nominees Limited	13,618,050	8.07%

# 4. 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 and upon a poll each share shall have one vote.

# 5(a). Unquoted Equity Securities

Range	Number of Holders	Number of Options on Issue	% Options Issued
1 – 1,000	-	-	-
1,001- 5,000	-	-	-
5,001-10,000	-	-	-
10,001 – 100,000	1	100,000	4.54%
100,001 and over	7	2,105,000	95.46%
Total	8	2,205,000	100.00%

5(b) 230,000 of the options are exercisable at \$0.64 each, 225,000 of the options are exercisable at \$0.15 each, and 1,750,000 of the options are exercisable at \$0.26 each.

