



## **Tissue Therapies Update on EU Sales Launch**

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has today confirmed that all milestones) are on track for the start of VitroGro<sup>(R)</sup> sales in early June 2012 in the UK and Europe.

Final validation data are as expected and confirm that the VitroGro<sup>(R)</sup> ECM manufacturing processes are reliable and compliant with the necessary Good Manufacturing Process (GMP) standards.

Working with our partner Quintiles, advertising for and interviewing of potential UK and European sales staff has identified a pool of strong, experienced candidates from whom final selection and employment offers will be made.

Key, influential wound healing clinicians in the UK and Europe are keen to be involved in the initial clinical use of VitroGro<sup>(R)</sup> ECM and a number of these are providing their expert advice on a range of launch activities including sales training and reimbursement.

Logistics, multilingual customer support, order and payment processes are also in place with our partner Movianto.

The CEO, Dr Steven Mercer said, "The company remains confident about CE mark approval. We will also be rolling out an integrated communications program for the launch of VitroGro<sup>(R)</sup>. This will include publications, scientific and clinical papers and presentations at selected conferences."

"We believe we have a proven, unprecedented product for the definitive treatment of diabetic and venous ulcers. VitroGro<sup>(R)</sup> ECM offers for the first time ever, consistent healing as well as better price performance than any product previously available to treat these debilitating and sometimes fatal wounds"

"We have the product to launch in the EU and \$10 million in cash. This is an exciting time for Tissue Therapies."

### For Further information

Dr Steven Mercer CEO, Tissue Therapies Limited Telephone: +61 (0)7 3334 3900

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**FISSUE THERAPIES** 



### What is VitroGro® ECM

- VitroGro® ECM is a biomimetic scaffold that is sterile, acellular and flowable (designed to be applied to the surface of wounds).
- It is an artificially created matrix protein designed from polypeptide sequences that provide attachment sites that guide cells during normal wound healing in healthy skin.
- In chronic (non-healing) wounds, skin cells are deprived of these attachment sites because the extracellular matrix (ECM) is degraded.
- VitroGro® ECM restores normal wound healing by replacing the degraded ECM with a scaffold containing the attachment sites that guide skin cell proliferation and migration (the essential processes of normal wound healing).
- VitroGro® ECM is a temporary matrix that is designed to be replaced through the normal processes of tissue restoration and turnover.
- VitroGro® ECM consistently and conveniently restores healing in chronic skin ulcers that have failed to respond to expert care using the best current treatments.
- Expert health economics modelling indicates that VitroGro® ECM offers the opportunity for substantially more cost effective treatment of wounds compared to the current standard of care.

## **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), Queensland University of Technology (QUT). VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and cell culture.

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

Tissue Therapies is also proceeding with the development of commercial applications of 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.

VitroGro® also provides a fundamental, transforming technology for completely defined cell culture reagents (ie. containing no purified animal or human proteins) to sustain and enhance the growth of live cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: www.tissuetherapies.com



# Tissue Therapies Limited ABN 45 101 955 088

# Appendix 4D ASX Half-Year Report 31 December 2011

Lodged with the ASX under Listing Rule 4.2A

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### RESULTS FOR ANNOUNCEMENT TO THE MARKET

### **Summary of Financial Information**

Extracts from this report for announcement to the market:

	6 months ended 31 December 2011	6 months ended 31 December 2010	Movement	Movement
	\$	\$	\$	%
Revenue from continuing operations	472,238	73,500	398,738	(542.5)
Loss after income tax for the half-year attributable to members	(2,450,470)	(3,321,806)	871,336	26.2
Total comprehensive income for the half- year attributable to members	(2,450,470)	(3,321,806)	871,336	26.2

### **Dividends**

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

### **Highlights of Results**

- The after-tax loss of \$2,450,470 was in line with budget expectations.
- Revenue of \$472,238 arose from research grants and interest earned on funds on deposit.
- Research and development expenditure of \$652,302 and expenditure on clinical trials of \$221,185 was incurred in pursuing the Company's key research and business priorities.
- Cash assets were \$10,472,432 at 31 December 2011.
- During November 2011, Quintiles was announced as the commercial partner with whom the Company will launch VitroGro® sales in the UK and Europe. The partnership provides:
  - Shared risk and reward with alignment of interests,
  - Strategic retention of branding and commercial control,
  - o Flexibility to allocate resources as sales and corporate needs evolve, and
  - The opportunity for a risk-mitigated and optimised launch with a partner that has an exceptional track record and pan-European presence.
- The Movianto Group was appointed for warehousing and pan-European customer care and distribution.
- During November 2011, United States FDA classified VitroGro® protein as a biologic product, crystallising further certainty for clinical trial, approval and reimbursement plans.
- Excellent results were announced from the 44 patient international venous ulcer trial:
  - VitroGro® ECM proved effective in achieving healing or reduction in wound size under real world conditions; 34% (15 patients) were completely healed; 43% (19 patients) were more than 90% healed; 82% (36 patients) were improved i.e. were partially or completely healed,
  - Average reduction in wound area was 56%; average ulcer size on entering the trial was 7.2 cm<sup>2</sup>; average age was 74 years; average time ulcers had no responded to expert care prior to entering the study was 36 months.
  - o Statistical analysis demonstrated treatment twice per week was no more effective than once per week,
  - The adverse event profile demonstrated that patients tolerate therapy with VitroGro® ECM well, and this was confirmed by patient and clinician acceptance of the therapy.
  - Independent health economic analysis of the VitroGro® ECM venous ulcer trail data demonstrated a cost effectiveness that is not available from current treatments; and
  - The results of this clinical trial are currently being prepared for scientific publication.
- During the half year ended 31 December 2011, further VitroGro® patents were granted in the EU, Hong Kong, and New Zealand.

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### **Ratios**

	Current period	Previous corresponding period
Loss before tax / revenue		
Loss from ordinary activities before tax as a percentage of revenue	(585.41%)	(4,782%)
Loss after tax / equity interests		
Loss from ordinary activities after tax attributable to members as a percentage of equity (similarly attributable) at the end of the period	(16.75%)	(71.11%)

### NTA backing

	At the end current period Cents	At the end of previous corresponding period Cents
Net tangible asset backing per ordinary security	8.46	3.13

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### **COMPLIANCE STATEMENT**

- This Appendix 4D has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting*, the Corporations Act 2001 and Corporations Regulations 2001; and other standards acceptable to the ASX.
- 2 This Appendix 4D has been prepared in accordance with Australian Accounting Standards.
- This Appendix 4D does give a true and fair view of the matters disclosed.
- This Appendix 4D is based on financial statements which have been reviewed and the review report contains no qualifications.
- 5 The entity has a formally constituted Audit and Risk Management Committee.

#### **TISSUE THERAPIES LIMITED**

Drummond Mckenzie
COMPANY SECRETARY

Brisbane, 7 February 2012

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### **DIRECTORS' REPORT**

Your directors present their report on Tissue Therapies Limited ("the Company") for the half-year ended 31 December 2011.

#### **Directors**

The names of directors who held office during or since the end of the half-year:

Mr Roger Clarke - Chairman
Mr Mel Bridges – Director
Dr Cherrell Hirst – Director
Mr Gregory Baynton – Director
Dr Steven Mercer – Executive Director

#### **Review of Operations**

- The after-tax loss of \$2,450,470 was in line with budget expectations.
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  - o Shared risk and reward with alignment of interests,
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  - Independent health economic analysis of the VitroGro® ECM venous ulcer trail data demonstrated a cost effectiveness that is not available from current treatments; and
  - o The results of this clinical trial are currently being prepared for scientific publication.
- During the half year ended 31 December 2011, further VitroGro® patents were granted in the EU, Hong Kong, and New Zealand.

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# DIRECTORS' REPORT (continued)

### **Auditor's Declaration**

The auditor's independence declaration under section 307C of the Corporations Act 2001 is attached to this Directors' Report for the half-year ended 31 December 2011.

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

Melvyn Bridges **DIRECTOR** 

Brisbane, 7 February 2012

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

I declare that, to the best of my knowledge and belief, in relation to the review for the half-year ended 31 December 2011 there have been:

- i. no contraventions of the auditor independence requirements as set out in the Corporations Act 2001 in relation to the review; and
- ii. no contraventions of any applicable code of professional conduct in relation to the review.

Lawler Hacketts Audit

Brisbane, 7 February 2012

L J Murphy Partner

### HALF-YEAR FINANCIAL STATEMENTS

### **Condensed Statement of Comprehensive Income**

	Note	Current period	Previous corresponding period \$
Continuing operations			
Revenue	2	145,150	-
Other income	2	327,088	73,500
		472,238	73,500
Research & development		(652,302)	(337,695)
Clinical trials		(221,185)	(1,969,609)
Administration		(1,051,254)	(550,762)
Occupancy		(13,465)	(8,663)
Marketing and business development		(10,767)	(9,970)
Regulatory and intellectual property		(485,244)	(189,477)
Manufacturing expenses		(25,501)	-
Raw materials and consumables		(145)	-
Finance costs		(3,155)	(1,557)
Depreciation		(7,689)	(6,902)
Unrealised foreign exchange losses		(45,204)	(62,197)
Inventory amortisation		(174,105)	(174,105)
Other expenses		(546,768)	(277,950)
Loss before income tax		(2,764,546)	(3,515,387)
Income tax benefit		314,076	193,581
Net loss after tax		(2,450,470)	(3,321,806)
Other comprehensive income/(loss)			
Other comprehensive income items			-
Income tax benefit relating to components of other comprehensive income			-
Other comprehensive income/(loss) after tax		•	-
Total comprehensive income/(loss)		(2,450,470)	(3,321,806)
Loss attributable to:			
Members of the entity		(2,450,470)	(3,321,806)
Total comprehensive income/(loss) attributable to			
Members of the entity		(2,450,470)	(3,321,806)
Earnings per share		Cents	Cents
Basic earnings per share	9	(1.45)	(2.40)
Diluted earnings per share	9	(1.45)	(2.40)

The above condensed statement of comprehensive income is to be read in conjunction with the accompanying notes to the financial statements.

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### **Condensed Statement of Financial Position**

		At end of current	At end of period for last annual report \$
	Note	period \$	
Current assets			
Cash and cash equivalents		10,472,432	15,416,321
Receivables		193,156	125,689
Inventories	4 (a)	1,513,054	574,651
Current tax assets		531,921	217,845
Other assets	5	2,034,128	545,695
Total current assets		14,744,691	16,880,201
Non-current assets			
Inventories	4 (b)	860,048	694,796
Property, plant and equipment		312,430	86,119
Intangible assets		342,250	342,250
Total non-current assets		1,514,728	1,123,165
Total assets		16,259,419	18,003,366
Current liabilities			
Payables		1,406,434	969,930
Financial liabilities		44,870	-
Total current liabilities		1,451,304	969,930
Non-current liabilities			
Payables		174,347	-
Total non-current liabilities		174,347	-
Total liabilities		1,625,651	969,930
Net assets		14,633,768	17,033,436
Equity			
Issued capital	6	39,575,806	39,525,004
Options reserve		356,799	356,799
Accumulated losses		(25,298,837)	(22,848,367)
Total equity		14,633,768	17,033,436

The above condensed statement of financial position is to be read in conjunction with the accompanying notes to the financial statements.

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### **Condensed Statement of Changes in Equity**

	Note	Current period \$	Previous corresponding period \$
Contributed equity			
Ordinary shares at beginning of period		39,525,004	25,276,808
Shares issued during period		59,893	15,000
Transaction costs		(9,091)	-
Balance of shares at end of period		39,575,806	25,291,808
Options reserve			
Options reserve at beginning of period		356,799	173,406
Share options expensed during the period		-	35,377
Balance of options reserve at end of period		356,799	208,783
Accumulated losses			
Accumulated losses at beginning of period		(22,848,367)	(17,507,819)
Losses to members of the entity		(2,450,470)	(3,321,806)
Accumulated losses at end of period		(25,298,837)	(20,829,625)
Total equity at the end of the period		14,633,768	4,670,966

The above condensed statement of changes in equity should be read in conjunction with the accompanying notes.

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### **Condensed Statement of Cash Flows**

	Note	Current period	Previous corresponding period \$
Cash flows related to operating activities			
Receipts from customers		-	-
Other – research grants received		145,150	129,419
Payments to suppliers and employees		(3,796,765)	(2,328,477)
Payments for research & development and clinical trials		(1,573,420)	(429,325)
Interest received		324,322	73,500
Income tax rebate received		-	277,000
Interest and other costs of finance paid		(3,155)	(1,557)
Net operating cash flows		(4,903,868)	(2,279,440)
Cash flows related to investing activities			
Payment for property, plant and equipment		(30,596)	
Net investing cash flows		(30,596)	
Cash flows related to financing activities			
Proceeds from issues of shares and other equity securities		-	15,000
Cost of share issue		(9,091)	
Net financing cash flows		(9,091)	15,000
Net increase (decrease) in cash held		(4,943,555)	(2,264,440)
Cash and cash equivalents at beginning of period		15,416,321	5,500,285
Foreign currency movement		(334)	(62,197)
Cash and cash equivalents at end of period	7	10,472,432	3,173,648

The above condensed statement of cash flows is to be read in conjunction with the accompanying notes to the financial statements.

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### **Notes to the Financial Statements**

### Note 1 Basis of preparation

These general purpose financial statements for the interim half-year reporting period ended 31 December 2011 have been prepared in accordance with requirements of the Corporations Act 2001 and Australian Accounting Standards including AASB 134 *Interim Financial Reporting*. Compliance with Australian Accounting Standards ensures that the financial statements and notes also comply with International Financial Reporting Standards.

This half-year financial report is intended to provide users with an update on the latest annual financial statements of Tissue Therapies Limited ("the Company"). As such, it does not contain information that represents relatively insignificant changes occurring during the half-year within the company. It is therefore recommended that this half-year financial report be read in conjunction with the annual financial statements of Tissue Therapies Limited for the year ended 30 June 2011, together with any public announcements made during the half-year.

The same accounting policies and methods of computation have been followed in this half-year financial report as were applied in the most recent annual financial statements.

### Reporting basis and conventions

The half-year financial report has been prepared on an accruals basis and is based on historical costs modified by the revaluation of selected non-current assets, financial assets and financial liabilities for which the fair value basis of accounting has been applied.

#### Note 2 Revenue and expenses

	Current period \$	Previous corresponding period \$
Revenue from operating activities		
Research grants	145,150	-
Total revenue from operating activities	145,150	_

Revenue from non operating activities		
Interest revenue	327,088	73,500
Other income from non operating activities	327,088	73,500

### Note 3 Segment Information

The company predominantly operates in one business segment being biotechnology.

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### Note 4(a) Inventories - current

	At end of current period	At end of period for last annual report
VitroGro ® & packaging components – at cost	1,513,054	574,651

### Note 4(b) Inventories - non-current

	At end of current period	At end of period for last annual report
VitroGro ® Components – at net realisable value	860,048	694,796

### Note 5 Other assets - current

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	At end of current period	At end of period for last annual report			
Inventory work-in-progress	1,989,065	491,912			
Other	45,063	53,783			
Total Other Assets - Current	2,034,128	545,695			

### Note 6 Issued and quoted securities at end of current period

Category of securities	Number	Issue price per security Cents	Amount paid up per security Cents	\$
Ordinary securities				
Opening balance at beginning of period – 1 July 2011	168,739,422			39,525,004
Ordinary shares issued to consultant for consultancy services	115,712	52c	52c	59,893
Transaction costs				(9,091)
Total Ordinary Securities	168,85 <u>5,</u> 134			39,575,806

### Note 7 Reconciliation of cash and cash equivalents

	At end of current period \$	At end of previous corresponding period \$
Cash on hand and at bank	68,710	80,534
Deposits at call	10,403,722	3,093,114
Total cash and cash equivalents at end of period	10,472,432	3,173,648

#### Note 8 Contingent assets and liabilities

There has been no change in contingent assets and liabilities since the last annual reporting date.

#### Note 9 Earnings per security ("EPS")

Details of the basic and diluted EPS are as follows:

	Current period Cents	Previous corresponding period Cents
Basic earnings per security	(1.45)	(2.40)
Diluted earnings per security	(1.45)	(2.40)
Weighted average number of ordinary shares used in calculation of Basic earnings per security	168,758,288	138,230,251
Weighted average number of ordinary shares used in calculation of Diluted earnings per security	168,758,288	138,230,251

The diluted EPS calculation includes that portion of share options assumed to be issued at nil consideration, weighted with reference to the date of conversion. The weighted average number included for the current period and previous corresponding period is nil due to the options outstanding for the periods not being considered dilutive as the EPS is negative.

### Note 10 Events occurring after the balance sheet date

Subsequent to 31 December 2011, significant progress has been made establishing sales teams, warehousing, customer care and distribution operations ready for sales launch in Europe.

A wholly-owned subsidiary Tissue Therapies Europe Limited was incorporated in the United Kingdom on 23 January 2012.

No other matter or circumstance has arisen since 31 December 2011 that has significantly affected, or may significantly affect the Company's operations, the results of those operations, or the Company's state of affairs in future financial years.

#### Note 11 Dividends

No dividend has been paid for the half-year ended 31 December 2011. As at 31 December 2011 and up until the date of this report, the directors have made no recommendation concerning dividends for the half-year, or any period thereafter.

# Note 12 Statement of Financial Position at 30 June 2011 - Financial Assets and Liabilities comparative figures

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

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### **DIRECTORS' DECLARATION**

The directors of the Company declare that:

- 1. The financial statements and notes, as set out on pages 8 to 14 are in accordance with the Corporations Act 2001, including:
  - a. complying with Accounting Standard AASB 134 Interim Financial Reporting; and
  - b. giving a true and fair view of the company's financial position as at 31 December 2011 and of its performance for the half-year ended on that date.
- 2. In the directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

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

### **TISSUE THERAPIES LIMITED**

Melvyn Bridges DIRECTOR

Brisbane, 7 February 2012



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

We have reviewed the accompanying half-year financial report of Tissue Therapies Limited ("the Company") which comprises the condensed statement of financial position as at 31 December 2011, and the condensed statement of comprehensive income, condensed statement of changes in equity and condensed statement of cash flows for the half-year ended on that date, notes comprising a statement of significant accounting policies and other explanatory notes, and the directors' declaration.

Directors' Responsibility for the Half-Year Financial Report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the Corporations Act 2001 including: giving a true and fair view of the Company's financial position as at 31 December 2011 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001. As the auditor of Tissue Therapies Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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

Independence

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

Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Tissue Therapies Limited is not in accordance with the Corporations Act 2001 including:

- (a) giving a true and fair view of the Company's financial position as at 31 December 2011 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.

. Lawler Hacketts Audit

Brisbane, 7 February 2012

L J Murphy Partner

Lawler Hacketts Audit ABN 33 873 151 348 Appendix 4D

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