Tissue Therapies Limited
ABN 45 101 955 088

Appendix 4D
ASX Half-Year Report
31 December 2012

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:

	Half-year Ended 31-Dec-12 $	Half-year Ended 31-Dec-11 $	Movement $	Movement %
Revenue from continuing operations	170,617	472,238	(301,621)	(63.9)
Profit/(Loss) after income tax for the half-year attributable to members	(3,079,946)	(2,450,470)	(629,476)	(25.7)
Total comprehensive income for the half- year attributable to members	(3,089,030)	(2,450,470)	(638,560)	(26.1)

NTA backing

	31-Dec-12 Cents	31-Dec-11 Cents
Net tangible asset backing per ordinary security	4.78	8.46

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

Your Directors present the highlights of results of Tissue Therapies Limited ("the Company) and controlled entities ("the Group) for the half-year ended 31 December 2012.

- The after-tax loss of $3,079,946 was in line with budget expectations.
- Revenue of $170,617 arose from research grants and interest earned on funds on deposit.
- Research and development expenditure of $644,854 and expenditure on clinical trials of $99,599 was incurred in pursuing the Group's key research and business priorities.
- Cash assets were $1,972,998 at 31 December 2012.
- The process for granting of CE Mark for VitroGro® ECM has progressed. This is the last step required for the start of sales in the EU (UK and Europe) and CE Mark will be used for applications for approval for sale in multiple other countries. The main points of the CE Mark process are:
  - The Group received written notice from the EU Notified Body which stated that all examiner queries had been adequately addressed by the Group and a CE Mark Certificate would be issued shortly (ASX announcement, 16 July 2012);
  - The EU Notified Body then called upon the UK Medicines and Healthcare products Regulatory Agency (MHRA) to review the classification of VitroGro® ECM as a Class III medical device under Rule 8 of the Devices Directive (ASX announcement, 8 August 2012);
  - The MHRA subsequently ruled VitroGro® ECM should be regarded and assessed as a Class III medical device under Rule 13 of the Devices Directive (ASX announcement, 30 October 2012), and
  - The MHRA ruling involved a requirement for the EMA to provide the Notified Body managing the approval process with a scientific opinion on the quality and safety of the product, taking into account the manufacturing process.
- While the deliberations involving the Notified Body, MHRA and the EMA have been protracted, the latest advice confirms all parties are in active dialogue and this is an important step towards starting the EMA Committee review, which is the only remaining hurdle to the start of sales.
- It should be noted that the EMA Committee review is an examination of manufacturing quality and safety data only. All other aspects of the approval for sale of VitroGro® ECM including indications for use, clinical effectiveness and patient safety have already been approved.
- To the extent allowed, the Group will continue to actively participate in the matter and cooperate with the authorities to bring the granting of CE Mark to a conclusion as soon as possible.
- The EMA review process must be completed within a statutory limit of 210 calendar days and the average duration is less than 210 days.

- The EMA review will provide a stronger regulatory approval and dossier for applications for approval in many countries outside the EU.
- During this time the Group is actively preparing for accelerated sales launches in additional EU countries, some Eastern European countries and other markets including, but not limited to, Australia, New Zealand, Canada, Turkey, Russia, the Middle East, South Africa and Latin America.
- The Group will also lodge the US FDA clinical trial applications in the next few months.
- The expanded EU sales launch of VitroGro® ECM will start the following business day once CE Mark is granted. VitroGro® ECM product is ready for sale in two European warehouses now and all customer service, sales and marketing processes are ready.

COMPLIANCE STATEMENT

1 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.

3 This Appendix 4D does give a true and fair view of the matters disclosed.

4 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, 20 February 2013

DIRECTORS' REPORT

Your directors present their report on Tissue Therapies Limited ("the Company") and controlled entities ("the Group") for the half-year ended 31 December 2012.

Directors

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

Mr Roger Clarke - Chairman
Dr Mel Bridges – Director
Dr Cherrell Hirst – Director
Mr Iain Ross – Director
Dr Steven Mercer – Executive Director

Review of Operations

- The after-tax loss of $3,079,946 was in line with budget expectations.
- Revenue of $170,617 arose from research grants and interest earned on funds on deposit.
- Research and development expenditure of $644,854 and expenditure on clinical trials of $99,599 was incurred in pursuing the Group's key research and business priorities.
- Cash assets were $1,972,998 at 31 December 2012.
- The process for granting of CE Mark for VitroGro® ECM has progressed. This is the last step required for the start of sales in the EU (UK and Europe) and CE Mark will be used for applications for approval for sale in multiple other countries. The main points of the CE Mark process are:
    - The Group received written notice from the EU Notified Body which stated that all examiner queries had been adequately addressed by the Group and a CE Mark Certificate would be issued shortly (ASX announcement, 16 July 2012);
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    - The MHRA ruling involved a requirement for the EMA to provide the Notified Body managing the approval process with a scientific opinion on the quality and safety of the product, taking into account the manufacturing process.
- While the deliberations involving the Notified Body, MHRA and the EMA have been protracted, the latest advice confirms all parties are in active dialogue and this is an important step towards starting the EMA Committee review, which is the only remaining hurdle to the start of sales.
- It should be noted that the EMA Committee review is an examination of manufacturing quality and safety data only. All other aspects of the approval for sale of VitroGro® ECM including indications for use, clinical effectiveness and patient safety have already been approved.
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- The EMA review process must be completed within a statutory limit of 210 calendar days and the average duration is less than 210 days.
- The EMA review will provide a stronger regulatory approval and dossier for applications for approval in many countries outside the EU.
- During this time the Group is actively preparing for accelerated sales launches in additional EU countries, some Eastern European countries and other markets including, but not limited to, Australia, New Zealand, Canada, Turkey, Russia, the Middle East, South Africa and Latin America.
- The Group will also lodge the US FDA clinical trial applications in the next few months.
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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 2012.

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

Melvyn Bridges
DIRECTOR

Brisbane, 20 February 2013

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 2012 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, 20 February 2013

L J Murphy
Partner

Lawler Hacketts Audit
ABN 33 873 151 348

www.lawlerhacketts.com.au

Brisbane
Level 3, 549 Queen Street
Brisbane QLD 4000 Australia

telephone 07 3839 9733
facsimile 07 3832 1407

advice@lawlerhacketts.com.au

HALF-YEAR FINANCIAL STATEMENTS

Condensed Consolidated Statement of Comprehensive Income

	Note	CONSOLIDATED 31-Dec-12 $	CONSOLIDATED 31-Dec-11 $
Continuing operations			
Revenue	2	95,150	145,150
Other income	2	75,467	327,088
		170,617	**472,238**
Research & development		(644,854)	(652,302)
Clinical trials expenses		(99,599)	(221,185)
Occupancy expenses		(121,993)	(13,465)
Marketing and business development		(137,455)	(10,767)
Regulatory approvals		(284,423)	(281,567)
Intellectual property		(246,231)	(203,677)
Sales and distribution		(102,070)	-
Transport and logistics		(98,053)	-
Inventory write-down to net realisable value		(33,950)	(174,105)
Employment expenses		(781,543)	(619,609)
Consultants		(350,737)	(493,606)
Administration		(339,292)	(431,646)
Depreciation		(42,622)	(7,689)
Finance costs		(8,051)	(3,155)
Loss on foreign exchange		(84,352)	(45,204)
Other expenses		(71,696)	(78,807)
Loss before income tax benefit		**(3,276,304)**	**(2,764,546)**
Income tax benefit		196,358	314,076
Net loss after tax		**(3,079,946)**	**(2,450,470)**
Other comprehensive income items			
Other comprehensive income:			
Foreign exchange translation reserve		(9,084)	-
Income tax relating to components of other comprehensive income		**-**	**-**
Other comprehensive income after tax		**(9,084)**	**-**
Total comprehensive income for the period		**(3,089,030)**	**(2,450,470)**
Loss attributable to members of the Company		**(3,079,946)**	**(2,450,470)**
Total comprehensive income attributable to members of the Company		**(3,089,030)**	**(2,450,470)**
Earnings per share		**Cents**	**Cents**
Basic earnings per share	9	(1.80)	(1.45)
Diluted earnings per share	9	(1.80)	(1.45)

The accompanying notes form part of these financial statements.

Condensed Consolidated Statement of Financial Position

	Note	CONSOLIDATED 31-Dec-12 $	CONSOLIDATED 30-Jun-12 $
Current assets			
Cash and cash equivalents		1,972,998	5,158,393
Receivables		216,078	122,391
Inventories	4 (a)	6,413,175	5,983,541
Current tax assets		200,912	393,730
Other assets	5	324,948	254,372
Total current assets		**9,128,111**	**11,912,427**
Non-current assets			
Inventories	4 (b)	271,602	305,552
Property, plant and equipment		345,584	370,499
Intangible assets		342,250	342,250
Other assets		1,525	1,525
Total non-current assets		**960,961**	**1,019,826**
Total assets		**10,089,072**	**12,932,253**
Current liabilities			
Payables		1,095,690	2,071,919
Current tax liabilities		10,188	5,649
Provisions		156,380	168,934
Financial liabilities		52,332	23,972
Other liabilities		29,964	29,964
Total current liabilities		**1,344,554**	**2,300,438**
Non-current liabilities			
Other liabilities		149,819	164,924
Total non-current liabilities		**149,819**	**164,924**
Total liabilities		**1,494,373**	**2,465,362**
Net assets		**8,594,699**	**10,466,891**
Equity			
Contributed equity	6	40,881,618	39,740,331
Reserves		92,953	121,986
Accumulated losses		(32,379,872)	(29,395,426)
Total equity		**8,594,699**	**10,466,891**

The accompanying notes form part of these financial statements.

Condensed Consolidated Statement of Changes in Equity

		Reserves			
	Share Capital $	**Option Reserve** $	**Foreign Exchange Translation Reserve** $	**Accumulated Losses** $	**Total** $
Total equity at 1 July 2011	39,525,004	356,799	-	(22,848,367)	17,033,436
Total comprehensive income	-	-	-	(2,450,470)	(2,450,470)
Transactions with owners in their capacity as owners:					
- Contributions of equity	59,893	-	-	-	59,893
- Transaction costs	(9,091)	-	-	-	(9,091)
Total transactions with owners	50,802	-	-	-	50,802
Total equity at 31 December 2011	39,575,806	356,799	-	(25,298,837)	14,633,768
Total equity at 1 July 2012	39,740,331	123,998	(2,012)	(29,395,426)	10,466,891
Total comprehensive income	-	-	(9,084)	(3,079,946)	(3,089,030)
Transactions with owners in their capacity as owners:					
- Contributions of equity	1,171,212	(449)	-	-	1,170,763
- Transaction costs	(29,925)	-	-	-	(29,925)
- Employee share options	-	76,000	-	-	76,000
- Option reserve expired	-	(95,500)	-	95,500	-
Total transactions with owners	1,141,287	(19,949)	-	95,500	1,216,838
Total equity at 31 December 2012	40,881,618	104,049	(11,096)	(32,379,872)	8,594,699

The accompanying notes form part of these financial statements.

Condensed Consolidated Statement of Cash Flows

	Note	CONSOLIDATED 31-Dec-12 $	CONSOLIDATED 31-Dec-11 $
Cash flows related to operating activities			
Receipts from customers		-	-
Other – research grants received		-	145,150
Payments to suppliers and employees		(3,564,227)	(3,796,765)
Payments for research & development and clinical trials		(1,152,312)	(1,573,420)
Interest received		88,430	324,322
Income tax rebate received		393,730	-
Interest and other costs of finance paid		(8,051)	(3,155)
Net cash provided by (used in) operating activities		**(4,242,430)**	**(4,903,868)**
Cash flows related to investing activities			
Payment for property, plant and equipment		(17,706)	(30,596)
Net cash provided by (used in) investing activities		**(17,706)**	**(30,596)**
Cash flows related to financing activities			
Proceeds from issues of shares and other equity securities		1,113,750	-
Cost of share issue		(29,925)	(9,091)
Net cash provided by (used in) financing activities		**1,083,825**	**(9,091)**
Net increase (decrease) in cash held		**(3,176,311)**	**(4,943,555)**
Cash and cash equivalents at beginning of period		5,158,393	15,416,321
Foreign currency movement		(9,084)	(334)
Cash and cash equivalents at end of period		**1,972,998**	**10,472,432**

The accompanying notes form part of these financial statements.

Notes to the Financial Statements

Note 1 Summary of Significant Accounting Policies

These consolidated interim financial statements and notes represent those of Tissue Therapies Limited ("the Company") and controlled entities ("the Group).

Tissue Therapies Limited is a public company incorporated and domiciled in Australia.

The financial statements were authorised for issue on 20 February 2013 by the directors of the Company.

Basis of Preparation

These general purpose interim financial statements for half-year reporting period ended 31 December 2012 have been prepared in accordance with requirements of the Corporations Act 2001 and Australian Accounting Standards including AASB 134 *Interim Financial Reporting*. The Group is for profit entity for financial reporting purposes under Australian Accounting Standards.

This half-year financial report is intended to provide users with an update on the latest annual financial statements of the Group. As such, it does not contain information that represents relatively insignificant changes occurring during the half-year within the Group. It is therefore recommended that this half-year financial report be read in conjunction with the annual financial statements of the Group for the year ended 30 June 2012, together with any public announcements made during the half-year.

Accounting Policies

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, except in relation to the matter discussed below.

Critical Accounting Estimates and Judgments

The critical estimates and judgments are consistent with those applied and disclosed in the 30 June 2012 annual report.

New and Revised Accounting Requirements applicable to the current half-year reporting period

A number of new and revised accounting standard requirements become mandatory for the first time during the half-year reporting period to 31 December 2012.

The Group has adopted all of the new and revised standards and interpretations that are relevant to their operations and effective for the current half-year. Adoption has not resulted in any changes to the Group's accounting policies and has no effect on the amounts reported for the current or prior half-year.

Uncertainty regarding the Recoverability of VitroGro® ECM Inventory

Subsequent to 31 December 2012 the Group was advised that the British Standards Institute (the EU Notified Body responsible for approval) was expecting the European Medical Agency to conclude its deliberations regarding the Companies application for review of VitroGro® ECM at the February 2013 meeting of the relevant subcommittee. Therefore, as a result of a delay in the sales of VitroGro® ECM and the shelf life assigned to the inventory there is uncertainty as to the recoverable value of the finished goods, unless an extension to the shelf life is granted by the Notified Body and the cost of relabeling of the finished goods can be absorbed by the available margin in the sales price.

In assessing the recoverable value of the inventory of finished goods, Management recognises that a routine regulatory procedure is available to the Company in order to extend the shelf life, based upon stability indicating data. In addition, further stability data has been generated at 31 December 2012 supporting the extension of the shelf life and therefore Management has assessed that the inventory is not impaired and no impairment provisions have been raised.

Management is therefore confident that the carrying value of the finished goods of VitroGro® ECM at 31 December 2012 is recoverable on the basis of the following circumstances:

- Successful resolution of the European regulatory process to allow sales of the product in line with forecast sales, or
- Granting of the expiry date extension under the routine regulatory process availed to the Company, and;
- The additional cost of relabeling the finished goods is absorbed by the available margin in the sales price.

Note 1 Summary of Significant Accounting Policies (CONTINUED)

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

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

Note 2 Revenue and expenses

	31-Dec-12 $	31-Dec-11 $
Revenue		
Research grants	95,150	145,150
Total revenue	**95,150**	**145,150**
Other income		
Interest revenue	75,467	327,088
Total other income	**75,467**	**327,088**

Note 3 Segment Information

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

Note 4(a) Inventories – current

	31-Dec-12 $	30-Jun-12 $
VitroGro® ECM – at cost	6,132,312	5,718,740
VitroGro® ECM – Work-in-progress – at cost	280,863	264,801
Total Inventories - Current	**6,413,175**	**5,983,541**

The inventory of finished goods of VitroGro® ECM is represented by a batch of VitroGro® ECM produced in March 2012 with a shelf life of 18 months. At 31 December 2012 stability indicating data has been generated supporting an extension to 24 months and further studies have been initiated to extend the shelf life beyond 32 months. In assessing the recoverable value of the inventory of VitroGro® ECM, Management recognises that a routine regulatory process is available to the Company under relevant regulatory systems, in the countries that the Company seeks to access for sales, in order to extend the shelf life, thereby incurring no impairment to the inventory and therefore no impairment provision has been raised.

Note 4(b) Inventories - non-current

	31-Dec-12 $	30-Jun-12 $
VitroGro® production cells and reference protein – at net realisable value	271,602	305,552

Note 5 Other assets – current

	31-Dec-12 $	30-Jun-12 $
Prepayments		
- Clinical trials expenses	222,229	147,523
- Other	102,719	106,849
Total Other Assets - Current	**324,948**	**254,372**

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				
01/07/12	Opening balance at beginning of period	169,357,192			39,740,331
09/07/12	Ordinary shares issued on exercise of Options	25,000	17c	17c	4,199
29/08/12	Ordinary shares issued by Placement	3,000,000	37c	37c	1,110,000
22/11/12	Ordinary shares issued to consultant for consultancy services	125,394	45c	45c	57,013
	Transaction costs				(29,925)
	Total Ordinary Securities	172,507,586			40,881,618

Note 7 Reconciliation of cash and cash equivalents

	31-Dec-12 $	30-Jun-12 $
Cash on hand and at bank	20,309	56,166
Deposits at call	1,952,689	5,102,227
Total cash and cash equivalents at end of period	**1,972,998**	**5,158,393**

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")

	31-Dec-12 $	31-Dec-11 $
Loss after income tax benefit attributable to the Company	(3,079,946)	(2,450,470)
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	171,432,890	168,758,288
Weighed average number of options outstanding which are considered potentially dilutive	-	-
Weighted average number of potential ordinary shares outstanding during the year used in calculation of Dilutive EPS	171,432,890	168,758,288

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

	Cents	Cents
Basic earnings per share	(1.80)	(1.45)
Diluted earnings per share	(1.80)	(1.45)

Note 10 Events occurring after the balance sheet date

Subsequent to 31 December 2012, the Group has been informed that the European Medicines Agency (EMA) discussed the VitroGro® ECM application during the January meeting of the Committee for Medicinal Products for Human Use but did not have sufficient time to complete their discussions in order to assign a procedural start date. The British Standard Institute (the Notified Body responsible for approval) believes a conclusion will be reached at the February meeting of the EMA committee. Therefore, the Group does not expect to receive a further update until approximately the 25th February 2013.

The Board has appointed advisers in respect of a capital raising.

No other matter or circumstance has arisen since 31 December 2012 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

Note 11 Dividends

No dividend has been paid for the half-year ended 31 December 2012. As at 31 December 2012 and up until the date of this report, the Directors have made no recommendation concerning dividends for the half-year, or any period thereafter.

DIRECTORS' DECLARATION

The directors of the Company declare that:

1. The financial statements and notes, as set out on pages 8 to 15 are in accordance with the Corporations Act 2001, including:

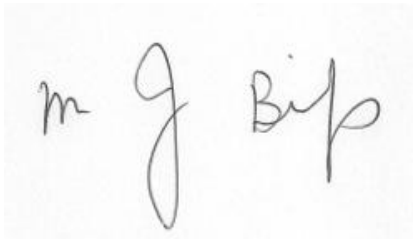
    a. complying with Accounting Standard AASB 134 *Interim Financial Reporting*; and

    b. giving a true and fair view of the consolidated entity's financial position as at 31 December 2012 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, 20 February 2013

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") and controlled entities ("the Consolidated Entity") which comprises the consolidated condensed statement of financial position as at 31 December 2012, the consolidated condensed statement of comprehensive income, consolidated condensed statement of changes in equity and consolidated condensed statement of cash flows for the half-year ended on that date, notes comprising a statement of significant accounting policies and other explanatory information, 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 2012 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 and controlled entities is not in accordance with the *Corporations Act 2001* including:

(a) giving a true and fair view of the Consolidated Entity's financial position as at 31 December 2012 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*.

Emphasis of Matter

Without qualification to the conclusion expressed above, attention is drawn to the following matter. As a result of the matters described in Note 1 to the financial statements, there is uncertainty as to whether the carrying value of finished goods of VitroGro® ECM as at 31 December 2012 is recoverable.

Lawler Hacketts Audit

L J Murphy
Partner

Brisbane, 20 February 2013

Lawler Hacketts Audit
ABN 33 873 151 348

Brisbane
Level 3, 549 Queen Street
Brisbane QLD 4000 Australia
telephone 07 3839 9733
facsimile 07 3832 1407

www.lawlerhacketts.com.au
advice@lawlerhacketts.com.au