# INTERIM REPORT

## FOR THE SIX MONTHS ENDED 31 JULY 2012

Tissue Regenix Group plc

## DIRECTORS

| | |
|---|---|
| John Samuel | (Executive Chairman) |
| Antony Odell | (Managing Director) |
| Ian Jefferson | (Chief Financial Officer) |
| Alan Aubrey | (Non-Executive Director) |
| Alan Miller | (Non-Executive Director) |
| Alexander Stevenson | (Non-Executive Director) |
| Michael Bretherton | (Non-Executive Director) |

## COMPANY SECRETARY

Ian Jefferson

## COMPANY WEBSITE

www.tissueregenix.com

## COMPANY NUMBER

5969271

## REGISTERED OFFICE

The Biocentre
Innovation Way
Heslington
York
North Yorkshire
YO10 5NY

## REGISTRAR

Capita Registrars Limited
The Registry
34 Beckenham Road
Beckenham
Kent
BR3 4TU

## AUDITOR

KPMG Audit LLP
1 The Embankment
Neville Street
Leeds
LS1 4DW

## LEGAL ADVISER

DLA Piper UK LLP
Princes Exchange
Princes Square
Leeds
LS1 4BY

## NOMINATED ADVISER AND BROKER

Peel Hunt Limited
Moor House
120 London Wall
London
EC2Y 5ET

# Contents

# Chairman's Statement

## Overview

We continue to make good progress in the development and commercialisation of our pipeline of products. We aim to become a global leader in regenerative medicine and having raised £25m (gross) by way of a share placing in December 2011 we are well placed to achieve that goal.

## The dCELL® process

Our proprietary platform technology, dCELL®, is protected by a library of patents. It is used to decellularise human or animal donor tissue in order to create biological scaffolds that are then implanted into patients to replace diseased or damaged parts of their body. Since the tissue has been decellularised there is no need for anti-rejection drugs. These scaffolds are also capable of regeneration through natural bodily functions and because they are inert when implanted, they are classified as medical devices. This means they are required to follow a regulatory pathway that is typically faster and less costly than, for example, a pharmaceutical product.

## Product Development

### *Advanced Wound Care*

The human dermis clinical trial on chronic wounds continues to produce encouraging results. Further interim data has been released today and the final results of the study will be available soon. We will also be undertaking a registry study to provide a UK database to demonstrate the effectiveness of the product. We are beginning discussions for a clinical study in the USA. Early discussions with potential suppliers of the human dermis material are underway and we also continue to develop the equivalent porcine product. We are in the process of hiring a head of wound care to lead the commercialisation opportunities we see across the wound care space.

### *Orthopaedic*

The preclinical study of the meniscus repair product has been encouraging with results expected to be released later this year. We will be looking to commence clinical trials in 2013 when we have completed biomechanical testing and refined the suturing technique. A US preclinical study is also planned following a pre-IDE discussion with the FDA. The anterior cruciate ligament repair product will be in preclinical studies by H1 2013 and we have begun discussions with the FDA in respect of approval requirements for the US market. As we move nearer to clinical and preclinical trials we are developing health economic models to support later commercialisation.

### *Cardiac*

Pilot work with cardiac patches for mitral valve repair and pericardial patching has gone well and we intend to commence preclinical studies in H1 2013. A number of product enhancements are being introduced to an existing bioprosthetic valve which will become the design for a dCELL® version prototype that will be available for preclinical trials by mid-2013. We have commenced discussions with tissue banks for the commercialisation of the dCELL® human heart valve and a porcine version will be undergoing process optimisation work by the end of this calendar year. In order to support these development and commercialisation plans we have recently appointed a head of the cardiac therapy area.

### *Vascular*

A pilot study for the AV graft is now in progress with plans for a preclinical study in H2 2013. Two year data was recently released for the existing vascular patch and we will be meeting the FDA shortly to progress US approval.

## Financial Review

Administrative expenditure increased to £2,087k (H1 2011: £1,466k) reflecting additional headcount and product development costs incurred as we started to deploy the funds raised on multiple development programmes. As a result of this investment the operating loss for the period increased to £2,085k (H1 2011: £1,358k). Net cash at the end of the period was £26,106k (H1 2011: £4,848k).

## Outlook

The programmes we have in place address acute needs in very large healthcare markets, including the US. Successful development of our range of cost effective products will also help relieve huge financial burdens being placed on healthcare providers around the world. Demand for products in regenerative medicine is forecast to increase and this, coupled with the chronic shortage of human donor tissue, gives me confidence that we are well positioned to create a global leader in our field.

**John Samuel**
Executive Chairman
4 October 2012

# Condensed Consolidated Statement of Comprehensive Income (Unaudited)

For the six months to 31 July 2012

| | Notes | Six months to 31 July 2012 £'000 | Six months to 31 July 2011 £'000 | Twelve months to 31 January 2012 £'000 |
|---|---|---|---|---|
| **Revenue** | 3 | 2 | 108 | 109 |
| Administrative expenses | | (2,087) | (1,466) | (3,097) |
| **Operating loss** | | (2,085) | (1,358) | (2,988) |
| Finance income | | 220 | 22 | 62 |
| **Loss before tax** | | (1,865) | (1,336) | (2,926) |
| Taxation | 4 | 100 | 75 | 239 |
| **Loss after tax attributable to equity holders of the parent** | | (1,765) | (1,261) | (2,687) |
| **Loss per share, basic and diluted:** | 5 | (0.28p) | (0.28p) | (0.57p) |

The loss for the period arises from the Group's continuing operations.

# Condensed Consolidated Statement of Changes in Equity (Unaudited)

## For the six months to 31 July 2012

| | Share Capital £'000 | Share Premium £'000 | Merger Reserve £'000 | Reverse Acquisition Reserve £'000 | Capital Reserves £'000 | Share Based Payments Reserve £'000 | Revenue Deficit Reserve £'000 | Total Equity £'000 |
|---|---|---|---|---|---|---|---|---|
| **At 31 January 2011** | 2,343 | 8,655 | 10,884 | (7,148) | 14,734 | 332 | (8,848) | 6,218 |
| Loss for the period | – | – | – | – | – | – | (1,261) | (1,261) |
| Issue of shares | 10 | 2 | – | – | 12 | – | (4) | 8 |
| Employee interest in jointly owned shares | – | – | – | – | – | – | 1 | 1 |
| Share based payment | – | – | – | – | – | 51 | – | 51 |
| **At 31 July 2011** | 2,353 | 8,657 | 10,884 | (7,148) | 14,746 | 383 | (10,112) | 5,017 |
| Loss for the period | – | – | – | – | – | – | (1,426) | (1,426) |
| Issue of shares | 909 | 24,092 | – | – | 25,001 | – | – | 25,001 |
| Expenses on issue of shares | – | (784) | – | – | (784) | – | – | (784) |
| Share based payment | – | – | – | – | – | 71 | – | 71 |
| **At 31 January 2012** | 3,262 | 31,965 | 10,884 | (7,148) | 38,963 | 454 | (11,538) | 27,879 |
| Loss for the period | – | – | – | – | – | – | (1,765) | (1,765) |
| Issue of shares | 2 | 1 | – | – | 3 | – | – | 3 |
| Share based payment | – | – | – | – | – | 53 | – | 53 |
| **At 31 July 2012** | 3,264 | 31,966 | 10,884 | (7,148) | 38,966 | 507 | (13,303) | 26,170 |

# Condensed Consolidated Statement of Financial Position (Unaudited)

As at 31 July 2012

| | Notes | 31 July 2012 £'000 | 31 July 2011 £'000 | 31 January 2012 £'000 |
|---|---|---|---|---|
| **Non-current assets** | | | | |
| Property, plant and equipment | | 199 | 169 | 157 |
| **Total non-current assets** | | 199 | 169 | 157 |
| **Current assets** | | | | |
| Trade and other receivables | | 562 | 328 | 350 |
| Cash and cash equivalent | | 26,106 | 4,848 | 28,021 |
| **Total current assets** | | 26,668 | 5,176 | 28,371 |
| **Total assets** | | 26,867 | 5,345 | 28,528 |
| **Current liabilities** | | | | |
| Trade and other payables | | (697) | (328) | (649) |
| **Total liabilities** | | (697) | (328) | (649) |
| **Net assets** | | 26,170 | 5,017 | 27,879 |
| **Equity** | | | | |
| Share capital | 6 | 3,264 | 2,353 | 3,262 |
| Share premium | 6 | 31,966 | 8,657 | 31,965 |
| Merger reserve | 6 | 10,884 | 10,884 | 10,884 |
| Reverse acquisition reserve | 6 | (7,148) | (7,148) | (7,148) |
| **Capital reserves** | | 38,966 | 14,746 | 38,963 |
| Share based payment reserve | | 507 | 383 | 454 |
| Revenue deficit reserve | 7 | (13,303) | (10,112) | (11,538) |
| **Total equity** | | 26,170 | 5,017 | 27,879 |

Approved by the Board and authorised for issue on 4 October 2012.

John Samuel
Executive Chairman

Ian Jefferson
Chief Financial Officer

# Condensed Consolidated Cash Flow Statement (Unaudited)

For the six months ended 31 July 2012

| | Six months to 31 July 2012 £'000 | Six months to 31 July 2011 £'000 | Twelve months to 31 January 2012 £'000 |
|---|---|---|---|
| **Operating activities** | | | |
| **Operating loss** | (2,085) | (1,358) | (2,988) |
| Adjustment for non-cash items: | | | |
| Depreciation of property, plant & equipment | 31 | 31 | 62 |
| Share based payment | 53 | 51 | 122 |
| Tax credit | – | 114 | 280 |
| **Operating cash outflow** | (2,001) | (1,162) | (2,524) |
| (Increase)/decrease in trade & other receivables | (115) | 28 | 2 |
| Decrease in trade & other payables | 49 | 73 | 396 |
| **Net cash outflow from operations** | (2,067) | (1,061) | (2,126) |
| **Investing activities** | | | |
| Interest received | 220 | 22 | 62 |
| Purchase of property, plant & equipment | (71) | (11) | (30) |
| **Net cash outflow from investing activities** | 149 | 11 | 32 |
| **Financing activities** | | | |
| Proceeds from issue of share capital | 3 | 8 | 25,009 |
| Sale of joint interest in shares to employees | – | 1 | 1 |
| Expense of issue of share capital | – | – | (784) |
| **Net cash inflow from financing activities** | 3 | 9 | 24,226 |
| **(Decrease)/increase in cash and cash equivalents** | (1,915) | (1,041) | 22,132 |
| Cash and cash equivalents at start of period | 28,021 | 5,889 | 5,889 |
| **Cash and cash equivalents at end of period** | 26,106 | 4,848 | 28,021 |

# Notes to the Condensed Financial Statements (Unaudited)

For the six months ended 31 July 2012

## 1. BASIS OF PREPARATION

The interim financial statements of Tissue Regenix Group Plc are unaudited condensed consolidated financial statements for the six months to 31 July 2012. These include unaudited comparatives for the six months to 31 July 2011 together with the audited accounts for the year to 31 January 2012.

These condensed consolidated financial statements do not constitute statutory accounts. The statutory accounts for the year to 31 January 2012 have been reported on by the auditors to Tissue Regenix Group Plc and have been filed with the Registrar of Companies. The report of the auditors was unqualified and did not contain a statement under section 498 of the Companies Act 2006.

## 2. SIGNIFICANT ACCOUNTING POLICIES

The condensed consolidated financial statements have been prepared under the historical cost convention in accordance with International Financial Reporting Standards as adopted by the European Union.

The accounting policies adopted are consistent with those followed in the preparation of the audited financial statements of Tissue Regenix Group Plc for the year ended 31 January 2012 and are disclosed in those statements.

## 3. SEGMENTAL REPORTING

At 31 July 2012, the Group operated in one business segment, that of the development and commercialisation of innovative platform technologies in the field of tissue engineering and regenerative medicine.

To date the bulk of revenues comprise grant income earned in the UK. All of the Group's assets are held in the UK and all of its capital expenditure arises in the UK.

## 4. TAXATION

| | Six months to 31 July 2012 £'000 | Six months to 31 July 2011 £'000 | Twelve months to 31 January 2012 £'000 |
|---|---|---|---|
| **Current Tax:** | | | |
| Tax credit on research and development costs in the period | 100 | 75 | 239 |
| | 100 | 75 | |
| **Deferred tax:** | | | |
| Origination and reversal of temporary timing differences | – | – | – |
| **Tax credit on loss on ordinary activities** | 100 | 75 | 239 |

The Group has accumulated losses available to carry forward against future trading profits. No deferred tax asset has been recognised in respect of tax losses.

## 5. LOSS PER SHARE (BASIC AND DILUTED)

Basic loss per share is calculated by dividing the loss attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period excluding own shares held jointly by the Tissue Regenix Employee Share Trust and certain employees. Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares in issue during the period to assume conversion of all dilutive potential ordinary shares.

| | Six months to 31 July 2012 £'000 | Six months to 31 July 2011 £'000 | Twelve months to 31 January 2012 £'000 |
|---|---|---|---|
| **Total loss attributable to the equity holders of the parent** | (1,765) | (1,261) | (2,687) |
| | **No.** | **No.** | **No.** |
| **Weighted average number of ordinary shares in issue during the period** | 635,267,519 | 452,466,581 | 469,184,667 |
| **Loss per share** | | | |
| Basic and diluted on loss for the period | (0.28)p | (0.28)p | (0.57)p |

The Company has issued employees options over 15,591,356 ordinary shares and there are 17,540,386 jointly owned shares which are potentially dilutive. There is, however, no dilutive effect of these issued options as there is a loss for each of the periods concerned.

# Notes to the Condensed Financial Statements (Unaudited)

For the six months ended 31 July 2012

## 6. SHARE CAPITAL

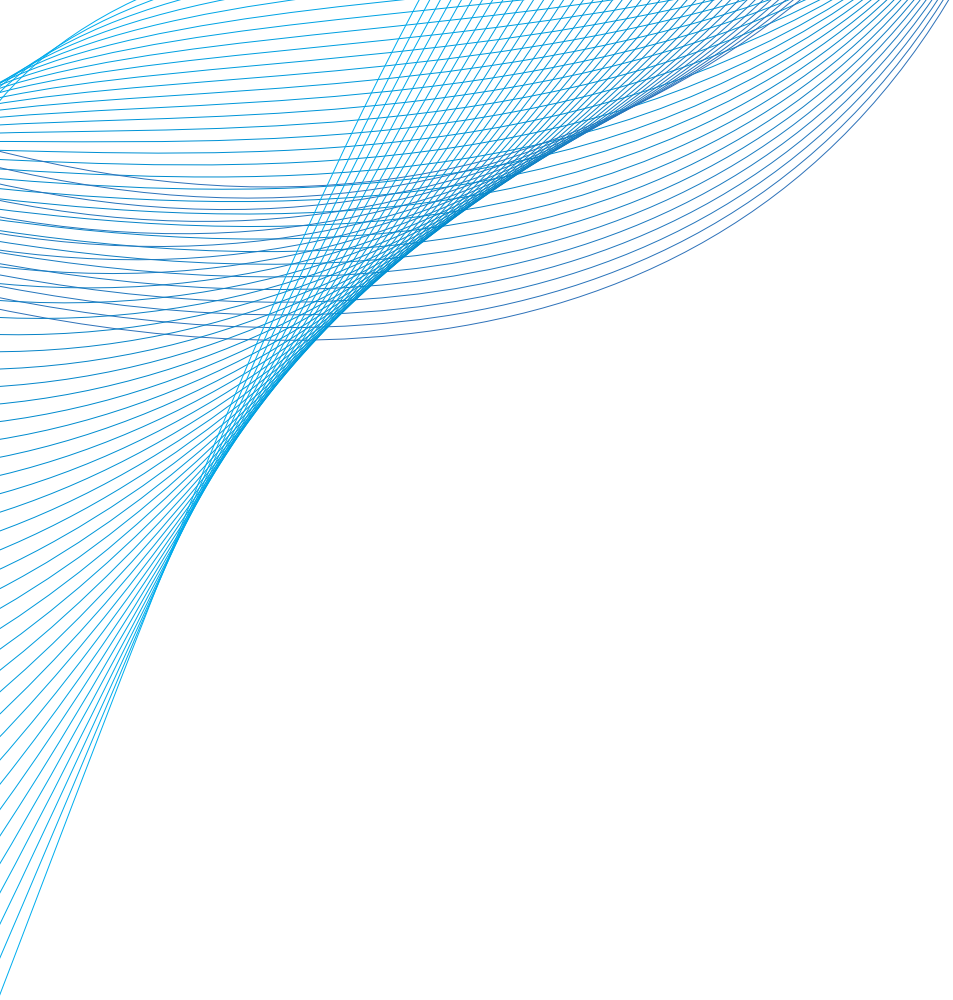
| | Number | Share Capital £'000 | Share Premium £'000 | Merger Reserve £'000 | Reverse Acquisition Reserve £'000 | Total £'000 |
|---|---|---|---|---|---|---|
| **Total Ordinary shares of 0.5p each as at 31 January 2011** | 468,597,903 | 2,343 | 8,655 | 10,884 | (7,148) | 14,734 |
| Issued on exercise of share options | 1,136,376 | 6 | 2 | – | – | 8 |
| Issued to Tissue Regenix Employee Share Trust | 827,586 | 4 | – | – | – | 4 |
| **Total Ordinary shares of 0.5p each as at 31 July 2011** | 470,561,865 | 2,353 | 8,657 | 10,884 | (7,148) | 14,746 |
| Issued for cash | 181,818,182 | 909 | 24,092 | – | – | 25,001 |
| Expenses of issue of shares | – | – | (784) | – | – | (784) |
| **Total Ordinary shares of 0.5p each as at 31 January 2012** | 652,380,047 | 3,262 | 31,965 | 10,884 | (7,148) | 38,963 |
| Issued on exercise of share options | 444,972 | 2 | 1 | – | – | 3 |
| **Total Ordinary shares of 0.5p each as at 31 July 2012** | 652,825,019 | 3,264 | 31,966 | 10,884 | (7,148) | 38,966 |

## 7. MOVEMENT IN REVENUE RESERVE AND OWN SHARES

| | Retained Deficit £'000 | Own Shares £'000 | Revenue Deficit Reserve £'000 |
|---|---|---|---|
| **At 31 January 2011** | (8,020) | (828) | (8,848) |
| Purchase of own shares | – | (4) | (4) |
| Employee interest in jointly held shares | – | 1 | 1 |
| Loss for the period | (1,261) | – | (1,261) |
| **At 31 July 2011** | (9,281) | (831) | (10,112) |
| Loss for the period | (1,426) | – | (1,426) |
| **At 31 January 2012** | (10,707) | (831) | (11,538) |
| Loss for the period | (1,765) | – | (1,765) |
| **At 31 July 2012** | (12,472) | (831) | (13,303) |

## 8. INTERIM FINANCIAL REPORT

A copy of this interim report will be distributed to shareholders and is also available on the Company's website at www.tissueregenix.com



Tissue Regenix Group plc
The Biocentre
Innovation Way
Heslington
York, YO10 5NY
United Kingdom

www.tissueregenix.com