

INTERIM REPORT  
FOR THE SIX MONTHS ENDED 31 JULY 2014



## **DIRECTORS**

John Samuel	(Chairman)
Antony Odell	(Chief Executive Officer)
Ian Jefferson	(Chief Financial Officer)
Alison Fielding	(Non-Executive Director)
Alan Miller	(Non-Executive Director)
Randeep Grewal	(Non-Executive Director)
Steve Couldwell	(Non-Executive Director)

## **COMPANY SECRETARY**

Ian Jefferson

## **COMPANY WEBSITE**

[www.tissueregenix.com](http://www.tissueregenix.com)

## **COMPANY NUMBER**

5969271

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## **NOMINATED ADVISER AND BROKER**

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## Chairman's Statement

### Overview

The first half of 2014 has arguably been the most exciting period in the Group's short history, with the successful commercial launch of *DermaPure*<sup>®</sup> in the USA, which allows us to target a market worth \$1.4 billion a year.

During the period we have focused heavily on developing our marketing and sales strategy and successfully implementing these plans in the USA. Tissue Regenix has formed an initial number of commercial partnerships to enable distribution of the product in the US.

Alongside the developments in wound care, the Group has also made steady progress in other areas of the business, including preparations for the European trial of the dCELL<sup>®</sup> meniscus in orthopaedics, and the attainment of a number of patents to protect our unique dCELL<sup>®</sup> technology.

### Wound care

The launch of *DermaPure*<sup>®</sup> in the USA represents a key opportunity for the Group. Tissue Regenix's *DermaPure*<sup>®</sup> was shown in the UK human clinical trial to be easily administered, and can be stored at room temperature, removing the need for expensive freezing or cryopreservation. *DermaPure*<sup>®</sup>, which is processed by our tissue bank partners Community Tissue Services ("CTS"), is initially being aimed at helping patients with diabetic foot ulcers, a condition which affects around 600,000 people in the USA each year, and patients with venous leg ulcers, which currently affect around 2.5 million people in the USA.

Tissue Regenix also received a preliminary positive decision for an assignment of a permanent Healthcare Common Procedure Coding System (HCPCS) "Q-code" for *DermaPure*<sup>®</sup>, which from January 2015 will allow Tissue Regenix to apply for wound care centre reimbursement of the product from local payer organisations. Payer organisations worldwide are focused on managing the gap between funding and medical costs, often in the context of a changing regulatory environment. Whilst these applications will take time to be processed the decision will allow greater access to *DermaPure*<sup>®</sup> for clinicians and provide an advanced treatment for patients with chronic (and potentially acute) wounds. To support this marketing activity, the Group also progressed the human clinical trial for diabetic foot ulcers.

In the United Kingdom, NHSBT has continued to roll out *DermaPure*<sup>®</sup> (known as dCELL<sup>®</sup> Human Dermis) in the period following its launch in January 2014.

### Orthopaedics

In July 2014 the Group received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to start the first UK human clinical trial of its dCELL<sup>®</sup> meniscal device to aid knee repairs, expected to commence before

the end of the calendar year. The trial approval marks a key milestone towards gaining EU clearance (and a CE Mark) which will enable full commercialisation of the dCELL<sup>®</sup> meniscus product, allowing it to be used by clinics and doctors to help UK and European patients. Meniscal injuries affect around 1.5 million people per year in the USA and Europe, with 61 people sustaining a meniscal tear per 100,000 population per year in the UK alone, and the dCELL<sup>®</sup> meniscus potentially addresses this substantial unmet clinical need.

#### IP protection

The Group's IP estate continued to develop with a number of patents granted in the period covering the use of Tissue Regenix technology in a range of applications. These include patents to aid meniscal repair in China and for use in bladder repair in both Europe and the USA. Tissue Regenix will continue to apply for similar patents worldwide to protect the Group's dCELL<sup>®</sup> technology.

#### Financial Review

As previously stated, Tissue Regenix has continued to make investments in product development to drive growth during the period and has maintained a robust cash position of £14.6m at the end of the first half (H1 2013: £21.7m). As planned, we expect to continue to use our cash resources to fund our development programmes, and expect cash utilisation to increase over the coming years as the programmes progress through pre-clinical and clinical trials.

#### Outlook

The launch of *DermaPure*<sup>®</sup> in the USA during the first six months of 2014 was an important milestone in Tissue Regenix's progress from its roots as a purely development-focused company to becoming a business with commercially available products. We are committed to bringing our pipeline of human and animal tissue products to market, to meet a range of clinical needs. Our focus on accelerating the delivery of our product pipeline and the upcoming clinical trial for the first of our orthopaedic products shows that we have the expertise and confidence to enter competitive but attractive global markets. The diversity and strength of the dCELL<sup>®</sup> platform coupled with our strong commercial focus provides a solid base to grow the business and the Group will continue to aim towards the full commercial rollout of our dCELL<sup>®</sup> technology across a range of target markets, including multiple applications where we see opportunity for *DermaPure*<sup>®</sup>, working towards our ambition to become a global leader in regenerative medicine.

**John Samuel**

Chairman

29 October 2014

## Condensed Consolidated Statement of Comprehensive Income (Unaudited)

For the six months to 31 July 2014

	Notes	6 months to 31 July 2014 £'000	6 months to 31 July 2013 £'000	12 months to 31 January 2014 £'000
<b>Revenue</b>		8	3	6
Administrative expenses		(3,835)	(2,503)	(6,583)
<b>Operating loss</b>		(3,827)	(2,500)	(6,577)
Finance income		97	152	274
<b>Loss before tax</b>		(3,730)	(2,348)	(6,303)
Taxation	3	300	200	710
<b>Loss after tax attributable to equity holders of the parent</b>		(3,430)	(2,148)	(5,593)
<b>Other Comprehensive Income:</b>				
Foreign currency translation differences – foreign operations		–	–	3
<b>TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR</b>		(3,430)	(2,148)	(5,590)
<b>Loss per share</b>				
Basic and diluted on loss from continuing operations	4	(0.54)p	(0.34)p	(0.88)p

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 2014

	Share Capital £'000	Share Premium £'000	Merger Reserve £'000	Reverse Acquisition Reserve £'000	Reserve For Own Shares £'000	Share Based Payment Reserve £'000	Retained Earnings Deficit £'000	Total Equity £'000
<b>At 31 January 2013</b>	3,264	31,966	10,884	(7,148)	(831)	536	(14,205)	24,466
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(2,148)	(2,148)
Share based payment	-	-	-	-	-	54	-	54
<b>At 31 July 2013</b>	3,264	31,966	10,884	(7,148)	(831)	590	(16,353)	22,372
Loss for the period	-	-	-	-	-	-	(3,445)	(3,445)
Other comprehensive income	-	-	-	-	-	-	3	3
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(3,442)	(3,442)
Exercise of share options	3	5	-	-	-	-	-	8
Share based payment	-	-	-	-	-	40	-	40
<b>At 31 January 2014</b>	3,267	31,971	10,884	(7,148)	(831)	630	(19,795)	18,978
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(3,430)	(3,430)
Exercise of share options	4	1	-	-	-	-	-	5
Share based payment	-	-	-	-	-	90	-	90
<b>At 31 July 2014</b>	3,271	31,972	10,884	(7,148)	(831)	720	(23,225)	15,643

# Condensed Consolidated Statement of Financial Position (Unaudited)

As at 31 July 2014

	Notes	31 July 2014 £'000	31 July 2013 £'000	31 January 2014 £'000
<b>Non-current assets</b>				
Property, plant and equipment		440	317	472
<b>Total non-current assets</b>		440	317	472
<b>Current assets</b>				
Inventory		9	–	–
Trade and other receivables		1,318	868	1,127
Cash and cash equivalent		14,578	21,671	18,483
<b>Total current assets</b>		15,905	22,539	19,610
<b>Total assets</b>		16,345	22,856	20,082
<b>Current liabilities</b>				
Trade and other payables		(702)	(484)	(1,104)
<b>Total liabilities</b>		(702)	(484)	(1,104)
<b>Net assets</b>		15,643	22,372	18,978
<b>Equity</b>				
Share capital	5	3,271	3,264	3,267
Share premium	5	31,972	31,966	31,971
Merger Reserve	5	10,884	10,884	10,884
Reverse acquisition reserve	5	(7,148)	(7,148)	(7,148)
Reserve for own shares		(831)	(831)	(831)
Share based payment reserve		720	590	630
Retained earnings deficit	6	(23,225)	(16,353)	(19,795)
<b>Total equity</b>		15,643	22,372	18,978

Approved by the Board and authorised for issue on 29 October 2014.

John Samuel  
(Executive Chairman)

Ian Jefferson  
(Chief Financial Officer)

# Condensed Consolidated Cash Flow Statement (Unaudited)

For the six months ended 31 July 2014

	6 months to 31 July 2014 £'000	6 months to 31 July 2013 £'000	12 months to 31 January 2014 £'000
<b>Operating activities</b>			
<b>Operating loss</b>	(3,827)	(2,500)	(6,577)
Adjustment for non-cash items:			
Depreciation of property, plant & equipment	76	54	124
Share based payment	90	54	94
Tax refunded	-	-	474
<b>Operating cash outflow</b>	(3,661)	(2,392)	(5,885)
Increase in inventory	(9)	-	-
Decrease/(increase) in trade & other receivables	109	39	(184)
(Decrease)/increase in trade & other payables	(402)	(201)	422
<b>Net cash outflow from operations</b>	(3,963)	(2,554)	(5,647)
<b>Investing activities</b>			
Interest received	97	152	274
Purchase of property, plant & equipment	(44)	(133)	(358)
<b>Net cash outflow from investing activities</b>	53	19	(84)
<b>Financing activities</b>			
Proceeds from issue of share capital	5	-	8
<b>Net cash inflow from financing activities</b>	5	-	8
Decrease in cash and cash equivalents	(3,905)	(2,535)	(5,723)
Cash and cash equivalents at start of period	18,483	24,206	24,206
<b>Cash and cash equivalents at end of period</b>	14,578	21,671	18,483

# Notes to the Condensed Financial Statements (Unaudited)

For the six months ended 31 July 2014

## 1. BASIS OF PREPARATION

The interim financial information set out in this statement for the six months ended 31 July 2014 and the comparative figures for the six months ended 31 July 2013 are unaudited. This information does not constitute statutory accounts as defined in Section 435 of the Companies Act 2006.

The comparative figures for the financial year ended 31 January 2014 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Company's auditors and delivered to the Registrar of Companies. The report of the auditor was (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

This interim statement, which is neither audited nor reviewed, has been prepared in accordance with the measurement and recognition criteria of Adopted IFRSs. It does not include all the information required for the full annual financial statements, and should be read in conjunction with the financial statements of the Group as at and for the year ended 31 January 2014. It does not comply with IAS 34 "Interim Financial Reporting" as is permissible under the rules of the AIM Market ("AIM").

The accounting policies applied in preparing these interim financial statements are the same as those applied in the preparation of the annual financial statements for the year ended 31 January 2014, as described in those financial statements other than standards, amendments and interpretations which became effective after 1 February 2014 and were adopted by the Group. These have had no significant impact on the Group's profit for the period or equity. The Board approved these interim financial statements on 26 September 2014.

## 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 2014 and are disclosed in those statements.

### 3. TAXATION

	6 months to 31 July 2014 £'000	6 months to 31 July 2013 £'000	12 months to 31 January 2014 £'000
<b>Current Tax:</b>			
Tax credit on research and development costs in the period	300	200	710
	300	200	710
<b>Deferred tax:</b>			
Origination and reversal of temporary timing differences	-	-	-
<b>Tax credit on loss on ordinary activities</b>	300	200	710

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.

### 4. 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.

	6 months to 31 July 2014 £'000	6 months to 31 July 2013 £'000	12 months to 31 January 2014 £'000
<b>Total loss attributable to the equity holders of the parent</b>	(3,430)	(2,148)	(5,593)
	No.	No.	No.
<b>Weighted average number of ordinary shares in issue during the period</b>	636,592,627	635,515,678	635,574,603
<b>Loss per share</b>			
Basic and diluted on loss for the period	(0.54)p	(0.34)p	(0.88)p

The Company has issued employees options over 22,756,940 ordinary shares and there are 16,940,386 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 2014

### 5. SHARE CAPITAL

	Number	Share Capital £'000	Share Premium £'000	Merger Reserve £'000	Reverse Acquisition Reserve £'000	Total £'000
<b>Total Ordinary shares of 0.5p each as at 31 January 2013</b>	652,825,019	3,264	31,966	10,884	(7,148)	38,966
Issued on exercise of share options	-	-	-	-	-	-
<b>Total Ordinary shares of 0.5p each as at 31 July 2013</b>	652,825,019	3,264	31,966	10,884	(7,148)	38,966
Issued on exercise of share options	662,338	3	5	-	-	8
<b>Total Ordinary shares of 0.5p each as at 31 January 2014</b>	653,487,357	3,267	31,971	10,884	(7,148)	38,974
Issued on exercise of share options	635,674	4	1	-	-	5
<b>Total Ordinary shares of 0.5p each as at 31 July 2014</b>	654,123,031	3,271	31,972	10,884	(7,148)	38,979

**6. MOVEMENT IN RETAINED EARNINGS AND RESERVE FOR OWN SHARES**

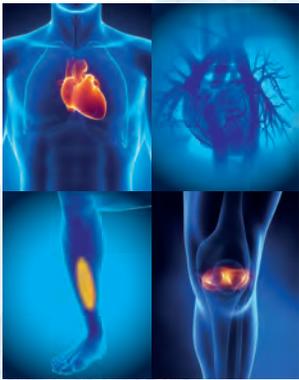
	Retained Earnings Deficit £'000	Reserve For Own Shares £'000
<b>At 31 January 2013</b>	(14,205)	(831)
Loss for the period	(2,148)	–
<b>At 31 July 2013</b>	(16,353)	(831)
Loss for the period	(3,445)	–
Exchange movement	3	–
<b>At 31 January 2014</b>	(19,795)	(831)
Loss for the period	(3,430)	–
<b>At 31 July 2014</b>	(23,225)	(831)

**7. 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](http://www.tissueregenix.com)







## **Tissue Regenix Group plc**

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