

CARING



DYNAMIC



PROGRESSIVE



WHO WE ARE

TISSUE REGENIX GROUP PLC IS A PIONEERING, INTERNATIONAL MEDICAL TECHNOLOGY COMPANY, LEADING IN THE DEVELOPMENT OF REGENERATIVE PRODUCTS TO MAKE REPLACEMENT NATIVE TISSUE USING BIOLOGICAL (HUMAN AND ANIMAL) TISSUES.



TO DATE, TISSUE REGENIX HAS RESEARCHED AND DEVELOPED APPLICATIONS FOR dCELL® ACROSS THREE CLINICAL AREAS: WOUND CARE, ORTHOPAEDICS AND CARDIAC.

CONTENTS

OVERVIEW

Highlights	01
Operational Review	02

FINANCIALS

Condensed Consolidated Statement of Comprehensive Income (Unaudited)	05
Condensed Consolidated Statement of Changes in Equity (Unaudited)	06
Condensed Consolidated Statement of Financial Position (Unaudited)	08
Condensed Consolidated Cash Flow Statement (Unaudited)	09
Notes to the Condensed Financial Statements (Unaudited)	10
Shareholder Notes	16



HIGHLIGHTS



“During this period Tissue Regenix Group has made significant progress in operations across both the US and EU, highlighted by a twofold increase in revenue in the US, confirming our ability to successfully commercialise products, whilst also identifying further market entry opportunities.”

JOHN SAMUEL
CHAIRMAN

During the period to 31 July 2016 the Group has continued to make significant progress in operations across both the US and EU.

Fundamental to this is the growing adoption of DermaPure® in the US Wound Care market, with momentum continuing beyond the initial £0.8m reported for the full year, now reflected in a two fold increase in revenue over the previous comparative period.

This, however, should not overshadow the significant strides made in Europe, with OrthoPure™ XT now increasingly close to a commercial market launch.

The decision to supersede our initial clinical trial for OrthoPure™ XM with a further iteration of the implant should ultimately facilitate its market introduction into Europe, but crucially also assist in the US market launch in the coming years.

Progress in the last six months continues to vindicate our confidence in our product portfolio, both in the marketplace and in the development pipeline.

As the development and expansion of the company continues in line with our ambitions and expectations, we are confident that our results for the full year will reflect this.

Highlights

- ▷ DELIVERED REVENUE OF £631K (2015: £252K) 150% INCREASE
- ▷ 510(K) MARKET CLEARANCE FOR SURGIPURE™ XD
- ▷ FIRST dCELL® PROCESS APPROVAL BY THE FDA
- ▷ ORTHOPURE™ XT REGULATORY PROCESS SHORTENED
- ▷ FIRST GPO CONTRACT SIGNED IN THE US FOR DERMAPURE®
- ▷ FURTHER MEDICARE APPROVALS FOR DERMAPURE® — 93% NOW COVERED
- ▷ APPOINTMENT OF VP ORTHOPEDICS NORTH AMERICA

OPERATIONAL REVIEW

02



ANTONY ODELL
CHIEF EXECUTIVE OFFICER

Overview

In the six months to July 2016 Tissue Regenix Group has continued to see commercial and corporate growth in line with our expectations and strategic goals. DermaPure® continues to perform well in the competitive US wound care market, our orthopaedic business is coming to the fore within Europe and significant progress has been made in bringing our dCELL® heart valves to the European market.

Alongside these early commercial milestones we continue the development of additional applications arising from our research pipeline agreements with The University of Leeds and research partner the Pontifical Catholic University of Paraná. Furthermore, we continue to exploit opportunities for product line extensions that would allow for a broader use of our existing products.

US

During the period our US business continued to make significant progress, as demonstrated in this set of results, with a two fold increase in sales comparative to the first six months of the previous year. We expect this year to follow a similar revenue profile as seen previously, accelerating towards the end, as demonstrated during H2 FY16 where the revenue increase was +131% against H1.

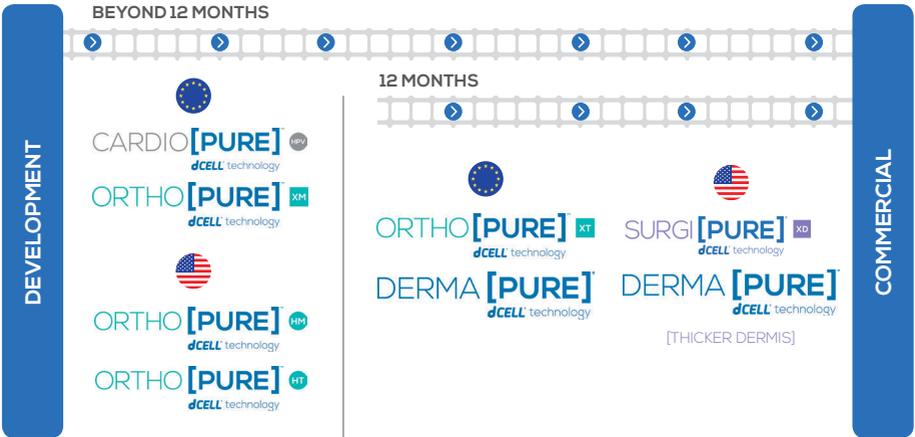
Further Medicare coverage has been gained, with now only one jurisdiction outstanding. Our

focus on adoption and advocacy continues as the importance of health economics increases within the US healthcare market, and the economic advantages of products such as DermaPure® become apparent.

As we look to meet the demand of new applications for DermaPure® we have expanded our portfolio of products to allow for larger and thicker sizes in response to physician feedback. We continue to pursue opportunities in different markets such as dentistry and burns and anticipate further progress in this regard in the coming year.

The 510(k) market clearance for SurgiPure™ XD was another major inflection point. This is the first time the FDA has reviewed the full dCELL® process and SurgiPure™ XD therefore becomes our first FDA approved product, with an expected launch in H217.

Alongside this we have also progressed with the groundwork for our US Orthopedic subsidiary, appointing a VP for North America. With an initial focus on human tissue applications, we have begun discussions with multiple potential partners. In conjunction with these developments, we have established a clinical advisory board consisting of five experts with varying specialties in sports medicine, with an emphasis on ligament reconstruction, meniscal replacement, and cartilage restoration. We expect this area of our business to develop significantly over the coming year.



Europe

Orthopaedics continues to be our primary focus within the European market and our recent announcement, that the CE mark submission for OrthoPure™ XT (porcine tendon) would be completed six months ahead of schedule is a testament to the hard work ongoing in our orthopaedic division, whilst also highlighting the growing need and demand for such a treatment within this field. We anticipate that we will be in a position to launch OrthoPure™ XT into the European market in H117.

The OrthoPure™ XM (porcine meniscus) clinical trial closed earlier in the year, with the clinical data showing biocompatibility and integration into the patient's tissues. Feedback from the trial led to the decision to undertake a second clinical trial with a modified implant to allow the same product to be marketed in both the EU and US.

GBM-V, our Joint Venture tissue bank in Rostock, Germany, continues to carve out a path for our human tissue applications in mainland Europe, with an initial focus on CardioPure™, dCELL® heart valves, and DermaPure®. We now have an experienced team in place to lead us through the regulatory process and currently remain on track to produce the first heart valves in H217.

Summary and Outlook

The next twelve months promise some significant milestones for Tissue Regenix, including the launch of our first orthopaedic application in Europe, the launch of our second wound care product, SurgiPure™ XD into the US and the ongoing regulatory submissions to the German authorities for decellurised tissues to be treated at GBM-V. Alongside this, the continued growth of DermaPure®, as evidenced by these results, and the ongoing development of our orthopaedic business within the US ensure that we remain on track to end our year accomplishing our corporate goals, and we look forward to reporting our progress over the coming months.

OPERATIONAL REVIEW

CONTINUED

04



IAN JEFFERSON
CHIEF FINANCIAL OFFICER

Financial Summary

For the 6 months ended 31 July 2016 Tissue Regenix Group delivered revenue of £631k (2015: £252k) generating an operating loss of £5,523k (2015: £4,133k). With finance income of £81k (2015: £116k) and a research and development tax credit of £280k (2015: £335k) the loss after tax was £5,162k (2015: £3,682k), of which £5,082k (2015: £3,682k) was attributable to the equity holders of the parent company. Cash balances at the end of the period were £13,515k (2015: £24,887k) and the Group was debt free. The results were in line with our expectations.

Wound Care

Wound care revenue for the period of £631k (2015: £244k) was derived from sales of DermaPure® in the USA, representing a more than two fold increase over the prior period. The local currency equivalents, to eliminate the effects of exchange, were \$891k (2015: \$371k). As was the case in the previous year, revenue phasing across the year is expected to be weighted towards H2. With more visibility now regarding the appointment of distributors and contract approvals, the 12-month revenue guidance range has been narrowed to \$2.5m - \$3.5m compared to the 12-month prior period of \$1.2m (however, please note shortened accounting period below). Gross margin for the period for the Wound Care division was 81% (2015: 75%). SG&A costs increased as expected, impacted by the full year effect of previous year direct sales hires and commission costs, which increase with revenue.

The commission costs were \$290k (2015: \$100k), which as a percentage of sales was therefore 32.5% (2015: 27.0%). Guidance for full year margin and commission percentage remain at c.80% and c.37.5% respectively.

Orthopaedics

The costs incurred of £1,300k (2015: £1,050k) consisted primarily of clinical trial costs as both OrthoPure™ XM and OrthoPure™ XT moved through the human trial phase. The costs were in line with our expectations and previous guidance. We expect to see the first revenue from this division in H117 following commercialisation of OrthoPure™ XT.

Cardiac

The results for this segment are not material during this period. However, the joint venture, GBM-V, set up earlier in the year remains on track to launch CardioPure™ heart valves in Germany during 2017.

Central

Operation costs are mainly incurred centrally and are in general not allocated to individual operating units. Costs remained flat over the period at £1,406k (2015: £1,417k).

Accounting reference date change

As noted previously the Group has changed its accounting reference date to 31 December. The next reporting period will therefore be for the 11 months to 31 December 2016.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED)

For the six months to 31 July 2016

	Notes	6 months to 31 July 2016 £'000	6 months to 31 July 2015 £'000	12 months to 31 Jan 2016 £'000
Revenue		631	252	816
Cost of sales		(119)	(62)	(154)
Gross profit		512	190	662
Administrative expenses		(6,035)	(4,323)	(10,904)
Operating loss		(5,523)	(4,133)	(10,242)
Finance income		81	116	213
Loss before tax		(5,442)	(4,017)	(10,029)
Taxation	4	280	335	527
Loss after tax		(5,162)	(3,682)	(9,502)
Attributable to:				
Equity holders of the parent		(5,082)	(3,682)	(9,410)
Non-controlling		(80)	–	(92)
		(5,162)	(3,682)	(9,502)
Other comprehensive income/(expense):				
Foreign currency translation differences – foreign operations		(38)	4	(1)
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR		(5,200)	(3,678)	(9,503)
Attributable to:				
Equity holders of the parent		(5,105)	(3,678)	(9,411)
Non-controlling interests		(95)	–	(92)
		(5,200)	(3,678)	(9,503)
Loss per share				
Basic and diluted on loss attributable to equity holders of the parent	5	(0.68)p	(0.50)p	(1.27)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 2016

Attributable to equity holders of parent

	Share capital £000	Share premium £000	Merger reserve £000
At 31 January 2015	3,271	31,972	10,884
Loss for the period	-	-	-
Other comprehensive expense	-	-	-
Loss and total comprehensive expense for the year	-	-	-
Issue of shares	526	18,422	-
Exercise of share options	1	23	-
Share based payment expense	-	-	-
At 31 July 2015	3,798	50,417	10,884
Loss and total comprehensive expense for the year	-	-	-
Non-controlling interest arising on creation of a joint venture	-	-	-
Exercise of share options	3	44	-
Share based payment expense	-	-	-
At 31 January 2016	3,801	50,461	10,884
Loss for the period	-	-	-
Other comprehensive expense	-	-	-
Loss and total comprehensive expense for the period	-	-	-
Share based payment expense	-	-	-
At 31 July 2016	3,801	50,461	10,884

Reverse acquisition reserve £000	Reserve for own shares £000	Share based payment reserve £000	Retained earnings deficit £000	Total £000	Non-controlling interests £000	Total equity £000
(7,148)	(831)	810	(27,380)	11,578	–	11,578
–	–	–	(3,682)	(3,682)	–	(3,682)
–	–	–	4	4	–	4
–	–	–	(3,678)	(3,678)	–	(3,678)
–	–	–	–	18,948	–	18,948
–	–	–	–	24	–	24
–	–	90	–	90	–	90
(7,148)	(831)	900	(31,058)	26,962	–	26,962
–	–	–	(5,733)	(5,733)	(92)	(5,825)
–	–	–	–	–	9	9
–	–	–	–	47	–	47
–	–	46	–	46	–	46
(7,148)	(831)	946	(36,791)	21,322	(83)	21,239
–	–	–	(5,082)	(5,082)	(80)	(5,162)
–	–	–	(23)	(23)	(15)	(38)
–	–	–	(5,105)	(5,105)	(95)	(5,200)
–	–	135	–	135	–	135
(7,148)	(831)	1,081	(41,896)	16,352	(178)	16,174

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED)

As at 31 July 2016

	Notes	31 July 2016 £'000	31 July 2015 £'000	31 Jan 2016 £'000
Non-current assets				
Property, plant and equipment		1,075	878	901
Total non-current assets		1,075	878	901
Current assets				
Inventory		128	17	64
Trade and other receivables		2,586	1,801	2,325
Cash and cash equivalent		13,515	24,887	19,907
Total current assets		16,229	26,705	22,296
Total assets		17,304	27,583	23,197
Current liabilities				
Trade and other payables		(1,130)	(621)	(1,958)
Total liabilities		(1,130)	(621)	(1,958)
Net assets		16,174	26,962	21,239
Equity				
Share capital	6	3,801	3,798	3,801
Share premium	6	50,461	50,417	50,461
Merger reserve	6	10,884	10,884	10,884
Reverse acquisition reserve	6	(7,148)	(7,148)	(7,148)
Reserve for own shares		(831)	(831)	(831)
Share based payment reserve		1,081	900	946
Retained earnings deficit	7	(41,896)	(31,058)	(36,791)
Equity attributable to equity holders of parent		16,352	26,962	21,322
Non-controlling interests		(178)	-	(83)
Total equity		16,174	26,962	21,239

Approved by the Board and authorised for issue on 12 October 2016

JOHN SAMUEL
CHAIRMAN

IAN JEFFERSON
CHIEF FINANCIAL OFFICER

CONDENSED CONSOLIDATED CASH FLOW STATEMENT (UNAUDITED)

For the six months ended 31 July 2016

	6 months to 31 July 2016 £'000	6 months to 31 July 2015 £'000	12 months to 31 Jan 2016 £'000
Operating Activities			
Operating loss	(5,523)	(4,133)	(10,242)
Adjustment for non-cash items:			
Depreciation of property, plant & equipment	158	118	245
Share based payment	135	90	136
Tax refunded	-	745	745
Operating cash outflow	(5,230)	(3,180)	(9,116)
(Increase)/decrease in inventory	(64)	17	(30)
Decrease/(increase) in trade & other receivables	19	(264)	(596)
(Decrease)/increase in trade & other payables	(866)	(470)	862
Net cash outflow from operations	(6,141)	(3,897)	(8,880)
Investing activities			
Interest received	81	116	213
Net cash acquired on creation of joint venture	-	-	9
Purchase of property, plant & equipment	(332)	(561)	(711)
Net cash outflow from investing activities	(251)	(445)	(489)
Financing activities			
Proceeds from issue of share capital	-	18,972	19,019
Net cash inflow from financing activities	-	18,972	19,019
(Decrease)/increase in cash and cash equivalents	(6,392)	14,630	9,650
Cash and cash equivalents at start of period	19,907	10,257	10,257
Cash and cash equivalents at end of period	13,515	24,887	19,907

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

For the six months ended 31 July 2016

1) BASIS OF PREPARATION

The interim financial information set out in this statement for the six months ended 31 July 2016 and the comparative figures for the six months ended 31 July 2015 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 2016 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 2016. It does not comply with IAS 34 "Interim Financial Reporting" as is permissible under the rules of the AIM Market ("AIM").

The financial information has been prepared on a going concern basis and is presented in sterling to the nearest £'000.

The preparation of financial information in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on management's best knowledge of the amount, event or actions, actual events ultimately may differ from those estimates.

The interim financial information does not include all financial risk management information and disclosures required in annual financial statements. There have been no significant changes in any risk or risk management policies since 31 January 2016. The principal risks and uncertainties are largely unchanged and are as disclosed in the Annual Report for the year ended 31 January 2016.

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 2016, as described in those financial statements other than standards, amendments and interpretations which became effective after 1 February 2016 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 12 October 2016.

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 2016 and are disclosed in those statements.

3) SEGMENTAL REPORTING

Operating segments

The Group is organised into Cardiac, Wound Care and Orthopaedics divisions for internal management, reporting and decision-making, based on the nature of the products of the Group's businesses. Managers have been appointed within these divisions, who report to the board. These are the reportable operating segments in accordance with IFRS8 "Operating Segments". The Directors recognise that the operations of the Group are dynamic and therefore this position will

be monitored as the Group develops. In accordance with IFRS8, the Group has derived the information for its operating segments using the information used by the Chief Operating Decision Maker. The Group has identified the Board of Directors as the Chief Operating Decision Maker as it is responsible for the allocation of resources to the operating segments and assessing their performance.

Central overheads, which primarily relate to operations of the Group function, are not allocated to the business units.

	Wound Care 6 months to 31 July		Orthopaedics 6 months to 31 July		Cardiac 6 months to 31 July		Central 6 months to 31 July		Total 6 months to 31 July	
	2016 £000	2015 £000	2016 £000	2015 £000	2016 £000	2015 £000	2016 £000	2015 £000	2016 £000	2015 £000
Revenue	631	244	-	-	-	-	-	8	631	252
Cost of sales	(119)	(62)	-	-	-	-	-	-	(119)	(62)
Gross Profit	512	182	-	-	-	-	-	8	512	190
SG&A	(3,074)	(1,749)	(1,300)	(1,050)	(255)	(107)	(1,406)	(1,417)	(6,035)	(4,323)
Operating loss	(2,562)	(1,567)	(1,300)	(1,050)	(255)	(107)	(1,406)	(1,409)	(5,523)	(4,133)
Finance income	-	-	-	-	-	-	81	116	81	116
Loss before taxation	(2,562)	(1,567)	(1,300)	(1,050)	(255)	(107)	(1,325)	(1,293)	(5,442)	(4,017)
Taxation	50	54	200	256	30	7	-	18	280	335
Loss for the year	(2,512)	(1,513)	(1,100)	(794)	(225)	(100)	(1,325)	(1,275)	(5,162)	(3,682)

	Wound Care 12 months to 31 Jan 2016 £000		Orthopaedics 12 months to 31 Jan 2016 £000		Cardiac 12 months to 31 Jan 2016 £000		Central 12 months to 31 Jan 2016 £000		Total 12 months to 31 Jan 2016 £000	
Revenue		808		-		-		8		816
Cost of sales		(154)		-		-		-		(154)
Gross Profit		654		-		-		8		662
SG&A		(4,938)		(2,382)		(352)		(3,232)		(10,904)
Operating loss		(4,284)		(2,382)		(352)		(3,224)		(10,242)
Finance income		-		-		-		213		213
Loss before taxation		(4,284)		(2,382)		(352)		(3,011)		(10,029)
Taxation		169		324		16		18		527
Loss for the year		(4,115)		(2,058)		(336)		(2,993)		(9,502)

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) CONTINUED

For the six months ended 31 July 2016

The following table provides disclosure of the Group's revenue by geographical market based on location of the customer:

	6 months to 31 July 2016 £'000	6 months to 31 July 2015 £'000	12 months to 31 Jan 2016 £'000
USA	631	244	808
Rest of world	–	8	8
	631	252	816

4) TAXATION

	6 months to 31 July 2016 £'000	6 months to 31 July 2015 £'000	12 months to 31 Jan 2016 £'000
Current tax:			
Tax credit on research and development costs in the period	280	335	527
	280	335	527
Deferred tax:			
Origination and reversal of temporary timing differences	–	–	–
Tax credit on loss on ordinary activities	280	335	527

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.

	6 months to 31 July 2016 £'000	6 months to 31 July 2015 £'000	12 months to 31 Jan 2016 £'000
Total loss attributable to the equity holders of the parent	(5,082)	(3,682)	(9,410)
	No.	No.	No.
Weighted average number of ordinary shares in issue during the period	743,183,878	737,434,237	739,919,809
Loss per share			
Basic and diluted on loss for the period	(0.68)p	(0.50)p	(1.27)p

The Company has issued employees options over 29,376,332 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) CONTINUED

For the six months ended 31 July 2016

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 2015	654,123,031	3,271	31,972	10,884	(7,148)	38,979
Issued for cash	105,263,158	526	18,422	–	–	18,948
Issued on exercise of share options	266,904	1	23	–	–	24
Total Ordinary shares of 0.5p each as at						
31 July 2015	759,653,093	3,798	50,417	10,884	(7,148)	57,951
Issued on exercise of share options	471,171	3	44	–	–	47
Total Ordinary shares of 0.5p each as at						
31 January 2016	760,124,264	3,801	50,461	10,884	(7,148)	57,998
Issued for cash						
Issued on exercise of share options	–	–	–	–	–	–
Total Ordinary shares of 0.5p each as at						
31 July 2016	760,124,264	3,801	50,461	10,884	(7,148)	57,998

7) MOVEMENT IN RETAINED EARNINGS AND RESERVE FOR OWN SHARES

	Retained earnings deficit £000	Reserve for own shares £000
At 31 January 2015	(27,380)	(831)
Loss for the period	(3,682)	–
Exchange movement	4	–
At 31 July 2015	(31,058)	(831)
Loss for the period	(5,728)	–
Exchange movement	(5)	–
At 31 January 2016	(36,791)	(831)
Loss for the period	(5,082)	–
Exchange movement	(23)	–
At 31 July 2016	(41,896)	(831)

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.

SHAREHOLDER NOTES

DIRECTORS AND OFFICERS

DIRECTORS

John Samuel	(Chairman)
Antony Odell	(Chief Executive Officer)
Ian Jefferson	(Chief Financial Officer)
Jonathan Glenn	(Non-Executive Director)
Alan Miller	(Non-Executive Director)
Randeep Singh Grewal	(Non-Executive Director)
Steven Couldwell	(Non-Executive Director)
Shervanthi Homer- Vanniasinkam	(Non-Executive Director)

COMPANY SECRETARY

Ian Jefferson

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