





TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

### Who we are and what we do

#### TISSUE REGENIX GROUP PLC IS

A PIONEERING, INTERNATIONAL MEDICAL TECHNOLOGY COMPANY. LEADING IN THE DEVELOPMENT OF REGENERATIVE PRODUCTS TO CREATE REPLACEMENT NATIVE TISSUE USING BIOLOGICAL (HUMAN AND ANIMAL) MATERIALS. WITH ITS INNOVATIVE PLATFORM TECHNOLOGY **dCELL®** IT IS REVOLUTIONISING THE TREATMENT OF PATIENTS WITH **WOUND CARE**, **ORTHOPAEDIC** AND **CARDIAC** APPLICATIONS.



#### dCELL® technology

The unique dCELL® technology allows Tissue Regenix to process both human and animal tissues, removing DNA and cellular material but leaving intact an acellular matrix within which the patient's own cells can repopulate and regenerate, creating like for like tissue.

This patented dCELL® technology platform allows us to address complex and varying clinical needs.

Learn more about dCELL® on page 2

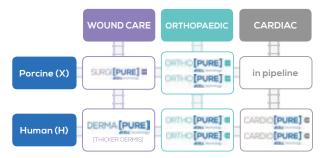
#### **Our Strengths**

- O A proven regenerative technology, producing outstanding clinical results
- O A dedicated and skilled management and scientific team
- O Global reach with offices in both Europe and North America
- Strong business–academia relationships, including The University of Leeds,UK and Pontifical Catholic University of Paraná, Brazil



More information is available in the strategic report on pages 4 to 17

### OUR TISSUE STRATEGY



#### NAVIGATING THE REPORT



FOR FURTHER INFORMATION WITHIN THIS DOCUMENT AND RELEVANT PAGE NUMBERS









 Entry into EU market through controlled joint venture GBM-V, first approvals expected H2 2017, with commercial availability in H1 2018.

### **Highlights**

- ▷ £1,322K REVENUE FROM DERMAPURE<sup>®</sup>, A 64% INCREASE IN SALES
- ▷ FIRST REVENUES FROM GBM-V
- ▷ SUBMISSION OF INITIAL CLINICAL DATA FOR ORTHOPURE™ XT CE MARK
- ▷ ESTABLISHMENT OF US ORTHOPAEDIC SUBSIDIARY
- > APPOINTMENT OF A US CLINICAL ADVISORY BOARD
- STRENGTHENED CORPORATE BOARD WITH CLINICAL EXPERTISE
- ▷ FURTHER MEDICARE COVERAGE
- ▷ INITIAL GPO AGREEMENTS SIGNED

OVERVIEW	
Corporate Structure	02
Technology	02
duct Portfolio	03
STRATEGIC REPORT	

Chairman's Statement	04
Marketplace	05
CEO Statement	07
Operational Review	
Wound Care	10
Orthopaedics	12
CFO Statement	14
Risks	16

GOVERNANCE	
Board of Directors	18
Governance Framework	20
Corporate Governance Statement	21
Directors' Remuneration Report	22
Directors' Report	26
Statement of Directors' Responsibilities	28

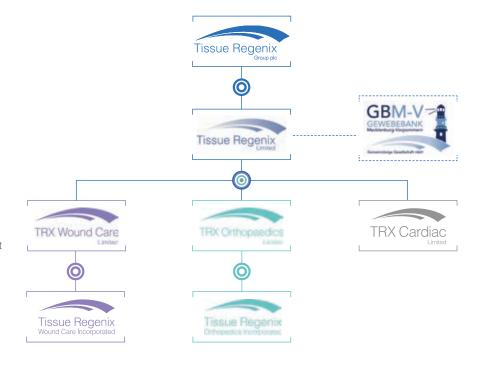
#### **FINANCIALS**

Independent Auditor's Report to the members of Tissue Regenix Group plc	29
Consolidated Statement of Comprehensive Income	30
Consolidated Statement of Changes in Equity	31
Consolidated Statement of Financial Position	32
Consolidated Statement of Cash Flows	33
Notes to the Financial Statements	34
Company Statement of Changes in Equity	51
Company Statement of Financial Position	52
Company Statement of Cash Flows	53
Notes to the Company Information	54
Notice of Annual General Meeting	56
Directors and Officers	IBC

### **Our Corporate Structure**

This structure ensures that the correct research and commercial expertise for each operational division, allowing it to be treated as an individual entity, and having the flexibility to meet the requirements of patients and clinicians within this space, whilst also maintaining the values and corporate leadership of the Tissue Regenix Group plc. The Corporate structure also allows for the isolation of one operational division should there be the opportunity for M&A activity.

In January 2016, GBM-V gmbh was established as a controlled joint venture in Germany to facilitate the commercialisation of our human tissue applications throughout Europe.



### **Our Technology:**

## The power of dCELL® technology.

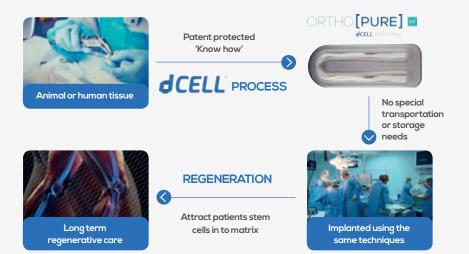
dCELL<sup>®</sup> technology offers a unique approach to regenerative medicine.

The dCELL® process is gentle, efficient, effective – and powerful. It can be applied to both donated human tissues (allografts), or animal tissues (xenografts). It results in allograft and xenograft tissue matrices that retain the tissues' native structure to allow repopulation and regeneration of the patients own tissue.

## The dCELL<sup>®</sup> difference is clear.

The dCELL<sup>®</sup> process removes DNA and cellular material from biological tissues, through a series of gentle washes, leaving an intact acellular matrix upon which the patient's cells can repopulate and regenerate, creating new, native tissue, which is recognised and accepted by the body, significantly reducing the risk of rejection.

dCELL<sup>®</sup> technology provides an enhanced healing environment, in terms of both natural, tissue-specific physical structure and bio-mechanical properties.



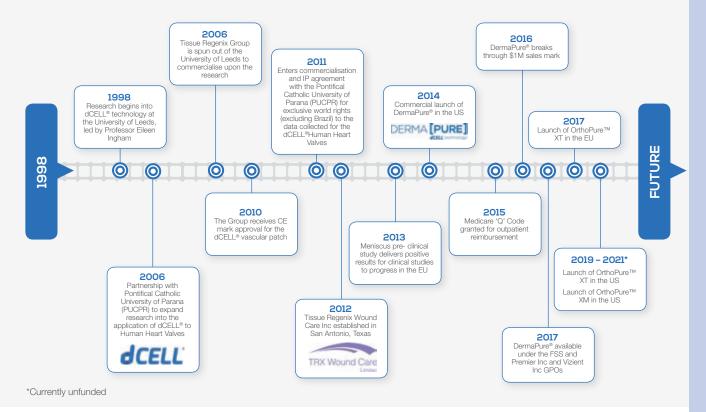
Tissue treated with dCELL<sup>®</sup> technology gives the patient a receptive scaffold that supports cell migration following implantation, while maintaining appropriate tissue strength. Once repopulation is complete, the regenerated tissue is effectively a natural part of the patient's own body. The potential applications of dCELL<sup>®</sup> are diverse and currently Tissue Regenix is focusing on addressing complex and unmet needs in three core clinical areas:

Wound care, orthopaedics and cardiac.



### **Product Portfolio**

#### **Development Timeline**



TISSUE REGENIX HAVE A PORTFOLIO OF PRODUCTS UTILISING PATENTED PLATFORM TECHNOLOGY **dCELL®** IN ALL THREE CORE FOCUS AREAS. THE NATURE OF THIS TECHNOLOGY PLATFORM ALLOWS A SERIES OF LINE EXTENSIONS FROM PRIMARY APPLICATIONS, TO CREATE AN EXCITING DEVELOPMENT PIPELINE.

#### dCELL<sup>®</sup> tissue

Due to the diversity of the dCELL® technology platform it can be applied to different biological tissues (animal or human) for the current applications in wound care, orthopaedics and cardiac.

Tissue Regenix employs a dual tissue strategy, and currently has a portfolio of human tissue applications under the core focus areas, whilst the xenograft product portfolio continues to expand. There is the scope to apply dCELL® to different biological tissues beyond human and porcine in the future.

## Where does this tissue come from?

The xenograft tissue is sourced from approved UK abattoirs as a by-product from selected animals that are entering the food chain. Breeds and tissue are carefully selected to strict specifications and enable Tissue Regenix to utilise tissue that would otherwise be wasted. The tissue is then processed using the patented dCELL<sup>®</sup> Technology which eliminates the risk of infection and is then packaged and distributed through the manufacturing facility in Leeds, ensuring that the whole development chain is carefully controlled.

#### Why porcine?

Although the dCELL® Technology process can be used to treat soft tissue from multiple sources, it is currently applied to porcine tissue. Porcine tissue is commonly used in medical procedures due to the genetic similarities between pigs and humans. For example, a pig tendon can offer the appropriate tensile strength, length and diameter to be used in ACL reconstruction.

#### What about human?

Human tissue is sourced from cadavers who have volunteered to leave their body for medical purposes after death. This means that it is not just the organs that are utilised, but also the corneas, skin and even bones.

### **Chairman's Statement**



"ACROSS THE 11 MONTHS TO 31 DECEMBER 2016 TISSUE REGENIX EXECUTED SEVERAL STEPS OF ITS EVOLVING COMMERCIALISATION STRATEGY AS OPERATIONS IN BOTH THE US AND EU CONTINUE TO EXPAND."

#### JOHN SAMUEL CHAIRMAN

The Group delivered combined revenues of £1,443k, which was bolstered by the first revenues from controlled joint venture GBM-V. Wound care delivered revenue of £1,322k, a 64% increase on the figures reported last year, and in line with expectations.

#### Strategy

Strategically, the Group has continued to evolve its commercialisation efforts spanning both the US and EU. The creation of controlled joint venture GBM-V has allowed the submission for regulatory approval to commence for allograft products within the EU, and we expect to be in a position to report positive newsflow throughout the year. Not only is this relevant for the joint venture in the EU, but also validates the commercial viability of this model for other potential partnerships.

The wound care division achieved significant success in executing the commercial strategy for DermaPure®, accessing the hospital setting. Of particular relevance was the award of GPO Agreements, especially Premier and post year end, Vizient, both of which were granted under their respective "Innovative Technology" programmes, providing an independent review and endorsement of the dCELL® technology. Under these agreements DermaPure is now accessible to over 1 million hospital beds in the US, complementing the comprehensive Medicare reimbursement covering 93% of Medicare beneficiaries. These agreements will be pivotal in the commercial traction and success over the coming year.

OrthoPure<sup>™</sup> XT, a decellularised porcine ligament for ACL reconstruction, successfully completed the clinical trial enrolment and it is expected that CE Mark approval and commercial roll-out will be achieved during 2017. This will be a significant step for both the Orthopaedics division and also the Company as a whole as it signifies commercialisation under each of the core business divisions. Having signed the first EU distribution agreements for OrthoPure<sup>™</sup> XT we are confident that the implementation of the distributor led commercialisation strategy will be successful throughout the coming year.

#### Governance

As the Company enters a phase of accelerated growth, necessary steps have been taken to ensure that the Company is aligned with the best corporate compliance and governance standards. This included the addition of Shervanthi Homer-Vanniansinkim who brings clinical expertise to the Board, complementing the commercial experience vested in the Non-Executive Directors. In January we also welcomed a new Chief Financial Officer, Paul Devlin. Paul brings with him significant experience of guiding companies through a period of rapid growth, mergers, acquisitions and joint ventures. It is expected that he will play a fundamental role in the strategic direction of the Company in the future.

#### Accounting Reference Date

As previously announced the Company has changed the accounting reference date to 31 December. These accounts are therefore reporting an 11 month period.

#### Finance

I draw your attention to the going concern statement in the Corporate Governance Statement and Note 1 to the financial accounts. The Directors are confident that additional funds will be made available to continue to fund the business.

#### Outlook

Significant progress has been made in the transition from development to commercialisation and we expect each division to reach a significant inflection point over the next year. The advances that have been made during the reported period are a reflection of the ongoing commitment and enthusiasm of the staff, and I would like to personally thank all for their continuing efforts. As we enter a phase of accelerated growth we anticipate to see our focus on commercialisation come to fruition.

#### JOHN SAMUEL

CHAIRMAN

2 June 2017





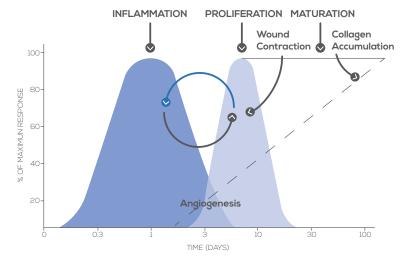
### **The Diabetes Epidemic**

It is estimated that 415 million people worldwide are suffering from diabetes, with 46% of this population remaining undiagnosed<sup>1</sup>. With the industrialised world suffering from the highest prevalence of diabetes, China, India and the USA top the list with an estimated combined 207 million sufferers.

Often underestimated are the serious complications associated with diabetes which can include: damage to the nerve and blood supply, particularly in the lower extremities (neuropathy and peripheral vascular disease), retinopathy (eyes), cardiovascular disease and nephropathy (kidneys).

The US currently spends more treating diabetes and its associated side effects than any other disease, with \$101.4bn spent in 2013<sup>2</sup>. Within the UK, the NHS will spend 9% of its annual budget on the treatment of type II diabetes, expected to be around  $\Omega$ 8.8bn per year<sup>3</sup>. Diabetes is the most common cause of non-traumatic limb amputation<sup>4</sup> with a diabetic amputation taking place somewhere in the world every 60 seconds<sup>5</sup>.

With such shocking statistics, the need for education and new novel treatments to address these side effects is more critical than ever. With 6% of diabetic patients suffering a diabetic foot ulcer, or wound, proper wound management is crucial<sup>6</sup>.



The difficulty faced by physicians treating these wounds is how to advance them to a state of healing.

Therefore, one of the challenges faced when healing chronic wounds is enabling the body to progress through the healing stages and naturally regenerate, allowing wound closure. Clearly, using a new technology such as DermaPure® to aid this progress becomes the optimum solution. DermaPure® provides the extra-cellular matrix for the patient's cells to repopulate, encouraging the body to progress through the stages of healing and establish a blood supply through angiogenesis, (the formation of new blood vessels) allowing for complete wound closure.

- 1. http://www.diabetes.co.uk/diabetes-prevalence.html
- <sup>2.</sup> http://www.cnbc.com/2016/12/27/diabetes-costing-americans-more-than-any-other-disease.html
- 3. https://www.england.nhs.uk/ourwork/qual-clin-lead/diabetes-prevention/
  - 4. https://www.nice.org.uk/guidance/ng19/chapter/introduction
  - 5. https://www.idf.org/webdata/docs/background\_info\_AFR.pdf
  - 6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4825895



#### US Healthcare Reimbursement

The US spends more on healthcare per capita than any other nation with spending per person equivalent to \$9,086 per year. The US is also the largest spender as a percentage of its GDP at 17.1%, almost 50% higher than the next largest payor<sup>1</sup>.

### So who funds these medical bills?

In 2015, the largest shares of total health care spending were sponsored by the federal government (28.7%) and households (27.7%). The private business share of health spending accounted for 19.9% of the total, state and local governments accounted for 17.1%, and other private revenues accounted for 6.7%<sup>2</sup>.

#### What is a GPO?

Group Purchasing Organisations (GPOs) are conglomerates of businesses providing similar services, allowing for them to leverage purchasing power and streamline efficiencies. A healthcare GPO can include members from both inpatient and outpatient settings, and can range from very large hospital groups to individual physician offices.

GPOs negotiate preferential pricing with vendors and establish a contract for the products that their members can access. Members typically prefer products that are included on their GPO contract. Therefore, securing GPO contracts is one of the keys to commercial success in the inpatient sector.

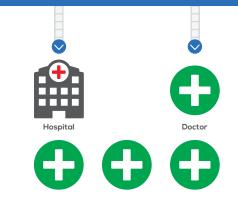
#### **GROUP PURCHASING ORGANISATION**







#### INTEGRATED DELIVERY NETWORK



- http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-aglobal-perspective
- https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ NationalHealthExpendData/NHE-Fact-Sheet.html



### **CEO Statement**



"WE HAVE MADE SIGNIFICANT PROGRESS FROM DEVELOPMENT TO COMMERCIALISATION AND EXPECT TO REACH A SIGNIFICANT INFLECTION POINT FOR EACH DIVISION IN THE COMING YEAR"

ANTONY ODELL CHIEF EXECUTIVE OFFICER

The changing macro environment presented both challenges and opportunities this year.

The Group has steadily progressed with programmes as we continue to evolve as a commercial company, seeking creative solutions to the challenges faced. The Group continues to pursue new business opportunities whilst maintaining focus on executing the long term strategy, creating shareholder value and, over time, generating financial returns.

Throughout the year the Group consolidated its presence in the US wound care market and is positioned for future entry into the European sports medicine and heart valve markets, both of which represent growth opportunities.

#### **Business Developments**

After establishing the controlled joint venture GBM-V in Germany in January 2016, significant progress has been made with regulatory submissions and barring any delays with this process, it is expected that commercialisation for both DermaPure® and CardioPure<sup>™</sup> human heart valves will commence throughout Europe during 2018. GBM-V is the first German multitissue bank, the objective being to process different human tissues at one facility. As demonstrated by the results, the first revenues were generated from this tissue bank which was achieved by the distribution of cryo-preserved corneas. The substantial progress made here validates the strategy employed and this business model paves the way for future alliances to be built.

#### **Divisional Overviews**

Our corporate structure vests the IP, finances and knowledge in the individual business divisions. This allows each division to remain focused, employing experts in each field for the development and commercialisation of products within these clinical areas. This model also allows the business to stay responsive and flexible to relevant business opportunities.

#### **Wound Care**

The US wound care division had a strong start to the year with further Medicare coverage cementing DermaPure<sup>®</sup> within the outpatient setting. However, it was the latter part of the year in which significant traction was gained, with approval of the first Group Purchasing Organisation (GPO) agreement in July, followed in December by Premier, the second largest GPO in the country. As illustrated in the marketplace section on page 6, these GPO approvals are pivotal to commercial success in the hospital setting, in which, there are significant benefits for DermaPure®. It was also announced after the year end that approval under Vizient, the largest GPO in the US, had been secured meaning that 75% of the hospital beds under GPO agreements in the US are now covered, complementing the 93% Medicare coverage held for outpatient settings. In conjunction to this, DermaPure® was also added to the Federal Supply Schedule in February 2017 allowing access to the 152 hospitals and 800 community based outpatient clinics under their jurisdiction, covering an additional 9 million patients.

This successful reimbursement structure allows for increasingly expansive commercial penetration into the wound care market in the current year.

The intention to launch SurgiPure<sup>™</sup> XD, a porcine dermis application for hernia repair, into the US market following the 510k approval was postponed as staff members were redeployed to accelerate the OrthoPure<sup>™</sup> XT timeline for Europe. However, it is expected that we will add SurgiPure<sup>™</sup> XD to the US wound care portfolio in early 2018.

#### **Orthopaedics**

Orthopaedic progression has been driven largely by OrthoPure™ XT, a porcine tissue application to address ACL reconstruction, which completed the necessary EU clinical trial enrolment and is currently progressing through the regulatory process for CE mark approval.

Due to the changes implemented by the introduction of the revised Medical Device Regulations, the timeline for approval was delayed. However, it is still expected that approval and launch will commence during 2017. The initial commitment of European distributors has been encouraging, having entered a number of agreements in preparation for a timely roll-out.

### CEO Statement CONTINUED

For launch, the initial focus will be on our key European markets which will include Germany, Spain and Poland. The Group envisages a roll-out plan over 12-18 months as the reimbursement strategy for each region is established, and engagement with appropriate distribution partners undertaken.

The US commercialisation strategy continues to evolve and it is expected that, given a suitable tissue bank partner is identified, the transfer of the technology process for OrthoPure™ HT, the human tissue version of our ACL product, will commence later this year with commercialisation to follow soon after, paving the way into the US sports medicine market. To aid in negotiating the complex US marketplace a prestigious Board of Clinical Advisers was appointed with whom we will work closely throughout this process, including:

- O Steven Arnoczky, DVM, Michigan State University, East Lansing, MI
- O David Caborn, MD, University of Louisville, Louisville, KY
- O Thomas Carter, MD, Team Physician for the Phoenix Suns, Phoenix, AZ
- O Philip Davidson, MD, Davidson Orthopedics, Salt Lake City, UT
- O Jack Farr II, MD, Orthoindy, Indianapolis, IN

#### Cardiac

Commercial progress this year was primarily focused on the GBM-V work, and the ongoing regulatory submissions to allow launch of the CardioPure™ HAV/HPV in Germany. The results being returned from Francisco da Costa's pioneering work in Brazil, which has now entered its 11th year, remain impressive and encouraging and was recognised by the Jefferey Borer Abstract Award in March 2016. The results have been displayed worldwide and interest in the decellularised human heart valves is ever increasing.

## Our 2017 Milestones and Objectives

As the Group continues to expand its commercial product portfolio and presence within relevant clinical application areas throughout different territories, the key milestones for 2017 are listed below. Associated to the successful execution of each are various risks, the main ones of which are listed below. More information on how the Group intend to mitigate some of these risks can be found on pages 16 to 17.

MILESTONE	RISKS
European launch of OrthoPure™ XT	Due to the change of Medical Device Regulations there is a risk of further regulatory delay. Once approval is granted it will be manufactured at our in-house manufacturing facility in Leeds relying on a successful ramp-up of processing.
European approval of DermaPure <sup>®</sup> and Human Heart Valves	We are currently working through the regulatory process for both products and there are therefore risks to the timelines for regulatory approval. As both are human tissue products there could be a risk to the supply of suitable materials.
Launch of thicker and larger DermaPure <sup>®</sup> sizes in the US	Reliance on partner to produce suitable amounts of product within the distribution timeline in order to meet demand.
US launch of OrthoPure™ HT	Finding a suitable tissue bank partner to source and process the donated tissue. Potential limitation of suitable donated tissue.
Establishment of OrthoPure™ XT clinical trial requirements for the US	Delay in regulatory requirements. Financial implications due to the cost associated with the clinical trials.

OBJECTIVE	HOW WE WILL ACHIEVE THIS:
Increase DermaPure <sup>®</sup> sales and market penetration	Now that we have achieved three GPO agreements, and 93% Medicare coverage we are in a position to translate this into commercial traction and increase our presence within the inpatient setting, where DermaPure® offers an effective clinical and economic solution.
Retain key staff and minimise employee turnover	We value the personal and professional development of our employees, actively encourage relevant training and qualifications and have a number of employee benefit opportunities in place to aid employee loyalty and satisfaction.
Engage Key Opinion Leaders and drive advocacy for the dCELL <sup>®</sup> Technology product portfolio	We already have a number of KOLs engaged for DermaPure <sup>®</sup> . Having appointed a clinical advisory board for Orthopaedics in the US we will look to leverage their expertise to educate and inform the wider clinical community.





#### **KPIs**

KPIs help us to track and monitor performance, against a defined set of financial and non-financial targets allowing teams to monitor their performance throughout every level of the business. Our executive management monitor against these targets with the Board ensuring that the KPIs in place accurately reflect the inflection points of the Group, and advising on strategy to ensure that these are met.

### OUR ONGOING KPIs

Key Group performance indicators are set out below:

- Monthly review of product development timelines and costs
- O Monthly review of revenue progress and forecasts
- Monitoring of cash balance and associated working capital requirements
- Monthly review of actual results against budget

#### **Our People**

Our talent is a key stakeholder in our future success and we strengthened our management team with the addition of a VP of Orthopaedics for the US, as well as addressing the growing national contracting positioning of DermaPure in the US by strengthening our leadership team to facilitate these contracts. We augmented our Board with the appointment of Shervanthi Homer – Vanniansinkim who brings extensive clinical expertise to the table, and has been a clinical adviser to the Group for a number years.

At the beginning of 2017 we welcomed a new CFO, Paul Devlin, who brings with him a wealth of experience in the merger and acquisition field, as well as joint ventures and business transformations. His experience will be key in guiding the Group through the next stages of development.

# Current Trading and Outlook

Following the award of two major GPO contracts with Premier and Vizient in December 2016 and March 2017 respectively, the Group now has 75% coverage for hospital based wounds in the US, complementing the 93% Medicare reimbursement coverage for outpatient settings. To identify the areas of highest opportunity and to maximise the sales potential of these GPO contracts, the Group undertook a detailed analysis of its addressable hospital market and has accordingly restructured its direct sales force on a regional basis to prioritise high potential hospitals, whilst continuing to use distributors to access other areas. To support this new focus, the Group has strengthened its US leadership team, acquiring specific expertise pivotal to the success of driving performance and pulling through clinical demand from the GPO agreements, which the Group expects will maximise sales execution and ultimately enhance revenue performance.

These operational changes were implemented in the first quarter of this year with the impact of these changes taking effect progressively throughout H1. Tissue Regenix achieved wound care revenue of \$0.6m in the 4 months to 30 April 2017, with 45% of revenue in April secured via GPO agreements. With the benefits of the restructured sales force already becoming evident and as individual hospital approvals increase, the Group expects sales in wound care to accelerate significantly in the second half of the year.

With DermaPure now positioned to meaningfully increase market penetration, the Group expects a significant and sustained acceleration in sales growth over the medium term based on DermaPure's superior patient outcomes, strong clinical support and increasingly broadly-based hospital approvals. As hospital-based adoption increases the Group believes that this will benefit its distributor channels as well as its ability to address the out-patient setting.

The one year clinical data for OrthoPure XT has been submitted to its notified body and the Group believes this will support the grant of a CE mark and allow for a commercial roll out during 2017 despite the added uncertainty that the new Medical Device Regulations have brought to the regulatory approval process.

In addition, GBM-V, the Group's controlled joint venture in Europe is expected to make an increased contribution during the first half of this year with momentum expected to continue as the year progresses.

The Group believes that the refocused sales approach targeting key markets, its broad development pipeline of innovative products offering exciting organic growth opportunities and its forthcoming entry into the US orthopaedics market in 2018, means that it is well placed for future growth.

### OPERATIONAL REVIEW Wound Care



"WE HAVE IDENTIFIED A NUMBER OF UNMET CLINICAL NEEDS, WHICH WE WILL ADDRESS WITH OUR INTENTION TO BRING TO MARKET THICKER AND LARGER SIZES OF DERMAPURE<sup>®</sup> THIS YEAR."

JOEL PICKERING, PRESIDENT, TISSUE REGENIX WOUND CARE, INC

Throughout the year, our focus has remained on the execution of a successful commercialisation strategy for DermaPure® in the US, and we have concentrated efforts on our long-term strategy to position DermaPure® within the inpatient care setting.

We have seen notable progress in the execution of our wound care strategy. The most significant, the approvals by Premier and Magnet Group Purchasing Organisations (GPOs), and Vizient, the largest GPO in the US. These agreements offer contracted access to approximately 75% of inpatient procedure volume in the US, and achieve an important milestone to facilitate access to the inpatient market.

These GPO agreements demonstrate the progression of our strategy, moving from an outpatient focus to also encompass the inpatient setting, and further strengthen our market penetration potential by complementing the 93% Medicare coverage we previously gained.

Further to the commercial value of these agreements, the approvals by Premier and Vizient were both granted under their respective innovative technology programmes, validating that DermaPure® offers unique attributes beyond current commercially available products, and may positively impact clinical care, safety and operational efficiencies.

#### DermaPure<sup>®</sup> Commercial Offering

As our strategy evolves, we continue to see opportunities for applications within different clinical areas, and will undertake the necessary clinical work in order to explore these potential opportunities.

We have identified a number of unmet clinical needs, which we will address with our intention to bring to market thicker and larger sizes of DermaPure<sup>®</sup> this year, thus allowing us to treat the larger, more complex wounds often associated with a hospital stay.

DERMAPURE® BENEFITS	COST OF CARE IMPACT				
Streamlined application process O Can by used "off the shelf" and tailor fit to wound size	Improved operational efficiencies <ul> <li>Reduces operating room time to prepare product</li> </ul>				
<ul> <li>Requires no thawing; stored at ambient temperature</li> <li>Comes hydrated; requires only simple rinse prior to use</li> </ul>	<ul> <li>No specialty refrigeration monitoring</li> </ul>				
	<ul> <li>Reduces waste associated with case cancellations for competitive thawed products</li> </ul>				
Supports efficient discharge to lower cost care setting	Improved clinical outcomes				
<ul> <li>Higher level of integration (vessel number and density) continues at day 28 (post-placement) and beyond</li> </ul>	<ul> <li>Treated wounds showed characteristics akin to acute (non- chronic) wound healing</li> </ul>				
	<ul> <li>Able to discharge patient to lower cost of care setting quickly and safely, reducing total costs to treat wound</li> </ul>				
Can be used to complete wound closure, if desired	Improved patient satisfaction				
O Provides epithelialisation over time and does not require a split	O Reduce the need for additional OR time / visits				
thickness skin graft to close	<ul> <li>Fewer applications to healing, facilitating return to quality of life, and lower out-of-pocket copay costs</li> </ul>				
Addresses foundation issues of chronic wounds	Differentiation relative to competing technologies				
O Creates strong foundation of angiogenesis	<ul> <li>Demonstrated evidence on wounds unresponsive to other modalities</li> </ul>				
	<ul> <li>O Outcomes based on clinical evidence with less than two applications</li> </ul>				



#### **Business Model**

We continue to exploit our hybrid sales model, utilising both direct sales reps as well as a number of distributors. Now that we have improved access to the inpatient market, via the GPO agreements, we expect to see an increase in utilisation within this setting. However, we also continue to maintain and develop our relationships within the outpatient setting which has contributed to our commercialisation success to date.

We also intend to bring to market SurgiPure<sup>™</sup> XD in the latter part of the year, after initially pushing back the launch date to allow for the redeployment of resources. A decellularised porcine dermis for the treatment of body wall defects and hernia repair, SurgiPure<sup>™</sup> XD will be positioned in the complex hernia segment where the market opportunity is currently valued at \$300m.

#### Summary

Throughout the last year, we focused on facilitating improved access for a number of our key markets, successfully gaining further Medicare coverage and GPO agreements. Having completed much of this necessary groundwork, we are now in a strong position to push forward with a more comprehensive commercialisation effort, and expect that we will see revenue growth to justify the efforts invested. DermaPure® continues to offer a costeffective solution for health care providers, and the potential for patients to heal without the need for multiple treatments. We expect to unlock the true value of DermaPure® in multiple care settings throughout this year.

(((I))) TRANSFORM YOUR APPROACH TO HEALING: SIGNAL THE BODY, NOT THE WOUND. DERMA [PURE]

### 

### MARKET OPPORTUNITY

In 2015 the US wound biologics market size was \$957m, with skin/dermal substitutes, such as DermaPure®, making up approximately 61% of this market, providing a market segment value of \$587.6m. It has been estimated that the wound biologics market will grow at a CAGR of 9.8%, eclipsing a projected value of \$1.5bn by 2020.

Approximately 8% of diabetic Medicare Beneficiaries will have a foot ulcer and 1.8% have an amputation.

### OPERATIONAL REVIEW Orthopaedics



"THROUGHOUT THE YEAR WE ACHIEVED SIGNIFICANT MILESTONES FOR THE COMMERCIALISATION OF ORTHOPURE™ XT IN EUROPE."

PETER HAMER, COMMERCIAL DIRECTOR, TISSUE REGENIX ORTHOPAEDICS LIMITED

Since the last set of results we have seen progress in both the EU and the US with our Orthopaedic product portfolio.

### EU

#### OrthoPure<sup>™</sup> XM

We were encouraged by the initial results seen in the clinical trial for OrthoPure<sup>™</sup> XM; proving the implant to be biocompatible, and showing integration into the patient's own tissue. However, OrthoPure<sup>™</sup> XM is currently undergoing an optimisation study to allow a single version to be marketed in both the EU and US. Further clarity around the steps needed to gain regulatory approval in the US was also established throughout this period.

#### OrthoPure<sup>™</sup> XT

Prominent progress has been made with OrthoPure<sup>™</sup> XT. We completed the clinical trial enrolment which allowed us to submit the encouraging initial six month clinical data for regulatory approval. It was expected that this approval would be granted by the end of CY16, a full six months ahead of schedule. However, the introduction of new Medical Device Regulations has resulted in an increased scrutiny of clinical results by the European Regulators and continues to make the precise timing of the CE mark approval for OrthoPure<sup>™</sup> XT difficult to predict.

A further submission of twelve month clinical data for OrthoPure™ XT was made, together with a revised packing format providing a shelf life increase from 6 months to 12 months. The product launch will follow shortly after CE mark approval is granted. It is currently expected that this will be achieved during 2017, with initial distributor agreements signed we expect to have a smooth commercial roll out in our key European markets.

#### US

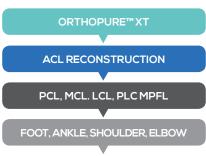
We significantly increased our market presence in the US throughout the year. In addition to the appointment of a VP Orthopaedics in March 2016, we have since appointed a prestigious clinical advisory board, and begun discussions with a number of potential tissue bank partners for our human tissue (allograft) applications.

As illustrated in the strategic report, we employ a dual tissue strategy and the commercialisation plan for our Orthopaedic products in the US is to lead with our allograft applications. The development of the OrthoPure<sup>™</sup> HT decellularisation process has been completed and we are now in a position to transfer to a US tissue bank processing and distribution partner once identified.

We have also been encouraged by initial conversations with the FDA, which are currently ongoing, to potentially accelerate a first in human US clinical study for OrthoPure™ XT. This study will facilitate a better understanding of milestones needed to enable market approval for OrthoPure™ XT in the USA.

#### **Potential Line Extensions**

Additional intra and extra articular indications are already in the late stages of development, as product line extensions. It is expected that regulatory submissions for these will also be made during 2017 and into 2018.





### MARKET OPPORTUNITY

The gold standard treatment for an ACL reconstruction is currently an autograft procedure. This involves "harvesting" tendon or ligament tissue from the patient's body. Autografts have been associated with an increase in operation time, complications and morbidity of second surgical site, increased rehabilitation time and a decrease in function at the harvest site.

Anterior Cruciate Ligament injury is very frequent, not only in professional athletes but also in anyone who practises sports regularly and increasingly in the elderly active populations. Conservative treatment usually fails and patients may show an accelerated onset of degenerative joint changes. ACL reconstruction aims to eliminate knee instability and prevent such degenerative changes and are amongst the most common sports medicine procedures performed globally each year at an estimated 720,000, creating a potential market of approximately \$2bn.

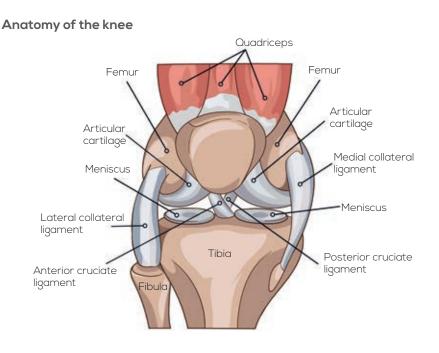


## 

#### Summary

Throughout the year we achieved significant milestones for the commercialisation of OrthoPure™ XT in Europe. We were encouraged by the initial clinical results returned from the trial and feel we are positioned to have a successful commercial launch into key European markets once CE mark approval is gained. Line extensions into additional application areas are being researched and it is expected that regulatory submission for these will quickly follow allowing for an early 2018 launch.

In the US, we have begun to establish the necessary regulatory work required to launch our porcine products into this market. In the meantime, we have been focused on establishing a foothold with the allograft derived version of our products and expect that we will have identified relevant partners, to allow for a technology transfer and launch towards the back end of the year.





#### What is sports medicine?

Sports medicine focuses on helping people recover from injury and prevent future injuries. Tissue Regenix focuses on soft tissue injuries which can affect ligaments and tendons.

OrthoPure<sup>™</sup> XT will initially address Anterior Cruciate Ligament (ACL) injuries, one of the most common injuries sustained through physical activity. The ACL is a fibrous band which runs diagonally in the middle of the front of the knee. Its primary function is stability, preventing the tibia (shin bone) sliding in front of the femur (thigh bone). The main causes of injury to the ACL are activities which involve a quick acceleration/ deceleration, change of direction, planting, twisting and jumping, and it therefore often affects participants in sports such as football, basketball, tennis, swimming and running.

However, it is unusual for such a trauma to the knee joint to occur in isolation; therefore, serious ACL injuries are often accompanied by damage to other knee ligaments, or a tear to the meniscus. The meniscus is the cushioning that sits between the knee bones, and a tear to this can lead to uneven wearing of the joint surface and possible early onset osteoarthritis.

TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

### **CFO Statement**



"THE GROUP REPORTED WOUND CARE REVENUES OF £1,322K FOR THE 11-MONTH PERIOD (JANUARY 2016: £808K), AN INCREASE OF 64%."

PAUL DEVLIN CHIEF FINANCIAL OFFICER

Tissue Regenix plc have grown sales by 77% to £1,443k in the 11 months to December 2016 (January 2016: £816k). Operating loss in the same period was £11,060k (January 2016: £10,242k). Finance income was £114k in the period (January 2016: £213k) with a research and development tax credit of £1,034k (January 2016: £527k) generating a loss after tax of £9,912k (January 2016: £9,502k), of which £9,786k was attributable to equity holders.

#### Accounting Reference Date Change

As announced at the last annual result, the Group's accounting reference period has been adjusted to a 31 December year end, meaning that the results now reported are for a shortened 11-month period, and moving forward will bring the fiscal year in line with the calendar year.

#### **Segmental Analysis**

A split of the Group's results by application area, as extracted from the operating segment analysis (see note 3), is shown below along with a further breakdown of administrative costs:

	Wound	d Care	Orthop	aedics	Car	diac	GB	MV	Cer	ntral	То	tal
	11 Months up to 31 Dec 2016 £000	12 Months up to 31 Jan 2016 £000										
Total segment	1,322	884	-	-	-	76	121	-		8	1,443	968
Inter-segment	-	(76)	-	_	-	(76)	-	_			-	(152)
Revenue	1,322	808	-	_	-	-	121	_	-	8	1,443	816
Cost of sales	(288)	(154)	-	_	-	-	(66)	_	-	-	(354)	(154)
Gross Profit	1,034	654	-	_	-	-	55	_	-	8	1,089	662
Administrative costs	(5,500)	(4,938)	(2,738)	(2,382)	(462)	(352)	(308)	(183)	(3,141)	(3,049)	(12,149)	(10,904)
Operating loss	(4,466)	(4,284)	(2,738)	(2,382)	(462)	(352)	(253)	(183)	(3,141)	(3,041)	(11,060)	(10,242)
Finance income	-	_	-	-	_	-		-	114	213	114	213
Loss before taxation	(4,466)	(4,284)	(2,738)	(2,382)	(462)	(352)	(253)	(183)	(3,027)	(2,828)	(10,946)	(10,029)
Taxation	323	169	600	324	111	16		_	-	18	1,034	527
Loss for the year	(4,143)	(4,115)	(2,138)	(2,058)	(351)	(336)	(253)	(183)	(3,027)	(2,810)	(9,912)	(9,502)



	Wound Care Orthopaedics		Car	Cardiac GB		3MV Ce		ntral To		otal		
	11 Months up to 31 Dec 2016 £000	12 Months up to 31 Jan 2016 £000										
Development	(388)	(1,108)	(2,376)	(2,279)	(363)	(289)	_	_	-	-	(3,127)	(3,676)
Sales and marketing*	(4,626)	(3,672)	(246)	_	_	_		_	_	_	(4,872)	(3,672)
Operations**	(486)	(158)	(116)	(103)	(99)	(63)	(308)	(183)	(3,141)	(3,049)	(4,150)	(3,556)
Administrative costs	(5,500)	(4,938)	(2,738)	(2,382)	(462)	(352)	(308)	(183)	(3,141)	(3,049)	(12,149)	(10,904)

\* Sales and Marketing for Wound Care includes the entire costs for our US entity. Included within these costs is £607k (2016: £303k) commission on sales

\*\* Operations includes travel, finance, board, legal, premises, depreciation, share based payment charge

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. For the first time, controlled joint venture GBM-V has been separately analysed. Central overheads, which primarily relate to operations of the Group function are generally not allocated to the business units. These accounts have been prepared on a going concern basis and I draw the readers attention to the going concern statement in the Corporate Governance Statement and Note 1 to the financial accounts.

#### Wound Care

The Wound Care division remains by far the largest contributor to sales for the Group, with revenues of £1,322k for the 11-month period (January 2016: £808k), an increase of 64%. We continue to implement our dual sales strategy, utilising both direct reps and distributors for DermaPure®. We also gained significant traction toward year end with the announcement of the Premier, Inc. GPO contract; however, due to the timing of the agreement it had no material impact on these figures. Following year end, we also gained approval under Vizient, Inc, the largest member owned GPO in the US. Combined, this allows for potential access to 75% of inpatient beds and we would expect to see the results of this reflected in the next set of annual results. The launch of SurgiPure<sup>™</sup> XD was postponed to allow for the redeployment of resources.

Gross margin for the 11 month period was 75%, in line with prior year (January 2016: 81%), and reflects the continued programme of providing evaluation units and improving market penetration. Additional product sizes have been introduced over the course of the year, adding to the product mix effect on the margin.

Development costs for the post market clinical data verification of DermaPure<sup>®</sup> charged to the P&L has decreased year on year to £388k (January 2016: £1,108k) as costs to the value of £550k were capitalised as SurgiPure<sup>™</sup> XD received 510k clearance, reflecting the move to a commercial product. Sales and Marketing costs of £4,626k were incurred in the period (January 2016: £3,672k), which are expected to yield revenue benefits in FY17. Commissions paid in the period of £607k (January 2016: £303k) were driven by the increase in sales via the distributor channel.

#### **Orthopaedics**

Investment in Orthopaedics continued in the 11 month period with development costs of £2,376k (January 2016: £2,279k), and the recruitment of two commercial positions; a VP Orthopaedics North America to lead our entry into the US market place with human tissue derived products, and a EU Sales and Marketing Manager for Orthopaedics in preparation for the launch and commercialisation of OrthoPure<sup>™</sup>XT. Costs have also been incurred on developing marketing material in advance of the launch of product into the market. Currently, OrthoPure<sup>™</sup> XT is expected to be launched during 2017, subject to CE mark approval.

#### Cardiac

The results for the year for this segment are not material. The joint venture tissue bank has however been separately reported on and is commented below. The £76k of income from prior year relates to licensing received in January 2016, which will fall into the following year as a result of the change in accounting reference date.

#### **GBM-V**

Our controlled joint venture processes our human tissue applications within Europe, and reported its first sales of £121k derived from the commercialisation of cryo-preserved corneas, it is expected that regulatory approval for dCELL<sup>®</sup> products DermaPure<sup>®</sup> and CardioPure<sup>™</sup> (human heart valves) will be achieved by year end, with commercialisation expected in the first half of 2018. GBM-V is consolidated for accounting purposes as the accounting standards require this due to having a majority of voting rights and therefore control.

#### Central

Central costs in the period were £3,141k (January 2016: £3,049k), with the increase being driven by relocating all UK personnel into one premises.

#### **Finance income**

Finance income decreased to £114k (January 2016: £213k) and represents interest earned on cash deposits. The Group follows a risk-averse policy of treasury management. Cash deposits are held across a number of counter parties with institutions of prime financial standing. The Group's primary objective is to minimise exposure to potential capital losses whilst at the same time securing prevailing market rates.

#### Taxation

The Group continues to submit enhanced research and development tax claims and elects to exchange tax losses for a cash refund. The expected refund for the period to December 2016 is £1,034k (January 2016: £527k). Tax losses carried forward by the Group at the end of December 2016 were £32,037k (January 2016: £23,772k). The Group therefore does not expect to pay corporation tax for a number of years. Once profitable, the Group also expects to fall within the Patent Box regime and benefit from the reduced corporation tax rate within it.

#### **Cash Balances**

As at 31 December 2016 the Group had cash resources of £8,173k (January 2016: £19,907k) and was debt free. The outflow in the year of £11,734k (January 2016: £9,650k inflow after £20m financing) is driven by the cash loss attributable to operating activities.

### **Risks**

THE BOARD CAREFULLY CONSIDERS THE RISKS FACING THE GROUP AND ENDEAVOURS TO MINIMISE THEIR IMPACT THROUGH THE NECESSARY MITIGATING ACTIONS. THE PROMINENT RISKS FACING THE GROUP AT THIS TIME ARE LISTED BELOW.

RISK AND IMPACT	MITIGATING FACTORS
Sourcing of Tissues As we have a variety of tissue derived products the supply of suitable donated human tissue could be a limitation. We also rely on sourcing human tissue from accredited tissue bank partners who carry their own company risks and potential failures. There are also ethical implications around the sourcing of human tissue and ensuring its proper use.	We employ a dual tissue strategy meaning that we can ensure that supply will meet demand with our porcine variations of products. Currently, we only have one tissue bank partner, therefore, we are actively seeking another source to mitigate the reliance on a single source. We will only partner with tissue banks, and in territories that meet our own ethical standards.
Intellectual Property The success of the Group hinges on our ability to exploit our intellectual property and ensure that this is not breached. We hold a number of process patents; however, these can be difficult to defend.	A significant amount of "know-how" is retained within the Company which is not disclosed under patents.
Management of Cash The Company is currently consuming cash to fund working capital. Whilst the funds raised are anticipated to provide funding for the foreseeable future. The Company must ensure adequate measures are in place to ensure to control and manage cash	The Company reports and forecasts cash on a regular basis ensuring sufficient funds are in place. These forecasts and reports are reviewed by the board monthly
Macroeconomic Risk There is currently uncertainty around the position of Britain's exit from the EU, the impact that this may have on regulatory pathways and the potential for political changes to the NHS. There have also been significant changes since the US election and it is still unclear how this may affect the healthcare and reimbursement systems long term.	Government imposed restrictions on healthcare spending work in our favour as dCELL <sup>®</sup> products can potentially offer optimal standard of care with less applications, or reduced rehab time. There is also a minimised re-operation rate, reduced risk of rejection and no need for anti- coagulant drugs.
<b>Clinical Trials and Regulatory Pathways</b> We currently have a number of ongoing clinical trials and are in the process of establishing the necessary work for US regulatory pathways for porcine orthopaedic applications. Failure to comply with the pageager clinical and chical work applications.	The Group has invested heavily in a robust regulatory and quality department ensuring that the Company operates within the necessary guidelines for each territory. We employ a number of external advisers to ensure that we remain within the restrictions imposed by clinical trials and to ensure correct reporting of all

with the necessary clinical and ethical work specific to each

country would present a barrier to entry and significant financial

imposed by clinical trials and to ensure correct reporting of all results. The manufacturing facility is ISO 13485 accredited, and we follow all regulatory imposed operational requirements.

implications.





#### **RISK AND IMPACT**

<b>Transfer of Technology to Partners</b> In order to process our human tissue applications we require the transfer of the technology to partners where there is the potential for a leak of Intellectual Property.	Any transfer of Intellectual Property or "know-how" is done so under strict legal agreements and the Group looks only to undertake such arrangements with partners, and in territories where there is appropriate legal protection.
<b>Retention of Staff</b> We have a number of roles which require specialised knowledge of the Technology, and Company, which are also privy to sensitive Intellectual Property. There are also commercial roles fundamental in building the commercial success of the Company across various subsidiaries and territories.	The Company ensure to an internal succession plan in place for all positions fundamental to the smooth operating of the Company and continually monitors the relevant talent pools for future recruitment. Staff privy to sensitive information are tied into non- disclosure agreements and were a breach of intellectual property to happen, all clinical data for dCELL® Technology is owned and specific to the Tissue Regenix Group.
Damage to Manufacturing Facility There is the potential for a damaging incident, e.g. fire, to occur at our manufacturing facility. This would have an impact on production of our porcine products and therefore potential sales.	We have a comprehensive risk analysis procedure in place and test all alarm systems on a weekly basis, whilst continually pact testing all electrical equipment. We have an out of hours team that are available around the clock should a breach occur out of operating hours. Our research and development laboratories are contained within separate building units, meaning that should there be an incident in one, it will not affect all business activities. Should a power outage occur, a number of generators can be employed to ensure that this does not affect the manufacturing process or loss of the temperature controlled materials.
<b>Product Quality</b> The Group operates in a highly regulated environment with strict quality requirements. Failure to meet these standards could result in the loss of reputation, loss of revenues, loss of a customer, recall costs as well as sanctions from the regulator.	The Group operates a strictly controlled Quality Management System and has in-house experts to ensure compliance with all regulatory requirements. We continually test the quality of our products in-house and have these results verified by external analysis.
<b>Competition</b> As the focus on regenerative medicine increases there may be products or companies that could be in direct competition with our product portfolio or decellularisation technology which could potentially have a detrimental effect on the commercial success of the Company. This now also includes to a much larger extent breakthrough a modern technology up as 2D printing	We continually monitor the competitive landscape in order to understand where best to position our products and the alternative treatment options that may be available.

**MITIGATING FACTORS** 

breakthroughs in modern technology such as 3D printing.

### **Board of Directors**





John Samuel joined Tissue Regenix Limited as Chairman in March 2008. John qualified as a Chartered Accountant with Price Waterhouse and has held a number of senior finance positions in industry. He was formerly the CEO of the Molnlycke Health Care Group, a global provider of single use surgical and wound care products to the healthcare sector. Until January 2010 he was a Partner with Apax Partners LLP. Currently he is also Chairman of Xeros Group Plc, and VernaCare Group Ltd.



#### **Antony Odell**

Chief Executive Officer

Antony Odell was appointed CEO of Tissue Regenix in October 2008 and has led its growth from a small privately held spin-out to the present time. He has over 30 years commercial experience in the medical technology sector. Antony has a strong corporate sector background having worked for Critikon, Johnson & Johnson Medical and was European Business Director for its Vascular Access franchise, General Manager (UK & Ireland) for Fresenius (Critical Care & Diagnostics) and International Knee Manager for Stryker (Howmedica International). Antony was also VP, Medical for BTG when the company was involved in early stage technology commercialisation and was CEO for a Scottish NHS cardiovascular device spin-out, Tayside Flow Technologies Ltd (now Vascular Flow Technologies Ltd).



#### **Paul Devlin**

Chief Financial Officer

Paul joined Tissue Regenix plc as CFO in January 2017, having spent the largest part of his career in businesses undergoing significant change. His experience includes listed and private equity owned businesses in the FMCG, food, pharmaceutical and healthcare technology sectors. Recent experience includes the sale of Fletchers Bakeries to Finsbury Food Group plc, part of which was the successful reverse listing of Fletchers on AIM. Previous employment includes Northern Foods plc, Mallinckrodt Inc., Bakkavor and Tunstall Healthcare.



#### **Jonathan Glenn**

Non-Executive Director

Jonathan was Group Finance Director of Consort Medical plc from September 2006 to December 2007 until he took up the position of Chief Executive Officer in December 2007. Prior to joining Consort Medical plc, Jonathan was global Head of Finance at Celltech Group plc and later Chief Financial Officer of Akubio Ltd, a Cambridge-based developer of instrumentation for the Life Sciences industry. Mr Glenn is a member of the Institute of Chartered Accountants in England and Wales.





#### **Alan Miller**

Non-Executive Director

Alan Miller is the Chief Investment Officer and a Founding Partner of SCM Direct, an online wealth management company. He was formerly the Chief Investment Officer and founding shareholder of New Star Asset Management from early 2001 until early 2007. Prior to that, Alan was a Director at Jupiter Asset Management in charge of their specialist high performance division between 1994 and 2000. He is also a qualified accountant and alumni of the London Business School.



## Randeep Singh Grewal Non-Executive Director

Randeep Grewal is a fund manager at Trium Capital LLP. He has 17 years of experience in institutional investing having worked at F&C Asset Management, ICAP Equities and Tudor Capital, where he spent ten years covering and investing in healthcare companies. He is also a non-executive director of BB Healthcare Investment Trust, listed on the London Stock Exchange, since December 2016. Randeep has been involved in a number of start-up and early stage companies both personally and as an investor. He read medicine at the University of Cambridge and trained in the NHS as a vascular surgeon for eight years.



#### Steven Couldwell

Non-Executive Director

With over 18 years of senior management experience, Steven Couldwell was formerly Chief Operating Officer and Head of Global Biosurgery division at Sanofi, which has revenues of approximately \$750m. He has a proven international track record in driving revenues and profit growth in the pharmaceutical, medical device and CRO industries. Steven was formerly Vice President and General Manager of Covance Laboratories Europe and worked for Smith & Nephew for almost 20 years in a number of roles including President Orthopaedics (Europe) and Senior VP Sales and Marketing for Smith & Nephew's Advanced Wound Management business.

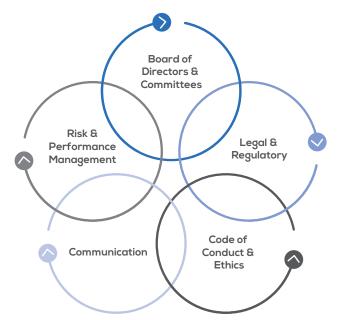


#### Shervanthi Homer-Vanniasinkam

Non-Executive Director

Shervanthi Homer-Vanniansinkim graduated from Mysore University in India in 1981. She later became a Fellow of the Royal College of Surgeons of Edinburgh in 1989, and a Fellow of the Royal College of Surgeons of England in 1998. She was appointed Consultant Vascular Surgeon at Leeds General Infirmary in 1995, a post she continues to hold. She also holds a number of appointments with various higher education and health trusts around the country including; Consultant Vascular Surgeon, The General Infirmary at Leeds, Clinical Sub-Dean, University of Leeds Medical School, Professor of Surgery (Founding), University of Warwick Medical School & University Hospitals Coventry and Warwickshire NHS Trust, Professor of Engineering and Surgery, University College London.

### **Governance Framework**



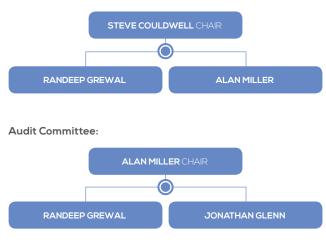
THE COMPANY EMPLOYS SEVERAL LEVELS OF CORPORATE GOVERNANCE MANAGEMENT IN ORDER TO MINIMISE RISK, ENSURE COMPLIANCE AND STRATEGIC ALIGNMENT THROUGHOUT ALL MEMBERS OF THE GROUP AND ITS SUBSIDIARY COMPANIES.

The structure of the internal control system is separated into many levels linked by consistent and transparent communications, both to internal and external stakeholders.

#### The Board of Directors & Committees:

Monitor the internal control system, reviewing accounting information, potential business risks, employee policies and market communications. The Board also splits into an Audit and Remuneration Committee to ensure compliance with market imposed regulations:

#### **Remuneration Committee:**



#### Legal & Regulatory

We employ a number of legal and regulatory advisers, for both our stock exchange listing, and also validation of our products and clinical trial pathways.

#### **Business Practices & Ethics**

As a Company that operates in a highly regulated and sensitive environment we ensure that we operate with a vigorous code of conduct and ethics. We also monitor any existing and potential partners to ensure that they align with our company values.

#### **Risk & Performance Management**

As a Company we are well aware of, and continually monitor, the primary risks to our business, and any external developments that occur that could have a detrimental effect on the performance of the Company and look to take the necessary actions to mitigate any impact that these could have on our performance.

Internally, we report our monthly performance against a number of objectives and COGs allowing us to track performance management, and identify and potential improvements to our structure and operational efficiencies.

#### Communications

We communicate any relevant Company news to external stakeholders in the most timely manner possible through the necessary news flow outlets. The Board reviews all relevant information to ensure that the correct information is adequately explained to offer transparency and a true reflection of the Company. Internal and cross company communications is equally as valued and we have a number of staff engagement initiatives in order to keep knowledge and alignment with the Corporate positioning, values and progress high.



### **Corporate Governance Statement**

#### **Corporate governance**

The Directors recognise the importance of sound corporate governance and have observed the principles of the UK Corporate Governance Code, to the extent that they consider them appropriate for the Group's size, throughout the accounting year.

#### **The Board**

The Board currently comprises three Executive Directors and five Non-Executive Directors.

#### **Audit Committee**

The Audit Committee's primary responsibilities are to monitor the integrity of the financial affairs and statements of the Company, to ensure that the financial performance of the Company and any subsidiary of the Company is properly measured and reported on, to review reports from the Company's Auditors relating to the accounting and internal controls and to make recommendations relating to the appointment of the external Auditors.

The Audit Committee comprises Alan Miller, who acts as chairman of the committee, Jonathan Glenn and Randeep Grewal.

#### **Internal Control**

The Board is responsible for maintaining a sound system of internal control. The Board's measures are designed to manage, not eliminate risk, and such a system provides reasonable but not absolute assurance against material misstatement or loss. The Board confirms that it has established the procedures necessary to implement the guidance "Internal Control Guidance for Directors on the Combined Code" (The Turnbull Report).

Some key features of the internal control system are:

- Management accounts information, budgets, forecasts and business risk issues are regularly reviewed by the Board who meet at least ten times per year;
- II. The Company has operational, accounting and employment policies in place;
- III. The Board actively identifies and evaluates the risks inherent in the business and ensures that appropriate controls and procedures are in place to manage these risks;
- IV. There is a clearly defined organisational structure; and
- There are well-established financial reporting and control systems.

#### **Going Concern**

As at 31 December 2016, the Group had £8.2m of cash and cash equivalents available to it, with an updated balance as of 30 April 2017 of £5.4m, providing the Group with sufficient funds until Q3 of the current year. The Directors have considered their obligation, in relation to the assessment of the going concern of the Group and each statutory entity within it and have reviewed the current budget cash forecasts and assumptions as well as the main risk factors facing the Group as set out on page 16.

The Directors reasonably believe that additional funds will be raised before current funding is exhausted that will provide the company with sufficient funds to continue its activities for not less than 12 months from the date of approval of these financial statements. The growing commercial traction of the wound care business in the US and the increasing contribution to Group revenue from the GBM-V controlled joint venture, also reduce the historic rate of cash consumption, which is currently £1m per month. These financial statements have therefore been prepared on a going concern basis.

### **Directors' Remuneration Report**

#### **Remuneration Policy**

The Group's policy is to provide Executive Directors with a competitive market-based package in order to reward individual and Group performance and deliver outstanding shareholder returns. The Remuneration Committee is committed to ensuring that the Company's key executive team is incentivized to drive sustainable earnings growth and returns to shareholders, thereby creating a genuinely strong alignment of interests between management and investors.

It is the Company's policy that Executive Directors should have contracts with an indefinite term providing for a maximum of six months' notice. In the event of early termination, the Directors' contracts provide for compensation up to a maximum of basic salary for the notice period.

Non-Executive Directors are employed on letters of appointment which may be terminated on not less than three months' notice.

Companies with securities listed on AIM do not need to comply with the UKLA Listing Rules. The Remuneration Committee is however committed to maintaining high standards of corporate governance and disclosure and has applied the guidelines as far as practical given the current size and development of the Company.

#### **Remuneration Committee**

The Remuneration Committee's primary responsibilities are to review the performance of the Executive Directors of the Company and to determine the broad policy and framework for their remuneration and the terms and conditions of their service and that of senior management (including the remuneration of and grant of options to such persons under any share scheme adopted by the Company). The Remuneration Committee comprises Steven Couldwell, who is chairman of the committee, Randeep Grewal, and Alan Miller. The committee meets no less than twice in each financial year.

The main elements of the remuneration packages for Executive Directors and senior management are:

#### **Basic annual salary**

The base salary is reviewed annually at the beginning of each year. The review process is undertaken by the Remuneration Committee and takes into account several factors, including the current position and development of the Group, individual contribution and market salaries for comparable organisations.

#### **Discretionary annual bonus**

All Executive Directors and senior managers are eligible for a discretionary annual bonus which is paid in accordance with a bonus scheme developed by the Remuneration Committee. This takes into account individual contribution, business performance and commercial progress, along with financial results.

On 24 April 2014 the Remuneration Committee approved the implementation of a deferred annual bonus plan to commence from the financial year ended 31 January 2014 (the "Deferred Annual Bonus Plan"). Under the terms of the Deferred Annual Bonus Plan directors and senior managers may waive up to 50% of their annual cash bonus and in return receive a share option over ordinary shares in the Company (the "Deferred Allocation"). The number of ordinary shares comprising the Deferred Allocation (i.e. subject to the option) will be calculated by dividing the amount of the cash bonus waived by the closing market value of the ordinary shares of the Company on the dealing day immediately prior to the date of deferral of the bonus. The Deferred Allocation option is not capable of exercise until the vesting date has been reached which is three years from the date of grant of the award. By participating in the Deferred Annual Bonus Plan Directors and senior managers will be entitled to receive a matching award at no additional cost (the "Matching Allocation"). The Matching Award will be an option over ordinary shares in the Company. The number of ordinary shares comprising the Matching Allocation will be equivalent to three times the number of ordinary shares received in the Deferred Allocation. Participants will not be entitled to receive the Matching Allocation until the vesting date is reached which is three years from the date of grant of the award. Additionally, participants will not be entitled to receive the Matching Award unless shares price growth performance targets have been achieved and those price targets sustained for 30 consecutive days.

#### Share incentive schemes

The Group operates a share option plan, under which certain Directors and senior management have been granted options to subscribe for ordinary shares. All options are equity settled. The options are subject to service and performance conditions, have an exercise price of between 0.5 pence and 22.5 pence and the vesting period is generally one-three years. If the options remain unexercised after a period of ten years from the date of grant, the options expire. The Group has no legal or constructive obligation to repurchase or settle the options in cash.

In addition, certain Executive Directors are eligible to acquire interests in ordinary shares in the Company to be owned jointly with the trustee of the Tissue Regenix Group Employee Share Trust (EBT) and under which, subject to meeting performance criteria conditions, most of any future increase in the value of the shares will accrue to the employees.

## Remuneration Policy for Non-Executive Directors

Remuneration for Non-Executive Directors is set by the Chairman and the Executive Members of the Board. Non-Executives do not participate in bonus schemes.



### **Directors' Remuneration**

The remuneration of the main Board Directors' of Tissue Regenix who served in the 11 months to 31 December 2016 was:

	Salary & fees £000	Bonus £000	Benefits £000	Total up to December 2016 £000	Total up to January 2016 £000
Antony Odell <sup>1</sup>	183	100	10	293	310
John Samuel <sup>1</sup>	99	-	-	99	100
lan Jefferson <sup>1*</sup>	240	-	12	252	212
Randeep Grewal	18	-	-	18	20
Steven Couldwell	23	-	-	23	25
Jonathan Glenn	21	-	-	21	-
Alan Miller	23	-	-	23	25
Shervanthi Homer-Vanniansinkim	15	-	-	15	-
Total	622	100	22	744	692

 In addition certain directors hold employee share scheme interests in the company. Fair value share based payment charges recognised in the consolidated statement of comprehensive income attributable to these directors are; John Samuel £4,000 (2015: £13,000), Antony Odell £45,000 (2016: £35,000), Ian Jefferson £NIL (2016: £46,000)

\* Included within this salary is £50,000 for exiting the business, and £52,500 payment in lieu of notice.

#### **Directors' Shareholdings**

Directors' interests in the shares of the Company, including family interests at 31 December 2016 were:

	Ordinary shares of 0.5p each			
	31 December 2016 Number	31 December 2016 %	31 January 2016 Number	31 January 2016 %
John Samuel <sup>2</sup>	24,276,928	3.19%	24,276,928	3.19%
Antony Odell <sup>2</sup>	5,572,800	0.73%	5,572,800	0.73%
lan Jefferson <sup>2</sup>	1,009,404	0.13%	1,009,404	0.13%
Alan Miller	21,886,988	2.88%	21,886,988	2.88%

<sup>2.</sup> Includes shares held jointly by the director and EBT as set out below.

### **Directors' Remuneration Report**

#### Directors' Interests in Jointly Owned EBT Shares and Share Options

Directors' interests in shares owned jointly with the Trustees of the Tissue Regenix Group Employee Benefit Trust (EBT) and in share options to acquire ordinary shares of 0.5 pence each in the Company at 31 January 2016 were:

	At				At	
	1 February 2016	Exercised during year	Lapsed during year	Granted during year	31 December 2016	Exercise price
Approved EMI scheme options						
Antony Odell <sup>1</sup>	8,307,608	_	_	-	8,307,608	0.73 pence
Antony Odell <sup>2</sup>	1,187,200	-	-	-	1,187,200	5.00 pence
Antony Odell <sup>3</sup>	577,777	_	_	-	577,777	22.50 pence
lan Jefferson <sup>4</sup>	872,727	_	-	-	872,727	13.75 pence
lan Jefferson <sup>3</sup>	577,777	-	-	-	577,777	22.50 pence
John Samuel⁵	2,400,000	-	-	-	2,400,000	5.00 pence
John Samuel <sup>3</sup>	577,777	-	-	-	577,777	22.50 pence
Unapproved scheme options						
Antony Odell <sup>6</sup>	422,223	-	-	-	422,223	22.50 pence
Antony Odell <sup>8</sup>	519,480	-	-		519,480	0.05 pence
Antony Odell <sup>10</sup>	_			1,021,936	1,021,936	0.05 pence
lan Jefferson <sup>6</sup>	122,779	_	_	-	122,779	22.50 pence
lan Jefferson <sup>7</sup>	346,936	_	260,202	-	86,734	0.05 pence
lan Jefferson <sup>9</sup>	505,976	_	379,182	-	126,794	0.05 pence
lan Jefferson <sup>11</sup>	_		629,031	838,708	209,677	0.05 pence
John Samuel <sup>6</sup>	88,890	_	_	-	88,890	22.50 pence
EBT scheme shares <sup>12</sup>						
Antony Odell	5,372,800	_	-	_	5,372,800	5.00 pence
lan Jefferson	827,586	-	-	_	827,586	14.50 pence
John Samuel	10,740,000	_	-	_	10,740,000	5.00 pence

1. There were no performance conditions in relation to the 8,307,608 options granted to Antony Odell prior to the reverse acquisition all of which were eligible to be exercised at 31 January 2016.

2. There were employment period and performance conditions in relation to the 1,187,200 options granted on 29 June 2010 which allowed for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant, subject to the Company's share price reaching 10 pence per share, 15 pence per share and 20 pence per share by the respective three vesting dates. As at 31 January 2016 all the performance conditions had been met and the options were eligible for exercise.

3. There were employment period and performance conditions in relation to the 577,777 options granted on 4 February 2014 which allowed for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant, subject to the Company's share price reaching 30 pence per share, 40 pence per share and 50 pence per share by the respective three vesting dates. As at 31 January 2016 none of the performance conditions had been met and no options were eligible for exercise.

4. There were employment period and performance conditions in relation to the 872,727 options granted on 6 July 2011 which allowed for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant, subject to the Company's share price reaching 15 pence per share, 20 pence per share and 25 pence per share by the respective three vesting dates. As at 31 January 2016 all the performance conditions had been met and the options were eligible for exercise.

5. There were employment period and performance conditions in relation to the 2,400,000 options granted on 29 June 2010 which allowed for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant, subject to the Company's share price reaching 10 pence per share, 15 pence per share and 20 pence per share by the respective three vesting dates. As at 31 January 2016 all the performance conditions had been met and the options were eligible for exercise.



- 6. There were employment period and performance conditions in relation to the 422,223, 122,779 and 88,890 options granted on 4 February 2014 which allowed for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant, subject to the Company's share price reaching 30 pence per share, 40 pence per share and 50 pence per share by the respective three vesting dates. As at 31 January 2016 none of the performance conditions had been met and no options were eligible for exercise.
- <sup>7.</sup> There were employment period and performance conditions in relation to the 346,936 options granted on 20 May 2014 under the Company Deferred Annual Bonus plan. 86,734 options vest after three years and correspond to the amount of bonus deferred by the participant. The remaining 260,202 options which relate to the matching award vest in three equal proportions three years after the date of grant, subject to the Company's share price reaching 30 pence per share, 40 pence per share and 50 pence per share by the vesting dates. As at 31 December 2016 the matching award had lapsed due to resignation.
- 8. There were employment period and performance conditions in relation to the 519,480 options granted on 12 May 2015 under the Company Deferred Annual Bonus plan. 129,870 options vest after three years and correspond to the amount of bonus deferred by the participant. The remaining 389,610 options which relate to the matching award vest in three equal proportions three years after the date of grant, subject to the Company's share price reaching 25 pence per share, 30 pence per share and 35 pence per share by the vesting dates. As at 31 January 2016 none of the performance conditions had been met and no options were eligible for exercise.
- 9. There were employment period and performance conditions in relation to the 505,976 options granted on 12 May 2015 under the Company Deferred Annual Bonus plan. 126,494 options vest after three years and correspond to the amount of bonus deferred by the participant. The remaining 379,482 options which relate to the matching award vest in three equal proportions three years after the date of grant, subject to the Company's share price reaching 25 pence per share, 30 pence per share and 35 pence per share by the vesting dates. As at 31 December 2016 the matching award had lapsed due to resignation.
- <sup>10.</sup> There were employment period and performance conditions in relation to the 1,021,936 options granted on 29 June 2016 under the Company Deferred Annual Bonus plan. 255,484 options vest after three years and correspond to the amount of bonus deferred by the participant. The remaining 766,452 options which relate to the matching award vest in three equal proportions three years after the date of grant, subject to the Company's share price reaching 20 pence per share, 25 pence per share and 30 pence per share by the vesting dates. As at 31 December 2016 none of the performance conditions had been met and no options were eligible for exercise
- <sup>11.</sup> There were employment period and performance conditions in relation to the 838,708 options granted on 29 June 2016 under the Company Deferred Annual Bonus plan. 209,677 options vest after three years and correspond to the amount of bonus deferred by the participant. The remaining 629,031 options which relate to the matching award vest in three equal proportions three years after the date of grant, subject to the Company's share price reaching 20 pence per share, 25 pence per share and 30 pence per share by the vesting dates. As at 31 December 2016 the matching award had lapsed due to resignation
- 12. The Tissue Regenix Group Employee Benefit Trust ("the EBT") was established with Osiris Management Services Limited appointed as trustee ("the Trustee") to enable the Trust to acquire ordinary shares in the Company and to make interests in those shares available for the benefit of current and future employees of the Company and its subsidiaries. Antony Odell and John Samuel have interests in ordinary shares in the Company which were acquired jointly with the Trustee in the market on 29 June 2010 at a price of 5 pence per share. Ian Jefferson has an interest in ordinary shares in the Company which were acquired jointly with the Trustee in the market on 25 July 2012 at a price of 14.25 pence. The shares were all acquired pursuant to certain conditions set out in Joint Owned Equity agreements ("JOEs"). Subject to meeting the performance criteria conditions set out in the JOEs, most of any future increase in the value of the shares will accrue to the employees provided that they have not ceased employment with the Group on or before the date that these conditions are met. The employees are also under certain circumstances able to benefit from an increase in the value of the Shares on a takeover, change of control, scheme of arrangement or a voluntary winding-up of the Company. Where the performance conditions are not met, the Trustee has an option to acquire the interests of the employees in the shares at a price equal to the original purchase cost they paid so that none of any increase in the value of the shares will accrue to the shares at a price equal to the original purchase cost they paid so that none of any increase in the value of the shares at a price equal to the original purchase cost they paid so that none of any increase in the value of the shares at 31 January 2015 was 15.38 pence per share, the highest and lowest prices during the year were 20.75 pence and 13.25 pence respectively. Further details of all share options and jointly owned shares held by the Trustee are set out in note 16 to the f

On behalf of the Board

STEVE COULDWELL

CHAIRMAN OF THE REMUNERATION COMMITTEE

2 June 2017

### **Directors' Report**

The Directors present their report and consolidated financial statements for the year ended 31 December 2016.

#### **Principal Activity**

The principal activity of the Group is the exploitation of innovative platform technologies in the field of tissue engineering and regenerative medicine. The Company is incorporated and domiciled in the UK.

#### **Business Model**

A description of the Company's activities and how it seeks to add value are included in the Chairman's statement and Chief Executive's report on pages 4 and 7 to 9.

#### **Business Review and Results**

A review of the Group's performance and future prospects is included in the Chairman's statement and Chief Executive's report on pages 4 and 7 to 9. The loss for the 11 months attributable to equity holders was (£9,787) (12 months to January 2016: £9,411k). The Directors do not recommend the payment of a dividend (2016: nil).

#### **Share Capital and Funding**

Full details of the Group and Company's share capital movements during the year are given in note 15 to the financial statements.

#### **Directors and Their Interests**

The following Directors held office in the year.

John Samuel Antony Odell Ian Jefferson (resigned 21 November 2016) Paul Devlin (appointed 06 January 2017) Steve Couldwell Jonathan Glenn Shervanthi Homer-Vanniansinkam (appointed 01 June 2016) Alan Miller Randeep Singh Grewal

Directors' interests in the shares of the Company, including family interests, are included in the Remuneration Report on pages 22 to 25.

#### **Directors' Indemnity Insurance**

The Group has maintained insurance throughout the year for its Directors and officers against the consequences of actions brought against them in relation to their duties for the Group.

#### **Substantial Shareholders**

As at 31 December 2016, shareholders holding more than 3% of the share capital of Tissue Regenix Group plc were:

Name of shareholder	Number of shares	% of voting rights
Invesco Limited	211,328,351	27.80
Woodford Investment Management LLP	147,057,872	19.35
Techtran Group Ltd	103,042,837	13.56
Baillie Gifford & Co Ltd	50,550,887	6.65
Leeds University	33,980,127	4.39
Jupiter	33,308,392	4.45
NFU Mutual	26,564,000	3.49
John Samuel*	24,276,928	3.19

\* Includes 10,740,000 shares held jointly by the Director and the Tissue Regenix Employee Share Trust.





### **Employment Policies**

The Group supports employment of disabled people where possible through recruitment, by retention of those who become disabled and generally through training, career development and promotion.

The Group is committed to keeping employees as fully informed as possible with regard to the Group's performance and prospects and seeks their views, wherever possible, on matters which affect them as employees.

## Statement as to Disclosure of Information to the Auditor

The Directors who were in office on the date of approval of these financial statements have confirmed, that as far as they are aware, that there is no relevant audit information of which the Auditor is unaware. Each of the Directors has confirmed that they have taken all the steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that it has been communicated to the Auditor.

#### **Auditor**

In accordance with section 489 of the Companies Act 2006, a resolution to appoint KPMG LLP as Auditor will be made to members at the Annual General Meeting.

On behalf of the Board

#### ANTONY ODELL

CHIEF EXECUTIVE OFFICER 2 June 2017

### **Statement of Directors' Responsibilities**

IN RESPECT OF THE ANNUAL REPORT AND THE FINANCIAL STATEMENTS

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and parent company financial statements for each financial year. As required by the AIM Rules of the London Stock Exchange they are required to prepare the Group financial statements in accordance with IFRSs as adopted by the EU and applicable law and have elected to prepare the parent company financial statements on the same basis.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and parent Company and of their profit or loss for that period. In preparing each of the Group and parent company financial statements, the Directors are required to:

- O select suitable accounting policies and then apply them consistently;
- O make judgements and estimates that are reasonable and prudent;
- O state whether they have been prepared in accordance with IFRSs as adopted by the EU; and
- O prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and the parent company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the parent company's transactions and disclose with reasonable accuracy at any time the financial position of the parent company and enable them to ensure that its financial statements comply with the Companies Act 2006. They have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.





## Independent Auditor's Report

TO THE MEMBERS OF TISSUE REGENIX GROUP PLC

We have audited the financial statements of Tissue Regenix Group plc for the period ended 31 December 2016 set out on pages 30 to 55. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the EU and, as regards the Parent Company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an Auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members, as a body, for our audit work, for this report, or for the opinions we have formed.

#### **Respective Responsibilities of Directors and Auditor**

As explained more fully in the Directors' Responsibilities Statement set out on page 28, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. Our responsibility is to audit, and express an opinion on, the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

#### Scope of the Audit of the Financial Statements

A description of the scope of an audit of financial statements is provided on the Financial Reporting Council's website at www.frc.org.uk/ auditscopeukprivate.

Opinion on financial statements

In our opinion:

- O the financial statements give a true and fair view of the state of the Group's and of the parent company's affairs as at 31 December 2016 and of the Group's loss for the period then ended;
- O the Group financial statements have been properly prepared in accordance with IFRSs as adopted by the EU;
- O the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the EU and as applied in accordance with the provisions of the Companies Act 2006; and
- O the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

#### **Opinion on Other Matters Prescribed by the Companies Act 2006**

In our opinion the information given in the Strategic Report and the Directors' Report for the financial year is consistent with the financial statements.

Based solely on the work required to be undertaken in the course of the audit of the financial statements and from reading the Strategic report and the Directors' report:

O we have not identified material misstatements in those reports; and

O in our opinion, those reports have been prepared in accordance with the Companies Act 2006.

#### Matters on Which We Are Required to Report by Exception

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- O adequate accounting records have not been kept by the Parent Company, or returns adequate for our audit have not been received from branches not visited by us; or
- O the Parent Company financial statements are not in agreement with the accounting records and returns; or
- O certain disclosures of Directors' remuneration specified by law are not made; or
- O we have not received all the information and explanations we require for our audit.

#### IAN BEAUMONT (SENIOR STATUTORY AUDITOR)

FOR AND ON BEHALF OF KPMG LLP, STATUTORY AUDITOR CHARTERED ACCOUNTANTS 1 SOVEREIGN SQUARE LEEDS LS1 4DA 2 June 2017

### **Consolidated Statement of Comprehensive Income**

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

	Notes	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
REVENUE	3	1,443	816
Cost of sales		(354)	(154)
GROSS PROFIT		1,089	662
Administrative expenses	3	(12,149)	(10,904)
OPERATING LOSS	4	(11,060)	(10,242)
Finance income	6	114	213
LOSS BEFORE TAXATION		(10,946)	(10,029)
Taxation	7	1,034	527
LOSS FOR PERIOD		(9,912)	(9,502)
ATTRIBUTABLE TO:			
Equity holders of the parent		(9,786)	(9,410)
Non-controlling interests		(126)	(92)
		(9,912)	(9,502)
OTHER COMPREHENSIVE INCOME:			
Foreign currency translation differences – foreign operations		(1)	(1)
TOTAL COMPREHENSIVE EXPENSE FOR THE PERIOD		(9,913)	(9,503)
ATTRIBUTABLE TO:			
Equity holders of the parent		(9,787)	(9,411)
Non-controlling interests		(126)	(92)
		(9,913)	(9,503)
LOSS PER SHARE			
Basic and diluted on loss attributable to equity holders of the parent	8	(1.29)p	(1.27)p

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

The accompanying notes form an integral part of the financial statements.



## **Consolidated Statement of Changes in Equity**

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

	Attributable to equity holders of the parent									
	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 £000	Non- controlling interests £000	Total equity £000
At 31 January 2015	3,271	31,972	10,884	(7,148)	(831)	810	(27,380)	11,578	-	11,578
Loss for the period	-	-	-	-	-	_	(9,410)	(9,410)	(92)	(9,502)
Other comprehensive expense	_	_	_	_	_	_	(1)	(1)	_	(1)
Loss and total comprehensive expense for the period	_	_	_	_	_	_	(9,411)	(9,411)	(92)	(9,503)
Non-controlling interest arising on creation of a joint venture	_	_	_	_	_	_	_	_	9	9
Issue of shares	526	18,421	_	-	-	_	-	18,947	-	18,947
Exercise of share options	4	68	_	_	_	_	_	72	_	72
Share based payment expense	_	_	_	_	_	136	_	136	_	136
At 31 January 2016	3,801	50,461	10,884	(7,148)	(831)	946	(36,791)	21,322	(83)	21,239
Loss for the period	-	-	-	-	-	-	(9,786)	(9,786)	(126)	(9,912)
Other comprehensive expense	_	_	_	_	_	_	(1)	(1)	_	(1)
Loss and total comprehensive expense for the period	_	_	_	_	_	_	(9,787)	(9,787)	(126)	(9,913)
Non-controlling interest arising on creation of a joint venture	_	_	_	_	_	_	_	_	_	_
Issue of shares	-	_	_	_	_	-	-	-	-	_
Exercise of share options	_	_	_	_	_	_	_	_	_	_
Share based payment expense	_	_	_	_	_	210	_	210	_	210
At 31 December 2016	3,801	50,461	10,884	(7,148)	(831)	1,156	(46,578)	11,745	(209)	11,536

The accompanying notes form an integral part of the financial statements.

### **Consolidated Statement of Financial Position**

AS AT 31 DECEMBER 2016

	Notes	As at 31 December 2016 £000	As at 31 January 2016 £000
ASSETS			
Non-current assets			
Property, plant and equipment	9	1,087	901
Intangible assets	10	550	-
TOTAL NON-CURRENT ASSETS		1,637	901
Current assets			
Inventory	n	661	64
Trade and other receivables	12	3,130	2,325
Cash and cash equivalents	13	8,173	19,907
TOTAL CURRENT ASSETS		11,964	22,296
TOTAL ASSETS		13,601	23,197
LIABILITIES			
Current liabilities			
Trade and other payables	14	(2,065)	(1,958)
TOTAL LIABILITIES		(2,065)	(1,958)
NET ASSETS		11,536	21,239
EQUITY			
Share capital	15	3,801	3,801
Share premium	15	50,461	50,461
Merger reserve	15	10,884	10,884
Reverse acquisition reserve	15	(7,148)	(7,148)
Reserve for own shares		(831)	(831)
Share based payment reserve	18	1,156	946
Retained earnings deficit	16	(46,578)	(36,791)
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF PARENT		11,745	21,322
Non-controlling interests		(209)	(83)
TOTAL EQUITY		11,536	21,239

Approved by the Board of Directors and authorised for issue on 2 June 2017.

The accompanying notes form an integral part of the financial statements.

JOHN SAMUEL PAUL DEVLIN CHAIRMAN

CHIEF FINANCIAL OFFICER

Company number: 5969271



### **Consolidated Statement of Cash Flows**

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

	Notes	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Operating activities			
Operating loss		(11,060)	(10,242)
Adjustment for:			
Depreciation of property, plant and equipment	9	301	245
Share based payment	18	210	136
Cash R&D tax credit received		319	745
Operating cash outflow		(10,230)	(9,116)
Increase in inventory		(597)	(30)
Increase in trade and other receivables		(90)	(596)
Increase in trade and other payables		106	862
Net cash outflow from operations		(10,811)	(8,880)
INVESTING ACTIVITIES			
Interest received	6	114	213
Net cash acquired on creation of joint venture	0		9
Capitalised development expenditure	10	(550)	0
Purchases of property, plant and equipment	9	(487)	(711)
Net cash (outflow)/inflow from investing activities		(923)	(489)
			( /
FINANCING ACTIVITIES			
Proceeds from issue of share capital	15	-	19,019
Net cash inflow from financing activities		-	19,019
(Decrease)/increase in cash and cash equivalents		(11,734)	9,650
Cash and cash equivalents at start of period		19,907	10,257
CASH AND CASH EQUIVALENTS AT END OF PERIOD		8,173	19,907

The accompanying notes form an integral part of the financial statements.

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

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

#### **1) BASIS OF PREPARATION**

The financial statements of Tissue Regenix Group plc are audited consolidated financial statements for the period to 31 December 2016. These include audited comparatives for the year to 31 January 2016.

As announced in the previous annual report the Board changed the accounting year end to 31st December to bring it in line with calendar year and therefore these accounts are showing an 11 month period to the comparative 12 month fiscal year.

The Group financial statements consolidate the financial statements of Tissue Regenix Group plc and the entities it controls, its subsidiaries.

#### **Going Concern**

At 31 December 2016, cash balances were £8.2m, with an updated cash balance as of 30 April 2017 of £5.4m, which is considered sufficient to meet the needs of the business until the end of Q3 2017. It is expected that the Group's historic cash burn of c.£1m a month is representative of the cash requirements for the Group to continue its ongoing activities for not less than the following 12 months. Significant milestones have been achieved during the year, with listings in the US with GPO's (Group Purchasing Organisations) covering 75% of the US inpatient market, along with 93% Medicare coverage for outpatient use, and the addition of Tissue Regenix to the Federal Supply Schedule, all of which demonstrate the viability of the Group's commercial model. In line with the Group's business plan further funding is envisaged as the Group seeks to commercialise and develop its products.

The Directors, having taken appropriate advice, reasonably believe that additional equity funds will be committed before the end of Q3 2017, to allow the Group to continue its operations and to continue to commercialise and develop its products; accordingly, the Directors have a reasonable expectation that the Group will have adequate resources to continue in operation for the foreseeable future.

Although there can be no certainty in relation to the Group's abilities to secure such funding, the Directors have a reasonable expectation that the Group will have adequate resources to continue in operation for the foreseeable future and consider it appropriate to continue to adopt the going concern basis in preparing the financial statements.

#### **2) SIGNIFICANT ACCOUNTING POLICIES**

The 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 principal accounting policies applied are set out below.

#### Revenue

Revenue is measured as the fair value of the consideration received or receivable in the normal course of business, net of discounts, VAT and other sales related taxes and is recognised to the extent that it is probable that the economic benefits associated with the transaction will flow into the Company.

Grant income is recognised as earned based on contractual conditions, generally as expenses are incurred.

#### **Foreign currencies**

The individual financial statements of each Group entity are presented in the currency of the primary economic environment in which the entity operates (its functional currency). For the purposes of the consolidated financial statements, the results and the financial position of each Group entity are expressed in Pounds Sterling, which are the functional currency of the Company and the presentational currency for the consolidated financial statements.

In preparing the financial statements of the individual entities, transactions in currencies other than the entity's functional currency (foreign currencies) are recorded at the rates of exchange prevailing at the dates of the transactions. At each balance sheet date, monetary items denominated on foreign currencies are retranslated at the rates prevailing at the balance sheet date. Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing at the date when the fair value was determined.

Non-monetary items that are measured in terms of historical cost in foreign currency are not retranslated.

The assets and liabilities of foreign operations are translated using exchange rates at the balance sheet date. The components of shareholders' equity are stated at historical value. An average exchange rate for the period is used to translate the results and cash flows of foreign operations. Exchange differences arising on translating the results and net assets of foreign operations are taken to the translation reserve in equity until the disposal of the investment. The gain or loss in the income statement on the disposal of foreign operations includes the release of the translation reserve relating to the operation that is being sold.



### **Research and development**

Research costs are charged to profit or loss as they are incurred. An intangible asset arising from development expenditure on an individual project is recognised only when all of the following criteria can be demonstrated:

- O it is technically feasible to complete the product and the Company is satisfied that appropriate regulatory hurdles have been, or will be achieved;
- O management intends to complete the product and use or sell it;
- O there is an ability to use or sell the product;
- O it can be demonstrated how the product will generate probable future economic benefits;
- O adequate technical, financial and other resources are available to complete the development, use or sell the product; and
- O expenditure attributable to the product can be reliably measured.

Such intangible assets are amortised on a straight-line basis from the point at which the assets are ready for use over the period of the expected benefit, and are reviewed for an indication of impairment at each reporting date. Other development costs are charged against profit or loss as incurred since the criteria for their recognition as an asset are not met.

The costs of an internally generated intangible asset comprise all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management. Directly attributable costs include employee costs incurred on technical development, testing and certification, materials consumed and any relevant third party cost. The costs of internally generated developments are recognised as intangible assets and are subsequently measured in the same way as externally acquired intangible assets. However, until completion of the development project, the assets are subject to impairment testing only.

#### Leases

Rentals payable under operating leases, which are leases where the lessor retains a significant proportion of the risks and benefits of the asset, are charged in the statement of comprehensive income on a straight-line basis over the expected lease term.

#### Property, plant and equipment

Property, plant and equipment assets are stated at historical cost.

Depreciation is provided on all property, plant and equipment assets at rates calculated to write each asset down to its estimated residual value evenly over its expected useful life, as follows:

Laboratory equipment	over 5 years
Computer equipment	over 3 years
Fixtures and fittings:	over 5 years

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 2) SIGNIFICANT ACCOUNTING POLICIES continued

### Impairment of property, plant and equipment and intangibles

At each reporting date, the Group reviews the carrying amounts of its property, plant and equipment and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any).

Discounted cash flow valuation techniques are generally applied for assessing recoverable amounts using three-year forward looking cash flow projections and terminal value estimates, together with discount rates appropriate to the risk of the related cash generating units.

If the recoverable amount of an asset is estimated to be less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. An impairment loss is recognised as an expense immediately.

#### Amortisation

Amortisation of intangibles is charged to the income statement on a straight-line basis over the estimated economical useful lives of intangible assets, from product launch unless such lives are indefinite. No capitalised development costs to date have been amortised.

#### Share based payments

#### **Share options**

Equity settled share based payment transactions are measured with reference to the fair value at the date of grant, recognised on a straightline basis over the vesting period, based on the Company's estimate of shares that will eventually vest. Fair value is measured using a binomial valuation model.

At each reporting date before vesting, the cumulative expense is calculated, representing the extent to which the vesting period has expired and management's best estimate of the achievement or otherwise of non-market conditions and the number of equity instruments that will ultimately vest. The movement in cumulative expense since the previous reporting date is recognised in the statement of comprehensive income, with a corresponding entry in equity.

#### **Jointly held shares**

Where an employee acquires an interest in shares in the Company jointly with the Tissue Regenix Employee Share Trust, the fair value benefit at the purchase date is recognised as an expense, with a corresponding increase to equity share based payment reserve on a straight-line basis, over the vesting period.

The fair value benefit is measured using a binomial valuation model, taking into account the terms and conditions upon which the jointly owned shares were purchased.

The expected life used in the model has been adjusted, based on management's best estimate, for the effect of non-transferability, sale restrictions, and behavioural considerations.

#### **Financial assets and liabilities**

#### Trade and other receivables

Trade and other receivables do not carry any interest and are initially recognised at fair value. They are subsequently measured at amortised cost using the effective interest rate method, less any provision for impairment.

Impairment provisions are recognised when there is objective evidence that the Group will be unable to collect all of the amounts due under the terms receivable, the amount of such a provision being the difference between the net carrying amount and the present value of the future expected cash flows associated with the impaired receivable.

#### Trade and other payables

Trade and other payables are not interest bearing and are initially recognised at fair value. They are subsequently measured at amortised cost using the effective interest method.

#### Cash and cash equivalents

Cash and cash equivalents comprise cash at hand and deposits on a term of not greater than 12 months.

#### Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax from proceeds.



### Taxation

The tax expense represents the sum of the tax currently payable and deferred tax.

The tax currently payable is based on taxable profit for the period. The Group's liability for current tax is calculated by using tax rates that have been enacted or substantively enacted by the reporting date.

Deferred tax is the tax expected to be payable or recoverable on differences between the carrying amount of assets and liabilities in the financial information and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the balance sheet liability method. Deferred tax liabilities are recognised for all taxable temporary differences and deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised. Deferred tax is calculated at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled using tax rates that have been enacted or substantively enacted by the reporting date. Deferred tax is charged or credited to profit or loss, except when it relates to items credited or charged directly to equity, in which case the deferred tax is also dealt with in equity.

#### **Controlled Joint Venture**

Tissue Regenix Group entered a joint venture in January 2016 establishing GBM-V. The figures for this entity are consolidated within these accounts due to Tissue Regenix Group having control because it owns the majority of the voting rights.

#### Critical accounting estimates and areas of judgement

Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Actual results may differ from these estimates. The estimates and assumptions that have the most significant effects on the carrying amounts of the assets and liabilities in the financial information are discussed below:

#### Equity settled share based payments

The estimation of share based payment costs requires the selection of an appropriate valuation method, consideration as to the inputs necessary for the valuation model chosen and the estimation of the number of awards that will ultimately vest. Inputs subject to judgement relate to the future volatility of the share price of comparable companies, the Group's expected dividend yields, risk free interest rates and expected lives of the options. The Directors draw on a variety of sources to aid in the determination of the appropriate data to use in such calculations. The share based payment charge for the period was £210,000 (31 January 2016: £136,000).

#### Capitalisation of development costs

The point at which development costs meet the criteria for capitalisation is a key judgement. During the year we capitalised development costs of £550,000 in respect of a product / products for which we received 510k clearance. We deem this to be the point at which it becomes probable that future economic benefits will be received from the product and hence the criteria for capitalisation are met. If we had not capitalised these development costs, then there would have been a further charge of £550,000 to the income statement

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 2) SIGNIFICANT ACCOUNTING POLICIES continued

### Accounting standards and interpretations not applied

At the date of authorisation of these financial statements, the following standards and interpretations relevant to the Group that have not been applied in these financial statements were in issue but not yet effective:

		Effective date
IFRS 9	Financial Instruments	1 January 2018
IFRS 15	Revenue from Contracts with Customers	1 January 2018
IFRS 16	Leases	1 January 2019
Annual improvement to IAS12	Recognition of Deferred Tax Assets for Unrealised Losses	1 January 2017

The Directors anticipate that the adoption of these Standards and Interpretations in future years will have no material impact on the financial statements of the Group.

No Standards or Interpretations adopted in the year had any material impact on the financial statements of the Group.

## **3) SEGMENTAL REPORTING**

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

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
USA	1,322	808
Rest of the World	121	8
	1,443	816

#### Analysis of revenue by customer

During the period ending 31 December 2016 the Group had two customers who individually exceeded 10% of revenue. These customers generated 12% and 10% of revenue respectively.

### **Operating segments**

The Group is organised into Cardiac, Wound Care, Orthopaedics and GBM-V divisions for internal management, reporting and decisionmaking, 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 IFRS 8 "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 IFRS 8, 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.



	Woun	d Care	Orthop	aedics	Car	diac	GB	MV	Cer	ntral	То	tal
	11 Months up to 31 Dec 2016 £000	12 Months up to 31 Jan 2016 £000										
Total segment	1,322	884	-	_	-	76	121	-	-	8	1,443	968
Inter-segment	-	(76)	-	_	-	(76)	-	-		-	-	(152)
Revenue	1,322	808	-	_	-	-	121	-	-	8	1,443	816
Cost of sales	(288)	(154)	-	_	-	-	(66)	-	-	_	(354)	(154)
Gross Profit	1,034	654	-	_	-	-	55	-	-	8	1,089	662
Administrative costs	(5,500)	(4,938)	(2,738)	(2,382)	(462)	(352)	(308)	(183)	(3,141)	(3,049)	(12,149)	(10,904)
Operating loss	(4,466)	(4,284)	(2,738)	(2,382)	(462)	(352)	(253)	(183)	(3,141)	(3,041)	(11,060)	(10,242)
Finance income	-	-	-	_	-	-		-	114	213	114	213
Loss before taxation	(4,466)	(4,284)	(2,738)	(2,382)	(462)	(352)	(253)	(183)	(3,027)	(2,828)	(10,946)	(10,029)
Taxation	323	169	600	324	111	16		-	-	18	1,034	527
Loss for the year	(4,143)	(4,115)	(2,138)	(2,058)	(351)	(336)	(253)	(183)	(3,027)	(2,810)	(9,912)	(9,502)

Administrative costs are broken down as follows:

	Wound	d Care	Orthop	aedics	Car	diac	GN	/IBV	Cer	ntral	То	tal
	11 Months up to 31 Dec 2016 £000	12 Months up to 31 Jan 2016 £000										
Development	(388)	(1,108)	(2,376)	(2,279)	(363)	(289)	_	_	-	-	(3,127)	(3,676)
Sales and marketing*	(4,626)	(3,672)	(246)	_	-	-	_	_	-	-	(4,872)	(3,672)
Operations**	(486)	(158)	(116)	(103)	(99)	(63)	(308)	(183)	(3,141)	(3,049)	(4,150)	(3,556)
Admin costs	(5,500)	(4,938)	(2,738)	(2,382)	(462)	(352)	(308)	(183)	(3,141)	(3,049)	(12,149)	(10,904)

\* Sales and Marketing for Wound Care includes the entire costs for our US entity. Included within these costs is £607k (2016: £303k) commission on sales

\*\* Operations includes travel, finance, board, legal, premises, depreciation, share based payment charge

### Other segment information

The Group's non-current assets are predominantly held by UK entities and consequently no geographical statement of financial position disclosures are required.

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

# 4) LOSS FROM OPERATIONS

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Loss from operations is stated after crediting:		
Grant income	-	-
Loss from operations is stated after charging to administrative expenses:		
Depreciation of plant and equipment (see note 9)	301	245
Operating lease rentals – land and buildings	64	341
Staff costs (see note 5)	7,026	4,798
Foreign exchange (gains)/losses	(115)	33
Research and development (inclusive of research and development personnel)	3,127	3,676
Auditor's remuneration:		
<ul> <li>fees payable to Company's Auditor for the audit of the Parent Company and consolidated financial statements</li> </ul>	11	11
- auditing the accounts of subsidiaries pursuant to legislation	20	18
Other services:		
- fees in relation to corporation tax	41	27
- fees in relation to other services	28	13
Total Auditor's remuneration	100	69

# **5) STAFF COSTS**

	11 Months up to 31 December 2016 Number	12 Months up to 31 January 2016 Number
The average monthly number of persons (including Directors) employed by the Group during the period was:		
Directors	7	6
Laboratory and administration staff	73	64
	80	70



	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	6,036	4,090
Share based expense (see note 18)	210	136
Social security, pension and healthcare costs	780	572
	7,026	4,798
Directors' remuneration included above comprised:		
Emoluments for qualifying services	744	788

Directors' emoluments disclosed above include £293,000 paid to the highest paid Director (Dec 2016: £310,000) as well as share based payments benefit of £45,000 (Jan 2016: £35,000).

# 6) FINANCE INCOME

11 Mont up 31 Decemb 20 £0	to er 16	12 Months up to 31 January 2016 £000
Bank interest receivable 1	14	213

# 7) TAXATION

## Tax on loss on ordinary activities

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Current tax:		
UK corporation tax credit on losses of period	(1,034)	(527)
	(1,034)	(527)
Deferred tax:		
Origination and reversal of temporary timing differences	-	_
Tax credit on loss on ordinary activities	(1,034)	(527)

The charge for the period can be reconciled to the loss before tax per the Statement of Comprehensive Income as follows:

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 7) TAXATION continued

## Factors affecting the current tax charges

The tax assessed for the period varies from the small company rate of corporation tax as explained below:

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
The tax assessed for the year varies from the small company rate of corporation tax as explained below:		
Loss on ordinary activities before tax	(10,946)	(10,029)
Tax at the standard rate of corporation tax 20%	(2,189)	(2,006)
Effects of:		
Expenses not deductible for tax purposes	-	27
Research and development tax credits received	(875)	(492)
Surrender of research and development relief for repayable tax credit	1,249	679
Research and development enhancement	(706)	(377)
Prior year adjustment	(158)	(35)
Unutilised tax losses	1,645	1,677
Tax credit for the period	(1,034)	(527)

#### **Deferred Tax**

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Tax losses		
Losses available to carry forward against future trading profits	32,037	23,772
Deferred tax asset – unrecognised*	5,767	4,279

\* The Company has not recognised a deferred tax asset relating to these losses as their recoverability is uncertain.



# 8) 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.

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Total loss attributable to the equity holders of the parent	(9,787)	(9,411)
	No.	No.
Weighted average number of ordinary shares in issue during the period	760,124,264	743,183,878
Loss per share		
Basic and diluted on loss for the period	(1.29)p	(1.27)p

The Company has issued employee options over 12,883,285 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.

# 9) PROPERTY, PLANT AND EQUIPMENT

	Laboratory equipment £000	Fixtures and fittings £000	Computer equipment £000	Total £000
Cost				
At 31 January 2015	742	53	133	928
Additions	198	357	156	711
At 31 January 2016	940	410	289	1,639
Additions	158	124	205	487
At 31 December 2016	1,098	534	494	2,126
Depreciation				
At 31 January 2015	357	41	95	493
Charge for the period	149	61	35	245
At 31 January 2016	506	102	130	738
Charge for the period	132	84	85	301
At 31 December 2016	638	186	215	1,039
Net book value				
At 31 December 2016	460	348	270	1 087

At 31 December 2016	460	348	279	1,087
At 31 January 2016	434	308	159	901
At 31 January 2015	385	12	38	435

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## **10) INTANGIBLES**

Development costs	£000 550	<b>£000</b>
Total	550	

## **11) INVENTORY**

	As at 31 December 2016 £000	As at 31 January 2016 £000
Raw materials and consumables	126	_
Work in progress	74	_
Finished goods including goods for resale	461	64
Total	661	64

The replacement cost of stocks approximates to the value at which they are stated in the accounts.

# 12) TRADE AND OTHER RECEIVABLES

	As at 31 December 2016 £000	As at 31 January 2016 £000
Trade debtors	427	398
Other receivables	2,231	1,464
Prepayments and accrued income	472	463
	3,130	2,325

The Directors consider that the carrying amount of trade and other receivables approximates to their fair value.

Trade debtors is reduced due to a provision valued at £90k (Jan 2016: £nil).

At year end £63K of the trade debtors value is past due that has no provision against (Jan 2016: £132K)

Trade debtors, split by the currency they will be settled, are shown below:

	As at 31 December 2016 £000	As at 31 January 2016 £000
US Dollars	339	398
Euros	88	-
Trade debtors	427	398



## 13) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES

The Company's activities expose it to a variety of financial risks: market risk, specifically interest rate risk; credit risk; and liquidity risk. The Company's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the Company's financial performance.

The management of these risks is vested in the Board of Directors. The policies for managing each of these risks are summarised below:

### Management of market risk

#### i) Interest rate risk

As the Company has no significant borrowings the risk is limited to the potential reduction in interest received on cash surpluses held. Interest rate risk is managed in accordance with the liquidity requirement of the Group, with a minimal amount of its cash surpluses held within short term accounts, which have variable interest rates attributable to them, to ensure that sufficient funds are available to cover the working capital requirements of the Company.

#### Interest rate sensitivity

The principal impact to the Company is the result of interest bearing cash and cash equivalent balances held as set out below:

	December 2016		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	7,654	519	8,173

	January 2016		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	18,725	1,182	19,907

Due to the high proportion of funds held on a fixed deposit, the impact of a 5% increase/decrease in interest rates would have an immaterial impact on the loss in each period.

#### Management of credit risk

The Company is exposed to credit risk from its operating activities; this principally arises from short term bank deposits. The Company seeks to minimise this risk by only depositing funds with banks with a high credit rating.

The maximum exposure to credit risk on the Company's financial assets is represented by their carrying amounts as outlined in the categorisation of financial instruments table below.

The Company does not consider that any changes in fair value of financial assets or liabilities in the year are attributable to credit risk.

#### Management of liquidity risk

The Company seeks to manage liquidity risk to ensure that sufficient liquidity is available to meet foreseeable needs and to invest cash assets safely and profitably.

No maturity analysis for financial liabilities is presented, as the Directors consider that liquidity risk is not material.

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 13) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES continued

The Company had cash and cash equivalents at each reporting date as is set out below.

	As at 31 December 2016 £000	As at 31 January 2016 £000
Cash and cash equivalents		
AA-	16	29
A	7,654	18,725
BBB+	503	1,153
	8,173	19,907

The above has been split by the Fitch rating system and gives an analysis of the credit rating of the financial institutions where cash balances are held.

#### Capital risk management

The Company manages its capital to ensure that the Company will be able to continue as a going concern while maximising the return to stakeholders. The Company's overall strategy is to minimise costs and liquidity risk.

The capital structure of the Company consists of equity attributable to the owners of the Company, comprising issued capital, reserves and retained earnings as disclosed in notes 15 and 16 and in the Statement of Changes in Equity.

#### **Categorisation of financial instrument**

Financial assets/(liabilities)	Loans and receivables £000	Financial liabilities at amortised cost £000	Total £000
At 31 December 2016			
Trade and other receivables	2,658	-	2,658
Cash and cash equivalents	8,173	-	8,173
Frade and other payables	-	(765)	(765)
	10,831	(765)	10,066

Financial assets/(liabilities)	Loans and receivables £000	Financial liabilities at amortised cost £000	Total £000
At 31 January 2016			
Trade and other receivables	1,862	_	1,862
Cash and cash equivalents	19,907	_	19,907
Trade and other payables	_	(573)	(573)
	21,769	(573)	21,196

The Company had no financial instruments measured at fair value.





# 14) TRADE AND OTHER PAYABLES

	As at 31 December 2016 £000	As at 31 January 2016 £000
Trade payables	618	501
Taxes and social security	147	72
Accruals	1,300	1,385
	2,065	1,958

The Directors consider that the carrying amount of trade and other payables approximates to their fair value.

Trade payables, split by the currency they will be settled in, are shown below:

	As at 31 December 2016 £000	As at 31 January 2016 £000
Sterling	150	170
US Dollars	332	242
Euros	136	89
Trade payables	618	501

## **15) SHARE CAPITAL**

	Number £000	Share capital £000	Share premium £000	Merger reserve £000	Reverse acquisition reserve £000	Total £000
Total ordinary shares of 0.5 p each as at 31 January 2015	654,123,031	3,271	31,972	10,884	(7,148)	38,979
Issue of shares	105,263,158	526	18,421	-		18,947
Share options exercised	738,075	4	68	_	_	72
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
Issue of shares	_	-	_	-	_	-
Share options exercised	_	-	_	-	_	-
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

As permitted by the provisions of the Companies Act 2006, the Company does not have an upper limit to its authorised share capital.

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 16) MOVEMENT IN RETAINED EARNINGS AND RESERVE FOR OWN SHARES

	Retained earnings deficit £000	Reserve for own shares £000
At 31 January 2016	(36,791)	(831)
Loss for the period	(9,912)	_
Exchange movement	(1)	_
Minority interest	126	_
At 31 December 2016	(46,578)	(831)

## **17) COMMITMENTS**

### **Operating lease commitments**

The Group leases premises under non-cancellable operating lease agreements. The future aggregate minimum lease and service charge payments under non-cancellable operating leases are as follows:

	As at 31 December 2016 £000	As at 31 January 2016 £000
Land and buildings:		
Amounts due within one year	64	124

## **18) SHARE BASED PAYMENTS**

## Share options and shares held in employee benefit trust ("EBT")

The Company operates a share option plan, under which certain employees have been granted options to subscribe for ordinary shares. All options are equity settled. The options have an exercise price of between 0.5p to 22.5p and a vesting period between one and three years. If the options remain unexercised after a period of ten years from the date of grant, the options expire. The Group has no legal or constructive obligation to repurchase or settle the options in cash.

The Group also operates a jointly owned EBT share scheme for senior management, under which the trustee of the Group sponsored EBT has acquired shares in the Group jointly with a number of employees. The shares were acquired pursuant to certain conditions, set out in Jointly Owned Equity agreements ("JOEs"). Subject to meeting the performance criteria conditions set out in the JOEs, the employees are able to benefit from most of any future increase in the value of the jointly owned EBT shares. The fair value benefit is measured using the binomial model, taking into account the terms and conditions upon which the jointly owned shares were purchased.



The number and weighted average exercise prices of share options and EBT shares are as follows:

	Number of share interests				Weighted average exercise
	EMI options	Unapproved options	EBT shares	Total	price per share (£)
At 31 January 2015	16,532,091	5,424,377	16,940,386	38,896,854	0.0706
Exercised in the period	(53,328)	(684,748)	-	(738,076)	0.0974
Lapsed during the period	(822,222)	(222,254)	-	(1,044,476)	0.1407
Issued in the period	1,430,839	2,939,098	-	4,369,937	0.1238
At 31 January 2016	17,087,380	7,456,473	16,940,386	41,484,239	0.0657
Exercised in the period	-	_	-	_	-
Lapsed during the period	(160,008)	(1,431,905)	_	(1,591,913)	0.0368
Issued in the period	-	5,094,124	-	5,094,124	0.0507
At 31 December 2016	16,927,372	11,118,692	16,940,386	44,986,450	0.0650

There were 17,199,750 share options outstanding at 31 December 2016 which was eligible to be exercised. The remaining options were not eligible to be exercised as these are subject to employment period and market based vesting conditions, some of which had not been met at 31 December 2016.

The performance conditions in relation to these options allows for vesting in three equal proportions on or after the three consecutive annual anniversaries from the date of grant subject to the Company's share price reaching certain hurdle values by the respective vesting dates.

There were 16,940,386 of the jointly held EBT shares which were eligible to vest as at 31 December 2016.

The fair value benefit received on share options granted is measured using the binomial model taking in to account the effects of the vesting and performance conditions, expected exercise price and the payment of the dividends by the Company. The fair value benefits received on EBT shares are measured using the Binomial model, taking into account the terms and conditions upon which the jointly owned shares were purchased. The following table lists the inputs to the models used:

	Options Granted year to 31 December 2016	EBT shares Granted year to 31 December 2016	Options Granted year to 31 January 2016
Dividend yield	-	-	-
Expected volatility	45%	-	47%
Risk-free interest rate (%)	0.9	-	0.9
Expected vesting life of EBT shares and options (years)	4	-	4
Weighted average share price (£)	0.0507	-	0.1238

Share options issued under the DAB scheme which are not exercised within four years from the date of grant will expire. Any other share options and employee interests in jointly owned EBT shares which are not exercised within ten years from the date of grant will expire.

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## 18) SHARE BASED PAYMENTS continued

A charge has been recognised in the Statement of Comprehensive Income for each year as follows:

	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Share options	210	136
Jointly owned shares	-	_
Total share based payments	210	136

## **19) RELATED PARTY TRANSACTIONS**

### Trading transactions with:

11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Transactions with significant shareholders:	
Patent support costs –	28

### Transactions with key management personnel

The Company's key management personnel comprise only the Directors of the Company.

During the year the Company entered into the following transactions in which the Directors had an interest:

#### Directors' remuneration:

Remuneration received by the Directors from the Company is set out below:

	11 Months up to	12 Months up to
	31 December 2016 £000	31 January 2016 £000
Short term employment benefits*	744	694

\* In addition, certain Directors hold share options and jointly owned shares in the Company for which a fair value share based charge of £72,000 has been recognised in the Consolidated Statement of Comprehensive Income (Jan 2016: £94,000).

During the period ended 31 December 2016, the Company entered into numerous transactions with its subsidiary company which net off on consolidation – these have not been shown above.

## **20) ULTIMATE CONTROLLING PARTY**

The Directors believe that there is no ultimate controlling party.



# **Company Statement of Changes in Equity**

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

	Attributable to the equity holders of the Company					
	Share capital £000	Share premium £000	Merger reserve £000	Share based payment reserve £000	Retained earnings reserve £000	Total £000
At 31 January 2015	3,271	31,972	10,884	737	(6,324)	40,540
Total expense and other comprehensive loss for the period	_	_	_	_	(1,203)	(1,203)
Issue of shares	526	18,421	_	_	_	18,947
Share options exercised	4	68	_	_	_	72
Share based payment expense	-	_	_	136	_	136
At 31 January 2016	3,801	50,461	10,884	873	(7,527)	58,492
Total expense and other comprehensive loss for the period	_	_	_	_	(1,701)	(1,701)
Issue of shares	_	_	_	_	_	_
Share options exercised	_	_	_	-	_	_
Share based payment expense	_	_	-	210	_	210
At 31 December 2016	3,801	50,461	10,884	1,083	(9,228)	57,001

The accompanying notes form an integral part of the financial statements.

# **Company Statement of Financial Position**

AS AT 31 DECEMBER 2016

		As at 31 December 2016	As at 31 January 2016
	Notes	£000	£000
ASSETS			
Non-current assets			
Investments	СЗ	12,922	12,922
Total non-current assets		12,922	12,922
Current assets			
Trade and other receivables	C4	63	60
Intercompany loan balance	C5	36,531	26,230
Cash and cash equivalents		7,819	19,598
		44,413	45,888
TOTAL ASSETS		57,335	58,810
LIABILITIES			
Current liabilities			
Trade and other payables	C6	(334)	(318)
TOTAL LIABILITIES		(334)	(318)
NET ASSETS		57,001	58,492
EQUITY			
Share capital	15	3,801	3,801
Share premium	15	50,461	50,461
Merger reserve	15	10,884	10,884
Share based payment reserve	18	1,083	873
Retained earnings deficit		(9,228)	(7,527)
TOTAL EQUITY		57,001	58,492

Approved by the Board of Directors and authorised for issue on 2 June 2017.

The accompanying notes form an integral part of the financial statements.

JOHN SAMUEL PAUL DEVLIN CHAIRMAN CHIEF FINANCI CHAIRMAN

CHIEF FINANCIAL OFFICER

Company number: 5969271



# **Company Statement of Cash Flows**

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

	Notes	11 Months up to 31 December 2016 £000	12 Months up to 31 January 2016 £000
Operating activities			
Loss before interest and tax		(1,815)	(1,416)
Adjustment for non-cash items:			
Share based payments	18	210	136
Operating cash outflow		(1,605)	(1,280)
Increase in trade and other receivables		(3)	(20)
Increase in trade and other payables		16	50
Net cash generated from operations		(1,592)	(1,250)
INVESTING ACTIVITIES			
Interest received		114	213
Loan to subsidiary undertaking	C5	(10,301)	(8,349)
Net cash generated from investing activities		(10,187)	(8,136)
FINANCING ACTIVITIES			
Proceeds from issue of share capital	15	-	19,019
Net cash used in financing activities		-	19,019
DECREASE IN CASH AND CASH EQUIVALENTS		(11,779)	9,633
Cash and cash equivalents at start of period		19,598	9,965
CASH AND CASH EQUIVALENTS AT END OF PERIOD		7,819	19,598

The accompanying notes form an integral part of the financial statements.

# Notes to the Company Information

FOR THE 11 MONTHS UP TO 31 DECEMBER 2016

## **C1. Principal accounting policies**

The separate financial statements of the Company are presented as required by the Companies Act 2006 and in accordance with IFRS.

The principal accounting policies adopted is the same as for those set out in the Group's financial statements.

## **C2.** Company results

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the Parent Company's statement of comprehensive income. The Parent Company's result for the period ended 31 December 2016 was a loss of £1,701k (2016: £1,203k).

The audit fee for the Company is set out in note 4 of the Group's financial statements.

## C3. Investment in subsidiary companies

At 31 December 2016, the Company held the following investments in subsidiaries:

Undertaking Sector			Share of issued capital and voting rights	
	Sector	2016	2016	
Tissue Regenix Limited	Regenerative medicine	100%	100%	
TRx Wound Care Limited	Regenerative medicine	100%	100%	
TRx Orthopaedics Limited	Regenerative medicine	100%	100%	
TRx Cardiac Limited	Regenerative medicine	100%	100%	
TRx Vascular Limited	Regenerative medicine	100%	100%	
Tissue Regenix Wound Care Inc*	Regenerative medicine	100%	100%	
TRx Orthopedic Inc*	Regenerative medicine	100%	100%	
GBM-V GmbH	Regenerative medicine	50%	50%	

\* Held through TRx Wound Care Limited

#### **Registered Addresses:**

Tissue Regenix Limited, TRx Wound Care Limited, TRx Orthopaedics Limited, TRx Cardiac Limited, TRx Vascular Limited: Unit 1 & 2, Astley Way, Astley Lane Industrial Estate, Swillington, Leeds, LS26 8XT

Tissue Regenix Wound Care Inc, TRx Orthopedic Inc: 2611 North Loop, 1604 West Suite 201, San Antonio, Texas, 78258

GBM-V Gmbh: Wilhelm-Külz-Platz 3. 18055 Rostock



	31 December 2016 £000	31 January 2016 £000
Cost		
At 1 January	14,707	14,707
Additions	-	-
At 31 December	14,707	14,707
Impairment		
At 1 January	(1,785)	(1,785)
At 31 December	(1,785)	(1,785)
Carrying value at 31 December	12,922	12,922

## C4. Trade and other receivables

	As at 31 December 2016 £000	As at 31 January 2016 £000
Prepayments and accrued income	39	40
Other debtors	24	20
	63	60

## C5. Current assets

	As at 31 December 2016 £000	As at 31 January 2016 £000
Intercompany loan	36,531	26,230

A loan of £36,531 was advanced to other subsidiary companies in the period. No interest was payable on the loan and is payable on demand

# C6. Trade and other payables

	As at 31 December 2016 £000	As at 31 January 2016 £000
Trade creditors	58	8
Taxes and social security	88	23
Accruals	188	287
	334	318

# **Notice of Annual General Meeting**

**Notice is given** that the 2017 annual general meeting of Tissue Regenix Group plc (**"Company"**) will be held at DLA Piper UK LLP, Princes Exchange, Princes Square, Leeds LS1 4BY on 30 June 2017 at 10.00 a.m. for the following purposes:

### To consider and, if thought fit, to pass the following resolutions as ordinary resolutions:

- 1. To receive the Company's annual accounts, strategic report and directors' and auditors' reports for the 11 month period ended 31 December 2016.
- 2. To appoint Paul John Devlin as a director of the Company.
- 3. To reappoint Alan Miller, who retires by rotation, as a director of the Company.
- 4. To reappoint Antony Odell, who retires by rotation, as a director of the Company.
- 5. To reappoint John Samuel, who retires by rotation, as a director of the Company.
- 6. To reappoint KPMG LLP as auditors of the Company.
- 7. To authorise the directors to determine the remuneration of the auditors.
- 8. That, pursuant to section 551 of the Companies Act 2006 ("Act"), the directors be generally and unconditionally authorised to allot Relevant Securities:
- 8.1 up to an aggregate nominal amount of £1,269,033; and
- 8.2 comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £1,269,033 in connection with an offer by way of a rights issue:
  - 8.2.1 to holders of ordinary shares in the capital of the Company in proportion (as nearly as practicable) to the respective numbers of ordinary shares held by them; and
  - 8.2.2 to holders of other equity securities in the capital of the Company, as required by the rights of those securities or, subject to such rights, as the directors otherwise consider necessary,

but subject to such exclusions or other arrangements as the directors may deem necessary or expedient in relation to treasury shares, fractional entitlements, record dates or any legal or practical problems under the laws of any territory or the requirements of any regulatory body or stock exchange,

provided that these authorities shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 30 September 2018 (whichever is the earlier), save that, in each case, the Company may make an offer or agreement before the authority expires which would or might require Relevant Securities to be allotted after the authority expires and the directors may allot Relevant Securities pursuant to any such offer or agreement as if the authority had not expired.

In this resolution, **"Relevant Securities"** means shares in the Company or rights to subscribe for or to convert any security into shares in the Company; a reference to the allotment of Relevant Securities includes the grant of such a right; and a reference to the nominal amount of a Relevant Security which is a right to subscribe for or to convert any security into shares in the Company is to the nominal amount of the shares which may be allotted pursuant to that right.



## To consider and, if thought fit, to pass the following resolutions as special resolutions:

- 9. That, subject to the passing of resolution 8 and pursuant to section 570 of the Act, the directors be and are generally empowered to allot equity securities (within the meaning of section 560 of the Act) for cash pursuant to the authority granted by resolution 8 as if section 561(1) of the Act did not apply to any such allotment, provided that this power shall be limited to the allotment of equity securities:
- 9.1 in connection with an offer of equity securities (whether by way of a rights issue, open offer or otherwise):
  - 9.1.1 to holders of ordinary shares in the capital of the Company in proportion (as nearly as practicable) to the respective numbers of ordinary shares held by them; and
  - 9.1.2 to holders of other equity securities in the capital of the Company, as required by the rights of those securities or, subject to such rights, as the directors otherwise consider necessary,

but subject to such exclusions or other arrangements as the directors may deem necessary or expedient in relation to treasury shares, fractional entitlements, record dates or any legal or practical problems under the laws of any territory or the requirements of any regulatory body or stock exchange; and

9.2 otherwise than pursuant to paragraph 9.1 of this resolution up to an aggregate nominal amount of £380,709,

and this power shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 30 September 2018 (whichever is the earlier), save that the Company may make an offer or agreement before this power expires which would or might require equity securities to be allotted for cash after this power expires and the directors may allot equity securities for cash pursuant to any such offer or agreement as if this power had not expired.

This power is in substitution for all existing powers under section 570 of the Act (which, to the extent unused at the date of this resolution, are revoked with immediate effect).

By order of the board **PAUL DEVLIN** COMPANY SECRETARY 2 June 2017

## **Registered office**

Units 1 & 2, Astley Way Astley Way Industrial Estate Swillington, Leeds LS26 8XT

Registered in England and Wales No. 05969271

# Notice of Annual General Meeting continued

## Notes

### Entitlement to attend and vote

1. The right to vote at the meeting is determined by reference to the register of members. Only those shareholders registered in the register of members of the Company as at close of business on 28 June 2017 (or, if the meeting is adjourned, close of business on the date which is two working days before the date of the adjourned meeting) shall be entitled to attend and vote at the meeting in respect of the number of shares registered in their name at that time. Changes to entries in the register of members after that time shall be disregarded in determining the rights of any person to attend or vote (and the number of votes they may cast) at the meeting.

#### Proxies

2. A shareholder is entitled to appoint another person as his or her proxy to exercise all or any of his or her rights to attend and to speak and vote at the meeting. A proxy need not be a shareholder of the Company.

A shareholder may appoint more than one proxy in relation to the meeting, provided that each proxy is appointed to exercise the rights attached to a different share or shares held by that shareholder. Failure to specify the number of shares each proxy appointment relates to or specifying a number which when taken together with the numbers of shares set out in the other proxy appointments is in excess of the number of shares held by the shareholder may result in the proxy appointment being invalid. A proxy may only be appointed in accordance with the procedures set out in notes 3 and 4 below and the notes to the proxy form.

The appointment of a proxy will not preclude a shareholder from attending and voting in person at the meeting.

3. A form of proxy is enclosed. When appointing more than one proxy, complete a separate proxy form in relation to each appointment. Additional proxy forms may be obtained by contacting the Company's registrar on 0871 664 0300 (Calls cost 12p per minute plus your phone company's access charge. Calls outside the United Kingdom will be charged at the applicable international rate. The Company's registrar is open between 09:00 - 17:30, Monday to Friday excluding public holidays in England and Wales) or the proxy form may be photocopied. State clearly on each proxy form the number of shares in relation to which the proxy is appointed.

To be valid, a proxy form must be received by post or (during normal business hours only) by hand at the offices of the Company's registrar, Capita Asset Services PXS, 34 Beckenham Road, Beckenham BR3 4TU, no later than 10.00 a.m. on 28 June 2017 (or, if the meeting is adjourned, no later than 48 hours before the time of any adjourned meeting).

4. CREST members who wish to appoint a proxy or proxies for the meeting (or any adjournment of it) through the CREST electronic proxy appointment service may do so by using the procedures described in the CREST Manual. CREST personal members or other CREST sponsored members, and those CREST members who have appointed a voting service provider(s), should refer to their CREST sponsor or voting service provider(s), who will be able to take the appropriate action on their behalf.

In order for a proxy appointment or instruction made using the CREST service to be valid, the appropriate CREST message (a **"CREST Proxy Instruction"**) must be properly authenticated in accordance with Euroclear UK & Ireland Limited's specifications and must contain the information required for such instructions, as described in the CREST Manual. The message, regardless of whether it constitutes the appointment of a proxy or is an amendment to the instruction given to a previously appointed proxy, must, in order to be valid, be transmitted so as to be received by Capita Registrars (ID RA10) no later than 10.00 a.m. on 28 June 2017 (or, if the meeting is adjourned, no later than 48 hours before the time of any adjourned meeting). For this purpose, the time of receipt will be taken to be the time (as determined by the timestamp applied to the message by the CREST Applications Host) from which Capita Registrars is able to retrieve the message by enquiry to CREST in the manner prescribed by CREST. After this time, any change of instructions to proxies appointed through CREST should be communicated to the appointee through other means.

CREST members and, where applicable, their CREST sponsors or voting service providers should note that Euroclear UK & Ireland Limited does not make available special procedures in CREST for any particular messages. Normal system timings and limitations will therefore apply in relation to the input of CREST Proxy Instructions. It is the responsibility of the CREST member concerned to take (or, if the CREST member is a CREST personal member or sponsored member or has appointed a voting service provider(s), to procure that his or her CREST sponsor or voting service provider(s) take(s)) such action as shall be necessary to ensure that a message is transmitted by means of the CREST system by any particular time. In this connection, CREST members and, where applicable, their CREST sponsors or voting service providers are referred, in particular, to those sections of the CREST Manual concerning practical limitations of the CREST system and timings.

The Company may treat a CREST Proxy Instruction as invalid in the circumstances set out in Regulation 35(5)(a) of the Uncertificated Securities Regulations 2001.

### **Corporate representatives**

5. A shareholder which is a corporation may authorise one or more persons to act as its representative(s) at the meeting. Each such representative may exercise (on behalf of the corporation) the same powers as the corporation could exercise if it were an individual shareholder, provided that (where there is more than one representative and the vote is otherwise than on a show of hands) they do not do so in relation to the same shares.

#### Documents available for inspection

- 6. The following documents will be available for inspection during normal business hours at the registered office of the Company from the date of this notice until the time of the meeting. They will also be available for inspection at the place of the meeting from at least 15 minutes before the meeting until it ends.
  - 6.1 Copies of the service contracts of the executive directors
  - 6.2 Copies of the letters of appointment of the non-executive directors.

### **Biographical details of directors**

7. Biographical details of all those directors who are offering themselves for reappointment at the meeting are set out on pages 18 and 19 of the enclosed annual report and accounts.



# **Directors and Officers**

## DIRECTORS

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

## **COMPANY SECRETARY**

Paul Devlin

Unit 1 & 2

## **COMPANY WEBSITE**

www.tissueregenix.com

## **COMPANY NUMBER**

05969271 (England & Wales)

## **REGISTERED OFFICE**

C Ti strial Estate 3:

Astley Way Astley Lane Industrial Estate Leeds West Yorkshire LS26 8XT

## **AUDITOR**

KPMG LLP 1 Sovereign Square Sovereign Street Leeds LS1 4DA

## REGISTRAR

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

## LEGAL ADVISER

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

## NOMINATED ADVISER AND BROKER

Jefferies International Ltd Vintners Place 68 Upper Thames Street London EC4V 3BJ

