





TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE YEAR ENDED 31 JANUARY 2016



# WHO WE ARE

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

**dCell® Technology** - Three Operating Divisions: **Wound Care**, **Orthopaedics** and **Cardiac** - Offices in the UK and the USA -Joint Venture in Germany



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



# dCELL® technology

Our unique dCELL<sup>®</sup> technology allows us to process both human and animal tissues, removing the DNA and cellular material but leaving intact an inert acellular matrix within which the patient's cells can repopulate, creating like for like tissue.

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

Learn more about dCELL® on page 8

# **Our Strengths**

- O A proven regenerative technology, producing outstanding clinical results
- O A dedicated and skilled research and development team
- O A global reach with offices in both Europe and North America
- O 10 years experience commercialising medical research
- O Strong business–academia relationships, including The University of Leeds and Pontifical Catholic University of Paraná





# NAVIGATING THE REPORT



FOR FURTHER INFORMATION WITHIN THIS DOCUMENT AND RELEVANT PAGE NUMBERS



ADDITIONAL INFORMATION ONLINE



SCAN THIS CODE TO SEE VIDEO



# HIGHLIGHTS



THE AVE

# WOUND CARE REVIEW



SEE PAGES 14 TO 16

## **ORTHOPAEDICS REVIEW**





SEE PAGES 18 TO 20

CARDIAC REVIEW

# **Operational Highlights**

- SALES OF DERMAPURE® SURPASS \$1M IN IT'S FIRST YEAR
- FIRST FDA MARKET CLEARANCE FOR A dCELL® APPLICATION, SURGIPURE XD\*
- KEY JOINT VENTURE AGREEMENT IN GERMANY, CREATING TISSUE BANK GBM-V
- ▷ GRANTED THE FIRST dCELL<sup>®</sup> HUMAN HEART VALVE LICENCE
- COMPLETION OF ENROLMENT FOR THE ORTHOPURE XM CLINICAL TRIAL\*
- REIMBURSEMENT COVERAGE FOR 74% OF TRADITIONAL MEDICARE BENEFICIARIES\* ACHIEVED FOR DERMAPURE<sup>®</sup>

\* Represents an activity between year end and publishing

# OVERVIEW

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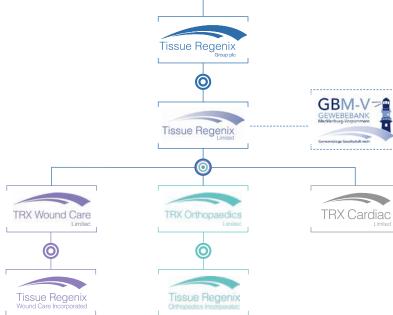
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# OUR CORPORATE STRUCTURE

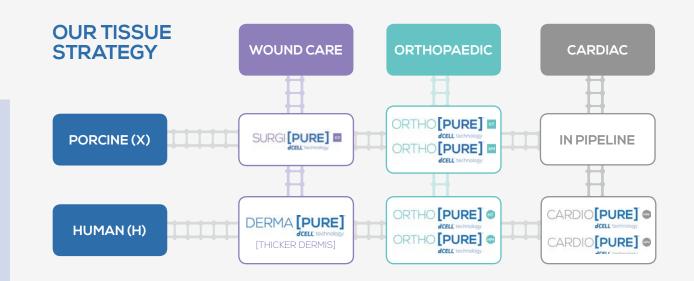
THE TISSUE REGENIX O GROUP STRUCTURE IS BROKEN DOWN INTO THREE OPERATIONAL DIVISIONS.





This structure allows us to ensure that we have the correct research and commercial expertise for each operational division, allowing us to treat each as an individual entity, and having the adaptability 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.

Due to the diversity of our platform technology dCELL<sup>®</sup>, we are able to apply it to different tissue applications. We currently have a portfolio of human tissue applications under each of our core focus areas, and are in the development stages of expanding our xenograft product portfolio. There is the scope to apply dCELL<sup>®</sup> to different animal tissues beyond human and porcine in the future.





# **GROUP AT A GLANCE**

TISSUE REGENIX GROUP IS AN INTERNATIONAL LEADER IN THE FIELD OF REGENERATIVE MEDICINE, WITH ITS INNOVATIVE PLATFORM TECHNOLOGY **dCELL®** REVOLUTIONISING THE TREATMENT OF PATIENTS IN **WOUND CARE**, **ORTHOPAEDIC** AND **CARDIAC** APPLICATIONS.

# **dCELL® TECHNOLOGY** - THREE OPERATING DIVISIONS – OFFICES IN THE UK AND THE USA – JOINT VENTURE IN GERMANY – GLOBAL RESEARCH PARTNERS.



# Tissue Regenix Wound Care, Inc.

- O Headquartered in San Antonio, Texas
- Commercialising DermaPure<sup>®</sup>, a decellurised human dermis for the treatment of chronic and acute wounds, achieving over \$1m sales revenue within it's first full year
- O FDA market clearance for SurgiPure<sup>™</sup> XD, expected launch H216
- In the process of establishing line extension products for other wound care needs
- Established network of 8 direct sales reps and 29 distributors





# **TRX Orthopaedics, Limited**

- Operating out of the UK with clinical sites across the EU
- Completed enrolment for the OrthoPure<sup>™</sup> XM (porcine meniscus) clinical trial
- O Expected to begin commercialisation within the EU in 2017
- Planning entry into the US marketplace, with human tissue applications through subsidiary Tissue Regenix Orthopedics, Inc.
- Appointed top level managers to facilitate this expansion



## TRX Cardiac Limited

- O Granted the first dCELL® heart valve licence in January 2016
- Supported by 10 years of clinical data from studies in Brazil
- Over 1,600 operations successfully completed
- O Entry into EU marketplace through Joint Venture creating GBM-V in Germany





# CHAIRMAN'S STATEMENT



"Tissue Regenix has delivered another promising year of continued progress, both in terms of commercialisation, and development from its pipeline of innovative regenerative solutions."

JOHN SAMUEL CHAIRMAN

# **Overview**

The twelve months to 31 January 2016 represented another progressive year for Tissue Regenix in its development as a maturing and commercially focussed company, vindicating the belief demonstrated when it was established ten years ago.

Surpassing the \$1m sales mark with DermaPure® validates the commercial viability of our technology and our approach to a hybrid distribution model; utilising third party distributors and strengthening our own salesforce is reaping benefits, a model in which we invested after the fundraise in February 2015.

FDA market clearance for medical device SurgiPure™ XD, the first for the Group, further strengthens our commercial position within the US and marks a significant step in the acceptance of our dCELL<sup>®</sup> technology.

We entered our first Joint Venture Agreement forming a partnership with the GTM-V tissue bank in Rostock, Germany, allowing us to grant for the first time, a dCELL® human heart valve licence.

Throughout the year we undertook a staged move to a new facility in Leeds and we anticipate that the consolidation of our managerial and manufacturing functions will bring further improvement to our corporate efficiency.

# The Regenerative Advantage

Regenerative solutions continue to lead the way in revolutionising medical treatments. With an ageing population suffering multiple ailments and injuries, with increasing participation in active sports, and with current treatment modalities having significant disadvantages in terms of side effects, treatment cost and intercurrent morbidity, the potential benefits of the regenerative approach are becoming increasingly clear. In a market that is expected to reach a value of \$11.5bn by 2022, Tissue Regenix is actively involved in three clinical areas at present, with considerable potential for further expansion.

#### Wound Care

We have taken significant steps in the commercialisation of our flagship product DermaPure<sup>®</sup> in the US, and given the potential size of the wound care market worldwide, we are confident that this success can be replicated in other markets. We are also well on the way to establishing additional applications for wound care, and expect to launch SurgiPure<sup>™</sup> XD into the US market in H216 after receiving FDA market clearance in March.

#### **Orthopaedics**

Our Orthopaedic clinical trials are currently ongoing, for both the OrthoPure™ XM and XT (porcine products), and we anticipate that we will have CE mark approval by early 2017. We have also strengthened our senior management team by appointing a VP of Orthopedics for North America, who will be key to guiding our entry into this market over the coming years with both our porcine products and human tissue applications.

#### Cardiac

Our relationship with Professor Francisco da Costa and research partner Pontifical Catholic University of Paraná, Curitiba, Brazil, has been ongoing for the last ten years and we are proud to now be in a position to present the ten year clinical follow-up data at prestigious conferences around the world. We hope to be able to bring dCELL<sup>®</sup> heart valves to European patients in the near future through our Joint Venture. We anticipate that this will be the first of an expanding network of agreements with international partners who share our ethical and commercial values.





# Human Resources

We continue to invest in the development and retention of our staff and have strengthened our senior management with the appointment of a VP for Orthopedics in the US. Alongside this we have expanded our senior sales team for DermaPure® and developed our production and manufacturing teams within the UK.

## Finance

With the Group now generating revenue the decision has been made to move our year end date to 31 December, to a more conventional commercial company reporting timeframe. We have also implemented, for the first time, segmental reporting for each of our operational divisions, in order to provide even greater transparency of the business as each of the operating divisions grow.

## **The Board**

In January we announced the appointment of Jonathan Glenn, CEO of Consort Medical plc, as a Non-Executive Director. With the expected rapid commercialisation of products over the coming years, the addition of Jonathan strengthens our commercial, and specifically, medical device industry expertise, to help guide Tissue Regenix through the next stages of its business plan.

# **Outlook**

An exciting and busy year lies ahead for Tissue Regenix and we are confident that we will continue to see notable progress across all three operating divisions in the coming months. dCELL® technology applications are well advanced in terms of clinical development and regulatory processes, and we anticipate that within the coming year we will be in a position to bring them to the European market, and begin our entry pathway in the US with our orthopaedic portfolio.

#### JOHN SAMUEL

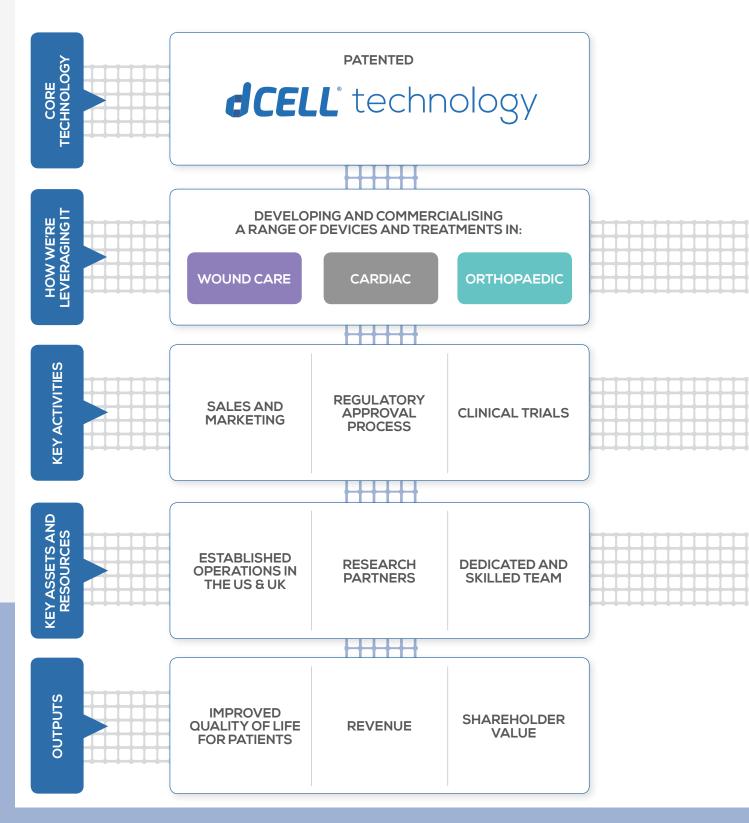
CHAIRMAN 23 May 2016



MORE INFORMATION ABOUT TISSUE REGENIX CAN BE FOUND IN OUR CEO STATEMENT ON PAGES 11 - 13 AND CFO STATEMENT ON PAGES 22 - 24.

# **BUSINESS MODEL**

WE ARE LEADING THE DEVELOPMENT OF REGENERATIVE MEDICAL SOLUTIONS TO MAKE REPLACEMENT TISSUES USING BIOLOGICAL (HUMAN AND ANIMAL) MATERIALS. HERE'S HOW WE DO IT.









## WOUND CARE

- O Commercialised DermaPure® in the USA
- Potential line extensions into burns and dental applications
- O SurgiPure awarded market clearance from the FDA

#### SALES AND MARKETING

- O 8 direct sales reps and 29 distributors across the US
- O Expansion of team within the US
- Peer reviewed presentations of clinical data at prestigious meetings and symposia around the world

#### ESTABLISHED OPERATIONS IN THE US AND THE UK

- O Manufacturing facility and corporate head office located in Swillington, Leeds
- D US subsidiary office in San Antonio, Texas
- O Commercial Directors appointed around both the EU and US



CARDIAC First dCELL<sup>®</sup> human heart valve licence granted

- O Joint Venture for market entry into the EU
- O 10 year clinical data available from Brazil

#### REGULATORY APPROVAL PROCESS

- O An experienced in-house regulatory team
- O First FDA market clearance for the US market, highlighting acceptance of dCELL® technology
- O CE mark application for Orthopaedic products (in progress)

#### **RESEARCH PARTNERS**

- O Strong relationships with academic institutions around the world to drive research of dCELL<sup>®</sup> applications
- O Retrospective study carried out with clinical centres in US for DermaPure®



#### ORTHOPAEDIC

- C Clinical trials for porcine applications in EU
- O Meniscus trial enrolment completed
- O ACL trial enrolment ongoing

## **CLINICAL TRIALS**

O Porcine Orthopaedic products are currently in clinical trials, highlighting our ability to successfully manage multiple trials spanning centres in several European countries

#### DEDICATED AND SKILLED TEAM

- O A respected Board with a mix of commercial and clinical expertise
- O Top level management team with a wealth of experience and a global reach
- O Senior scientists with extensive dCELL® knowledge







# OUR TECHNOLOGY: OUR PLATFORM

# **dCELL** technology

# The power of dCELL® technology.

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

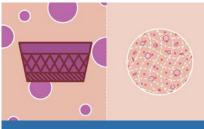
The dCELL® process is gentle, efficient, effective — and powerful. It results in allograft and xenograft tissue matrices that are up to 99% DNA free, but retains the tissues' native growth factors, collagen and elastin throughout the process. It can be applied to both donated human tissues (allografts), or animal tissues (xenografts).

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

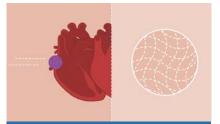
The dCELL® process removes DNA and cellular material from donor tissues, through a series of gentle washes, leaving an intact acellular matrix upon which the patient's cells can repopulate and colonise, creating new, like - for - like tissue, which is recognised and accepted by the body, significantly reducing the risk of rejection.

dCELL<sup>®</sup> technology provides an enhanced healing environment, in terms of both natural, tissue-specific physical structure and biochemical 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 re-population is complete, the regenerated tissue is effectively a natural part of the patient's own body.  If the tissue matrix is broken or damaged the body can become unable to repair itself and we are left with a wound, disease or injury



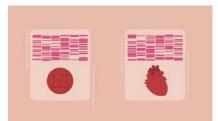
3 dCELL removes DNA and cellular material from donor tissue through a series of gentle washes



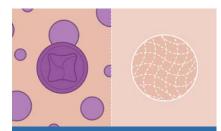
S Your own cells can then populate and regenerate new tissue true to your own body

The potential applications of dCELL® are diverse and currently Tissue Regenix is focusing on addressing complex and unmet needs in three core clinical areas:

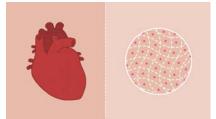
Wound care, orthopaedics and cardiac.



Sometimes this can be replaced with donor material however, the body will often reject this tissue as it does not contain your own specific DNA code



4 But crucially leaves intact an acellular matrix



6 This is recognised and accepted by your body, significantly reducing the risk of rejection



SCAN THE OR CODE TO SEE OUR dCELL® VIDEO

ALTERNATIVELY MORE INFORMATION CAN BE FOUND ONLINE: WWW.TISSUEREGENIX.COM



# **OUR PRODUCTS PORTFOLIO**

WE HAVE A PORTFOLIO OF PRODUCTS UTILISING OUR PATENTED PLATFORM TECHNOLOGY dCELL® IN ALL THREE OF OUR CORE FOCUS AREAS. THE NATURE OF OUR TECHNOLOGY PLATFORM ALLOWS US TO HAVE A SERIES OF LINE EXTENSIONS FROM OUR PRIMARY APPLICATIONS, SOME OF WHICH ARE CURRENTLY IN DEVELOPMENT.

## WOUND CARE

### 

DermaPure<sup>®</sup> is used for the treatment of chronic or acute wounds. Initially aimed at treating the problematic ulcers caused as a side effect of diabetes, a study found that DermaPure<sup>®</sup> application resulted in rapid development of the capillary network and cellular proliferation from day 7. Potential line extensions for DermaPure<sup>®</sup> are currently being investigated, including burns, orthopaedics and dentistry.

#### 

SurgiPure<sup>™</sup> XD Surgical Tissue Matrix is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or buttressing material to obtain the desired surgical outcome.

# ORTHOPAEDICS

## 

Made from decellurised porcine meniscus, OrthoPure™ XM is used to replace the tissue removed during a partial meniscopy. OrthoPure™ XM allows the rebalance of the knee joint after surgery which could over time reduce the incidence of osteoarthritis.

#### 

OrthoPure™ XT is a decellurised porcine tendon. Initially aimed at ACL repair, common in many recreational sporting injuries, it could however, in time, be used for the treatment of other ligament or tendon injuries.

Human tissue application for both the meniscus and tendon are also in the pipeline.

CARDIAC



A decellurised human pulmonary or aortic heart valve, now clinically proven to offer long-term efficacy without loss of haemodynamic function and with a low incidence of repeat surgery being required.

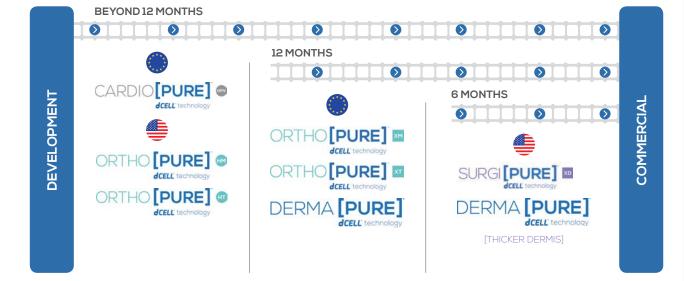
#### Potential line extensions Pipeline

- O Small joint tendons (hand/foot)
- O Heart tissue repairs

#### Developments

(Not in current business plan) O Cartilage repair

- O Large vessels (leg/arm)
- Small vessels (CABG)
- O Bladder repair
- O Liver



TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE YEAR ENDED 31 JANUARY 2016

# OUR DEVELOPMENT OBJECTIVES

OUR STRATEGIC FOCUS CENTRES AROUND THE EXPLOITATION OF OUR PATENTED dCELL® TECHNOLOGY, AND THROUGHOUT OUR OPERATING AREAS, COMMERCIALISING A DUAL TISSUE STRATEGY ENCOMPASSING BOTH HUMAN AND ANIMAL TISSUE TYPES.



OUR STRATEGIC OBJECTIVES ARE TO:	HOW
Build the evidence base for the use of dCELL <sup>®</sup> technology	Establishing a group of Key Opinion Leaders (KOL) in each of our clinical areas. Ongoing clinical trials and post clinical data collection. Presentation of this data at prestigious conferences and in peer review journals.
Develop our core focus areas of wound care, orthopaedics and cardiac	Pursuing CE and FDA approval for our products. We actively research and establish the market need in each geographic area and tailor our route to market and portfolio of products offered to meet this. We also ensure we protect our IP globally through applying for and protecting a series of patents.
Develop our route to market for human tissue products throughout different applications and geographies	Established a Joint Venture in Germany to bring our human tissue dCELL® heart valve and DermaPure® to the EU market. We hope to roll this model out into other territories with global partners.
	Vendere can be found of pages 20 EI
Develop our route to market for animal tissue products throughout different applications and geographies	Gained FDA market clearance for our first porcine application SurgiPure XD for hernia repair. Currently undergoing clinical trials for CE marks for our porcine orthopaedic applications for knee repair.
Continue to work with our higher education and research partners around the world to research potential applications for dCELL <sup>®</sup> technology	We maintain strong relationships with our higher education and research partners, working closely with the University of Leeds, University of York and the Pontifical Catholic University of Paraná, to establish a pipeline of potential dCELL <sup>®</sup> applications.



# **CEO STATEMENT**



"During the year to 31 January 2016 Tissue Regenix made significant progress in both the commercial and development businesses of the Group. We continue to carefully monitor our commitments to ensure that we can deliver in line with expectations, and bring our products to the market in the safest and most time efficient manner over the coming year."

ANTONY ODELL CHIEF EXECUTIVE OFFICER

# **Our Highlights**

In the year since our last report, Tissue Regenix has taken great strides in realising its true potential, gaining commercial traction with our wound care products, surpassing \$1m revenue with DermaPure<sup>®</sup> in its first full year of commercialisation, and receiving our first 510k whilst also undertaking the groundwork to allow for a successful launch of our orthopaedic products during 2017.

We have entered our first Joint Venture Agreement, highlighting the corporate maturity of the Group as we embark on a new business model, enabling us to roll out our dCELL<sup>®</sup> human tissue products in Europe.

The move to our new manufacturing facilities' consolidating our UK operations' was completed on time and on budget, ensuring that we are in a position to meet our production demands in the coming years, as well as ensuring that we can meet the requirements of the FDA for products such as SurgiPure™ XD.



More information is available in the strategic report on pages 4–25

# Finance

During the year we invested in our sales and distribution infrastructure for DermaPure® in the US, and our porcine orthopaedic applications within the EU. Following the £19m fundraise undertaken in February 2015, we maintain a strong financial position.



# Strategy

As a company operating in a rapidly developing industry sector, we have remained committed to our core strategic focuses of wound care, orthopaedics and cardiac, with a specific geographic focus on the EU and the US, and a dual tissue strategy utilising both human and animal (xeno) tissues.

However, we also pride ourselves in having the flexibility and commercial confidence to pursue new opportunities as they arise, as was demonstrated in January 2016 when we entered our first Joint Venture Agreement with GTM-V in Rostock, Germany, establishing tissue bank GBM-V. This new business model will allow us to deploy our human tissue products throughout Germany, and the wider EU.



More information about our JV is available on page 20-21

# **Regulatory Pathways**

We have an experienced in-house regulatory and quality team which is successfully leading our regulatory applications and entry into global markets. In March 2016 we received our first 510(k) market clearance from the FDA for SurgiPure™ XD, a decellurised porcine dermis for soft tissue defects. This represents an important step since it is the FDA's first in-depth review of a dCELL<sup>®</sup> process, as part of the approval which encourages us in planning for future regulatory submissions in the US.

We have also undertaken a two part submission for CE marking, which should reduce the time needed for final approval of the OrthoPure<sup>™</sup> products, by ensuring that once the required clinical data has been collected we are in a position to submit the final application for approval.

Our entry into the German market will be managed by our partners from GTM-V who have extensive experience of the German regulatory system, one of the toughest within Europe, thus setting a high benchmark for the dCELL® products to meet, which allows us to feel confident that further EU approvals will be more readily secured.



# KEY PERFORMANCE INDICATORS

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
- O Monthly review of actual results against budget

# Licensing and IP

Through GBM-V, our JV company, we granted for the first time a licence to CardioPure<sup>™</sup>, the dCELL<sup>®</sup> human heart valve. We expect to be in a position to roll out the first dCELL<sup>®</sup> human heart valves in 2017, subject to approval from the necessary German authorities. GBM- V has also been granted a licence to DermaPure<sup>®</sup>, the first commercial licence for this product outside of the US.

We continue to maintain our relationship with the NHSBT who were granted an exclusive royalty-free licence for the use of DermaPure<sup>®</sup> within the UK, and our research partner Pontifical Catholic University of Paraná, who we continue to work with closely in developing our cardiac applications. Outside of the already granted licences we also have a portfolio of products and line extensions that we are currently developing, and will, if relevant, review licensing to a suitable partner, as well as holding the IP to the dCELL<sup>®</sup> products that will be manufactured in-house by Tissue Regenix. We continue to protect our intellectual property by securing a number of global patents, and ensuring we take the necessary precautionary steps and action needed to secure these.

# **Licences Granted**



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# **IP in Development**



# Operations

In April 2015 we commenced the move to our new manufacturing facility outside of Leeds. Having undergone renovations to bring it in line with our needs from both a regulatory and manufacturing standpoint, we achieved ISO13485 certification for the whole of our UK operations, which supports the future manufacture of products for Europe and the rest of the world from this facility. We have now consolidated our entire UK operation to this one site, which has the capacity to meet our expanding manufacturing needs in the coming years, for both our orthopaedic and wound care porcine products. We believe that this strategic decision will create further synergies in the manufacturing and development arms, enhancing the corporate cohesion and global reach of the Company.

We have expanded the number of top level managers within the US to facilitate the growth of our wound care division, making senior appointments to both our sales and marketing teams, thus driving further market penetration and brand awareness. In March 2016 we also made our first appointment to Tissue Regenix Orthopedic, Inc. filling the post of VP Orthopedics for North America to lead our entry into this marketplace over the coming years.

# Current Trading and Outlook

We expect this progress to continue in the next year as we bring to market SurgiPure™ XD, progress with CE mark application for OrthoPure™, and begin our entry into the US market with our human tissue orthopaedic applications.

DermaPure<sup>®</sup> now has an established foothold within the US, and we hope to receive the remaining approvals and become available to 100% of medicare beneficiaries in the coming months. Alongside this we will continue to penetrate the private payer market and establish further revenue-generating opportunities.

Our Joint Venture Agreement in Germany allows us to pursue new business opportunities and begin our entry into the European market with our human tissue applications, and additionally allows us to enter the cardiac field, something which we feel will underline the unique efficacy of our dCELL® technology.

## Conclusion

Tissue Regenix this year celebrates its tenth anniversary, having fulfilled the promise of its early research and development roots.

With accelerating sales, increasing market visibility in the US, new partners, creating new opportunities, and potential licensing and commercial breakthroughs in Europe, the Company continues to expand and develop as originally envisaged, and we remain optimistic that it will reach its fullest potential across our key focus areas.

At the same time, as a British company, strategically allied with British educational establishments, it remains a source of pride that was granted a revenue-free license for human tissue applications (only) of dCELL® to the NHS in partnership with the National Blood Transfusion Service (NHSBT) who developed DermaPure®, which Tissue Regenix is now commercialising globally outside of the UK.

We are still at an early stage in exploring the potential clinical applications of the dCELL<sup>®</sup> platform which is showing its true potential to provide solutions in a wide variety of medical arenas.

With the support of our strong blue chip investor base I am confident that the benefits to clinicians and patients will continue to expand over the coming years.

#### ANTONY ODELL

CHIEF EXECUTIVE OFFICER 23 May 2016



# OPERATIONAL REVIEW WOUND CARE



FY16 was the first full financial year for the commercialisation of DermaPure<sup>®</sup>. We exceeded our expectations, gaining reimbursement coverage encompassing 74% of Medicare beneficiaries, with 63% of this within the first eight months. Our goal for the next year is to complete our coverage under the Medicare system, and to expand our presence with private insurers. We surpassed \$1m in sales which highlights how we have managed to successfully implement our hybrid sales strategy in a relatively short time, following the fund-raise and investment into this infrastructure in February 2015.

The occurrence of acute and chronic wounds continues to rise as the diabetic epidemic continues. Many patients when not treated aggressively can experience diabetic foot complications which can ultimately lead to amputation. The cost of this is proving to be comparable to diseases such as breast cancer and colorectal cancer.

# 4-10% of diabetic patients

will suffer a diabetic ulcer complication, with the healthcare costs for treating this being on a par with, or more expensive than, many cancers.

US Wound Biologics Market BioMedGPS, LLC. https://www.smarttrak.net



**GREG BILA** PRESIDENT, TISSUE REGENIX WOUND CARE, INC.



solution for healthcare providers, and provides the opportunity for patients to return to, and enjoy, an enhanced quality of life without the need for multiple treatments.

Tiissue Regenix Wound Care, Inc. is now looking to commercialise a number of other products utilising the same dCELL<sup>®</sup> technology to address different wound care conditions. We received our first FDA market clearance for a medical device, and it is expected that the launch of SurgiPure<sup>™</sup> XD, a decellurised porcine dermis used for the treatment of hernias and body wall defects, will occur in H2 CY16. We also continue to pursue other commercial opportunities such as line extensions with DermaPure<sup>®</sup> for the treatment of burns and dental applications, as well as trauma and tissue augmentation procedures.

## **Highlights**:

- Generated \$1.2m in top line sales revenue in FY16
- First FDA market clearance for a medical device with SurgiPure<sup>™</sup> XD.
- DermaPure<sup>®</sup> received outpatient coding and reimbursement coverage representing 74% of the traditional Medicare population within the US.
- Rapid expansion of sales presence by recruiting direct sales representatives and distributors into high potential areas of opportunity.
- Enlisted 12 key wound healthcare professionals who have written 14 clinical abstracts on the use of DermaPure<sup>®</sup>.

# Tissue Regenix Wound Care Incorporated

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MORE INFORMATION CAN BE FOUND ONLINE: WWW.TISSUEREGENIXUS.COM

# Annual Direct Healthcare Costs

Leukemia La complication de la c

Diabetic Foot & Ankle 2013. © 2013 Neal R. Barshes et al. Published: 10 October 2013; The system of care for the diabetic foot: objectives, outcomes, and opportunities; http://diabeticfootandankle.net/index.php/dfa/ article/view/21847/html#CIT0005\_21847



# **RACHEL'S** STORY

# WITH ONE APPLICATION OF DERMAPURE®. THE WOUND HEALED IN 4 WEEKS. RACHEL AND JONES' SPIRITS WERE LIFTED TREMENDOUSLY.

STRATEGIC REPORT

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Rachel is 84 years old. She has suffered with a pressure ulcer for four years and additionally has bilateral below knee amputations. Because of the pressure ulcer she became bedbound and had to move out of her home in North Carolina to live in a nursing home away from her husband, Jones. She has been living away from her husband and their home for a number of years and was unable to get out of bed during this time frame. Jones would visit her every day so that they could sit together and watch the birds - a pastime they enjoy. He even placed bird feeders outside of her window. Rachel's doctors tried several different treatments to close the wound, to no avail. Her emotional as well as physical state was suffering and she gave up all hope of any type of recovery. In the summer of 2015, her physician heard of DermaPure<sup>®</sup>

With one application of DermaPure®, the wound healed in 4 weeks. Rachel and Jones' spirits were lifted tremendously. She was able to get out of her bed for the first time in years. A couple of months later, Jones took his wife home for a few hours to celebrate their 57th wedding anniversary.

To learn more about Rachel's story visit www.tissueregenix.com or scan the QR code at the bottom of the page.

Since this story was captured Rachel has been fitted with prosthetic legs, and is making progress learning to stand and walk. Jones still visits every day and is hopeful that he will soon be able to take her home permanently.





SCAN THE OR CODE TO SEE RACHELS VIDEO

ALTERNATIVELY MORE INFORMATION CAN BE FOUND ONLINE: WWW.TISSUEREGENIX.COM

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

**dCELL** technology

# **PRODUCT PIPELINE**

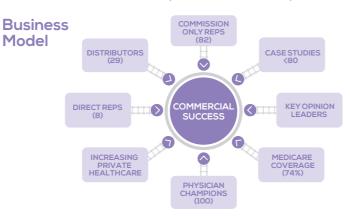
<b>()</b> F	PRODUCT	Ø
	DERMA [PURE]	

## Market **DermaPure**<sup>®</sup>

It is estimated that the US Government's spending on wound care is close to \$20bn per annum, and has a CAGR between 4-5%. This is partly down to the inexorable rise in diabetes and pre-diabetes, with the CDC estimating that 86m people in the US have pre-diabetes, 29.1m children and adults have diabetes, and 8.9m are undiagnosed.

Most advanced wound care product categories have experienced price erosion while novel ones, such as dermal substitutes and growth factors, are perceived as more advanced treatment options that still contain a higher level of pricing power. DermaPure® is a skin substitute that is reimbursed within the high cost treatment category by Medicare, vielding greater reimbursement. The skin substitute market is estimated to continue to grow with a CAGR of 15% over the next five years.

INTENDED USE		
Acute and chronic wounds	Allograft dermis	June 2014
Soft tissue augmentation, Traumatic wounds, Tendon repair	Allograft dermis	H2 2016
Hernia repair, body wall defects	Xenograft dermis	H2 2016



## SurgiPure<sup>™</sup> XD

Having received FDA market clearance in March 2016, we expect to launch SurgiPure<sup>™</sup> XD into the US market in H2 CY2016.

Aimed at body wall defects and hernia repair, a market valued at \$1bn within the US alone, SurgiPure™ XD will be positioned within the complex hernia segment where there are currently fewer treatment options, with the market opportunity currently valued at \$300m.

## In Summary

DermaPure® has made significant progress over the last 12 months, securing Medicare coverage and reimbursement, and also raising its profile as a 'go-to' wound care treatment, showing exceptional clinical results which have been published in several peer reviewed posters and journals. With the FDA market approval for SurgiPure™ XD we anticipate a launch in H2 CY16 and continue to actively look to commercialise line extensions for these products.

#### **GREG BILA**

PRESIDENT 23 May 2016

# OPERATIONAL REVIEW ORTHOPAEDICS



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We have made significant progress with our orthopaedic portfolio this year. Commencing the trials for both OrthoPure<sup>™</sup> XM and OrthoPure<sup>™</sup> XT, we now await to submit the final clinical data needed for our CE mark application and we hope to receive approval in early 2017.

We are delighted to welcome to the Orthopaedic team Drew Distin, who will lead our entry into the US marketplace, and we now feel that we have the strength and experience within our senior commercial team to drive market penetration in both the EU and US.

Our initial focus within the US will be on the human tissue applications, again addressing both ligament reconstruction and meniscus replacement, which we hope to launch over the coming year, once a suitable tissue bank partner has been indentified.

# OrthoPure<sup>™</sup> XM

The meniscus is a crescent shaped fibrocartilage tissue structure on either side of the knee joint. It acts as a highly efficient shock absorber between the bones of the upper and lower leg. It can be damaged by injury (sports) or overuse, causing pain, swelling and locking of the knee.

By substituting the tissue removed during a partial menisectomy with OrthoPure<sup>™</sup> XM the body can be stimulated to repair and regenerate its own tissue, solving the underlying problem as well as treating the symptoms caused by it. "WE HAVE TAKEN SIGNIFICANT STEPS TOWARDS BRINGING OUR PORCINE PRODUCTS TO THE EU MARKET DURING THE YEAR. LOOKING FORWARD, WE EXPECT TO BEGIN OUR ENTRY INTO THE US MARKET AND HUMAN TISSUE APPLICATIONS IN THE COMING YEAR."

PETER HAMER COMMERCIAL DIRECTOR TISSUE REGENIX ORTHOPAEDICS LIMITED



# OrthoPure<sup>™</sup> XT

Injuries to the Anterior Cruciate Ligament (ACL) are one of the most common and devastating knee injuries, mainly sustained through sports participation and any activities that involve jumping and twisting, causing pain, swelling, muscle weakness and instability. Over time ACL injuries are also associated with damage to the meniscus and joint surfaces, the onset of osteoarthritis and eventually joint replacement.

OrthoPure<sup>™</sup> XT is an off-the-shelf biological solution for ACL reconstruction providing a strong stable fixation that over time becomes the patient's own ACL.

## Opportunity for OrthoPure<sup>™</sup> Products

Each year, there are around 1.5 million meniscal tears in Europe and the USA. The majority of these tears are not repairable and are treated with keyhole surgery techniques where the torn or damaged tissue is removed in a procedure known as a partial menisectomy. In many cases the pain returns due to the loss of tissue and shock absorbing functions of a healthy meniscus, and over a longer period of time, if left untreated, can lead to joint surface damage (articular cartilage), the onset of osteoarthritis and eventually joint replacement. Allograft meniscal transplantation is currently the only commonly accepted surgical procedure for patients with a deficient meniscus, though rarely performed.



Therefore, there is currently a large unmet need to restore the healthy function of the joint through a quick, minimally invasive procedure.

There around 900,000 ACL reconstructions in the EU and the USA each year. Nearly all these procedures are performed with either an autograft (taken from the patient) or an allograft (taken from human tissue banks). Autografts have been associated with an increase in operation and rehabilitation time, and weakness around the area from where the graft has been taken. Allografts have been associated with supply constraints, variable tissue quality and possible disease transmission.







# **PRODUCT PIPELINE**

(	PRODUCT			
		Partial menisectomy replacement	Porcine meniscus	CE mark application expected H1 2017
		Ligament reconstruction	Porcine ligament	CE mark application expected H1 2017
	ORTHO [PURE] @	Partial menisectomy replacement	Human meniscus	TBC US 2017
		Ligament reconstruction	Human ligament	TBC US 2017

# Significant Market Trends

- Multi-ligament reconstructions are on the rise
- More female athletes are undergoing procedures, with studies showing a higher incidence of re-injury for young female athletes with a hamstring autograft
- Recent studies show less than optimal results with some prevalent processing methods
- Older patients more likely to require allograft rather than autograft

# Benefits of Xenograft dCELL® Products:

consistent quality

- No fluctuation in quantity or size choices
- O Gives surgeons reliable implants of
- Can plan pre-operatively for tunnel diameter, fixation device, instrumentation
- Mechanical characteristics equal to existing options
- Potential for faster surgery, quicker rehabilitation and earlier return to activity
- Room temperature storage allows for intraoperative decision to implant

# **In Summary**

The ultimate goal of both OrthoPure<sup>™</sup> XM and OrthoPure<sup>™</sup> XT is to offer surgeons a readily available, healthy, strong and consistently sized graft material that is stored at room temperature, and is believed to offer more reliable mechanical characteristics than current options.

Our mission with OrthoPure<sup>™</sup> XT and XM is to reduce patients' knee pain and instabilities, allowing them to return to the quality of life experienced prior to the injury. In the short term, OrthoPure<sup>™</sup> XT eliminates the need for the "donor site" surgery during autograft procedures, reducing patient pain, and may therefore lead to faster recovery times. OrthoPure<sup>™</sup> XM helps restore the shock absorbing function of the meniscus, which in the longer term could potentially delay the onset of osteoarthritis and the need for further surgical procedures, ultimately reducing the growing economic burden on healthcare systems.



SCAN THE OR CODE TO SEE THE ORTHOPAEDICS VIDEO

> ALTERNATIVELY MORE INFORMATION CAN BE FOUND ONLINE: WWW.TISSUEREGENIX.COM

# OPERATIONAL REVIEW CARDIAC



Since our last Annual Report TRX Cardiac has taken significant steps in realising the exciting potential of dCELL® cardiac applications.

Based on ten years of clinical data from Professor Francisco da Costa's pioneering work at the Pontifical Catholic University of Paraná (PUCPR), and the Santa Casa hospital, Brazil, relating to CardioPure dCELL® pulmonary and aortic heart valves, the results of which confirm the success of dCELL® in this field, TRX granted the first licence for decellurised heart valves in Europe. Taking a new business approach to allow European clinicians and patients access to this technology, TRX entered a Joint Venture in Rostock, Germany, establishing tissue bank. GBM-V with partner GTM-V. As Germany has particularly stringent human tissue regulations, it provides a high benchmark from which wider EU approvals can be sought, with the expectation of a global roll out in the coming years. We anticipate to be in a position to release the first decellurised tissues from GBM-V in 2017.

"THIS HAS BEEN A FORMATIVE YEAR FOR CARDIAC, COLLECTING TEN YEAR CLINICAL FOLLOW UP DATA FROM OUR PARTNER IN BRAZIL, AND GRANTING OUR FIRST dCELL<sup>®</sup> HUMAN HEART VALVE LICENCE, PAVING OUR WAY TO ENTER THE EU MARKET."

#### ANDREA RAUSCH

COMMERCIAL DIRECTOR, TRX CARDIAC LIMITED



# Highlights

 $\, \odot \,$  Joint Venture entered in Germany

- Ten years of follow up data in 100 patients who received an aortic dCELL<sup>®</sup> homograft valve
- Multicentre follow up study of children below 12 years of age at the time of implant who received a complete dCELL<sup>®</sup> pulmonary heart valve, showing very promising initial results
- Presentations of these findings at prestigious conferences around the world

#### **Key Findings**

The ten year follow up clinical data from Brazil presented by Professor Francisco da Costa revealed excellent and exciting results. These were particularly significant given the average age of these aortic valve patients was young, and all were considered to be high risk. The data collected confirms that the dCELL® human aortic heart valve can provide a more effective treatment than standard cryopreserved valve substitutes.

The data showed:

- Freedom from reoperation in this high risk group was 89% after ten years
- O Partial cellular repopulation of the valve
- CT scans showed absence of calcification even in the valve root, essential in this treatment, where, in younger patients, it is a significant problem.

# TRX Cardiac

MORE INFORMATION ON OUR JOINT VENTURE CAN BE FOUND ON PAGES 20-21

The data was presented at the following Congress presentations:

# CONGRESS PRESENTATIONS AORTIC IN 2015

EATB European Annual Tissue Bank Meeting, Split, Croatia, **1-30 October 2015** 

HVS Heart Valve Society Meeting, Monaco **6-9 May 2015** 

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# **PRODUCT PIPELINE**

# INTENDED USE O DESCRIPTION Replacement of diseased,

damaged, malformed or

malfunctioning native or

prosthetic pulmonary valves

Replacement of diseased,

damaged, malformed or

malfunctioning native or

prosthetic aortic valves

## Market

PRODUCT

The global market for heart valve replacement procedures is around 225,000<sup>1</sup>.

An average of 425 people each day or one every three minutes<sup>2</sup> will die from cardiovascular (heart and circulatory) disease (CVD) in the UK. In adult patients with valvular problems the aortic valve tends to be the main area of concern, with the pulmonary being problematic in younger patients. However, scientific opinion suggests "In younger patients, nearly 65% of Homografts degenerate after five years"3.

This highlights the need for a longer lasting biological heart valve replacement which could prevent the trauma of reoperation. The dCELL® heart valve regenerates to become part of the patient's body, providing a more durable repair with a significantly reduced risk of rejection and infection.

It is not just the physical and emotional implications to the patients, but the increasing economic burden on healthcare systems around the world which makes this significant, with the British Heart Foundation estimating that the healthcare costs in the UK alone (associated with CVD) to be upto £11bn4.

As average life expectancy increases, so too does the expectation to remain physically active, with a high quality of life, for much longer. The freedom from reoperation or need for antirejection drugs allows patients to lead almost a completely normal, physically active life. It could also significantly reduce the economic consequences of this problem.

# In Summary

Human pulmonary

heart valve

Human aortic

heart valve

CardioPure addresses the unmet clinical and economic needs of the healthcare community for longer lasting biological heart valve replacements, aimed especially at preventing costly reoperations in the paediatric and younger patient population while also addressing the lifestyle needs of an ageing, but increasingly active older patient population, increasing life expectancy and enhancing their quality of life.

**O** TIME TO MARKET

Initial licence granted

H1 CY16 EU launch

expected H1 CY17

On the market in Brazil

Initial licence granted

H1 CY16 EU launch

expected H1 CY17

On the market in Brazil

- http://www.medsolution.com/surgery
- cardiothoracic-heartvalv.asp
- www.bhf.org.uk/research/heart-statistics Poynter for CHSS, 2013
  - www.bhf.org.uk/research/heart-statistics

# **GABRIELY'S** STORY

I FEEL GOOD, I FEEL CALM AND VERY CONFIDENT. I CAN IMAGINE MANY THINGS FOR HER FUTURE. TODAY, SEVEN YEARS AFTER THE SURGERY, I CAN BE MORE RELAXED AND CONFIDENT ABOUT HER FUTURE. GABRIELY'S MOTHER

Gabriely is twelve years old. Today she enjoys participating in sport and other physical activities as do most children of her age.

However, this has not always been the case.

When Gabriely was born she was found to have aortic stenosis and at just five days old underwent her first cardiac surgery. Unfortunately, this initial procedure was unsuccessful and thirty days later Gabriely required further heart valve surgery, having two major surgical interventions before she was even six weeks old.

Throughout her early years she required carefully monitored medication, but even with that Gabriely was unable to participate in normal childhood activities with her friends, and so when she was three years old the decision was made that she needed to have a heart valve replacement.

Although at the time there were several therapeutic options available, for a young girl, the potential drawbacks of these could impact the rest of her life. As a growing child she could well need to undergo further major cardiac surgery in the future, and would require anti-coagulant drugs for the rest of her life, both meaning that it would also be unlikely that she would be able to have her own children.

Then the family heard about dCELL®.

Gabriely received a dCELL® valve in October 2007 and has since had no need for medication or reoperation; she is now only required to have a follow up appointment once a year.

Thankfully, nine years later Gabriely is now living the life of a normal twelve year old girl to the full, enjoying ballet and playing with her friends.

Gabriely and her family now look forward to a positive future. Gabriely hopes that the she will become a paediatrician, so that she can help children in similar situations.

Thanks to dCELL®, that dream could very well become a reality.









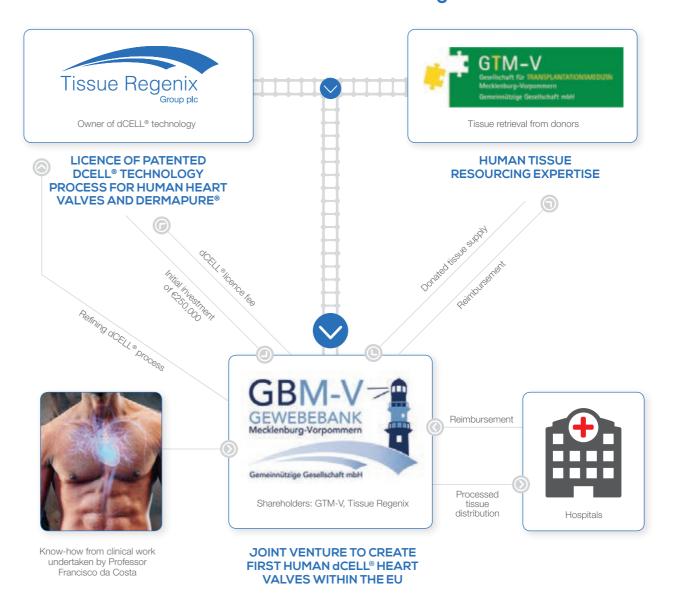


# STRATEGIC REPORT

# JOINT VENTURE OVERVIEW

A GROUNDBREAKING DEVELOPMENT FOR TISSUE REGENIX WAS THE ESTABLISHMENT OF THE GROUP'S JOINT VENTURE AGREEMENT, SIGNED IN JANUARY 2016, WITH THE GERMAN TISSUE BANK GTM-V BASED IN ROSTOCK, GERMANY.

# How TRX and GTM-V work together







# **GBM-V**

The partnership with GTM-V, the founders of which are widely respected in the tissue bank sector, to create GBM-V will be a key factor in the expansion of Tissue Regenix's market penetration into continental Europe.

Granting for the first time the licence to the dCELL® heart valve, it is hoped that regulatory approval from the German authorities will be gained to commence a roll out during 2017. It is also the first commercial licence for the Group's DermaPure® product outside of the US.

With the stringent regulatory process within Germany relating to human tissue applications, we anticipate that once we have gained approval there, we will be in a position to seek approval from other EU countries. This new partnership offers a number of advantages for both parties. Tissue Regenix gains an ethically aligned partner, who will be responsible for the procurement of donor tissue, and who have extensive experience in managing the necessary regulatory approvals by the German authorities while GTM-V will have access to the patented dCELL<sup>®</sup> process for both heart valves and DermaPure<sup>®</sup>.

It is expected that this business model will be rolled out globally with other partners in the coming years to allow access to a full portfolio of dCELL® human tissue applications to patients and healthcare providers around the world. Tissue Regenix will select a limited number of respected partners whose policies and ethical approach align with the Group's.



SCAN THE QR CODE TO SEE OUR JOINT VENTURE VIDEO

ALTERNATIVELY MORE INFORMATION CAN BE FOUND ONLINE: WWW.TISSUEREGENIX.COM

# **CFO STATEMENT**



"Tissue Regenix Group plc ended FY16 in line with our expectations. Taking our first product through it's first full year we generated revenue of £816k, and maintained a strong cash balance at the end of the period of £19,907k."

## IAN JEFFERSON

CHIEF FINANCIAL OFFICER

For the year ended 31 January 2016 Tissue Regenix Group plc delivered revenue of £816k (2015: £100k) and generated an operating loss of £10,242k (2015: £8,369k). With finance income of £213k (2015: £168k) and a research and development tax credit of £527k (2015: £620k) the loss after tax was £9,502k (2015: £7,581k) of which £9,410k (2015: £7,581k) was attributable to the equity holders of the parent Company. Cash balances at the end of the period were £19,907k (2015: £10,257k). The results were in line with our expectations.

## **Segmental Analysis**

A split of the Group's results by operational division, 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	Cen	tral	Tot	tal
	2016 £000	2015 £000								
Total segment	884	72	-	-	76	_	8	28	968	100
Inter-segment	(76)	-			(76)	_	-	-	(152)	_
Revenue	808	72	-	_	-	_	8	28	816	100
Cost of sales	(154)	(32)	-	_	_	_	-	_	(154)	(32)
Gross Profit	654	40	-	_	-	_	8	28	662	68
Administrative costs	(4,938)	(2,843)	(2,382)	(2,054)	(352)	(250)	(3,232)	(3,290)	(10,904)	(8,437)
Operating loss	(4,284)	(2,803)	(2,382)	(2,054)	(352)	(250)	(3,224)	(3,262)	(10,242)	(8,369)
Finance income	-	-	-	-	-	_	213	168	213	168
Loss before taxation	(4,284)	(2,803)	(2,382)	(2,054)	(352)	(250)	(3,011)	(3,094)	(10,029)	(8,201)
Taxation	169	50	324	510	16	60	18	_	527	620
Loss for the year	(4,115)	(2,753)	(2,058)	(1,544)	(336)	(190)	(2,993)	(3,094)	(9,502)	(7,581)

	Wound	Care	Orthop	aedics	Carc	diac	Cen	tral	Tot	al
	2016 £000	2015 £000								
							2000	2000		
Development	(1,108)	(1,029)	(2,279)	(2,032)	(289)	(235)	-	-	(3,676)	(3,296)
Sales and marketing <sup>†</sup>	(3,672)	(1,766)	-	-	-	-	-	-	(3,672)	(1,766)
Operations *	(158)	(48)	(103)	(22)	(63)	(15)	(3,232)	(3,290)	(3,556)	(3,375)
Admin costs	(4,938)	(2,843)	(2,382)	(2,054)	(352)	(250)	(3,232)	(3,290)	(10,904)	(8,437)

 $^{\ast}$  Central costs include plc, the Board, operations, finance and facilities.

<sup>+</sup> Sales and marketing for Wound Care includes the entire costs for our US entity. Included within these costs is £303k (2015: £21k) commission on sales.





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

# Wound Care

Group revenue for the year was generated almost entirely from the Wound Care division with revenue of £808k (2015: £72k). Launched in the second half of the prior year, FY16 represents the first full year of sales for DermaPure<sup>®</sup>. Delivering £808k (\$1.2m) of revenue from our first product launched in the USA, demonstrates the successful transition from development to commercialisation, a significant achievement. Moving forward we anticipate continued acceleration of DermaPure® revenue. The exact timing of distributor appointments and contract approvals is highly variable, therefore our revenue expectation range for the next 12 months is between \$2.5-\$4.5m. However, as described on page 24 our next accounting period will be shortened to 31 December 2016, a period of 11 months. The expected reported revenue in the current period will therefore be proportionally smaller. As announced earlier in the year, SurgiPure™ XD has been granted 510k approval in the USA and it is anticipated that the product will be launched in H2 CY16. We therefore do not expect a material impact on revenue from this product in the current period.

Gross margin for the year for the Wound

Care division was 81% (2015: 56%). The margin in both years was impacted by the provision of free of charge evaluation units to potential new customers. This was naturally higher in the initial months after product launch and therefore affected 2015 more significantly than 2016. As recurring business has been established the number of evaluation units has reduced as a proportion of total units shipped resulting in an increase in the margin achieved. The underlying margin on product sales, excluding the evaluation units, was 86% (2015: 82%), the variance in the underlying margin being the result of product size mix.

Development costs at £1,108k (2015: £1,029k) resulted from the associated expense of the on going randomised clinical trial of DermaPure®, to collect clinical evidence for use supporting the sales and marketing functions, and the 510k process costs for SurgiPure<sup>™</sup> XD. We expect these costs to be slightly lower in the current period as the DermaPure® trial is coming to an end and SurgiPure™ XD is in the final qualification stages before product launch. Sales and marketing expenditure of £3,672k (2015: £1,766k) represents the costs of our US entity. The increase during the year resulted from the planned recruitment of additional direct sales heads, marketing costs to support the roll out of DermaPure® and commission costs on sales. The commission costs were £303k (2015: £21k), which as a percentage of sales was therefore 37.5% (2015: 29.2%). The commission percentages paid vary between salaried reps, external distributors and commission- only reps. The overall percentage paid will therefore vary depending on the sales mix but is

anticipated to move towards 35%. For the current period the total sales and marketing costs will increase due to a combination of commission ramping in line with revenue growth, the full year effect of hires in FY16 and several new appointments being made to support the distribution side of our hybrid sales model.

With the working capital and start-up costs of the US operation the Group has a net outflow of US dollars. The recent strength of the US dollar rate means that this outflow is proportionally more expensive when translated into sterling, the Group's functional currency. However, this situation will reverse when the US operation becomes profitable and cash generative.

## **Orthopaedics**

Significant progress was made during the period with both OrthoPure<sup>™</sup> XM and OrthoPure<sup>™</sup> XT. The development costs incurred of £2,279k (2015: £2,032k) consisted primarily of the pre-clinical and clinical trial costs of both these products as they moved into the human trial phase. We would anticipate these costs increasing in the current period as the implanted patient numbers grow and we move towards CE marking. Product launch for orthopaedic products is expected in the first half of CY17.

## Cardiac

There are no material results for year for this division. However, a significant step forward was made with the creation of a Joint Venture tissue bank in Germany in January 2016, an important first step in the process of commercialising our human heart valve

# **CFO STATEMENT** CONTINUED

technology in Europe. Details on the Joint Venture are included in the Strategic Review on pages 20-21.

### Central

Operation costs are mainly incurred centrally and are in general not allocated to individual operating divisions. Costs have been kept under control and remained flat over the period at £3,232k (2015: £3,290).

#### **Finance Income**

Finance income increased to £213k (2015: £168k) and represents interest earned on cash deposits. The increased interest reflects the additional cash held on deposit subsequent to the equity fund-raise in February 2015.

The Group follows a risk-averse policy of treasury management. Cash deposits are held across a number of counterparties and are held only 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 year to 31 January 2016 is £492k (2015: £620k).

Tax losses carried forward by the Group at the end of January 2016 were £23,772k (2015: £16,121k). 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 January 2016 the Group had cash resources of £19,907k (2015: £10,257k) and was debt free. The increase in cash balances resulted from an equity placing in February 2015 which raised £18,947k after expenses. Adjusting for the fund-raise the outflow of cash from other activities was £9,297k (2015: £8,226k). The bulk of this outflow, £9,116k (2015: £8,038k), related to the "cash" operating loss (operating loss excluding non-cash items).

### Accounting Reference **Date Change**

Historically, the Group had a 31 July year end, consistent with its origins as a University spin-out. On reversal onto AIM in 2010 the Group adopted the accounting reference date of 31 January in line with the vehicle into which it reversed. However, now that the Group is entering its commercial phase the Board has decided to change the accounting reference date to 31 December,

primarily to bring it in line with a more conventional commercial company reporting timeframe and to provide ease of reference for investors, customers, managers and emplovees.

The effect of the change to the accounting reference date is to shorten the next accounting period to 31 December 2016, a period of 11 months. The Group will therefore have the following reporting dates:

- O Unaudited results for the 6 months to 31 July 2016
- O Audited results for the 11 months to 31 December 2016

The Group will subsequently publish its half-yearly reports to 30 June and annual report and accounts to 31 December in accordance with the AIM Rules for Companies.

#### IAN JEFFERSON

CHIEF FINANCIAL OFFICER 23 May 2016





# **RISKS**

# Key Risks

The Board carefully considers the risks facing the Group and endeavours to minimise the impact of those risks. The key risks are as follows:

- O Regulatory risk. Regulatory approval timelines can be affected by a number of factors such as trial recruitment rates, clinical results and changes to regulatory requirements which are outside the control of the Group. However, all of the Group's products follow well established regulatory routes and the Group employs experienced regulatory personnel to navigate the process.
- O Intellectual property protection. The commercial success of the Group may depend on its ability to protect and exercise its intellectual property rights. Some of the patents held by the Group are process patents which can be difficult to defend. However, the Group retains a significant amount of know-how, not disclosed in the patents, which offers protection in this area. Some of the intellectual property in the Group, including know-how, is transferred to partners who undertake tissue processing on behalf of the Group. These transfers of intellectual property are undertaken under strict legal agreements but the Group acknowledges that there is a risk of IP leakage as a result and hence endeavours to only undertake such arrangements with parties and in territories where there is appropriate legal protection.
- Competition. Although the Directors believe that for certain of the Group's products there is limited direct competition, there may be products and competitors that they are currently unaware of which could have a detrimental effect on the Group's trading performance. Furthermore, some of the Group's products will be sold in more competitive environments. The Group therefore expects a balanced exposure to competition with some offerings facing little competition, but others facing significantly more.
- Attraction and retention of key employees. The Group depends on the Directors and certain other key employees spread across its various subsidiaries. The ability to attract



and retain key employees cannot be guaranteed. However, the Group endeavours to ensure succession planning where possible and ensures that remuneration and incentive packages are in line with industry standards.

- O **Development risk**. There can be no guarantee that any of the products currently in development will be developed into commercially viable products, meet regulatory requirements or be manufactured in commercial quantities at an acceptable expense or marketed successfully and profitably. However, both DermaPure®, approved in the US under the HCTP guidelines, and SurgiPure<sup>™</sup> XD with FDA 510(k) market approval, demonstrated that the development process works and similar processes are being utilised for the subsequent products. Additionally, the Group employs experienced development and commercial personnel who have experience of successfully bringing such products to the market.
- O Sourcing risk. For the human tissue derived products, the Group relies on third party tissue banks to provide the source material for processing with the dCELL<sup>®</sup> technology. There can be no assurance that sufficient source material will be available to match demand.

- Product Quality Risk. The Group operates in highly regulated markets with strict quality requirements. Any quality failure involving the Group's products could lead to the loss of reputation, loss of revenues, the loss of a customer, recall costs as well as sanctions from a regulator. To mitigate this, the Group operates within a strictly controlled Quality Management System.
- O Manufacturing. Problems with the scale up of our manufacturing process, failure to comply with manufacturing regulations or pass regulatory inspections or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.

#### **Future Developments**

Future developments are described in the Chairman's statement and Chief Executive's Review on pages 4- 5 and 11-13.

On behalf of the Board

#### ANTONY ODELL

CHIEF EXECUTIVE OFFICER 23 May 2016

# **BOARD OF DIRECTORS**



John Samuel Chairman

#### Chairman

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.



# 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 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 UK NHS cardiovascular device spin-out, Tayside Flow Technologies Ltd (now Vascular Flow Technologies Ltd).



# lan Jefferson

Chief Financial Officer lan Jefferson joined Tissue Regenix Group plc as Chief Financial Officer in June 2011. lan was formerly Chief Executive Officer of AIM listed COE Group Plc. Having initially joined COE as CFO in 2007 he became CEO in 2008, restructured the Group and then successfully planned and executed its sale. Prior to COE, lan held a number of senior finance positions within LSEquoted companies, most recently as Group Financial Controller of The 600 Group Plc. He has a comprehensive financial and operations background and extensive experience of organisational transformation and M&A. A qualified chartered accountant, lan holds a BSc in Physics with Electronics from Manchester University and an MSc in Applied Radiation Physics from Birmingham University.





# **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 a founding partner of SCM Private, the 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, he 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.





Non-Executive Director

Randeep is currently a portfolio manager for the Trium Multi-Strategy Fund having worked in the institutional investment arena since 1998 including Senior Portfolio Manager and member of the European equities team at F&C Asset Management. Previously he held investment analyst and portfolio management roles at ICAP Equities and Tudor Capital, where he spent ten years covering and investing in healthcare companies. Randeep qualified in Medicine from the University of Cambridge (after graduation he trained as a general and vascular surgeon for eight years - and obtained his fellowship of the Royal College of Surgeons (England)). He is also a mentor at Level 39 (Europe's largest Fintech Incubator).



# **Steven Couldwell**

Non-Executive Director

Steven Couldwell has a proven international track record in driving revenues and profit growth in both the medical device and CRO industries. With over 14 years of senior management experience, Steven is currently Chief Operating Officer at Sanofi Biosurgery, which has revenues of approximately \$750m. Steven was also 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.

# **DIRECTORS' REPORT**

The Directors present their report and consolidated financial statements for the year ended 31 January 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 Group's activities and how it seeks to add value are included in the Strategic report on pages 4-25.

### **Business review and results**

A review of the Group's performance and future prospects is included in the Strategic report on pages 4-25. The loss for the year attributable to equity holders was  $\pounds9,410k$  (2015:  $\pounds7,581k$ ). The Directors do not recommend the payment of a dividend (2015: nil).

### Share capital and funding

Full details of the Group and Company's share capital movements during the year are given in note 13 of the financial statements. During the year the Company raised £20m (before expenses) by way of a share placing.

## **Directors and their interests**

The following Directors held office in the year.

John Samuel Antony Odell Ian Jefferson Jonathan Glenn (appointed 19 January 2016) Alan Miller Alison Fielding (resigned 26 February 2015) Randeep Singh Grewal Steven Couldwell

Directors' interests in the shares of the Company, including family interests, are included in the Remuneration Report on pages 30-33.

## **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 30 April 2016, shareholders holding more than 3% of the share capital of Tissue Regenix Group plc were:

Woodford Investment Management LLP         130,506,642         17.1           Techtran Group Ltd         103,042,837         13.5           Baillie Gifford & Co Ltd         54,508,667         7.1           Jupiter         34,742,431         4.5           Leeds University         33,980,127         4.4           NFU Mutual         28,394,099         3.7	Name of shareholder	Number of shares	% of voting rights
Techtran Group Ltd         103,042,837         13.5           Baillie Gifford & Co Ltd         54,508,667         7.1           Jupiter         34,742,431         4.5           Leeds University         33,980,127         4.4           NFU Mutual         28,394,099         3.7	Invesco Limited	211,328,351	27.80
Baillie Gifford & Co Ltd       54,508,667       7.1         Jupiter       34,742,431       4.5         Leeds University       33,980,127       4.4         NFU Mutual       28,394,099       3.7	Woodford Investment Management LLP	130,506,642	17.17
Jupiter         34,742,431         4.5           Leeds University         33,980,127         4.4           NFU Mutual         28,394,099         3.7	Techtran Group Ltd	103,042,837	13.56
Leeds University         33,980,127         4.4           NFU Mutual         28,394,099         3.7	Baillie Gifford & Co Ltd	54,508,667	7.17
NFU Mutual 28,394,099 3.7	Jupiter	34,742,431	4.57
	Leeds University	33,980,127	4.47
John Samuel* 24,276,928 3.7	NFU Mutual	28,394,099	3.74
	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, there is no relevant audit information of which the Auditor is unaware. Each of the Directors have 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 23 May 2016

# 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 incentivised 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, Jonathan Glenn 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. These metrics include; 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 Allocation 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.

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# **Directors' Remuneration**

The remuneration of the main Board Directors of Tissue Regenix who served in the year to 31 January 2016 was:

	Salary & fees £000	Bonus £000	Benefits £000	Total 2016 £000	Total 2015 £000
Antony Odell <sup>1</sup>	185	110	15	310	249
John Samuel <sup>1</sup>	100	-	-	100	100
lan Jefferson <sup>1</sup>	137	65	10	212	180
Randeep Grewal	20	-	-	20	20
Steven Couldwell	25	-	-	25	20
Alison Fielding <sup>2</sup>	2	-	-	2	25
Alan Miller	25	-	-	25	25
Total	494	175	25	694	619

 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 £13,000 (2015: £32,000), Antony Odell £35,000 (2015: £47,000), Ian Jefferson £46,000 (2015: £51,000).

2. Alison Fielding resigned on 26 February 2015.

# **Directors' Shareholdings**

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

	Ordinary shares of 0.5p each				
	2016 Number	<b>2016</b> %	2015 Number	2015 %	
John Samuel <sup>3</sup>	24,276,928	3.19%	24,276,928	3.71%	
Antony Odell <sup>3</sup>	5,572,800	0.73%	5,572,800	0.85%	
lan Jefferson <sup>3</sup>	1,009,404	0.13%	1,009,404	0.15%	
Alison Fielding	2,279,661	0.30%	2,279,661	0.35%	
Alan Miller	21,886,988	2.88%	21,486,988	3.28%	

<sup>3</sup> Includes shares held jointly by the Director and EBT as set out below.

# DIRECTORS' REMUNERATION REPORT CONTINUED

# 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	Exercised	Lapsed	Granted	31 January	
	2015	during year	during year	during year	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
lan Jefferson <sup>6</sup>	122,779	_	-	_	122,779	22.50 pence
lan Jefferson <sup>7</sup>	346,936	_	_	-	346,936	0.05 pence
lan Jefferson <sup>9</sup>	_	_	_	505,976	505,976	0.05 pence
John Samuel <sup>6</sup>	88,890	_	-	-	88,890	22.50 pence
EBT scheme shares <sup>10</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

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- 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.
- 7. 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 January 2016 none of the performance conditions had been met and no options were eligible for exercise.
- a. 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 January 2016 none of the performance conditions had been met and no options were eligible for exercise.
- 10. 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 ordinary 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 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 financial statements.

On behalf of the Board

#### STEVE COULDWELL

CHAIRMAN OF THE REMUNERATION COMMITTEE 23 May 2016

# **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

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The Board currently comprises three Executive Directors and four 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 Auditor relating to the accounting and internal controls; and to make recommendations relating to the appointment of the external Auditor.

The Audit Committee comprises Alan Miller, who acts as chairman of the committee, Steven Couldwell, 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
- (v) there are well-established financial reporting and control systems.

### **Going Concern**

At 31 January 2016, the Group had £19.9m of cash and cash equivalents available to it. 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.

After due enquiry, the Directors consider that the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the financial statements.





# STATEMENT OF DIRECTORS' RESPONSIBILITIES

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 Group financial statements in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union ("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 the parent Company and of their profit or loss for that period. In preparing each of the Group and the parent Company financial statements, the Directors are required to:

- a. select suitable accounting policies and then apply them consistently;
- b. make judgements and estimates that are reasonable and prudent;
- c. state whether they have been prepared in accordance with IFRS as adopted by the EU; and
- d. 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 to enable them to ensure that the financial statements comply with the Companies Act 2006. They have a 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 Tissue Regenix Group website, www.tissueregenix.com.

Legislation in the United Kingdom 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 year ended 31 January 2016 set out on pages 37 to 58. 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 35, 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:

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- 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 January 2016 and of the group's loss for the year 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 and, as regards the group financial statements, Article 4 of the IAS Regulation.

### Opinion on other matters prescribed by the Companies Act 2006

In our opinion:

- O the part of the Directors' Remuneration Report to be audited has been properly prepared in accordance with the Companies Act 2006; and
- O the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared 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 and the part of the Directors' Remuneration Report to be audited 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 23 May 2016



# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

for the year ended 31 January 2016

	Notes	2016 £000	2015 £000
REVENUE	3	816	100
Cost of sales		(154)	(32)
GROSS PROFIT		662	68
Administrative expenses	3	(10,904)	(8,437)
OPERATING LOSS		(10,242)	(8,369)
Finance income	6	213	168
LOSS BEFORE TAXATION		(10,029)	(8,201)
Taxation	7	527	620
LOSS FOR YEAR		(9,502)	(7,581)
ATTRIBUTABLE TO:			
Equity holders of the parent		(9,410)	(7,581)
Non-controlling interests		(92)	-
		(9,502)	(7,581)
OTHER COMPREHENSIVE INCOME:			
Foreign currency translation differences – foreign operations		(1)	(4)
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR	_	(9,503)	(7,585)
ATTRIBUTABLE TO:			
Equity holders of the parent		(9,411)	(7,585)
Non-controlling interests		(92)	_
	_	(9,503)	(7,585)
LOSS PER SHARE			
Basic and diluted on loss attributable to equity holders of the parent	8	(1.27)p	(1.19)p
The loss for the year arises from the Group's continuing the operations			

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

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

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 January 2016

	Attributable to equity holders of the parent Share									
	Share capital £000	Share premium £000	Merger reserve £000	Reverse acquisition reserve £000	Reserve for own shares £000	based payment reserve £000	Retained earnings deficit £000	Total £000	Non- controlling interests £000	Total equity £000
At 31 January 2014	3,267	31,971	10,884	(7,148)	(831)	630	(19,795)	18,978	-	18,978
Loss for the year	_	_	_	-	_	-	(7,581)	(7,581)	-	(7,581)
Other comprehensive expense	_	_	_	_	_	_	(4)	(4)	_	(4)
Loss and total comprehensive expense for the year	_	_	_	_	_	_	(7,585)	(7,585)	_	(7,585)
Exercise of share options	4	1	_	_	_	_	_	5	_	5
Share based payment expense	_	_	_	_	_	180	_	180	_	180
At 31 January 2015	3,271	31,972	10,884	(7,148)	(831)	810	(27,380)	11,578		11,578
Loss for the year	-	-	-	-	-	_	(9,410)	(9,410)	(92)	(9,502)
Other comprehensive expense	_	_	_	_	_	_	(1)	(1)	_	(1)
Loss and total comprehensive expense for the year	_	_	_	_	_	_	(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



# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

as at 31 January 2016

		2016	2015
ASSETS	Notes	000£	£000
Non-current assets		004	105
Property, plant and equipment	9	901	435
TOTAL NON-CURRENT ASSETS		901	435
Current assets			
Inventory		64	34
Trade and other receivables	10	2,325	1,947
Cash and cash equivalents	11	19,907	10,257
TOTAL CURRENT ASSETS		22,296	12,238
TOTAL ASSETS		23,197	12,673
LIABILITIES			
Current liabilities			
Trade and other payables	12	(1,958)	(1,095)
TOTAL LIABILITIES		(1,958)	(1,095)
NET ASSETS		21,239	11,578
EQUITY			
Share capital	13	3,801	3,271
Share premium	13	50,461	31,972
Merger reserve	13	10,884	10,884
Reverse acquisition reserve	13	(7,148)	(7,148)
Reserve for own shares		(831)	(831)
Share based payment reserve	16	946	810
Retained earnings deficit	14	(36,791)	(27,380)
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF PARENT		21,322	11,578
Non-controlling interests		(83)	-
TOTAL EQUITY		21,239	11,578

Approved by the Board of Directors and authorised for issue on 23 May 2016.

JOHN SAMUEL IAN JEFFERSON CHAIRMAN

CHIEF FINANCIAL OFFICER

Company number: 5969271

# CONSOLIDATED STATEMENT OF CASH FLOWS

for the year ended 31 January 2016

	Notes	2016 £000	2015 £000
Operating activities			
Operating loss		(10,242)	(8,369)
Adjustment for non-cash items:		(10,212)	(0,000)
Depreciation of property, plant and equipment	9	245	151
Share based payment	16	136	180
R&D tax credit	10	745	-
Operating cash outflow		(9,116)	(8,038)
			(= .)
Increase in inventory		(30)	(34)
Increase in trade and other receivables		(596)	(200)
Increase/(decrease) in trade and other payables		862	(13)
Net cash outflow from operations		(8,880)	(8,285)
INVESTING ACTIVITIES			
Interest received		213	168
Net cash acquired on creation of joint venture		9	_
Purchases of property, plant and equipment	9	(711)	(114)
Net cash (outflow)/inflow from investing activities		(489)	54
FINANCING ACTIVITIES			
Proceeds from issue of share capital	13	19,019	5
Net cash inflow from financing activities		19,019	5
Increase/(decrease) in cash and cash equivalents		9,650	(8,226)
Cash and cash equivalents at start of year		10,257	18,483
CASH AND CASH EQUIVALENTS AT END OF YEAR		19,907	10,257

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# NOTES TO THE FINANCIAL STATEMENTS

for the year ended 31 January 2016

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

The financial statements of Tissue Regenix Group plc are audited consolidated financial statements for the year to 31 January 2016. These include audited comparatives for the year to 31 January 2015.

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

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. In assessing control, the Group takes into consideration potential voting rights that are currently exercisable. The acquisition date is the date on which control is transferred to the acquirer. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Losses applicable to the non-controlling interests in a subsidiary are allocated to the non-controlling interests even if doing so causes the non-controlling interests to have a deficit balance. Intra-group balances and transactions, and any unrealised income and expenses arising from intra-group transactions, are eliminated.

### **Going Concern**

As at 31 January 2016, the Group had £19.9m of cash and cash equivalents available to it. 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 34.

After due enquiry, the Directors consider that the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they 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 comprises sales of products to third parties at amounts invoiced net of trade discounts and rebates, excluding taxes on revenue. Revenue from the sale of products is recognised upon transfer to the customer of the significant risks and rewards of ownership. This is generally when goods are delivered to customers. Sales of inventory located at customer premises and available for customers' immediate use are recognised when notification is received that the product has been implanted or used.

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 is 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 operation 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.

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

#### **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.

No development costs to date have been capitalised as intangible assets.

#### 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
Office furniture and equipment	over 5 years

### Impairment of property, plant and equipment

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.

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### 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.

### 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:

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

#### 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 year was £136,000 (31 January 2015: £180,000).

#### **Research and development costs**

Careful judgement by the Directors is applied when deciding whether the recognition requirements for capitalising development costs have been met. This is necessary as the economic success of any product development is uncertain and may be subject to future technical problems. Judgements are based on the information available at each reporting date which includes the progress with testing and certification and progress on, for example, establishment of commercial arrangements with third parties. In addition, all internal activities related to research and development of new products are continuously monitored by the Directors. To date, no development costs have been capitalised.

### 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 11	Accounting for Acquisitions of Interests in Joint Operations – Amendments to IFRS 11	1 January 2017
IFRS 15	Revenue from contracts with customers	1 January 2019
IFRS 16 and 38	Clarification of Acceptable Methods of Depreciation and Amortisation – Amendments to IAS 16 and IAS 38	1 January 2017
IAS 7	Disclosure initiative – Amendments to IAS 7	1 January 2018
IAS 12	Recognition of Deferred Tax Assets for Unrealised Losses – Amendment to IAS 12	1 January 2018
Annual improvement to I	FRS – 2012-2014 Cycle	1 January 2016

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:

	2016 £000	2015 £000
USA	808	72
Rest of world	8	28
	816	100

### Analysis of revenue by customer

During the year ending 31 January 2016 the Group had two customers who individually exceeded 10% of revenue. These customers generated 12% and 11% of revenue respectively. During the year ending 31 January 2015 the Group had three customers who individually exceeded 10% of revenue. These customers generated 28%, 25% and 18% of revenue respectively.

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### **Operating segments**

The Group is organised into Cardiac, Wound Care and Orthopaedics divisions for internal management, reporting and decision-making, based on the nature of the products of the Group's businesses. Managers have been appointed within these divisions, who report to the Board. These are the reportable operating segments in accordance with 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.

	Wound Care		Orthopaedics		Cardiac		Central		Total	
	2016 £000	2015 £000								
Total segment	884	72	-	-	76	-	8	28	968	100
Inter-segment	(76)	-			(76)	_	-	_	(152)	_
Revenue	808	72	-	-	-	_	8	28	816	100
Cost of sales	(154)	(32)	-	_	-	-	-	_	(154)	(32)
Gross Profit	654	40	-	-	-	_	8	28	662	68
Administrative costs	(4,938)	(2,843)	(2,382)	(2,054)	(352)	(250)	(3,232)	(3,290)	(10,904)	(8,437)
Operating loss	(4,284)	(2,803)	(2,382)	(2,054)	(352)	(250)	(3,224)	(3,262)	(10,242)	(8,369)
Finance income	-	_	-	_	-	-	213	168	213	168
Loss before taxation	(4,284)	(2,803)	(2,382)	(2,054)	(352)	(250)	(3,011)	(3,094)	(10,029)	(8,201)
Taxation	169	50	324	510	16	60	18	-	527	620
Loss for the year	(4,115)	(2,753)	(2,058)	(1,544)	(336)	(190)	(2,993)	(3,094)	(9,502)	(7,581)

Administrative costs are broken down as follows:

	Wound Care		Orthopaedics		Carc	Cardiac		tral	Total	
	2016	2015	2016	2015	2016	2015	2016	2015	2016	2015
	£000	£000	£000	£000	£000	£000	£000	£000	£000	£000
Development	(1,108)	(1,029)	(2,279)	(2,032)	(289)	(235)	-	_	(3,676)	(3,296)
Sales and marketing <sup>†</sup>	(3,672)	(1,766)	-	_	-	-	-	_	(3,672)	(1,766)
Operations *	(158)	(48)	(103)	(22)	(63)	(15)	(3,232)	(3,290)	(3,556)	(3,375)
Admin costs	(4,938)	(2,843)	(2,382)	(2,054)	(352)	(250)	(3,232)	(3,290)	(10,904)	(8,437)

\* Central costs include plc, the Board, operations, finance and facilities.

<sup>+</sup> Sales and marketing for Wound Care includes the entire costs for our US entity. Included within these costs is £303k (2015: £21k) commission on sales.

### 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.

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

## 4) LOSS FROM OPERATIONS

	2016 £000	2015 £000
Loss from operations is stated after crediting:		
Grant income	-	20
Loss from operations is stated after charging to administrative expenses:		
Depreciation of plant and equipment (see note 9)	245	151
Operating lease rentals - land and buildings	341	407
Staff costs	4,798	3,612
Foreign exchange losses	33	27
Research and development (inclusive of research and development personnel)	3,676	3,296
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	10
- auditing the accounts of subsidiaries pursuant to legislation	18	17
Other services:		
- fees in relation to corporation tax	27	22
- fees in relation to other services	13	25
Total auditor's remuneration	69	74

## **5) STAFF COSTS**

	2016 Number	2015 Number
The average monthly number of persons (including Directors) employed by the Group during the year was:		
Directors	6	7
Laboratory and administration staff	64	53
	70	60
	2016 £000	2015 £000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	4,090	3,094
Share based expense (see note 16)	136	180
Social security, pension and healthcare costs	572	338
	4,798	3,612
Directors' remuneration included above comprised:		
Emoluments for qualifying services	788	749

Directors' emoluments disclosed above include £310,000 paid to the highest paid Director (2015: £249,000) as well as share based payments benefit of £35,000 (2015: £47,000).



## **6) FINANCE INCOME**

	2016 £000	2015 £000
Bank interest receivable	213	168

## 7) TAXATION

### Tax on loss on ordinary activities

	2016 £000	2015 £000
Current tax:		
UK corporation tax credit on losses of period	(527)	(620)
	(527)	(620)
Deferred tax:		
Origination and reversal of temporary timing differences	-	_
Tax credit on loss on ordinary activities	(527)	(620)

The charge for the year can be reconciled to the loss before tax per the statement of comprehensive income as follows:

### Factors affecting the current tax charges

	2016 £000	2015 £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	(10,029)	(8,201)
Tax at the standard rate of corporation tax 20%	(2,006)	(1,640)
Effects of:		
Expenses not deductible for tax purposes	27	36
Research and development tax credits received	(492)	(620)
Surrender of research and development relief for repayable tax credit	679	919
Research and development enhancement	(377)	(510)
Prior year adjustment	(35)	-
Unutilised tax losses	1,677	1,195
Tax credit for the year	(527)	(620)
Deferred tax		
	2016	2015
	£000	£000
Tax losses		
Losses available to carry forward against future trading profits	23,772	16,121
Deferred tax asset – unrecognised*	4,279	3,224

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

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

### 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 year 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 year to assume conversion of all dilutive potential ordinary shares.

	2016 £000	2015 £000
Total loss attributable to the equity holders of the parent	(9,410)	(7,581)
	No.	No.
Weighted average number of ordinary shares in issue during the year	743,183,878	636,890,061
Loss per share		
Basic and diluted on loss for the year	(1.27)p	(1.19)p

The Company has issued employee options over 24,543,853 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 years concerned.

## 9) PROPERTY, PLANT AND EQUIPMENT

	Laboratory equipment £000	Fixtures and fittings £000	Computer equipment £000	Total £000
Cost				
At 31 January 2014	653	52	109	814
Additions	89	1	24	114
At 31 January 2015	742	53	133	928
Additions	198	357	156	711
At 31 January 2016	940	410	289	1,639
Depreciation				
At 31 January 2014	241	33	68	342
Charge for the year	116	8	27	151
At 31 January 2015	357	41	95	493
Charge for the year	149	61	35	245
At 31 January 2016	506	102	130	738
Net book value			·	
At 31 January 2016	434	308	159	901
At 31 January 2015	385	12	38	435
At 31 January 2014	412	19	41	472

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## 10) TRADE AND OTHER RECEIVABLES

	2016	2015
	£000	£000
Trade debtors	398	40
Other receivables	1,464	1,415
Prepayments and accrued income	463	492
	2.325	1.947

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

No provisions are held against receivables and no amounts past due have been impaired.

### 11) 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:

		2016	
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	18,725	1,182	19,907
		2015	
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	9,306	951	10,257

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 year.

#### Management of credit risk

The Company is exposed to credit risk from its operating activities, principally arising 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 overleaf.

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.

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

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

	2016 £000	2015 £000
Cash and cash equivalents		
AA-	29	49
A	18,725	10,208
BBB+	1,153	_
	19,907	10,257

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 13 and 14 and in the statement of changes in equity.

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

		Financial liabilities at	
Financial assets/(liabilities)	Loans and receivables £000	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
rade and other payables	-	(573)	(573)
	21,769	(573)	21,196

Financial assets/(liabilities)	Loans and receivables £000	Financial liabilities at amortised cost £000	Total £000
At 31 January 2015			
Trade and other receivables	1,455	_	1,455
Cash and cash equivalents	10,257	_	10,257
Trade and other payables	-	(385)	(385)
	11,712	(385)	11,327

The Company had no financial instruments measured at fair value.



## 12) TRADE AND OTHER PAYABLES

	2016 £000	2015 £000
Trade payables	501	312
Taxes and social security	72	73
Accruals	1,385	710
	1,958	1,095

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

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

	2016	2015
Sterling	170	168
US dollars	242	118
Euros	89	26
Trade payables	501	312

## **13) 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 2014	653,487,357	3,267	31,971	10,884	(7,148)	38,974
Share options exercised	635,674	4	1	_	_	5
Total ordinary shares of 0.5p each as at 31 January 2015	654,123,031	3,271	31,972	10,884	(7,148)	38,979
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

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

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

	Retained earnings deficit £000	Reserve for own shares £000
At 31 January 2014	(19,795)	(831)
Loss for the year	(7,581)	-
Exchange movement	(4)	-
At 31 January 2015	(27,380)	(831)
Loss for the year	(9,410)	-
Exchange movement	(1)	_
At 31 January 2016	(36,791)	(831)

TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE YEAR ENDED 31 JANUARY 2016

# NOTES TO THE FINANCIAL STATEMENTS CONTINUED

for the year ended 31 January 2016

### **15) COMMITMENTS**

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### **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:

	2016 £000	2015 £000
Land and buildings:		
Amounts due within one year	124	175

### **16) 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 and 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 2014	15,532,204	4,824,029	16,940,386	37,296,619	0.0505
Exercised in the year	(635,674)	_	_	(635,674)	0.0073
Lapsed during the year	(319,992)	(480,480)	-	(800,472)	0.1033
Issued in the year	1,955,553	1,080,828	-	3,036,381	0.1993
At 31 January 2015	16,532,091	5,424,377	16,940,386	38,896,854	0.0706
Exercised in the year	(53,328)	(684,748)	_	(738,076)	0.0974
Lapsed during the year	(822,222)	(222,254)	_	(1,044,476)	0.1407
Issued in the year	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

There were 16,801,151 share options outstanding at 31 January 2016 which were 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 January 2016.

The performance conditions in relation to these options allow 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 jointly held EBT shares which were eligible to vest as at 31 January 2016. The remaining shares were not eligible to vest because the related employment period conditions and some of the performance conditions under the JOEs had not been met.

The fair value benefit received on share options granted is measured using the Binomial model, taking into account the effects of the vesting and performance conditions, expected exercise price and the payment of the dividends by the Company. The fair value benefit received on EBT shares is 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 January 2016	EBT shares Granted year to 31 January 2016	Options Granted year to 31 January 2015
Dividend yield	-	-	-
Expected volatility	47%	-	47%
Risk-free interest rate (%)	0.9	-	0.9
Expected vesting life of EBT shares and options (years)	4	-	4
Weighted average share price (£)	0.1238	-	0.1993

Share options issue 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.

A charge has been recognised in the statement of comprehensive income for each year as follows:

	2016	2015
	£000	£000
Share options	136	178
Jointly owned shares	-	2
Total share based payments	136	180

## **17) RELATED PARTY TRANSACTIONS**

#### Trading transactions with:

	2016	2015
	£000	£000
Transactions with significant shareholders:		
Patent support costs	28	76

### 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:

	2016 £000	2015 £000
Short-term employment benefits*	694	619

\* In addition, certain Directors hold share options and jointly owned shares in the Company for which a fair value share based charge of £94,000 has been recognised in the consolidated statement of comprehensive income (2015: £130,000).

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

# COMPANY STATEMENT OF CHANGES IN EQUITY

for the year ended 31 January 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 2014	3,267	31,971	10,884	557	(5,285)	41,394
Total expense and other comprehensive loss for the year	_	_	_	_	(1,039)	(1,039)
Share options exercised	4	1	-	_	_	5
Share based payment expense	-	_	-	180	_	180
At 31 January 2015	3,271	31,972	10,884	737	(6,324)	40,540
Total expense and other comprehensive loss for the year	_	_	_	_	(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



# COMPANY STATEMENT OF FINANCIAL POSITION

for the year ended 31 January 2016

			0015
	Notes	2016 £000	2015 £000
ASSETS			
Non-current assets			
Investments	C3	12,922	12,922
Total non-current assets		12,922	12,922
Current assets			
Trade and other receivables	C4	60	40
Intercompany loan balance	C5	26,230	17,881
Cash and cash equivalents		19,598	9,965
		45,888	27,886
TOTAL ASSETS		58,810	40,808
LIABILITIES			
Current liabilities			
Trade and other payables	C6	(318)	(268)
TOTAL LIABILITIES		(318)	(268)
NET ASSETS		58,492	40,540
EQUITY			
Share capital	13	3,801	3,271
Share premium	13	50,461	31,972
Merger reserve	13	10,884	10,884
Share based payment reserve	16	873	737
Retained earnings deficit		(7,527)	(6,324)
TOTAL EQUITY		58,492	40,540

Approved by the Board of Directors and authorised for issue on 23 May 2016.

JOHN SAMUEL CHAIRMAN IAN JEFFERSON CHIEF FINANCIAL OFFICER

Company number: 5969271

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# COMPANY STATEMENT OF CASH FLOWS

for the year ended 31 January 2016

	Notes	2016 £000	2015 £000
Operating activities			
Loss before interest and tax		(1,416)	(1,207)
Adjustment for non-cash items:			
Share based payments	16	136	180
Operating cash outflow		(1,280)	(1,027)
(Increase)/decrease in trade and other receivables		(20)	9
Increase in trade and other payables		50	50
Net cash generated from operations		(1,250)	(968)
INVESTING ACTIVITIES			
Interest received		213	168
Loan to subsidiary undertaking	C5	(8,349)	(7,649)
Net cash generated from investing activities		(8,136)	(7,481)
FINANCING ACTIVITIES			
Proceeds from issue of share capital	13	19,019	5
Net cash used in financing activities		19,019	5
INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		9,633	(8,444)
Cash and cash equivalents at start of year		9,965	18,409
CASH AND CASH EQUIVALENTS AT END OF YEAR		19,598	9,965



# NOTES TO THE COMPANY INFORMATION

for the year ended 31 January 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 are 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 year ended 31 January 2016 was a loss of £1,203k (2014: £1,039k).

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 January 2016, the Company held the following investments in subsidiaries:

			Share of issued capital and voting rights		
Undertaking	Sector	2016	2015		
Tissue Regenix Limited	Regenerative medicine	<b>100%</b>	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%		
Tissue Regenix Orthopedic Inc*	Regenerative medicine	100%	_		
GBM-V GmbH	Regenerative medicine	50%	_		
* Held through TRx Wound Care Limited					

Cost	2016 £000	2015 £000
At 1 February	14,707	14,707
Additions	-	-
At 31 January	14,707	14,707
Impairment		
At 1 February	(1,785)	(1,785)
At 31 January	(1,785)	(1,785)
Carrying value at 31 January	12,922	12,922

# NOTES TO THE COMPANY INFORMATION CONTINUED

for the year ended 31 January 2016

## C4. TRADE AND OTHER RECEIVABLES

£000	£000
40	10
20	30
60	40

	2016 £000	2015 £000
Intercompany loan	26,230	17,881

A loan of £26,230 was advanced to other subsidiary companies in the year. No interest was payable on the loan.

### **C6. TRADE AND OTHER PAYABLES**

	2016	2015
	£000	£000
Trade creditors	8	40
Taxes and social security	23	19
Accruals	287	209
	318	268

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# NOTICE OF ANNUAL GENERAL MEETING

**Notice is given** that the 2016 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 4 July 2016 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 year ended 31 January 2016.
- 2. To appoint Jonathan Glenn as a director of the Company.
- 3. To reappoint lan Jefferson, who retires by rotation, as a director of the Company.
- 4. To reappoint Steven Couldwell, who retires by rotation, as a director of the Company.
- 5. To reappoint Randeep Grewal, 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 £1,266,873; and
  - 8.2 comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £1,266,873 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 4 October 2017 (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.

These authorities are in substitution for all existing authorities under section 551 of the Act (which, to the extent unused at the date of this resolution, are revoked with immediate effect).

# NOTICE OF ANNUAL GENERAL MEETING CONTINUED

### 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 £380,062,

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 4 October 2017 (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).

- 10. That, pursuant to section 701 of the Act, the Company be and is generally and unconditionally authorised to make market purchases (within the meaning of section 693(4) of the Act) of ordinary shares of 0.5p each in the capital of the Company ("Shares"), provided that:
  - 10.1 the maximum aggregate number of Shares which may be purchased is 76,012,426;
  - 10.2 the minimum price (excluding expenses) which may be paid for a Share is 0.5p;
  - 10.3 the maximum price (excluding expenses) which may be paid for a Share is an amount equal to 105 per cent of the average of the middle market quotations for a Share as derived from the Daily Official List of the London Stock Exchange plc for the five business days immediately preceding the day on which the purchase is made;

and (unless previously revoked, varied or renewed) this authority shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 4 October 2017 (whichever is the earlier), save that the Company may enter into a contract to purchase Shares before this authority expires under which such purchase will or may be completed or executed wholly or partly after this authority expires and may make a purchase of Shares pursuant to any such contract as if this authority had not expired.

By order of the board

### IAN JEFFERSON

SECRETARY 23 MAY 2016

### **Registered office**

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

Registered in England and Wales No. 05969271

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### Entitlement to attend and vote 1.

Notes

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 6.00 p.m. on 30 June 2016 (or, if the meeting is adjourned, 6.00 p.m. 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 1, 34 Beckenham Road, Beckenham BR3 4TU, no later than 10.00 a.m. on 2 July 2016 (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 2 July 2016 (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.

# NOTICE OF ANNUAL GENERAL MEETING CONTINUED

### **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 26 and 27 of the enclosed annual report and accounts.

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TISSUE REGENIX GROUP PLC ANNUAL REPORT AND ACCOUNTS FOR THE YEAR ENDED 31 JANUARY 2016

# SHAREHOLDER NOTES

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# **DIRECTORS AND OFFICERS**

## DIRECTORS

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

### **COMPANY SECRETARY**

lan Jefferson

### **COMPANY WEBSITE**

www.tissueregenix.com

## COMPANY NUMBER

05969271 (England& Wales)

### **REGISTERED OFFICE**

Unit 1 and 2 Astley Way Astley Lane Industrial Estate Swillington Leeds 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

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