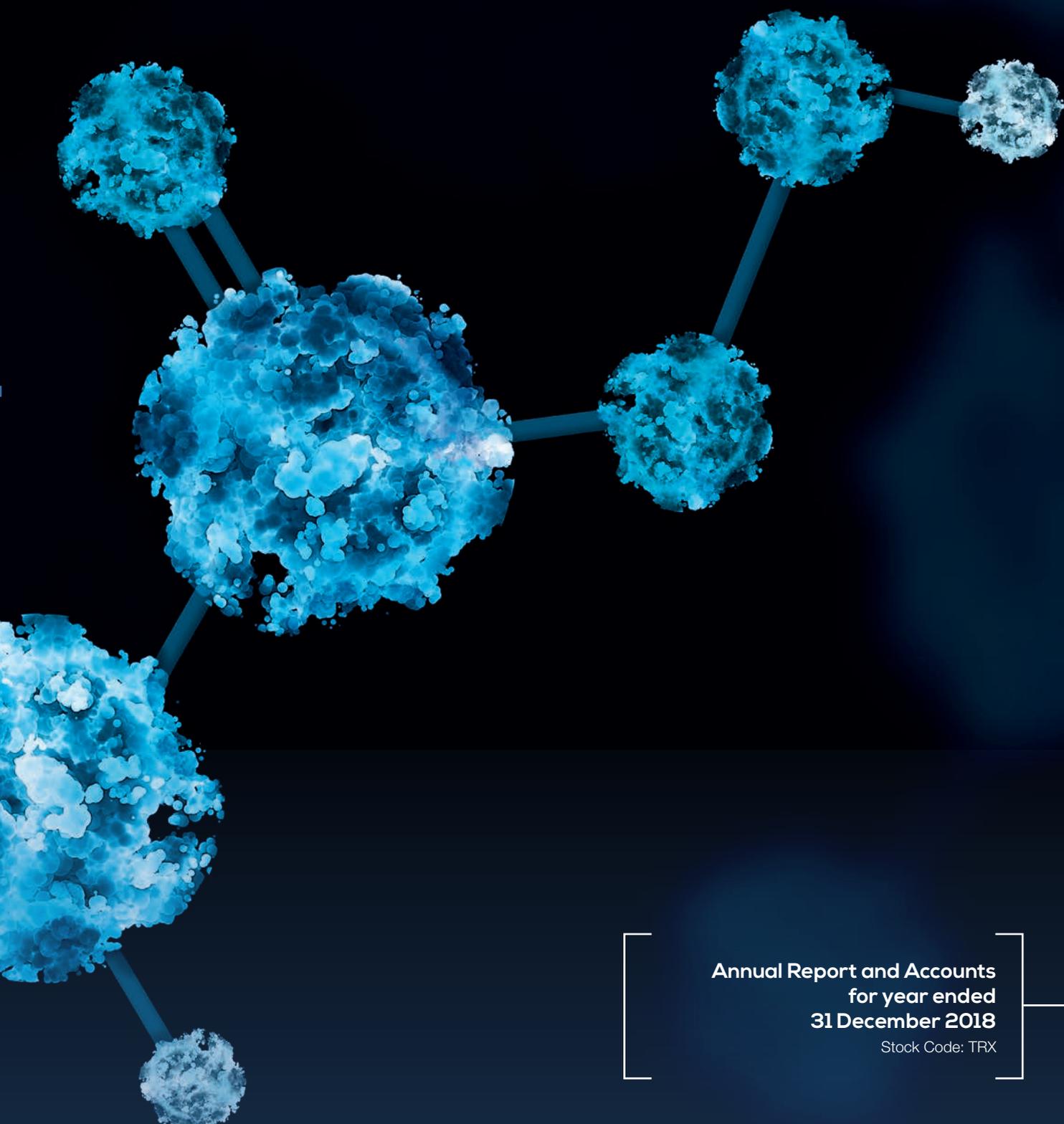




Tissue Regenix

Group plc



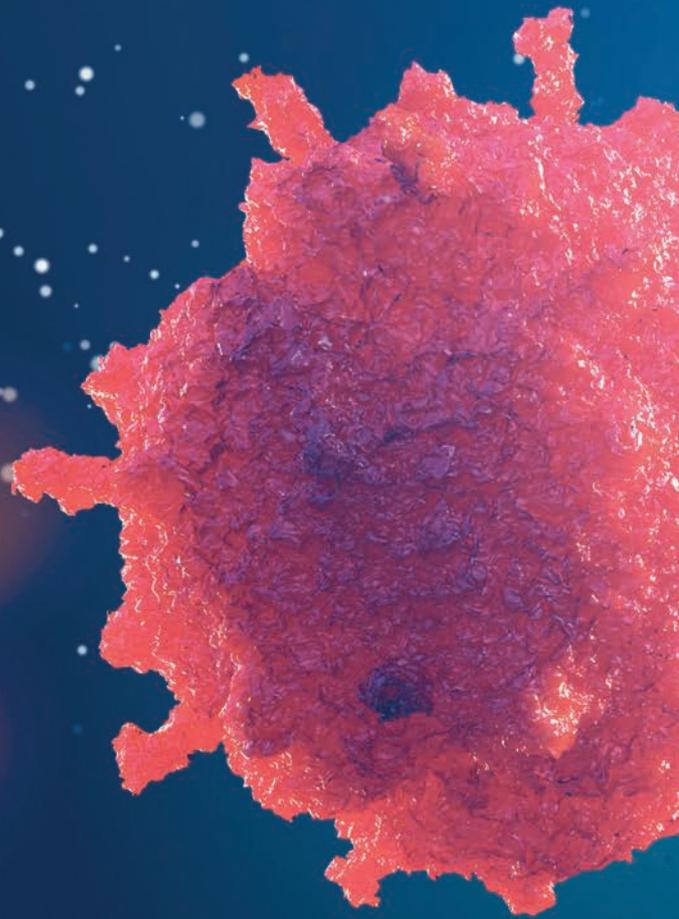
**Annual Report and Accounts
for year ended
31 December 2018**

Stock Code: TRX

Who we are

TISSUE REGENIX GROUP is a pioneering, international medical technology company, focusing on the development of regenerative products utilising our two platform technologies, dCELL[®], addressing soft tissue needs, and BioRinse[™], providing inductive bone allografts.

We are helping to transform the treatment of patients in three key areas: BioSurgery, Orthopaedics (sports medicine/ spine) and Dental, with an active development programme in the Cardiac field.



OUR VISION

To establish Tissue Regenix Group as a leader in the science and innovation of regenerative medicine. Transforming patient care and delivering favourable health economic outcomes.

INVESTMENT CASE



Two novel regenerative medicine platforms for the treatment of soft tissues and bone



International manufacturing capabilities
Expansive distribution opportunities



Multiple commercialisation opportunities – innovative product portfolio and pipeline



Tissue processing science and development expertise



Differentiated clinical outcomes

OUR VALUES



Dedication to Patients



Passion for Innovation



Driving for Excellence



Uncompromising Integrity

 Read more about our Sustainability on pages 28 and 29

Highlights

Group sales increased to £11.6m (2017: £5.2m) +47% pro forma, driven by;

- DermaPure® sales grew by 75% on a reported basis, to £3.4m (2017: £1.9m)
- CellRight contribution of £6.4m via Orthopaedics & Dental, +31% on a pro forma basis
- Increased sales from GBM-V by 62% to £1.8m (2017: £1.1m)

Significantly reduced Group LBIT for the period £8.7m (2017: £10.8m)

Strategic partnerships signed

- Arthrex BioRinse OEM US distribution agreement
- Arthrex EU distribution agreement
- ARMS medical DermaPure distribution agreement
- A number of further strategic opportunities identified

HTA Licence

- Granted for the import of BioRinse™ products into the UK, and over time, as a gateway to Europe

Integration activities

- In-house manufacturing of DermaPure® commenced ahead of schedule
- Global employee engagement programme launched – “Verto”

DermaPure® positioning

- GPO agreements signed- Premier three year extension
- Premier Supplier Horizon Award
- Commercial “Accelerator” programme established – “Narrow & Deep”

Clinical data programmes

- OrthoPure XT two year clinical data submitted to the regulatory body for CE mark approval
- DermaPure® clinical trial for urogynaecology in partnership with ARMS medical
- Protocol for 100 patient prospective observational clinical trial for DermaPure® in orthopaedic trauma

R&D, Product pipeline

- Ongoing discussions with significant R&D partners, initial projects chartered
- SurgiPure XD commercial manufacturing commenced at Leeds facility
- Launch pathway for OrthoPure XT established

Governance

- QCA Corporate Governance Code implemented
- FDA audit Q1 2019 completed
- American Association of Tissue Banks audit Q1 2019

Overview

Who we are	IFC
Directors and Officers	IBC
Highlights	01
Chairman’s statement	02
Global operations infrastructure	03
At a glance	04
Q&A with CEO	06

Strategic report

Our markets	08
Our divisions	09
Business model	10
Our strategic growth drivers	12
Future milestones: strategy in action	14
Case Studies	15
Key performance indicators	16
Business review	18
Financial overview	23
Risk	25
Sustainability	28

Governance

Profile of the current Directors	30
Governance Framework	32
Directors’ Remuneration Report	36
Directors’ Report	39
Statement of Directors’ Responsibilities	41

Financials

Independent Auditor’s Report	42
Consolidated Statement of Comprehensive Income	46
Consolidated Statement of Financial Position	47
Consolidated Statement of Changes in Equity	48
Consolidated Statement of Cash Flows	49
Notes to the Financial Statements	50
Company Statement of Changes in Equity	66
Company Statement of Financial Position	67
Company Statement of Cash Flows	68
Notes to the Company Financial Statements	69
Notice of Annual General Meeting	73

Chairman's statement



JOHN SAMUEL
Chairman

"We remain focused on delivering positive, sustainable growth across all divisions of the business. Our strategic realignment has been successful and having integrated CellRight Technologies into the Group, we have achieved considerable commercial and operational progress. We are well positioned to capitalise on these achievements, as well as bring new products to the market throughout the year."

INTRODUCTION

2018 was a successful and transformative year.

Following the repositioning of the DermaPure® product range we are starting to generate real commercial traction with our dCELL® technology as the market recognises the benefits these products can offer both patients and the wider healthcare sector. Following the acquisition of CellRight Technologies Inc in late 2017 our strategic approach has enabled us to integrate this business effectively and realise the synergistic benefits the BioRinse™ Technology can offer.

Our Strategy

Following the successful integration of the businesses throughout 2018 we saw benefits materialise through commercial catalysts such as the Arthrex US, and laterally the UK distribution agreements, the ARMS medical distribution agreement and further GPO approvals. This year we expect that these milestones will act as the foundations for us to drive momentum and deliver top line revenue growth.

 **Read more about our strategy on pages 12-13.**

Financial Performance

We finished the year in line with Board expectations, posting sales that have grown by 47% pro forma year-on-year across the three operating divisions. We achieved a strong cash position of £7.8m, due to efficient management of working capital provisions and an improved LBIT of £8.7m.

The Board

In December we announced that Steve Couldwell, CEO would be taking a leave of absence during Q1 for health reasons. I would like to thank Gareth Jones who joined the Company in Q4 and has stepped into the COO role on an interim basis. Steve continues to be central to our activities and I expect a full return shortly.

 **Read more about our Board on pages 30-31.**

Corporate Governance

There were many changes implemented throughout 2018 with regard to the Corporate Governance framework, most notably, in September 2018, the changes to the AIM Rules for Companies. The Board have implemented the Quoted Companies Alliance Corporate Governance Code.

 **Read more about our Corporate Governance within the Governance report on pages 32-41.**

Our People

Through the continued hard work and commitment of our employees we have delivered a transformational year of growth and progress and I would like to extend my thanks to all involved. Jesus Hernandez, CEO of CellRight Technologies retired as planned in April 2019. He played a fundamental role in guiding the businesses through the integration process and we wish him well in his future endeavours.

We have appointed Daniel Lee who has nearly 30 years of experience within the industry to the position of President of US Operations, and since joining in Q1 2019 has already implemented operational efficiencies within the San Antonio facility.

I would also like to take this opportunity to acknowledge the achievements that have been made since Steve Couldwell was appointed CEO. Steve has led the refinement of the commercial strategy, as well as alignment of the businesses following the acquisition, and the internal employee engagement initiatives.

His experience and hard-work has been invaluable and plays a fundamental part in the results that we can now report.

As a Board, we also understand that this progress would not be possible without the dedication and motivation of our employees and the responsibility that we hold to ensure that their development and training allows us, as a business, to stay at the forefront of regenerative medicine developments. Alongside this, we seek to establish a supportive and innovative working environment allowing for professional development. It is our responsibility to ensure that the Company is supported by the correct calibre of people and talent to secure its ongoing success.

 **Read more about our Sustainability on pages 28 and 29.**

Post balance sheet event

On 3 June 2019, the Group entered into a new loan facility providing a total of \$20m. \$10.5m is available for immediate drawdown with the remaining \$9.5m available subject to the satisfaction of certain conditions at a later date. We believe that this provides the funding required to continue the growth and expansion of the business in line with expectations. It will provide the opportunity to expand our manufacturing capacity in order to sustain future business growth, build our clinical and health economic real world data to support brand differentiation, as well as supporting the continued working capital expenditure as we move towards self-sustainability in the near future.

Outlook

We have successfully delivered a strong financial performance while building solid commercial foundations. With opportunities in additional geographic territories, and additional product launches in the pipeline, we believe that we can deliver continued growth in 2019 and beyond. We have grown the business in line with our expectations and projections and the Board and I remain confident that, with a revised focus on the development of strategic partnerships, we can achieve sustainable profitability and enhance shareholder returns. The Board remains confident in the performance of the business and the commercial expectations for 2019.

John Samuel
Chairman

GLOBAL OPERATIONS INFRASTRUCTURE

Platform for international expansion



TISSUE REGENIX
LEEDS, UK

Porcine Tissue
Manufactured in-house in Leeds, UK

GBM-V ROSTOCK, GERMANY



Human Tissue EU
Manufactured at GBM-V in Rostock, Germany

CELLRIGHT TECHNOLOGIES
SAN ANTONIO, TEXAS



Human Tissue US
Transition dCELL® production to CellRight, Texas

2018 Key Milestones

- February 2018 – TRX BioSurgery rebrand, launched and exclusive distribution agreement with ARMS medical for DermaPure®
- March 2018 – Delivered US Arthrex agreement for BioRinse™ Products under on brand ‘Allosync’
- April 2018 – DermaPure® manufacturing transferred into CellRight facility ahead of schedule
- May 2018 – TRX BioSurgery awarded GPO agreement with Premier, Inc.
- June 2018 – Awarded supplier horizon award by GPO, Vizient, Inc. for TRX BioSurgery

- June 2018 – Human Tissue Authority license granted for the importation of human tissue products from the US to the UK facility
- June 2018 – Employee engagement programme ‘Verto’ launched
- September 2018 – Interim Results announced +61% pro forma top line growth
- October 2018 – Gareth Jones commences position as Chief Financial Officer
- November 2018 – Pan European distribution agreement signed with Arthrex, Inc. for the BioRinse™ portfolio
- December 2018 – DermaPure® clinical case series results published

At a glance

Through our platform technologies, Tissue Regenix are focused on the development of regenerative medicine products, in three key clinical areas; BioSurgery, Orthopaedics and Dental with an active development programme in the Cardiac field.

INNOVATIVE PLATFORM TECHNOLOGIES

Addressing clinical needs through complementary soft tissue and bone platforms

dCELL®

dCELL® Technology - Gentle soft tissue decellularisation process, removes DNA and cellular material to reduce risk of rejection.

Differentiated Characteristics:

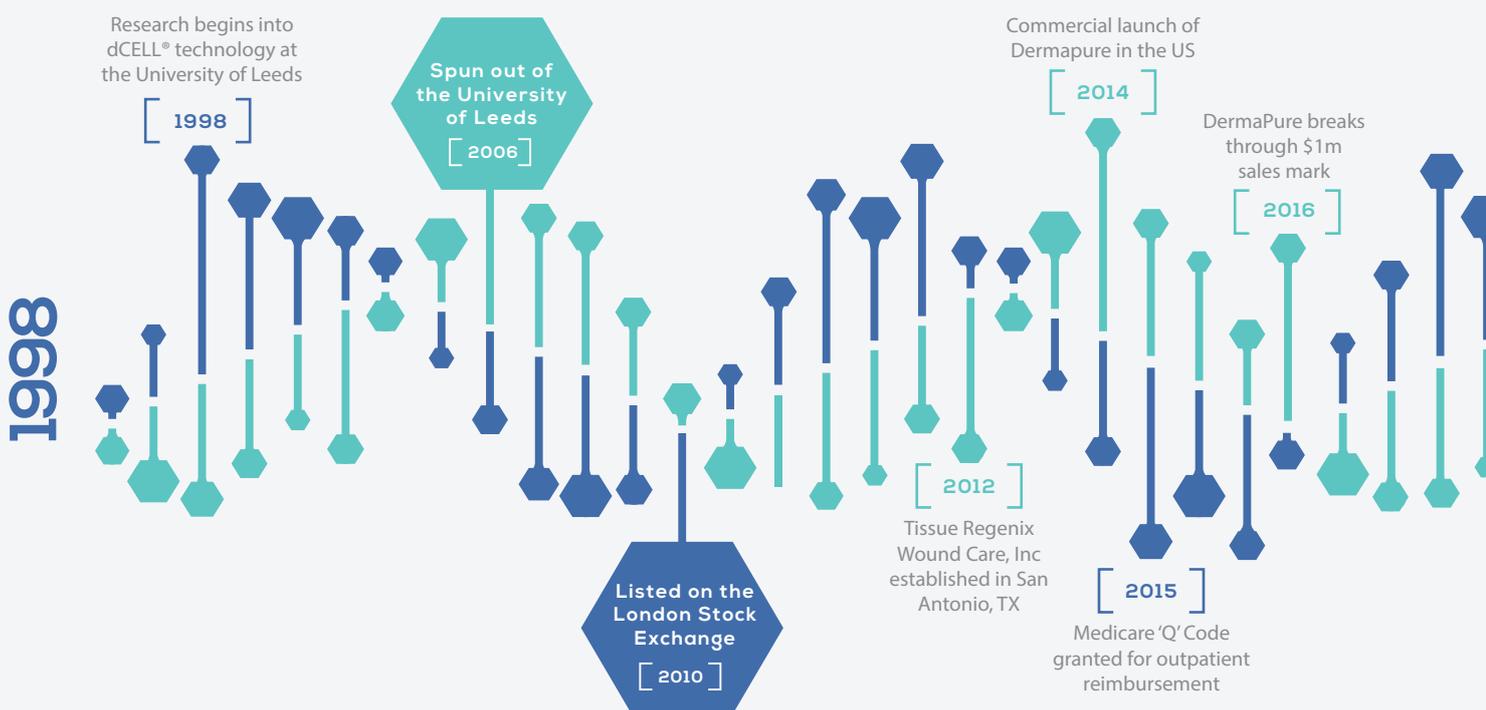
- Maintaining the natural acellular scaffold of the tissue structure to allow for cellular proliferation
- Supports regeneration of native tissue
- Can be applied to both human or animal tissue sources
- Favourable health economic benefits due to reduced operation time, reduction in rehab activities, no anti coagulant drugs and stored at room temperature.

BIO RinSE™

BioRinSE™ Technology - Natural bone filler solutions verified to be osteoinductive to stimulate and regenerate native bone growth.

Differentiated Characteristics:

- Maintaining the five key natural bone growth factors and Bone Morphogenic Proteins that promote active regeneration
- Contains 100% allograft bone, proven to produce better clinical outcomes
- Verified to be osteoinductive
- Ability to deliver malleable bone collagen scaffolds in various physical forms to meet clinical needs.



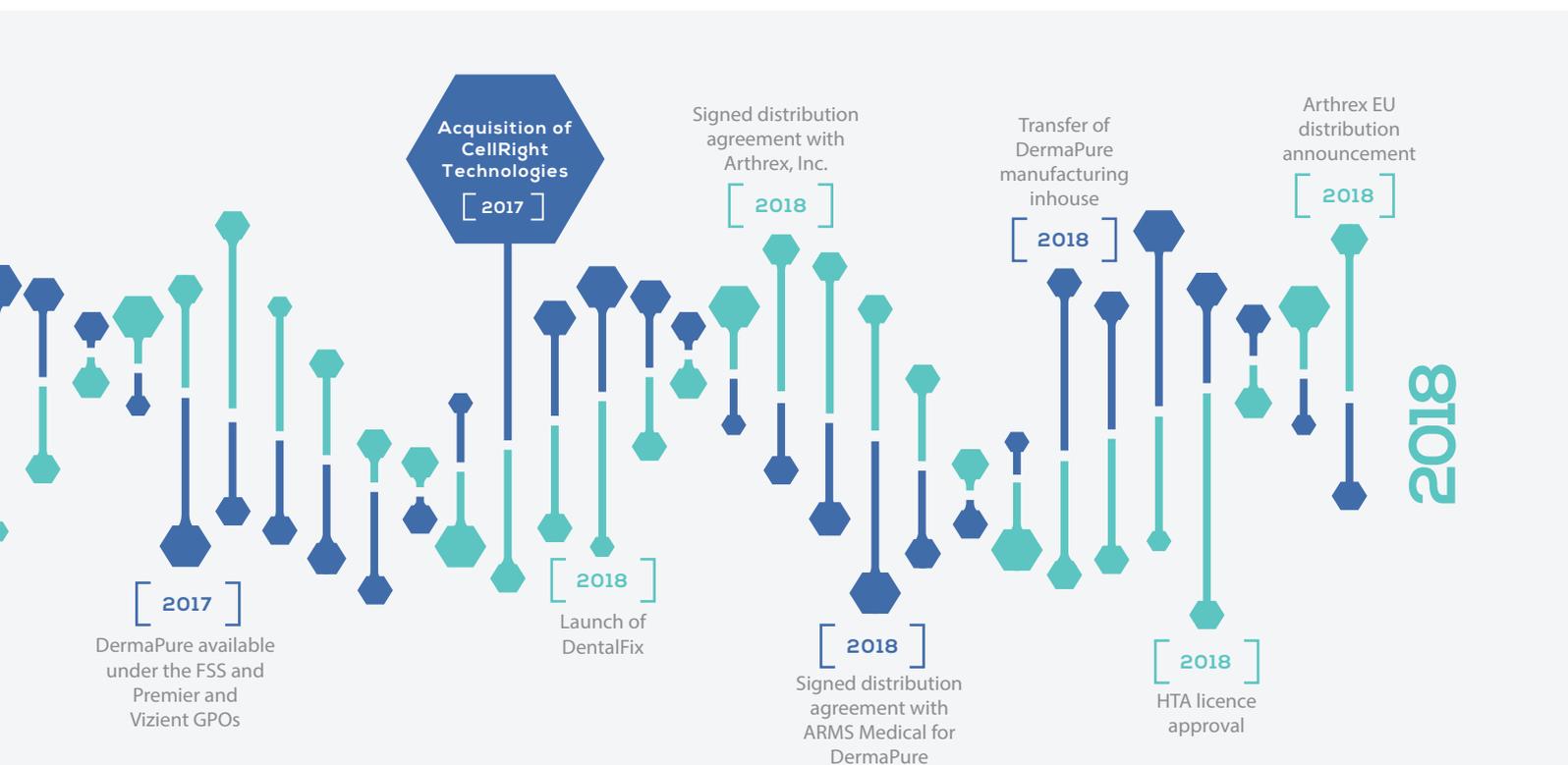
Exchange

TISSUE REGENIX GROUP

Focused on four strategic drivers of growth



Read more about our Strategic Objectives pages 12-13.



Q&A with CEO Steve Couldwell



STEVE COULDWELL
Chief Executive Officer

This completes your first full year as CEO of the Company. What were your first impressions and what do you see as the greatest achievements throughout this time?

When I became CEO I came from a unique position of having been a Non- Executive Director for five years. This meant that I had a good understanding of the business, the commercial opportunities and the potential of the technology platforms.

My first impressions of the business were very positive. We have a committed and hardworking team of people, differentiated technology platforms and vast market potential.

Throughout the last year all divisions of the business have achieved solid progression. We set ourselves a number of commercial and operational milestones in Q1 2018 and were successful in hitting all as we progressed through the year. For me, the significant inflection points were the announcement of the Arthrex US distribution agreement, where three of the BioRinse™ products were taken under Arthrex's own brand "AlloSync", a significant third-party validation of the technology. The HTA licence granted to the UK facility in June allows us to import our BioRinse™ portfolio into the UK and Continental Europe. This development also led to a further agreement with Arthrex for the distribution of products in the European markets.

In addition, we repositioned DermaPure® for use in surgical indications and have achieved significant penetration in this area, both with the exclusive distribution agreement with ARMS medical for use in uro-gynaecology procedures and conversion of use in many of the large hospital groups such as the Cleveland Clinic, Mount Sinai and the Mayo Clinic; all of which provide strong foundations from which to grow.

How would you describe the Group's financial performance?

I believe that 2018 has been the most commercially progressive year for the Company; it is also the first full year of the Group encompassing the CellRight business.

Delivering top line revenue of £11.6m shows the demand for the product portfolio, and the stability of the Group, delivering year-on-year growth of 47% pro forma, while also undertaking the integration activities.

Of particular note I feel, is the performance of DermaPure® realising an increase of 75% to £3.4m on a reported basis, testament to the repositioning of the product into surgical indications. Outside of this, the strategic partnerships signed have aided 31% growth in the Orthopaedics & Dental areas, where the BioRinse™ portfolio is utilised.

GBM-V, our joint venture in Germany, has increased their output of corneal products which has led to revenue growing to £1.8m, also bringing them closer to a self-sufficient position.

In addition to increasing revenues we have implemented several initiatives to reduce our working capital expenditure and end the year with a strong cash position of £7.8m.

We exited 2018 with a positive momentum and in 2019 we expect to deliver a year of further significant growth, moving towards our goal of achieving cash break-even and delivering sustainable profitability in the years to come. The trading for 2019 remains inline with Board expectations.

What do you view as the Company's key strengths?

We have many strengths as a growing company. We listed on AIM as a development company in 2010 and have now launched products as we begin our commercial journey. We are well positioned with a strong portfolio of differentiated products, which offer many operational, clinical and commercial synergies. With manufacturing facilities in the US, UK and Germany, we are well placed geographically to target these key markets and have a good understanding of the regulatory framework required for each.

As with any company, our main strengths lie with the calibre and commitment of our people. We are fortunate to have a blend of respected academic advisers and experienced commercial and operational staff across our organisation. In June 2018 we commenced a Company-wide vision and culture programme, 'Verto' which engaged with every employee across the Group and aligned our vision, mission and values, updated our internal communications infrastructure and developed an engagement platform for employees to utilise in order for them to influence the working culture of the business moving forward.

What are the greatest market opportunities and challenges for the Group?

The market opportunity is vast, that said, in a diverse industry we need to retain our focus on key markets and clinical application areas identified in order to deliver growth in line with our expectations.

We believe our greatest opportunity lies within the osteobiologics market where we believe we have the potential to build a \$200m business with our current IP, product portfolio and commercial strategy in conjunction with our strategic partners such as Arthrex.

In the near term, a part of this will be within the sports medicine market with the imminent launch of OrthoPure XT in the EU. This will offer physicians an alternative to the current gold standard care, harvesting an autograft from the patient's own muscles or tendons, therefore reducing operation time and potentially leading to enhanced rehabilitation.

You have spoken about an "evolution of strategy". Could you explain a little more about what this entails?

Yes, as the organisation develops we will refine our market opportunity, product positioning and physician conversion.

With DermaPure® we were initially focused on chronic and acute wound care, allowing us to build a roster of clinical case studies in the outpatient setting, and establish 100% Medicare coverage. This in turn supported the clinical validation of the product as it evolved to uses in the surgical suite, with both Vizient and Premier, the two largest GPOs in the US granting DermaPure® innovative technology status. This success led us to migrate our commercial focus towards hospital-based "in theatre surgical applications". As the clinical benefits of the product were showcased, further clinical opportunities were presented such as uro-gynaecology applications. With a small direct sales force, the importance of partnerships, such as the agreement with ARMS medical for DermaPure® distribution into the urogy market, becomes more apparent in order to build scale. This allows our direct sales force to remain focused on hospital conversions and adopting a "narrow and deep" philosophy with the aim to convert each relevant physician to the use of DermaPure® within our targeted institutions.

Historically, CellRight had pursued a distributor-focused model however, with the OEM Arthrex agreement in the US and subsequent distribution agreement for the BioRinse™ portfolio in the UK, the importance of strategic partnerships is apparent. From a commercial perspective this significantly enhances our sales efforts in current markets due to the increased sales representative footprint, but also allows for the expansion into new geographic territories.

With our experience in product R&D we can also look to further these partnerships by pursuing joint IP and development opportunities to leverage each party's expertise to increase our competitive advantage.

To this end we realigned our strategic focus and identified four key pillars to our success: to accelerate our US market penetration, exploit the global market potential, broaden our strategic partnerships and strengthen our portfolio.

 **Read more about our strategic growth drivers on page 12.**

What do you see as the main inflection points for the year ahead?

2018 was an excellent year for us in terms of establishing a strong commercial, operational and financial foundation. We now need to "kick on" in 2019 and capitalise on the opportunities we have identified and established.

We look forward to the launch of OrthoPure XT into the European market. As with any medical device launch, we expect surgeon conversion to be a gradual process with the real top line revenues from this product becoming apparent in FY2020. This year's focus will be to establish "adopters" of the product who will help us drive usage and develop clinical case studies with which we can further expand clinical acceptance.

In November 2018 we announced an extension to our Arthrex partnership to distribute the BioRinse™ portfolio into the EU market. This a significant milestone in our strategy of building our strategic partnerships and entering new territories, and we expect to see an uptick from this agreement in our top line towards the end of 2019.

With additional market opportunities for product line extensions I would expect to see developments in this area, which should be relatively quick to bring to market and expand our opportunities into new clinical settings.

Looking into the future, having transferred the manufacturing of DermaPure® in to the CellRight facility we are careful to ensure that

manufacturing capacity does not become a constraint on our commercialisation programme and plans are underway to scope out the requirements for additional manufacturing facilities.

How do you view success?

Success for me comes in many forms. Clearly, there is the need and expectation to deliver financially and create a value adding investment for our supportive shareholders. However, in order to do so, we need to establish and maintain the appropriate commercial foundations and have an engaged and committed workforce. Therefore, outside of our financial achievements I feel it necessary to track ourselves against a number of non-financial KPIs in order to establish a sustainable and integrated business.

We must also keep at the forefront of our minds the patients that we serve, and the positive impact our products can have on their standard of life. The ultimate success to me will be delivering this positive impact to patients on a global scale.

 **Read more about our KPIs on page 16.**

Our markets

Regenerative medicine

Regenerative medicine is an innovative and expanding field, researching the potential of tissue engineering to offer a natural recovery by triggering a response through the body's own cells, and enable the natural regeneration of the patient's own tissues.

With the demand for less invasive, longer lasting treatment modalities, regenerative medicine is an increasingly important approach as it removes the need for synthetic (plastic or metal) replacements, and reduces the risk of rejection, while offering the potential for less time-consuming and more cost-effective treatments, that can ultimately deliver superior clinical outcomes.

Tissue Regenix patented dCELL® Technology and proprietary BioRinse™ technology platforms are ideally suited to meet the ever growing unmet clinical need as a result of the opportunities presented by increasing demographic demands and health economic pressures for regenerative solutions.

What is regenerative medicine?

Regenerative medicine is an interdisciplinary field which focuses on providing safe and reliable ways to repair, restore, or replace damaged tissues or organs. The two main components of regenerative medicine are stem cell therapy and tissue engineering.

The benefits of regenerative medicine

With the average age of the world's population drastically increasing, there are pressures on the healthcare system to support patients' desire to be active for longer. This puts a huge economic strain on healthcare providers who, due to the lifespan of many current treatments, are having to perform operations and procedures multiple times on patients in order to give them the mobility they seek.

Regenerative medicine has the ability to alleviate some of this economic pressure as it can provide patients with longer lasting solutions, reducing the need for immunosuppressant drugs, examinations and multiple operations.

The physical and psychological benefits to patients are significant. With the potential to return to the desired standard of life with a reduction in physical pain and the need to continue to live with repeated follow up appointments, which can lead to stress, anxiety and a lack of confidence in physical ability.

These innovations in regenerative medicine can also benefit wider society with the potential to address a variety of incurable diseases, address the problem of organ shortage and ease economic pressures by reducing treatment costs.

What does the future of regenerative medicine look like?

According to Sharlini Sankaran, PhD, executive director of Duke's Regeneration Next Initiative, "One day, patients will have access to regenerative medicine treatments that will circumvent the complications of organ donation. We will be able to use our bodies' own innate repair mechanisms to eliminate the wait time, cost, and limited supply of organ transplantation. Instead of transplanting organs, we will know how to repair our own." And this is just one of the exciting possibilities that could come out of developments in regenerative medicine.

"We're entering a new era. More and more we are going to see regenerative medicine use cellular and molecular tools to treat devastating diseases with no current therapy."

– Dr Michael Rudnicki, Director, Regenerative Medicine Program and Sprott Centre for Stem Cell Research at The Ottawa Hospital Foundation

(<https://ohfoundation.ca/regenerative-medicine-and-stem-cell-research/>)

Market Opportunities

"The global regenerative medicine market was valued at \$5.444Bn in 2016, and is estimated to reach \$39.325Bn by 2023, registering a CAGR of 32.2% from 2017 to 2023."

(<https://www.alliedmarketresearch.com/regenerative-medicines-market>)

- iDATA Research Inc – US Market Report Suite for Soft Tissue Reinforcement and Regeneration, Page 181
- iDATA Research Inc – US Market Report Suite for Soft Tissue Reinforcement and Regeneration, Page 181
- Orthoworld Annual Report 2017
- Orthoworld Annual Report 2017
- iDATA – Awaiting source
- iDATA – Awaiting source

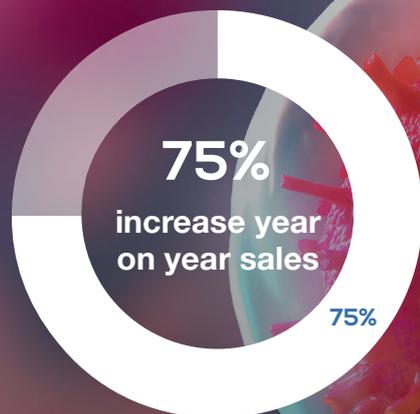
SECTOR	SIZE \$	GROWTH %	COMPETITION
Soft Tissue	3bn ¹	^7.7% ²	Integra, LifeNet, LifeCell
Orthopaedics	5.1bn ³	^3.1% ⁴	DePuy, Precision, Medtronic, RTI
Dental	0.4bn ⁵	^10+ ⁶	Geistlich, BioHorizons, Zimmer Biomet

Our divisions

The Group comprises of key operating divisions allowing each to have the optimal strategy, management and access to relevant Key Opinion Leaders. This also allows us to internally monitor return on investments, and report against each division financially.

BIOSURGERY

Repair and replacement of soft tissue - dCELL®



Route to market

- Direct sales representatives
- Local distributors
- Partners – ARMS Medical
- Scientific positioning with clinical affairs representatives
- “Narrow and Deep” – sales philosophy, engage an ‘internal disciple’ in key institutions with a focus on orthopaedic trauma surgeons.

Growth drivers

- Focus on large volume accounts
- 2018 growth +75% on a reported basis
- Expand partners for specific fields of use and OEM opportunities in; wound clinics, hernia, plastics
- New product development related to market opportunities
- Expand Group Purchasing Organisation coverage and distributor network.

ORTHOPAEDICS & DENTAL

Repair and augmentation of bone and soft tissue – BioRinse™ & dCELL®



Route to market

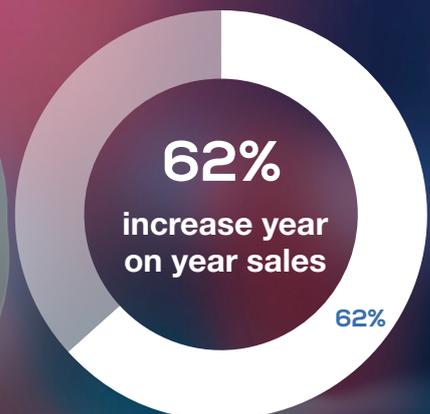
- Strategic Partners – Arthrex, Inc.
- Brand and OEM label opportunities – supplier for the Arthrex brand “AlloSync”
- Local distributors

Growth drivers

- Organic growth potential
- Launch of OrthoPure XT in the EU
- Expand commercial scale – three additional Regional Sales Directors appointed 1.1.19
- New distribution partners
- Expand portfolio penetration in existing accounts, with additional product potential; AmnioWorks, DermaPure® and SurgiPure XD.

GBM-V & CARDIAC

Multi-tissue bank facility, working on pulmonary and aortic heart valve regulatory approvals



Route to market

- Currently distributing corneas directly to dedicated, targeted hospitals through a network of pioneering Key Opinion Leaders.

Growth drivers

- Future regulatory clearance and launch of CardioPure products in Germany
- Potential decellularisation of additional tissues; vessels; tendons; amnion.

Business model

Our business model ensures that our growing portfolio of soft tissue and bone products are delivered to healthcare professionals and patients through a hybrid sales model of both direct sales reps and through selected distribution partners.

OUR KEY RESOURCES

OUR OFFERING



People

Our people are key to our continued growth due to their experience, qualifications and commitment.



IP

Provides protection for the technologies at the heart of our business, a fundamental resource for our growth.



Working capital

Supports the product development pipeline and enables us to make investments that support our future growth.



Manufacturing capabilities

Fundamental in ensuring the production and development of our products on a global scale.



Strategic partnerships

Allowing faster market penetration, physician conversion and delivering revenue growth.



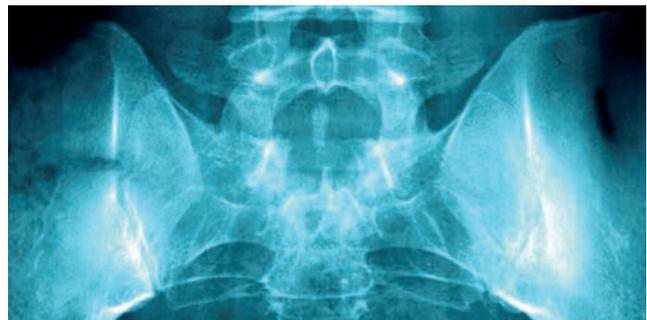
Licensing and distribution agreements

Ensuring we can serve the market potential.

BioRinse™ Technology

Natural bone filler solutions guaranteed to be osteoinductive to stimulate and regenerate native bone growth.

This process could provide better patient outcomes as it contains 100% allograft bone, maintaining the five key natural bone growth factors and is able to deliver these properties through malleable bone collagen in various physical forms.



dCELL® Technology

Gentle soft tissue decellularisation process, removing DNA and cellular material to reduce risk of rejection.

The dCELL® process involves the creation of biological scaffolds which are essentially inert. By removing DNA and cellular material from biological tissues, 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, and stimulating a natural healing process.



In order to continue to create value for our stakeholders, we invest in the Group's key resources. For example, we develop our people and our IP, as well as furthering our manufacturing capabilities.

OUR KEY ACTIVITIES

01

Commercialisation

Currently a portfolio of 12 product lines on the market which we intend to expand into further territories and have a plan for new product line developments.

02

R&D

Ensure that we have an innovative product pipeline, maintain product differentiation, optimise our margins and have a competitive market offering.

03

Distribution and licensing

Building a network of key distributors and evaluating licensing opportunities for new geographic territories.

OUR COMPETITIVE ADVANTAGE



Distributor Network

We are able to leverage cross-selling opportunities through our expansive distributor network and industry relationships.



Team

Our experienced management team, well qualified and trained employees, and knowledgeable Board ensure we have the capabilities to deliver future growth.



R&D

We have an innovative product pipeline with multiple opportunities to develop the commercialisation of our platform technologies.



Products

Performance of our products in the clinical environment provides us with a competitive advantage over competitors.



Manufacturing

We have international manufacturing capabilities and an expanded geographic presence due to the CellRight acquisition.

WE CREATE VALUE FOR OUR STAKEHOLDERS

Patients

Providing a return to a better quality of life, differentiated clinical outcomes and optimised care costs.

Physicians and Healthcare Providers

Products with ease of use which will benefit their patients and provide economic benefits to the healthcare system.

Employees

We provide training and development opportunities, promote a positive professional culture, and support a healthy lifestyle balance.

Partners

Strong strategic partnerships with growing business and continued growth opportunities in the long term.

Shareholders

Investment in a Group with growth opportunities which is focused on creating sustainable value for both shareholders and addressing wider socio-economic issues.

 [Read more about our Stakeholders on pages 28 and 29](#)

Our strategic growth drivers

Strategic Objective	Description	2018 Performance
 <p>Accelerate US market penetration</p>	<p>The US is the largest healthcare market in the world and where we see the greatest opportunity.</p> <p>We intend to leverage our platform technologies dCELL® and BioRinse™ to further our market penetration through a hybrid sales model, a combination of direct sales, distribution and OEM agreements.</p>	<ul style="list-style-type: none"> - Significant OEM agreement signed with Arthrex for the BioRinse™ portfolio in the US market; - Extension to the Premier, Inc. GPO Agreement; - “Supplier Horizon Award” achievement from GPO, Vizient, Inc; - Uptake by prestigious US establishments such as the Cleveland Clinic.
 <p>Exploit global market potential</p>	<p>Our current commercialisation efforts are focused on the US markets; however, there is the opportunity and market demand for us to enter new territories.</p>	<ul style="list-style-type: none"> - Extension of the Arthrex partnership to bring the BioRinse™ portfolio into the UK and EU; - Distribution agreement signed for the spine market in the UK.
 <p>Broaden strategic partnerships</p>	<p>At the beginning of 2018 we revised our commercial strategy with a focus on establishing and building strategic partnerships to further our market access and penetration.</p> <p>This also allows for the potential to increase OEM agreements and initiate discussions around joint IP collaborations.</p>	<ul style="list-style-type: none"> - Distribution agreement signed with ARMS Medical for the use of DermaPure® in urogynaecology procedures; - Distribution agreement signed with Pennine Healthcare for the UK distribution of BioRinse™ products into the spine market; - Arthrex extension into other EU markets for sports medicine applications.
 <p>Strengthen portfolio</p>	<p>Our success is reliant upon the ability to commercialise our current portfolio and the potential for augmenting this with line extensions and new innovative products.</p> <p>We therefore look to establish a database of compelling real world clinical data to validate our technology platforms and further our physician conversion rates.</p> <p>These clinical data portfolios are also imperative when we seek new strategic partnership opportunities and when navigating regulatory clearance in new territories.</p>	<ul style="list-style-type: none"> - Two-year clinical data collection for OrthoPure XT; - CE mark application for OrthoPure XT submitted; - New product development “stage and gate” process implemented; - DermaPure® post marketing study protocol for the collection of real world clinical data developed.

Our vision is to establish TRG as a leader in the science and innovation of regenerative medicine. We are building towards a \$200m Global Orthobiologics business.

Focus and Goals for 2019

Link to KPIs

Link to Risks

Scale:

- Focus on higher volume accounts;
- SurgiPure XD US launch;
- Expand partners for specific fields of use and OEM;
- New Product Development related to market opportunities;
- Expand Group Purchasing Organisation coverage;
- Expand commercial scale;
- Expand portfolio penetration in existing accounts.

Group sales growth

IP collaboration and exploitation

- Clinical
- Commercial
- Operational
- HR

Europe

- Extend Human Tissue portfolio opportunities via Arthrex EU Agreement;
- Launch OrthoPure XT (Porcine Tendon).

China

- Ongoing discussion for licensing and distribution opportunities.

Latin America

- Working towards distribution agreements in several countries for BioRinse™ products.

Increase number of strategic partnerships and distribution opportunities

- Clinical
- Commercial
- Operational

Continue to refocus:

- Tissue Regenix Group will work in conjunction with partners' R&D teams;
- Additional regions identified to broaden geographic reach;
- Development programmes underway with key industry players.

IP collaboration and exploitation

Group Sales growth

- Clinical
- Commercial
- Operational

Data: drive decision makers through empirical data

- Commencement of DermaPure® post marketing trial;
- Prospective clinical and health economic studies;
- Two year clinical data collected for OrthoPure XT, will continue to five years;
- Product line extension potential to augment product portfolio and an expedited route to market;
- Increase speed at which products are brought to market;
- Strengthen R&D capabilities.

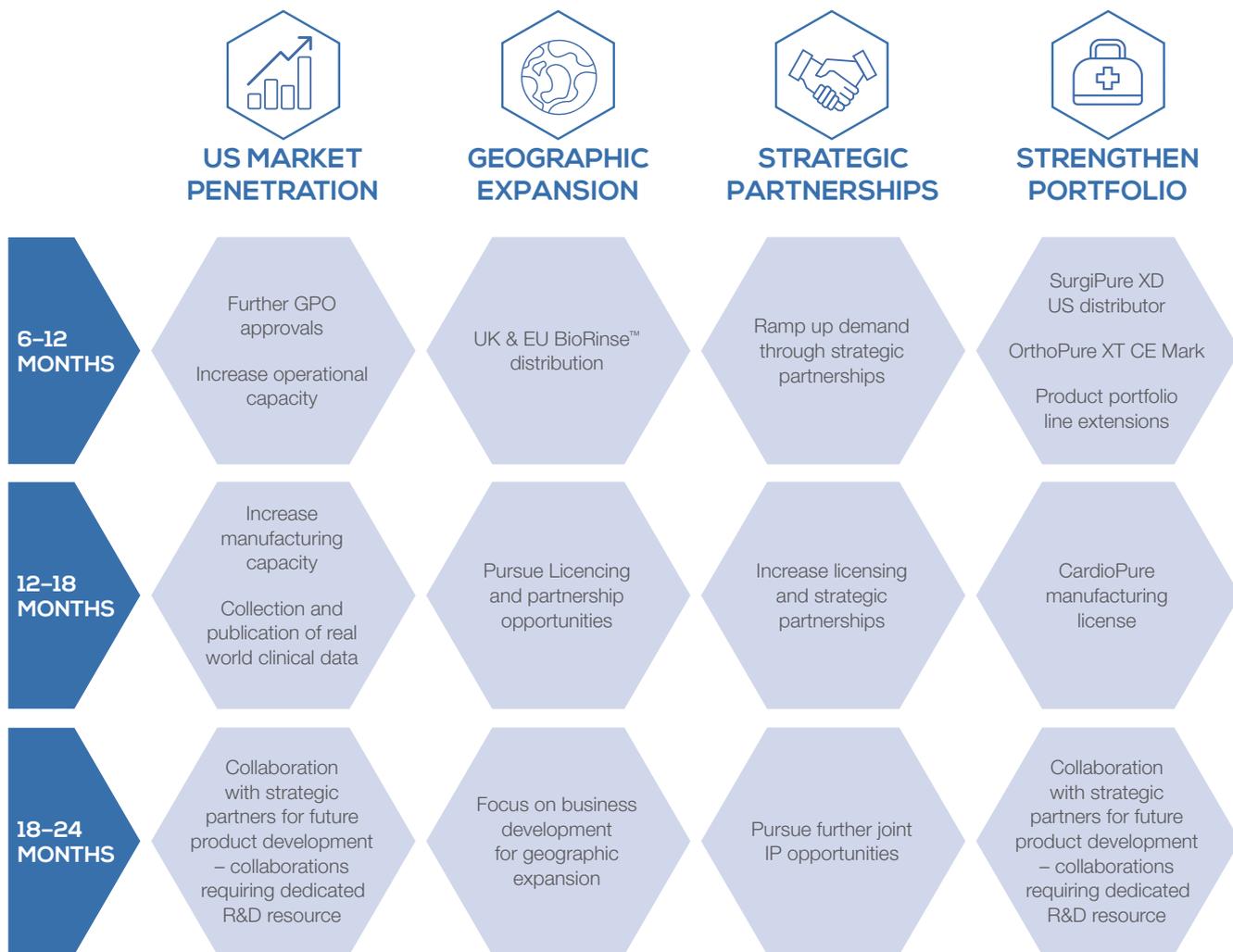
IP collaboration and exploitation

Clinical data collection

Group sales growth

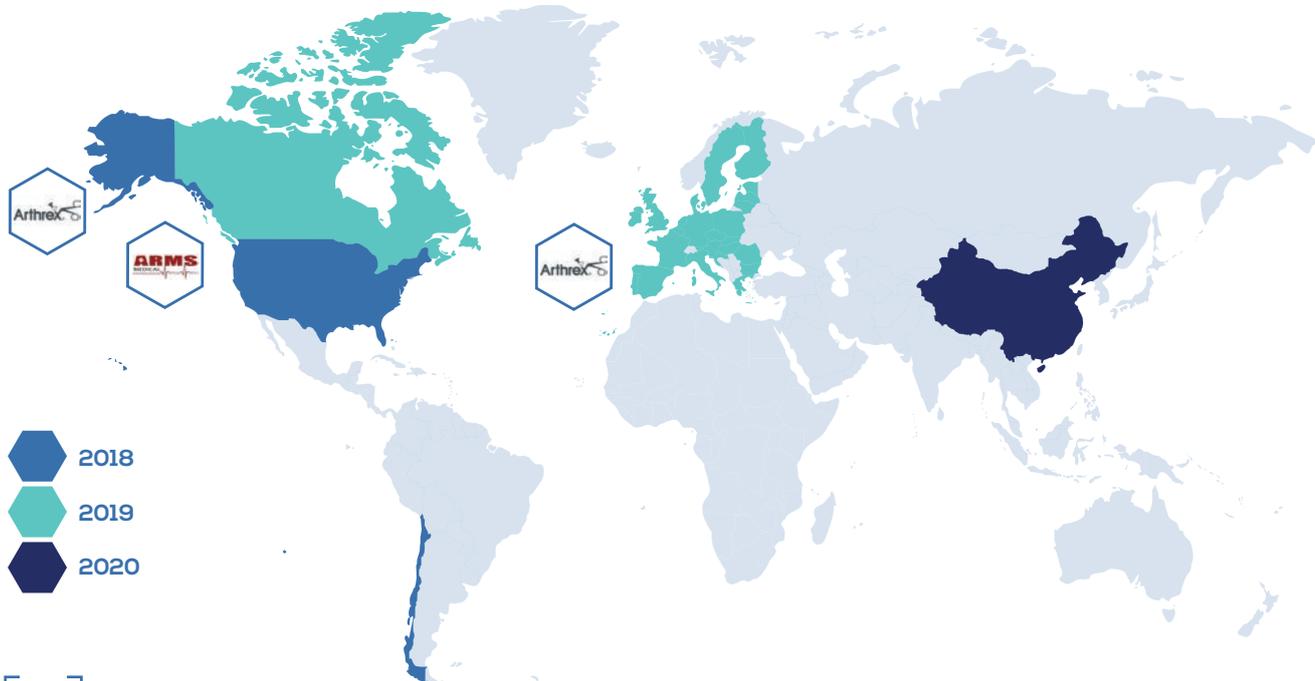
- Operational
- Clinical
- Commercial
- HR

Future milestones: strategy in action



COMMERCIALISATION

Intended geographic footprint expansion through a network of distributors and potential strategic partnerships and licencing agreements.



Case studies

Since repositioning into the hospital space we have had the opportunity to move DermaPure® into orthopaedic applications and leveraged our relationships in the dental market to initiate use in this area. Below are two case studies highlighting the outcomes in these applications.

Case study 1

Utilization of a Next Generation Decellularized Dermal Allograft to Augment the Repair of a Partial Right Maxillectomy and Tooth Extraction after Metastatic Prostate Cancer and Osteoradionecrosis of the Jaw.

Brian Smith, DMD, MD

Camden, NJ
Board Certified,
American Board of Oral and Maxillofacial Surgery

CLINICAL PRESENTATION:

- 71 year-old male with history of metastatic Castrate-Resistant Prostate Cancer (CRPC) with bone metastasis. Treated previously with multiple chemotherapeutic regimens.
- Diagnosed with probable medication-related osteonecrosis of the jaw (MRONJ); Surgery scheduled.

SURGEON PERSPECTIVE:

- "With the total loss of sinus mucosa and structural integrity of the maxilla, there was a high risk of surgical site dehiscence and oral-antral fistula. The use of the internal membrane closure with DermaPure® avoided wound dehiscence, promoted healing, and helped maintain structural integrity of the maxillary nasal complex."

POST-OPERATIVE NOTE:

- Full healing of wound in 3 weeks (Figure 4).
- Able to eat without difficulty.



Fig 1 – After tooth extraction and debridement



Fig 2 – After implantation of DermaPure® graft



Fig 3 – After flap closure



Fig 4 – Complete healing after 3 weeks

Case study 2

Utilization of a Next Generation Decellularized Dermal Allograft to Augment the Repair of a Massive Rotator Cuff Tear Involving the Supraspinatus and Infraspinatus Tendons.

Robert F. Hines, MD

Oklahoma City, OK
Board Certified,
American Board of Orthopaedic Surgeons

CLINICAL PRESENTATION:

- 44 year-old male, healthy police/SWAT officer who slipped and fell on his elbow, dislocating his shoulder. Shoulder was reduced, and patient underwent rehab for six weeks, but made no progress.
- MRI revealed 4 – 5 cm tears (figures 1 and 2) in the supraspinatus and infraspinatus tendons, no muscle atrophy and no labral tears.

SURGEON PERSPECTIVE:

- "DermaPure® added augmentation to this massive rotator cuff repair. At 3 months post-op, this patient continues with the 10 pound lifting restriction and remains pain free. All of the patients in which I have utilized DermaPure® for augmentation of the rotator cuff repair, no longer required narcotics for pain management by post-op day 4 – 7."

POST-OPERATIVE NOTE:

- By post op day 4, the patient no longer required narcotics for pain management.
- Patient is being followed routinely to assess clinical outcomes.



Fig 1 – Tendon tears



Fig 2 – Tendon tears



Fig 3 – DermaPure® Implantation

Key performance indicators

KPI	Definition	Why this is important
FINANCIAL		
Group sales growth	An increase in the top line revenue delivered across all commercialised divisions.	In order to reach sustainable profitability, Group revenues must increase in order to become a self-sustaining and profitable company able to make returns to shareholders and invest in development accordingly.
Cash position	Maintaining sufficient cash resources that enables the business to develop is critical to the evolution of the Group.	As with any development stage business maintaining sufficient cash resources and the effective deployment thereof is critical to the long-term success of the business.
CLINICAL		
IP collaboration and exploitation	Intellectual property is at the heart of our business with both the dCELL [®] and BioRinse [™] portfolios. Collaborations allow us to expand the potential of these IP platforms as we explore licensing deals and future R&D opportunities.	Our business is built around two platform technologies and our ability to successfully protect, commercialise and differentiate our products. IP collaborations allow us to leverage our R&D capabilities and utilise the larger marketing arms of partners.
Clinical data collection	The regulatory pathways for our porcine products is dependent upon the ability to produce, run, and monitor a successful clinical trial. Real world clinical data is collected in post marketing studies to continue to demonstrate our differentiating factors and health economic and clinical arguments.	Collecting real world clinical data is imperative for us in order to increase the advocacy of our products, prove our differentiating factors and drive physician adoption and patient outcomes.
COMMERCIAL		
Increase number of strategic partnerships and distribution opportunities	Strategic partnerships are key to our new commercialisation strategy allowing us to access partner's distribution networks, potential licencing deals and R&D work.	These partnerships allow us to accelerate our market penetration by accessing larger distribution and sales networks.
HR		
Staff retention and development	The retention and development of employees is key as we invest in relevant training, qualifications and development whilst also ensuring that succession plans are in place.	Our industry is highly skilled and reliant upon employees with the correct qualifications, training and experience. Therefore, staff retention is key and the ability to attract and maintain the best talent in the industry provides us with a competitive edge.
ENVIRONMENTAL SUSTAINABILITY		
Responsible energy consumption	As our processes require specialised equipment and specific storage conditions we must ensure that we take all available options to reduce our energy consumption and increase our environmental sustainability.	With increasing focus on businesses environmental footprints it is imperative that we take all available measures to reduce our energy consumption and operate in a sustainable and responsible manner.

Commentary

Link to Strategy

We have successfully grown our sales year-on-year, with a 47% pro forma increase in FY2018 even while integrating the Companies.

We must maintain and accelerate this momentum having laid the key foundations for successful business growth: manufacturing capabilities, clinical advocacy, strategic partnerships and distribution opportunities.



A blend of all four strategic growth drivers is required to facilitate successful Group sales growth.

At December 2018 cash resources were reported at £7.8m, better than expected due to effective management of working capital.



A blend of all 4 strategic growth drivers.

We have successfully defended our patents against infringement and have opened conversations with third parties around further licensing opportunities, both geographically and for new product developments.

During 2019 we would expect a number of these discussions to come to fruition.



Objective 2

– Broaden strategic partnerships

Objective 3

– Strengthen portfolio.

We have several ongoing clinical programmes both for regulatory clearance and to further our clinical and health economic arguments. These include two year clinical data collected for OrthoPure XT, prospective observational study for DermaPure®, a urogyn clinical study in collaboration with ARMS Medical and scoping for a BioRinse™ observational study in dental.

We continue to work closely with our KOL and clinical advisory groups in order to collect the most relevant real world clinical data and expect that we will publish additional case series reports throughout the year.



Objective 3

– Strengthen portfolio.

During 2018 we made significant progress signing partnerships with Arthrex, Inc. for the US distribution of select BioRinse™ products and ARMS Medical for the use of DermaPure® in urogynaecology procedures.

We have initiated preliminary conversations with a number of other potential partners, in terms of both geographic distribution opportunities and R&D projects. We expect that during 2019 select conversations will progress to the point of announcement.



Objective 2

– Broaden strategic partnerships.

Objective 4

– Exploit global market potential.

In 2018 we launched an employee engagement programme across the whole global Group called “Verto”. This aimed to address employee concerns and provide a platform from which they can engage and shape the future of their working environment. More information can be found on page 28.

During 2019 we expect to bring this foundation work to a close and implement an internal infrastructure that will allow consistent and easily accessible cross company communications allowing us to benefit from the sharing of knowledge, experience and key relationships across all facets of the business.



A blend of all 4 strategic growth drivers.

During 2018 we implemented several changes in order to reduce our energy consumption. These included the installation of more efficient air con and heating units in each office or meeting room and motion sensor activated lighting in communal areas to ensure that there is not waste in terms of electricity.

Moving forward, during 2019 we intend to update our waste management system to ensure that we recycle as much as possible as well as implementing an improved waste collection timetable to reduce the emissions associated with this activity.



A blend of all 4 strategic growth drivers.

 Read more about our Sustainability on pages 28 and 29

Business review

OUR MANAGEMENT TEAM

We have an experienced and motivated top level management team. With specialists leading each area we ensure that we can execute against the deliverable strategy outlined for each division. Alongside this, we have Executive Directors who have extensive experience in the healthcare industry and the capital markets, and an experienced and well balanced Board of Directors.

Steve Couldwell,
CEO, Tissue Regenix Group

Full biography available on page 30.

Gareth Jones
CFO, Tissue Regenix Group

Full biography available on page 30.



Mike Izon
R&D Director

Mike Izon joined as Head of QAVRA and Clinical at Tissue Regenix in November 2014. With a background in pharmaceutical products and medical devices, Mike has worked over the last 10 years as a consultant, trainer and assessor for the certification and registration of medical devices. Having worked extensively with early stage medical device development companies, Mike has also worked with household names such as Procter & Gamble, Clairol and Sanofi Aventis to achieve worldwide market clearance for a range of products and technologies.



Daniel Lee
President, US Operations

Daniel R. Lee has nearly 30 years experience in the medical device and biologics industry ranging from product innovation to commercialization to corporate management. He joined CellRight Technologies® as President of U.S. Operations in January 2019. Prior to joining CellRight, Danny was the Chief Executive Officer for Scaffold Biologics and Aperion Biologics. His previous senior management roles included global marketing for OsteoBiologics (acquired by Smith & Nephew Endoscopy in 1996) and marketing activities for Regeneration Technologies (now RTI Surgical), a leading allograft tissue processor. Danny spent the first ten years of his career in R&D with the U.S. Surgical Corporation (now Medtronic). Danny received his B.E.S. degree in Materials Science and Engineering from the Johns Hopkins University and his M.S. in Biomedical Engineering from the University of Alabama at Birmingham. He has thirteen patents on implants and instruments used in orthopaedic and general surgery.

60,000 people die from pressure ulcers started in hospitals in the US per year¹



Drew Distin
President, TRX Orthopaedics

Drew Distin joined TRX Orthopaedics when the new division was launched in March 2016. Drew oversees all aspects of operations for the orthopaedic division, and works in close cooperation with the corporate headquarters and product development team in the UK.

Drew has over 20 years' experience in the orthopaedic industry, having held senior management roles in sales, marketing and product development in companies such as CryoLife, RTI Biologics and Osiris Therapeutics. His main focus over the last several years has been in the specialties of tissue regeneration, orthobiologics and cartilage restoration.



Joel Pickering
President, TRX BioSurgery

Joel Pickering joined Tissue Regenix Wound Care Inc. in October 2015 to assume the leadership of the US marketing organization. Joel moved into the position of President in January 2017 and now guides the commercial marketing strategy for DermaPure® and SurgiPure® in the United States.

Joel brings a wealth of wound care marketing experience dating back to 1996 with such companies as J&J Medical, Lifecell, Convatec and KCI. Prior to joining Tissue Regenix, Joel served as VP of Marketing and Communications for Novation with responsibility for driving Novation growth in the US.

Through his time in the wound care category, Joel has launched several new brands and driven many established brands to category leading shares through a combination of vision, communication and team leadership.



Andrea Rausch
Commercial Director, Cardiac

Andrea Rausch was appointed as Business Development Manager in the Tissue Regenix Cardiac team in August 2012. Andrea joined Tissue Regenix from Sorin Group, a global medical device company and a leader in the development of medical technologies for cardiac surgery and for the treatment of cardiac rhythm disorders.

For two years, she was Global Marketing Manager at Sorin for the Perceval Programme, a new treatment option for aortic valve disease, having been Business Line Leader and Strategic Sales and Marketing Manager of the Heart Valves team in Germany for five years before this.

¹: *Greenwald L. Medicare Deadline Spurs Hospitals to Prevent Pressure Ulcers. E-Zine. 2007. <http://ezinearticles.com/?Medicare-Deadline-Spurs-Hospitals-to-Prevent-Pressure-Ulcers&id=846302>

Business review

continued

Our business is split into individual operating divisions to address different clinical application areas. This allows us to ensure that we appoint the most relevant management team and sales force in order to drive market penetration, product advocacy and communicate the clinical benefits for each. Below is an overview of each divisions achievements throughout the year.

BIOSURGERY

2018 has been an exceptional year for the BioSurgery division, growing revenue by 79% on a constant currency basis, highlighting the increasing market demand for DermaPure® and the advantages of our refined strategic focus.

Expanded GPO coverage and Strategic Partnerships

We have continued to expand our Group Purchasing Organization (GPO) approvals and now have coverage in institutions accounting for 95% of the total spend under these agreements. This has opened up opportunities for us in the hospital arena, where we have seen the utilisation of DermaPure® move into new indications within the surgical suite, augmenting our historic woundcare applications.

This was expedited by the ARMS medical agreement which was announced in February 2018 moving DermaPure® into women's health and particularly urogynecology applications. With an increasing focus on the safety of alternative solutions, such as a mesh treatments, where historically between 150,000-200,000 procedures per year in the US result in serious complications¹, around 5% of the total number performed, DermaPure® offers advantages due to its natural regenerative properties. The uptake that we have seen has driven the advocacy of the product within this application area with over 300 patients treated by mid-July and the demand in this area has led to the ongoing development of a DermaPure® product tailored specifically for this application, which we hope to bring to market during 2019.

Improved DermaPure® Positioning

Orthopaedic trauma is another area in which we have seen significant clinician interest, with DermaPure® being used in tendon wrapping for the achilles tendon through to rotator cuff repair in the shoulder. As we drive clinician conversion in this area we are undertaking several case studies in order to strengthen our clinical data. You can read a case study on page 15.

This verifies the benefits of our 'narrow & deep' sales philosophy which we have implemented in targeted key institutions, resulting in greater conversion of applicable physicians and has also expanded our network of Key Opinion Leaders (KOLs) who are driving the advocacy of the product throughout their peer groups.

Surgeons are becoming increasingly aware of the benefits that DermaPure® can offer to both the patient and healthcare provider. This was highlighted by the world-renowned Cleveland Clinic which began using DermaPure® in 2018, with a case series being shown at the prestigious VEITH Symposium.

SurgiPure XD

SurgiPure XD, a porcine dermis for use in hernia repair was previously granted 510(K) approval for the US and underwent a soft launch at the end of 2018. SurgiPure XD will be manufactured at our facility in Leeds and is the first commercial dCELL® product to be manufactured there. We expect to engage multiple relevant distributors for this product during 2019.

Outlook

2018 was a successful year for TRX BioSurgery having repositioned DermaPure® in the hospital arena, forged key distribution partnerships, increased the clinical application areas and grown our clinician advocacy and clinical case studies. With these foundations now in place we expect 2019 to deliver strong returns as we look to augment our product portfolio with additional sizes of DermaPure®, launch SurgiPure XD with distribution partners and increase our GPO coverage accessing a new pool of physicians and patients. In order to meet our projected level of sales we have augmented our in-house manufacturing of DermaPure by renewing our agreement with Community Tissue Services as a third-party manufacturer, allowing us the capacity required to meet our customers' expectations during 2019 and beyond.

1. Shlomo Raz, professor of urology and pelvic reconstruction at UCLA school of medicine https://www.washingtonpost.com/national/health-science/vaginal-mesh-has-caused-health-problems-in-many-women-even-as-some-surgeons-vouch-for-its-safety-and-efficacy/2019/01/18/1c4a2332-ff0f-11e8-ad40-cdfd0e0dd65a_story.html?utm_term=.004a67e3ab2b

2. iData Research 2016

3. Ortho World Annual Report 2017

4. iData Research 2016

The projected US market for dental bone graft substitutes in FY2019 is \$233.3m²

ORTHOPAEDICS AND DENTAL

The year to 31 December 2018 was again positive for the orthopaedics and dental division, with a 31% pro forma increase in revenue, primarily consisting of the BioRinse™ portfolio, and was the first year in which we benefited from the CellRight acquisition for a full fiscal year. In addition to the BioRinse™ portfolio there is the potential for dCELL® products to also be utilized in this space, with orthopaedic trauma, sports medicine and foot and ankle applications for DermaPure® the opportunity for collaboration between the operating divisions offers opportunities to further our market penetration.

Strategic Partnerships

In March 2018 we announced the first of several notable strategic partnerships with Arthrex, Inc. who took three of the BioRinse™ portfolio under their own brand 'AlloSync' for distribution in the US. Arthrex are one of the largest sports medicine company's in the world having over 2,700 sales reps globally. The US distribution agreement offers third-party validation of the differentiation of the BioRinse™ technology and strong advocacy to leverage when securing new customers.

We expanded the Arthrex relationship in November 2018, by entering a branded distribution agreement in the EU, following the approval of the Human Tissue Authority (HTA) license which allows for the importation of our human tissue products from the US into the UK. Initially our focus will be on the UK market before expanding into additional European countries; the first training for the Arthrex European sales reps was undertaken at the facility in Leeds in Q1 2019, and we expect this agreement to gain traction over the next 12-18 months as we continue with the education process and physician conversion.

To accommodate the increasing demand for our products and the scale of these new partnerships we expanded our BioRinse™ manufacturing capacity through the commencement of a second shift within the San Antonio facility in Q1 2019.

dCELL® Technology

OrthoPure XT, continues to progress through the regulatory approval process for a CE mark. We have collated the 2 year clinical data which has been submitted to our notified body and continues to show clinical evidence as a suitable choice for ACL reconstruction, with biomechanical testing equivalent to current graft choices, including allograft or autograft. During 2018 we commenced discussions with the FDA around a pre-clinical trial for OrthoPure XT in the US. After scoping this out the strategic decision was made to keep our resources focussed on the E.U market launch. Likewise, with increasing demand on our dCELL manufacturing capacity the launch of pathfinder product OrthoPure HT has been paused.

We remain confident in the clinical outcome and health economic benefits provided by the product and are poised to commercialise as soon as the approval is granted. Our launch timeline has been delayed by the ongoing implementation of the Medical Device Regulations across Europe and the additional strain that this has placed on the notified bodies. Our initial focus will be the UK market where we have several Key Opinion Leaders ready to utilise the product, before further expanding into Europe, as we gain country registrations, through a network of distributors.

Dental

In dental, we see huge potential for the use of both the dCELL® and BioRinse™ portfolios. Throughout 2019 we will concentrate on further penetration of the US market which accounts for half of the total global market.

With a favourable reimbursement framework, consisting primarily of cash payments dental is an area which we believe has a vast market opportunity that we will be able to penetrate quickly with both product portfolios. We see use across the dental market, including general dentists and maxillofacial specialists for routine and complex or corrective cases. The BioRinse™ portfolio is being utilised in procedures such as ridge augmentation whilst DermaPure® provides a soft tissue covering following extraction or in cases of receding gumlines.

A case study can be viewed on page 15.

The US orthobiologics market was worth an estimated \$3.4bn in 2017³

Outlook

During 2018 we achieved several important commercial milestones that allowed the orthopaedics and dental division to accelerate its growth trajectory. The agreement with Arthrex offers third party validation of the differentiation of the products and shows the level of external confidence in our BioRinse™ products. With the further expansion of this partnership into Europe offering potential access to new markets by leveraging their commercial experience and infrastructure and we are confident that this growth will continue throughout 2019.

To maintain these important relationships, in Q1 2019 we appointed a number of commercial heads including a VP of strategic partnerships, and two additional regional sales directors to support our expected growth in this division.

Business review

continued

**Overall market value
for dental biologics
in the United States
\$426.2m⁴**

CARDIAC & GBM-V

Our cardiac division continues to develop a strong clinical data portfolio from the collaborative work with Dr Francisco da Costa in Brazil, with the data from a multicentre paediatric trial being presented at the Heart Valve Society meeting in Sitges in April 2019. We are excited to share this data which further highlights the advantages of our CardioPure products specifically in younger patients who typically experience a higher instance of re-operation or rejection.

The work with our colleagues at GBM-V continues to develop and we are confident that after navigating the regulatory pathway we will be able to launch the CardioPure product in Germany in 2020 as planned.

In addition, GBM-V have established new supply agreements with additional tissue banks ensuring that the supply of donor materials is consistent to allow the cornea business to continue to grow, evidenced in the top line revenue figures which increased by 62%. This also allows a greater deal of cash self-sufficiency, an important aspect of the Group reducing its overall cash dependency and cash burn.

The main focus of GBM-V continues to be the regulatory clearance and launch for the CardioPure product line.

COMMERCIAL

Invested in Operations and Management

In June 2018 we were awarded a Human Tissue Authority (HTA) license for our facility in Leeds. This allows us to import the BioRinse™ portfolio from the US into the UK for distribution primarily under the Arthrex agreement. The UK facility will be used as a hub to allow for further European distribution as individual Country registrations are granted.

In the US, we transferred the processing of DermaPure® in-house, allowing for end to end control of the manufacturing process, product quality and product mix. As demand for the products increased we sourced additional capacity and reduced our manufacturing risk by engaging with Community Tissue Services to assist with processing efficiency, donor yield and supplementary supply.

Additionally, we commenced a second shift within the San Antonio facility to increase the output of BioRinse™ products. This will allow us to meet the increased demand driven by the throughput of our partnership agreements in the short term whilst we explore options to increase manufacturing capacity.

Clinical

In order to strengthen our product positioning and differentiation we are enhancing the clinical data package to highlight both the clinical and health economic advantages that DermaPure® can offer. We increased our Key Opinion Leaders and have undertaken a number of case studies in order to highlight its use in the various procedures. During 2018 we established a protocol for a multi-centre prospective observational study which we intend to commence in the first half of 2019. In addition, we augmented our clinical team adding an additional three clinical affairs managers to ensure that commercial reps and distributors have the required clinical support.

Alongside this, we are also running a number of case series for both the dCELL® and BioRinse™ portfolios to enable peer to peer discussions and the collection of real life, practical examples.

Delivering new Product Development and I.P.

As we build relationships with strategic partners we also look to align ourselves with their product development and R&D functions. The Group has vast experience of bringing products from concept to completion and has the agility to undertake these tasks quickly. This allows us to identify opportunities and quickly create a prototype for testing. Moving forward we look to develop these skills further and deepen the relationships allowing us to be positioned as an R&D partner to larger industry players.

We continue to protect and monitor our intellectual property by maintaining several patents worldwide for the dCELL® portfolio encompassing both the core dCELL® Technology and individual product processes.

The BioRinse™ portfolio remains protected by know-how and we continue to register trademarks for all relevant logos and trade names.

As we look to expand the opportunities for each product portfolio and exploit the Global market potential, we also look to create efficiencies in the processing and manufacturing to allow for a reduction in both the associated time and financial cost while maintaining the integrity of the product to allow for superior clinical outcomes.

Management

In November 2018 Gareth Jones joined as Group CFO and later stepped into the interim role of COO whilst CEO Steve Couldwell took a period of leave for health reasons.

Outlook

We focus ourselves around two platform technologies, in three key clinical application areas with four strategic growth drivers.

As we look to expand our commercial presence across the globe, the opportunity for us to license our technology platforms to potential strategic partners in new territories offers a route to market, market expertise and access to scalability. This also allows our direct sales and management team to remain focused on key markets, in which we are seeing increasing market penetration and a growth trajectory.

Our strategy around establishing strategic partnerships to help scale our commercialisation efforts has proven fruitful throughout 2018 and we expect this to continue as we pursue further partnership opportunities.

Outside of establishing these partnerships we have identified several commercial synergies to leverage across our portfolio, for example the use of DermaPure® in orthopaedic trauma and dental procedures. This has also led to specific product specifications being sought that we can bring to market quickly to address these procedures.

The Group has made significant commercial progress throughout the last year and we have positioned ourselves to continue to develop and grow this momentum. Focusing on our identified strategic drivers of growth we expect to continue to build strong commercial foundations which will drive our success far into the future.

Financial overview

47% top line revenue growth on a proforma, constant currency basis, increasing to £11.6m.

Revenue

In the year ended 31 December 2018 revenue increased by 122% to £11,619K (2017: £5,233K). Revenue from the legacy Tissue Regenix dCELL® product DermaPure® increased 75% to £3,381K (2017: £1,932k) driven by increased GPO penetration, a strategic partnership with ARMS Medical and a move into the Orthopaedic trauma space. With these initiatives in their infancy, we expect this growth to continue during 2019.

CellRight Technologies, reported under the Orthopaedics and Dental division, grew revenue 31% year on year to £6.4m (2017: £4.9m) on a pro forma basis. In March 2018 we announced a strategic partnership with Athrex, one of the world's leading orthopaedic and sports medicine companies, and later successfully expanded this agreement. They initially took 3 BioRinse products under their own brand 'AlloSync'. Following the approval of a Human Tissue Authority License for the UK facility, we extended this partnership to cover the EU and received our first orders in Q1 2019. This is a partnership we expect to continue to grow substantially during FY 2019.

The remaining top line revenue growth was derived from GBM-v, our controlled joint venture in Germany. GBM-v was able to significantly increase the volume of corneas processed during the year resulting in revenue growing by 62% to £1,842K (2017: £1,135K)

Cost of sales and gross profit

The revenue growth and full year effect of CellRight has resulted in a commensurate increase in gross profit by 127% to £5,917K (2017: £2,606K). Gross margin percentage increased marginally from 50% to 51% due to a combination of favourable product mix and realised production efficiencies. As the business continues to deliver products in greater quantities it has been possible to realise synergies along with our in-house manufacturing capabilities and the established nature of the CellRight business.

Included in cost of sales is, cost of product of £4,723K (2017: £2,039K) and third party commissions of £979K (2017: £588K).

Administrative Expenses

Administrative expenses increased by £1,184K from £13,422K to £14,606K. This included £423K (2017: £1,098K) of exceptional costs.

Admin expenses before exceptional items increased by £1,859K (mainly attributable to a full year effect of CellRight being in the Group). Overheads included staff costs (53%), sales and marketing (8%), research and development (12%), establishment and administration costs (30%). Operating loss was narrowed to £8,689K (2017: £10,816K).

Exceptional items

Cost relating to the settlement of a LifeNet litigation case are accounted in the exceptional items, covering a final legal payment and insurance upfront excess. There are no other costs to be incurred relating to this case.

Finance income / charges

Finance income of £72K (2017: £47K) represents interest earned on cash deposits. Finance charges of £262K (2017 – nil) relate to the discounting of earnout consideration on the CellRight acquisition in line with IFRS (discount rate of 10% applied).

Taxation

The Group submits enhanced research and development tax claims and elects to exchange tax losses for a cash refund. The refund receivable for the year ended 31 December 2018 is £790K (2017: £1,348K). This fall was due to a reduction in tax credits claimed as the Group commercialises additional products moving them out of the R&D phase.

Corporation Tax payable in the US amounted to £72K (2017: £nil) due to the profits of CellRight.

Gross tax losses carried forward in the UK were £43,352K (2017: £35,819K). The Group does not currently pay tax in the UK. A deferred tax asset has not been recognised as the timing and recoverable value of the tax losses is uncertain.

Loss for the year

Loss for the year was £8,259K (2017: Loss £9,421K). The number of shares in issue at the reporting date was 1,171,730,823 (2017: 1,170,990,924) resulting in a basic loss per share of (0.70p) (2017: loss (1.00p)).

Financial overview

continued

Balance sheet

At 31 December 2018 the Group had net assets of £32,570K (2017: £39,522K) of which cash in hand totalled £7,816K (2017: £16,423K) which was ahead of expectations.

Intangible assets increased to £19,938k (2017: £19,305k) as foreign exchange revaluation exceeded amortisation. A further £116,000 of development costs were capitalised.

Net working capital increased slightly to £3,054k (2017: £2,596k) which reflect the continued growth of the business. The balance sheet includes corporations tax receivable of £1,200k (2017: £1,665k) in respect of UK research and development tax credits.

Cash absorbed by operations was £6,838K (2017: £9,786K) as we continue to move towards breakeven and subsequent profitability.

Year end cash position ahead of expectation at £7,816K

Following the acquisition of CellRight, the business successfully achieved the revenue performance criteria necessary for the payment of the first milestone. This was due following the completion of revenue criteria in the first twelve months post acquisition. This payment amounted to £1,564K and, at this stage, it is currently expected that the second milestone, of equivalent value, will be paid in full in September 2019.

Dividend

No dividend has been proposed for the year to 31 December 2018 (2017:Nil)

Accounting policies

The Group's consolidated financial information has been prepared in accordance with International Financial Reporting Standards as adopted in the EU. The Group's significant accounting policies which have been applied consistently throughout the year are set out on pages 50 to 54.

Going Concern

As at 31 December 2018, the Group had £7,816k 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 pages 25 to 27.

As separately reported, the Group has successfully raised a debt facility totalling \$20m, of which \$10.5m became available immediately to the Group to drawdown at completion. The Directors are therefore confident the Group has adequate financial resources to fund its activities for the forthcoming period.

Principal risks and uncertainties

The principal risks and uncertainties facing the Group are set out on pages 25 to 27.

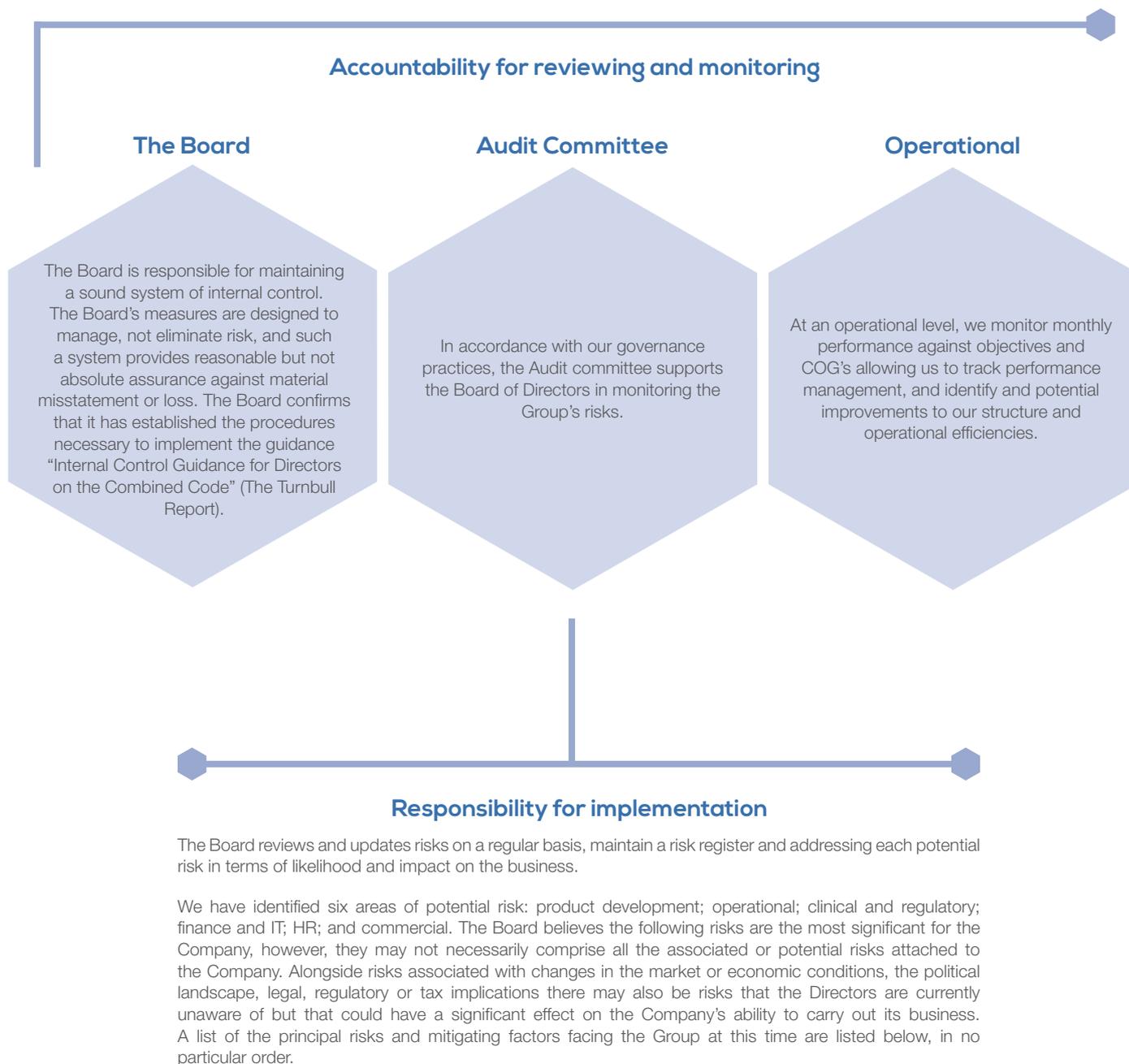
Cautionary Statement

The Strategic report, containing the Strategic and Financial reports of the Group contain forward looking statements that are subject to risk factors associated with, amongst other things, economic and business circumstances occurring from time to time within the markets in which the Group operates. The expectations expressed within these statements are believed to be reasonable but could be affected by a wide variety of variables out-with the Group's control. These variables could cause the results to differ materially from current expectations. The forward-looking statements reflect the knowledge and information available at the time of preparation.

Significant commercial milestones achieved

Risks

OUR RISK MANAGEMENT FRAMEWORK



Risks

continued

Risk	Potential Impact	Mitigating Factors	Trend
 <h2>Product Development</h2>			
<p>Risk that products fail to perform as expected.</p>	<p>The business is dependent upon its ability to bring its novel regenerative solutions to market and provide patients and physicians with an optimal clinical outcome and health economic advantages. Should the products fail to perform there would be a detrimental effect on the Company's reputation, financial position and R&D capabilities.</p>	<p>The Group continues to collect clinical data on the products brought to market, head-to-head comparisons with competitor products are undertaken, benchmarking along with data already produced to help ensure that products are developed with a competitive edge.</p>	
 <h2>Operational</h2>			
<p>Risk that as the business looks to expand there is a risk that demand will outstrip supply.</p>	<p>Our commercial strategy is built around the establishment of successful strategic and distribution partnerships which increase the demand on our production and manufacturing capabilities. This could result in the loss of business through customer dissatisfaction and reputational damage.</p>	<p>Additional short-term capacity is being secured via outsourcing and a second shift. Longer term a programme is underway to secure additional manufacturing capacity.</p>	
<p>Risk of facility shutdown due to loss of licence via inspection or other investigation e.g. FDA, or damage to a manufacturing facility due to fire, arson, floods or other adverse events.</p>	<p>As the Group manufacture most products in-house, the loss of a manufacturing facility would clearly have a detrimental effect on the ability to meet customer demand. Should an adverse event happen there would be a loss of stock and raw materials which would have financial implications on the Company.</p>	<p>The Group has a track record of positive feedback following inspections, including the FDA Audit in Q1 2019, and established control environments. Facility insurance is in place in case of adverse event, and second source manufacturing options are identified.</p>	
<p>Risk of overdependence on single supplier.</p>	<p>With the novel technology processes requiring specific raw materials, the loss of a supplier could have a detrimental effect on the ability to produce the media required for the process. As the products are based around animal or human tissues, failure to source good quality, ethically-handled tissues would result in the inability to produce products in line with specifications and therefore incur reputational damage, customer dissatisfaction and potential regulatory breaches.</p>	<p>Business interruption insurance is in place, alternative suppliers are being sought where appropriate to ensure that there is always a secondary source for both raw goods, and if needed, secondary manufacturing capacity. All suppliers undergo a stringent audit to ensure that they meet the Company's internal standards and those imposed by third party moderators.</p>	
 <h2>Clinical and Regulatory</h2>			
<p>Risk of loss of licence or restrictions due to regulatory failings.</p>	<p>As the Company operates in a highly regulated environment, the loss of a licence to manufacture or sell products within a territory would result in reputational and financial damage to the Company.</p>	<p>The business has a track record of positive feedback following inspections and established control environments. The Company employs regulatory experts for each territory in which manufacturing takes place or where the Company looks to navigate a regulatory clearance for a product.</p>	
<p>Risk that products fail and cause death or injury on implantation into patients.</p>	<p>Should a product fail upon implantation or incur an adverse reaction due to the product properties, the Company would be at risk of legal action, potential loss of earnings through product retraction from the market and reputational damage.</p>	<p>Before commercialisation a series of safety checks is run dependent on the nature of the product. For porcine products this will initially be within an animal model. Once this is shown to have safely passed a regulated clinical trial addressing specific protocol to judge the performance and safety of the product is commenced. An external regulatory body review is undertaken and comprehensive training for sales reps and surgeons prior to the utilisation of the product is provided. For human tissue products the necessary clinical performance trials are commenced prior to commercialisation and all products are issued with a detailed instructions for use.</p>	

The Board carefully considers the risks facing the Group and endeavours to minimise their impact through the necessary mitigating actions.

Risk	Potential Impact	Mitigating Factors	Trend
 <p>Finance and IT</p> <p>Risk that there are insufficient funds to deliver products to market.</p>	<p>Our success is dependent on our ability to successfully exploit our platform technologies and commercialise our products; this takes investment in the production, marketing and infrastructure to do so. As we produce our products in-house we also need to ensure that we have the capacity for growth in order to meet customer demands. Insufficient cash would result in a decline in these activities and the future R&D potential.</p>	<p>The Board has oversight of all significant cash spends and a process is in place for efficient cash management with a monitored return on investment.</p> <p>A well established control environment is in place to assess the funding requirements of the business, which includes strategic reviews, forecasts and monthly reporting.</p>	
 <p>HR</p> <p>Risk of potential loss of key staff resulting in a loss of key information, contacts and processes.</p>	<p>The dCELL® process is patent protected, however the BioRinse™ process is based on “know-how” and the Company has a number of trade secrets which it looks to maintain. There is also the potential that agreements are based around an individual and not through a relationship with the Group which could result in a loss of business.</p>	<p>The Remuneration Committee is in place to benchmark salaries and incentive schemes. Addition of more management level staff has allowed knowledge to be spread across teams and is less centred on individuals. We have also implemented an employee engagement initiative to keep staff engaged and ensure a healthy work/life balance. Contracts of employment are drafted to include the necessary confidentiality clauses.</p>	
 <p>Commercial</p> <p>Risk that competitor products reach the market first and/or products outperform Tissue Regenix products and the business fails to keep up with developments and new products coming onto the market.</p> <p>Risk of price erosion through inability to offer a competitive product.</p>	<p>Should there be a competitor that outperforms one of the products there is the potential that we will lose customers and contracts. Should a competitor release a product before us they could potentially have an advantage in gaining significant market share.</p> <p>Due to the reimbursement framework in the industry and the territories in which the Company has commercialised, it is paramount to offer a competitively priced product and therefore need to ensure that cost of goods remain at a level from which a superior, yet affordable option can be produced.</p>	<p>We continually review competitors and the commercial landscape and look to stay ahead of the trend with innovative product development, and line extensions. The Company seeks market opportunities and tailors product development to address this, as well as continuing to collect post marketing clinical data to ensure that the product offering remains differentiated.</p> <p>The Company maintains a high focus on potential margin reduction with specific programmes implemented to ensure that this remains on track.</p>	 
 <p>Political and economic landscape</p> <p>Risk of significant changes in the political or economic landscape</p>	<p>With both the UK and the US undergoing periods of political uncertainty there is the potential that this could affect our ability to commercialise and import/export our products. With regards to Brexit it is currently unclear how the decision to leave the EU could affect the Company. For example, there may be changes implemented to the regulatory system under which our products are approved, import / export regulations could be affected and economic volatility and uncertainty may be possible.</p>	<p>The Group continues to monitor developments relating to Brexit and receives relevant updates from advisers to ensure any potential risks are understood and mitigating actions implemented if needed. With the establishment of a controlled joint venture in Germany, the Company holds a corporate position within the EU and would therefore maintain a presence in both the UK and EU following the final decision. The necessary actions have been undertaken to ensure that any regulatory clearance application would be registered across both the UK and wider EU to allow for country registrations and commercialisation.</p>	

Sustainability

Tissue Regenix's vision to become a leader in regenerative medicine is underpinned by its core values to maintain a sustainable, ethical and responsible Company. Fundamental to this are our people and our approach to social, environmental and political issues which could affect our ability to deliver our novel products and improve patient care and clinical outcomes.

CORPORATE

Tissue Regenix recognises that it holds a corporate responsibility to its employees, customers, partners, suppliers and shareholders. To this end, the Group ensures to set and maintain the highest working, ethical and management standards.

The Group employs a strict corporate governance code and relies on its experienced management team to ensure that all regulatory requirements across all business functions are met.

ETHICAL

Operating in an industry based upon the processing of human and animal derived tissues demands the highest ethical standards. The Group aspires to maintain the highest ethical standards across all business functions and relations. The Group undertakes regular audit checks to ensure that partners, suppliers and employees comply with the ethical standards and operate to meet our expectations. Furthermore, the nature of the industry means that as a business we are held to the highest standards and regularly receive inspections and audits from external organisations including the FDA and American Association of Tissue Banks.

EMPLOYEES

Regenerative medicine is a skilled and technical industry. We must ensure to retain a workforce with the necessary skills and knowledge, and balance of academic and commercial experience to maintain a competitive position among our peers.

Our people are our biggest asset and will ultimately drive the success of our business. We therefore look to maintain an equal, open and supportive work environment within which they can excel to their fullest potential.

SUPPORTING DEVELOPMENT

We encourage our employees to continue their professional and personal development through both further academic qualifications and practical training. Each employee is expected to identify further development opportunities, both to stay compliant with industry standards but also to develop and deepen their own understanding and further future opportunities.

With strong higher education links we often undertake student placements to develop their experience and practical understanding of the business.

HEALTH AND SAFETY

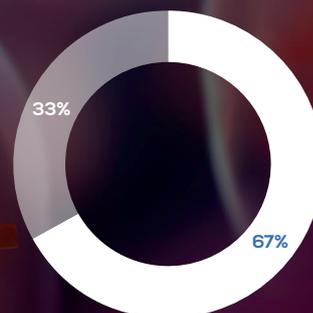
Working in a highly regulated and on occasion hazardous environment, we take our Health and Safety management very seriously and the Board supports a strong infrastructure to identify, control and manage risks through a series of proactive policies and procedures. With an appointed Health and Safety officer and committee, we ensure to undertake proactive actions to identify any potential hazards and monitor any outstanding actions resulting from non-compliance or near miss incidents identified. There are monthly meetings which all employees are invited to attend and a written report provided to the Board. We see the development and maintenance of a robust health and safety culture as a necessary responsibility to protect our employees, customers, suppliers and all external stakeholders.

EQUAL OPPORTUNITIES

We see ourselves as an equal opportunities employer and do not discriminate on the basis of age, gender, ethnicity, religion, disability, sexual orientation or marital status. All employees are expected to conduct themselves in an appropriate manner adhering to our discrimination policy.

In all aspects of the business we look to conduct ourselves in ways which are compliant with laws and regulations, providing our employees with a work environment which is professional, ethical and fair.

Gender diversity



■ Female ■ Male

REWARDING AND RETAINING TALENT

All employees are offered a comprehensive benefits package encompassing both lifestyle and financial rewards. Every employee is offered the opportunity to participate in the Company health insurance scheme for both themselves and members of their family. There is also an active pension scheme and life insurance policy and to ensure a supportive family environment, flexible working where possible to accommodate childcare needs, a comprehensive parental leave policy and the option to receive childcare vouchers.

We encourage participation in the Company's success and invite employees to undertake the SAYE share option scheme opened every year. This allows the employees to invest and benefit from the future success of the Company.



GLOBAL VISION AND CULTURE PROGRAMME, "VERTO"

With the increasing importance and focus on employee engagement and happiness at work, in June 2018 we commenced an employee engagement initiative: "Verto".

The initial objective was to ensure that there was consistency and clarity across the Company following the acquisition of CellRight Technologies in 2017 and embrace the different cultures that a global organisation has.

Verto allowed us a platform from which to engage and inspire our employees. We conducted interviews with every employee across the Group to identify their main concerns and action points to address. This resulted in the creation of six workstreams led by members of the Global Leadership Team with participants split across each business location, division and level.

These workstreams address: Branding and External Perception; Communications and Engagement; Leadership; Vision, Mission and Strategy; Values and Behaviours and People and Development.

The workstreams ensure that all employees have an infrastructure that they can utilise to access all relevant information, contact peers and ensure alignment and input into the new vision, mission and strategy.

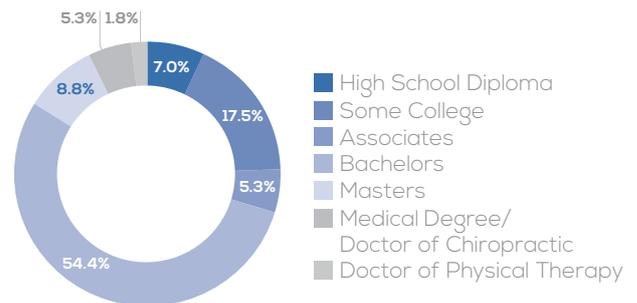
To date, we have received superb engagement from our employees across the Group and fully intend to maintain this programme, with ongoing plans for further initiative implementation.

OUR VISION

To establish TRG as a leader in the science and innovation of regenerative medicine. Transforming patient care and delivering favourable health economic outcomes.

QUALIFICATIONS

Our people are well trained and qualified, thereby enabling the Group to achieve strategic success. We actively encourage further education and ensure that our workforce is continuously trained and developed. Across the business over 54% of employees hold a bachelor's degree, with a further 16% holding a master's or doctorate, highlighting the calibre of our people. We believe that we have created a supportive and educational working environment.



IMPROVED PATIENT CARE AND HEALTH ECONOMICS

Tissue Regenix regenerative platforms and products can enable the bettering of patient care, allowing a return to their required standard of living, transforming their lives.

On top of this, it allows for economic advantages in the cost of care by reducing hospital stays and time for healing and rehabilitation, recurring operations and in some cases a reduction in pain.

OUR VALUES AND BEHAVIOURS

Our values and behaviours align with our Company vision and mission, driving a culture that will enable the Group to achieve the strategic objectives and vision.



Dedication to Patients



Driving for Excellence



Passion for Innovation



Uncompromising Integrity

The Strategic Report on pages 8 to 29 was approved by the Board on 3 June 2019.

Steve Couldwell

CEO, Tissue Regenix Group

Profile of the current Directors

KEY

Committees

-  Audit Committee
-  Chair of Audit Committee

-  Remuneration Committee
-  Chair of Remuneration Committee

Skills

-  Industry
-  Accounting
-  Commercial
-  Clinical



Joined the Group: March 2008

JOHN SAMUEL Non - Executive Chairman

Skills:    **External Appointments:** Chairman, Vernacare Group Ltd

Bio:

John Samuel joined Tissue Regenix in March 2008. John qualified as a Chartered Accountant with Price Waterhouse and has held a number of senior finance positions in industry, including as Financial Director of Whesoe plc and Ellis & Everard plc. 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. John is also Chairman of Vernacare Group Ltd, and previously Xeros Technology, stepping down in H1 2019.



Joined the Group: June 2013

STEVE COULDWELL Chief Executive Officer

Skills:   **External Appointments:** Non-Executive Director of Zilico Ltd

Bio:

Steve has over 25 years' experience in the pharmaceutical and medical device industry. He was formerly Chief Operating Officer and Head of Global Biosurgery division at Sanofi, which has revenues of approximately \$750m. With a proven international track record in driving revenues and profit growth in the pharmaceutical, medical device and CRO industries, Steve was formerly Vice President and General Manager of Covance Laboratories Europe and worked for Smith & Nephew for almost 20 years in a number of roles including President Orthopaedics (Europe) and Senior VP Sales and Marketing for Smith & Nephew's Advanced Wound Management business.



Joined the Group: October 2018

GARETH JONES Chief Financial Officer

Skills:   **External Appointments:** N/A

Bio:

Gareth has 27 years' experience in finance having qualified as a Chartered Accountant in 1993 with PwC. In recent years he has worked as Chief Financial Officer for LSE listed Applied Graphene Material. Prior to this he was at Emco Wheaton Division of private equity owned Gardner Denver Inc., the global provider of industrial equipment, technologies and services, where he joined as Finance Director in 2013. Prior to this he spent seven years as Finance Director of private equity backed start-up, Vireol Bio-Industries plc, which was seeking funding to design, construct and operate a bioethanol process facility. Between 1995 and 2006 Gareth was employed by Syltone plc. After its acquisition by Gardner Denver Inc. in 2004, Gareth became European Finance Director and then Divisional Finance Director of the Blower Division. In this capacity he was responsible for the day-to-day financial operations of the Group's largest division, operating across four continents, with revenues of circa. \$480m. He graduated from the University of Nottingham in 1989 with a BEng.



JONATHAN GLENN
Non-Executive Director

Skills: IN AC **Committees:** **External Appointments:** CEO Consort Medical plc

Bio:

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. Jonathan is a member of the Institute of Chartered Accountants in England and Wales.

Joined the Group: January 2016



SHERVANTHI HOMER-VANNIASINKAM
Non-Executive Director

Skills: CL **External Appointments:** N/A

Bio:

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

Joined the Group: June 2016



ALAN MILLER
Non-Executive Director

Skills: AC **Committees:** **External Appointments:** N/A

Bio:

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

Joined the Group: March 2008



RANDEEP SINGH GREWAL
Non-Executive Director

Skills: IN AC **Committees:** **External Appointments:** NED at BB Healthcare

Bio:

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

Joined the Group: June 2013

Corporate governance



The Company deploys several levels of Corporate Governance Management in order to minimise risk and ensure compliance and strategic alignment throughout all members of the Group and its subsidiary companies.

INTRODUCTION

The Board of Tissue Regenix Group plc recognises the importance of strong corporate governance and business ethics. During 2018 the Company adopted the latest Quoted Company Alliance Corporate Governance Code, which came into effect in September 2018. More details of how we have implemented the code are available on the Company website www.tissueregenix.com

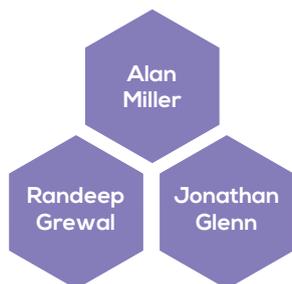
CULTURE AND BUSINESS ETHICS

As a company that operates in a highly regulated and sensitive environment, we ensure that we operate with a vigorous code of conduct and ethics. We also monitor any existing and potential partners to ensure that they align with our Company values. We look to always operate with the highest standards and integrity in any activity we undertake as a business and expect our employees to embrace this culture and values of the Company. We believe that we can only truly be successful if we are engaged with each individual employee.

The Board of Directors and Committees

The Board is ultimately responsible for business strategy and the financial robustness of the Group, monitoring the internal control system, reviewing accounting information, potential business risks, employee policies and market communications. The Board also operates two subcommittees, the Audit and Remuneration Committees, to ensure compliance with market regulations.

Audit Committee:



Remuneration Committee:



Legal and Regulatory

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

Risk and Performance Management

As a company we are aware of, and continually monitor, the primary risks to our business, and any external developments that occur that could have a detrimental effect on the performance of the Company. The Board maintains the responsibility for identifying the main business risks faced by the Group and the necessary mitigating actions to be taken to manage these proactively. Internally, we report our monthly performance against a number of objectives and cost of goods allowing us to track performance management and identify any potential improvements to our structure and operational efficiencies. These risks are categorised into seven types being; Operational; Clinical and Regulatory; Commercial; Product Development; Finance & IT; HR; and Political and Economic landscape. More about the principal risks for the Company can be found on pages 25 to 27.

Communications

The Board recognises the importance of maintaining good communication with all stakeholders and Shareholders. We look to communicate in the timeliest manner possible through a variety of different mediums. The Board reviews all relevant information to ensure that the correct information is adequately explained to offer transparency and be a true reflection of the Company. Executive Directors and the Chairman are available to meet with institutional investors and analysts following the interim and annual results and at any other appropriate time during the year. The Interim and Annual Reports are sent to all shareholders, who are encouraged to attend the Company's Annual General Meeting. These reports can also be found on the Company website, along with any regulatory news releases, analyst notes, presentations and webcasts. Internal and cross-company communications are equally as valued, and we have a number of staff engagement initiatives in order to keep knowledge and alignment with the corporate positioning, values and progress high.

Our Communication Channels

Stakeholder	Why	How
Shareholders	<ul style="list-style-type: none"> Financial position and results Corporate strategy and milestones Corporate Governance 	<ul style="list-style-type: none"> Investor relations activities Annual Report & Accounts Analyst notes Webcasts, presentations and interviews
Employees	<ul style="list-style-type: none"> Inclusion Development Health and Safety and HR 	<ul style="list-style-type: none"> Email updates Town halls Team training Employee surveys
Customers	<ul style="list-style-type: none"> Customer retention Customer identification Understanding their needs Product education 	<ul style="list-style-type: none"> One-to-one meetings Practical training sessions Conference attendance Technical literature
Suppliers	<ul style="list-style-type: none"> Supply chain management 	<ul style="list-style-type: none"> Regular business planning meetings Supplier audits Expected Code of Conduct

Corporate Governance

The Directors recognise the importance of sound corporate governance and in September 2018 applied the Quoted Company Alliance Corporate Governance Code for small-mid size quoted Companies.

The Board

The Board of Directors currently comprises two Executive Directors, a Non-Executive Chairman, and four Non-Executive Directors (NEDs). The Board considers that its size and composition, balance of skills and experience is currently in line with the requirements of the business. There is a clear division of responsibilities between the Chairman and the CEO. The Chairman is primarily responsible for leading the Board and makes himself available to meet with shareholders. The CEO is responsible for the execution of the Group's agreed strategy and the day-to-day running of the Company. Training is made available to each of the NEDs to ensure that they are completely aware of their regulatory responsibilities and requirements. The Board aims to meet a minimum of ten times a year and Directors are encouraged to attend all meetings with allowances being made for the attendance via Skype if physical attendance is not possible.

Corporate governance

continued

THE ROLES OF THE BOARD

John Samuel - Chairman

- Provides a sounding board for the CEO on key business decisions
- Ensure effective communications with shareholders and stakeholders
- Facilitates discussions of the Board and ensures contributions from all Executive and Non-Executive Directors are considered
- Ensures the effectiveness of the Board in all decision-making

Steve Couldwell – CEO

- Develops and implements the Group's strategy with input for the rest of the Board, management team and its advisors
- Responsible for the overall operational activity of the Group
- Manages the day-to-day business of the Group and leads the strategic direction
- Promotes the Company Vision, Mission, Values and Culture throughout the Group

Gareth Jones – CFO and Company Secretary

- Responsible to the Board and for ensuring its compliance with procedures and regulations
- Responsible for advising the Board on all governance matters
- Responsible under the Chairman for ensuring that the Board receives timely and accurate information.

Non-Executive Directors

- Constructively challenge the Executive Directors on matters affecting the Group
- Bring complementary skills and experience to the Board
- Help develop strategy and bring an independent outlook
- Chair the Audit Committee (Alan Miller)
- Chair the Remuneration Committee (Randeep Grewal)

Leadership & Effectiveness

The Board has extensive operational, commercial and industry experience, augmented by clinical specialists. As a team the Board also benefits from significant financial, public company and transactional experience.

Board meetings are encouraged to be open for discussion and constructive allowing all members to express their views and overall it is determined that the Board operates in an effective manner where all members are considered to have made a valuable contribution to the leadership of the Company.

Furthermore, the Board recognizes its regulatory responsibilities and requirements and it is felt that the appropriate processes are in place for setting the strategic direction of the Group, whilst maintaining the highest standards always.

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.

The Audit Committee recommends to the Board the appointment and re-appointment of external auditors. During the year the Audit committee undertook an audit tender process which resulted in RSM UK Audit LLP replacing KPMG LLP as the Group's auditors.

The Audit committee considers the scope and results of the external audit and its cost effectiveness. It also reviews the fees, independence and objectivity of the external auditors by discussing with the auditors their annual assessment regarding their independence, policies and procedures and analysing the fees for audit and non-audit work.

The Group's external auditors have unrestricted access to the Audit Committee and attend the Audit Committee meetings throughout the year. The Executive Directors attend Audit Committee meetings by invitation only.

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

Remuneration Committee

The Remuneration Committee report is set out on pages 36 to 39.

Internal Control

The Board is responsible for maintaining a sound system of internal control. The Board's measures are designed to manage rather than 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 in the "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 which meets at least ten times per year;
- The Company has operational, accounting and employment policies in place;
- 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;
- There is a clearly defined organisational structure; and
- There are well-established financial reporting and control systems.

Going Concern

As at 31 December 2018, the Group had £7,816k of cash and cash equivalents available to it and on 3 June 2019 the group entered into a new debt facility providing total funds of \$20m of which \$10.5m is available immediately, \$5m is available from 2020 subject to further equity funding, and \$2.5m is available from 2021 on achievement of sales targets, with a further \$2m available to draw down at any time. The new debt facility comprises a term loan of \$15m, repayable over four years from 2020 to 2024 and a revolving credit facility of \$5m.

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 through to 31 December 2020 as well as the main risk factors facing the Group as set out on pages 26–27. The Directors have also considered the mitigating actions that could be taken in the event that the conditional elements of the new debt facility do not become available.

After due enquiry and consideration, and taking account of the currently available elements of the new debt facility, the Directors consider that the Group has adequate financial resource to continue in operational existence for at least 12 months from the date of approval of these financial statements. Accordingly, they have adopted the going concern basis in preparing the financial statements.

Directors' remuneration report

Remuneration Policy

The Group's remuneration policy is to provide Executive Directors with a competitive market-based package in order to reward individual and Group performance and deliver outstanding shareholder returns.

The Remuneration Committee is committed to ensuring that the Company's key executive team is incentivized to drive sustainable earnings growth and returns to shareholders, thereby creating a genuinely strong alignment of interests between management and investors.

It is the Company's policy that Executive Directors should have contracts with an indefinite term providing for a maximum of six months' notice. In the event of early termination, the Executive 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 Randeep Grewal as Chair of the Committee, Alan Miller and Jonathan Glenn. 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 taking into account several factors, including the current position and development of the Group, individual contribution and market salaries for comparable organisations.

Discretionary Annual Bonus

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

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

Additionally, participants will not be entitled to receive the Matching Award unless shares price growth performance targets have been achieved and those price targets sustained for 30 consecutive days.

Share Incentive Schemes

The Group operates a share option plan, under which certain Executive 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 1–3 years. If the options remain unexercised after a period of 10 years from the date of grant, the options expire. The Group has no legal or constructive obligation to repurchase or settle the options in cash.

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

Remuneration Policy for Non-Executive Directors

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

Directors' Remuneration

The remuneration of the main Board Directors of Tissue Regenix who served in the year to 31 December 2018 was:

	Salary & fees £000	Bonus £000	Benefits £000	Total up to December 2018 £000	Total up to December 2017 £000
John Samuel	111	–	–	111	110
Steven Couldwell	225	120	11	356	63
Gareth Jones (appointed 29 October 2018)	31	–	2	33	–
Randeep Grewal	35	–	–	35	28
Jonathan Glenn	30	–	–	30	30
Alan Miller	35	–	–	35	33
Shervanthi Homer-Vanniasinkam	30	–	–	30	30
Antony Odell (resigned 1 November 2017)	–	–	–	–	343
Paul Devlin (resigned 31 January 2018)	15	–	–	15	185
Total	512	120	13	645	822

* Included within this salary is £50,000 for exiting the business, and £85,000 in lieu of notice

Within the 2017 total the bonus was nil and the benefits were £29K split Antony Odell £20K, Paul Devlin £8K, Steven Couldwell £1K.

Directors' Shareholdings

Directors' interests in the shares of the Company, including family interests at 31 December 2018 were:

	31 December 2018 Number	31 December 2018 %	31 December 2017 Number	31 December 2017 %
John Samuel (note 2)	26,276,928	2.22%	26,276,928	2.22%
Alan Miller	22,886,988	1.97%	22,886,988	1.97%
Steven Couldwell	300,000	0.03%	300,000	0.03%
Jonathan Glenn	600,000	0.06%	600,000	0.06%
Shervanthi Homer-Vanniasinkam	250,000	0.02%	250,000	0.02%

Note 2. Includes shares held jointly by the Director and EBT as set out overleaf.

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 December 2018 were:

	At 1 January 2018	Exercised during year	Lapsed during year	Granted during year	At 31 December 2018	Exercise price
Approved EMI scheme options						
John Samuel (Note 1)	2,400,000	–	–	–	2,400,000	5.00 pence
John Samuel (Note 2)	577,777	–	–	–	577,777	22.50 pence
Paul Devlin (Note 4)	2,272,727	–	2,272,727	–	–	11.00 pence
Unapproved scheme options						
John Samuel (Note 3)	88,890	–	–	–	88,890	22.50 pence
Steven Couldwell (Note 5)	–	–	–	10,000,000	10,000,000	0.08 pence
EBT scheme shares (Note 6)						
John Samuel	10,740,000	–	–	–	10,740,000	5.00 pence

Note 1. 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 December 2018 all the performance conditions had been met and the options were eligible for exercise.

Note 2. 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 December 2018 none of the performance conditions had been met and no options were eligible for exercise.

Note 3. There were employment period and performance conditions in relation to the 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 December 2018 none of the performance conditions had been met and no options were eligible for exercise.

Note 4. There were employment period and performance conditions in relation to the 2,272,727 options granted on 21 July 2017 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 30 pence per share by the respective three vesting dates. As at 31 December 2018 none of the performance conditions had been met and the options lapsed.

Note 5. There were employment period and performance conditions in relation to the 10,000,000 options granted on 02 January 2018 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 8 pence per share, 10 pence per share and 12 pence per share by the respective three vesting dates. As at 31 December 2018 none of the performance conditions had been met.

Note 6. The Tissue Regenix Group Employee Benefit Trust ("the EBT") was established with Osiris Management Services Limited appointed as trustee ("the Trustee") to enable the Trust to acquire ordinary shares in the Company and to make interests in those shares available for the benefit of current and future employees of the Company and its subsidiaries. Antony Odell and John Samuel have interests in ordinary shares in the Company which were acquired jointly with the Trustee in the market on 29 June 2010 at a price of 5 pence per share. Ian Jefferson has an interest in ordinary shares in the Company which were acquired jointly with the Trustee in the market on 25 July 2012 at a price of 14.25 pence. The shares were all acquired pursuant to certain conditions set out in Joint Owned Equity agreements ("JOEs"). Subject to meeting the performance criteria conditions set out in the JOEs, most of any future increase in the value of the shares will accrue to the employees provided that they have not ceased employment with the Group on or before the date that these conditions are met. The employees are also under certain circumstances able to benefit from an increase in the value of the shares on a takeover, change of control, scheme of arrangement or a voluntary winding-up of the Company. Where the performance conditions are not met, the Trustee has an option to acquire the interests of the employees in the shares at a price equal to the original purchase cost they paid so that none of any increase in the value of the shares will accrue to them. The market price of the shares at 31 December 2018 was 6.50 pence per share, the highest and lowest prices during the year were 11.50 pence and 6.50 pence respectively. Further details of all share options and jointly owned shares held by the Trustee are set out in note 19 to the financial statements.

On behalf of the Board

Randeep Grewal

Chairman of the Remuneration Committee

4 June 2019

Directors' report

The Directors present their report and consolidated financial statements for the Tissue Regenix Group plc, and its subsidiary undertakings for the year ended 31 December 2018.

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 and is listed on the London Stock Exchange Alternative Invest Market. The subsidiary undertakings principally affecting the Group are listed in note C5 of the Company's financial statements.

Business Model

A description of the Company's business model is included on pages 10 to 11. Explanations of activities and how it seeks to add value are included in the Chairman's Statement on page 02 and Chief Executive's Q&A and Operational Review report on pages 06 to 07 and 18 to 24.

Business Review and Results

A review of the Group's performance and future prospects is included in the Chairman's Statement on page 02 and Chief Executive's Q&A and Operational Report on pages 06 to 07 and 18 to 24, as well as the future milestones and KPIs set out on pages 14 to 16. The loss for the 12 months attributable to equity holders of the parent was (£8,186K) (2017: £9,221). The Directors do not recommend the payment of a dividend (2017: nil).

Share Capital and Funding

Full details of the Group and Company's share capital movements during the year are given in note 17 to the financial statements.

Directors and Their Interests

The following Directors held office in the year:

John Samuel
Steve Couldwell
Gareth Jones (appointed 29 October 2019)
Jonathan Glenn
Shervanthi Homer-Vanniasinkam
Alan Miller
Randeep Singh Grewal

Directors' interests in the shares of the Company, including family interests, are included in the Remuneration Report on pages 36 to 38.

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.

Corporate Governance

The Corporate Governance report is set out on pages 32 to 35.

Directors' report continued

Substantial Shareholders

As at 31 December 2018, shareholders holding more than 3% of the share capital of Tissue Regenix Group plc were:

Name of shareholder	Number of shares	% of voting rights
Invesco Limited	336,709,939	28.98
Woodford Investment Management Ltd	307,163,872	26.23
IP Group	160,837,567	13.74
Baillie Gifford & Co Ltd	70,764,595	6.04
Jupiter Asset Management	69,740,965	5.96
Director and Related Holdings(s)	50,313,916*	4.33

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

Employment Policies

The Group is committed to keeping employees as fully informed as possible regarding the Group's performance and prospects and seeks their views, wherever possible, on matters which affect them as employees. More information can be found in our Sustainability report on pages 28 to 29.

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 has confirmed that they have taken all the steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that it has been communicated to the Auditor.

Financial Instruments

Further details of financial risk management objectives and policies are set out on pages 25 to 27 and in note 14 of the financial statements.

Auditor

On 14 November 2018 KMPG resigned as Auditor and subsequently RSM UK Audit LLP (RSM) were appointed. RSM have indicated willingness to continue in office, in accordance with the recommendation of the Audit Committee and section 489 of the Companies Act 2006. A resolution to reappoint RSM as the Company's Auditor will be proposed at the forthcoming Annual General Meeting.

Strategic Report

The Group has chosen in accordance with Companies Act 2006 s414C (11) to set out in the Group's strategic report information required by Large and Medium -sized Companies and Groups (Accounts and Reports) Regulations 2008, Sch 7 to be contained in the directors' report in relation to research and development and future developments.

The Directors Report was approved by the Board on 3 June 2019.

On behalf of the Board

Steve Couldwell

Chief Executive Officer

Statement of directors' responsibilities

In respect of the Annual Report and the financial statements

The directors are responsible for preparing the Strategic Report and the Directors' Report, and the financial statements in accordance with applicable law and regulations.

Company law requires the directors to prepare group and company financial statements for each financial year. They are required by the AIM Rules of the London Stock Exchange to prepare group financial statements in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union ("EU") and have elected under Company law to prepare the company financial statements in accordance with IFRS as adopted by the EU.

The group financial statements are required by law and IFRS adopted by the EU to present fairly the financial position and performance of the group; the Companies Act 2006 provides in relation to such financial statements that references in the relevant part of that Act to financial statements giving a true and fair view are references to their achieving a fair presentation.

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 company and of the profit or loss of the group for that period.

In preparing each of the group and company financial statements, the directors are required to:

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

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the group's and the company's transactions and disclose with reasonable accuracy at any time the financial position of the group and the company and enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the group and the company and hence for taking reasonable steps for the prevention and detection of 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.

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

OPINION

We have audited the financial statements of Tissue Regenix Group Plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2018 which comprise the consolidated statement of comprehensive income, the consolidated and parent company statements of changes in equity, the consolidated and parent company statements of financial position, the consolidated and parent company statements of cash flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union and, as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2018 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

BASIS FOR OPINION

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to SME listed entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

CONCLUSIONS RELATING TO GOING CONCERN

We have nothing to report in respect of the following matters in relation to which the ISAs (UK) require us to report to you where:

- the directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the group's or the parent company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

KEY AUDIT MATTERS

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the group and parent company financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on the overall audit strategy, the allocation of resources in the audit and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the group and parent company financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters

Group key audit matters

Impairment testing on CellRight Technologies LLC ("CellRight") cash generating unit

As disclosed in note 11, the CellRight cash generating unit (CGU) includes goodwill of £15.3m. CellRight was acquired in 2017 and the presence of goodwill requires an impairment test to be performed at least annually. Any recorded impairment charge would most likely have a material impact on the financial statements and we therefore considered this matter to be one of the matters of most significance in the current year audit.

Impairment testing requires management to compare the carrying amount of the CGU's attributable assets and liabilities with the higher of fair value less costs of disposal and value in use ("recoverable amount"). Where the carrying amount is higher than recoverable amount then an impairment charge arises. Impairment testing involves a significant degree of judgement because management's determination of value in use is based on a number of assumptions including an assessment of future performance and the selection of an appropriate discount rate.

Management provided us with an impairment model for the CellRight CGU as detailed in note 11 that showed no impairment provision was necessary. We performed audit work on this model by:

- Assessing the appropriateness and application of the model used including consideration of the assumptions made about the discount rate and the expected future trading performance,
- Reviewing historic performance and accuracy of forecasting and considering sensitivities reflecting changes in growth rates and the discount rate.

We discussed the forecasts, discount rate and sensitivity analysis with management and challenged key assumptions, requesting evidence where available to support management's conclusions.

Parent company key audit matters

Recoverability of intragroup receivables

The parent company has receivable balances from subsidiary undertakings that are currently loss making. These balances are interest free and repayable on demand and at the balance sheet date the subsidiary undertakings do not have sufficient liquid assets to make repayment should the parent company call in the loans. One of the most significant matters in the current year audit of the parent company is therefore that these receivable balances may be impaired and an Expected Credit Loss ("ECL") provision required following the introduction of IFRS9 Financial Instruments. At the 31 December 2018, the carrying value of amounts due from group undertakings amounted to £64.4m after recording an ECL provision of £1.3m (see note C7).

We obtained management's calculation of expected credit losses and the underlying calculations prepared to support the carrying value of these receivable balances. In addition, we reviewed and challenged the assumptions utilised in the model, consulted with a valuation specialist and considered the adequacy of the disclosures set out in notes C2 and C7 regarding the key judgements made by management in their ECL provision calculation.

Potential impairment of investment in subsidiary undertakings

The parent company has a significant investment in its subsidiary undertaking (Tissue Regenix Limited) and that entity and the other indirectly held subsidiary undertakings of the group are currently loss making. One of the most significant matters in the current year audit of the parent company is therefore that this investment balance may be impaired and require an impairment provision. As disclosed in note C5, the carrying value of this investment at 31 December 2018 was £18.6m.

We discussed with management whether the carrying value of the investment was supportable taking into account the strategic plans established by the board in respect of the group and we obtained management's assessment of recoverable amount. We challenged management to consider both fair value less costs of disposal and value in use using forecasts consistent with those adopted for management's going concern assessment. We consulted with a valuation specialist regarding management's assessment of fair value less costs of disposal with reference to share price performance and assessed the reasonableness of disclosures set out in note C2.

OUR APPLICATION OF MATERIALITY

When establishing our overall audit strategy, we set certain thresholds which help us to determine the nature, timing and extent of our audit procedures. When evaluating whether the effects of misstatements, both individually and on the financial statements as a whole, could reasonably influence the economic decisions of the users we take into account the qualitative nature and the size of the misstatements. During planning materiality for the group financial statements as a whole was calculated as £271,000, which was not significantly changed during the course of our audit. Materiality for the parent company financial statements as a whole was calculated as £215,000, which was not significantly changed during the course of our audit. We agreed with the Audit Committee that we would report to them all unadjusted differences in excess of £5,000, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds.

AN OVERVIEW OF THE SCOPE OF OUR AUDIT

Our group audit scope included the full scope audit of all components requiring a statutory audit and any other financially significant components being those with revenue, profit before tax or net assets individually in excess of 20% of the relevant group metric. These were performed at a materiality level determined by reference to the scale of the business concerned. Our full scope audit work covered 100% of group revenue, 100% of group loss before taxation, and 100% of group net assets.

Independent auditor's report continued

To the members of Tissue Regenix Group PLC

OTHER INFORMATION

The directors are responsible for the other information. The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

OPINIONS ON OTHER MATTERS PRESCRIBED BY THE COMPANIES ACT 2006

In our opinion, based on the work undertaken in the course of the audit:

- 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; and
- the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements.

MATTERS ON WHICH WE ARE REQUIRED TO REPORT BY EXCEPTION

In the light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report or the Directors' Report.

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

- 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
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

RESPONSIBILITIES OF DIRECTORS

As explained more fully in the directors' responsibilities statement set out on page 41, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion.

Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: <http://www.frc.org.uk/auditorsresponsibilities>. This description forms part of our auditor's report.

USE OF OUR REPORT

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.

MICHAEL THORNTON

(SENIOR STATUTORY AUDITOR)

For and on behalf of RSM UK AUDIT LLP, Statutory Auditor
Chartered Accountants
Central Square
5th Floor
29 Wellington Street
Leeds
LS1 4DL
3 June 2019

Consolidated statement of comprehensive income

For the year ended 31 December 2018

	Notes	Year to 31 December 2018 £000	Year to 31 December 2017 £000
REVENUE	3	11,619	5,233
Cost of sales		(5,702)	(2,627)
GROSS PROFIT		5,917	2,606
Administrative expenses before exceptional items	3	(14,183)	(12,324)
Exceptional items	4	(423)	(1,098)
Total administrative expenses		(14,606)	(13,422)
OPERATING LOSS	4	(8,689)	(10,816)
Finance income	6	72	47
Finance charges	7	(262)	–
LOSS BEFORE TAXATION		(8,879)	(10,769)
Tax	8	620	1,348
LOSS FOR YEAR		(8,259)	(9,421)
ATTRIBUTABLE TO:			
Equity holders of the parent	9	(8,186)	(9,221)
Non-controlling interests		(73)	(200)
		(8,259)	(9,421)
OTHER COMPREHENSIVE INCOME:			
Foreign currency translation differences – foreign operations		1,360	(614)
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR		(6,899)	(10,035)
ATTRIBUTABLE TO:			
Equity holders of the parent		(6,826)	(9,835)
Non-controlling interests		(73)	(200)
		(6,899)	(10,035)
LOSS PER SHARE			
Basic and diluted loss attributable to equity holders of parent	9	(0.70)p	(1.00)p

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

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

Consolidated statement of financial position

At 31 December 2018

	Notes	31 December 2018 £000	31 December 2017 £000
ASSETS			
Non-current assets			
Property, plant and equipment	10	2,828	2,994
Intangible assets	11	19,938	19,305
TOTAL NON-CURRENT ASSETS		22,766	22,299
Current assets			
Inventory	12	2,330	2,872
Trade and other receivables	13	3,551	2,503
Corporation tax receivable	13	1,200	1,665
Cash and cash equivalents	14	7,816	16,423
TOTAL CURRENT ASSETS		14,897	23,463
TOTAL ASSETS		37,663	45,762
LIABILITIES			
Non-current liabilities			
Other payables	15	–	(635)
Deferred Tax	16	(791)	(824)
TOTAL NON-CURRENT LIABILITIES		(791)	(1,459)
Current liabilities			
Trade and other payables	15	(4,302)	(4,781)
TOTAL CURRENT LIABILITIES		(4,302)	(4,781)
TOTAL LIABILITIES		(5,093)	(6,240)
NET ASSETS		32,570	39,522
EQUITY			
Share capital	17	5,859	5,855
Share premium	17	86,398	86,398
Merger reserve	17	10,884	10,884
Reverse acquisition reserve	17	(7,148)	(7,148)
Reserve for own shares		(831)	(831)
Share based payment reserve	19	1,129	1,186
Retained earnings deficit		(63,239)	(56,413)
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF PARENT		33,052	39,931
Non-controlling interests	20	(482)	(409)
TOTAL EQUITY		32,570	39,522

Approved by the Board of Directors and authorised for issue on 3 June 2019.

Steven Couldwell

Chief Executive Officer

Company number: 5969271

Consolidated statement of changes in equity

For the year ended 31 December 2018

	Attributable to equity holders of parent									
	Share capital £000	Share premium £000	Merger reserve £000	Reverse acquisition reserve £000	Reserve for own shares £000	Share based payment reserve £000	Retained earnings deficit £000	Total £000	Non-controlling interests £000	Total equity £000
At 31 December 2016	3,801	50,461	10,884	(7,148)	(831)	1,156	(46,578)	11,745	(209)	11,536
Loss for the period	-	-	-	-	-	-	(9,221)	(9,221)	(200)	(9,421)
Other comprehensive expense	-	-	-	-	-	-	(614)	(614)	-	(614)
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(9,835)	(9,835)	(200)	(10,035)
Issue of shares	2,000	38,000	-	-	-	-	-	40,000	-	40,000
Cost of issue of new equity	-	(2,318)	-	-	-	-	-	(2,318)	-	(2,318)
Exercise of share options	54	255	-	-	-	-	-	309	-	309
Share based payment expense	-	-	-	-	-	30	-	30	-	30
At 31 December 2017	5,855	86,398	10,884	(7,148)	(831)	1,186	(56,413)	39,931	(409)	39,522
Loss for the period	-	-	-	-	-	-	(8,186)	(8,186)	(73)	(8,259)
Other comprehensive expense	-	-	-	-	-	-	1,360	1,360	-	1,360
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(6,826)	(6,826)	(73)	(6,899)
Exercise of share options	4	-	-	-	-	-	-	4	-	4
Share based payment credit	-	-	-	-	-	(57)	-	(57)	-	(57)
At 31 December 2018	5,859	86,398	10,884	(7,148)	(831)	1,129	(63,239)	33,052	(482)	32,570

Consolidated statement of cash flows

For the year ended 31 December 2018

	Notes	Year to 31 December 2018 £000	Year to 31 December 2017 £000
OPERATING ACTIVITIES			
Loss before taxation		(8,879)	(10,769)
Adjustment for:			
Depreciation of property, plant and equipment	10	598	482
Amortisation of intangible assets	11	575	225
Share based payments	19	(57)	30
Interest receivable	6	(72)	(47)
Interest payable	7	262	–
Operating cash outflow before working capital movements		(7,573)	(10,079)
Decrease/(Increase) in inventory	12	542	(503)
(Increase) in trade and other receivables		(1,188)	(783)
(Decrease)/Increase in trade and other payables		156	38
Cash outflows from operations		(8,063)	(11,327)
Research & Development tax credit received		1,225	1,541
Net cash outflow from operations		(6,838)	(9,786)
INVESTING ACTIVITIES			
Interest received	6	72	47
Purchases of property, plant and equipment	10	(290)	(130)
Capitalised development expenditure	11	(116)	(93)
Acquisition of subsidiary (including contingent consideration)		(1,564)	(19,945)
Net cash (outflow) from investing activities		(1,898)	(20,121)
FINANCING ACTIVITIES			
Proceeds from issue of share capital	17	–	37,682
Proceeds from exercised share options		4	309
Net cash inflow from financing activities		4	37,991
(Decrease)/Increase in cash and cash equivalents		(8,732)	8,084
Foreign exchange translation movement		125	166
Cash and cash equivalents at start of period		16,423	8,173
CASH AND CASH EQUIVALENTS AT END OF PERIOD		7,816	16,423

Notes to the financial statements

For the year ended 31 December 2018

1) BASIS OF PREPARATION

The financial statements of Tissue Regenix Group plc are audited consolidated financial statements for the year ended 31 December 2018. These include audited comparatives for the year ended 31 December 2017.

The Company is incorporated and domiciled in the United Kingdom and its registered number is 5969271. The address of the registered office is Unit 1 and 2 Astley Way, Astley Industrial Estate, Swillington LS26 8XT. The Company was incorporated on 17 October 2006. The principle activity of Tissue Regenix Group is develop, manufacture and commercialise biological medical devices.

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

Going Concern

As at 31 December 2018, the Group had £7,816k of cash and cash equivalents available to it and on 3 June 2019 the group entered into a new debt facility providing total funds of \$20m of which \$10.5m is available immediately, \$5m is available from 2020 subject to further equity funding, and \$2.5m is available from 2021 on achievement of sales targets, with a further \$2m available to draw down at any time. The new debt facility comprises a term loan of \$15m, repayable over four years from 2020 to 2024 and a revolving credit facility of \$5m.

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 through to 31 December 2020 as well as the main risk factors facing the Group as set out on pages 26–27. The Directors have also considered the mitigating actions that could be taken in the event that the conditional elements of the new debt facility do not become available.

After due enquiry and consideration, and taking account of the currently available elements of the new debt facility, the Directors consider that the Group has adequate financial resource to continue in operational existence for at least 12 months from the date of approval of these financial statements. Accordingly, they have adopted 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.

Basis of Consolidation

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. 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.

Controlled Joint Venture

Tissue Regenix Group entered a joint venture in January 2016 establishing GBM-V GmbH a company in Germany.

The results for this entity are consolidated within these accounts because the Group controls the majority of the voting rights.

Transactions eliminated on consolidation

Intra-group balances and transactions, and any unrealised income and expenses arising from intra-group transactions, are eliminated. Unrealised gains arising from transactions with equity-accounted investees are eliminated against the investment to the extent of the Group's interest in the investee. Unrealised losses are eliminated in the same way as unrealised gains, but only to the extent that there is no evidence of impairment.

Goodwill

Goodwill arising on the acquisition of a subsidiary undertaking is the difference between the fair value of the consideration payable and the fair value of the identifiable assets, liabilities and contingent liabilities acquired. Goodwill is tested annually for impairment as described below.

Revenue

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

Bill and hold sales

The Group has some bill-and-hold arrangements with customers, and this revenue is recognised when the company considers that performance obligations have been met and they meet the below requirements:

- The reason for the bill-and-hold arrangement must be substantive (for example, the arrangement might be requested by the customer) to facilitate their shipping arrangements;
- The product must be identified separately as belonging to the customer (that is, it cannot be used by the supplier to satisfy other orders);
- The product must currently be ready for physical transfer to the customer;
- The vendor cannot have the ability to use the product, or to direct it to another customer

Foreign Currencies

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

Exchange differences arising on transaction and monetary items in the financial statements of individual entities are recorded as a profit or loss within the income statement.

The assets and liabilities of foreign operations are translated into sterling 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 recorded in other comprehensive income and taken to the translation reserve in equity until the disposal of the investment.

Research and Development

Research costs are charged to profit and 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:

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

Exceptional Items

Items which are significant by virtue of their size or nature and/or which are considered non-recurring are classified as an exceptional operating item. Such items, which include for example costs relating to acquisitions, litigation charges etc, are included within the appropriate consolidated income statement category but are highlighted separately. Exceptional operating items are excluded from the profit measures used by the Directors to monitor underlying performance.

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.

Inventories

Inventories are recognised at the lower of cost and net realisable value. Cost is determined using the first in, first out method. Appropriate provisions for estimated irrecoverable amounts are recognised in the income statement when there is objective evidence that the assets are impaired.

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:

Buildings	over 39 years
Laboratory equipment	over 5–7 years
Computer equipment	over 3 years
Fixtures and fittings	over 5 years

Land is not depreciated.

Notes to the financial statements continued

For the year ended 31 December 2018

2) SIGNIFICANT ACCOUNTING POLICIES continued

Intangible Assets

Intangible assets are stated at fair value at acquisition. Subsequently held at cost and amortisation is provided on all intangibles over its expected useful life.

Trademarks	over 5 years
Customer relationships	over 10 years
Process & IT technology	over 10 years
Supplier agreements	over 5 years

Impairment of Property, Plant and Equipment and Intangible Assets

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 5-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.

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 straight-line 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.

IFRS 9 introduces a new impairment model. Under IAS 39, an entity only considers those impairments that arise as a result of incurred loss events. The effects of possible future loss events cannot be considered, even when they are expected.

IFRS 9 introduces a new expected credit loss ('ECL') model which broadens the information that an entity is required to consider when determining its expectations of impairment. Under this new model, expectations of future events must be taken into account and this will result in the earlier recognition of larger impairments.

Impairment provisions are recognised for the group as follows, representing the probability of default over the contracted life of these balances.

Not overdue	0% of aged receivables
0 to 3 months overdue	0% of aged receivables
3 to 4 months overdue	25% of aged receivables
4 to 5 months overdue	50% of aged receivables
Over 5 months overdue	100% of aged receivables

Trade and other payables

Trade and other payables are not interest bearing and are initially recognised at fair value except contingent consideration which is recognised initially and subsequently 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 6 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.

Taxation

Tax on the profit or loss for the year comprises current and deferred tax. Tax is recognised in the profit and loss account except to the extent that it relates to items recognised directly in equity or other comprehensive income, in which case it is recognised directly in equity or other comprehensive income.

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the balance sheet date, and any adjustment to tax payable in respect of previous years.

Deferred tax is provided on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. The following temporary differences are not provided for: the initial recognition of goodwill; the initial recognition of assets or liabilities that affect neither accounting nor taxable profit other than in a business combination, and differences relating to investments in subsidiaries to the extent that they will probably not reverse in the foreseeable future. The amount of deferred tax provided is based on the expected manner of realisation or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the balance sheet date.

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:

Estimates

Equity settled share based payments

The estimation of share based payment costs requires the selection of an appropriate valuation method, consideration as to the inputs necessary for the valuation model chosen and the estimation of the number of awards that will ultimately vest. Inputs subject to judgement relate to the future volatility of the share price of comparable companies, the Group's expected dividend yields, risk free interest rates and expected lives of the options. The Directors draw on a variety of sources to aid in the determination of the appropriate data to use in such calculations. The share based payment charge for the period was a credit of £57,000 (2017 charge: £30,000).

Judgements

Deferred tax

The actual tax on the Company's profits is determined according to complex laws and regulations. Where the effect of these laws and regulations is unclear, estimates are used in determining the liability for the tax to be paid on profits which are recognised in the financial statements. The Company considers the estimates, assumptions and judgements to be reasonable, but this can involve complex issues which may take a number of years to resolve. The final determination of tax liabilities could be different from the estimates reflected in the financial statements. Deferred tax assets and liabilities require management judgement in determining the amounts to be recognised. In particular, judgement is used when assessing the extent to which deferred tax assets should be recognised with consideration given to the timing and level of future taxable income. In the current year, given that the group is still loss making, the Directors judgement is not to recognise a deferred tax asset in respect of tax losses. Deferred tax not recognised for 2018 is £7,370k (2017: £6,089).

Capitalisation of development costs

The point at which development costs meet the criteria for capitalisation is a key judgement. During the year we capitalised development costs of £116,000 in respect of a product which we received US regulatory clearance to sell the product (510K approval). We deem this to be the point at which it becomes probable that future economic benefits will be received from the product and hence the criteria for capitalisation are met.

Impairment testing of non-current assets

The point of whether to impair non-current assets is a key judgment. During the year management reviewed all non-current assets and using current business forecasts decided that all non-current assets did not require impairment. See Note 11 for more detail.

Notes to the financial statements continued

For the year ended 31 December 2018

2) SIGNIFICANT ACCOUNTING POLICIES continued

Accounting Standards and Interpretations Not Applied

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

		Effective date
IFRS 16	Leases	1 January 2019
Amendments to IAS 28	Long-term Interests in Associates and Joint Ventures	1 January 2019
Annual Improvements to IFRS Standards 2015–2017 cycle	–	1 January 2019

New standards and amendments to standards adopted in the year

During the year, the Group adopted the following standards effective from the 1st January 2018. The Group has applied these standards in the preparation of the financial statements, and has not adopted any new or amended standards early.

IFRS 15 – Revenue from contracts with customers

IFRS 15 is effective for periods beginning on or after 1st January 2018. IFRS 15 introduces a five step approach to the timing of revenue recognition based on performance obligations in customer contracts. It replaces existing revenue recognition guidance, including IAS 18 Revenue, IAS 11 Construction Contracts and IFRIC 13 Customer loyalty Programmes.

On 1 January 2018, the Group adopted IFRS 15 Revenue from contracts with customers using the modified retrospective method for contracts which were not completed as of that date. The Group applied the practical expedients in relation to contracts with variable consideration and contracts that were completed at the beginning of the earliest period presented and/or modified before the beginning of the earliest period presented.

Under IFRS 15, revenue is recognised as the performance obligations to deliver products or services are satisfied and revenue is recorded based on the amount of consideration expected to be received in exchange for satisfying the performance obligations. The Group undertook a detailed impact assessment applying IFRS 15 to all the existing ways in which the Group delivers products or services to customers to identify divergence with previous accounting practice governed by IAS 18 Revenue and concluded that IFRS 15 does not have a significant impact on the timing and recognition of revenue. Accordingly, there was no adjustment required on transition to IFRS 15.

IFRS – 9 Financial instruments

IFRS 9 'Financial instruments' replaces IAS 39 'Financial instruments: Recognition and Measurement'. The standard is effective for accounting periods beginning on or after 1 January 2018. The standard covers three elements:

- Classification and measurement: Changes to a more principle based approach to classify financial assets as either held at amortised cost, fair value through other comprehensive income (FVOCI) or fair value through profit or loss, dependent on the business model and cash flow characteristics of the financial asset;
- Impairment: Moves to an impairment model based on expected credit losses based on a three-stage approach; and
- Hedge accounting: The IFRS 9 hedge accounting requirements are designed to allow hedge accounting to be more closely aligned with the Group's underlying risk management.

The Group does not hold complex financial instruments and therefore the majority of changes to the standard do not change the existing accounting for assets or liabilities held. All financial assets and liabilities will continue to be measured at amortised cost with the exception of contingent consideration which is held at fair value. The Group has applied the simplified method of the expected credit loss model when calculating impairment losses on its financial assets measured at amortised cost, such as trade receivables. This resulted in greater judgement due to the need to factor in forward looking information when estimating the appropriate amount of provisions.

In applying IFRS 9 the Group considered the probability of a default occurring over the contractual life of its trade receivables balances on initial recognition of those assets.

The Group has chosen not to restate comparatives on adoption of IFRS 9 given the immaterial nature of the transitional impacts and, therefore, these changes have been processed in the current year.

New standards to be adopted in future years

IFRS 16 Leases

IFRS 16 introduces a single lease accounting model. This standard requires lessees to account for all leases under a single on balance sheet model. Under the new standard, a lessee is required to recognise all lease assets and liabilities on the balance sheet; recognise amortisation of leased assets and interest on lease liabilities over the lease term; and separately present the principal amount of cash paid and interest in the cash flow statement. The requirements of IFRS 16 extend to certain service contracts, leased property and leased vehicles which may impact the Group. Accordingly, management has initiated an impact assessment in respect of IFRS 16 and while it is expected that on adoption the impact will be immaterial, further work is required before this can be quantified.

3) SEGMENTAL REPORTING

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

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
USA	9,434	4,098
Rest of world	2,185	1,135
	11,619	5,233

Analysis of revenue by customer

During the year ending 31 December 2018 the Group had no customers who individually exceeded 10% of revenue (2017:13% and 11%).

Operating segments

The Group is organised into BioSurgery, Orthopaedics & Dental, Cardiac and Other 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 Chief Executive Officer. These are the reportable operating segments in accordance with IFRS8 "Operating Segments". The Directors recognise that the operations of the Group are dynamic and therefore this position will be monitored as the Group develops.

In accordance with IFRS8, the Group has derived the information for its operating segments using the information used by the Chief Operating Decision Maker. The Group has identified the Chief Executive Officer as the Chief Operating Decision Maker as he 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 unit.

	BioSurgery		Orthopaedics & Dental		Cardiac		Other		Central		Total	
	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000										
Revenue	3,381	1,932	6,396	2,166	–	–	1,842	1,135	–	–	11,619	5,233
Cost of sales	(1,769)	(916)	(2,676)	(829)	–	–	(1,257)	(882)	–	–	(5,702)	(2,627)
Gross Profit	1,612	1,016	3,720	1,337	–	–	585	253	–	–	5,917	2,606
Administrative costs	(4,169)	(4,737)	(4,992)	(3,297)	(428)	(481)	(551)	(484)	(4,043)	(3,325)	(14,183)	(12,324)
Exceptional costs	–	–	–	–	–	–	–	–	(423)	(1,098)	(423)	(1,098)
Operating loss	(2,557)	(3,721)	(1,272)	(1,960)	(428)	(481)	34	(231)	(4,466)	(4,423)	(8,689)	(10,816)
Finance income/ (expense)	–	–	–	3	–	–	–	–	(190)	44	(190)	47
Loss before taxation	(2,557)	(3,721)	(1,272)	(1,957)	(428)	(481)	34	(231)	(4,656)	(4,379)	(8,879)	(10,769)
Taxation	73	372	543	722	102	254	–	–	(98)	–	620	1,348
Loss for the year	(2,484)	(3,349)	(729)	(1,235)	(326)	(227)	34	(231)	(4,754)	(4,379)	(8,259)	(9,421)

Revenue from all operating segments derives from the sale of biologic medical devices.

Notes to the financial statements continued

For the year ended 31 December 2018

3) SEGMENTAL REPORTING continued

Administrative costs are broken down as follows:

	BioSurgery		Orthopaedics & Dental		Cardiac		Other		Central		Total	
	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000	Year to 31 Dec 2018 £000	Year to 31 Dec 2017 £000
Staff costs	(2,936)	(3,343)	(2,639)	(1,837)	(222)	(281)	(297)	(181)	(1,365)	(1,135)	(7,459)	(6,777)
Sales and marketing costs	(901)	(64)	(125)	(17)	(25)	(4)	(20)	(21)	-	-	(1,071)	(106)
Research and development	(164)	(277)	(1,307)	(894)	(164)	(147)	-	(32)	-	-	(1,635)	(1,350)
Depreciation and amortisation	(20)	(25)	(279)	(97)	-	-	(7)	(25)	(867)	(560)	(1,173)	(707)
Establishment and administration costs	(148)	(1,028)	(642)	(452)	(17)	(49)	(227)	(225)	(1,811)	(1,630)	(2,845)	(3,384)
Administrative costs	(4,169)	(4,737)	(4,992)	(3,297)	(428)	(481)	(551)	(484)	(4,043)	(3,325)	(14,183)	(12,324)

Balance Sheet

	BioSurgery		Orthopaedics/ Dental		Cardiac		Other		Central		Total	
	2018 £000	2017 £000	2018 £000	2017 £000	2018 £000	2017 £000	2018 £000	2017 £000	2018 £000	2017 £000	2018 £000	2017 £000
Non-current assets												
Intangible Assets	759	643	4,649	4,373	-	-	-	-	14,530	14,289	19,938	19,305
Property, Plant & Equipment	20	2	2,153	2,290	-	-	101	69	264	503	2,538	2,864
Additions	6	38	204	-	-	-	54	40	26	52	290	130
Total non-current assets	785	683	7,006	6,663	-	-	155	109	14,820	14,844	22,766	22,299
Current assets												
Inventory	222	648	1,957	2,123	-	-	74	15	77	86	2,330	2,872
Trade & other receivables	939	780	2,856	2,138	200	221	121	348	635	681	4,751	4,168
Cash & cash equivalents	170	254	409	89	2	6	35	47	7,200	16,027	7,816	16,423
Total current assets	1,331	1,682	5,222	4,350	202	227	230	410	7,912	16,794	14,897	23,463
Total assets	2,116	2,365	12,228	11,013	202	227	385	519	22,732	31,638	37,663	45,762
Current liabilities												
Trade & other payables	(553)	(697)	(2,474)	(1,998)	(42)	(22)	(102)	(271)	(1,922)	(3,252)	(5,093)	(6,240)
Total liabilities	(553)	(697)	(2,474)	(1,998)	(42)	(22)	(102)	(271)	(1,922)	(3,252)	(5,093)	(6,240)
Net Assets	1,563	1,668	9,754	9,015	160	205	283	248	20,810	28,386	32,570	39,522

4) LOSS FROM OPERATIONS

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Loss from operations is stated after charging:		
Depreciation of plant and equipment (see note 10)	598	482
Amortisation	575	225
Operating lease rentals – land and buildings	85	85
Expensed inventory	4,723	2,039
Staff costs (see note 5)	7,459	6,777
Foreign exchange losses	55	264
Research and development (exclusive of research and development staff costs)	1,635	1,350
Sales and marketing costs (exclusive of sales and marketing staff costs and commissions)	1,071	105
Exceptional items:		
Costs of acquisition of subsidiary	–	996
Litigation costs	423	102
Auditor remuneration:		
– fees payable to Company's Auditor for the audit of the parent Company and consolidated financial statements	20	20
– auditing the accounts of subsidiaries pursuant to legislation	56	60
Other services:		
– fees in relation to corporation tax	24	32
– fees in relation to other services	–	161
Total auditors' remuneration	100	273

5) STAFF COSTS

	Year to 31 December 2018 Number	Year to 31 December 2017 Number
The average monthly number of persons (including Directors) employed by the Group during the period was:		
Directors	7	7
Laboratory and administration staff	79	72
	86	79
	£000	£000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	6,405	6,035
Share based expense (see note 19)	(57)	30
Social security, pension & healthcare costs	1,111	712
	7,459	6,777
Directors' remuneration included above comprised:		
Emoluments for qualifying services	645	822

Social security, pension and healthcare costs include pension contributions of £91k (2017: £95k)

Directors' emoluments disclosed above include £356,000 paid to the highest paid Director (2017: £343,000). The share based payments charge for Directors was £71,000 (2017: nil).

6) FINANCE INCOME

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Bank interest receivable	72	47

Notes to the financial statements continued

For the year ended 31 December 2018

7) FINANCE CHARGES

	31 December 2018 £000	31 December 2017 £000
Imputed interest on deferred consideration	(262)	–

8) TAXATION

Tax on loss on ordinary activities

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Current tax:		
UK corporation tax credit on losses of period	(790)	(1,348)
US corporation tax payable	72	–
	718	(1,348)
Deferred tax:		
Origination and reversal of temporary timing differences	98	–
Tax credit on loss on ordinary activities	(620)	(1,348)

Factors affecting the current tax charges

The tax assessed for the year varies from the main rate of corporation tax as explained below:

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
The tax assessed for the period varies from the small company rate of corporation tax as explained below:		
Loss on ordinary activities before tax	(8,879)	(10,769)
Tax at the standard rate of corporation tax 19% (2017: 19.25%)	(1,687)	(2,074)
Effects of:		
Research and development tax credits received	(583)	(799)
Surrender of research and development relief for repayable tax credit	792	1,098
Research and development enhancement	(448)	(621)
Prior period adjustment	(141)	(549)
Other	170	–
Unutilised tax losses	1,277	1,597
Tax credit for the period	(620)	(1,348)

Deferred Tax

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Tax losses		
Losses available to carry forward against future trading profits	43,254	35,819
Deferred tax asset – unrecognised*	7,353	6,089

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

9) LOSS PER SHARE (BASIC AND DILUTED)

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

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares in issue during the year to assume conversion of all dilutive potential ordinary shares.

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Total loss attributable to the equity holders of the parent	(8,186)	(9,221)
	No.	No.
Weighted average number of ordinary shares in issue during the year	1,171,633,442	920,506,514
Loss per share		
Basic and diluted loss for the year	(0.70)p	(1.00)p

The Company has issued employee options over 53,577,615 (2017: 53,119,254) ordinary shares and there are 16,112,800 jointly owned shares which are potentially dilutive. There is, however, no dilutive effect of these issued options as there is a loss for each of the periods concerned.

10) PROPERTY, PLANT AND EQUIPMENT

	Building & land £000	Laboratory equipment £000	Fixtures & fittings £000	Computer equipment £000	Total £000
Cost					
At 31 December 2016	–	1,098	534	494	2,126
Additions	–	88	20	22	130
Additions from Acquisition	849	1,361	49	–	2,259
At 31 December 2017	849	2,547	603	516	4,515
Exchange Adjustment	93	70	13	16	192
Additions	–	200	32	58	290
Transfers	1,059	(1,091)	32	–	–
At 31 December 2018	2,001	1,726	680	590	4,997
Depreciation					
At 31 December 2016	–	638	186	215	1,039
Charge for the period	5	241	110	126	482
At 31 December 2017	5	879	296	341	1,521
Exchange Adjustment	2	34	5	9	50
Charge for the period	60	289	124	125	598
Transfers	11	(13)	2	–	–
At 31 December 2018	78	1,189	427	475	2,169
Net book value					
At 31 December 2018	1,923	537	253	115	2,828
At 31 December 2017	844	1,668	307	175	2,994
At 31 December 2016	–	460	348	279	1,087

Transfers from Laboratory Equipment to Building & Land include £1.1m for a clean room buildout for which there was no change to the depreciation charged up to the point of transfer.

Notes to the financial statements continued

For the year ended 31 December 2018

11) INTANGIBLE ASSETS

	Development costs £000	Goodwill £000	Customer relationships £000	Trademarks £000	Process Tech £000	Supplier agreements £000	Total £000
Cost							
At 31 December 2016	550	–	–	–	–	–	550
Additions	93	14,504	2,234	592	1,112	445	18,980
At 31 December 2017	643	14,504	2,234	592	1,112	445	19,530
Additions	116	–	–	–	–	–	116
Exchange adjustment	–	829	130	38	70	28	1,095
At 31 December 2018	759	15,333	2,364	630	1,182	473	20,741
Amortisation							
At 31 December 2016	–	–	–	–	–	–	–
Charge for the period	–	–	92	49	46	38	225
At 31 December 2017	–	–	92	49	46	38	225
Charge for the period	–	–	236	126	118	95	575
Exchange adjustment	–	–	1	1	1	–	3
At 31 December 2018	–	–	329	176	165	133	803
Net book value							
At 31 December 2018	759	15,333	2,035	454	1,017	340	19,938
At 31 December 2017	643	14,504	2,142	543	1,066	407	19,305
At 31 December 2016	550	–	–	–	–	–	550

Remaining amortisation periods are: Customer relationships: 3.8 years, Trade marks: 8.8 years, Process Tech: 8.8 years, Supplier agreements: 3.8 years.

Impairment of Non-Financial Assets

Goodwill is monitored by management at the Cash Generating Unit (“CGU”) level. A CGU is considered to be an individual company. The group tests goodwill for impairment on at least an annual basis by comparing the carrying amount of the CGU with its value in use. Value in use is estimated based on future cash flow discounted to present value using a pre-tax discount rate that reflects current market assessments of the time value of money. An impairment charge arises where the carrying value exceeds the value in use.

The carrying amount of the CellRight Technologies CGU has been tested for impairment using a discounted cash flow model based on the following assumptions:

- Most recent Board approved budgets /forecasts for the next 5 years
- Expected future cash flows based on EBITDA adjusted for expected Capex and working capital movements
- A terminal year perpetuity based on the final year forecast and a terminal growth rate of 2%
- Sales growth based on forecasts and prior-year performance in the region of 30% CAGR for the five year period (consistent with industry average)
- Gross margins projected based on those achieved historically
- Discount rate (pre-tax weighted average cost of capital “WACC”) of 19%

The Directors considered a sensitivity to the forecasts where revenues were 5% lower than forecast. In this instance the financial model showed no impairment.

On the above basis, the Directors have concluded that there is no material impairment for the CGU and they consider that there are no other reasonably possible changes to a key assumption which would give rise to an impairment charge.

12) INVENTORY

	At 31 December 2018 £000	At 31 December 2017 £000
Raw materials and consumables	871	1,130
Work in progress	939	941
Finished goods including goods for resale	520	801
Total	2,330	2,872

Inventory for Finished goods are shown net of provision £176,000 (2017:nil)

13) TRADE AND OTHER RECEIVABLES

	At 31 December 2018 £000	At 31 December 2017 £000
Trade debtors	2,465	1,466
Tax debtors	1,200	1,665
Other receivables	530	529
Prepayments and accrued income	556	508
	4,751	4,168

The Directors consider that the carrying amounts of trade and other receivables approximate to their fair values.

Trade debtors are shown net of provisions of £245,000 (2017: £24,000)

	2018 £000	2017 £000
Trade receivables	2,710	1,490
Less: Allowance for expected credit losses (2017: Provision for impairment of receivables)	(245)	(24)
	2,465	1,466

Allowance for expected credit losses

The Group has recognised a loss of £245,000 in profit or loss in respect of the expected credit losses for the year ended 31 December 2018.

The aging of the receivables and allowance for expected credit losses provided for above are as follows:

	Expected credit loss rate	Carrying amount 2018 £000	Allowance for expected credit losses 2018 £000
Consolidated			
not overdue	0%	1,668	-
0 to 3 months overdue	0%	678	-
3 to 4 months overdue	25%	90	22
4 to 5 months overdue	50%	102	51
over 5 months overdue	100%	172	172
		2,710	245

Average Credit terms with customers is 31 days (2017: 30 days)

Trade receivables, are analysed by the currencies of settlement below:

	At 31 December 2018 £000	At 31 December 2017 £000
US Dollars	2,345	1,112
Euros	119	354
Sterling	1	-
Trade debtors	2,465	1,466

14) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES

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

Interest rate risk

As the Group 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 Group.

Notes to the financial statements continued

For the year ended 31 December 2018

14) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES continued

Interest rate sensitivity

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

	December 2018		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	6,043	1,773	7,816

	December 2017		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	15,007	1,416	16,423

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

Management of credit risk

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

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

The Group 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 Group 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.

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

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Cash and cash equivalents		
AA-	35	-
A+	1,404	5,092
A	6,377	10,248
BBB+	-	1,083
	7,816	16,423

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

The capital structure of the Group consists of equity attributable to the owners of the Group, comprising issued capital, reserves and retained earnings as disclosed in note 17 and 18 and in the Statement of Changes in Equity.

Foreign currency risk management

The group's exposure to currency exchange rates arises principally from sales and purchases in the Group's overseas subsidiaries which are denominated and settled in local currency. While this provides a element of natural hedging, there is an element of residual risk that can impact the performance of the results of the Group over the course of each financial reporting period. Foreign currency transactions are principally denominated in Dollars and Euros, and the associated foreign currency denominated financial assets and liabilities are set out below:

	2018 \$000	2017 \$000	2018 €000	2017 €000
Financial assets	2,345	1,112	119	354
Financial liabilities	(1,717)	(2,899)	(37)	(294)
Short-term exposure	628	(1,787)	82	60

The Group has exposure to the movements in the exchange rates in the Dollar and Euro at 31 December 2018. An analysis of the effect of a reasonable possible movement in exchange rates shows that a movement of 10% in the exchange rate could result in net foreign currency gains of £80k (2017: £241K against the Dollar and gain £7K (2017: £5K) against the Euro.

Categorisation of financial instrument

Financial assets/(liabilities)	Loans and receivables at amortised cost £000	Financial liabilities at amortised cost £000	Financial liabilities held at fair value £000	Total £000
At 31 December 2018				
Trade and other receivables	2,995	-	-	2,995
Cash and cash equivalents	7,816	-	-	7,816
Trade and other payables	-	(2,751)	(1,475)	(4,226)
	10,811	(2,751)	(1,475)	6,585

Financial assets/(liabilities)	Loans and receivables at amortised cost £000	Financial liabilities at amortised cost £000	Financial liabilities held at fair value £000	Total £000
At 31 December 2017				
Trade and other receivables	1,995	-	-	1,995
Cash and cash equivalents	16,423	-	-	16,423
Trade and other payables	-	(2,627)	(2,637)	(5,264)
	18,418	(2,627)	(2,637)	13,154

15) TRADE AND OTHER PAYABLES

	At 31 December 2018 £000	At 31 December 2017 £000
Trade payables	855	1,519
Taxes and social security	76	152
Accruals	1,896	1,108
Contingent consideration	1,475	2,637
	4,302	5,416

Contingent consideration

The Group has agreed to pay the contingent consideration on the CellRight Technologies LLC acquisition if Gross Revenue during the first year after acquisition equalled or exceeds seven million dollars (\$7,000,000), in an amount equal to \$2,036,201.46. This milestone was achieved and paid in 2018. The Group has agreed to pay a second milestone if Gross Revenue during the second annual period equals or exceeds twelve million five hundred thousand dollars (\$12,500,000) an amount equal to \$2,036,201.46. This is carried in the accounts at fair value, was discounted (see note 7) and translated at closing rate.

The Directors consider that the carrying amount of trade and other payables approximates to their fair value. Trade payables are analysed by the currencies of settlement below:

	At 31 December 2018 £000	At 31 December 2017 £000
Sterling	242	262
US Dollars	576	963
Euros	37	294
Trade payables	855	1,519

16) DEFERRED TAX LIABILITIES

	Totals £000
As at December 2017	824
Amortisation charge	(98)
Exchange adjustment	65
As at December 2018	791

The deferred tax liability relates wholly to non-current assets recognised on acquisition of CellRight Technologies LLC.

Notes to the financial statements continued

For the year ended 31 December 2018

17) SHARE CAPITAL AND RESERVES

	Number	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 December 2016	760,124,264	3,801	50,461	10,884	(7,148)	57,998
Issue of shares	400,000,000	2,000	35,682	–	–	37,682
Share options exercised	10,866,660	54	255	–	–	309
Total Ordinary shares of 0.5p each as at 31 December 2017	1,170,990,924	5,855	86,398	10,884	(7,148)	95,989
Share options exercised	739,899	4	–	–	–	4
Total Ordinary shares of 0.5p each as at 31 December 2018	1,171,730,823	5,859	86,398	10,884	(7,148)	95,993

As permitted by the provisions of the Companies Act 2006, the Company does not have an upper limit to its authorised share capital. All shares are ordinary shares which are fully paid and entitle the holder to full voting rights, to full participation or distribution of dividends.

18) COMMITMENTS

Operating lease commitments

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

	As at 31 December 2018 £000	As at 31 December 2017 £000
Land and buildings:		
Amounts due within one year	61	85
Amounts due between 1–5 years	–	61
Total	61	146

19) SHARE BASED PAYMENTS

Share options and shares held in employee benefit trust (“EBT”)

The Company operates a share option plan, under which certain employees have been granted options to subscribe for ordinary shares. All options are equity settled. The options have an exercise price of between 0.5p to 22.5p and a vesting period between 1 and 3 years. If the options remain unexercised after a period of 10 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 price per share (£)	
	EMI options	Unapproved options	EBT shares	SAYE options		Total
At 31 December 2016	16,927,372	11,118,692	16,940,386	1,510,557	46,497,007	0.0650
Exercised in the period	(9,180,335)	(1,809,494)	(827,586)	–	(11,817,415)	0.0473
Lapsed during year	(1,408,719)	(3,113,324)	–	(1,419,331)	(5,941,374)	0.0913
Issued in the year	4,863,634	33,790,347	–	1,838,855	40,492,836	0.2740
At 31 December 2017	11,201,952	39,986,221	16,112,800	1,930,081	69,231,054	0.0934
Exercised in the period	–	(739,899)	–	–	(739,899)	0.005
Lapsed during year	(5,934,236)	(3,631,300)	–	(928,503)	(10,494,039)	0.1098
Issued in the year	–	11,227,008	–	476,291	11,703,299	0.0714
At 31 December 2018	5,267,716	46,842,030	16,112,800	1,477,869	69,700,415	0.0882

There were 4,361,603 share options outstanding at 31 December 2018 (2017: 7,499,918) eligible to be exercised. The remaining options were not eligible to be exercised as these are subject to employment period and market based vesting conditions, some of which had not been met at 31 December 2018.

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

There were 16,112,800 of the jointly held EBT shares which were eligible to vest as at 31 December 2018.

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

	Options Granted year to 31 December 2018	EBT shares Granted year to 31 December 2018	Options Granted year to 31 December 2017	EBT shares Granted year to 31 December 2017
Dividend yield	-	-	-	-
Expected volatility (%)	42	-	46	-
Risk free interest rate (%)	1.0	-	1.0	-
Expected vesting life of EBT shares and options (years)	3	-	4	-
Weighted average share price (£)	0.0822	-	0.0934	-

Share options issues under the Deferred Annual Bonus scheme which are not exercised within 4 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 10 years from the date of grant will expire. The weighted average remaining contractual life of options outstanding at the end of the financial year was 6.8 years (2017: 6.6 years).

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

	Share based payment reserves £000
At 31 December 2016	1,156
Charge in the period	30
At 31 December 2017	1,186
Charge in the period	(57)
At 31 December 2018	1,129

20) NON-CONTROLLING INTEREST

	2018 £000	2017 £000
As at 31 December 2017	(409)	(209)
Attributable loss for the period	(73)	(200)
As at 31 December 2018	(482)	(409)

The non-controlling interest has 50% (2017: 50%) equity holding. GBM-V GmbH contributed revenue of £1,842k (2017: £1,135k) and profit/loss before tax of £34k (2017: £(231k)) for the year.

21) RELATED PARTY TRANSACTIONS

Transactions with key management personnel

The Company's key management personnel comprise of only the Directors of the Group. During the year the Group entered into the following transactions in which the Directors had an interest:

Directors' remuneration:

Remuneration received by the Directors (including Employers NI) from the Group is set out below:

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Short-term employment benefits	709	822

During the year ended 31 December 2018, the Company entered into numerous transactions with its subsidiary companies which net off on consolidation – these have not been shown above.

22) ULTIMATE CONTROLLING PARTY

The Directors believe that there is no ultimate controlling party.

23) POST BALANCE SHEET EVENTS

On 3 June 2019, the Group entered into a new loan facility providing a total facility of \$20m. \$10.5m is available for immediate drawdown. The remaining \$9.5m will become available subject to the satisfaction of certain conditions.

Company statement of changes in equity

For the year ended 31 December 2018

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 December 2016	3,801	50,461	10,884	1,083	(9,330)	56,899
Total expense and other comprehensive loss for the period	-	-	-	-	(1,793)	(1,793)
Issue of shares	2,000	38,000	-	-	-	40,000
Cost of issue of new equity	-	(2,318)	-	-	-	(2,318)
Share options exercised	54	255	-	-	-	309
Share based payment expense	-	-	-	30	-	30
At 31 December 2017	5,855	86,398	10,884	1,113	(11,123)	93,127
Total expense and other comprehensive loss for the period	-	-	-	-	(2,342)	(2,342)
Share options exercised	4	-	-	-	-	4
Share based payment credit	-	-	-	(57)	-	(57)
At 31 December 2018	5,859	86,398	10,884	1,056	(13,465)	90,732

Company statement of financial position

At 31 December 2018

	Notes	At 31 December 2018 £000	At 31 December 2017 £000
ASSETS			
Non-current assets			
Investments	C5	18,594	12,922
Total non-current assets		18,594	12,922
Current assets			
Trade and other receivables	C6	253	250
Intercompany loan balance	C7	65,196	64,390
Cash and cash equivalents	C9	7,162	15,949
Total current assets		72,611	80,589
TOTAL ASSETS		91,205	93,511
LIABILITIES			
Current liabilities			
Trade and other payables	C8	(473)	(384)
TOTAL LIABILITIES		(473)	(384)
NET ASSETS		90,732	93,127
EQUITY			
Share capital	17	5,859	5,855
Share premium	17	86,398	86,398
Merger reserve	17	10,884	10,884
Share based payment reserve	19	1,056	1,113
Retained earnings deficit		(13,465)	(11,123)
TOTAL EQUITY		90,732	93,127

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent Company's statement of comprehensive income. The parent Company's result for the period ended 31 December 2018 was a loss of £2,342,000 (2017: £1,793,000).

Approved by the Board of Directors and authorised for issue on 3 June 2019.

Steve Couldwell

Chief Executive Officer

Company statement of cash flows

For the year ended 31 December 2018

Company number: 5969271

	Notes	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Operating activities			
Loss before interest and tax		(3,152)	(1,837)
Adjustment for non-cash items:			
Share based payments	19	(57)	30
Impairments		1,310	–
Operating cash outflow		(1,899)	(1,807)
(Increase) in trade and other receivables		(3)	(187)
Increase/(Decrease) in trade and other payables		89	(52)
Net cash absorbed by operations		(1,813)	(2,046)
INVESTING ACTIVITIES			
Interest received		810	44
Loan to subsidiary undertaking	C10	(7,788)	(27,859)
Net cash used in investing activities		(6,978)	(27,815)
FINANCING ACTIVITIES			
Proceeds from issue of share capital	17	–	37,682
Proceeds from exercise of share options	17	4	309
Net cash generated from financing activities		4	37,991
(DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		(8,787)	8,130
Cash and cash equivalents at start of period		15,949	7,819
CASH AND CASH EQUIVALENTS AT END OF PERIOD		7,162	15,949

Notes to the company financial statements

For the year ended 31 December 2018

C1. PRINCIPAL ACCOUNTING POLICIES

The separate financial statements of the Company are presented as required by the Companies Act 2006 and in accordance with International Financial Reporting Standards as adopted by the EU.

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

Adoption of new and revised standards

The Company has applied IFRS 9 'Financial Instruments' for the first time in the year ended 31 December 2018. As a result of the adoption of IFRS 9 the Company has adopted consequential changes to IAS 1 Presentation of financial statements. In addition, the Company has applied the consequential amendments to IFRS 7 Financial Instruments: Disclosure to the current period only. Comparatives have not been restated as the cumulative catch-up approach has been applied. Any adjustments arising on transition to IFRS 9 are recognised in opening equity. Therefore, information presented for 2017 does not reflect the requirements of IFRS 9 and is not comparable with the information presented for the year ended 31 December 2018.

All the Company's financial assets were previously classified as loans and receivables under IAS 39 and are classified as assets at amortised cost under IFRS 9. The only change in measurement of financial assets on application of IFRS 9 arises from impairment of financial assets. IFRS 9 requires impairments of financial assets to be assessed using an 'expected loss' model. While there is no change from the 'incurred loss' model previously applied under IAS 39 at 1 January 2018, the reduction in the Company's share price at the end of the year has given rise to an impairment loss of £1,310,000 recognised at 31 December 2018 (note C7).

Investments

Fixed asset investments, including investments in subsidiaries, are stated at cost and reviewed for impairment if there are any indications that the carrying value may not be recoverable.

C2. CRITICAL ACCOUNTING ESTIMATES

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

Critical judgements:

Recoverability of receivables from subsidiaries and impairment of financial assets

Receivables from subsidiaries represent loans and interest free amounts advanced to group companies that are repayable on demand. In accordance with IFRS 9 'Financial Instruments', where the counterparty would not be able to repay the loan if demanded at the reporting date, the company has made an assessment of expected credit losses. Having considered multiple scenarios on the manner, timing, quantum and probability of recovery on the receivables, no lifetime expected credit loss was recognised on adoption of IFRS 9 'Financial Instruments', and so no adjustment to opening retained earnings has been made. Following a reduction in the Company's share price during the course of the year, which in turn has adversely affected the likely outcome of the downside scenarios considered by management in relation to the recovery of receivables from subsidiaries, the assessment of lifetime expected credit loss was revised to £1,310,000 as at 31 December 2018. The calculation of the allowance for lifetime expected credit losses requires a significant degree of estimation and judgement, in particular determining the probability weighted likely outcome for each scenario considered and in using a range of market capitalisations to determine the amount recovered in each scenario. Whilst the Directors considered future cash flows over time, the ECL calculation was based on a sale of the business in the event that repayment of the loans was demanded.

Potential impairment of investments

As the market capitalisation of the Company was less than the carrying value of the Company's net assets at 31 December 2018, an impairment review was carried out in respect of the carrying value of the investment in subsidiaries of £18,594,000. In accordance with IAS36 and as detailed in the group's accounting policy, this required management to make an estimate of the recoverable amount of the investment balance. Having regard to the group's market capitalisation for 2018 as a whole, and other factors relevant to the group's share price performance, the Directors have concluded that no impairment provision is necessary. Whilst the Directors considered future cash flows over time, the ECL calculation was based on a sale of the business in the event that repayment of the loans was demanded.

C3. COMPANY RESULTS

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent Company's statement of comprehensive income. The parent Company's result for the period ended 31 December 2018 was a loss of £2,342,000 (2017: £1,793,000).

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

C4. STAFF COSTS

	Year to 31 December 2018 Number	Year to 31 December 2017 Number
The average monthly number of persons (including Directors) employed by the Group during the period was:		
Directors	7	7
Administration staff	1	1
	8	8
	£000	£000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	692	813
Social security, pension & healthcare costs	114	124
	806	937

Social security, pension and healthcare casts include pension contributions £23k (2017: £27k).

Notes to the company financial statements continued

For the year ended 31 December 2018

C5. INVESTMENT IN SUBSIDIARY COMPANIES

All other companies except Tissue Regenix Limited are held through Tissue Regenix Limited

	31 December 2018 £000	31 December 2017 £000
Cost	14,707	14,707
Additions	6,500	–
Transfer	(828)	–
Impairment	(1,785)	(1,785)
Carrying value at 31 December 2017	18,594	12,922

Additions during the year have been settled through the conversion of loans historically advanced to subsidiary undertakings into equity.

At 31 December 2018, the Company held the following investments in subsidiaries:

Undertaking	Sector	Share of issued capital and voting rights	
		2018	2017
Tissue Regenix Limited	Regenerative medicine	100%	100%
TRx Wound Care Limited	Regenerative medicine	100%	100%
TRx Orthopaedics Limited	Regenerative medicine	100%	100%
TRx Cardiac Limited	Regenerative medicine	100%	100%
TRx Vascular Limited	Regenerative medicine	100%	100%
Tissue Regenix Wound Care Inc*	Regenerative medicine	100%	100%
Tissue Regenix Orthopedics Inc [^]	Regenerative medicine	100%	100%
Tissue Regenix Holdings Limited	Holding company	100%	100%
Tissue Regenix Holdings Inc**	Holding company	100%	100%
CellRight Technologies LLC [†]	Regenerative medicine	100%	100%
GBM-V GmbH	Regenerative medicine	50%	50%

* Held through TRx Wound Care Limited [^]Held through TRx Orthopaedics Limited **Held through Tissue Regenix Holdings Limited

[†]Held through Tissue Regenix Holdings Inc All others are held through Tissue Regenix Limited.

Registered Addresses:

Tissue Regenix Limited, TRx Wound Care Limited, TRx Orthopaedics Limited, TRx Cardiac Limited, TRx Vascular Limited:

Unit 1&2, Astley Way, Astley Lane Industrial Estate, Swillington, Leeds LS26 8XT.

Tissue Regenix Wound Care Inc, TRx Orthopedics Inc, CellRight Technologies LLC:

1808 Universal City Boulevard, Universal City Texas, 78148.

GBM-V GmbH: Schillingallee 68, 18057, Rostock, Germany

C6. TRADE AND OTHER RECEIVABLES

	31 December 2018 £000	31 December 2017 £000
Prepayments & accrued income	38	42
Other debtors	215	208
	253	250

C7. CURRENT ASSETS

	At 31 December 2018 £000	At 31 December 2017 £000
Intercompany loans	65,196	64,390

Intercompany loans includes £828,000 due from group's EBT (see note C10). No interest was payable on loans to subsidiary undertakings and the loans are repayable on demand.

In accordance with IFRS 9 'Financial Instruments', where the counterparty would not be able to repay the loan if demanded when due at the reporting date, the Company has made an assessment of expected credit losses with reference to an appropriate method of recovery.

Having considered multiple scenarios on the manner, timing, quantum and probability of recovery on the receivables, no lifetime expected credit loss was recognised on adoption of IFRS 9 'Financial Instruments', and so no adjustment to opening retained earnings has been made. Following a reduction in the Company's share price during the course of the year, which in turn has adversely affected the likely outcome of the multiple scenarios considered by management in relation to the recovery of receivables from subsidiaries, the assessment of lifetime expected credit loss was revised to £1,310,000 as at 31 December 2018.

The opening provision for expected credit losses was £nil. The expected credit loss provision charged to the income statement in the period was £1,310,000, resulting in a closing provision for expected credit losses of £1,310,000.

C8. TRADE AND OTHER PAYABLES

	At 31 December 2018 £000	At 31 December 2017 £000
Trade creditors	82	91
Taxes & social security	34	108
Accruals	357	185
	473	384

C9. RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES

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

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 Company, with a minimal amount of its cash surpluses held within short-term accounts, which have variable interest rates attributable to them, to ensure that sufficient funds are available to cover the working capital requirements of the Company.

Interest rate sensitivity

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

	December 2018		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	6,057	1,105	7,162

	December 2017		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	15,007	942	15,949

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

Management of credit risk

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

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

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

Management of liquidity risk

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

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

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

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Cash and cash equivalents		
A+	1,000	5,007
A	6,162	10,000
BBB+	-	942

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.

Notes to the company financial statements continued

For the year ended 31 December 2018

C9 RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES

continued

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 note 17 and in the Statement of Changes in Equity.

Categorisation of financial instrument

Financial assets/(liabilities)

Financial assets/(liabilities)	Loans and receivables at amortised cost £000	Financial liabilities at amortised cost £000	Total £000
At 31 December 2018			
Trade and other receivables	215	–	215
Cash and cash equivalents	7,162	–	7,162
Intercompany loans	65,196	–	65,196
Trade and other payables	–	(439)	(439)
	72,573	(439)	72,134
At 31 December 2017			
Trade and other receivables	208	–	208
Cash and cash equivalents	15,949	–	15,949
Intercompany loans	64,390	–	64,390
Trade and other payables	–	(276)	(276)
	80,547	(276)	80,271

C10. RELATED PARTY TRANSACTIONS

Transactions with key management personnel

The Company's key management personnel comprise only the Directors of the Group. During the year the Group entered into the following transactions in which the Directors had an interest:

Directors' remuneration:

Remuneration received by the Directors (including Employers NI) from the Group is set out below:

	Year to 31 December 2018 £000	Year to 31 December 2017 £000
Short-term employment benefits	709	822

Intercompany loans during and at the end of the year (before provisions for expected credit losses of £1,310k (2017: nil) were as follows:

	Tissue Regenix Limited	TRx Cardiac Limited	TRx Orthopedics Limited	TRx Wound Care Limited	Total
At 31 December 2017	45,001	109	3,488	15,792	64,390
(Repayment)/Advance in the year	5,379	38	257	2,114	7,788
Equity conversion	(6,500)	–	–	–	(6,500)
At 31 December 2018	43,880	147	3,745	17,906	65,678

The Company has entered into a number of unsecured related party transactions with its subsidiary undertakings. The most significant transactions carried out between the Company and its subsidiary undertakings are mainly for short and long-term financing. Amounts owed from these entities are interest free and repayable on demand. The company also has a loan with the Employee Benefit Trust of £828,000. This is included as a debtor as there is a contractual loan agreement between the Company and the Trust.

Notice of annual general meeting

Notice is given that the 2019 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 27 June 2019 at 10 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 December 2018.
2. To appoint Gareth Jones as a director of the Company.
3. To reappoint Steven Couldwell who retires by rotation, as a director of the Company.
4. To reappoint Randeep Grewal who retires by rotation, as a director of the Company.
5. To appoint RSM UK Audit LLP as auditors of the Company.
6. To authorise the directors to determine the remuneration of the auditors.
7. That, pursuant to section 551 of the Companies Act 2006 (“Act”), the directors be generally and unconditionally authorised to allot Relevant Securities:
 - 7.1 up to an aggregate nominal amount of £1,952,884; and
 - 7.2 comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £1,952,884 in connection with an offer by way of a rights issue:
 - 7.2.1 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
 - 7.2.2 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 27 September 2020 (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).

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

8. That, subject to the passing of resolution 7 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 7 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:
 - 8.1 in connection with an offer of equity securities (whether by way of a rights issue, open offer or otherwise, but, in the case of an allotment pursuant to the authority granted by paragraph 7.2 of resolution 7, such power shall be limited to the allotment of equity securities in connection with an offer by way of a rights issue):
 - 8.1.1 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
 - 8.1.2 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

- 8.2 otherwise than pursuant to paragraph 8.1 of this resolution up to an aggregate nominal amount of £585,865,

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 27 September 2020 (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).

Notice of annual general meeting continued

9. 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:
- 9.1 the maximum aggregate number of Shares which may be purchased is 117,173,082;
- 9.2 the minimum price (excluding expenses) which may be paid for a Share is 0.5p;
- 9.3 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 27 September 2020 (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

Gareth Jones

Secretary

2019

Registered office

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

Registered in England and Wales No. 05969271

Notes

Entitlement to attend and vote

1. The right to vote at the meeting is determined by reference to the register of members. Only those shareholders registered in the register of members of the Company as at the close of business on 25 June 2019 (or, if the meeting is adjourned, close of business on the date which is two working days before the date of the adjourned meeting) shall be entitled to attend and vote at the meeting in respect of the number of shares registered in their name at that time. Changes to entries in the register of members after that time shall be disregarded in determining the rights of any person to attend or vote (and the number of votes they may cast) at the meeting.

Proxies

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

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

A proxy may only be appointed in accordance with the procedures set out in notes 3 and 4 below and the notes to the proxy form.

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

3. A form of proxy is enclosed. When appointing more than one proxy, complete a separate proxy form in relation to each appointment. Additional proxy forms may be obtained by contacting the Company's registrar on 0871 664 0300 (Calls cost 12p per minute plus your phone company's access charge. Calls outside the United Kingdom will be charged at the applicable international rate. The Company's registrar is open between 09:00a.m. – 17:30p.m., 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, Link Asset Services PXS 1, 34 Beckenham Road, Beckenham BR3 4TU, no later than 10 a.m. on 25 June 2019 (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 Link Asset Services (ID RA10) no later than 10 a.m. on 25 June 2019 (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 Link Asset Services 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 30 and 31 of the enclosed annual report and accounts.

Directors and Officers

DIRECTORS

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

COMPANY SECRETARY

Gareth Jones

COMPANY WEBSITE

www.tissueregenix.com

COMPANY NUMBER

05969271 (England & Wales)

REGISTERED OFFICE

Unit 1 & 2
Astley Way
Astley Lane Industrial Estate
Leeds
West Yorkshire
LS26 8XT

REGISTRAR

Link Asset Services
The Registry
34 Beckenham Road
Beckenham
Kent
BR3 4TU

AUDITOR

RSM UK Audit LLP
Central Square
29 Wellington Street
Leeds
LS1 4DL

LEGAL ADVISER

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

NOMINATED ADVISER AND BROKER

Stifel Nicolaus Europe Ltd
150 Cheapside
London
EC2V 6ET

Tissue Regenix Group plc
Unit 1 and 2
Astley Way
Astley Lane Industrial Estate
Swillington
Leeds
LS26 8XT

www.tissueregenix.com

