

ANNUAL REPORT

AND ACCOUNTS

FOR YEAR ENDED 31 DECEMBER 2019

Who we are

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

We are currently 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.

Investment case

01

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

02

International manufacturing capabilities

03

Expansive distribution opportunities

04

Multiple commercialisation opportunities – innovative product portfolio and pipeline

05

Tissue processing science and development expertise

06

Differentiated clinical outcomes

Our vision

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

Our values



Dedication to patients



Passion for innovation



Drive for excellence



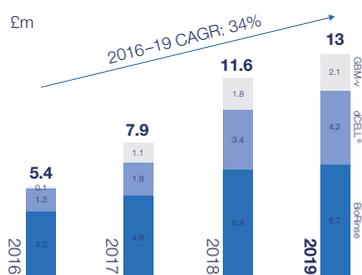
Uncompromising integrity

Company snapshot

- **£13.0m** revenue FY2019
- **12% growth** year-on-year
- **£2.4m** net cash at 31 Dec 2019
- **£14.6m gross equity fundraise undertaken post year end, subject to approval**
- **Specialist sales and distribution partners**

Highlights

Financial



Revenue growth by product Annual growth (including impact of FX)

BioRinse	+23%	+31%	+5%
dCELL®	+46%	+79%	+25%

¹ Revenue by product on a pro-forma basis. BioRinse acquired as part of July 2017 acquisition of CellRight Technologies, LLC. 2016 financials relate to 11 months to 31 December 2016.

£13.0m

Group sales increased (2018: £11.6m) +12%, driven by:

- DermaPure sales increased by 25% to £4.2m (2018: £3.4m), due to the increasing demand within the urogynaecology market and greater penetration into key accounts
- Orthopaedics and Dental revenue of £6.7m (2018: £6.4m) +5%
- Joint venture GBM-v achieved sales of £2.1m (2018: £1.8m) +13%

£2.4m

Cash balance at 31 December 2019

- Cash balance is after drawing down £1.0m of the Revolving Credit Facility (“RCF”)
- Secured debt facility of up to \$20m with MidCap Financial Trust (“MidCap”) drawing down an initial \$7.5m and accessing the \$3m RCF in June 2019
- Repaid \$5.5m of MidCap Term Loan following renegotiation in November 2019
- Completed an equity fundraise via placement of ordinary shares raising gross proceeds of £14.6m on 22 May 2020, conditional on shareholder approval at a General Meeting of shareholders and also to admission of the fundraising shares to trading on AIM

Operational

Operations

- Orthopaedic donor throughput more than doubled between Q1 and Q4 2019
- Second shift commenced in San Antonio facility
- Sub-contracted a percentage of DermaPure production to Community Tissue Services (“CTS”)
- Lease signed on an additional 21,000 sq ft facility in San Antonio
- \$0.3m grant from Universal City to commence utility infrastructure work
- Established donor services team and enhanced supply chain
- Further Group Purchasing Organisation approval for DermaPure increasing coverage to c.95% of US GPO hospitals
- Soft launch of DermaPure non-oriented, specifically for applications in urogynaecology
- Further approvals in major hospital institutions

R&D, Clinical

- 11 new DermaPure clinical case studies undertaken for new applications
- Continuation of OrthoPure XT clinical data collection

Management

- Daniel Lee appointed President, US Operations, January 2019
- Tina Trimble appointed VP, Donor Services, March 2019
- Gareth Jones appointed interim CEO, August 2019
- Kirsten Lund appointed Group Finance Director, November 2019
- Lance Johnson appointed VP, Quality and Regulatory, November 2019

Post balance sheet events

- Company subject to cyber attack in January 2020, which was resolved with no long term impact
- Q1 2020 revenue increased 18% year-on-year
- US Government backed loans of \$1m secured April 2020 to assist with US cost base during COVID-19 pandemic
- UK manufacturing staff furloughed due to COVID-19 pandemic
- New strategic collaboration with a top 10 global healthcare company for white label manufacturing announced May 2020
- CE Mark approval for OrthoPure XT received May 2020

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Chairman's statement



Jonathan Glenn

INTERIM NON-EXECUTIVE
CHAIRMAN



We remain focused on delivering positive, sustainable growth across key divisions of the business. Our strategic realignment has been successful, and having fully 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 to grow our addressable market opportunities through the launch of new products, and partnerships, during 2020 and beyond.

Introduction

During 2019 our focus was on optimising our supply chain and operational processes, which allows us to develop and maintain strong working relationships with our current and potential strategic partners. As previously announced we have experienced capacity constraints at our San Antonio facility however, despite this, we still reported top-line revenue growth of 12%, and saw continued significant demand for our products. As a result of the operational initiatives implemented throughout the year, we believe we are now positioned to achieve continued top-line growth into the future.

Financial performance

The Group recorded top-line revenue of £13.0m (2018: £11.6m) however, the overall performance was impacted by the capacity constraints experienced. This particularly affected our BioRinse orthopaedic portfolio, where we continue to see high levels of demand, from both our current customers and partners such as Arthrex, Inc. and also potential future opportunities that we are not currently positioned to serve until the additional capacity expansion project is completed.

Our DermaPure portfolio, under the BioSurgery division, continued to see strong growth, increasing sales by 25% year-on-year, derived primarily from further penetration into key hospital accounts and the urogynaecology market, with strategic partner, ARMS Medical.

Our controlled joint venture, GBM-v, has continued to increase revenue from their corneal business and is now financially self-sufficient.

The Company renegotiated the terms of the MidCap Financial funding, secured in June 2019, repaying \$5.5m of the initial \$7.5m term loan and at the year end the Group

recorded a cash position of £2.4m after drawing down £1m of the MidCap Revolving Credit Facility. The Board has successfully secured alternative financing, details of which were announced post year end, as discussed further below.

Operations

Following the review of our supply chain and operational processes we implemented several initiatives, including commencement of the recruitment and training of a second shift at the facility in San Antonio. However, due to the three-four month lead time for the BioRinse orthopaedic portfolio, the benefits of this increased processing became evident towards the end of the year, with an uptick in sales during Q4 which we expect to continue into 2020.



READ MORE IN THE INTERIM CEO REPORT
ON PAGES 18-21.

Our strategy

We made the strategic decision to shift our focus away from R&D and concentrate on the commercialisation of the existing product lines. This still allows for product line extensions, such as DermaPure non-oriented, to be brought to market in a cost efficient and timely manner, but removes the cost and burden of organic product development and pre-clinical trials, as we focus on reaching break even and increasing value for our stakeholders.

We have continued to strengthen our relationships with key strategic partners, including Arthrex and ARMS Medical. We have also identified additional opportunities and distribution agreements that target products and therapeutic areas which are complementary to current processing activities and will diversify the Group's sales portfolio.



READ MORE ABOUT OUR STRATEGY
ON PAGES 10-11.

Management

Following a recurrence of his illness, Steve Couldwell retired from the position of Chief Executive Officer (CEO) in August 2019. On behalf of the Board I would like to thank Steve for his commitment and exceptional leadership as both CEO and, prior to this, a Non-Executive Director of the Company. Gareth Jones, Chief Operating Officer, stepped into the interim CEO position where he remains, and Mike Barker joined as interim Chief Finance Officer in January 2019 before being formally appointed in August 2019. Due to family circumstances, Mike stepped down from this position in November; I would like to thank Mike for his support and guidance in what was a challenging time for the management team. Kirsten Lund, Group Financial Controller, was promoted to Group Finance Director in November 2019.

We strengthened our operational management team in the US appointing Daniel Lee, President of US Operations, in January 2019, and Tina Trimble, VP Donor Services, in March 2019. Both bring significant experience to the team and have been at the forefront of implementing the successful operational improvements.



READ MORE ABOUT OUR MANAGEMENT TEAM ON PAGES 16–17.

Shareholders

In June 2019, Woodford Investment Management, the second largest shareholder of the Tissue Regenix Group, suspended their Equity Income Fund, instigating a period of uncertainty. During the year the composition and nature of our investor base changed with an increase in smaller funds and individual shareholders. On behalf of the Board I would like to thank all of our shareholders for their continued support of the business.

Our employees

Our employees remain a key stakeholder in the success of our business. We look to maintain a collaborative and supportive working environment where everyone can excel, and I would like to thank all employees for their continued hard work and commitment. Due to the shift in our strategy to focus on the commercial growth of our existing product portfolio, and as the Group looks to maintain cash reserves, a restructuring of our employee base was undertaken in Q4 2019, resulting in a number of redundancies, primarily from the R&D and clinical teams in the UK.

Post balance sheet events

In January 2020, the Company was subject to a cyber attack at our base in San Antonio, Texas. There is not expected to be any long-term financial implications and, as announced on 15 April 2020, Q1 2020 sales grew by 18% year-on-year, confirming that sales were not materially impacted by this event.

As with all businesses, the COVID-19 pandemic has been a challenging time. However, I am encouraged by the work undertaken by the management team to ensure the health and wellbeing of our employees and stakeholders whilst also allowing processing at our San Antonio facility to continue in line with all relevant US Government protocols. We recently received US Government backed loans of \$1m to assist with the payroll, health insurance and utility and rent payments in the US during this time. Further details of this can be found in the financial overview on page 21.

In the UK, following UK Government advice, our technical and operations staff were furloughed and processing halted once we ensured there was sufficient levels of finished goods to meet near-term demand.

During March 2020, John Samuel stepped down from the position of Executive Chairman and as a Director of the Board. John had been a Director of the Company for 12 years and played an important role in building the Company from a start up to its current form. On behalf of the Board and all stakeholders, I would like to thank John for his unwavering commitment to the Company throughout this time.

In line with our refocused strategy, in May 2020 we entered a white label (unbranded) manufacturing agreement, launching a new product line with a top 10 global healthcare company. It is expected that this agreement will have a material impact on our top-line revenue during the next two years.

In addition, OrthoPure XT, a decellularised xenograft ligament was awarded a CE mark in May 2020.

Outlook

We believe there is strong underlying demand for our portfolio of products, which is further illustrated by our recent announcement regarding a new strategic collaboration.

The COVID-19 pandemic has affected most businesses during H1 2020. As previously communicated, a number of elective surgical procedures that utilise our products have been postponed and there remains ongoing uncertainty around level and duration of the disruption from the pandemic and therefore, the time it will take to perform any delayed surgical procedures thereafter. However, the Group has continued to work closely with partners and distributors during this time and we remain confident that, once appropriate, we are well positioned to service the demand for our products and address these clinical requirements.

Post-period, on 22 May 2020, we announced that gross proceeds of £14.6m had been conditionally raised through an offer of new ordinary shares in the Company to institutional and qualifying retail investors.

This fundraise is conditional on shareholder approval at a General Meeting of shareholders to be held on 9 June 2020, and also to admission of the fundraising shares to trading on AIM. If this does not occur, the Directors would consider alternative sources of funding, however the Group would only have sufficient working capital to trade through to the first week of August without taking any mitigating measures and the Directors may not be in a position to pursue further the commercial activities of the Group and in such circumstances would need to take immediate steps to protect the position of its creditors.

The injection of capital from this fundraising will allow the Group to accelerate the planned capacity expansion of its US manufacturing facility and capabilities. Additionally, during 2019, we made significant progress in optimising processes at the current facility, such that donor throughput had more than doubled by the end of the year. Together this investment and the current operational initiatives will enable us to meet the anticipated future demand for our products, and allow us to realise new opportunities that we foresee emerging once the impact of the COVID-19 pandemic has passed. This, we believe, will translate into a step change for the business. Therefore, despite the current near-term uncertainty resulting from the COVID-19 pandemic, the Board remains confident in the Group's future prospects.

Jonathan Glenn

Interim Chairman

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.

 READ MORE ABOUT OUR STRATEGIC GROWTH DRIVERS PAGES 10-11.

Two innovative technology platforms
-
Three key clinical focus areas
-
Four strategic growth drivers

Innovative platform technologies

Addressing clinical needs through complementary bone and soft tissue platforms

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

dCELL®

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

Differentiated characteristics:

- Maintains the natural acellular scaffold of the tissue structure to allow for cellular proliferation
- Supports regeneration of native tissue
- Stored at room temperature
- Can be applied to both human or animal tissue sources
- Favourable health economic benefits due to reduced operation time, reduction in rehabilitation required, no anticoagulant drugs

Product portfolio

Two high growth product lines focused on bone and skin:

Healthcare area	Bone	Skin
Technology platform	BioRinse®	dCELL®
FY19 revenue	£6.7m	£4.2m
Products		
	ConCelltrate®	DermaPure®
Applications	<ul style="list-style-type: none"> ○ Foot/ankle ○ Spine ○ Dental ○ Orthopaedics 	<ul style="list-style-type: none"> ○ Urogynaecology ○ Sports medicine ○ Open wound ○ Plastics
Differentiators	<ul style="list-style-type: none"> + Induces new bone growth + Faster healing + Superior handling + Reduced flush out 	<ul style="list-style-type: none"> + Clinical outcomes + No second graft site required + Stored at room temperature + Superior handling

Product pipeline

The Group has a novel product portfolio of both soft tissue and bone applications to address a number of clinical indications.

Product	Application/indication	Phase	Primary market
DermaPure – Decellularised allograft tissue	Orthopaedics, trauma, woundcare	HCT/Ps	USA
DermaPure Non-Oriented – Decellularised allograft tissue with no basement membrane	Urogynaecology and surgical	Registered with the FDA as HCT/Ps	USA
SurgiPure XD – Decellularised xenograft tissue	Hernia repair	510(K) Clearance	USA
OrthoPure XT – Decellularised xenograft ligament	Anterior cruciate ligament	CE Mark certified	UK and EU
ConCelltrate 100 – Demineralised allograft bone matrix	Orthopaedics, spine	Registered with the FDA as HCT/Ps	USA
Matrix OI FlexIt – Demineralised cortical bone strip	Maxillofacial, periodontal defects	Registered with the FDA as HCT/Ps	USA
Matrix OI 100 DBM – Demineralised cortical fibres and fillers with mineralised cancellous fibres	Spinal, lumbar fusions, non-structural bone-grafting	Registered with the FDA as HCT/Ps	USA
Matrix OI Strips & Blocks – Stem cell containment scaffold that minimises the use of fixations devices	Orthopaedics, spinal	Registered with the FDA as HCT/Ps	USA
MatrixCollect 100 DBM – Demineralised allograft bone putty	Orthopaedics, spinal	Registered with the FDA as HCT/Ps	USA
MartixCollect 100 DBM Crunch – Demineralised allograft bone matrix containing cancellous chips	Orthopaedics, spinal	Registered with the FDA as HCT/Ps	USA
Matrix IQ – Decellularised allograft tissue	Maxillofacial and dental	Registered with the FDA as HCT/Ps	USA
AmnioWorks – Human Amniotic membrane	Surgical graft	Registered with the FDA as HCT/Ps	USA
DentalFix – mineralised particulate allografts featuring a unique elongated shape	Dental and maxillofacial	Registered with the FDA as HCT/Ps	USA

Key:

Tissue types:

Allograft – donated human tissues/bone
 Xenograft – donated porcine (pig) tissue
 Amniotic membrane – inner most layer of the placenta recovered following delivery of the child
 Demineralised Cortical bone – the outer part of the bone, which retains biologic properties including growth factors
 Demineralised Cancellous bone – porous bone matrix which provides a scaffold to allow growth of the patient's own bone.

Phase:

Registered with FDA as HCT/Ps – USA regulatory pathway

Human cells, tissues, and cellular and tissue-based products (HCT/Ps) consist of human cells or tissues intended for implantation, transplantation, infusion or transfer into a human recipient.¹ Products must be:

- Minimally manipulated
- Intended for homologous use only

510(k) clearance – USA regulatory pathway

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device.²

CE Mark approval – UK & EU regulatory pathway

Demonstrate that the medical device meets the requirements in the Medical Devices Directive (MDD) by carrying out a conformity assessment. The assessment route depends on the classification of the device.

The CE mark can be placed on the product to show that the medical device has met the requirements when it has passed the conformity assessment.³

¹ <http://www.aabb.org/advocacy/regulatorygovernment/ct/hctps/Pages/default.aspx>

² <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>

³ <https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark>

Our markets

Regenerative medicine

The demand for biologic regenerative treatments is driven by a demographic shift towards a more active, older generation and an increase in lifestyle-related illnesses such as obesity and diabetes.

Tissue Regenix is helping to transform the treatment of patients in three key areas: BioSurgery, Orthopaedics and Dental, with an active development programme in Cardiac applications. Our products address sports medicine, spine, degenerative diseases, surgical and oral conditions.

What is regenerative medicine?

Regenerative medicine is an interdisciplinary field that 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.

Health economics

The shift in demographics has increased the strain on both private and public healthcare systems, as they look to accommodate an increasing number of patients and procedures within limited budgets. In order to maintain the level of mobility they seek, patients are requiring repeated surgeries and therefore new novel technologies are emerging to combat this.

Market opportunities



Health systems need to be transformed so that they can ensure affordable access to evidence-based medical interventions that respond to the needs of older people and can help prevent care dependency later in life¹.

Regenerative medicine has the potential to assist with this growing global dilemma as it has been shown to minimise healing time, hospital stays and rehabilitation spends, reducing the overall end-to-end spend for multiple procedures.

Increasing clinical demand

Regenerative, biologic solutions are being utilised in an increasing number of clinical applications and one area where Tissue Regenix has seen increasing market demand is urogynaecology.

With over 100,000² women in the US filing personal injury lawsuits following complications from the implantation of transvaginal mesh patches, the FDA acted in April 2019 ordering manufacturers of surgical mesh to stop selling all devices intended for transvaginal repair of pelvic organ prolapse³. As these products were withdrawn from the market there was a clear need for a biologic solution for the approximately 200,000⁴ women in the US who undergo surgical procedures each year.

Regulatory environment

The medical device and biologics industry is highly regulated with specific country and institutional regulations for the approval and use of products. Our human tissue products are regulated under the HCT/P pathway for minimally manipulated tissues in the US, whilst in Europe where we look to commercialise our xenograft tissues, we are subject to the Medicines and Healthcare products Regulatory Agency (MHRA), and also, the Medical Device Regulations, introduced in 2017.

Following Britain's exit from the European Union, the MHRA has confirmed that during the transition period to the 31 December 2020, CE Certificates will continue to be valid for both EU and UK markets.

¹ <https://www.who.int/ageing/health-systems/en/>

² <https://www.meshmedicaldevicenewsdesk.com/mesh-lawsuit/>

³ <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-womens-health-orders-manufacturers-surgical-mesh-intended-transvaginal>

⁴ <https://www.uptodate.com/contents/pelvic-organ-prolapse-in-women-choosing-a-primary-surgical-procedure>

Global operations infrastructure

Platform for international expansion

CellRight Technologies San Antonio, Texas

- Human Tissue US
- Processing dCELL® and BioRinse products



Tissue Regenix Leeds, UK

- Porcine Tissue
- Processing SurgiPure XD and OrthoPure XT



GBM-v Rostock Germany

- Human Tissue EU
- Corneas and working on regulatory approvals for Cardiac products



Our divisions

Our divisions

The Group comprises of three key operating divisions allowing each to function independently and appoint the optimal commercial strategy, management and access to relevant Key Opinion Leaders. This also allows us the benefits of operational synergies across the Group while reporting against each division financially.

BioSurgery

Repair and replacement of soft tissue – dCELL®

2019 achievements

- Soft launch for product line extension DermaPure non-oriented
- Increased inventory by outsourcing some DermaPure production to CTS
- Secured a number of prestigious marque accounts
- Achieved further GPO approval taking total to c.95% of hospitals covered

Through demonstrating our product differentiators and clinical outcomes during 2019 we have gained:

11 new case studies (8 Orthopaedics, 2 General, 1 Oral/maxillofacial)
7 poster presentations

Surgeon specialty	Number of new healthcare professionals with agreements
Orthopaedics	7
Vascular	1
Plastics	2
Urology	1
General	1

2020 milestones

- Full roll out of DermaPure non-oriented
- Identify potential distribution opportunities for SurgiPure XD
- Further expansion into the North American market and overseas markets
- Secure a strategic partner for woundcare applications

25%

increase year-on-year sales

Orthopaedics & Dental

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

2019 achievements

- Increased processing throughput for orthopaedic (BioRinse) portfolio
- Increased amniotic product processing and throughput
- Revamped donor services team and recruited employees with key skills
- Recruited and introduced a second shift at San Antonio facility

Through demonstrating our product differentiators and clinical outcomes during 2019 we have gained:

2 new case studies
5 new KOL/healthcare professionals

2020 milestones

- Secure additional strategic partnerships
- Launch additional product lines in collaboration with strategic partners
- Complete phase one of the facility expansion project
- Review opportunities for OrthoPure XT following CE Mark approval

Processing

more than **doubled** in the year

GBM-v & Cardiac

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

2019 achievements

- Increased sales of cornea products by 13% year-on-year
- Progressed CardioPure regulatory clearance application

2020 milestones

- Achieve marketing authorisation in Germany for cryopreserved valves, CardioPure dCELL heart valves and Pulmonary Patch
- Start commercial distribution of CardioPure products
- Develop proposition to contract manufacture cardiac tissue products for other European tissue banks

GBM-V

Financially self sustainable

Business model

We aim to implement a business model that ensures our product portfolios have the market reach and penetration to deliver novel, regenerative solutions to patients, and provide returns to our shareholders. Through a combination of strategic partnerships, distributors and direct sales, we believe we have a balanced and robust business model to drive our commercial growth, achieve our key performance indicators and transform patient care.

Our key resources



People

Our employees 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 global market potential.

Our offering



BioRinse™ Technology

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

This process has the potential to provide better clinical outcomes as it contains 100% allograft bone, maintaining the five key natural bone growth factors, and can 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, improving our manufacturing capabilities.



Our key activities

01

Commercialisation

Currently we have a portfolio of 12 primary product lines on the market, with new product line extensions in the pipeline. It is also our intention to expand into new geographic territories.



02

Optimisation

Ensuring that we 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 can leverage cross-selling opportunities through our distributor network and industry relationships.



Team

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



Innovation

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 expanding geographic presence.

We create value for our stakeholders

Patients

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

Partners

Strong strategic partnerships with large scale businesses and continued growth opportunities in the long term.

Physicians and healthcare providers

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

Shareholders

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

Employees

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



READ MORE ABOUT OUR STAKEHOLDERS ON PAGES 28 AND 29.

Our strategic growth drivers

Strategic objective

Description

2019 performance



Accelerate US market penetration

The US is the largest healthcare market in the world and where we see the greatest opportunity.

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.

- Second shift commenced in San Antonio facility
- Achieved further GPO coverage taking total to c.95% for DermaPure
- Secured additional prestigious hospital accounts
- DermaPure non-oriented soft launch
- New dental distributors signed
- Further penetration into high volume accounts



Exploit global market potential

Our current commercialisation efforts are focused on the US markets; however, there is the opportunity and market demand for us to enter new geographic territories.

We have been restricted in our ability to provide our BioRinse products for international expansion due to our processing capacity constraints. However, where opportunities have arisen that can be fulfilled without detrimental impact on existing business, we have supplied product into other territories such as Canada, Central America, South America and Saudi Arabia.



Broaden strategic partnerships

At the beginning of 2018 we revised our commercial strategy, which we continue to implement, with a focus on establishing and building strategic partnerships to further our market penetration.

This allows for the potential to increase OEM agreements and initiate discussions around joint IP collaborations.

- Continued to strengthen relationships with existing strategic partners, particularly Arthrex, Inc. and ARMS Medical.
- Brought DermaPure non-oriented to market following consultation with ARMS Medical
- Entered discussions with other significant parties for IP and product development collaborations



Strengthen portfolio

Our success is reliant upon the ability to commercialise our current product portfolio and the potential for augmenting this with line extensions and new innovative products.

We therefore look to establish a database of compelling clinical data to validate our technology platforms and further our physician conversion rates.

These clinical data portfolios are also imperative when we seek new strategic partnership opportunities and when navigating regulatory clearance in new territories.

- Undertaken 11 additional DermaPure case studies for different clinical applications
- Signed 12 new Key Opinion Leaders for DermaPure
- Launched DermaPure non-oriented
- Undertaken two case studies for BioRinse portfolio



Focus and goals for 2020	Link to KPIs	Link to risks
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- Commence phase one of capacity expansion programme
- Strengthen relationships with strategic partners
- Extended roll out of DermaPure non-oriented product
- Expand distribution network
- Launch new product SKUs

- Group sales growth
- Increase number of strategic partnership and distribution opportunities

- Finance – Insufficient funds to invest in the required expansion
- Operational – The Group is unable to expand in line with demand

- Commence phase one of the capacity expansion project
- Evaluate opportunities for OrthoPure XT in the UK and select European markets
- Ramp up European market awareness of BioRinse products through our distribution network
- Enter distribution arrangements with overseas partners for the supply of our dCELL® product range
- Investigate potential licencing opportunities in other geographic territories

- Group sales growth
- Increase number of strategic partnerships and distribution opportunities

- Finance – Insufficient funds to invest in the required expansion
- Operational – The Group is unable to expand in line with demand
- Clinical & Regulatory – Loss of license or restriction due to regulatory failings
- Political landscape

- Ramp up DermaPure non-oriented opportunity and market penetration in partnership with ARMS Medical
- Launch new product developments with strategic partners
- Enter new clinical applications and geographic territories with new and existing strategic partners
- Identify potential distribution opportunities for SurgiPure XD

- Group sales growth
- Clinical data collection

- Operational - The Group is unable to expand in line with demand
- Commercial - Competitor product could reach the market first or outperform the Group's products

- Evaluate opportunities for OrthoPure XT in the UK and select European markets
- Launch new product developments with strategic partners
- Collect additional real work clinical data through case studies
- Commence post marketing clinical studies

- Clinical data collection
- Improve product portfolio and pipeline
- IP collaboration

- Clinical & Regulatory – Loss of license or restriction due to regulatory failings
- Commercial – Competitor product could reach the market first or outperform the Group's products
- Finance – Insufficient funds to commence or complete trials
- Operational – The Group is unable to expand in line with demand

 READ MORE ABOUT OUR KPIs ON PAGES 14 AND 15.

 READ MORE ABOUT OUR RISKS ON PAGES 22 TO 25.

Future milestones: strategy in action

Strategic objective	Focus	Near 6–12 months
 <p>Accelerate US market penetration</p>	<p>Drive sales growth of current products in the US market through current direct and indirect distribution channels and increasing GPO relationships</p>	<ul style="list-style-type: none"> – Launch DermaPure non-oriented for urogynaecology applications – Increase operational capacity through commencement of phase 1 of the capacity expansion programme
 <p>Exploit global market potential</p>	<p>Continue to build global sales reach through expansion of distribution partnerships and licensing agreements</p>	<ul style="list-style-type: none"> – Target additional territories for distribution and licensing opportunities
 <p>Broaden strategic partnerships</p>	<p>Pursue further, and develop existing distribution, licensing or IP collaboration partnerships</p>	<ul style="list-style-type: none"> – Sign up additional strategic partnerships for OEM and product collaboration opportunities
 <p>Strengthen portfolio</p>	<p>Bring new products and product line extensions to market from pipeline of products currently in development</p>	<ul style="list-style-type: none"> – Identify potential distribution opportunities for SurgiPure XD – Evaluate opportunities for OrthoPure XT in the UK and select European markets



Mid 12–18 months

- Collection and publication of real world clinical data
- Assess capital availability for phase 2 of the capacity expansion programme

Long 18+ months

- Collaboration with strategic partners for future product development

- Continued expansion of UK and EU BioRinse distribution opportunities
- Pursue licensing and partnership opportunities

- Focus on business development for geographic expansion

- Increase licensing and strategic partnerships

- Pursue further joint IP opportunities

- CardioPure manufacturing and marketing license

- Collaboration with strategic partners for future product development

Key performance indicators

KPI	Definition	Why this is important?
FINANCIAL		
Cash position	Maintaining sufficient cash resources to enable the business to develop.	Ensuring sufficient cash resources to support the investment and working capital requirements of the Group for the long-term success of the business.
Group sales growth	An increase in top-line revenue delivered across key commercial divisions.	In order to reach sustainable profitability, Group sales must increase to allow investment in development and make returns to shareholders.
CLINICAL		
Clinical data collection	Clinical data is increasing in importance as physicians and healthcare providers seek the best products for both clinical outcomes and economic value.	The regulatory pathways for our porcine products is dependent upon the ability to produce, run and monitor a successful clinical trial. Clinical data is collected in post marketing studies to demonstrate our differentiating factors and reinforce the economic and clinical benefits, and drive clinical adoption.
IP collaboration and exploitation	Intellectual property is at the heart of our business for both dCELL [®] and BioRinse portfolios. Collaboration allows 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 collaboration allows us to leverage our R&D capabilities while utilising the large marketing and distribution arms of our partners.
COMMERCIAL		
Improve product portfolio and pipeline	In order to ensure the business can continue to develop there is a need to continually assess, and when appropriate, develop and launch products where market needs are identified.	In order to improve our competitive advantage, it is important that we augment our product portfolio with product line extensions, which increase our market penetration and augment the existing product portfolio; these line extensions generally have an expedited route to market and favourable margins.
Increase number of strategic partners and distribution opportunities	Strategic partnerships are key to our commercialisation strategy, allowing us to access partners' distribution networks, potential licensing opportunities and R&D collaboration.	To enable our products to reach the largest possible audience, it is important that we continually develop our routes to market and expand our network with new partners.
OPERATIONAL		
Increase manufacturing capacity	We must ensure that we have enough processing capacity to meet the growing demand, with the correct technical and operational experts to facilitate this.	As we look to grow our top-line revenue, and further market penetration with our strategic partners, we must be able to process enough inventory to meet demand. Without this, we risk losing potential partners as they move their requirements elsewhere.
HR		
Staff retention and development	The retention and development of employees is key as we invest in relevant training, qualifications and development, while 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	With increasing scrutiny 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.	Our facilities require specific storage, temperature and air quality, all of which can consume a large volume of energy, especially when required 24 hours a day. We must ensure that we take all available options to reduce our energy consumption and increase our environmental sustainability.

Commentary

Link to strategy

Following the repayment of \$5.5m to MidCap Financial our cash resources were limited and started to hinder the growth of the Group. However, it is believed that the equity placing announced post year-end will allow for the investment into facilities and working capital to drive the future success of the business.



A blend of all four strategic growth drivers

Despite operational challenges due to manufacturing capacity constraints during 2019 we increased the top-line sales by 12% year-on-year. As we see the additional supply coming online, through the operational initiatives implemented, to meet this growing demand, we expect this top-line sales growth to accelerate.



A blend of all four strategic growth drivers

We continue to collect clinical data to strengthen our portfolio following the CE mark certification for OrthoPure XT to supplement the three years clinical data, to date. We have a number of respected Key Opinion Leaders who work with us undertaking case studies and presenting at prestigious conferences across the world. During 2019 we undertook 11 new case studies for DermaPure, and 2 for BioRinse products. We look to continue to increase the number of case studies collected moving forward.



Accelerate market penetration
Strengthen portfolio

We continuously review our IP portfolio to ensure that we have in place the correct level of protection for patents and processes in territories and ensure that infringement does not occur. Although the dCELL process is patent protected, we keep the BioRinse process as know-how in order to protect this IP.



Strengthen portfolio
Accelerate market penetration

During 2019 we launched DermaPure non-oriented specifically for urogynaecological applications, which provides increased yields from donors by utilising different layers of the dermis and has a favourable margin impact due to the minimal additional work required.



Strengthen portfolio
Accelerate market penetration

During 2019 we expanded our GPO approvals to c.95% of the US hospitals under these agreements allowing them to access DermaPure. This extensive coverage has enabled us to expand our distribution network and customer base which now includes several key hospital accounts.



Broaden strategic partnerships

During 2019 we initiated a second shift for processing in our San Antonio facility, specifically for the BioRinse product portfolio, whilst outsourcing a percentage of our DermaPure production to CTS. We also signed a lease on a 21,000 sq ft facility that will allow us to expand further once the required funding is secured.



Accelerate US market penetration
Exploit global market potential
Broaden strategic partnerships

In Q4 2019 we undertook a restructuring of our employee base to focus on commercialisation and operational activities. As part of this exercise we increased the number of processors and key operational hires in the US, allowing us to commence a second shift for BioRinse processing. Our succession plan came to the fore with the promotion of Kirsten Lund to Group Finance Director.



A blend of all four strategic growth drivers

During the year we implemented an energy reduction programme at the UK manufacturing facility to allow for more efficient clean room operation and shut down during periods of inactivity leading to an overall energy saving of 35%.



A blend of all four strategic growth drivers

Our management team

We have a senior management team with extensive experience in the healthcare industry and the capital markets. They are challenged and supported by both an experienced and well balanced Board of Non-Executive Directors, together with the teams of employees that they lead.



GARETH JONES
Interim CEO

Gareth has 27 years' experience in finance having qualified as a Chartered Accountant in 1993 with PwC. Gareth joined Tissue Regenix in November 2018 as CFO before moving into the COO position, then stepping into the interim CEO role August 2019.

In recent years he has worked as Chief Financial Officer for LSE listed Applied Graphene Materials. Previously, 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. 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 c.\$480m. He graduated from the University of Nottingham in 1989 with a BEng.



KIRSTEN LUND
Group Finance Director and
Company Secretary

Kirsten Lund was promoted to the position of Group Finance Director in November 2019 after being Group Financial Controller for over a year. Kirsten leads the finance teams in both the UK and US, and advises the Board on all financial matters relating to the Group.

After joining Tissue Regenix in 2010 as Finance and Administration Assistant, Kirsten successfully completed the ACCA qualification, achieving chartered status in 2015. Kirsten has been a key member of the team throughout the last 10 years. Utilising the knowledge acquired over the years in the healthcare sector, Kirsten provides invaluable experience and understanding around the Company structure and routes to market, and works closely with the management team to help drive forward the strategy of the business.



DANIEL LEE
President US Operations

Daniel Lee has nearly 30 years' experience in the medical device and biologics industry, ranging from product innovation to commercialisation 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 include 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 10 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 13 patents on implants and instruments used in orthopaedic and general surgery.



JOEL PICKERING
President, TRX BioSurgery

Joel Pickering joined Tissue Regenix Wound Care Inc. in October 2015 to assume the leadership of the US marketing organisation. Joel moved into the position of President in January 2017 and now guides the commercial marketing strategy for DermaPure® in the United States. Joel brings a wealth of wound care marketing experience dating back to 1996, with companies such 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 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.



MIKE IZON
R&D Director

Mike Izon joined as Head of QA/RA 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.

Interim CEO operational review



Gareth Jones

INTERIM CEO



In 2019 we focused on optimising our operational capabilities to enable us to deliver the ever-increasing volume of product demanded by our customer base.

During 2019 we implemented a number of efficiency improvements throughout our supply chain and operations, as we look to increase throughput at our San Antonio facility to service the increasing commercial demand from both existing, and new partners, and extend our reach into additional territories where we see significant opportunities.

Divisional performance

BioSurgery reported significant underlying growth, with a 25% year-on-year increase.

This was largely driven by our strategic partnership with ARMS Medical, specialist distributor for the urogynaecology applications. Demand is growing in the urogynaecology marketplace due to the withdrawal of many synthetic mesh products. In September 2019, we undertook a soft launch for a 'non-oriented' DermaPure product to specifically address these applications.

This product is processed from the second layer of dermis tissue and therefore has no basement membrane; however, it maintains the same biomechanical properties, extracellular matrix and regenerative activity of DermaPure. Removing the requirement for orientation makes handling and application in surgical settings much simpler, and initial feedback from clinicians has been extremely positive; we therefore see great potential for this product line extension in the future. Outside of the clinical benefits, this product line extension allows for the utilisation of layers of the dermis, which were previously unsuitable for processing, thereby improving donor yields and the number of patients treated.

After outsourcing a percentage of our DermaPure production to Community Tissue Services (CTS), we worked closely with them throughout the year to improve both processing efficiencies and yields. Production transfers can be operationally challenging, however, having devoted the necessary resources to ensuring a smooth transition, we anticipate a significant increase in output from this partner during 2020.

The Orthopaedics and Dental division was more significantly impacted due to the capacity constraints experienced throughout the year, resulting in year-on-year growth of 5%.

Recognising the need to improve our supply chain, during H1 2019 we created a donor services team, recruiting additional specialist skills. The team worked closely with the production staff and this manifested in donor processing increasing by more than double throughout the year, with a commensurate increase seen in yields in the latter months as supply chain initiatives were pulled through. In order to ensure that we can continue to increase our processing and meet demand, we now have agreements in place with a number of donor recovery agencies resulting in improved access to donors meeting our quality criteria.

In conjunction with this, during H1 we commenced the hiring and training of technicians in order to commence a second shift for processing of the BioRinse products. Due to the highly skilled nature of this work, in a regulated environment, the hiring process takes time as technicians need to undergo a rigorous training programme, which coupled with the three to four month lead time for the osteoinductivity testing for this product range, meant that we did not start to see the benefits of this in our revenues until late in Q4. However, it is anticipated that moving forward into 2020 the additional revenue associated with these initiatives will become apparent on a consistent basis. The revamping of the front end of the business has meant that we are in a far stronger position to capitalise on commercial opportunities during 2020 and beyond.

In Germany, the Company's controlled joint venture, GBM-v, has continued to increase sales from their cornea products and has reached a point of becoming financially self-sustainable through the revenues generated. They continue to pursue the required regulatory clearance for the CardioPure portfolio and work closely with the team in the UK in order to decipher the best path forward for this portfolio.

Funding

In June 2019 we announced a credit facility of up to \$20m with MidCap, via a term loan split into three tranches and a Revolving Credit Facility ("RCF"). We immediately drew down the initial \$7.5m term loan and were granted access to a \$3m RCF; the additional tranches were contingent upon agreed revenue targets and a \$5m net equity raise. In November, due to operational challenges discussed, we renegotiated this agreement repaying \$5.5m of the term loan.

This repayment reduced our net cash position at 31 December 2019 to £2.4m. However, the Company implemented several cost saving initiatives to extend the cash runway including the restructuring of the employee base. In Q4 2019, a number of positions were made redundant, largely in the R&D and clinical function in Leeds; a cost saving that

is expected to deliver £1m per annum from 2020. In the trading statement released on 22 January 2020, the first signs of these cost savings were evident. As we move towards break even we will continue to assess our cost base to ensure funds are deployed in the most efficient manner.

Personnel

Following his appointment in January 2019 as President of US Operations, Daniel Lee has been a key member of the team working to increase our throughput, improve yields, and meet customer demand.

Alongside Daniel, in Q1 2019 Tina Trimble joined as VP Donor Services. Tina is well respected throughout the industry holding a seat on the Board of the American Association of Tissue Banks, and has become a key member of our team, implementing several initiatives in order to improve our donor sourcing and processing.

Product pipeline

During 2019 we undertook a soft launch of DermaPure non-oriented, specifically for use in urogynaecology applications, with our strategic partner ARMS Medical, and to date have received positive feedback from clinicians.

Capacity expansion project

As previously documented we are challenged with capacity constraints at our San Antonio facility. In the existing facility we currently face two limiting factors: namely, space for freezers, which limits the amount of donor tissue we can hold on site, and clean room capacity. We currently have five clean rooms, of which four are dedicated to BioRinse products, and one that processes DermaPure.

With the support of the MidCap funding we were able to take the first steps towards increasing our manufacturing footprint, securing a ten year lease on a 21,000 sq. ft facility adjacent to our existing facility in San Antonio, Texas. We believe our plans, which are in two phases, will provide a significant capacity increase and help us fulfil the demand for our products. However, these expansion plans are subject to completion of the recent funding.

We signed the lease, with an option to buy, on the new facility in August 2019. Universal City provided a grant of \$0.3m to support and permit the upgrades of utilities and infrastructure serving the new facility, which has now been completed.

Phase one of the expansion project will involve moving the freezer capacity into the new facility, allowing for two additional clean rooms to be developed, bringing the total number of clean rooms to seven, in

the current facility. This would also increase our potential freezer capacity by threefold allowing us to hold more donor tissue onsite. We would expect this phase to be completed in around six months, which given the three to four month lead time for BioRinse products, would allow for the first revenues to become evident roughly nine to ten months after commencement of this phase.

Our current intention is for phase two to provide a further ten clean rooms in the new facility. The timing of this phase has not yet been finalised. Once fully operational, it is expected that this completed expansion programme will increase the Company's revenue generation potential by up to c.\$36m per year.

Revenue per additional clean room is inherently an estimate and depends on several factors including the product mix, the number of shifts, the availability of technicians and donor tissue and continuing product demand. Nonetheless, we are confident that enough demand exists to justify the capacity expansions outlined above.

Post balance sheet events

In January 2020 the Group was hit by a cyber attack, which temporarily impacted our ability to process at the facility in San Antonio. We quickly implemented an action plan to mitigate the potential impact, and believe that there were no indications of any external transfer of sensitive or financial data from the business. There was a short-term impact on our ability to service customer demand as we were unable to release batches for distribution in line with the necessary regulations.

During the weeks that followed the attack, the San Antonio team worked to catch up with this demand, and in April 2020 we were able to report that, despite this incident, revenue increased by 18% year-on-year for Q1 2020. Following the incident, the Company reported this attack to all relevant authorities as required, has reviewed its IT service providers and implemented additional data security procedures to reduce the risk of a similar incident in the future.

As with most businesses, the Company was impacted by the COVID-19 pandemic that began in Q1 2020. The priority of the Company throughout this time was to protect the health and wellbeing of our employees and stakeholders, and the Company ensured to implement all relevant government-led policies in relation to this. By undertaking certain initiatives, there was minimal disruption to the processing undertaken at the facility in San Antonio, which continued to show strong production throughput. As the impact of COVID-19 becomes more evident, we will continue to monitor and adapt our approach. During Q2 it is apparent that reprioritisation of healthcare professionals

during this time will lead to a notable decline in the number of elective procedures undertaken at hospitals, which was initially most evident in the urogynaecology and dental applications. We continue to work closely with our partners and distributors to ensure that, once these procedures are recommenced in a normalised manner, enough inventory of all products will be available to meet demand.

At the facility in Leeds where processing of the porcine products is undertaken, in-line with the UK Government guidelines, our technical and operations staff were furloughed until at least the end of June 2020. However, the Group holds sufficient inventory to meet near-term demand of these particular products.

As a result of the uncertainties surrounding the level and duration of disruption from COVID-19, we are unable to determine how long it will take to catch up on postponed surgical procedures therefore, while sales were not materially impacted during Q1 2020, the Board is not able to provide clarity on the outlook for 2020 until there is greater visibility around the market environment.

In May 2020 we announced a strategic collaboration with a top 10 global healthcare company to bring to market a newly developed product line. This agreement for white label manufacturing follows collaboration between the R&D teams of both companies using one of the Group's proprietary technology platforms to address orthopaedic soft tissue repairs. Agreements such as this underscore the differentiation of, and increasing market demand for, our products, providing further validation of the exciting growth potential for the business once we have completed the planned expansion of our processing capacity, and ensures that we continue to drive our commercial strategy forward, as illustrated by our strategic growth drivers, for the continued success of the business.

We were also awarded the CE Mark certification for OrthoPure XT in May 2020, for use in revision of the Anterior Cruciate Ligament following re-rupture and also the reconstruction of other knee ligaments, including multi-ligament procedures following trauma.

On 22 May 2020 the Group announced that it had completed an equity fundraising, by issuance of ordinary shares, to raise gross proceeds of £14.6m, which provided the resolutions are passed at the General Meeting on the 9 June, will allow for the commencement of the capacity expansion programme and provide sufficient working capital until at least December 2021. We believe that this investment will move the Group into a new sphere of opportunity and competitive market positioning.

Financial overview

Revenue

In the year ended 31 December 2019 revenue increase by 12% on an underlying basis or 8% constant currency basis to £13,033k (2018: £11,619k). As expected, the year was second half weighted (47%/53%) as throughput in our San Antonio facility more than tripled in the year. However, due to the lead times involved it is expected that a significant proportion of this increased processing will become available for sale during H1 2020.

Revenue from the BioSurgery division, which utilises the legacy Tissue Regenix dCELL® Technology in product DermaPure®, reported a year-on-year increase in revenues of 25% to £4,233k (2018: £3,381k). The withdrawal of many synthetic products from the urogynecology market meant that there was increasing demand for biologic products such as DermaPure®. Working closely with our strategic partner, ARMS Medical, we saw strong demand in this sector, resulting in a year-on-year growth of 57%. The expectation going into 2020 is that this sector will continue to experience high levels of growth.

We continued to expand our GPO coverage and now have access to c.95% of relevant US hospitals under GPO agreements. This coverage enabled the business to continue to grow its distribution network in the US and secure several leading marquee accounts.

The Orthopaedics and Dental division reported annual revenues of £6,724k (2018: £6,396k), an increase of 5% year-on-year. The capacity constraints within the San Antonio facility meant that output for this division was constrained. Despite these limitations, demand for products within this division remain strong, and following several operational changes within the San Antonio facility during 2019, we expect the orthopaedic portfolio to experience a notable increase in output in 2020.

Our controlled joint venture in Germany, GBM-v reported high levels of demand for its cornea products, with year-on-year growth of 13% to £2,076k (2018: £1,842k).

Cost of sales and gross profit

Gross profit for the year is £6,019k (2018: £5,917k). Gross margin percentage decreased to 46% (2018: 51%) due to product mix with the CellRight BioRinse portfolio contributing a lower percentage of overall sales due to capacity constraints, which have been addressed throughout the year, as discussed. As the business continues to increase capacity to meet demand, the margins are expected to recover throughout 2020.

Included in costs of sales is cost of product £5,803k (2018:£4,723k) and third party commissions £1,211k (2018: £979k).

Administrative expenses

During the year administrative expenses decreased by £985k to £13,198k (2018: £14,183k), excluding exceptional costs, largely due to a reduction in research and development and sales and marketing costs. The increased focus on commercial activities meant that the Group was able to reduce its research and development expenditure by £268k to £1,368k (2018: £1,635k). In addition, the Group sought to reduce its overhead cost base resulting in 18 positions being made redundant in Q4 2019, largely from the UK side of the business.

Exceptional items

Net assets were assessed for impairment and a expense of £1,311k was posted in recognition of SurgiPure development costs in BioSurgery segment and fixed assets in the Central and Other segment.

Redundancy costs in relation to the 18 positions made redundant in Q4 2019 are accounted for in exceptional items and amounted to £164k.

Litigation costs of £69k were charged in the year.

A credit of £1,523k was due to the CellRight contingent consideration which was not met.

Finance income/charges

Finance income of £17k (2018: £72k) represented interest earned on cash deposits. Finance charges for the year were reported at £477k (2018: £262k), and related primarily to interest charges and associated costs for the MidCap loan arrangement.

Taxation

The Group continues to invest in developing its product offering, and as such is eligible to submit enhanced research and development tax claims, enabling it to exchange tax losses for a cash refund. In the year to December 2019, a refund of £488k was receivable (2018: £790k). The year-on-year reduction was a result of the business continuing to move its resources away from research and development to more commercial activities.

Corporation tax payable in the US amounted to £29k (2018: £72k). Gross tax losses carried forward in the UK were £43,533k (2018: £43,254k). The Group does not currently pay tax in the UK. A deferred tax asset has not been recognised as the timing and recoverability of the tax losses remain uncertain.

Loss for the year

The loss for the year was £7,106k (2018: loss £8,259k) resulting in a basic loss per share of (0.60p) (2018: loss (0.70p)).

Balance sheet

At December 2019, the Group had net assets of £24,595k (2018: £32,570k) of which cash in hand totalled £2,380k (2018: £7,816k).

Intangible assets decreased through amortisation charges in the year. A further £213k of development costs were capitalised in the year, which were then fully impaired at year end.

In addition to testing the CellRight cash generating unit (CGU) for impairment, a full impairment test was performed on the Group's CGUs as the Group's market capitalisation at 31 December 2019 was lower than net assets. This impairment testing resulted in an impairment of £1,311k, which has been disclosed within exceptional items.

Net working capital decreased in the year, which reflects the continued growth of the business. The balance sheet included corporations tax receivable of £1,035k (2018: £1,200k) in respect of UK research and development tax credits.

As part of the CellRight Technologies acquisition agreement financial milestone payments were contingent upon certain revenue targets being achieved. The capacity constraints experienced at the San Antonio facility meant that these goals were not met for 2019, as such the costs totalling £1,523k were released. This was the last financial milestone due for payment under this acquisition.

Borrowings

Non-current liabilities represent the £2,286k debt facility. This includes £1,525k of the term loan and £761k of the revolving credit facility. More information on page 64.

Dividend

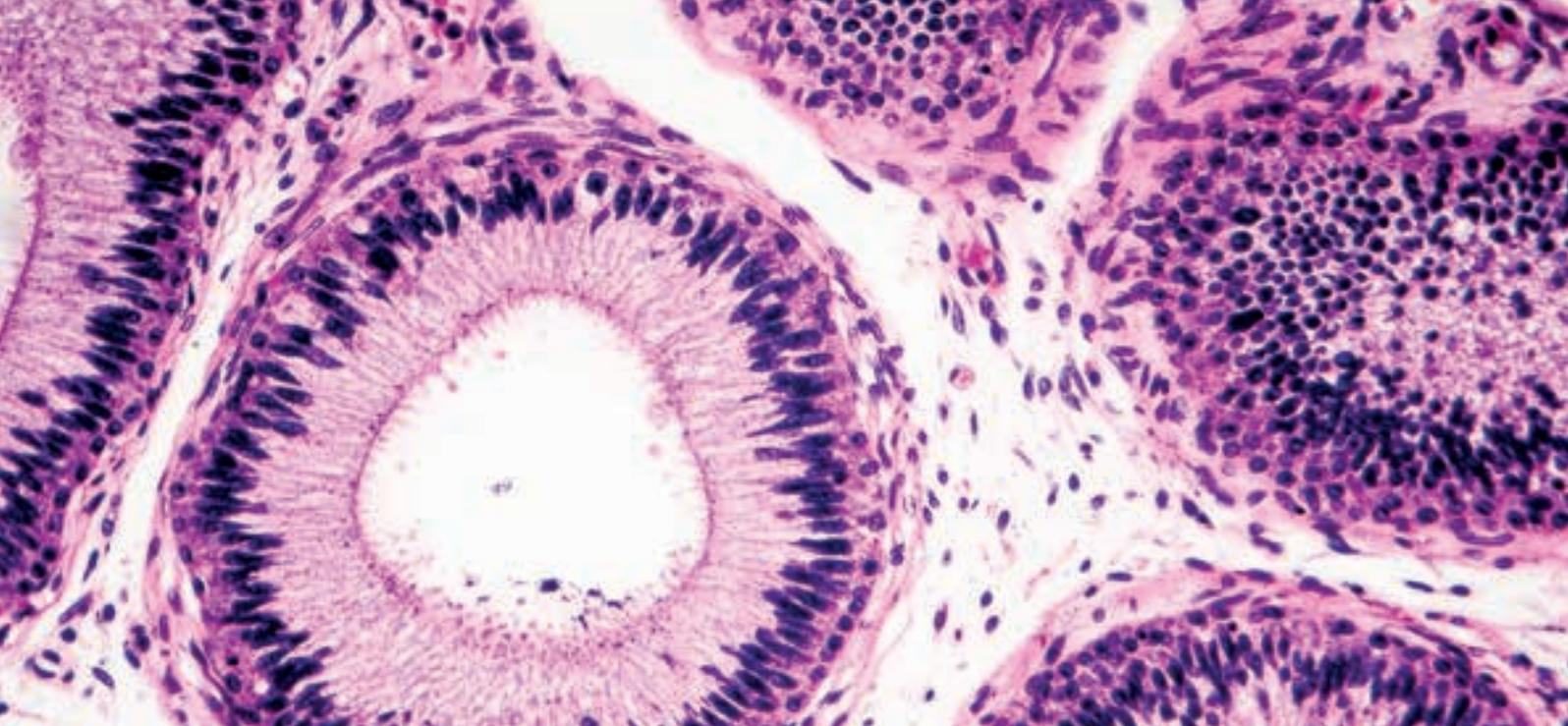
No dividend has been proposed for the year to 31 December 2019 (2018: Nil).

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

These financial statements have been prepared on a going concern basis, given the current cash flow projections forecast for the Group to 31 December 2021. Funding



requirements are reviewed on a regular basis by the Group's Chief Executive Officer and Group Finance Director and are reported to the Board at each Board meeting, as well as on an ad hoc basis, if requested. Until sufficient cash is generated from its operations, the Group remains reliant on external funding including current debt facilities provided by MidCap, to meet its working capital requirements, capital investment programme and other financial commitments.

On 22 May, the Group announced that gross proceeds of £14.6m had been conditionally raised through an offer of new ordinary shares in the Company to Institutional and other qualifying investors. This fundraising is conditional on shareholder approval at a General Meeting of shareholders to be held on 9 June 2020 and also to admission of the fundraising shares to trading on AIM. In reporting the Group's finances on a going concern basis, the Directors have assumed the appropriate resolutions at this Meeting will be passed. However, if the necessary resolution is not passed, the fundraising will not proceed and the Company would not have funds immediately available to continue executing its current business plan. In this eventuality, the Directors would need to consider alternative sources of adequate funding. Should the Company be unable to raise enough funds, shareholders could be at risk of losing all or a substantial amount of their investment.

The COVID-19 pandemic has affected most businesses during H1 2020. As a result of the reprioritisation of healthcare professionals during this time, there has been a decline in elective procedures undertaken across a number of medical specialities that use our products. Given the uncertainty around the level and duration of disruption from COVID-19,

it is difficult to determine how long the current situation may last, and the time taken to catch-up any postponed surgical procedures thereafter. However, the Board, in compiling possible cashflow projections for the business, has considered a number of scenarios regarding the effect of reduced and delayed revenues due to COVID-19, and has undertaken market soundings regarding the likely timeframe for the recommencement of procedures. It has concluded that, if additional funds are received as expected, there will not be a significant long-lasting impact on the capability of the business to carry out its commercial activities.

In summary, the Directors have considered their obligations in relation to the assessment of the going concern basis for preparation of the financial statements 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 22 to 25. They have concluded that it remains appropriate to prepare the financial statements on a going concern basis, noting that assumptions relating to the completion of the fundraising give rise to a material level of uncertainty in respect of the going concern assumption.

The financial statements do not include any adjustments that would result in the basis of preparation as a going concern being inappropriate.

Post balance sheet events

The Group was victim to a cyber attack in January 2020; no material financial impact has been determined and operations are fully back up and running.

Due to the impact of the COVID-19 pandemic in Q1 2020, UK operations and technical staff were furloughed under the Government job retention scheme, and processing at the UK

facility was temporarily halted. In the US, due to initiatives implemented, processing at this facility continued without disruption however, due to the reprioritisation of healthcare professionals during this time, elective surgeries such as urogynaecology or dental procedures were postponed. The Company secured over \$1m of US Government backed loans to assist with the US overhead costs during this time. These loans have a two-year term and carry a 1% annual interest rate deferred for six months. However, under the Loan agreements, the principal will not require repayment if the funds are used to support employee payroll, healthcare, utilities and rent payments within the US during the next two months. The Company intends to use the funds to support these activities and therefore expects the Loan not to require repayment.

Principal risks and uncertainties

The principal risks and uncertainties facing the Group are set out on pages 22 to 25.

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 beyond 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.

Risks

Our risk management framework

Accountability for reviewing and monitoring

The Board

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

Audit Committee

In accordance with our governance practices, the Audit Committee supports the Board of Directors in monitoring the Group's risks.

Operational

At an operational level, we monitor monthly performance against objectives allowing us to track performance management, and identify any potential improvements to our structure and operational efficiencies, as well as monitoring and updating any existing or potential risks and corresponding mitigating actions.

Responsibility for implementation

The Board reviews and updates risks on a regular basis, maintains a risk register and addresses each potential risk in terms of likelihood and impact on the business.

We have identified six areas of potential risk: product development; operational; clinical and regulatory; finance and IT; HR; and commercial. The Board believes the following risks are the most significant for the Company, however, they may not necessarily comprise all the associated or potential risks attached to the Company. Alongside risks associated with changes in the market or economic conditions, the political landscape, legal, regulatory or tax implications, there may also be risks that the Directors are currently unaware of but that could have a significant effect on the Group's ability to carry out its business. A list of the principal risks and mitigating factors facing the Group at this time are listed below.

Risk	Potential impact	Mitigating factors	Trend
 Finance and IT			
Risk that there are insufficient funds to deliver products to the market, invest in required expansion or provide the working capital required	<p>We require investment into our infrastructure to bring our product portfolios to market and service the increasing demand from our current and future customers. Without this, the Group will be unable to deliver the anticipated future revenue growth.</p>	<p>The Board has oversight of all significant cash spends and a well-established control environment, which includes internal forecasting, monthly reporting and approval limits on all purchase orders.</p> <p>In order to maintain the cash position, the Company reviews business priorities and demands to ensure that funds are invested in the most appropriate manner to deliver a return on investment and grow the business positively.</p>	
Risk that the Group will be subject to a cyber security breach or failure of IT systems	<p>The Company is reliant upon systems to allow for, amongst other things, the accurate records and reporting of donors. Any potential failure of systems could impact the Group's ability to process and distribute products, lead to a data security breach, loss of financial information and have potential financial implications.</p>	<p>The Group was hit by a cyber security attack in January 2020. No ongoing material impact to the business was experienced, however, processing was temporarily halted at the San Antonio facility while the restoration and testing of systems was completed. The Group has since reviewed its IT service providers and security procedures and continues to do so on an ongoing basis moving forward.</p>	
 Operational			
Risk that the Group may experience an adverse event resulting in a loss of license or facility shutdown e.g. damage due to fire, arson, flood or other adverse events, or retraction of licence from the FDA, AATB, HTA or other regulatory body	<p>As the Group manufactures most products in-house the loss of a manufacturing facility would 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 significant financial implications.</p>	<p>The Group has a track record of positive feedback following audits and inspections and has established control environments and procedures. Facility insurance is in place in case of adverse events and second source manufacturing options have been identified.</p>	
Risk of over dependency on single supplier or in-house processing	<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. 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 identified to ensure that there is always a secondary source for raw goods, and potential manufacturing capacity. We have expanded the number of donor services agencies in the US that we work with and have two suppliers of porcine tissues in the UK. All suppliers undergo a stringent audit to ensure that they meet the Company's internal standards and those imposed by third party moderators.</p>	
Risk that the business is unable to expand in line with growing demand	<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. If we are unable to expand in line with this demand this could result in a loss of business through customer dissatisfaction and reputational damage.</p>	<p>Additional processing for the dCELL® DermaPure product was obtained through Community Tissue Services, which in turn freed up additional capacity for the BioRinse product portfolio in the San Antonio facility, and a second shift was also commenced in the San Antonio facility.</p> <p>Additional capacity was also secured in August 2019 when the Company took out a lease on a 21,000 sq ft facility; this capacity is expected to become operational once the necessary funding is secured.</p>	

Risks

continued

Risk	Potential impact	Mitigating factors	Trend
 Clinical and regulatory			
Risk that products fail and cause death or injury on implantation into patients	Should a product fail upon implantation or incur an adverse reaction due to the product properties, the Group would be at risk of legal action, potential loss of earnings through product retraction from the market and reputational damage.	Before commercialisation, a series of clinical and safety checks are run dependent on the nature of the product. For our porcine products that require a full clinical trial, this will initially be within an animal model to confirm its safety before progressing to the regulated clinical trial to judge the performance of the product. An external regulatory body review is undertaken and once market clearance is gained, comprehensive training is provided for sales representatives and surgeons prior to utilisation of the product. For our human tissue products, the necessary clinical performance trials are commenced prior to commercialisation and all products are issued with detailed instructions for use.	
Risk of loss of license or restrictions due to regulatory failings	As the Group operates in a highly regulated environment the loss of a license to manufacture or sell products within a territory would result in reputational and financial damage to the Company.	The Group employs regulatory experts for each territory in which manufacturing takes place, or where the Group looks to navigate a regulatory clearance for a product. The Group also has a track record of positive feedback following external audits and inspections and operated in established control environments.	
 Commercial			
Risk that a competitor product reaches the market first and/or products outperform Tissue Regenix products, and the business fails to keep up with developments and new products coming to the market	Should there be a competitive product that outperforms one of the Tissue Regenix products we could lose customers and distribution opportunities. Should a competitor bring a product to market before us they could potentially have an advantage in gaining market share.	We continually monitor the commercial and competitive landscape and look to stay ahead of the trend with innovative product development and line extensions. The Group works with partners to identify potential market opportunities as it did with ARMS Medical to soft launch the DermaPure non-oriented product. The Group also continues to collect post marketing clinical data to ensure that the product offering remains differentiated.	



Risk	Potential impact	Mitigating factors	Trend
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 HR			
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<p>Risk of potential loss of key staff resulting in a loss of key information, contacts or know-how</p>	<p>The dCELL[®] process is patent protected, however, the BioRinse process is based on know-how and the Company has several trade secrets that it looks to protect. As our commercial pipeline is based upon key strategic and distribution partnerships, as well as direct sales, there is the potential that customers may feel a loyalty to a person rather than the brand.</p>	<p>The Remuneration Committee is in place to ensure that salaries and incentive schemes are benchmarked against industry standards.</p> <p>Contracts of employment are drafted to include the necessary confidentiality and non-compete clauses. The addition of key hires in the US operations team has decreased the dependence on individuals.</p>	
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 Political and economic landscape			
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<p>Risk of significant change in political or economic landscape</p>	<p>With both the UK and US undergoing periods of political uncertainty there is the potential that this could affect our ability to commercialise and import/export our products.</p>	<p>We have applied for and maintain the relevant licenses necessary for import/export of our products, including HTA and FDA approvals.</p> <p>With the initial Brexit process now confirmed we are working with the notified and regulatory bodies to assess the impact and mitigating factors we can undertake to minimise the effect of this following the expiry of the transition period.</p>	
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 Social and environmental			
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<p>Risk of unexpected social or environmental event that could affect the Group's ability to process or commercialise its product portfolio</p>	<p>As seen with the COVID-19 pandemic in H1 2020, there may be events that are outside of the control of the Group that have social or environmental impacts on the ability of the Group to continue to process its products due to, amongst other things, lack of suitable donor materials, personal protective equipment for staff or inability of staff to attend the workplace. Such events may also have an impact on the level of applicable procedures being undertaken by healthcare professionals and therefore impact the Group's revenue expectations.</p>	<p>The Group ensures to maintain sufficient stock of all required personal protective equipment and donor materials to allow for the continuation of processing should supply of these items become temporarily compromised. Due to the nature of the processing and facilities, hygiene and cleanliness is always of the highest priority. During the COVID-19 pandemic, processing continued at the facility in San Antonio with staggered shift patterns to minimise the number of employees on site at once and individual working in the clean rooms ensuring that we continue to have supply to meet the expected demand.</p>	
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Sustainability

CORPORATE

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

The Group employs a strict Corporate Governance Code and relies on its experienced management team and Board of Directors to ensure that all regulatory requirements across all business functions are met.

ETHICS AND COMPLIANCE

Operating in an industry based upon the processing of donated human or animal tissues demands the highest ethical standards throughout every facet of the Company. The Group aspires to implement and maintain these standards across all business functions and relations. The Company 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 by regulatory bodies, and regularly receive audits and inspections from external organisations such as the US Food and Drug Administration, Human Tissue Authority and American Association of Tissue Banks. The Group has a track record of passing all regulatory inspections and where recommendations are made to improve the control environment the Group would look to implement where applicable, as soon as practically possible.

Modern Slavery Statement

Tissue Regenix Group is committed to respecting human rights across all its operations and aims to work at the highest international standards in addition to local requirements. The Group fully supports the Modern Slavery Act 2015 and seeks to ensure the Group's activities and those in its supply chains do not infringe on, or encourage, human rights abuses.

Anti-corruption and anti-bribery matters

Group policies are in place for topics such as anti-bribery and anti-corruption. These policies are regularly reviewed by the Executive management team and HR departments, copies of policies are provided to all employees during their induction and changes or updates are communicated to staff accordingly.

EMPLOYEES

At the core of our business is our talented employee base, which drives the success of the Group. Through our values and behaviours, we look to develop a working environment in which employees are supported, continue development and can perform to the best of their abilities. We encourage teamwork and openness in the work place, through Company-wide policies and procedures, and by addressing the individual needs of employees to provide a functional working environment that enables a healthy work/life balance.

EQUAL OPPORTUNITIES

The Group is committed to ensuring that equal opportunities are provided to all employees and potential employees, 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 non-discrimination policy.

In all aspects of our business the Group looks to act in ways that are compliant with the necessary laws and regulations, providing our employees with a work environment that is professional, ethical and fair.

ENVIRONMENTAL SUSTANABILITY

As with all businesses the emphasis on environmental sustainability is of the utmost importance and is subject to increasing scrutiny and regulation. It is the responsibility of all employees to follow the initiatives implemented to decrease our carbon footprint, energy consumption and environmental sustainability efforts.

Throughout 2019 the Group successfully achieved a number of environmental milestones:

- Reduced energy consumption by 35% at the UK manufacturing facility, by implementing an energy reduction programme including improvement of operational procedures to allow more effective clean room operation including shut down during periods of inactivity
- Reduced our paper usage by moving to electronic documentation in our donor services and areas of our quality and regulatory functions in the San Antonio facility
- Replaced existing fluorescent lighting with energy efficient LED bulbs reducing our associated electrical consumption by 75%

We also ensure to maintain cardboard and plastic recycling units on site to encourage staff to dispose of waste responsibly and ensure where possible that any waste items associated with business functions are disposed of in this manner.

We discourage any unnecessary business travel, and aim to undertake meetings via video conferencing or telephone to minimise our carbon emissions.

CORPORATE SOCIAL RESPONSIBILITIES ("CSR")

Operating in a highly regulated environment, with particular sensitivities and responsibilities around the human donor processing, the Group ensures to operate with a high level of CSR across the business every day. Through the gift of donation we have the ability to positively impact hundreds of patients' lives, therefore, we must treat each donation with the utmost respect and provide the next of kin with information around how many patients the donation has helped, if requested; something that can often help in the grieving process.

HEALTH AND SAFETY

We see the development and maintenance of a robust health and safety framework as a necessity in order to protect our employees, customers, suppliers and external stakeholders. The Board reviews a health and safety report as part of the monthly Board pack, which contains information on any near miss events, accidents, incidents and preventative measures implemented. Over the last 12 months we have identified and replaced disinfectants used in operational cleaning to reduce the use of more hazardous chemicals that have now been classified as suspect carcinogen (having the potential to cause cancer).

IMPROVED PATIENT CARE AND HEALTH ECONOMIC OUTCOMES

Tissue Regenix dCELL® and BioRinse Technology platforms process products that can enable improvements in patient care, enhancing their standard of living, which can often be transformative for their lives.

On top of this, it allows for economic advantages in the cost of care by reducing the hospital stay length, minimised rehabilitation, in some orthopaedic cases, a reduction in reoccurring operations, and in many circumstances, a reduction in associated pain.

ENGAGEMENT AND COMMUNICATION

The Group endeavours to undertake engagement and communications with all stakeholder groups whether they are employees, investors, partners, suppliers, customers or key opinion leaders, and considers how the day-to-day activities of the Group, and the principal decisions taken throughout the year, could affect each stakeholder group.

During 2019 the Group finalised an employee engagement programme. This is now engrained into the fabric of the business covering multiple areas from employee engagement to individual development. A key focus of this was establishing the vision, mission, values and behaviours that form an integral part of the Tissue Regenix Group ethos and culture.

Values and behaviours

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



Dedication to patients

Our patients are at the heart of everything we do, and we are committed to delivering life-changing solutions



Passion for innovation

We harness creativity across all areas of our business to generate novel and effective solutions



Uncompromising integrity

We take pride in what we do and are committed to the highest standards of ethics, honesty and fairness to earn the respect of all our stakeholders.



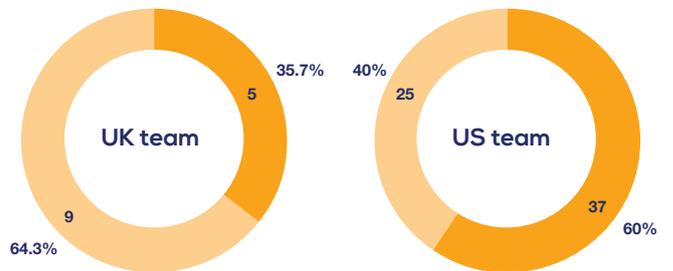
Driving for excellence

We continually seek excellence by delivering against our objectives and holding each other to account to perform to the best of our ability.

Gender diversity

Geographical split

● Male ● Female

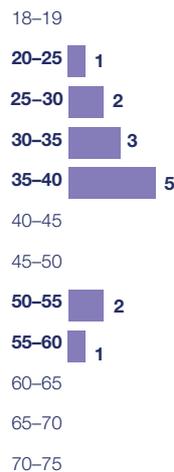


Level

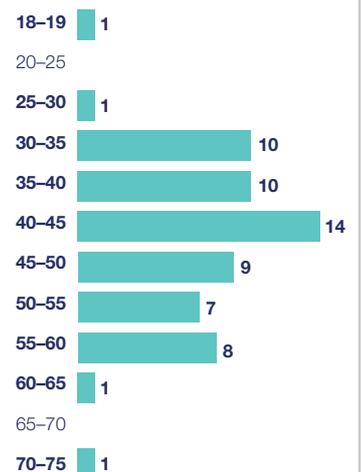


Age group

UK team



US team



Vision and mission



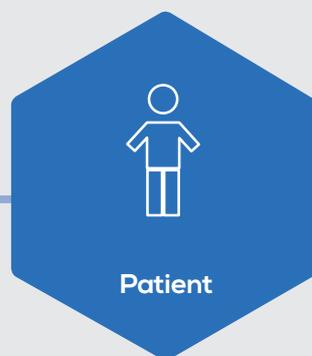
Physicians

We will **partner** with physicians to provide trusted solutions that deliver superior clinical and health economic outcomes utilising our core technology platforms for both allograft and xenograft tissue.



Employees

We will **foster** a vibrant and diverse culture that rewards performance and accountability, nurturing career development.



Patient

Mission
Restoring patient function and vitality



Customer

We will **deliver** to our customers via unparalleled service, innovative solutions that challenge the existing market place assumptions on clinical efficacy and value.



Shareholders

We will **deliver** market performances that make Tissue Regenix a focus of strategic investment for investors, providing sustained and predictable growth with above category returns.

Section 172 statement and non-financial information statement

The Directors of Tissue Regenix Group plc consider, both individually and together, that they have acted in the way they consider, in good faith, would be most likely to promote the success of the Company for the benefit of its members as a whole (having regard to the stakeholders and matters set out in s.172(1)(a-f) of the Act) in the decisions taken during the year ended 31 December 2019.

Section 172 of the UK's Companies Act describes a company director's general duty to promote the success of the company:

A director of a company must act in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole, and in doing so have regard (amongst other matters) to: the likely consequences of any decisions in the long term; the interests of the company's employees; the need to foster the company's business relationships with suppliers, customers and others; the impact of the company's operations on the community and the environment; the desirability of the company maintaining a

reputation for high standards of business conduct; and the need to act fairly as between members of the company.

Overview of how the Board performed its duty to promote the success of the Group

The following table summarises how the Board has met the s172 obligations throughout the year for the various stakeholder groups.

Stakeholder group	Why?	How?	What were the key topics of engagement and consideration in principal decisions
Investors	<p>We strive to engage with our investor base and obtain investor buy-in and confidence in our commercial strategy and strategic objectives, which is discussed in more detail on pages 10 to 11.</p> <p>A supportive base of investors interested in a long-term holding in the Company provides the stability need to allow us to execute the agreed strategy and deliver improved financial results.</p>	<p>The Board is fully committed to having open and transparent dialogues with all shareholders. Throughout the year management and Directors look to meet with, and update, institutional and retail investors through a variety of platforms; whether it be by face-to-face meeting, telephone conversation, AGM, retail investor forum, website or social media, or news announcements.</p>	<p>Key topics of engagement for investors throughout the year was around:</p> <p>The MidCap debt instrument and subsequent restructuring of this, as well as the overall financial position of the Group.</p> <p>Full year and interim financial results and reports.</p> <p>The changes to the Executive management team.</p> <p>Consideration in principal decisions:</p> <p>The Board considered the implications of the MidCap Financial loan facility on existing equity investors. As encouraged by significant shareholders who were looking to ease the requirement of further equity financing, it was agreed that this facility would provide the necessary capital with favourable non-dilutive qualities for existing shareholders.</p> <p>The Board consulted with shareholders regarding the potential capacity expansion project to ensure that this investment would create shareholder value.</p>
Employees	<p>The long-term success of the Company is built around our highly skilled and experienced workforce.</p> <p>Our technicians are highly specialised, and we have world class research and development expertise at all facilities. We continue to expand our network of partner and distributor relationships who are managed by our experienced sales and marketing teams.</p> <p>We look to create an environment where all employees can excel and value both practical experience as well as academic qualifications. We believe in investing in our workforce to maintain a low turn-over rate and build an agile and adaptive workforce who can successfully navigate the ever-evolving industry landscape to maintain our competitive positioning. We support employees with further education and qualifications, in-house support for the development of managerial roles and provide a remuneration and benefits framework that supports a healthy work/life balance.</p>	<p>Our Employee Engagement initiatives are discussed further in the sustainability report set out on pages 26 to 27.</p> <p>Throughout the year management hold a number of town hall meetings where employees are fully briefed on Company developments and have an open forum to ask questions.</p> <p>Email updates are also issued as Company news is announced to ensure that all employees are aware of the latest developments.</p> <p>Team meetings are encouraged at least once a week, with line managers then reporting directly into the CEO every week to ensure cohesion across the business. This also allows any concerns from employees to be raised with line managers and escalated to the Executive team in a timely manner if required.</p> <p>Employees also have access to the non-executive directors. During H2 2019, Randeep Grewal undertook two trips to the US to meet the US management team.</p>	<p>Key topics of engagement for employees throughout the year was around:</p> <p>The change of Executive management as Steve Couldwell retired from the position of CEO.</p> <p>The financial position of the Group as the MidCap financing was secured and restructured.</p> <p>The commencement of a second shift to increase processing capacity at the facility in San Antonio.</p> <p>The restructuring of the business in Q4 2019, which led to a number of redundancies.</p> <p>Health and safety protocols and procedures.</p> <p>Updates to quality management systems and training records.</p> <p>Consideration in principal decisions:</p> <p>The Remuneration Committee considered and approved a new bonus structure, as well as the launch of an employee save as you earn scheme.</p> <p>In reviewing the Group's strategy and restructuring, consideration was given to the vision, mission, values and behaviours as discussed on pages 26 to 27, which all employees had helped to shape.</p>

Stakeholder group	Why?	How?	What were the key topics of engagement and consideration in principal decisions
Customers and Key Opinion Leaders	<p>We work with several prestigious key opinion leaders across clinical settings in order to assist with physician conversion and drive the clinical discussion around the differentiators of our product portfolio.</p> <p>This type of engagement and clinical advocacy is crucial as we work to grow our product and brand recognition and increase the number of patients who can benefit from our market-leading product portfolio.</p>	<p>Our clinical affairs team work closely with our key opinion leaders and engage with them for a number of clinical case studies, which can be then used as evidence when discussing with new potential customers.</p> <p>Practical training sessions are undertaken to ensure that correct application and utilisation of our products is achieved, therefore improving the occurrence of superior clinical outcomes.</p> <p>We aim to attend relevant industry conferences throughout the year to increase our network of clinical professions and grow our brand exposure.</p>	<p>Key topics of engagement for customers and key opinion leaders throughout the year was around:</p> <p>Product line extensions and product improvement.</p> <p>Capacity constraint management.</p> <p>Clinical case study opportunities and outcomes.</p> <p>Consideration in principal decisions:</p> <p>When setting the Group's budget and operational priorities the Board consider the needs of customers and how to best meet their requirements</p> <p>The Board review consultation with Key Opinion Leaders and customers to drive product development and augmentation initiatives in order to optimise our product portfolio. This led to the development and soft launch of DermaPure non-oriented during 2019.</p>
Suppliers	<p>Suppliers are fundamental to the Group's ability to source high-quality raw materials and ethically sourced and handled tissues. We look to partner with suppliers who can augment our internal capabilities and build long-term beneficial relationships ultimately delivering end customer value.</p>	<p>The Group has in place a code of conduct and integrity that it expects all suppliers to meet. Audits of suppliers take place to ensure that donated porcine or human tissue is handled ethically and in line with the Group's standards. The Executive management review supplier payment practices and ensure that all suppliers are paid in a timely manner, and cost of such supplies is in line with industry standards. The Board monitors risks associated with suppliers and ensures that second sourcing options are available to minimise any business disruption should a supplier relationship fail.</p>	<p>Key topics of engagement for suppliers throughout the year was around:</p> <p>Ability to meet increasing demand as we scale the business.</p> <p>Ethics and code of conduct particularly regarding sourcing and handling of materials.</p> <p>Consideration in principal decisions:</p> <p>The Board consider and review suppliers when approving the Group strategy and commercial expansion plans to ensure that enough high-quality materials are sourced at reasonable prices to allow ramp up of processing.</p>
Society (including environment)	<p>The Group is committed to operating with a high level of corporate social responsibility and environmental sustainability. Minimising its environmental impact to benefit society as a whole.</p>	<p>The Group has implemented a number of initiatives with relation to the Group's energy consumption and carbon footprints. Details of these can be found on page 26.</p> <p>The Board have in place a stringent code of conduct and ethics and ensures to adhere to these in order to protect the wider society; this includes the auditing of suppliers to ensure that all human rights are adhered to and anti-bribery and anti-corruption policies.</p>	<p>Consideration in principle decisions:</p> <p>A focus throughout the year was to decrease the Group's energy consumption carbon footprint and waste management, protecting the wider society and local communities in which we are based.</p>

Non-financial information statement

The below table summarises where non-financial information is included in the Annual Report and Accounts:

Reporting requirements	Page location
Environmental matters	Environmental KPI on page 14 and performance on page 26
Employees	As discussed in sustainability pages 26 to 27
Human rights	Modern slavery statement on page 26
Anti-corruption and anti-bribery matters	Ethics and compliance on page 26
Social matters	As discussed in sustainability pages 26 to 27
Business model	Business model on pages 08 to 09
Principal risks	Risk management on pages 22 to 25
Non-financial KPIs	Key performance indicators on pages 14 to 15

The Strategic Report on pages 06 to 29 was approved by the Board on 4 June 2020.

Gareth Jones

Interim Chief Executive Officer, 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: January 2016

JONATHAN GLENN
Interim Non-Executive Chair

2019 Committees:  

Skills:   

External appointments: N/A

Bio:

Jonathan was most recently CEO of Consort Medical from December 2007 until its acquisition for £505m by Recipharm AB in early 2020. Jonathan originally joined Consort Medical as Group Finance Director from September 2006 to December 2007, and prior to this 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: October 2018

GARETH JONES
Interim CEO

2019 Committees: N/A

Skills:  

External appointments: N/A

Bio:

Gareth has 27 years' experience in finance having qualified as a Chartered Accountant in 1993 with PwC. Gareth joined Tissue Regenix in October 2018 as CFO before moving into the interim CEO role August 2019. In recent years he has worked as Chief Financial Officer for LSE listed Applied Graphene Material. Previously 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. 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 c.\$480m. He graduated from the University of Nottingham in 1989 with a BEng.



Joined the Group: March 2008

ALAN MILLER
Non-Executive Director

2019 Committees:  

Skills: 

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 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: June 2013

RANDEEP SINGH GREWAL
Non-Executive Director

2019 Committees:  

Skills:   

External appointments:

Chairman, BB Healthcare
Non-Executive Director, Hox Therapeutics Limited

Bio:

Randeep Grewal has over 20 years of experience in investing having worked most recently at Trium Capital, as well as F&C Asset Management, ICAP Equities and Tudor Capital, where he spent 10 years covering and investing in healthcare companies. He also became non-executive director of BB Healthcare Investment Trust, listed on the London Stock Exchange, in December 2016 before becoming Chairman in July 2019. Randeep has been involved in a number of start-up and early stage companies both personally and as an investor. He read medicine at the University of Cambridge.



Joined the Group: June 2016

SHERVANTHI HOMER-VANNIASINKAM
Non-Executive Director

2019 Committees: N/A

Skills: 

External appointments: N/A

Bio:

Shervanthi Homer-Vanniasinkam graduated in medicine from Mysore University Medical School in India, and is a Fellow of both the Royal College of Surgeons of Edinburgh, and the Royal College of Surgeons of England. She was appointed Consultant Vascular Surgeon at Leeds General Infirmary in 1995, a post she continues to hold. Her concomitant posts include: Founding Co-director of the novel medical undergraduate scholarship programme, EXSEL@Leeds; Founding Professor of Surgery, University of Warwick Medical School & University Hospitals Coventry and Warwickshire; Professor of Engineering & Surgery, University College London.

Professor Homer-Vanniasinkam has published over 100 papers and book chapters, delivered over 300 presentations, and has a significant research grant portfolio (several £m, to date). She has an outstanding track record of national (Universities of Leeds, London, Warwick) and international (Harvard, Yale, Singapore, India) collaborative research programmes that encompass basic, translational and clinical studies. Professor Homer-Vanniasinkam is currently a Visiting Scholar at Harvard University and the Yeoh Ghim Seng Visiting Professor of Surgery at the National University of Singapore.

Corporate governance

As an AIM listed Company, the Board of Tissue Regenix Group recognises the importance for strong corporate governance and business ethics. The Company adopted the latest Quoted Company Alliance Corporate Governance Code, which came into effect in September 2018, and has employed these guidelines as far as possible. The Board is ultimately accountable to the Company's shareholders for good corporate governance, and this report along with the audit, remuneration and risk reports, highlight the steps taken to ensure that the Company takes action to comply with the standards.

The roles and responsibilities of the Board

The Board is responsible for ensuring that a successful business strategy is implemented across the Group to drive commercial success and deliver value for shareholders.

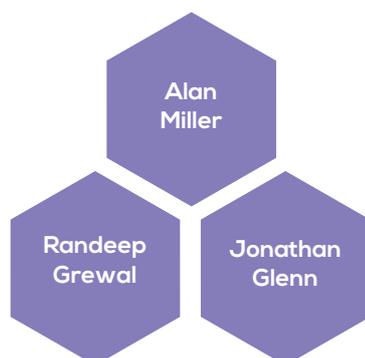
The Board is comprised of two independent Non-Executive Directors, one Non-Executive Director¹, the interim Non-Executive Chairman, and one Executive Director, the Interim Chief Executive Officer (CEO). The Board considers its size, composition and balance of skills is currently in line with the requirements of the Group, with a mix of financial, clinical and commercial expertise to advise the Group on its chosen commercial strategy.

There is a clear division of responsibility between the Board Chair and CEO position, with the Chairman advising and leading the Board, as well as making himself available to meet with shareholders. The CEO is responsible for the day-to-day execution of the agreed strategy and ensuring operational compliance. Training is made available to each Non-Executive Director (NED) to ensure that they are completely aware of their regulatory responsibilities and requirements.

The Board aims to meet formally at least 10 times a year, with provision being made to join via telephone if a member of the Board is unable to attend in person. Outside of the scheduled meetings the Board will meet to discuss ad hoc business events where necessary, and the CEO keeps the Board fully informed of any business developments that could positively or negatively impact the performance or value of the Company; any business decisions that require formal Board approval, or any event that could impact the Board or individual member carrying out their duties and regulatory responsibilities.

The Board also operates two sub-committees, the Audit and Remuneration Committees, to ensure compliance with market regulations.

Audit Committee



The 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, and to review reports from the Company's external auditors relating to the accounting and internal controls. The Audit Committee also recommends to the Board the appointment and reappointment of external 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 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 the Audit Committee meeting by invitation only.

The 2019 Audit Committee comprises of Alan Miller, who acts as Chairman of the Committee, Jonathan Glenn and Randeep Grewal.

The Remuneration Committee Report

The Remuneration Committee report is available on pages 36 to 38.

The 2019 Remuneration Committee comprises of Randeep Grewal, who acts as Chairman of the Committee, Jonathan Glenn and Alan Miller.

Since taking up the position of interim Non-Executive Chairperson in March 2020, Jonathan Glenn has stepped down from the Remuneration Committee with Shervanthi Homer-Vanniasinkam taking this place.

Remuneration Committee



¹ Alan Miller, Non-Executive Director, is no longer considered to be independent due to tenure on the Board.

The roles of the Board

Jonathan Glenn – Interim Non-Executive Chair

- Ensures the effectiveness of the Board in all decision-making
- Provides guidance to the CEO on key business decisions
- Facilitates discussions of the Board and ensures that all contributions from Executive and Non-Executive Directors are considered
- Makes himself available to all shareholders to ensure effective communications

Gareth Jones – Interim CEO

- Responsible for the overall operational effectiveness of the business
- Manages the day-to-day business and leads the strategic direction as advised by the Board Chair and Non-Executive Directors
- Ensure effective communication with all employees and promotes collaborative working and cohesion between all members of the global leadership team
- Proactively meets with existing and potential investors to relay the corporate story and investment case
- Ensures that the Board Chair and Non-Executive Directors are provided with a comprehensive and accurate business update every month via both Board packs and, when applicable, Board meetings

Company Secretary – Kirsten Lund

- Responsible to the Board and ensuring compliance with all statutory regulations
- Responsible for advising the Board on all Governance matters
- Provides support to Non-Executive Directors
- Responsible under the direction of the CEO, for ensuring that the Board receives accurate and timely information

Non – Executive Directors

- Help to develop the business strategy and bring an independent outlook
- Chair and participate in the Audit and Remuneration Committees
- Challenge and support the Executive Director on the main issues affecting the Group
- Bring a range of complementary experience to the Board to assist with business decision-making
- Are available if shareholders want to raise concerns that normal channels have failed to resolve

Internal control

The Board is responsible for maintaining a sound system of internal controls. These measures are designed to minimise any potential risks identified 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:

- well established financial reporting and control systems;
- the Board actively identifies, evaluates and monitors the risks inherent in the business and ensure that appropriate controls and procedures are in place to manage these risks;
- there is a clearly designed organisation and reporting structure; and
- the Company has operational, accounting and employment policies in place.

In addition, the Board regularly assess the internal control environment under which the business operates and where appropriate implements additional measures to ensure that adequate controls are maintained.

Quoted Company Alliance Corporate Governance Code

The Board has concluded that the most applicable corporate governance framework for the Company to follow would be the Quoted Company Alliance Corporate Governance Code, which the Group implemented in September 2018. Below is an overview as to how the Company addresses the 10 points of the Code.

1. “Establish a strategy and business model which promote long-term value for shareholders”

Tissue Regenix Group has established a portfolio of regenerative medical products, based on two platform technologies, to address critical and increasing clinical needs, transforming patient care and providing favourable health economic outcomes. We aim to expand the adoption of our dCELL® and BioRinse technologies and become a partner of choice for both clinicians and strategic partners. We aim to optimise the adoption of our products and drive additional revenues more rapidly through product line extensions, which have a quick route to market, and address specific clinical requirements where we see significant opportunities. Underpinning this, the business has adopted four key strategic growth drivers that it believes will accelerate market

penetration and revenue growth, namely: accelerate US market penetration; exploit global market potential; broaden strategic partnerships; and strengthen the portfolio. More details of these strategic growth drivers can be found on pages 10 to 11 of this report.

2. “Seek to understand and meet shareholder needs and expectations”

The Group actively engages with its shareholders throughout the year both through direct meetings, website communications and stock exchange announcements. Commissioned analyst research notes are made available on the Company’s website as well as clinical case studies and published papers.

Senior management, typically the CEO and Group Finance Director aim to meet with, or speak with, significant shareholders at least twice in a year usually after the interim and annual results announcements, to provide an update on strategy and progress of the Company and the Group as a whole, and to receive shareholder feedback. The Company also undertakes several publicly available updates to all shareholders, through forums such as interviews, trading updates and PR announcements.

The Company holds an Annual General Meeting each year at which all shareholders are welcome to attend and speak with management.

Company contact details are included on the Company’s website and on all regulatory announcements.

3. “Take into account wider stakeholder and social responsibilities and their implications for long-term success”

The Board of Directors of the Company considers relationships with stakeholders of the Tissue Regenix Group as fundamental to its success.

During 2018 the Company embarked on an employee engagement programme, which is now engrained into the fabric of the business, covering multiple areas from employee engagement to individual development, and drives the Company culture, vision and mission, and values and behaviours. More information can be found in the sustainability report on pages 26 to 27.

In relation to our joint venture company GBM-v in Rostock, Germany, quarterly Board meetings are held involving both joint venture parties along with less formal monthly update calls.

Corporate governance

continued

In respect of organ procurement and tissue sourcing, Tissue Regenix actively audits these suppliers on a regular basis to ensure that tissues are from a properly regulated source and obtained and handled with the highest ethical standards.

The nature of our business means that we pay close attention to our corporate social responsibilities, tracking each donation, and wherever requested, by either regulatory bodies or next of kin, providing further information around the use of donation.

As a global Company we consider our carbon footprint and environmental responsibility ensuring that any significant international air travel is essential and could not be facilitated by alternative means, such as a WebEx meeting. During 2019 we also undertook an energy reduction programme at the UK manufacturing facility leading to a 35% energy saving.

Further details of our corporate social responsibility strategy are set out at page 26 of this report.

The Board considers feedback from its advisers and stakeholders formally at its monthly Board meetings or sooner on a more informal basis as required.

4. "Embed effective risk management, considering both opportunities and threats, throughout the organisation"

The Board carefully considers the strengths, weaknesses, opportunities and risks facing Tissue Regenix Group, and endeavours to minimise the impact of weaknesses and risks by employing the necessary mitigation actions. Tissue Regenix Group is a pioneering international medical technology company, focusing on the development of regenerative products utilising two platform technologies. We are helping to transform the treatment of patients in four key areas: BioSurgery (soft tissue replacement and repair in wounds, urogynaecology and trauma), Orthopaedics and Dental, with an ongoing development programme for Cardiac applications. We process tissues at our facilities in the UK, Europe and North America. Tissue Regenix Group has an experienced and dedicated management and scientific team, and the prominent risks facing the Group are kept under review and updated as necessary; details are set out on pages 22 to 25 of this report.

As noted above, the Group regularly audits its suppliers to ensure that the highest ethical standards are maintained.

In respect of its intellectual property rights, the Group engages a professional patent and trademark attorney to monitor its intellectual property portfolio.

Tissue Regenix maintains a central finance team, currently based in the UK, but with two permanent team members in the US. The Group seeks to operate consistent accounting policies and engages annual external audits from professional auditors of its financial results and reports, findings from which will be presented to the Board and made available to all shareholders. The Board review monthly financial reports including key performance indicators provided by the Group Finance Director in respect of the management of cash within the business and review against budgets and forecasts.

The Group also has a number of operational controls that all employees are expected to adhere to including management structure, Board reserved matters, financial monitoring, internal policies, codes of conduct and training, health and safety monitoring and IT controls.

5. "Maintain the Board as a well-functioning, balanced team led by the Chair"

The Board is comprised of two independent Non-Executive Directors, one Non-Executive Director, the Non-Executive Chairman, and one Executive Director, the Chief Executive Officer. The Non-Executive Directors bring a mix of financial, clinical and industry experience to the Board, and the Board believes that its composition is suitable for the Company requirements.

At least 10 formal Board meetings are held each year with enough notice for Directors to participate. A monthly Board report is produced, and meeting agendas and Board papers are produced in advance of each meeting so that the Board can properly consider the matters to be discussed. The Company maintains minutes of the Board meetings. Directors are also expected to make themselves available on an ad hoc basis for consultation if the need arises.

There are two Committees of the Board, the Audit Committee and the Remuneration Committee, each of which are formed of three of the Non-Executive Directors of the Company, with each Committee having policies to govern how they are run. The Directors who form these two Committees have financial experience so are appropriate persons to advise on these matters. The Audit Committee meets at least twice per year and is chaired by Alan Miller who has relevant financial experience. The Remuneration Committee meets no fewer than twice per year, and is chaired by Randeep Grewal who has financial experience and experience of being a fund manager and investor. Further details of these Committees can be found on page 32 of this Annual Report.

A Nomination Committee has been set up in order to assess the structure, size and composition of the Board as well as the appointment of any new Director, as and when appropriate. For senior level appointments the Board will engage the expertise of a relevant recruitment company to assist with the search and hiring of a relevant individual.

The Non-Executive Directors are appointed through formal non-executive appointment letters, which contain a three-month notice period. The non-executive appointment letters contain an indicative time commitment of 20 days per annum; however, these indicate that this is an estimate and that all Directors are expected to commit sufficient time to fully discharge their responsibilities. The Company has not had any issues with regular non-attendance at meetings.

Executive Directors have formal service contracts, which require them to work full-time in the business and have no other significant outside business commitments. These service agreements have a maximum of six-months' notice to terminate.

The Company follows the provisions in its Articles of Association in respect of the retirement and reappointment of Directors at its Annual General Meeting each year.

The Board is satisfied that it has a suitable balance between independence and knowledge of the business to allow it to discharge its duties and responsibilities effectively and that effective controls have been put in place.

6. “Ensure that, between them, the Directors have the necessary up-to-date experience, skills and capabilities”

The Board is satisfied that it has an effective balance of skills and relevant experience to operate effectively.

Each Board member brings a different set of capabilities, for example, all the Directors other than Shervanthi Homer-Vanniasinkam have financial experience, both Shervanthi Homer-Vanniasinkam and Randeep Grewal have clinical experience, and Gareth Jones and Jonathan Glenn both have relevant international industry experience.

The Board maintains its skillset through their day-to-day roles and uses external advisers to enhance its knowledge where necessary. If any member of the Board considers that additional training is required to fulfil their role, the Company would seek to provide such training as and when necessary.

The Company keeps in regular contact with its nomad, Stifel Nicolaus Europe, typically meeting once every two weeks and ad hoc as required. The Company also seeks advice from its legal advisers and accountants as and where necessary including, for example, in relation to the acquisition of CellRight Technologies LLC. The Company employs RSM UK Audit LLP to audit its Annual Accounts and Report.

The Company Secretary role is currently held by the Group Finance Director, Kirsten Lund.

Given the size of the Company, it has not sought to formally appoint a Senior Independent Director; however, Alan Miller is the longest serving Non-Executive Director.

7. “Evaluate Board performance based on clear and relevant objectives, seeking continuous improvement”

The CEO and Group Finance Director of the Company are measured against a clearly defined set of personal objectives agreed by the Board and monitored by the Remuneration Committee. The Board keeps under review its composition and the balance of skills and experience of Non-Executive Directors.

8. “Promote a corporate culture that is based on ethical values and behaviours”

As a Company that operates in a highly regulated and sensitive environment, the Company ensures that it operates with a vigorous code of conduct and ethics. Tissue Regenix Group strives to maintain a sustainable, ethical and responsible Company.

The Group, led by the Interim Chief Executive Officer, maintains open and transparent channels of communication with all employees in order to promote values and behaviours which consistently reflect the Group’s ethos.

Operating in an industry based upon processing of human and animal derived tissues demands the highest ethical standards, and the Group aspires to maintain these across all business functions and relations. The Company undertakes regular audit checks to ensure that partners, suppliers and employees comply with the ethical standards and operate to meet our expectations.

9. “Maintain governance structures and processes that are fit for purpose and support good decision-making by the Board”

Please see the details of the Board and its Committees set out in respect of principles 5, 6 and 7 above. Details of the main roles of the Audit Committee and Remuneration Committee are set out in this Annual Report on page 32, and the Company’s website.

A Nomination Committee has been set up in order to assess the structure, size and composition of the Board as well as the appointment of any new Director, as and when appropriate. For senior level appointments the Board will engage the expertise of a relevant recruitment company to assist with the search and hiring of a relevant individual.

In addition to this, the Group operates a clear list of matters which are reserved for the Board.

To supplement the Board, the Group maintains a team of senior management to inform the Board and keep it abreast of key developments throughout its business. The senior management are detailed on the Company’s website and includes for example: Daniel Lee, President US Operations; Mike Izon, R&D Director; and Joel Pickering, President of the BioSurgery division, as well as other relevant senior managers. As well as the main Board, Tissue Regenix participates in the board of its joint venture company, GBM-v along with its joint venture partner. Having close ties to the senior management team and joint venture partners in this way allows the Group to ensure that all divisions of the business are kept up to date and facilitates the Group in ensuring that all its divisions are compliant with the Group’s codes and practices.

10. “Communicate how the Company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders”

Please see responses in respect of principles 2, 3 and 5 above in relation to shareholder communications and meetings, and Board communications and meetings. In addition to this, the Company communicates with its shareholders through regulatory announcements and its Annual Report. Reports from both the Remuneration Committee and the Audit Committee are set out in the Annual Report. The Company also hold an Annual General Meeting, which all shareholders are invited to attend. In the event that the Company received a significant proportion of votes against a resolution at a General Meeting, it would seek to review the rationale for this and consider appropriate actions.

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 management team is incentivised to drive sustainable earnings growth and returns to shareholders, thereby creating a genuinely strong alignment of interests between management and investors.

It is the Company's policy that Executive Directors should have contracts with an indefinite term providing for a maximum of six months' notice. In the event of early termination, the 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 no 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 2019 Remuneration Committee comprises Randeep Grewal as Chair of the Committee, Alan Miller and Jonathan Glenn. The Committee meets no fewer 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 Allocation will be an option over ordinary shares in the Company.

The number of ordinary shares comprising the Matching Allocation will be equivalent to three times the number of ordinary shares received in the Deferred Allocation. Participants will not be entitled to receive the Matching Allocation until the vesting date is reached, which is three years from the date of grant of the award.

Additionally, participants will not be entitled to receive the Matching Allocation unless share 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 2019 was:

	Salary and fees £000	Bonus £000	Benefits £000	Total up to December 2019 £000	Total up to December 2018 £000
John Samuel	111	–	–	111	111
Steven Couldwell (resigned 30/07/2019)	141	60	2	203	356
Gareth Jones*	188	50	12	250	33
Randeep Grewal	35	–	–	35	35
Jonathan Glenn	30	–	–	30	30
Alan Miller	35	–	–	35	35
Shervanthi Homer-Vanniasinkam	30	–	–	30	30
Michel Barker (appointed on 28th August and resigned 18th November 2019)	38	–	2	40	–
Paul Devlin (resigned 31 January 2018)	–	–	–	–	15
Total	608	110	16	734	645

Within 2018 the total bonus payments were £120k and benefits were £13k.

*Gareth Jones was awarded a bonus of £120k in respect of his performance during 2019. Given the cash position of the Company as at the year end, payment of this bonus was deferred pending an improvement in the cash position, for instance following the completion of a successful fundraise. Given this conditionality, the accounting standards require us to recognise this in the year it is paid and therefore it does not show in the above table. Gareth has decided to invest the vast majority of the net proceeds of this bonus into the recently announced fundraise.

Directors' shareholdings

Directors' interests in the shares of the Company, including family interests at 31 December 2019 were:

	31 December 2019 Number	31 December 2019 %	31 December 2018 Number	31 December 2018 %
John Samuel (Note 1)	26,276,928	2.22%	26,276,928	2.22%
Alan Miller	22,886,988	1.97%	22,886,988	1.97%
Jonathan Glenn	600,000	0.06%	600,000	0.06%
Shervanthi Homer-Vanniasinkam	250,000	0.02%	250,000	0.02%

Note 1 includes shares held jointly by the Director and EBT as set out overleaf in Note 3.

Directors' interests 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 2019 were:

	At 1 January 2019	Lapsed during year	At 31 December 2019	Exercise price
John Samuel	2,400,000	–	2,400,000	5.00 pence
John Samuel (Note 1)	577,777	–	577,777	22.50 pence
Unapproved scheme options				
John Samuel (Note 2)	88,890	–	88,890	22.50 pence
Steven Couldwell	10,000,000	10,000,000	–	8.00 pence
EBT scheme shares (Note 3)				
John Samuel	10,740,000	–	10,740,000	5.00 pence

Directors' remuneration report

continued

Note 1. 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 2019 none of the performance conditions had been met and no options were eligible for exercise.

Note 2. 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 2019 none of the performance conditions had been met and no options were eligible for exercise.

Note 3. 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. John Samuel has 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. 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 2019 was 1.0 pence per share, the highest and lowest prices during the year were 8.25 pence and 0.6 pence respectively. Further details of all share options and jointly owned shares held by the Trustee are set out in note 16 to the financial statements.

On behalf of the Board

Randeep Grewal

Chairman of the Remuneration Committee

4 June 2020

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 2019.

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 08 to 09. Explanations of activities and how it seeks to add value are included in the Chairman's statement on page 02 to 03 and Interim CEO operational review report on pages 18 to 19 as well as the KPI report on pages 14 to 15 and future milestones on pages 12 to 13.

Business review and results

A review of the Group's performance and future prospects is included in the Chairman's statement on pages 02 to 03 and Interim CEO operational report on pages 18 to 19, as well as the future milestones on pages 12 to 13 and KPIs set out on pages 14 to 15. A review of the Group's financial performance is within the financial overview on pages 20 to 21. The loss for the 12 months attributable to equity holders of the parent was (£7,697k) (2018: £8,186k). The Directors do not recommend the payment of a dividend (2018: nil).

Share capital and funding

Full details of the Group and Company's share capital movements during the year are given in note 19 to the financial statements.

Directors and their interests

The following Directors held office in the year:

John Samuel – resigned 20 March 2020
 Steve Couldwell – retired 1 August 2019
 Gareth Jones
 Mike Barker – appointed 28 August 2019; retired 18 November 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.

Substantial shareholders

As at 31 December 2019, shareholders holding more than 3% of the share capital of Tissue Regenix Group plc were:

Name of shareholder	Number of shares	% of voting rights
Link Group*	234,212,642	19.98
IP Group	153,042,837	13.06
Jupiter Asset Management	99,740,965	8.51
Director and Related Holdings(s)	50,313,916**	4.33

*Link Group were appointed as administrators for the Woodford Equity Income Fund

**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 26 to 27.

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 22 to 25 and in note 14 of the financial statements.

Auditor

RSM UK Audit LLP 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 206 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 and important events affecting the Group since the end of the year.

The Directors Report was approved by the Board on 4 June 2020.

On behalf of the Board

Gareth Jones

Interim 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 2019 which comprise the consolidated statement of comprehensive income, the consolidated and parent company statements of financial position, the consolidated and parent company statements of changes in equity, the consolidated and parent company statements of cash flow and the 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 2019 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.

Material uncertainty related to going concern

We draw attention to note 1 in the financial statements, which indicates that the fundraising announced on 22 May 2020 is conditional upon shareholder approval in a general meeting. As stated in note 1, these events or conditions, along with the other matters as set forth in note 1, indicate that a material uncertainty exists that may cast significant doubt on the group's and the parent company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Summary of our audit approach

Key audit matters

- Group
 - Goodwill impairment
- Parent Company
 - Impairment of intercompany receivables

Materiality

- Group
 - Overall materiality: £297,000
 - Performance materiality: £222,000
- Parent Company
 - Overall materiality: £169,000
 - Performance materiality: £127,000

Scope

Our audit procedures covered 100% of revenue, 100% of total assets and 100% of loss before tax.

Independent auditor's report continued

To the members of Tissue Regenix Group PLC

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.

In addition to the matters described in the Material uncertainty related to going concern section, we have determined the matters described below to be the key audit matters to be communicated in our report.

Goodwill impairment

Key audit matter description	<p>As disclosed in note 11, the CellRight Technologies LLC ("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. The CellRight CGU is a legal entity in its own right and forms part of the Orthopaedics and Dental operating segment.</p> <p>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.</p> <p>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 (the "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 in a high growth sector and the selection of an appropriate discount rate.</p>
How the matter was addressed in the audit	<p>Management provided us with an impairment model for the CellRight CGU as detailed in note 11 that showed no impairment was necessary. The value in use calculation is dependent upon cash flows derived from expected EBITDA, working capital movements and capital expenditure requirements. We identified that the two key assumptions within the model were revenue growth (which was 26% compound annual growth over the five-year forecast period, reducing to long term growth of 2% thereafter) and the use of a weighted average cost of capital (WACC) of 13.5% for the discount rate.</p> <p>We performed audit work on this model by:</p> <ul style="list-style-type: none">Using a specialist to check the calculations within the model and to obtain an independent estimate of the WACC.Challenging management to support the revenue growth rate within the model and comparing forecast growth with available market reports.Considering the sensitivity of the headroom within the model to reasonably possible changes in the revenue growth rate.
Key observations	<p>As a result of our work we concurred with management's assessment that there was no impairment and we ensured that the disclosure in note 11 made it clear the calculation of value in use is sensitive to a reasonably possible change in sales growth rates.</p>

Impairment of intercompany receivables (parent company only)

Key audit matter description	<p>The parent company has receivable balances from subsidiary undertakings that are currently loss making. The receivables are repayable on demand and the subsidiary undertakings do not have sufficient liquid assets to make repayment should the parent company call in the receivable balance.</p> <p>One of the most significant matters in the current year audit of the parent company is that these receivable balances may be impaired and management are required to calculate an expected credit loss ("ECL") provision in accordance with IFRS9 Financial Instruments. The calculation of ECLs involves a significant degree of judgement as management have to make assumptions about future cash generation and consider multiple scenarios through which the balances may be recovered.</p> <p>Given the magnitude of these receivable balances and the potential for impairment we considered this matter to be one of the matters of most significance in the current year audit.</p> <p>At the 31 December 2019, the carrying value of amounts due from group undertakings amounted to £20.6m after recording an ECL provision of £49.9m (see note C7).</p>
How the matter was addressed in the audit	<p>We obtained management's calculation of the ECL and the underlying calculations prepared to support the carrying value of the balance and performed work as follows:</p> <ul style="list-style-type: none"> ○ Assessed the reasonableness of the scenarios considered by management and the probabilities assigned to each. ○ Ensured that the cash flow forecasts used were consistent with those contained within impairment tests performed on CellRight and the group's net assets (as disclosed at note 11). ○ Recalculated the computation of the ECL.
Key observations	<p>As a result of our work we concurred with management's calculated ECL and we ensured that the key estimates within the calculation were adequately disclosed within the critical estimates at note C2.</p>

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. Based on our professional judgement, we determined materiality as follows:

	Group	Parent company
Overall materiality	£297,000	£169,000
Basis for determining overall materiality	2.3% of Revenue	0.4% of net assets. The percentage applied to the benchmark has been restricted for the purpose of calculating an appropriate component materiality.
Rationale for benchmark applied	Revenue selected given shareholder and stakeholder focus on revenue growth. The group is still in relatively early phase of development and revenue growth is critical to reducing significant operating losses.	Net assets selected as the parent company is purely a holding company and no income statement is presented.
Performance materiality	£222,000	£127,000
Basis for determining performance materiality	75% of overall materiality	75% of overall materiality
Reporting of misstatements to the Audit Committee	Misstatements in excess of £15,000 and misstatements below that threshold that, in our view, warranted reporting on qualitative grounds.	Misstatements in excess of £8,000 and misstatements below that threshold that, in our view, warranted reporting on qualitative grounds.

Independent auditor's report continued

To the members of Tissue Regenix Group PLC

An overview of the scope of our audit

The group consists of 11 components, located in the United Kingdom, USA and Germany. The coverage achieved by our audit procedures was:

	Number of components	Revenue	Total assets	Profit before tax
Full scope audit	9	100%	100%	94%
Specific audit procedures	1	-%	-%	6%
Total	10	100%	100%	100%

Specific audit procedures were performed on one component as they contained the Borrowings secured by the group during the year and the related finance costs. Analytical procedures were performed at group level for the remaining component.

Of the above, a full scope audit for 1 component was undertaken by a component auditor. Whilst not significant in its own right, this component contained material amounts of revenue.

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, 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
Fifth Floor
29 Wellington Street
Leeds LS1 4DL
4 June 2020

Consolidated statement of comprehensive income

For the year ended 31 December 2019

	Notes	2019 £000	2018 £000
REVENUE	3	13,033	11,619
Cost of sales		(7,014)	(5,702)
GROSS PROFIT		6,019	5,917
Administrative expenses before exceptional items	3	(13,198)	(14,183)
Exceptional items	4	(21)	(423)
Total administrative expenses		(13,219)	(14,606)
OPERATING LOSS		(7,200)	(8,689)
Finance income	6	17	72
Finance charges	7	(477)	(262)
LOSS BEFORE TAXATION		(7,660)	(8,879)
Tax	8	554	620
LOSS FOR YEAR		(7,106)	(8,259)
ATTRIBUTABLE TO:			
Equity holders of the parent	9	(6,973)	(8,186)
Non-controlling interests		(133)	(73)
		(7,106)	(8,259)
OTHER COMPREHENSIVE INCOME:			
Foreign currency translation differences – foreign operations		(724)	1,360
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR		(7,830)	(6,899)
ATTRIBUTABLE TO:			
Equity holders of the parent		(7,697)	(6,826)
Non-controlling interests		(133)	(73)
		(7,830)	(6,899)
LOSS PER SHARE			
Basic and diluted loss attributable to equity holders of parent	9	(0.60)p	(0.70)p

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

Consolidated statement of financial position

At 31 December 2019

	Notes	2019 £000	2018 £000
ASSETS			
Non-current assets			
Property, plant and equipment	10	2,357	2,828
Intangible assets	11	17,999	19,938
TOTAL NON-CURRENT ASSETS		20,356	22,766
CURRENT ASSETS			
Inventory	12	4,185	2,330
Trade and other receivables	13	2,539	3,551
Corporation tax receivable		1,035	1,200
Cash and cash equivalents	14	2,380	7,816
TOTAL CURRENT ASSETS		10,139	14,897
TOTAL ASSETS		30,495	37,663
LIABILITIES			
Non-current liabilities			
Borrowings	16	(2,115)	–
Deferred tax	18	(670)	(791)
TOTAL NON-CURRENT LIABILITIES		(2,785)	(791)
Current liabilities			
Borrowings	16	(171)	–
Trade and other payables	15	(2,944)	(4,302)
TOTAL CURRENT LIABILITIES		(3,115)	(4,302)
TOTAL LIABILITIES		(5,900)	(5,093)
NET ASSETS		24,595	32,570
EQUITY			
Share capital	19	5,859	5,859
Share premium		86,399	86,398
Merger reserve		10,884	10,884
Reverse acquisition reserve		(7,148)	(7,148)
Reserve for own shares		(831)	(831)
Share based payment reserve	20	983	1,129
Retained earnings deficit		(70,936)	(63,239)
EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF PARENT		25,210	33,052
Non-controlling interests	21	(615)	(482)
TOTAL EQUITY		24,595	32,570

The consolidated financial statements were approved by the Board of Directors on 4 June 2020 and were signed on its behalf by:

Gareth Jones

Interim Chief Executive Officer

Company number: 05969271

Consolidated statement of changes in equity

For the year ended 31 December 2019

	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 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 income	-	-	-	-	-	-	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
Loss for the period	-	-	-	-	-	-	(6,973)	(6,973)	(133)	(7,106)
Other comprehensive expense	-	-	-	-	-	-	(724)	(724)	-	(724)
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(7,697)	(7,697)	(133)	(7,830)
Exercise of share options	-	1	-	-	-	-	-	1	-	1
Share based payment credit	-	-	-	-	-	(146)	-	(146)	-	(146)
At 31 December 2019	5,859	86,399	10,884	(7,148)	(831)	983	(70,936)	25,210	(615)	24,595

Consolidated statement of cash flows

For the year ended 31 December 2019

	Notes	2019 £000	2018 £000
OPERATING ACTIVITIES			
Loss before taxation		(7,660)	(8,879)
Adjustment for:			
Depreciation of property, plant and equipment	10	476	598
Amortisation of intangible assets	11	570	575
Impairment of intangible assets and property, plant and equipment	10/11	1,311	–
Share based payments	20	(146)	(57)
Interest receivable	6	(17)	(72)
Interest payable	7	477	262
Operating cash outflow before working capital movements		(4,989)	(7,573)
Decrease/(Increase) in inventory		(1,855)	542
Decrease/(Increase) in trade and other receivables		1,076	(1,188)
(Decrease)/Increase in trade and other payables		(1,567)	156
Cash outflows from operations		(7,335)	(8,063)
Research & Development tax credit received		653	1,225
Net cash outflow from operations		(6,682)	(6,838)
INVESTING ACTIVITIES			
Interest received	6	17	72
Purchases of property, plant and equipment	10	(438)	(290)
Capitalised development expenditure	11	(213)	(116)
Acquisition of subsidiary		–	(1,564)
Net cash outflow from investing activities		(634)	(1,898)
FINANCING ACTIVITIES			
Interest paid		(384)	–
Proceeds from exercise of share options		1	4
Proceeds from new loans		6,479	–
Repayment of loans		(4,193)	–
Net cash inflow from financing activities		1,903	4
Decrease in cash and cash equivalents		(5,413)	(8,732)
Foreign exchange translation movement		(23)	125
Cash and cash equivalents at start of period		7,816	16,423
CASH AND CASH EQUIVALENTS AT END OF PERIOD		2,380	7,816

Notes to the financial statements

For the year ended 31 December 2019

1) BASIS OF PREPARATION

The financial statements of Tissue Regenix Group plc are audited consolidated financial statements for the year ended 31 December 2019.

These include audited comparatives for the year ended 31 December 2018.

The Company is incorporated and domiciled in the United Kingdom and its registered number is 05969271. 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 principal activity of Tissue Regenix Group is to 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

These financial statements have been prepared on a going concern basis, given the current cash flow projections forecast for the Group to 31 December 2021. Funding requirements are reviewed on a regular basis by the Group's Chief Executive Officer and Group Finance Director and are reported to the Board at each Board meeting, as well as on an ad hoc basis, if requested. Until sufficient cash is generated from its operations, the Group remains reliant on external funding including current debt facilities provided by MidCap, to meet its working capital requirements, capital investment programme and other financial commitments.

On 22 May, the Group announced that gross proceeds of £14.6m had been conditionally raised through an offer of new ordinary shares in the Company to Institutional and other qualifying investors. This fundraise is conditional on shareholder approval at a General Meeting of shareholders to be held on 9 June 2020 and also to admission of the fundraising shares to trading on AIM. In reporting the Group's finances on a going concern basis, the Directors have assumed the appropriate resolutions at this Meeting will be passed. However, if the necessary resolution is not passed, the fundraising will not proceed and the Company would not have funds immediately available to continue executing its current business plan. In this eventuality, the Directors would need to consider alternative sources of adequate funding. Should the Company be unable to raise enough funds, shareholders could be at risk of losing all or a substantial amount of their investment.

The COVID-19 pandemic has affected most businesses during H1 2020. As a result of the reprioritisation of healthcare professionals during this time, there has been a decline in elective procedures undertaken across a number of medical specialities that use our products. Given the uncertainty around the level and duration of disruption from COVID-19, it is difficult to determine how long the current situation may last, and the time taken to catch-up any postponed surgical procedures thereafter. However, the Board, in compiling possible cashflow projections for the business, has considered a number of scenarios regarding the effect of reduced and delayed revenues due to COVID-19 and, has undertaken market soundings regarding the likely timeframe for the recommencement of procedures. It has concluded that, if additional funds are received as expected, there will not be a significant long-lasting impact on the capability of the business to carry out its commercial activities.

In summary, the Directors have considered their obligations in relation to the assessment of the going concern basis for preparation of the financial statements 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 22 to 25. They have concluded that it remains appropriate to prepare the financial statements on a going concern basis, noting that assumptions relating to the completion of the fundraise give rise to a material level of uncertainty in respect of the going concern assumption.

The financial statements do not include any adjustments that would result in the basis of preparation as a going concern being inappropriate.

2) SIGNIFICANT ACCOUNTING POLICIES

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 financial statements 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 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 following criteria:

- The reason for the bill-and-hold arrangement must be substantive (usually the arrangement has been 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 to satisfy other orders);
- The product must be ready for physical transfer to the customer; and
- The Group 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 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.

Inventories

Inventories are recognised at the lower of cost and net realisable value. Cost is determined using the first in, first out method and represents the purchase cost, including transport, for raw materials, together with a proportion of manufacturing overheads based on normal levels of activity for work in progress and finished goods. Appropriate provisions for estimated irrecoverable amounts are recognised in the income statement when there is objective evidence that the assets are impaired.

Notes to the financial statements continued

For the year ended 31 December 2019

2) SIGNIFICANT ACCOUNTING POLICIES continued

Property, Plant and Equipment

Property, plant and equipment assets are stated at their historical cost of acquisition less any provision for depreciation or impairment.

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.	

Intangible Assets

Intangible assets are stated at fair value at acquisition. They are subsequently held at cost less any provision for impairment or amortisation. Intangible assets are amortised through administrative expenses within the income statement over their expected useful life as follows:

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). For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash generating units).

Discounted cash flow valuation techniques are generally applied for assessing recoverable amounts using Board approved 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 of the option at the purchase date is recognised 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.

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.

An expected credit loss ('ECL') model, as introduced under IFRS 9, broadens the information that an entity is required to consider when determining its expectations of impairment. Under this model, expectations of future events must be taken into account and this will result in the earlier recognition of larger impairments against trade and other receivables.

In applying the ECL model the company considered the probability of a default occurring over the contractual life of its trade receivables balances on initial recognition of those assets.

Impairment provisions are recognised for the group as follows, representing the expected credit losses over the contracted life of these balances.

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

2) SIGNIFICANT ACCOUNTING POLICIES continued

Trade and other payables

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

Borrowings

Borrowings are interest bearing and are initially recognised at fair value less the directly attributable costs of issue. 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.

Leases

On commencement of a contract which gives the Group the right to use assets for a period of time in exchange for consideration, the Group recognises a right-of-use asset and a lease liability unless the lease qualifies as a 'short-term' lease (term is twelve months or less with no option to purchase the lease asset) or a 'low-value' lease (where the underlying asset is £4,000 or less when new).

The lease liability is initially measured at the present value of the lease payments during the lease term discounted using the interest rate implicit in the lease, or the incremental borrowing rate if the interest rate implicit in the lease cannot be readily determined. The lease term is the non-cancellable period of the lease plus extension periods that the Group is reasonably certain to exercise and termination periods that the Group is reasonably certain not to exercise. Lease payments include fixed payments, less any lease incentives receivable, variable lease payments dependant on an index or a rate and any residual value guarantees.

The lease liability is subsequently increased for a constant periodic rate of interest on the remaining balance of the lease liability and reduced for lease payments. Interest on the lease liability is recognised in profit or loss. Variable lease payments not included in the measurement of the lease liability as they are not dependent on an index or rate, are recognised in profit or loss in the period in which the event or condition that triggers those payments occurs.

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

Deferred tax

Deferred tax assets 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 2019 is £7,451k (2018: £7,353k).

Impairment testing of non-current assets

At each reporting date the directors review the carrying amount of the Group's non-current assets to determine whether there has been any indication that those assets have suffered an impairment loss. In the current year the group market capitalisation at 31 December 2019 was lower than net assets and therefore a full impairment test has been performed on the group's net assets. This resulted in an impairment charge of £972k against intangible assets and £339k against property, plant and equipment. Further details are provided in notes 10 and 11. The point of whether to impair non-current assets is a key judgement.

Notes to the financial statements continued

For the year ended 31 December 2019

2) SIGNIFICANT ACCOUNTING POLICIES continued

New accounting standards and amendments adopted in the year

During the year, the Company adopted the following standards effective from the 1st January 2019. The Company has applied these standards in the preparation of the financial statements, and has not adopted any new or amended standards early.

Initial application of IFRS 16 Leases

The Group has applied IFRS 16 Leases for the first time in the year ended 31 December 2019. IFRS 16 replaces IAS 17 Leases. The Group previously split leases between 'finance leases' that transferred substantially all the risks and rewards incidental to ownership of the asset to the Group, and 'operating leases'. The main change on application of IFRS 16 is the accounting for 'operating leases' where rentals payable (as adjusted for lease incentives) were previously expensed under IAS 17 on a straight-line basis over the lease term.

The Group entered into a new agreement in relation to a property located in the USA on 14 August 2019. The landlord is currently in the process of performing additional work and hence did not make the property available for use by the Group. Therefore, in accordance with IFRS 16, the lease has not commenced as at 31 December 2019. The lease on the UK property at Swillington, Leeds expired during the period and is currently rented on a month-to-month basis.

No right-of-use assets and lease liabilities were identified at the transition date due to application of the "short-term" and "low value" exemptions. The prior year financial statements disclosed the Swillington lease liability of £61,000 expiring within one year – the "short term" exemption was specifically applied to this lease.

Impact of other new International Financial Reporting Standards

The following other new standards and amended standards, none of which have had a material impact on these financial statements, are mandatory and relevant to the Group for the first time for the financial period commencing 1 January 2019:

- IFRIC23: Uncertainty over Income Tax Treatments
- Amendments to IAS 19: Plan amendment, curtailment or settlement
- Annual Improvements to IFRS Standards 2015-2017 Cycle

Accounting standards in issue but not yet effective

At the date of authorisation of these financial statements the following standards and interpretations, which have not been applied in these financial statements and which are considered potentially relevant, were in issue but not yet effective (and in some cases had not yet been adopted by the EU):

- Amendments to References to the Conceptual Framework in IFRS Standards
- Amendments to IAS 1 and IAS 8: Definition of Material
- Amendments to IFRS 3 Business Combinations

The Directors anticipate that the adoption of the amendments to standards in future periods will have no material impact on the recognition and measurement of assets, liabilities and the associated performance of the Group or the Company when the relevant standards and interpretations come into effect.

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 2019 £000	Year to 31 December 2018 £000
USA	10,679	9,434
Rest of world	2,354	2,185
	13,033	11,619

Analysis of revenue by customer

During the year ending 31 December 2019 the Group had no customers who individually exceeded 10% of revenue (2018:no customers).

3) SEGMENTAL REPORTING continued

Operating segments

The Group is organised into BioSurgery, Orthopaedics & Dental, Cardiac and GBM-V 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		GBM-V		Central		Total	
	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000
Revenue	4,233	3,381	6,724	6,396	–	–	2,076	1,842	–	–	13,033	11,619
Cost of sales	(2,535)	(1,769)	(3,076)	(2,676)	–	–	(1,403)	(1,257)	–	–	(7,014)	(5,702)
Gross Profit	1,698	1,612	3,648	3,720	–	–	673	585	–	–	6,019	5,917
Administrative costs	(3,729)	(4,169)	(4,553)	(4,992)	(328)	(428)	(663)	(551)	(3,925)	(4,043)	(13,198)	(14,183)
Exceptional costs:												
Contingent consideration	–	–	1,523	–	–	–	–	–	–	–	1,523	–
Impairment of assets	(983)	–	–	–	–	–	(152)	–	(176)	–	(1,311)	–
Restructuring costs	(72)	–	–	–	–	–	–	–	(92)	–	(164)	–
Litigation costs	(69)	(423)	–	–	–	–	–	–	–	–	(69)	(423)
Operating loss	(3,155)	(2,980)	(618)	(1,272)	(328)	(428)	(142)	34	(4,193)	(4,043)	(7,200)	(8,689)
Finance income/(expense)	–	–	–	–	–	–	–	–	(460)	(190)	(460)	(190)
Loss before taxation	(3,155)	(2,980)	(618)	(1,272)	(328)	(428)	(142)	34	(4,653)	(4,233)	(7,660)	(8,879)
Taxation	159	73	283	543	80	102	–	–	32	(98)	554	620
Loss for the year	(2,996)	(2,907)	(901)	(729)	(248)	(326)	(142)	34	(4,621)	(4,331)	(7,106)	(8,259)

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

Administrative expenses are broken down as follows:

	BioSurgery		Orthopaedics & Dental		Cardiac		GBM-V		Central		Total	
	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000
Staff costs	(2,862)	(2,936)	(2,931)	(2,639)	(134)	(222)	(349)	(297)	(889)	(1,365)	(7,165)	(7,459)
Sales and marketing costs	(395)	(901)	(136)	(125)	(5)	(25)	(15)	(20)	(204)	–	(755)	(1,071)
Research and development	(256)	(164)	(530)	(1,307)	(168)	(164)	(4)	–	(409)	–	(1,367)	(1,635)
Depreciation and amortisation	(15)	(20)	(276)	(279)	–	–	(17)	(7)	(739)	(867)	(1,047)	(1,173)
Establishment and administration costs	(201)	(148)	(680)	(642)	(21)	(17)	(278)	(227)	(1,684)	(1,811)	(2,864)	(2,845)
Administrative costs	(3,729)	(4,169)	(4,553)	(4,992)	(328)	(428)	(663)	(551)	(3,925)	(4,043)	(13,198)	(14,183)

Notes to the financial statements continued

For the year ended 31 December 2019

3) SEGMENTAL REPORTING continued

The balance sheet can be analysed segmentally as follows:

	BioSurgery		Orthopaedics & Dental		Cardiac		GBM-V		Central		Total	
	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000	2019 £000	2018 £000
Non-current assets												
Intangible assets	-	759	17,999	19,179	-	-	-	-	-	-	17,999	19,938
Property, Plant & Equipment	-	26	2,357	2,356	-	-	-	156	-	290	2,357	2,828
Total non-current assets	-	785	20,356	21,535	-	-	-	156	-	290	20,356	22,766
Current assets												
Inventory	345	222	3,661	1,957	-	-	122	74	57	77	4,185	2,330
Trade & other receivables	1,078	939	1,666	2,856	155	200	138	121	537	635	3,574	4,751
Cash & cash equivalents	495	170	87	409	8	2	33	35	1,757	7,200	2,380	7,816
Total current assets	1,918	1,331	5,414	5,222	163	202	293	230	2,351	7,912	10,139	14,897
Total assets	1,918	2,116	25,770	26,757	163	202	293	386	2,351	8,202	30,495	37,663
Current liabilities												
Trade & other payables	(586)	(553)	(2,163)	(2,474)	(42)	(42)	(112)	(102)	(882)	(1,922)	(3,785)	(5,093)
Borrowings	-	-	(2,115)	-	-	-	-	-	-	-	(2,115)	-
Total liabilities	(586)	(553)	(4,278)	(2,474)	(42)	(42)	(112)	(102)	(882)	(1,922)	(5,900)	(5,093)
Net assets	1,332	1,563	21,492	24,283	121	160	181	284	1,469	6,280	24,595	32,570
Capital expenditure	6	6	349	204	-	-	-	54	83	26	438	290
Additions to intangible assets	213	116	-	-	-	-	-	-	-	-	213	116

4) LOSS FROM OPERATIONS

	2019 £000	2018 £000
Loss from operations is stated after charging/(crediting):		
Depreciation of plant and equipment (see note 10)	476	598
Amortisation of intangible asset (see note 11)	571	575
Rentals subject to "short lease" exemption	213	-
Rentals under operating leases- land and buildings	-	85
Expensed inventory	5,803	4,723
Staff costs (see note 5)	7,165	7,459
Foreign exchange (gains)/losses	(1)	55
Research and development (exclusive of research and development staff costs)	1,368	1,635
Sales and marketing costs (exclusive of sales and marketing staff costs and commissions)	755	1,071
Exceptional items:		
Restructuring costs	164	-
Remeasurement of contingent consideration	(1,523)	-
Impairment of non-current assets	1,311	-
Litigation costs	69	423
	21	423
Auditor remuneration:		
- fees payable to Company's Auditor for the audit of the parent Company and consolidated financial statements	20	20
- auditing the financial statements of subsidiaries pursuant to legislation	53	56
Other services:		
- fees in relation to corporation tax	43	24
Total auditor's remuneration	116	100

5) STAFF COSTS

	2019 Number	2018 Number
The average monthly number of persons (including Directors) employed by the Group during the period was:		
Directors	7	7
Laboratory and administration staff	92	79
	99	86

	£000	£000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	6,178	6,405
Share based payments (see note 21)	(194)	(57)
Social security, pension & healthcare costs	1,181	1,111
	7,165	7,459
Directors' remuneration included above comprised:		
Emoluments for qualifying services	734	645

Social security, pension and healthcare costs include pension contributions of £71k (2018: £95k)

Directors' emoluments disclosed above include £250,000 paid to the highest paid Director (2018: £356,000). The share-based payments charge for Directors was nil (2018: £71,000).

6) FINANCE INCOME

	2019 £000	2018 £000
Bank interest receivable	17	72

7) FINANCE CHARGES

	2019 £000	2018 £000
Imputed interest on deferred consideration	(93)	(262)
Interest on bank loans	(384)	-
	(477)	(262)

8) TAXATION

Tax on loss on ordinary activities

	2019 £000	2018 £000
Current tax:		
UK corporation tax credit on losses of period	(488)	(790)
US corporation tax payable	29	72
	(459)	(718)
Deferred tax:		
Origination and reversal of temporary timing differences	(95)	98
Tax credit on loss on ordinary activities	(554)	(620)

Factors affecting the current tax charges

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

	2019 £000	2018 £000
Loss on ordinary activities before tax	(7,660)	(8,879)
Tax at the standard rate of corporation tax 19% (2018:19%)	(1,456)	(1,687)
Effects of:		
Research and development tax credits received	(468)	(583)
Surrender of research and development relief for repayable tax credit including enhancement	305	203
Other	85	170
Unutilised tax losses	980	1,277
Tax credit for the period	(554)	(620)

Notes to the financial statements continued

For the year ended 31 December 2019

8) TAXATION continued

Unrecognised deferred tax

	2019 £000	2018 £000
Tax losses		
Losses available to carry forward against future trading profits	43,533	43,254
Deferred tax asset – unrecognised* 17%	7,404	7,353

*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.

	2019 £000	2018 £000
Total loss attributable to the equity holders of the parent	(6,973)	(8,186)

	No.	No.
Weighted average number of ordinary shares in issue during the year	1,171,867,216	1,171,633,442
Loss per share		
Basic and diluted loss for the year	(0.60)p	(0.70)p

As set out in note 19. The Company has issued options over 19,553,729 (2018: 53,577,615) ordinary shares and there are 16,112,800 (2018: 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 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
Exchange Adjustment	(70)	(40)	(5)	(10)	(125)
Additions	–	318	92	28	438
Disposals	–	–	–	(2)	(2)
Transfers	–	–	–	–	–
At 31 December 2019	1,931	2,004	767	606	5,308
Depreciation					
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
Exchange Adjustment	(1)	(24)	(1)	(5)	(31)
Charge for the period	45	248	124	59	476
Disposals	–	–	–	(2)	(2)
Impairment (note 11)	–	123	179	37	339
At 31 December 2019	122	1,536	729	564	2,951
Net book value					
At 31 December 2019	1,809	468	38	42	2,357
At 31 December 2018	1,923	537	253	115	2,828
At 31 December 2017	844	1,668	307	175	2,994

Transfers from Laboratory Equipment to Building & Land include nil (2018: £1.1m) for a clean room buildout for which there was no change to the depreciation charged up to the point of transfer.

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 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
Additions*	213	–	–	–	–	–	213
Exchange adjustment	–	(71)	(294)	(78)	(147)	(59)	(649)
At 31 December 2019	972	15,262	2,070	552	1,035	414	20,305
Amortisation							
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
Charge for the period	–	–	234	125	117	94	570
Exchange adjustment	–	–	(15)	(8)	(9)	(7)	(39)
Impairment (see below)	972	–	–	–	–	–	972
At 31 December 2019	972	–	548	293	273	220	2,306
Net book value							
At 31 December 2019	–	15,262	1,522	259	762	194	17,999
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

*Additions in both years arose from internal development.

Goodwill relates entirely to the acquisition of CellRight Technologies LLC in 2017 and is subject to annual impairment testing as described below. The remaining amortisation periods for intangible assets which all arose on the acquisition of CellRight Technologies LLC are: Customer relationships: 2.8 years, Trade marks: 7.8 years, Process Tech: 7.8 years, Supplier agreements: 2.8 years.

Impairment of non-current assets

Annual impairment test on CellRight Technologies LLC ("CellRight")

The Group tests the CellRight cash generating unit (CGU) on an annual basis, or more frequently where impairment indicators exist, by comparing the carrying value 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 of 13.5% 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 inputs into cash flow forecasts are based on the most recent budgets/forecasts approved and reviewed by the Directors for the following year and extended forward for the next four years based on expected growth within that CGU over that period. At the end of year five, a terminal value is calculated using a long-term growth assumption of 2%.

The key inputs to the cash flow forecasts are:

- forecasted changes in volumes (by consideration of future sales plans and production capacity);
- revenues (by management's growth estimates of revenue to existing and new customers based on an understanding of the needs of those customers obtained through working relationships);
- gross margin and overheads (by assessing efficiency of processes and underlying anticipated purchase prices);
- future anticipated capital expenditure; and
- movements in working capital.

The critical assumption within the cash flow forecasts relates to sales growth which is inherently difficult to forecast in a rapidly growing marketplace. Across the five year forecast period, the compound annual growth rate (CAGR) is expected to be 26%. The impairment test prepared indicates that there is substantial headroom between the value in use of £51,927k and the carrying value of £23,662k and the Directors have therefore concluded that there is no impairment within the CellRight CGU. However, in drawing this conclusion the Directors note the importance of achieving the anticipated CAGR and have calculated that an impairment arises in the event that the CAGR falls to 19% across the five year period.

Notes to the financial statements continued

For the year ended 31 December 2019

11) INTANGIBLE ASSETS continued

Group impairment test

Prior to any impairment, the Company's net assets totalled £25,922k at 31 December 2019. Following a significant decline in the Company's share price over the year, this was above the market capitalisation of the Group at 31 December 2019 (£11,200k).

In accordance with IAS 36, the Directors have considered whether this situation was an indicator of impairment and concluded that an impairment review should be performed at 31 December 2019. This was performed for each CGU by comparing the carrying value of the CGU with its recoverable amount. The Directors determined that the CGUs of the group were consistent with the operating segments set out in note 3 with the exception of the Orthopaedics and dental segment which was split between CellRight and the other parts of the Orthopedic segment.

The inputs into the cashflows for the value in use calculation were taken from the same five year forecast model as for the CellRight test described above. Therefore the key assumptions are summarised above.

As a result of the testing, impairment charges totaling £1,311k arose in respect of the following CGUs where the recoverable amount of the CGUs non-current assets was determined to be £nil:

- BioSurgery – carrying amount at 31 December 2019 of £1,792k, of which £809k was working capital and deemed recoverable whilst an impairment charge of £983k arose against non-current assets (comprising £972k of development costs and £11k of property, plant and equipment).
- GBM-V – carrying amount at 31 December 2019 of £324k, of which £172,000 was working capital and deemed recoverable whilst an impairment charge of £152k arose against property, plant and equipment.
- Central – carrying amount at 31 December 2019 of £65,000 of which £176,000 related to property, plant and equipment and against which a full impairment charge has been recorded.

Having completed this impairment review, the Directors note that substantially all of the group's net assets are allocated to the CellRight CGU. Details of the annual impairment review on CellRight are set out above.

12) INVENTORY

	2019 £000	2018 £000
Raw materials and consumables	1,199	871
Work in progress	2,271	939
Finished goods including goods for resale	715	520
Total	4,185	2,330

Inventory is presented net of a provision of £nil (2018:£176,000).

13) TRADE AND OTHER RECEIVABLES

	2019 £000	2018 £000
Trade debtors	1,719	2,465
Other receivables	341	530
Prepayments and accrued income	479	556
Total	2,539	3,551

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

	2019 £000	2018 £000
Trade receivables	1,813	2,710
Less: Allowance for expected credit losses	(94)	(245)
Total	1,719	2,465

13) TRADE AND OTHER RECEIVABLES continued

Allowance for expected credit losses

The Group has recognised a loss of £94,000 (2018: £245,000) in profit or loss in respect of the expected credit losses for the year ended 31 December 2019. The aging of the receivables and allowance for expected credit losses provided for above are as follows:

	Expected credit loss rate	Carrying amount 2019 £000	Allowance for expected credit losses 2019 £000	Carrying amount 2018 £000	Allowance for expected credit losses 2018 £000
not overdue	0%	1,565	–	1,668	–
0 to 3 months overdue	0%	131	–	678	–
3 to 4 months overdue	25%	30	8	90	22
4 to 5 months overdue	50%	1	–	102	51
over 5 months overdue	100%	86	86	172	172
		1,813	94	2,710	245

The average Credit terms with customers is 40 days (2018: 31 days)

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

	At 31 December 2019 £000	At 31 December 2018 £000
US Dollars	1,601	2,345
Euros	118	119
Sterling	–	1
Trade debtors	1,719	2,465

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 major change in risk management of financial assets and liabilities during the year was entering into the Borrowing facility with Mid Cap as described in note 16. 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

The risk in the potential movement in interest received on cash surpluses held is limited. 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.

The risk associated with movements in interest on the Groups borrowings is also limited due to low levels of borrowing which were £2,286k at 31 December 2019 (2018: £nil).

Interest rate sensitivity

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

Asset / (liability)	December 2019		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	1,078	1,302	2,380
Borrowings	–	(2,286)	(2,286)

Asset / (liability)	December 2018		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	6,043	1,773	7,816

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. The impact of a 5% increase/decrease in interest rates on the Group borrowing would have an immaterial impact on the loss of the period.

Notes to the financial statements continued

For the year ended 31 December 2019

14) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES continued

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.

Trade debtor credit risk is mitigated by carrying out a credit review on all customers and setting a credit allowance that reflects the 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.

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

	2019 £000	2018 £000
Cash and cash equivalents		
AA-	–	35
A+	1,000	1,404
A	1,380	6,377
	2,380	7,816

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.

With the exception of borrowings detailed in note 16 all of the group's financial liabilities mature within less than 6 months (2018: all within 6 months). At 31 December 2019 the group was in compliance with all terms relating to the MidCap facilities and undrawn committed facilities of £787k were available to draw down. The maturity of borrowings was as follows:

	2019 £000	2018 £000
Less than 6 months	–	–
6 months to 1 year	171	–
1 year to 2 years	342	–
2 years to 5 years	1,773	–
	2,286	–

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 19 and in the Statement of Changes in Equity.

Foreign currency risk management

The group's exposure to currency exchange rates arises principally from assets and liabilities which are denominated and settled in local currency. While the combination of assets and liabilities provides an 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:

	2019 \$000	2018 \$000	2019 €000	2018 €000
Financial assets	1,601	2,345	121	119
Financial liabilities	(4,118)	(1,717)	(67)	(37)
Short-term exposure	(2,517)	628	54	82

The Group has exposure to the movements in the exchange rates in the Dollar and Euro at 31 December 2019. An analysis of the effect of a reasonably possible movement in exchange rates shows that a movement of 10% in the exchange rate could result in net foreign currency gains of £311k (2018: £80k) against the Dollar and gain £5k (2018: £7k) against the Euro.

14) RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES continued

Categorisation of financial instrument

Financial assets/(liabilities)	Financial assets at amortised cost £000	Financial liabilities at amortised cost £000	Financial liabilities held at fair value £000	Total £000
At 31 December 2019				
Trade and other receivables	2,060	–	–	2,060
Cash and cash equivalents	2,380	–	–	2,380
Borrowings	–	(2,286)	–	(2,286)
Trade and other payables	–	(2,868)	–	(2,868)
	4,440	(5,154)		(714)

Financial assets/(liabilities)	Financial assets 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

15) TRADE AND OTHER PAYABLES

	At 31 December 2019 £000	At 31 December 2018 £000
Current:		
Trade payables	1,650	855
Taxes and social security	76	76
Accruals	1,218	1,896
Contingent consideration (see below)	–	1,475
	2,944	4,302

Contingent consideration

As part of the acquisition of CellRight Technologies LLC in 2017, the Group agreed to pay a second milestone if gross revenue during the second annual period equalled or exceeded \$12.5m. The milestone was not achieved and the contingent consideration was therefore released to the income statement.

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

	At 31 December 2019 £000	At 31 December 2018 £000
Sterling	310	242
US Dollars	1,273	576
Euros	67	37
Trade payables	1,650	855

Notes to the financial statements continued

For the year ended 31 December 2019

16) BORROWINGS

At 31 December 2019	Interest rate %	Maturity	Current £'000	Non-current £'000
Term Loan	US LIBOR+2.25%	Jun 2024	171	1,627
Revolving Credit	US LIBOR+4.5%	Jun 2024	–	761
Gross borrowings			171	2,388
Less capitalised debt issue costs			–	(273)
Borrowings			171	2,115

The Group had no borrowings at the prior year end.

A dollar denominated new bank facility was signed by the Group in June 2019 with MidCap Financial Trust (“MidCap”). The bank loans outstanding at 31 December 2019 are represented by the following:

Term Loan: 5 years to June 2024. \$2m current facility. Originally \$7.5m was drawn in June and subsequently \$5.5m was repaid as reported by the Company. Interest maximum 2.25% above US LIBOR. Repayments of £85,500 per quarter from July 2020. Maturity analysis as detailed in note 14.

Revolving Credit: Repayable in full on June 2024 at the latest. \$3m maximum drawing. Interest maximum 4.5% above US LIBOR.

As part of these facilities, MidCap hold security over the Groups freehold property in San Antonio and IP in respect of the Term Loan. The carrying amount of these assets pledged as security was £1.8m and £nil at 31 December 2019 (2018: £nil).

Also as part of these facilities, a warrant equating to 3% of the value of term loan was granted to Mid Cap based equating to an option over 3,096,798 at an exercise prices of £0.0574. The warrant gave rise to a share based payment charge as detailed in note 20.

Debt issue costs of £303k have been capitalised against the loan and will be amortised to the income statement over the life of the term loan.

17) COMMITMENTS

Operating lease commitments

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

	2019 £000	2018 £000
Land and buildings:		
Amounts due within one year	–	61
Amounts due between 1–5 years	–	–
Total	–	61

18) DEFERRED TAX LIABILITIES

	Totals £000
As at December 2018	791
Release to the income statement	(95)
Exchange adjustment	(26)
As at December 2019	670

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

19) SHARE CAPITAL

	Number	Share capital £000
Total Ordinary shares of 0.5p each as at 31 December 2017	1,170,990,924	5,855
Share options exercised	739,899	4
Total Ordinary shares of 0.5p each as at 31 December 2018	1,171,730,823	5,859
Share options exercised	240,499	–
Total Ordinary shares of 0.5p each as at 31 December 2019	1,171,971,322	5,859

Reserves of the Group represent the following:

Share Premium

Consideration received for shares issued above their nominal value net of transaction costs.

Merger Reserve

Consideration and nominal value of the shares issued during a merger and the fair value of the assets transferred differ.

Reverse Acquisition

Retained earnings of an acquisition

Own shares held

The Company's authority to purchase its own shares is set out in its Articles of Association and approved by the shareholders at the Annual General Meeting.

Share-based Payment Reserve (note 20)

The cumulative share-based payment expense.

Retained Earnings

Cumulative profit and loss net of distributions to owners.

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.

As described in note 20, there were employee related share options outstanding at 31 December 2019 over 32,569,731 shares (2018: 69,700,415 shares) and options issued to providers of borrowings over 3,096,798 shares (2018: nil).

20) 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 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
Exercised in the period	–	(240,499)	–	–	(240,499)	0.0050
Lapsed during year	–	(41,842,799)	–	(1,749,766)	(43,592,565)	0.1010
Issued in the year	–	–	–	6,702,380	6,702,380	0.0281
At 31 December 2019	5,267,716	4,758,732	16,112,800	6,430,483	32,569,731	0.0596

Excluding the EBT shares, there were 4,361,603 share options outstanding at 31 December 2019 (2018: 4,361,603) 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 2019. The range of exercise prices applicable to share options is between 0.5p and 22.5p.

There were 16,112,800 of the jointly held EBT shares which were eligible to vest as at 31 December 2019.

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.

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 2019	EBT shares Granted year to 31 December 2019	Options Granted year to 31 December 2018
Dividend yield	–	–	–
Expected volatility (%)	47	–	42
Risk free interest rate (%)	1.0	–	1.0
Expected vesting life of EBT shares and options (years)	3	–	3
Weighted average share price (£)	0.0596	–	0.00822

Share options issued under the Deferred Annual Bonus scheme (which is within the unapproved options) 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 5.8 years (2018: 6.8 years).

Notes to the financial statements continued

For the year ended 31 December 2019

20) SHARE BASED PAYMENTS continued

Other Share Options

Warrants were issued in the year to Mid Cap as part of the group's new borrowing facilities. Options over 3,096,798 shares were granted at an exercise price of 5.74p. The binomial model was used to value the share based payment charge and that the assumptions adopted are consistent with those used in the calculation of 2019 employee share based payments above except the vesting period of nil. The warrants were measured using an option pricing model as the Directors have concluded that there is no other reliable way of measuring the service received.

A credit/(charge) has been recognised in the statement of comprehensive income for the year as follows:

	Share based payment reserves £000
At 31 December 2017	1,186
Credit in the period	(57)
At 31 December 2018	1,129
Credit in respect of employment related share options	(242)
Charge for warrants issued to MidCap	96
At 31 December 2019	983

21) NON-CONTROLLING INTEREST

	2019 £000	2018 £000
As at 31 December 2018	(482)	(409)
Attributable loss for the period	(133)	(73)
As at 31 December 2019	(615)	(482)

The non-controlling interest has 50% (2018: 50%) equity holding. GBM-V GmbH contributed revenue of £2,076k (2018: £1,842k) and a loss before tax of £(142k) (2018: £34k) for the year. Further financial information relating to GBM-V GmbH can be found in the segmental analysis in note 3.

22) 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:

	2019 £000	2018 £000
Short-term employment benefits	836	709

23) ULTIMATE CONTROLLING PARTY

The Directors believe that there is no ultimate controlling party.

24) POST BALANCE SHEET EVENTS

On 22 May, the Group announced that gross proceeds of £14.6m had been conditionally raised through an offer of new ordinary shares in the Company to Institutional and qualifying retail investors. All conditions attached to this fundraise have since been satisfied, save for the requirement that the issuance of these new shares be approved at a General Meeting of shareholders to be held on 9 June 2020.

The COVID-19 pandemic has affected most businesses during H1 2020. As a result of the reprioritisation of healthcare professionals during this time, there has been a decline in elective procedures undertaken across a number of medical specialities that use our products. Given the uncertainty around the level and duration of disruption from COVID-19, it is difficult to determine how long the current situation may last, and the time taken to catch-up any postponed surgical procedures thereafter. However, the Board, in compiling possible cashflow projections for the business, has considered a number of scenarios regarding the effect of reduced and delayed revenues due to COVID-19 and, has undertaken market soundings regarding the likely timeframe for the recommencement of procedures. It has concluded that, if additional funds are received as expected, there will not be a significant long-lasting impact on the capability of the business to carry out its commercial activities. Whilst COVID-19 has had a significant short term impact on the business, the Directors remain confident with the long term prospects for the group and they do not therefore believe that the pandemic gives rise to any particular concerns regarding the carrying values of assets reported at 31 December 2019.

Company statement of changes in equity

For the year ended 31 December 2019

	Share capital £000	Share premium £000	Merger reserve £000	Share based payment reserve £000	Retained earnings reserve £000	Total £000
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
Total expense and other comprehensive loss for the period	-	-	-	-	(50,001)	(50,001)
Share options exercised	-	1	-	-	-	1
Share based payment credit	-	-	-	(146)	-	(146)
At 31 December 2019	5,859	86,399	10,884	910	(63,466)	40,586

Company statement of financial position

At 31 December 2019

	Notes	2019 £000	Restated 2018 £000
ASSETS			
Non-current assets			
Investments	C5	18,594	18,594
Intercompany loan receivables	C7	3,860	12,954
Total non-current assets		22,454	31,548
Current assets			
Trade and other receivables	C6	218	253
Intercompany loan receivables	C7	16,757	52,242
Cash and cash equivalents	C9	1,669	7,162
Total current assets		18,644	59,657
TOTAL ASSETS		41,098	91,205
LIABILITIES			
Current liabilities			
Trade and other payables	C8	(512)	(473)
TOTAL LIABILITIES		(512)	(473)
NET ASSETS		40,586	90,732
EQUITY			
Share capital	19	5,859	5,859
Share premium		86,399	86,398
Merger reserve		10,884	10,884
Share based payment reserve	20	910	1,056
Retained earnings deficit		(63,466)	(13,465)
TOTAL EQUITY		40,586	90,732

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 2019 was a loss of £50,001k (2018: £2,342k).

The Company financial statements were approved by the Board of Directors and authorised for issue on 4 June 2020 and were signed on its behalf by

Gareth Jones

Interim Chief Executive Officer

Company number: 05969271

Company statement of cash flows

For the year ended 31 December 2019

	Notes	2019 £000	2018 £000
Operating activities			
Loss before interest and tax		(50,646)	(3,152)
Adjustment for non-cash items:			
Share based payments	20	(146)	(57)
Impairment of intercompany loan receivables		48,600	1,310
Operating cash outflow		(2,192)	(1,899)
Decrease/(Increase) in trade and other receivables		35	(3)
Increase in trade and other payables		39	89
Net cash absorbed by operations		(2,118)	(1,813)
INVESTING ACTIVITIES			
Interest received		645	810
Loan to subsidiary undertaking	C10	(4,021)	(7,788)
Net cash used in investing activities		(3,376)	(6,978)
FINANCING ACTIVITIES			
Proceeds from exercise of share options		1	4
Net cash generated from financing activities		1	4
DECREASE IN CASH AND CASH EQUIVALENTS		(5,493)	(8,787)
Cash and cash equivalents at start of period		7,162	15,949
CASH AND CASH EQUIVALENTS AT END OF PERIOD		1,669	7,162

Notes to the company financial statements

For the year ended 31 December 2019

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

During the year, the Company adopted the following standards effective from the 1st January 2019. The Company has applied these standards in the preparation of the financial statements, and has not adopted any new or amended standards early.

Initial application of IFRS 16 Leases

The Company has applied IFRS 16 Leases for the first time in the year ended 31 December 2019. IFRS 16 replaces IAS 17 Leases. The Group previously split leases between 'finance leases' that transferred substantially all the risks and rewards incidental to ownership of the asset to the Group, and 'operating leases'. The main change on application of IFRS 16 is the accounting for 'operating leases' where rentals payable (as adjusted for lease incentives) were previously expensed under IAS 17 on a straight-line basis over the lease term.

The Company has no right of use assets or leases as at 31 December 2019.

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 estimates:

Recoverability of receivables from subsidiaries and impairment of financial assets

Amounts owed by subsidiary undertakings represent loans made to the Company's main subsidiary

The gross loan advanced by the Company is £70,699,000k (2018: £66,506,000). In accordance with IFRS 9 Financial Instruments, as the subsidiary undertakings cannot repay the loan 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, a cumulative lifetime expected credit loss (ECL) of £49,910,000 has been recognised at 31 December 2019 (2018: £1,310,000).

The calculation of the allowance for lifetime expected credit losses requires a significant degree of estimation and judgement, in particular in determining the probability weighted likely outcome for each scenario considered. The Directors assessment of ECL included repayment through future cash flows over time (which are inherently difficult to forecast for the Company at its current stage of development) and also the amount that could be realised through an immediate sale of the subsidiary undertakings. The Directors' assessment of repayment through future cash flows included a scenario where the loan was not recovered in full. The Directors' allocated a probability weighting of 90% to scenarios where recovery would be repayment over time, and 10% to the scenario where immediate sale of the subsidiary undertaking was contemplated.

Given the quantum of the provision recorded at 31 December 2019, the outcome is materially sensitive to the key assumptions inherent in the calculation. The carrying value of amounts owned by subsidiary undertakings at 31 December 2019 is disclosed in note C10 to the financial statements.

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 2019 was a loss of £50,001k (2018: £2,342k).

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

C4. STAFF COSTS

	2019 Number	2018 Number
The average monthly number of persons (including Directors) employed by the Company during the period was:		
Directors	7	7
Administration staff	1	1
	8	8
	£000	£000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	941	692
Social security, pension & healthcare costs	144	114
	1,085	806

Social security, pension and healthcare costs include pension contributions £20k (2018: £23k).

C5. INVESTMENT IN SUBSIDIARY COMPANIES

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

	2019 £000	2018 £000
Cost	18,594	14,707
Additions	–	6,500
Transfer	–	(828)
Impairment	–	(1,785)
Carrying value at 31 December 2019	18,594	18,594

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

At 31 December 2019, the Company held the following investments in subsidiaries:

Undertaking	Sector	Share of issued capital and voting rights	
		2019	2018
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	Dormant	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, Tissue Regenix Holdings 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, Tissue Regenix Holding Inc: 1808 Universal City Boulevard, Universal City Texas, 78148.

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

Notes to the company financial statements continued

For the year ended 31 December 2019

C6. TRADE AND OTHER RECEIVABLES

	2019 £000	2018 £000
Prepayments & accrued income	22	38
Other debtors	196	215
	218	253

C7. INTERCOMPANY LOAN RECEIVABLES

	2019 £000	Restated 2018 £000
Gross intercompany loan receivables	70,527	66,506
Less: Expected credit losses	(49,910)	(1,301)
	20,617	65,196
Comprising:		
Non-current assets	3,860	12,954
Current assets	16,757	52,242
	20,617	65,196

Intercompany loans includes £828,000 gross before provision of £642,889 due from group's EBT (2018: £828,000) (see note C10). No interest was payable on loans to subsidiary undertakings and the loans are repayable on demand except for £13,217,878 unsecured loan to Tissue Regenix Limited that is charged 4% above the Bank of England base rate and repayable in 2024.

During the year the Directors identified that intercompany loan receivables due after one year were previously classified incorrectly as current assets. The comparative figures have been restated to reclassify £12,954,000 of intercompany loan receivables from current assets to non-current assets. This restatement has no impact on reported profits for the year ended 31 December 2018 or reported net assets at that date.

C8. TRADE AND OTHER PAYABLES

	2019 £000	2018 £000
Trade creditors	124	82
Taxes & social security	30	34
Accruals	358	357
	512	473

C9. RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES

The Company activities expose it to a variety of financial risks: market risk, 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.

C9. RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES Continued

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

	December 2019		
	Fixed rate £000	Floating rate £000	Total £000
Cash and cash equivalents	1,092	577	1,669

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

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 and loans advanced to subsidiary undertakings. The Company seeks to minimise this risk by only depositing funds with banks with a high credit rating and through careful monitoring of the operations of subsidiaries.

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.

Management of liquidity risk

The Company seeks to manage liquidity risk to ensure that sufficient funding 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.

	2019 £000	2018 £000
Cash and cash equivalents		
A+	1,000	1,000
A	669	6,162
BBB+	-	-

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

Capital risk management

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

The capital structure of the Company consists of equity attributable to the owners of the Company, comprising issued capital, reserves and retained earnings as disclosed in note 19 and in the Statement of Changes in Equity.

Notes to the company financial statements continued

For the year ended 31 December 2019

C9. RISK MANAGEMENT OF FINANCIAL ASSETS AND LIABILITIES Continued

Categorisation of financial instrument

Financial assets/(liabilities)

Financial assets/(liabilities)	Financial assets at amortised cost £000	Financial liabilities at amortised cost £000	Total £000
At 31 December 2019			
Trade and other receivables	196	–	196
Cash and cash equivalents	1,669	–	1,669
Intercompany loans	20,617	–	20,617
Trade and other payables	–	(482)	(482)
	22,482	(482)	22,000
	Financial assets 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

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:

	2019 £000	2018 £000
Short-term employment benefits	836	709

Intercompany loans during and at the end of the year (before provisions for expected credit losses of £49,910k (2018: £1,310k) were as follows:

	Tissue Regenix Limited	TRx Cardiac Limited	TRx Orthopedics Limited	TRx Wound Care Limited	Total
At 31 December 2018	43,880	147	3,745	17,906	65,678
(Repayment)/Advance in the year	3,579	27	(309)	724	4,021
Equity conversion	–	–	–	–	–
At 31 December 2019	47,459	174	3,436	18,630	69,699
Impairment provision:					
At 31 December 2018	(1,310)	–	–	–	(1,310)
At 31 December 2019	(39,267)	–	–	(10,000)	(49,267)

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. The company also has a loan with the Employee Benefit Trust of (2018: £828,000) against which an impairment provision of £643,000 has been recorded (2018: £nil). 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 2020 Annual General Meeting of Tissue Regenix Group plc (“Company”) will be held at the offices of Squire Patton Boggs (UK) LLP at 6 Wellington Place, Leeds LS1 4AP on 30 June 2020 at 10.00 a.m. for the following purposes:

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

1. To receive the Company’s annual accounts, strategic report and directors’ and auditors’ reports for the year ended 31 December 2019.
2. To reappoint Alan Miller who retires by rotation, as a director of the Company.
3. To reappoint Jonathan Glenn who retires by rotation, as a director of the Company.
4. To reappoint Shervanthi Homer-Vanniasinkam who retires by rotation, as a director of the Company.
5. To reappoint 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, as set out in either resolution 7.1 or 7.2 below (being alternative resolutions depending on the outcome of the general meeting of the Company to be held on 9 June 2020 (“2020 General Meeting”))
 - 7.1. in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are duly passed at the 2020 General Meeting:
 - 7.1.1 up to an aggregate nominal amount of £2,339,999; or
 - 7.1.2 comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £2,339,999 in connection with an offer by way of a rights issue:
 - 7.1.2.1. 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
 - 7.1.2.2. to holders of other equity securities in the capital of the Company, as required by the rights of those securities or, subject to such rights, as the directors otherwise consider necessary,

but subject to such exclusions or other arrangements as the directors may deem necessary or expedient in relation to treasury shares, fractional entitlements, record dates or any legal or practical problems under the laws of any territory or the requirements of any regulatory body or stock exchange, provided that these authorities shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 30 September 2021 (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; or

- 7.2 in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are not duly passed at the 2020 General Meeting:
 - 7.2.1 up to an aggregate nominal amount of £1,953,285; or
 - 7.2.2 comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £1,953,285 in connection with an offer by way of a rights issue:
 - 7.2.2.1 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
 - 7.2.2.2 to holders of other equity securities in the capital of the Company, as required by the rights of those securities or, subject to such rights, as the directors otherwise consider necessary,

but subject to such exclusions or other arrangements as the directors may deem necessary or expedient in relation to treasury shares, fractional entitlements, record dates or any legal or practical problems under the laws of any territory or the requirements of any regulatory body or stock exchange, provided that these authorities shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 30 September 2021 (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; or

In this resolution 7, “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):
 - 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

Notice of annual general meeting

8.2 otherwise than pursuant to paragraph 8.1 of this resolution, up to an aggregate nominal value as set out in either resolution 8.2.1 or 8.2.2. below (being alternative resolutions depending on the outcome of the 2020 General Meeting):

8.2.1. in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are duly passed at the 2020 General Meeting, up to an aggregate nominal amount of £701,999; or

8.2.2. in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are not duly passed at the 2020 General Meeting, up to an aggregate nominal amount of £585,985,

and this power shall expire at the conclusion of the next annual general meeting of the Company after the passing of this resolution or on 30 September 2021 (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).

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 in the capital of the Company ("Shares"), provided that:

9.1. in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are duly passed at the 2020 General Meeting:

9.1.1. the maximum aggregate number of Shares which may be purchased is 701,999,753; and

9.1.2. the minimum price (excluding expenses) which may be paid for a Share is 0.1p; or

9.2. in the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are not duly passed at the 2020 General Meeting:

9.2.1. the maximum aggregate number of Shares which may be purchased is 117,197,132; and

9.2.2. the minimum price (excluding expenses) which may be paid for a Share is 0.5p; and

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 30 September 2021 (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

Kirsten Lund

Secretary

4 June 2020

Registered office

Units 1 & 2, Astley Way
Astley Lane 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 28 June 2020 (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.
2. **In light of the spread of COVID-19 in the UK and associated measures put in place by the UK Government, the Company encourages shareholders not to attend the meeting in person. Instead, shareholders who wish to vote are encouraged to complete a form of proxy, appointing the chairman of the meeting as their proxy, in accordance with the instructions in notes 3-5 below. Shareholders are advised that, if they attempt to attend the meeting in person, they may be denied entry to the venue.**

Proxies

3. 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 4 and 5 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.

4. 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 +44 (0) 371 664 0300 (Calls are charged at the standard geographic rate and will vary by provider. Calls outside the United Kingdom will be charged at the applicable international rate. We are open between 09:00 - 17:30, Monday to Friday excluding public holidays in England and Wales) or the proxy form may be photocopied. State clearly on each proxy form the number of shares in relation to which the proxy is appointed.

To be valid, a proxy form must be received by post or (during normal business hours only) by hand at the offices of the Company's registrar, Link Asset Services PXS 1, 34 Beckenham Road, Beckenham BR3 4TU, no later than 10.00 a.m. on 28 June 2020 (or, if the meeting is adjourned, no later than 48 hours before the time of any adjourned meeting).

5. 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 10.00 a.m. on 28 June 2020 (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.

Corporate representatives

6. 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

7. Subject to the restrictions imposed as a result of the spread of COVID-19 in the UK, 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:

7.1 Copies of the service contracts of the executive directors.

7.2 Copies of the letters of appointment of the non-executive directors.

Notice of annual general meeting

Biographical details of directors

8. 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.

Share capital

9. As at 4 June 2020 (the last practicable business day prior to the date of this notice), the Company's issued share capital comprised 1,171,971,322 ordinary shares of 0.5 pence each. Each ordinary share carries the right to vote at a general meeting of the Company and, therefore, the total number of voting rights in the Company as at the date of this document is 1,171,971,322.
10. In the event that the resolutions set out in the notice of general meeting of the Company dated 22 May 2020 are duly passed at the 2020 General Meeting and the 5,848,026,212 ordinary shares of 0.1 pence each are issued by the board of directors of the Company pursuant to the Fundraising (as such term is defined in the circular of the Company dated 22 May 2020), the Company's total number of voting rights in the Company as at the date of the annual general meeting will be 7,019,997,534.

Directors and Officers

DIRECTORS

Gareth Jones	(Interim Chief Executive Officer)
Jonathan Glenn	(Interim Non-Executive Chariman)
Alan Miller	(Non-Executive Director)
Randeep Singh Grewal	(Non-Executive Director)
Shervanthi Homer-Vanniasinkam	(Non-Executive Director)

COMPANY SECRETARY

Kirsten Lund

COMPANY WEBSITE

www.tissueregenix.com

COMPANY NUMBER

05969271 (England & Wales)

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