

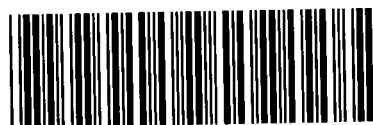


Focusing on the development of regenerative products

Annual Report and Financials
for year ended **31 December 2020**

Stock Code: TRX

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TISSUE REGENIX GROUP
("TISSUE REGENIX") IS
AN INTERNATIONAL,
PIONEERING MEDICAL
TECHNOLOGY COMPANY

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WHO WE ARE

TISSUE REGENIX GROUP

Focusing on the development of regenerative products using our two platform technologies, dCELL®, addressing soft tissue needs, and BioRinse®, providing sterile bone allografts.

We are currently helping to transform the treatment of patients in key surgical applications: BioSurgery, Orthopaedics (sports medicine/spine), Dental, General, Plastic Surgery, Urology/Gynaecology, Ophthalmology, and Cardiac.

Investment case

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

02 International manufacturing capabilities

03 Expansive distribution and commercialisation opportunities

04 Innovative product portfolio and pipeline

05 Tissue processing science and development expertise

06 Differentiated clinical outcomes

Our vision

To establish Tissue Regenix as a global 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

Group snapshot

- ▷ £12.8m revenue FY2020
- ▷ £9.6m cash at 31 December 2020
- ▷ £13.8m (net) equity fundraise, June 2020
- ▷ Capacity expansion programme commenced in San Antonio
- ▷ Distribution via strategic partners, direct specialist sales and distribution partners
- ▷ Two new product launches undertaken during 2020

HIGHLIGHTS

Financial

- ▶ Completed an equity fundraise via placement of ordinary shares raising net proceeds of £13.8m, June 2020
- ▶ Implemented cost reduction initiatives reducing the overhead cost base by £400,000

Revenue growth by product

Annual growth (including impact of FX)

	FY18	FY19	FY20
BioRinse®	31%	5%	11%
dCELL®	79%	25%	(22)%

£12.8mGroup sales decreased
(2019: £13.0m) -2%, driven by:

- ▶ Orthopaedics and Dental revenue of £7.4m, +11% (2019: £6.7m)
- ▶ Joint venture GBM-v achieved sales of £2.1m (2019: £2.1m)
- ▶ DermaPure® sales decreased by 22% to £3.3m (2019: £4.2m)

£9.6mCash balance at 31 December 2020
(2019: £2.4m)**Operational**

Operations

- ▶ Capacity expansion programme commenced in San Antonio, July 2020
- ▶ CE Mark approval for OrthoPure® XT, June 2020
- ▶ Relocation of UK facility to Garforth, Leeds, October 2020
- ▶ Operational improvement initiatives implemented at San Antonio facility

R&D, Clinical

- ▶ 19 new DermaPure® clinical case studies undertaken for new applications
- ▶ 2 case studies commenced for BioRinse® orthopaedic applications
- ▶ OrthoPure® XT prospective and two-year follow up clinical data white papers publicly available
- ▶ Continuation of OrthoPure® XT clinical data collection

Commercial

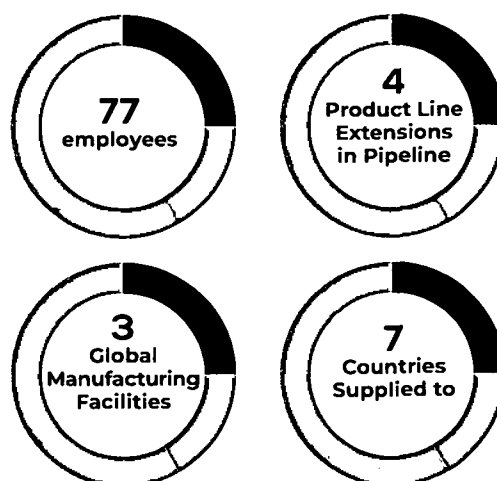
- ▶ New strategic collaboration with a top 10 global healthcare company for white label manufacturing
- ▶ EU and UK distribution agreements signed for OrthoPure® XT
- ▶ Additional commercial opportunities secured for growth product lines such as AmnioWorks™, diversifying the sales portfolio

Management / Governance

- ▶ Daniel Lee appointed as Chief Executive Officer
- ▶ Jonathan Glenn appointed interim Non-Executive Chairman
- ▶ Corporate governance review undertaken and initiatives being implemented

Post balance sheet events

- ▶ Trevor Phillips and Brian Phillips (no relation) appointed as Independent Non-Executive Directors
- ▶ David Cocke appointed Chief Financial Officer, January 2021
- ▶ Restructuring of US Operations, estimated to save c.\$700k on an annualised basis, January 2021
- ▶ Occupation of initial phase of the facility expansion in San Antonio, Texas, March 2021
- ▶ Jonathan Glenn appointed Non-Executive Chairman, February 2021



CHAIRMAN'S STATEMENT

Introduction

With the outbreak of the COVID-19 pandemic, 2020 was always going to be a challenging year for the Group, however, the management team dealt with the demands admirably and also achieved a significant number of milestones. The pandemic had a significant impact on our ability to grow our top line revenue due to the postponement of many elective surgical procedures, and a slowdown of product approvals in new hospital institutions. Despite this, we were successful in achieving several commercial milestones upon which the Company can build its future success.


Financial performance

The Group reported top-line revenue of £12.8m (2019: £13.0m) which is down 2% as a result of the COVID-19 pandemic. Despite the decline in surgeries caused by the pandemic, the BioRinse® portfolio returned 11% growth driven mainly by increased penetration of the AmnioWorks™ product line.

The DermaPure® portfolio was hit more sharply by the pandemic, with revenue dropping 22%, as the indications, DermaPure® targets were more affected by the cessation of elective surgeries in the US.

Our controlled joint venture, GBM-v, maintained its revenues at 2019 levels despite surgical lockdowns in its German cornea business.

As part of its COVID-19 response, the US subsidiaries applied and received loans under the US Government's PPP program. These loans may be converted into grants if used for permitted purposes. The Group believes it has met these conditions and has accordingly classified the proceeds of £815k as Grant Income, in addition to £40k received through the UK furlough scheme.

 More information on our Financial performance can be found on pages 34 and 37

Shareholders and Funding

In June 2020, the Group successfully raised £13.8m (net) (£14.6m gross) of funding through a placement of equity. This, together with a restructuring and optimisation of the cost base has ensured the Group is in a significantly stronger financial position in 2021 and are able to continue to weather the impact of the enduring COVID-19 pandemic.

Furthermore, this injection of capital has allowed for the commencement of the capacity expansion programme in San Antonio, Texas. Phase 1 of this programme, which commenced in July 2020, is expected to increase the BioRinse® processing capacity by c.50% once operational, alleviating the capacity constraints which have historically impinged on the growth of the business.


In order to facilitate this placing, the Group attracted a number of new institutional and private investors which has significantly changed the size and shape of our shareholder base. I would like to thank all of our new and existing shareholders for their continued support.

Operations and the impact of COVID-19

The COVID-19 pandemic and associated restrictions provided an unprecedented and complex landscape to navigate, however, we successfully maintained all operations at the San Antonio facility allowing us to continue to service customer demand, whilst also building inventory to meet the projected demand once a normalised level of procedures has returned. Outside of this, as mentioned above, the commencement of the first phase of the capacity expansion project in July 2020 will provide additional capacity from H1 2021.

Throughout the pandemic, the main priority of the Board has been the wellbeing and safeguarding of our employees, customers, suppliers and all other stakeholders. In the UK, operations and technical staff were furloughed from March in accordance with the UK Government advice. However, with the launch of OrthoPure® XT scheduled for Q4 2020 all staff were re-engaged in July to ensure this timeline could be met.

Outside of this, the Group continued to implement several overhead cost reduction initiatives and the decision was made to relocate the UK head office and manufacturing facility to Garforth, Leeds from October 2020 which is expected to deliver annualised savings of £0.4m from 2021.

 More information on our Operations can be found on pages 28 to 33



Our 2020 performance was strong against the difficult backdrop of COVID-19, and the Group achieved significant operational and commercial progress. Securing the additional funding to invest in starting our US facility expansion, coupled with significant opportunities that lie before us, has the potential to change the trajectory of the Group. With the introduction of two new non-executive directors and Danny and David leading the senior management team, the Group is in a strong position for future success once healthcare systems return to a normalised level of operation."

Jonathan Glenn
Chairman

CHAIRMAN'S STATEMENT

CONTINUED

Our strategy

Our strategy has evolved with the main focus now being the commercialisation of our product pipeline. A key factor in the success of this is our ability to attract and maintain significant strategic partners and key customers. During 2020, we successfully launched a new product under a white label opportunity with a top 10 global healthcare company, signed additional customers, particularly focusing on our lesser known product lines, and expanded into the UK and EU markets with the launch of OrthoPure® XT.

We continue to seek new partnership opportunities and have identified additional product line extensions and therapeutic areas which will drive market adoption and penetration, whilst diversifying the Group's sales portfolio and geographic outreach which we can pursue once the additional processing capacity is fully operational.

Management

In November 2020, Gareth Jones, interim CEO resigned from his position within the Company. After reviewing the strategic direction of the business and running a formal process with an external recruitment firm, the Board made the decision to appoint Daniel (Danny) Lee as CEO of the Group. Danny, who has over 30 years of industry experience, joined as President of US Operations in January 2019 and has been responsible for leading the capacity expansion and optimisation programme in San Antonio.

Following the year end, in January 2021, David Cocke was appointed as CFO for the Group and is based alongside Danny in San Antonio. David has 30 years experience in senior finance and operations roles having previously been CFO

at Aperion Biologics, Inc. and founding NuPak Medical in 1997 which was later acquired by Katena Products, Inc in 2017.

I would like to take this opportunity to welcome both Danny and David to the Group and on behalf of the Board, I would like to thank Gareth for his commitment and leadership throughout what was a particularly challenging year for business.

The Board

The Board of Directors underwent a number of other changes during 2020 in order to ensure that its size, composition and skill set remained relevant to the requirements and strategy of the Group. After significant tenures on the Board, both Alan Miller and Randeep Grewal resigned their positions as Non-Executive Directors, following which Trevor Phillips and Brian Phillips (no relation) were appointed. Brian and Trevor bring a wealth of experience particularly regarding operations and corporate development in the lifescience industry and financial management, which will be key in driving the Company's future success.

In March 2020, John Samuel, former Executive Chairman, also resigned from the Board and I stepped up to fill the Chairman's role on an interim basis and latterly on a permanent basis. With the appointment of Danny Lee as permanent CEO, David Cocke as CFO and two new Non-Executive Directors, Tissue Regenix has a strong new team to lead the Group forward.

Our employees

Our skilled employees are a key stakeholder in the success of the Group and I would like to thank them for their ongoing hard work and commitment. 2020 has been an uncertain



year, particularly for the UK employees who were furloughed for a period of time due to the pandemic, but through their continued commitment and focus on maintaining a COVID-19 free work environment, the Group has emerged in a stronger position to execute our strategic growth drivers, increasing our market penetration and moving closer to profitability.

Post balance sheet events

As we transitioned into 2021, COVID-19 continued to impact the return of elective surgeries. The Group continued to service its customers and partners and positioned the business to be ready for a resumption of the growth it experienced prior to the COVID-19 outbreak.

The expansion plans for the San Antonio facility continued and the initial phase was successfully completed and occupied in March 2021. The expansion enabled the company to transfer its distribution and freezer facilities to the new building which provides the additional capacity for donor tissue, the foundation for growth. The new facility provides a more centralised and efficient arrangement for product distribution needs in the short and long term. In our existing building, the relocation of the freezer facility now enables us to expand our clean rooms which will provide additional processing capacity during H1 2021. The relocation of distribution to the new building, provides the departments remaining in our existing facility the ability to increase their capacity and throughput, as well as the space for future needs.

Outlook

During 2020, the Group achieved a number of significant milestones and we remain focused and committed to creating long-term, sustainable value for our shareholders by increasing our market penetration through leveraging relationships with strategic partners, and improving our portfolio offering with product line extensions for identified, underserved clinical applications.

The capacity expansion programme will alleviate the supply issues that have previously hindered the growth of the Group and moving forward will provide a step-change in the trajectory of the business as we secure additional distribution contracts and have the ability to increase our geographic outreach.

Having successfully entered the UK and specific EU markets with OrthoPure® XT, and establishing our white label manufacturing capabilities with a large global partner, the Board has confidence in the prospects of the Group once the COVID-19 pandemic has subsided and healthcare procedures return to a normalised level.

Jonathan Glenn
Chairman

27 April 2021



AT A GLANCE

Two innovative technology platforms. Multiple clinical application areas. Four strategic growth drivers.

Through our platform technologies, Tissue Regenix is focused on the commercialisation of regenerative medicine products, helping to transform the treatment of patients in key surgical applications:

BioSurgery, Orthopaedics (sports medicine/spine), Dental, General, Plastic Surgery, Urology/Gynaecology, Ophthalmology and Cardiac.

Innovative platform technologies

Addressing clinical needs through complementary bone and soft tissue platforms

dCELL

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

Differentiated characteristics:

- ▶ Maintains the natural scaffold structure of the tissue and provides an acellular 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

BIORINSE

Natural bone void filling solutions verified to be osteoinductive to stimulate and regenerate native bone

Differentiated characteristics:

- ▶ Maintaining the key natural bone growth factors and bone morphogenic proteins that promote active regeneration
- ▶ Contains 100% allograft bone, proven to produce better clinical outcomes
- ▶ Every lot verified to be osteoinductive post sterilization
- ▶ Ability to deliver biological scaffolds in various physical forms to meet clinical needs

Product portfolio

High growth product lines focused on bone, skin (dermis) and birth tissue

Bone

BioRinse®



Flagship Products ConCelltrate®

Applications

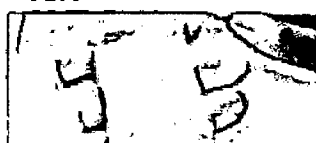
- ▶ Spine
- ▶ Foot/ankle
- ▶ Dental
- ▶ Orthopaedics

Differentiators

- ▶ Induces new bone growth
- ▶ Faster healing
- ▶ Superior handling
- ▶ Reduced flush out

Soft Tissue

dCELL®



Flagship Products DermaPure®

Applications

- ▶ Urogynaecology
- ▶ Sports medicine
- ▶ Open wound
- ▶ Plastics

Differentiators

- ▶ Clinical outcomes
- ▶ No second graft site required
- ▶ Stored at room temperature
- ▶ Superior handling

Birth Tissue

Proprietary



Flagship Products AmnioWorks®

Applications

- ▶ Ophthalmology
- ▶ Wound covering

Differentiators

- ▶ Clinical outcomes
- ▶ Barrier can provide faster healing
- ▶ Stored at room temperature

PRODUCT PIPELINE

The Group has a novel product portfolio to address a number of clinical indications.

Product	Application/indication	Classification	Primary market
DermaPure [®] – Decellularised allograft dermal tissue	Orthopaedics, trauma, wound care	HCT/Ps	USA
DermaPure [®] Non-Oriented – Decellularised allograft dermal tissue with no basement membrane	Urogynaecology, general surgery	HCT/Ps	USA
SurgiPure XD – Decellularised xenograft dermal tissue	Hernia repair	510(k) device clearance, Class II	USA
OrthoPure [®] XT – Decellularised xenograft tendon	Revision, multiligament ligament reconstruction, including primary reconstruction when autograft is unavailable	Class III device, CE Mark received	UK and EU
ConCelltrate 100 – Demineralised allograft bone matrix	Orthopaedics, spine	HCT/Ps	USA
Matrix OI FlexIt – Demineralised cortical bone strip	Maxillofacial, periodontal defects	HCT/Ps	USA
Matrix OI 100 DBM – Demineralised cortical fibres and fillers with mineralised cancellous fibres	Spine, non-structural bone-grafting	HCT/Ps	USA
Matrix OI Strips & Blocks – Cell containment scaffold that minimises and compliments the use of fixation devices	Orthopaedics, spine	HCT/Ps	USA
MatrixCollect 100 DBM – Demineralised allograft bone putty	Orthopaedics, trauma, spine	HCT/Ps	USA
MatrixCollect 100 DBM Crunch – Demineralised allograft bone matrix containing cancellous chips	Orthopaedics, trauma, spine	HCT/Ps	USA
Matrix IQ – Decellularised allograft dermal tissue	Dental and maxillofacial	HCT/Ps	USA
AmnioWorks [™] – Allograft Amniotic membrane	Ophthalmology, wound care	HCT/Ps	USA
DentalFix – mineralised particulate allografts featuring a unique elongated shape	Dental and maxillofacial	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 dense part of the bone, which has been processed to retain biologic properties including growth factors

Demineralised Cancellous bone – porous bone matrix which retains biologic properties and provides a scaffold to allow growth of the patient's own bone

Classification:

HCT/Ps – USA classification

Human cells and tissue-based products (HCT/Ps) consisting 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) or the more recent Medical Device Regulation (MDR) 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>

CAPACITY EXPANSION PROJECT

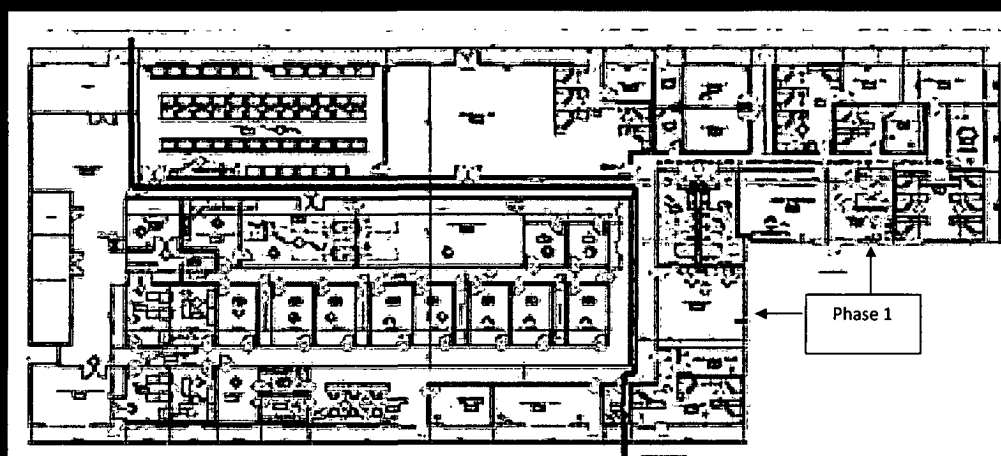
Securing the additional funding in June 2020 allowed the Group to commence a capacity expansion programme at the facility in San Antonio in July 2020.

The project is to be split in phases to allow for the efficient deployment of capital, as well as ensuring to bring capacity online in a controlled and managed process.

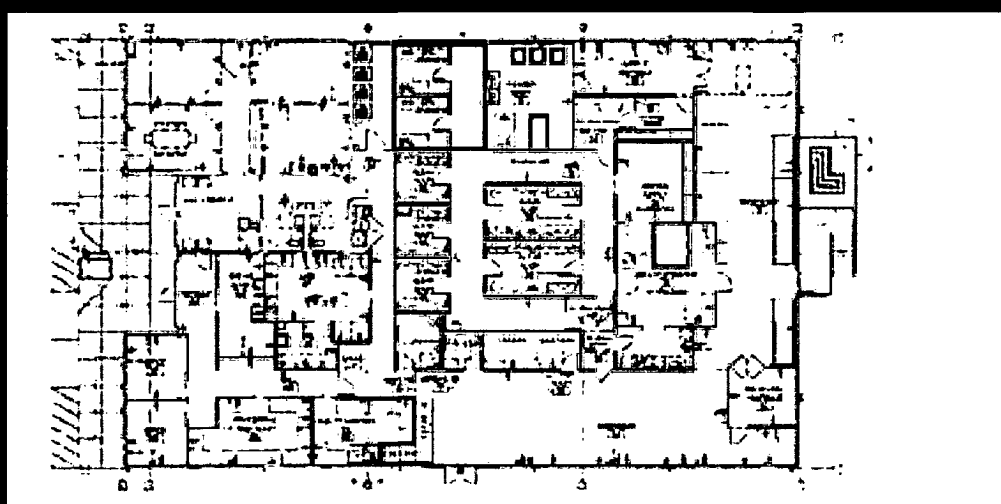
Phase 1 commenced in July 2020 and involved moving freezer space and distribution functions into the new facility, allowing two additional sterile packaging clean rooms to be installed in the existing facility and increasing the BioRinse® processing capacity by c.50%. This was completed in March 2021 however, due to the significant lead time required for the osteoinductive testing of our BioRinse® portfolio, the first products processed from phase one of the expansion are expected to be available during Q3 2021.

Phase 2 of the expansion project will entail up to a further potential ten clean rooms in the new facility, which would take approximately 12 months to build. Due to the deferment of surgical procedures as a result of COVID-19 and the production improvements in the existing facility, along with the increased capacity offered by phase 1, commencement of phase 2 has been put under review by the Board to ensure that the market demand has recovered sufficiently before the investment is made.

Phase 1 in new facility

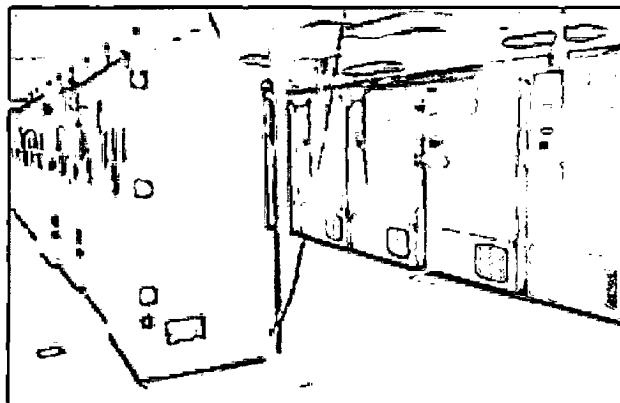
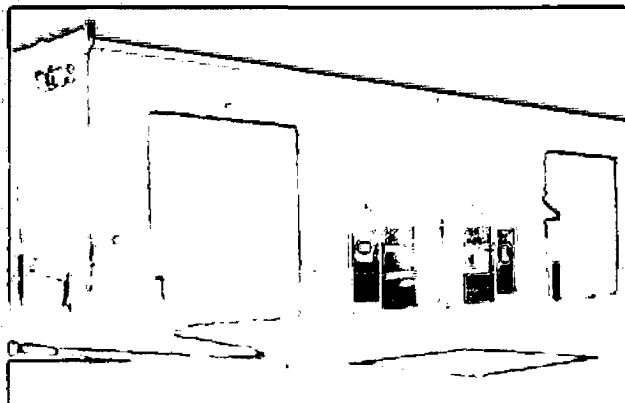


Phase 1 in Existing Facility



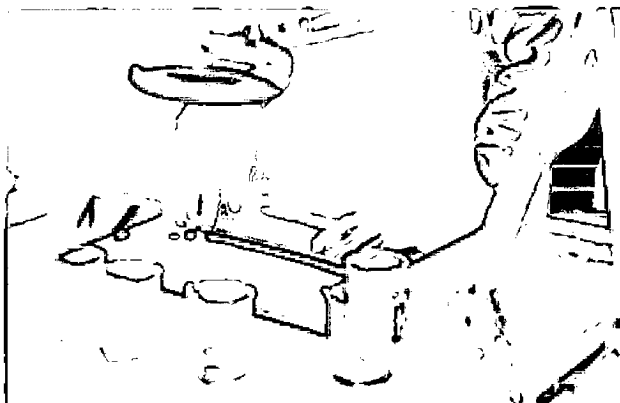
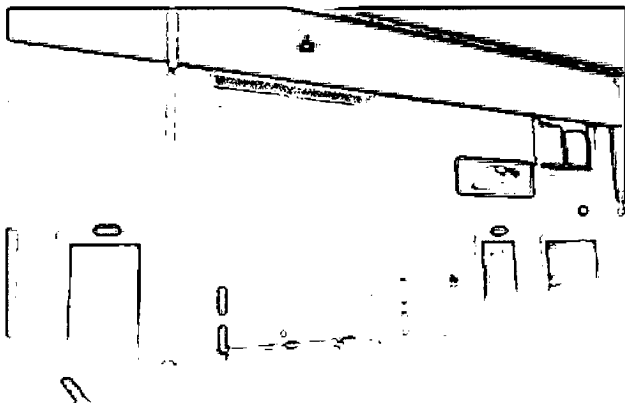
San Antonio, Texas

- Human Tissue US
- Processing of dCELL[®] and BioRinse[®] products



Tissue Regenix Leeds, UK

- Porcine Tissue
- Processing of OrthoPure[®] XT



GBM-v Rostock Germany

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



OUR MARKETS

Regenerative medicine

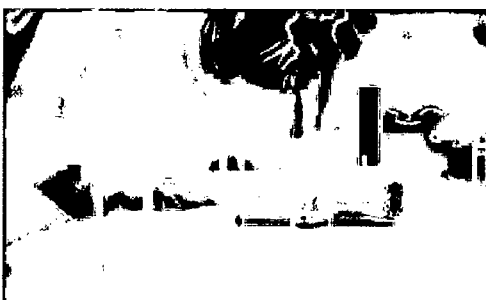
Regenerative medicine is an interdisciplinary field that seeks to develop the science and tools that can help repair or replace damaged or diseased human cells or tissues to restore normal function, and holds the promise of revolutionising treatment in the 21st century.¹ The demand for regenerative solutions is driven by demographic shifts both in terms of lifestyle-related illness such as obesity and diabetes, for example, it is projected that by 2045 the United States will have 30.4m people with diabetes;² and also the expectation to maintain one's quality of life.

Health economics

The expectation amongst patients to maintain levels of mobility and health for much longer is driving the emergence of new novel technologies that can remove the need for repeated or ongoing surgeries and medical care, ultimately reducing the overall cost of this treatment cycle. Although there is a wide acceptance of the value of human tissue products in areas such as organ donation, and minimally manipulated human tissues, there are still many insurance companies that will not yet sanction coverage of the more novel therapies, which can lead to expensive and lengthy clinical trials, particularly for xenograft (porcine) tissues.

The impact of COVID-19

COVID-19 has had a significant impact on the healthcare markets. In the US, following the Centers for Medicare and Medicaid Services (CMS) releasing guidelines recommending postponing or cancelling elective, non-essential medical, surgical, and dental procedures to preserve resources for treating COVID-19 patients, it is predicted that hospitals in the US lost between 30-55% of their elective patients between March and April³, a figure that likely increased during the second and more aggressive wave of the pandemic that hit the US in the fall and winter. Although it is expected that once a vaccine has been significantly rolled-out, elective surgeries will return to pre-pandemic levels, the question remains however, at what pace.



Market opportunities

The Global Regenerative medicine market is projected to reach \$151,949m by 2026 demonstrating a CAGR of 26.1% during 2019-2026,⁴ addressing a growing number of clinical needs and Tissue Regenix is helping to transform the treatment of patients in key surgical applications: BioSurgery, Orthopaedics (sports medicine/spine, Dental, General, Plastic Surgery, Urology, Gynaecology, Ophthalmology and Cardiac).

Our products address sports medicine, spine, degenerative diseases, traumatic, surgical and oral conditions. The Group is now focused on commercialisation of its existing product lines and also the launch of product line extensions for specific applications where a growing clinical demand is seen.

During 2020, the Group launched a new soft tissue orthopaedic product under a white label distribution agreement in the US with a major strategic partner, and OrthoPure® XT, a decellularised porcine tendon for the reconstruction of knee ligaments in the EU. The first market targeted was the UK where the addressable market is expected to be £27m.

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 361 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. The Group has worked closely with notified and regulatory bodies to ensure that all required certification is in place to retain CE mark certification and allow the exportation of products, following the exit of the UK from the European Union.



- ¹ <https://nrc.ukri.org/research/initiatives/regenerative-medicine/>
- ² <https://www2.deloitte.com/uk/en/pages/covid-19/articles/impact-covid19-healthcare-systems.html>
- ³ "How The COVID-19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead," Health Affairs Blog, October 8, 2020.DOI: 10.1377/hblog20201006.263687
- ⁴ <https://www.fortunebusinessinsights.com/industry-reports/regenerative-medicine-market-100970>

OUR DIVISIONS

The Group comprises of three key commercial divisions allowing each to function independently and pursue the appropriate commercial strategy, access to relevant Key Opinion Leaders and experienced management teams. This also allows for the benefits of operational synergies across the Group whilst reporting against each division individually.

Due to the COVID-19 pandemic, some 2020 commercial milestones have rolled forward into 2021.

BioSurgery

Repair and replacement of soft tissue – dCELL®

2020 achievements

- ▶ Full roll out of DermaPure® non-oriented
- ▶ 19 new clinical case studies
- ▶ Gained approval in five new large hospital systems

2021 milestones

- ▶ Further expansion into the North American markets
- ▶ Secure a strategic partner for wound care and other applications
- ▶ Launch product line extension specifically for urogynaecology applications
- ▶ Launch product line extension for wound care/dermis applications

GBM-v & Cardiac

Multi-tissue bank facility, supplying corneas and the development of human tissue

2020 achievements

- ▶ Restructured Cardiac division to recognise significant overhead cost reductions

2021 milestones

- ▶ Further expansion into the German cornea replacement market
- ▶ Consider complementary product lines for ophthalmic indications

Orthopaedics & Dental

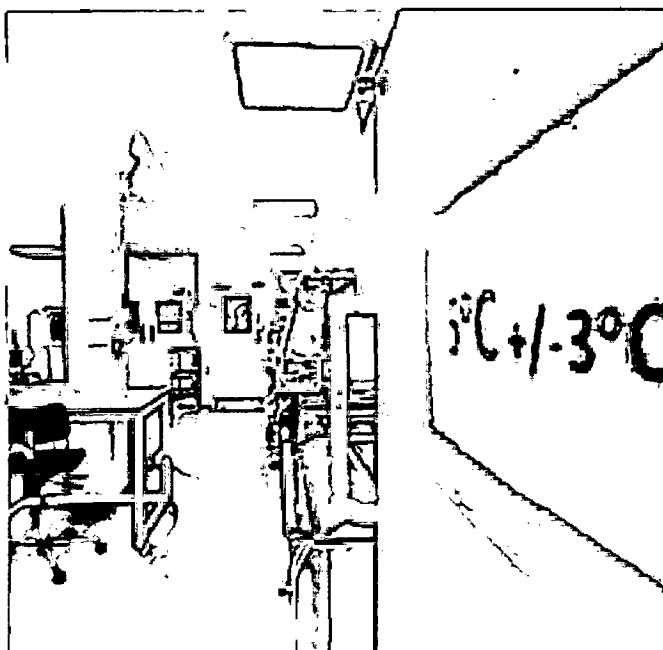
Repair and augmentation of bone and soft tissue – BioRinse® & dCELL®

2020 achievements

- ▶ Continued to develop efficiencies to increase capacity in existing facility which resulted in a c36% increase in processing of musculoskeletal tissue
- ▶ Secured additional strategic partnerships for both US and overseas opportunities
- ▶ Entered a white label distribution agreement with top 10 global healthcare company for new soft tissue orthopaedic product
- ▶ Commenced phase one of the facility expansion project
- ▶ Received CE Mark approval for OrthoPure® XT
- ▶ Entered UK and European distribution agreements for OrthoPure® XT

2021 milestones

- ▶ Further expand European rollout of OrthoPure® XT
- ▶ Bring online phase one of capacity expansion programme
- ▶ Work with current strategic partners to expand distribution of current product portfolio and identify and launch new product line extensions
- ▶ Secure additional material strategic partnerships



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 expand our reach and serve the global market potential.

Our offering

BIORINSE.

BioRinse® Technology

Natural bone filler solutions tested for osteoinductivity to stimulate and regenerate native bone growth.

This process has the potential to provide superior clinical outcomes as it contains 100% allograft bone, demonstrating the presence of the key natural bone growth factors, and in a natural carrier available in various physical forms.

dCELL.

dCELL® Technology

Gentle soft tissue decellularisation process, removing DNA and cellular material to encourage integration and minimise the 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 14 primary product lines on the market (excluding white label), 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.

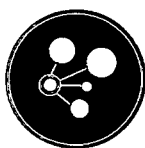


03

Distribution and licensing

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

Our competitive advantages



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 Sustainability on pages 44 to 45

OUR STRATEGIC GROWTH DRIVERS

Strategic objective	Description	2020 performance	Focus and goals for 2021+
 Accelerate US market penetration	<p>The US is the largest healthcare market in the world and where we see the greatest opportunity.</p> <p>We intend to leverage our platform technologies dCELL® and BioRinse® to further our market penetration through a hybrid sales model, a combination of direct sales, distribution and OEM agreements.</p>	<ul style="list-style-type: none"> ▶ Commenced phase one of capacity expansion programme ▶ Entered white label distribution agreement ▶ Strengthened relationships with strategic partners ▶ Extended roll out of DermaPure® non-oriented product ▶ Expanded distribution network ▶ With the increased supply chain and production capabilities, expanded distribution of amniotic products to further diversify product mix 	<ul style="list-style-type: none"> ▶ Bring onstream phase one of capacity expansion programme ▶ Launch new product line extensions and SKUs ▶ Assess the commencement of phase two of capacity expansion programme ▶ Increase collection of real world clinical data highlighting our product differentiators
 Exploit global market potential	<p>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.</p>	<ul style="list-style-type: none"> ▶ Commenced phase one of the capacity expansion programme ▶ Entered into UK and EU distribution agreements for OrthoPure® XT ▶ Expanded network of distributors outside of the main US market ▶ Identified potential licensing opportunities in other geographic areas 	<ul style="list-style-type: none"> ▶ Bring onstream phase one of capacity expansion programme ▶ Secure additional distribution partners for the roll out of OrthoPure® XT ▶ Ramp up market awareness of BioRinse® products outside of US market ▶ Enter distribution arrangements with overseas partners for the supply of our dCELL® product range ▶ Continue to pursue potential licensing opportunities in other geographic territories

Link to KPIs	Link to risks	Commentary
<ul style="list-style-type: none"> ▶ Group sales growth ▶ Increase number of strategic partnership and distribution opportunities 	<ul style="list-style-type: none"> ▶ Finance – Insufficient funds to invest in the required expansion ▶ Operational – The Group is unable to expand in line with demand ▶ Clinical and Regulatory – Changes in regulatory pathways for products 	<p>Although COVID-19 may have slowed the commercial expansion of the Company the injection of Capital from the equity fundraise in June has allowed us to commence the facility expansion programme in San Antonio and will provide sufficient working capital to support Company growth and drive towards profitability. Therefore, although we do not consider cash resources a major risk, should the pandemic continue this could become a more pressing concern. During 2021, we will focus on exploiting the milestones achieved in 2020 and pursuing further opportunities with product line extensions and additional capacity.</p>



➔ Read more about our KPIs on pages 22 and 23

➔ Read more about our Risks on pages 38 and 43

<ul style="list-style-type: none"> ▶ Group sales growth ▶ Increase number of strategic partnerships and distribution opportunities 	<ul style="list-style-type: none"> ▶ Operational – The Group is unable to expand in line with demand ▶ Clinical and Regulatory – Loss of license or restriction due to regulatory failings ▶ Significant change in political or economic landscape 	<p>Historically, capacity constraints have impacted the Group's ability to produce sufficient product to service demand outside of the core US markets. However, with the capacity constraints being alleviated by the capacity expansion programme, we envisage that the Group will be able to expand its outreach into additional geographic territories during 2021 and beyond.</p>
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OUR STRATEGIC GROWTH DRIVERS

CONTINUED

Strategic objective	Description	2020 performance	Focus and goals for 2021+
 <p>Broaden strategic partnerships</p>	<p>Our commercial strategy focuses on establishing and building strategic partnerships to further our market penetration.</p> <p>This allows for the potential to increase OEM agreements and initiate discussions around joint IP collaborations, as well as extending our geographic reach. Key to this, is also increasing our real world clinical data collection to highlight our clinical differentiators for customers, reimbursement agencies, and strategic partners.</p>	<ul style="list-style-type: none"> ▶ Entered white label manufacturing agreement for new product with top 10 global healthcare company ▶ Secured additional strategic and distribution partners for existing product portfolio ▶ Launched OrthoPure® XT into the European market securing distribution partners in the UK, Poland and Portugal 	<ul style="list-style-type: none"> ▶ Ramp up market penetration of our smaller product lines in collaboration with strategic partners ▶ Launch new product developments with strategic partners ▶ Enter new clinical applications and geographic territories with new and existing strategic partners
 <p>Strengthen portfolio</p>	<p>Our success is reliant upon the ability to commercialise our current product portfolio and the potential for augmenting this with product line extensions and new innovative products.</p> <p>We look to establish a database of compelling clinical data to validate our technology platforms and further our physician conversion rates.</p> <p>These clinical data portfolios are also imperative when we seek new strategic partnership opportunities for negotiating favourable reimbursement pricing and when navigating regulatory clearance in new territories.</p>	<ul style="list-style-type: none"> ▶ Launched new product in collaboration with top 10 global healthcare company ▶ Received CE Mark approval for OrthoPure® XT to commence European roll out ▶ Collated two year clinical data for OrthoPure® XT, now publicly available ▶ 19 new DermaPure® clinical case studies ▶ Two new BioRinse® clinical case studies 	<ul style="list-style-type: none"> ▶ Expand opportunities for OrthoPure® XT in the UK and select European markets ▶ Launch new product developments with strategic partners, specifically for urogynaecology and wound care applications ▶ Commence post marketing clinical studies

Link to KPIs

- ▶ Group sales growth
- ▶ Clinical data collection

Link to risks

- ▶ Operational - The Group is unable to expand in line with demand
- ▶ Commercial - Competitor product could reach the market first, offer pricing advantages or outperform the Group's products
- ▶ Clinical - Risk of loss of license or restrictions

Commentary

Despite the challenges that COVID-19 presented to the commercial landscape during 2020, the Group was successful in broadening our base of strategic partnerships and OEM agreements, and remains well positioned to build on these relationships moving forward.

➔ Read more about our KPIs on pages 22 and 23

➔ Read more about our Risks on pages 38 and 43

- ▶ Clinical data collection
- ▶ Improve breadth of product portfolio and pipeline
- ▶ IP collaboration

- ▶ Clinical and 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
- ▶ Clinical and Regulatory - Changes to the regulatory landscape for our products

During 2020, we brought to market two new products that diversify our product portfolio and also provide additional opportunities with new strategic partners and expand our geographic footprint.

During 2021, we intend to expand the market penetration and opportunities for these products as well as develop further product line extensions to address specific clinical applications where we see a market opportunity and have the capabilities to execute quickly.

FUTURE MILESTONES: STRATEGY IN ACTION

Strategic objectives



Accelerate US market penetration

Focus

Drive sales growth of product portfolios in the US market through current and potential direct and indirect distribution channels and increasing GPO relationships and penetration

Near 6–12 months

- ▶ Bring onstream phase 1 of the capacity expansion programme
- ▶ Assess commencement of phase 2 of the capacity expansion programme
- ▶ Bring to market new product line extensions
- ▶ Further develop strategic partnerships and identify additional partnerships which will complement our growing portfolio
- ▶ Increase collection of real world clinical data

Mid 12–18 months

- ▶ Look to secure new significant strategic partnerships
- ▶ Continue to identify product opportunities and commercial partnerships

Long 18+ months

- ▶ Further collaboration with strategic partners for future product development, including combination products

Exploit global market potential

Focus

Continue to build global sales reach through expansion of distribution partnerships and licensing agreements

Near 6–12 months

- ▶ Continued expansion of UK and EU BioRinse® distribution opportunities
- ▶ Roll out of OrthoPure® XT distribution partnerships in the EU

Mid 12–18 months

- ▶ Expand network of distributors outside of the main US and EU markets
- ▶ Pursue licensing and partnership opportunities to expand geographic reach

Long 18+ months

- ▶ Focus on business development for geographic expansion

Broaden strategic partnerships

Focus

Pursue further, and develop existing distribution, licensing or IP collaboration partnerships

Near 6–12 months

- ▶ Enter new clinical application areas and launch product line extensions with existing partners
- ▶ Sign agreements with additional strategic partners

Mid 12–18 months

- ▶ Increase licensing and strategic partnerships

Long 18+ months

- ▶ Pursue further joint IP opportunities



Strengthen Portfolio

Focus

Bring new products and product line extensions to market from pipeline of products currently in development

Near 6–12 months

- ▶ Launch new product line developments
- ▶ Expand rollout of OrthoPure® XT in the UK and select European markets

Mid 12–18 months

- ▶ Pursue internal and external opportunities to broaden product portfolio

Long 18+ months

- ▶ 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 long-term objectives, Group sales must increase to justify investment into further 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 for our allograft and xenograft products to demonstrate our differentiating factors and reinforce the economic and clinical benefits, driving 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 product line extensions 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 address market needs, increase our market penetration and complement the existing product portfolio; these line extensions generally have an expedited route to market, established distribution pathways 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 career 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 strategic growth drivers

In June 2020, the Group secured £13.8m (net) of equity funding which has allowed for the commencement of phase one of the capacity expansion programme in the US and offers sufficient working capital to support the Group for the foreseeable future. Cash must now be carefully managed to ensure the efficient deployment of capital and an appropriately sized overhead cost base.

A blend of all four strategic growth drivers

2020 was a challenging year commercially due to the impact of COVID-19 on the healthcare markets, but despite this, we maintained our overall top-line revenue. However, with the launch of two new product lines, additional strategic partnerships and the commencement of the capacity expansion programme, the Group is now better positioned to grow top-line revenue during 2021 and beyond once healthcare markets and elective procedures return to a more normalised level.

A blend of all four strategic growth drivers

Real world clinical data is increasingly important to our commercial success as we showcase the differentiating properties of our novel product portfolios. During 2020 we continued to collect clinical data for OrthoPure[®] XT and made publicly available the pre-clinical and two-year follow-up data. A number of case studies were undertaken by our Key Opinion Leaders ('KOL') for DermaPure[®] highlighting the different clinical applications in which it can be successfully utilised. As we continue to grow the availability of clinical data for our BioRinse[®] portfolio, we have commenced a number of case studies both with our strategic partners, and KOLs, results of which we would expect to publish during 2021.

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 and to monitor and ensure that infringement does not occur.

Strengthen portfolio

Although the dCELL[®] process is patent protected, we keep the BioRinse[®] process as a trade secret to protect this IP.

Accelerate market penetration

Securing the equity funding in June 2020 allowed for the commencement of phase one of the capacity expansion programme in San Antonio. The addition of new freezer facilities will triple the Company's donor tissue storage capacity and the new distribution area will enable the Company to integrate distribution and finished goods into a more efficient operating space. Commencement of phase two will be monitored and initiated when appropriate to ensure that the capital investment is deployed efficiently and capacity constraints are not experienced in the future.

Accelerate US market penetration

Exploit global market potential

Broaden strategic partnerships

2020 provided many challenges commercially due to the impact of COVID 19. However, we continued to strengthen our relationships with key strategic partners as well as securing additional opportunities, demonstrated by our white label manufacturing agreement. With a focus on augmenting our sales portfolio we also pursued a number of additional opportunities for our amniotic membrane product and secured distribution partners in key European territories for OrthoPure[®] XT.

Broaden strategic partnerships

During 2020, we launched two new product lines which augment our sales portfolio. Firstly, a soft tissue orthopaedics product under a white label manufacturing agreement with a top 10 global healthcare company, in the US market; and OrthoPure[®] XT, a decellularised porcine tendon, for distribution in select European markets.

Strengthen portfolio

Accelerate market penetration

Following the restructuring of the employee base in 2019, our staff retention throughout 2020 has been extremely high. The change at the Executive management level, with Daniel Lee stepping into the CEO position, and later David Cocke joining as CFO, will provide stability in the leadership moving forward and the departure of Mike Izon as R&D Director at the end of the year allowed for the promotion of Christine Powley to Technical and Operations Director, UK.

A blend of all four strategic growth drivers

As we look to increase our manufacturing capabilities we remain conscious about how this will impact our environmental footprint. Throughout 2020, we have continued with the upgrade of lighting in our offices, clean rooms and sterile packaging clean rooms to LED. The replacement of our air compressor and drying unit to a more efficient unit was undertaken to reduce this energy consumption by 70%. Alongside this, there were a number of design improvements implemented throughout the new building process to address these issues.

A blend of all four strategic growth drivers

OUR MANAGEMENT TEAM

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



Daniel Lee
Chief Executive Officer
(CEO)

Daniel Lee has nearly 30 years' experience in the medical device and biologics industry, ranging from product innovation to commercialisation to corporate management. Daniel was appointed CEO in November 2020 after initially joining Tissue Regenix Group as President of U.S. Operations in January 2019. Prior to this, 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.

Danny is also a Certified Tissue Bank Specialist (CTBS) from the American Association of Tissue Banks (AATB).



David Cocke
Chief Financial Officer
(CFO)

David C. Cocke has over 29 years of experience in the medical device industry holding senior finance and operations positions. In 1997, David was a founding partner of NuPak Medical, an ISO-certified contract manufacturer of sterile disposable medical devices. NuPak Medical was acquired by Katena Products, Inc. in 2017 and David remained with the business post-acquisition until joining Tissue Regenix in January 2021. David was also Chief Financial Officer at Aperion Biologics from 2008-2017. Prior to this, David was Senior Director for Finance and Operations at Kinetic Concepts from 1993-1996.

David began his career in the corporate finance sector, working at GE Capital in its Corporate Finance Group and at Salomon Brothers Inc in its Investment Banking Group.

David received his B.B.A in Business Honors (magna cum laude) from the University of Texas at Austin and his M.B.A from the University of Virginia's Darden Graduate School of Business Administration. He has two patents covering medical devices.



Gerald Sharpe
Vice President - Strategic
Partnerships

Gerald Sharpe has over 10 years' experience in the orthobiologics industry, working for two differentiated allograft tissue processors. His focus is commercialisation and business development. He joined CellRight Technologies as Regional Sales Manager in September 2014, before being appointed as Vice President - Strategic Partnerships in January 2019. Gerald is proficient in spine, sports medicine, foot and ankle, dental, and ocular aspects of the business.

Prior to joining CellRight, Gerald was Regional Sales Manager and Director of Client Services for TissueNet. His previous sales roles include Vice President of Business Development for SolomonFX.

Gerald received his Bachelor of Science degree in Marketing from the University of Central Florida.



Christine Rowley
Technical and Operations
Director, UK

Christine has over 16 years' experience in the medical device biologics industry, joining Tissue Regenix in 2010. She has worked in all areas of product development and commercialisation, and has led the development of the OrthoPure® XT device from product feasibility through to market approval and launch. Christine's experience covers a wide range of activities, including new product development, process optimisation and design transfer, design verification and validation, clinical trial design and execution, regulatory submissions, and quality control, almost exclusively working with class III xenograft implants.

Christine has held leadership roles within the product development, regulatory, clinical and quality sectors, and has achieved market clearance of xenograft medical devices in multiple countries worldwide. Christine has several patents associated with the decellularisation and manipulation of collagenous tissues for potential health care benefits. Christine has a Bachelor of Science degree in Biological Sciences from the University of Exeter (UK).

OUR MANAGEMENT TEAM



Tina Trimble
VP, Donor Services, US

Tina Trimble has 30+ years' of tissue banking industry experience and joined CellRight Technologies as VP, Donor Services in March 2019. Tina has worked with other tissue banks in leadership roles such as Community Tissue Services, Regeneration Technologies, Tutogen Medical and most recently, Bone Bank Allografts.

Tina is a Certified Tissue Bank Specialist, and currently serves on the American Association of Tissue Banks (AATB) Exam Committee, American Board of Accredited Tissue Banks, Birth Tissue Council and most recently on the AATB Board of Governors 2018-2020 and Chair of the Processing and Distribution Council. Prior to that, Tina served on the AATB Accreditation Committee, VC Processing and Distribution Council, Education and Program committees and is currently a member of AORN and ASQ.



Lance Johnson
VP, Quality and Regulatory, US

Lance Johnson has over 30 years' experience in FDA Requirements and Quality Systems. His experience includes over 10 years at the executive level for primarily class III medical device implant companies. Prior to joining CellRight Technologies as VP, QA/RA, Lance was the Vice President of Quality for EndoStim Inc, an active implant device manufacturer located in Austin, TX. Lance also worked in the xenograft device industry as VP of Quality for Aperion Biologics, and in the orthopedic spine industry as Quality Manager for Zimmer Spine and Abbott Spine.

In addition to his industry experience, he spent 16 years as an active investigator with the FDA. Lance specialised in medical device compliance and worked in both the San Francisco and Dallas districts. He spent 12 years as the resident in charge of the Austin, Texas field office and as contributor to the FDA international cadre.

Lance received his Bachelor of Science degree in Biotechnology from Oklahoma State University.



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 supports the CFO and leads the finance teams in both the UK and US, and advised 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.



Patti Gary
Vice President,
Clinical Affairs

Patti J. Gary has nearly 30 years of experience in the medical device and tissue industry. Her experience provides a unique combination of sales and clinical roles. She joined Tissue Regenix as Senior Director of Clinical Affairs in July 2013, before being appointed to VP of Clinical Affairs in March 2015.

Prior to joining Tissue Regenix, Patti was Sales Director for PolyRemedy. Her previous roles include Professional Education Manager, Corporate Healthcare Director and Director of Clinical Services for Systagenix (acquired by Acelity). Prior to Systagenix, Patti was Post-Acute National Accounts Director and District Sales Manager for Acelity. Her journey in industry began at Hill-Rom as an Account Manager. Patti was also the owner and President of Positive Outcomes, Inc. where she developed clinical and financial tools (HealQuest, HealPROtocols and Healware) to drive standardized processes for wound management. HealPROtocols was acquired by Acelity. Her depth of knowledge spans clinical, regulatory, reimbursement and sales, all of which have contributed to her success. Patti is a Registered Nurse and a Certified Wound Care Nurse. She graduated from Louisiana State University Health Sciences Center School of Nursing.

CEO OPERATIONAL REVIEW

2020 performance

The Group performed strongly during 2020 despite the COVID-19 backdrop, delivering top-line revenues consistent with 2019 and achieving significant operational and commercial success. We improved our performance against key performance indicators in a year where many companies experienced a downturn in demand as hospital resources were redirected, and this is a testament to our products, partners and employees.


Financial Performance

Our Orthopaedics and Dental division is comprised primarily of our BioRinse® portfolio, reported sales of £7,446K (2019: £6,724K), an increase of 11% driven largely by strong performances by our partners, the diversity of our markets, and the addition of distributors for smaller product lines. The most significant increase was seen in our amniotic membrane product line which was achieved primarily through strategic partnerships in ophthalmology, a growth opportunity for the Company. Over time, sales from the OrthoPure® XT product line will be captured under this division however, with its launch in November 2020 the contribution to the 2020 revenue line was not material.

The BioSurgery division maintained its increased focus on soft tissue orthopaedic and urogynaecology procedures which were established during 2019, however, these areas were more significantly impacted by the postponement and cancellation of elective surgical procedures caused by the COVID-19 pandemic, and consequently lead to a 22% reduction for revenues under this division. We continue to work closely with our customers, distributors and strategic partners and it is expected that once these procedures recommence, the demand for our DermaPure® and DermaPure® non-oriented products will continue to increase.

Alongside this, the Group initiated a number of overhead cost reduction initiatives, which reduced our overhead cost base by £1.7m, and the full annualised saving of c.£400k from the UK facility move in October 2020 will not be fully realised until 2021. We have continued to focus on our overhead cost base and following the year end announced restructuring of the US business which once annualised will realise a further c.\$700k saving.

The completion of the £14.6m (gross) equity fundraising in June 2020 has provided a strong cash position for the Group, with these resources allowing for investment into phase 1 of the capacity expansion programme in San Antonio. It will provide sufficient working capital to support the Group for the foreseeable future.

 Read more about our Financial overview on pages 34 and 37

Operations

Operationally, 2020 was a successful year for the Group with the additional funding allowing for the commencement of the capacity expansion programme in San Antonio. Previously, the Group was hindered by a lack of freezer storage and distribution facilities which restricted the number of donors we could hold on site for processing; and efficiencies in our ability to ship finished goods in-line with peak demand. The new distribution facility consolidates this function into a single location and provides labour and time savings in processing orders. Phase 1 of the capacity expansion will move all freezer space into the new facility increasing our capacity. This in turn will allow for two additional sterile packaging clean rooms to be installed in the space formerly occupied by freezers in the original building. These changes alone should provide additional flexibility and increase our BioRinse® portfolio processing capacity by c.50%, which we expect will be easily absorbed by the demand we see from existing partners and customers. This expansion will also improve the efficiency for processing the DermaPure® portfolio of products. Furthermore, we intend to build up to an additional 10 clean rooms in the new facility in phase 2, which will allow for the continued expansion of our customer base, product portfolio and geographic reach. Due to the impact of COVID-19 on the healthcare markets, the initiation of this phase has been placed under review to ensure the efficient deployment of capital and a return to normalised market conditions. Once Phase 2 is fully operational, it is expected that this expansion programme will meet our processing requirements for the next 5-7 years.

The relocation of our UK facility was undertaken in October 2020 once the required inventory for the launch of OrthoPure® XT had been processed. As part of this relocation, many aspects of the production process have been successfully outsourced reducing our dependency on in-house manufacturing.



I am honoured to have been appointed as CEO to lead the Group through its next stages of development. 2020 was a challenging year, but under the circumstances, a successful period for the Group. The year was primarily highlighted by our financial performance relative to other industry participants, and securing the necessary funding to support the organisation and invest in the required capacity expansion programme. Alongside this, we secured a number of additional distribution and white label agreements for organic growth in the US and extending our geographical outreach through the receipt of the CE Mark for OrthoPure®XT which allowed us to begin our commercialisation efforts within the EU. Having been with the Group for two years as President of US Operations, I was familiar with much of the business. However, since moving into this role, I can see expansive opportunities that lie before us to enable our global growth in regenerative medicine."

Daniel Lee
Chief Executive Officer

CEO OPERATIONAL REVIEW

CONTINUED

In January 2020, the Group was the victim of a cyber attack, which temporarily affected our ability to process at the facility in San Antonio. We quickly implemented an action plan to provide forensic data, remediate our services and mitigate the potential consequences. Although there was a short-term impact on our ability to service customer demand as we were unable to release inventory for distribution in-line with the necessary quality regulations, during the weeks that followed the attack, the San Antonio team worked to catch up with this demand. The Company reported the attack to all relevant authorities, has reviewed its IT service providers and implemented additional data security procedures to reduce the risk of a similar incident occurring in the future.

The impact of COVID-19

The pandemic stunted the surgical marketplace when hospitals, governments and health care providers halted elective procedures across all specialties. The postponement of surgical procedures, which was initially most evident in the urogynaecology and dental applications, has led to business disruption in terms of unpredictable inventory and manufacturing forecasts.

By undertaking certain initiatives, which were updated throughout the year based on guidelines issued by the government and other credible sources, there was minimal disruption to the processing undertaken at the facility in San Antonio, which continued to show strong production throughput. Although COVID-19 did not impact production in San Antonio, it did have an impact on our supply chain of donors. To address the delays in donor sourcing, we broadened our donor sourcing agencies by taking into account factors such as geography and recovery structures. As the impact of COVID-19 became more evident, we monitored and adapted our approach through a combination of communication with partners and altering our processing and production priorities. During Q3, regional markets started to regain momentum but COVID-19 continued to have an impact nationally as 2020 came to an end.

Strategy

Whilst in the position as President of US Operations, I was involved in shaping the strategic direction for the US business and the required capacity expansion project. Therefore, the strategy as highlighted by the previous Executive management at the time of the fundraise is one that I continue to endorse and look to our strategic growth drivers as the map to our future success. During 2020, we were successful in securing a number of commercial and operational milestones and improving our performance against key performance indicators, such as increasing our strategic partnerships and therefore, US market penetration.

Commercial and R&D

Following the restructuring of the business in late 2019, we continue to pursue the commercialisation of current product lines as our top priority and look to augment this with product line extensions that are faster to market and address a specific clinical application and need. One of these areas was a focus on our amnion based products which has increased nearly four-fold year on year.

During 2020, we launched OrthoPure® XT into the UK and select European markets following the receipt of CE mark certification. OrthoPure® XT is used in the reconstruction of the Anterior Cruciate Ligament following re-rupture, the reconstruction of other knee ligaments in multi-ligament procedures following trauma, and primary ACL procedures where the autograft is unavailable or inadequate.

The Group has been working to launch this product for a number of years and successfully undertook a comprehensive clinical trial, resulting in white papers describing the pre-clinical and two-year clinical follow-up.

We also strengthened our white label manufacturing which will supplement our own branded portfolio, increase market opportunities and provide revenue generating streams for the business. In May, we announced that we had signed a white label agreement with a top 10 global healthcare company for a new soft tissue orthopaedic product; this was the culmination of two years work between our R&D and commercial teams alongside our new partner. Although there has been a positive response to this product, it is expected that the full impact of this product line will not be seen until 2021 once the COVID-19 pandemic has subsided. The additional capacity provided by the expansion programme will allow us to expand our white label offering and it is this type of activity which we hope to replicate with additional strategic partners in the future. During the year we

also added several additional private label agreements for our growth product lines, such as AmnioWorks™, which have the potential to generate revenue and diversify our spectrum of products and specialties moving forward.

One of our focus areas during 2020 was the identification of product line extensions to strengthen both our product portfolio and market position. We expect that during 2021 a number of these identified product line extensions or improvement opportunities from our product portfolio will come to fruition, driving the organic growth rate, specifically as we look to tailor our soft tissue offering to clinical applications where we see a lack of suitable biologic alternatives and meet market expectations.

Culture

The Group is reliant upon our employees to ensure that the value of our novel technology platforms realises its true potential and becomes the clinician's product of choice to improve the lives of as many patients as possible.

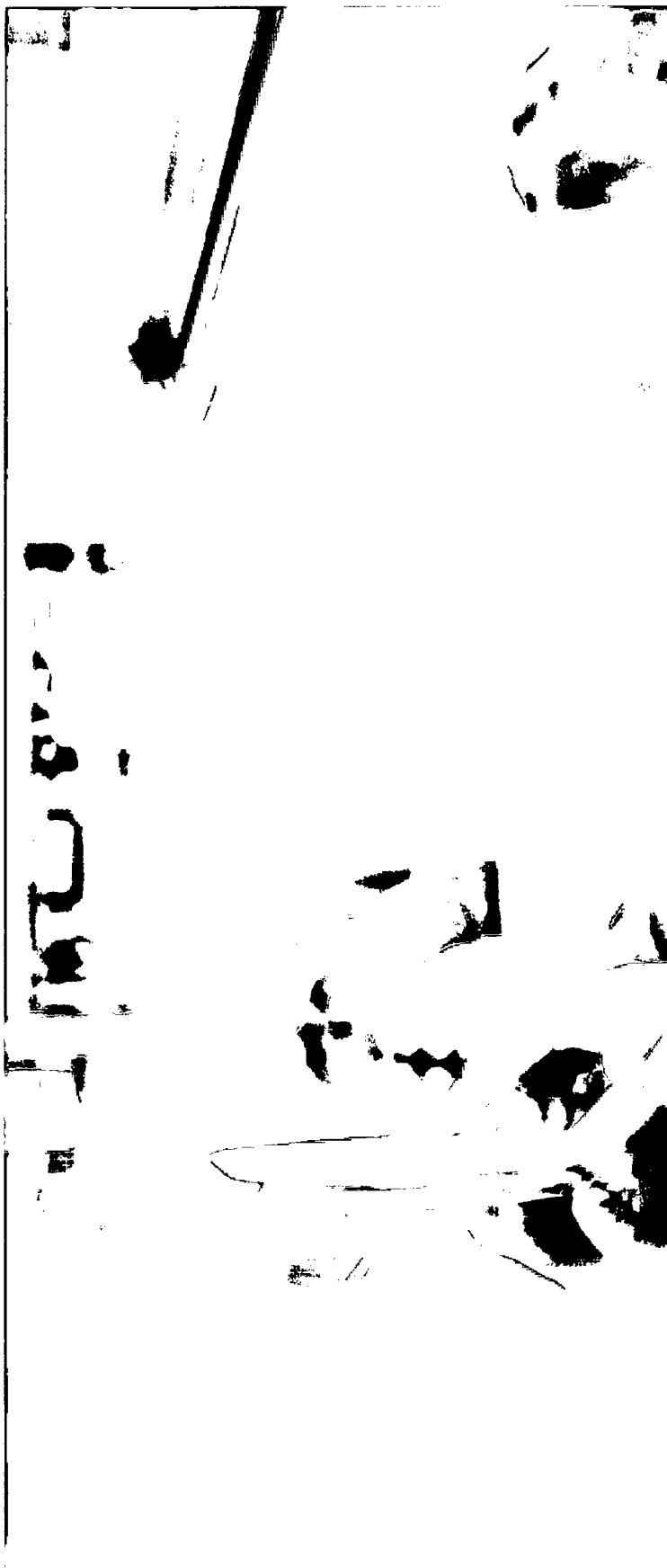
Central to this is the corporate culture we create, and I strongly support the Group's vision, mission, values and behaviours which we expect every employee to uphold and which guides the corporate strategy and decision making. 2020 also provided the challenge of COVID-19, requiring a combination of remote and on-site working to ensure a safe and healthy workplace. This culture ensured that the Company is fair, ethical and supportive towards all employees and stakeholders, making it a place where people want to work, and excel, as well as being a Company that customers and industry peers want to partner with.

2021 priorities

The COVID-19 pandemic continues to have a significant impact on the healthcare industry. However, we remain focused on developing the aspects of the business within our control, continuing our efforts to more effectively utilise our resources and position the Group with a competitive edge once the situation begins to normalise.

This includes the completion of Phase 1 of the capacity expansion programme and ensuring that all operational procedures are implemented to allow for a smooth transition to the increased processing capacity. With this increased capacity, we can continue the positive discussions that have commenced with existing and new strategic partners.

Alongside this, we will be in a position to commence the processing and launch of product line extensions that have been identified due to market demand which will augment our product portfolio.



CEO OPERATIONAL REVIEW

CONTINUED

Our commercial focus to this point has primarily been on the US market where there is significant demand. However, with the increased capacity and expansion of distribution networks, during 2021 and beyond we will seek to expand our geographic outreach into new territories for our dCELL® and BioRinse® portfolios. Following the successful launch of OrthoPure® XT into the UK and select EU markets during Q4 2020, we will continue to rollout this product into additional target markets.

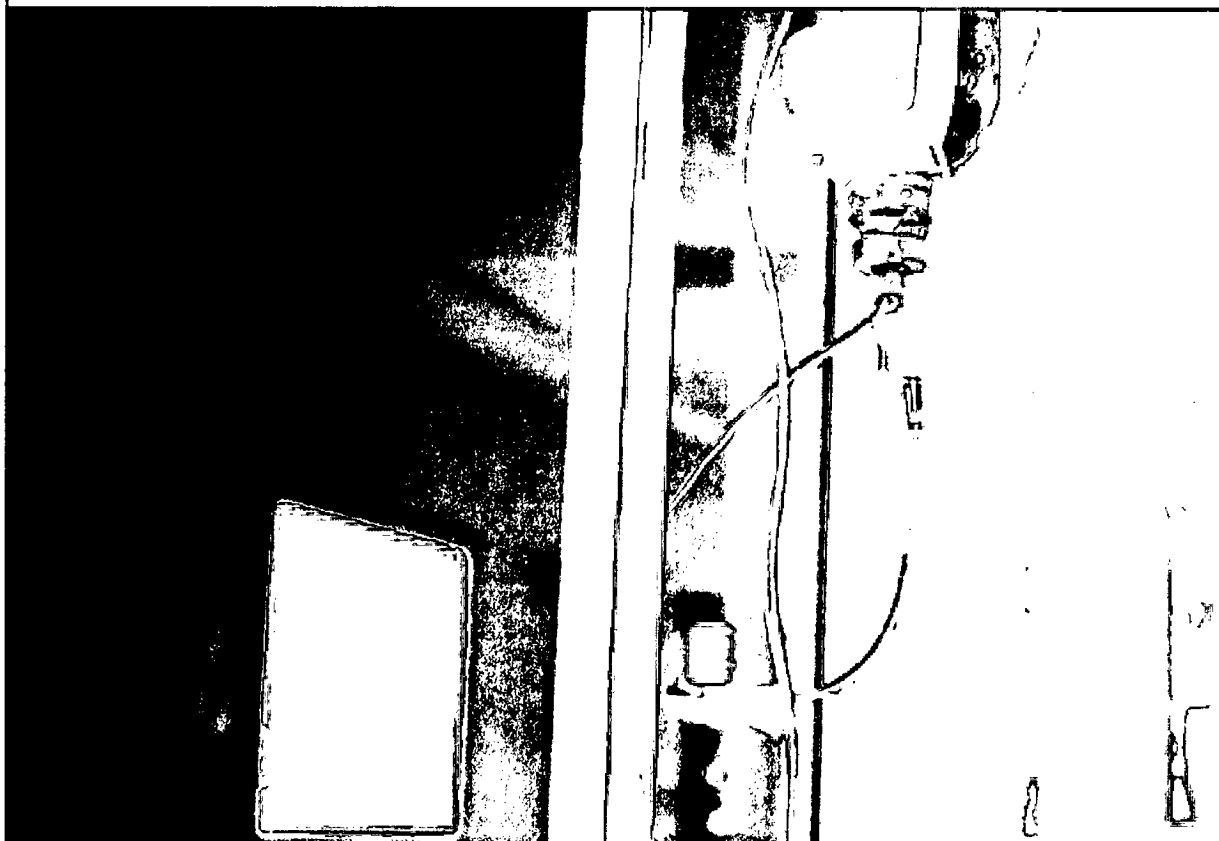
Post balance sheet events

As we moved into 2021, the Company was still impacted by the COVID-19 pandemic as elective surgical procedures in many institutions were still on hold and postponed. Commercial representatives were prevented from entering institutions to meet with clinicians and administrators. Many patients also delayed surgeries due to COVID-19 fears, family finances, lost time at work, lack of insurance or employment, and other considerations. The arrival of vaccines and the drop in positivity rates brought hope and optimism. There were indications of the return of normal market conditions but many expect disruptions to continue to mid 2021. It remains difficult to predict at what pace a return to pre-pandemic procedure levels will occur. All of our divisions continued to exercise caution and protect the safety and well-being of our employees. By continuing the initiatives

we began in 2020 and implementing any relevant government policies, no disruptions in operations and no positions were impacted by the pandemic.

On 5 January, we continued to enhance our organisational excellence with the confirmation of Brian Phillips and Trevor Phillips as independent Non-Executive Directors of Tissue Regenix. Brian Phillips assumed the Chair of the Audit Committee and Trevor Phillips assumed the Chair of the Remuneration Committee.

On 21 January, we added David Cocke as our Chief Financial Officer and Executive Board member. David has over 29 years of experience in the medical device industry holding senior finance and operations positions. David founded NuPak Medical, an ISO-certified contract manufacturer of sterile disposable medical devices, which was acquired by Katena Products, Inc. in 2017. David remained with the business post-acquisition until early 2021, leading the expansion to double the clean room capacity and assembly space on time and on budget. I had the opportunity to work with David at Aperion Biologics where he was the Chief Financial Officer and where we successfully supported the Board in raising \$21m from venture capital and private investors. David's experience in financial systems, management and operations will be invaluable to the Group as we undertake the next stages of our growth programme.



In late January further re-structuring of the US business was undertaken to rationalise resources across the business. It is expected to reduce the overhead cost base by c \$700k on an annualised basis.

On 26 February, we announced that the Board had appointed Jonathan Glenn to the position of Non-Executive Chairman. Jonathan joined the Group in January 2016 and his leadership had been invaluable as a Board member and as Interim Chairman. We look forward to his continued contribution to the Group.

On 18 March, we announced that we have completed the initial phase of our expansion plans at our San Antonio Texas facility. This expansion into the 21,000 sq. ft. facility adjacent to our existing facility was the first stage of our plans to address manufacturing capacity constraints. This initial part of the expansion project comprised of relocating facilities designated for distribution and frozen tissue storage, both of which had outgrown their existing space in the San Antonio facility. The new freezer facility triples the Company's current storage capacity allowing Tissue Regenix to hold more donor tissue on site. The new distribution area enables the Company to integrate distribution and finished goods into a more efficient operating space.

Work has also started on the construction of two additional clean rooms at the existing San Antonio facility, bringing the total number of clean rooms to seven and providing additional capacity and flexibility. The move of distribution and finished goods to the new building provides expansion space for supporting departments in our existing facility. These developments, which will complete phase 1 of the expansion project, are scheduled for completion during H1 2021. The decision to do this in phases was advantageous by enabling us to be efficient with our capital and plan our expansion in line with the return to pre-pandemic procedure levels. We anticipate as the markets normalise and demand returns, we can justify the investment into the additional phase of the capacity expansion.

Daniel Lee
Chief Executive Officer

27 April 2021




FINANCIAL OVERVIEW

Revenue

In the year ended 31 December 2020 revenue decreased by 2% on an underlying basis or 0% constant currency basis to £12,829k (2019: £13,033k).

The financial performance for the year was impacted by the ongoing COVID-19 pandemic which became evident from Q2 onwards, together with material cash constraints that the business experienced in the first half of the period. Notwithstanding this, the Orthopaedics & Dental segment successfully grew top line sales by 11%, to £7,446k (2019: £6,724k) largely driven by a strong Q1 performance. In addition, it maintained strong relationships with strategic partners and saw an increase in the utilisation of a newer, growth product line, AmnioWorks™, which will be utilized in surgical specialties such as ophthalmology.

Revenue from DermaPure®, under the BioSurgery division, was more significantly impacted by the pandemic and associated restrictions, as US hospitals postponed elective surgical procedures, such as urogynaecology and soft tissue orthopaedics, where the DermaPure® products would be utilized, resulting in a 22% decrease in revenues to £3,308k (2019: £4,233k) for this division. There is beginning to be a slight uptick in the recommencement of these procedures as the US vaccine roll-out continues and patient confidence returns, however, it remains difficult to predict at what pace a return to pre-pandemic procedural levels will occur.

The Group's joint venture, GBM-V, based in Rostock, has been impacted by the German lockdown restrictions that were in place for much of the last year, however, the business unit continued to service the cornea market where possible and maintained revenues of £2,075k (2019: £2,076k) in line with prior year results.

Grant income

During the year, the US subsidiaries of the group were successful in the application of the US Government PPP loans. The loans have a two year term and carry a 1% annual interest rate deferred for six months, however, under the loan agreement, the total amount of the loan will not require repayment if the funds are used to support employee payroll, healthcare, utilities and rent payment within the US during the six months post funding. The Group believes they have met the conditions and have classified the proceeds £815k (2019: nil) as Grant Income. The UK furlough scheme also provided support for the Group during COVID-19, which amounted to £40k in Grant Income.

Exceptional items

Restructuring costs for the year totalled £353k (2019: £21k) with £252k relating to the reduction in staff and consultants in the Central segment were charged in the year.

Restructuring costs of £101k due to the reduction in staff and consultants were charged to the Cardiac & Other segment in 2020.

Exceptional items includes a £6,130k non-cash impairment charge arising from the annual impairment test on the CellRight Technologies cash generating unit. The uncertainty created by the COVID-19 pandemic necessarily resulted in more conservative forecasting of future cash flows which in turn gave rise to the reported impairment. Further details on the impairment test can be found in note 12.

Cost of sales and gross profit

Gross profit for the year is £5,896k (2019: £6,019k). Gross margin percentage remained the same at 46% (2019: 46%).

Included in costs of sales is cost of product £5,990k (2019: £5,803k) and third party commissions of £943k (2019: £1,211k).

Administrative expenses

During 2020, administrative expenses before exceptional items decreased by £3,132k to £10,066k (2019: £13,198k), largely due to a reduction of £2,600k in spending at the Central overhead function to £1,325k (2019: £3,925k). This reduction was driven by the downsizing in Q4 2019 which resulted in 18 positions being made redundant in addition to £736k reduced depreciation and amortisation after the impairment recorded in 2019. In addition, certain expenses related to ongoing clinical trials of OrthoPure[®] XT (£215k) are now capitalised due to the recently received CE Mark. Historically these expenses were expensed as incurred, but accounting standards require these to be capitalised once relevant conditions have been met. Administrative expenses at the BioSurgery division decreased £1,069k to £2,660k (2019: £3,729k) due primarily to reduced staffing levels which decreased £756k to £2,106k (2019: £2,862k).

Finance income/charges

Finance income of £2k (2019: £17k) represented interest earned on cash deposits. Finance charges for the year were reported at £445k (2019: £477k) and related to interest charges and associated costs for the MidCap loan arrangement of £245k (2019: £384k) in addition to interest arising due to the adoption of IFRS16 of £200k (2019: nil).

Taxation

The Group continues to invest in developing its product offering, and as such, is eligible to submit enhanced research and development tax claims in the UK, enabling it to exchange tax losses for a cash refund. In the year to December 2020, a refund of £440k was receivable (2019: £488k). 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.

Gross tax losses carried forward in the UK were £51,104k (2019: £43,533k). 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. Corporation tax payable in the US amounted to £0k (2019: £29k).

Loss for the year

The loss for the year was £9,708k (2019 loss: £7,106k) resulting in a basic loss per share of (0.22p) (2019 loss per share: 0.60p).

Balance sheet

At December 2020, the Group had net assets of £27,847k (2019: £24,595k) of which cash in hand totalled £9,550k (2019: £2,380k).

Inventory increased by £2,887k to £7,072k (2019: £4,185k) as the BioSurgery and Orthopaedics & Dental segments added to stock levels to support projected business growth.

Property, plant and equipment increased by £895k to £3,252k (2019: £2,357k) related to the expansion of the US manufacturing facility.

A Right of Use asset was recorded in 2020 of £2,458k in accordance with IFRS 16, Leasing (2019: nil). The Group took on property leases in the US and UK, resulting in a Right of Use Asset and a related Lease liability on the balance sheet.

Intangible assets decreased to £10,931k (2019: £17,999k) through amortisation charges in the year and the non-cash charge against Goodwill of £6,130k (2019: nil). A further £215k of development costs were capitalised in the year.

Working capital increased in the year to £7,277k (2019: £4,644k) driven by increased inventory (£2,887k increase). The balance sheet included corporation tax receivable of £825k (2019: £1,035k) in respect of UK research and development tax credits.



FINANCIAL OVERVIEW

CONTINUED

Borrowings

Non-current liabilities represent the £2,790k debt facility. This includes £1,473k of the term loan and £1,507k of the revolving credit facility, net of £190k of capitalised debt issue costs. The debt facilities mature in 2024 with quarterly principal repayments on the term loan of \$500k per quarter starting in July 2023. The Group is in compliance with the financial covenants related to the debt facilities as of the date of this report.

More information on these obligations is provided on page 91.

Dividend

No dividend has been proposed for the year to 31 December 2020 (2019: Nil).

Accounting policies

Following the departure from the EU, the Group's consolidated financial information has been prepared in accordance with International Accounting Standards in conformity with the UK Companies Act 2006. The Group's significant accounting policies, which have been applied consistently throughout the year, are set out on pages 73 to 77.

Going concern

The Group financial statements have been prepared on a going concern basis based on cash flow projections approved by the Board for the Group for the period to 31 December 2022 (the "Cash Flow Projections").

Funding requirements are reviewed on a regular basis by the Group's Chief Executive Officer and Chief Financial Officer and are reported to the Board at each Board meeting, as well as on an ad hoc basis, if requested. The Cash Flow Projections show that the Group will continue to consume cash over the forecast period. Until sufficient cash is generated from its operations, the Group remains reliant on cash reserves of £9.6m at 31 December 2020 and the ongoing support of MidCap Financial Trust ("MidCap") (borrowings of £2.8m at 31 December 2020) to meet its working capital requirements, capital investment programme and other financial commitments.

The COVID-19 pandemic has affected most businesses during 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 the Cash Flow Projections, has considered a downside scenario 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 there will not be a significant long-lasting impact on the capability of the business to carry



out its commercial activities. The Cash Flow Projections prepared by the board, including the downside scenario, indicate that the Group will still have cash reserves at the end of the forecast period.

The Group's Cash Flow Projections also assume that the MidCap facilities are available throughout the forecast period as they are repayable in 2024. The availability of these facilities is dependent upon compliance with a rolling twelve month revenue covenant which is measured on a monthly basis. The Cash Flow Projections indicate compliance with this covenant throughout the forecast period. The scenario reflecting very low growth indicates that this covenant may be breached in the second half of 2022. That scenario also shows that the MidCap facility could be repaid from cash reserves in the event that repayment was demanded by MidCap.

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 have reviewed the Cash Flow Projections. On the basis of their assessment, they have concluded that the going concern basis remains appropriate for use in these financial statements.

Post balance sheet events

The Group has remained committed to appropriately sizing its overhead cost base and expenditure. To this end, further restructuring of the US business was undertaken in January 2021 to rationalise resources

across the business which is expected to reduce the overhead cost base by c. \$700k on a normalised annualised basis. With respect to the COVID-19 pandemic, there is beginning to be a slight development in the commencement of surgical procedures in the United States as the vaccine roll-out continues and patient confidence returns. However, it remains difficult to predict at what pace a return to pre-pandemic procedural levels will occur.

Principal risks & uncertainties

The principal risks and uncertainties facing the Group are set out on pages 38 to 43.

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.

David Cooke
Chief Financial Officer
27 April 2021




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 implements measures that 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 under the QCA Corporate Governance Code.

Operational




At an operational level, we monitor monthly performance against objectives allowing us to track performance 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. In accordance with our governance practices, the Audit Committee supports the Board of Directors in monitoring the Group's risks.

We have identified six areas of potential risk: Finance & IT, Operational, Clinical & Regulatory, Commercial, HR and the wider political and social environments. The Board believes the following risks are the most significant for the Group, however, they may not necessarily comprise all the associated or potential risks attached to the Group. 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 equity fundraise in June 2020 provides both investment and working capital required by the Group for the foreseeable future however, the ongoing impact of COVID-19 on the healthcare markets may alter the investment or working capital deployment timetables.</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.</p>	
Risk that there is a lack of financial contingencies or adverse performance leads to a lack of liquidity	<p>Should there be a lack of financial contingencies in place, the Group could be affected by limited cash resources to support the working capital and investment requirements. Similarly, should the Group have an adverse financial performance, this would impact the financial resources of the Company and its ability to reach profitability.</p>	<p>Alongside the recent fundraise which provides the Group with the opportunity to grow both its operational and commercial opportunities significantly, a robust overhead cost reduction programme was also undertaken during 2020. It is expected that this will continue during 2021 and in conjunction with the capacity expansion programme and development of strategic partnerships and other customers, will drive the Groups performance and ensure a suitable level of financial contingency remains.</p>	
Risk that the Group will be subject to a cyber security breach, failure of IT systems, or a catastrophic failure resulting in a significant data loss	<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 subject to a cyber security incident in January 2020. No ongoing material impact to the business was experienced, however, processing and production 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 implemented additional security procedures and continues to do so on an ongoing basis moving forward. The Group has an established disaster recovery plan and ensures that secure back ups are held off-site in case of any potential breach.</p>	




Key

 Increasing
  Decreasing
  No change

RISKS

CONTINUED

Risk	Potential impact	Mitigating factors	Trend
 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. Once the new facility in San Antonio is fully operational, this will offer a separate manufacturing facility which will further reduce the risk.</p> <p>COVID-19 provided a real-time test however, by implementing initiatives operations at the facility in San Antonio were successfully maintained throughout the course of the pandemic.</p> <p>Following the relocation of the UK facility in October 2020, it was successfully audited and accredited by the regulatory authorities in Q1 2021.</p>	
Risk of over dependency on single supplier including failure to secure sufficient tissue, 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 for the decellularisation techniques. 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 and alternative suppliers are identified to ensure that there is always a secondary source for raw materials. We have an experienced donor recovery manager who has expanded the number of donor services agencies that we work with in the US, whilst in the UK we have two suppliers for the required porcine tissues. All suppliers are comprehensively qualified to meet the Company's internal standards and then imposed by third party moderators. A percentage of our DermaPure[®] processing is outsourced to a processing partner CTS and as above, once the new facility in San Antonio is fully operational, this will offer a separate manufacturing facility reducing the dependence on one facility in-house processing.</p>	
Risk that products supplied by sub-contractor is of inferior quality	<p>Due to the capacity constraints that have historically impinged the growth of the Company, additional manufacturing resources were secured via a third party. If the product supplied by this partner is of inferior quality to that processed in-house there is the risk of reputational damage and financial losses to the Company.</p>	<p>Regular audits are undertaken at key suppliers and sub-contractors and all suppliers and sub-contractors are subjected to a qualification process. In addition raw materials are inspected prior to use to ensure they conform to specifications. We also undertake regular quality checks of the finished products and commit sufficient time to training and supporting the processing teams to ensure that processing techniques are standardised and technicians are fully trained.</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>The Group identified capacity constraints as an issue and took steps such as initiating a second shift and outsourcing a percentage of the DermaPure[®] processing to initially alleviate these constraints. Following the fundraising in June 2020, the Group commenced a capacity expansion programme in the US which should come onstream during H1 2021 and provide a c.50% uplift on the current BioRinse[®] processing levels. The capacity expansion programme has been split into phases with the additional uplift provided by phase two yet to commence.</p>	

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, qualification and validation studies 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 operates in established control environments.	

Key



Increasing



Decreasing







No change

RISKS

CONTINUED

Risk	Potential impact	Mitigating factors	Trend
 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	<p>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.</p>	<p>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. The Group also continues to collect post marketing clinical data to ensure that the product offering remains differentiated.</p>	
Risk of overdependence on a single customer, the loss of which would be significant	<p>The Group has a number of key customer's however, should the Group be overdependent on a single customer and not maintain a diversified customer base, the Group could become exposed if that customer reduced their ordering pattern or move their business elsewhere. In this case, the Group could be subject to material losses in terms of revenue and also experience a backlog of inventory that had been processed in line with expectations.</p>	<p>The Group is augmenting its product portfolio with additional product line extensions and product launches, which diversify the clinical applications and customer base. During 2020, the Group signed a white label manufacturing agreement with a significant distribution partner as well as securing a number of additional customers for smaller products lines. Furthermore, following the launch of OrthoPure[®] XT, the Group has extended its distribution network into the EU.</p>	
 HR			
Risk of potential loss of key staff resulting in a loss of key information, contacts or know-how, or skills shortages which may lead to over-reliance on key individuals	<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. The industry that we operate in is highly skilled and it is important that we can continue to attract and retain the highly skilled individuals required.</p>	<p>The Remuneration Committee is in place to ensure that salaries and incentive schemes are benchmarked against industry standards and reviewed on an annual basis.</p> <p>Contracts of employment are drafted to include the necessary confidentiality and non-compete clauses. Any potential skill shortages in our employee base are identified and we continuously monitor the market to ensure that suitable individuals can be recruited. Internally, we look to ensure that succession planning is implemented to minimise the potential impact should any senior level roles choose to exit the business.</p>	

Risk	Potential impact	Mitigating factors	Trend
 Political and economic landscape			
Risk of significant change in political or economic landscape	<p>The UK and the US have both experienced recent periods of political uncertainty, primarily due to Brexit negotiations, Presidential Elections and COVID-19. 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>We have worked closely with the notified and regulatory bodies in the UK and Europe to ensure that we hold the required certification to continue commercialisation with the EU following the Brexit transition period.</p>	
 Social and environmental			
Risk of unexpected social or environmental event that could affect the Group's ability to process or commercialise its product portfolio	<p>As seen with the COVID-19 pandemic in 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 a transition to work from home for certain staff and staggered shift patterns to minimise the number of employees on site at once with individual working in the clean rooms ensuring that we continue to have product supply to meet the expected demand.</p>	

Key



Increasing



Decreasing



No change

Corporate

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

The Group follows the QCA 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 Group. The Group aspires to implement and maintain these standards across all business functions and relations. The Group undertakes regular audits of partners, suppliers and employees to ensure that they 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 likewise 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 positive track record of passing all regulatory inspections and where recommendations are made to improve the control environment, the Group looks to implement where applicable, as soon as practically possible.

Modern slavery statement

The 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 to develop and can perform to the best of their abilities. We encourage teamwork and openness in the workplace, 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 sustainability

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.

During 2020, the Group continued to implement environmental sustainability initiatives:

- ▷ Continued to upgrade to LED lighting alternatives in our offices, clean rooms and sterile packaging areas
- ▷ Switched to plastic bins rather than cardboard boxes in our WIP storage area which will reduce our cardboard waste
- ▷ Replacement of our air compressor and drying unit with a smaller, more efficient unit which is expected to reduce this energy consumption by c.70%
- ▷ In our facility expansion, the design included energy saving LED lighting with self-dimming or motion sensors throughout the facility, higher efficiency heating and cooling units and greater use of solid flooring versus carpeting. Regarding equipment, we will be implementing high efficiency ultra-low temperature freezers which use natural refrigerants

Corporate social responsibilities ("CSR")

Operating in a highly regulated environment, with particular sensitivities and responsibilities around human donor processing, the Group ensures to operate with a high level of CSR across the business every day. Through the gift of tissue donation we have the ability to positively impact hundreds of patients' lives, therefore, we must treat each gift 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. During 2020, no serious adverse events were experienced.

Improved patient care and health economic outcomes

Tissue Regenix technology platforms dCELL[®] and BioRinse[®], process products that can enable improvements in patient care, enhancing or restoring their quality of life, which can often be transformative.

On top of this, it allows for economic advantages in the cost of care by reducing the hospital stay or additional treatments, better clinical outcomes and 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, donor families 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.

The Group has an established vision, mission, values and behaviours that form an integral part of the Tissue Regenix Group ethos and culture.

During 2020, the Group also looked to improve its communication and engagement with retail investors by allowing participation in the equity fundraising through a PrimaryBid offering and undertaking Company presentations through the investor meet platform.

Values and behaviours

Our values and behaviours 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

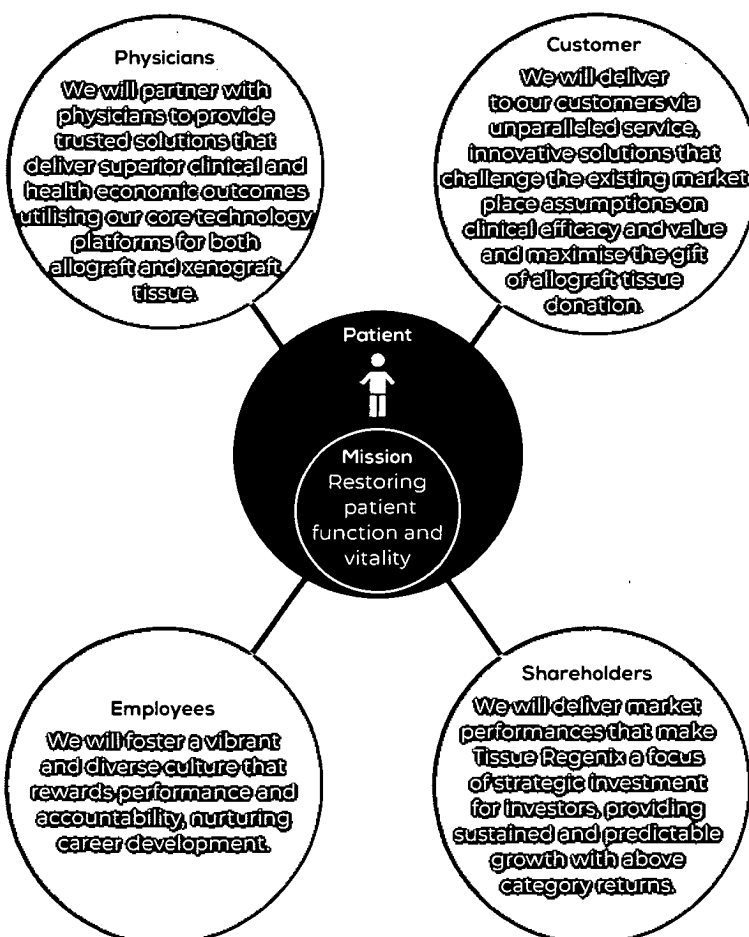
We take pride in what we do and are committed to the highest standards of ethics, honesty and fairness to earn the respect of all our stakeholders



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

Vision and mission



SECTION 172 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 2020.

Stakeholder group	Why?	How?
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 16 to 19.</p> <p>A supportive base of investors interested in a long-term holding in the Group provides the stability required 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 or presentation, website or social media, or news announcements.</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 processing and development expertise at all facilities. We continue to expand our network of partner and distributor relationships who are managed by our experienced commercial 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 and is competitive with industry standards.</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>

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 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, 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.

What were the key topics of engagement and consideration in principal decisions, 2020

Key topics of engagement for investors throughout the year was around:

The equity fundraise and financing and investment required for the future of the business.
The changes to the Executive management team.
Changes to the Non-Executive Directors.
The response and implications of the COVID-19 pandemic.
Full year and interim financial results and reports.

Consideration in principal decisions:

The Board consulted with shareholders regarding the future funding of the Group and provided frequent updates to the market around the cash runway and requirements of the Group. The Board also ensured that shareholders were aware of the capacity expansion project, the investment that this would require and the potential shareholder value created. During the year there was also a number of changes to the Executive management and Board composition, the Board considered the skill set and experience required to lead the business successfully through the next stages of commercialisation and achieve the long term Group strategy and employed changes accordingly to achieve the best results.

Key topics of engagement for employees throughout the year was around:

The change of Executive management as Daniel Lee was appointed to the position of CEO.
The financial position of the Group and the requirement for future funding.
The response to the COVID-19 pandemic and the decision to furlough UK members of staff.
The commencement of the capacity expansion project in San Antonio.
The relocation of the UK facility from Swillington, Leeds to Garforth, Leeds.
Health and safety protocols and procedures.
Updates to quality management systems and training records.

Consideration in principal decisions:

The most significant decision affecting our employees during 2020 was the Group's response to the COVID-19 pandemic. In the UK the decision was made to furlough operations and technical employees during the first UK lockdown, all employees were re-engaged in July and have successfully been retained throughout subsequent lockdowns. In the US, we maintained operations throughout and implemented additional operating procedures to ensure that employees were properly safeguarded from any potential risks.

Alongside this, as part of the overhead cost reduction initiatives the decision was made to relocate the UK facility. In order to retain our skilled workforce, it was important that any move remain within a commutable distance from the facility in Swillington. The move to nearby Garforth was undertaken in October 2020 and as part of this, elements of the production cycle were outsourced to allow for the downsizing which had to be carefully managed to ensure no future impact on the business.

The changes to the Executive management team were carefully communicated to the employees to ensure that all were comfortable with the change from a UK based CEO to US however, as Danny Lee had been a part of the senior management team for a period of time, this change was widely accepted.

SECTION 172 STATEMENT

CONTINUED

Stakeholder group	Why?	How?
Customers and Key Opinion Leaders	<p>We, including our strategic partners, work with several prestigious key opinion leaders across clinical settings in order to assist with physician conversion and drive the clinical discussion around the differentiating properties of our product portfolio.</p> <p>This type of engagement and clinical advocacy is crucial as we work to grow our clinical data portfolio, improve 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 then be used as evidence when discussing with new potential customers.</p> <p>Due to the COVID-19 pandemic, our methods of interacting with our key opinion leaders and customers has evolved to accommodate travel restrictions and the cancellation of face-to-face meetings. In place we have undertaken a number of meetings and training opportunities over social media and digital meeting platforms.</p> <p>The TRX BioSurgery Distributor Depot was also launched, a dedicated secure website hosting all of the information and training aids potentially required by customers and distributors in one easily accessible location.</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>During 2020, ensuring strong relationships with suppliers was a key priority to ensure delivery and payment practices were transparent and business expectations and requirements could be met</p> <p>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>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 costs of such supplies are in line with industry standards.</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 ensures to monitor and improve its environmental impact and sustainability through upgrading current practices and implementing new initiatives during the capacity expansion project.</p> <p>The Group also looks to engage with the local communities and support relevant charities wherever possible.</p>

What were the key topics of engagement and consideration in principal decisions, 2020

Key topics of engagement for customers and key opinion leaders throughout the year was around:

Changing practices and expectations regarding performance of clinical solutions.

Different ordering patterns due to COVID-19.

New product development opportunities.

Consideration in principal decisions:

When deciding the Group's course of action in response to the COVID-19 pandemic, management liaised closely with customers and key opinion leaders to plan out processing and inventory requirements.

The Group also launched a new soft tissue orthopaedic product into the US market in May 2020, in collaboration with a top 10 global healthcare company. Due to the wider market dynamics and the group's cash position at that time, the Board carefully considered the implications of launching a product at this time.

Key topics of engagement for suppliers throughout the year was around:

The implication of the COVID-19 pandemic. Including different ordering patterns, availability of supplies (especially PPE), and any payment practices.

Consideration in principal decisions:

The Board consider and review suppliers when approving the Groups strategy and commercial expansion plans to ensure that enough high-quality materials are sourced at reasonable prices to allow for continuation and ramp up of processing.

Consultation with key suppliers was undertaken ahead of a commitment to continue processing during the COVID-19 pandemic to ensure that donors and supplies of all required materials and PPE could be sourced and maintained.

The Board was presented with the overall plan and proposals from multiple contractors as well as management's recommendation, with a decision being made based on cost, timing and references.

Consideration in principle decisions:

During the planning of the capacity expansion project in San Antonio, careful consideration was given to the energy usage and environmental impact of the new building.

Likewise, with the relocation of the UK facility the Group looked to implement initiatives to ensure that the new production processes did not have a negative impact on the Group's environmental footprint.

Non-financial information

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 22 and performance on page 44
Employees	As discussed in sustainability pages 44 to 45
Human rights	Modern slavery statement on page 44
Anti-corruption and anti-bribery matters	Ethics and compliance on page 44
Social matters	As discussed in sustainability pages 44 to 45
Business model	Business model on pages 14 to 15
Principal risks	Risk management on pages 38 to 43
Non-financial KPIs	Key performance indicators on pages 22 to 23

The Strategic Report on pages 10 to 49 was approved by the Board on 27 April 2021.

Daniel Lee

Chief Executive Officer, Tissue Regenix Group

PROFILE OF THE CURRENT DIRECTORS



Jonathan Glenn
Non-Executive Chair

Joined the group: January 2016

Committees: ○

External appointments: N/A

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.



Daniel Lee
Chief Executive Officer

Joined the group: January 2019

Committees: N/A

External appointments: N/A

Daniel R. Lee has nearly 30 years experience in the medical device and biologics industry ranging from product innovation to commercialisation to corporate management. He joined Tissue Regenix Group as President of US Operations in January 2019, before being appointed as CEO of the Tissue Regenix Group in November 2020.

Prior to joining this, Danny was the Chief Executive Officer for Scaffold Biologics and Aperion Biologics. His previous senior management roles included global marketing for OsteoBiologics (acquired by Smith & Nephew Endoscopy in 1996) and marketing activities for Regeneration Technologies (now RTI Surgical), a leading allograft tissue processor. Danny spent the first ten years of his career in R&D with the U.S. Surgical Corporation (now Medtronic). Danny received his B.E.S. degree in Materials Science and Engineering from the Johns Hopkins University and his M.S. in Biomedical Engineering from the University of Alabama at Birmingham. He has 13 patents on implants and instruments used in orthopedic and general surgery. Danny is also a Certified Tissue Bank Specialist (CTBS) from the American Association of Tissue Banks (AATB).



David Cocke
Chief Financial Officer

Joined the group: January 2021

Committees: N/A

External appointments: N/A

David C. Cocke has over 29 years of experience in the medical device industry holding senior finance and operations positions. In 1997, David was a founding partner of NuPak Medical, an ISO-certified contract manufacturer of sterile disposable medical devices. NuPak Medical was acquired by Katena Products, Inc. in 2017 and David remained with the business post-acquisition until joining Tissue Regenix in January 2021. David was also Chief Financial Officer at Aperion Biologics from 2008-2017. Prior to this, David was Senior Director for Finance and Operations at Kinetic Concepts from 1993-1996.

David began his career in the corporate finance sector, working at GE Capital in its Corporate Finance Group and at Salomon Brothers Inc in its Investment Banking Group.

David received his B.B.A in Business Honors (magna cum laude) from the University of Texas at Austin and his M.B.A from the University of Virginia's Darden Graduate School of Business Administration. He has two patents covering medical devices.



**Shervanthi
Homer-Vanniasinkam**
Non-Executive Director

Joined the group: June 2016

Committees:  

External appointments: N/A

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 Chim Seng Visiting Professor of Surgery at the National University of Singapore.



Trevor Phillips
Non-Executive Director

Joined the group: January 2021

Committees:  

External appointments:
**Chairman of the Board at
NEPeSMO**

Trevor Phillips is the current Chairman of the Board at NEPeSMO and has extensive experience in the UK and US in corporate development, M&A and operations in the pharmaceutical and life science industries, including previously held positions as Executive Chairman of hVIVO (2017-2020), Chief Operating Officer for Vectura Group plc (2011-2017) and former CEO and COO of Critical Therapeutics, Inc. (2002-2008). Trevor holds a BSc, Microbiology from the University of Reading, a PhD, Microbial Biochemistry from Swansea University and an MBA from Henley Business School.



Brian Phillips
Non-Executive Director

Joined the group: January 2021





Committees:  

External appointments: N/A

Brian Phillips is an entrepreneurial investment professional with over 25 years' experience. Brian is the current Principal of Ethos partners which he co-founded in 2018 to assist individuals in establishing a portfolio of assets under private equity investments. Prior to this, Brian was Chief Investment Officer at Greenhill Capital Partners Europe LLP where he was responsible for setting up their UK business (2006-2010) and Managing Director of LGV Capital (2000-2006). Brian holds a B.Acc from Glasgow University and qualified as a Chartered Accountant with KMPG.

Key

Committees

-  Audit Committee
-  Chair of Audit Committee
-  Remuneration Committee
-  Chair of Remuneration Committee

CORPORATE GOVERNANCE

As an AIM listed Company, the Board of Tissue Regenix Group recognises the importance of strong corporate governance and business ethics. The Group adopted the latest Quoted Company Alliance (QCA) Corporate Governance Code, and has implemented these guidelines as far as possible. The QCA Code is based around 10 principles which it considers to be appropriate for small to mid-size companies, with companies following this code expected to comply with these principles or explain why they should deviate away from the principle and disclosures.

The Board is ultimately accountable to the Group'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 Group takes action to comply with the expected 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 three independent Non-Executive Directors, the Non-Executive Chairman, and two Executive Directors, the Chief Executive Officer and the Chief Financial Officer. The Board reviewed its size, composition and balance of skills during 2020 and following the resignation of Randeep Grewal and Alan Miller, subsequently appointed Trevor Phillips and Brian Phillips to the Board as independent Non-Executive Directors. The Board considers that its composition is now in line with the current requirements of the Group, with a mix of financial, clinical, commercial and operational expertise to advise the Group on its chosen commercial strategy.

There is a clear division of responsibility between the Chair of the Board and CEO position. The Chair advises and leads the Board, as well as making themselves available to meet with shareholders and Company management, as required. The CEO is responsible for the day-to-day execution of the agreed strategy and ensuring operational compliance.

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. During 2020, due to the social distancing and lockdown restrictions imposed in response to COVID-19, Board meetings were held via video conferencing and telephone. It is expected that as the CEO and CFO are now based in the US, Board meetings will continue in this format. 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. 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 also operates two sub-committees, the Audit and Remuneration Committees, to ensure compliance with market regulations.

The Audit Committee

Details of all Board members can be found on pages 50 to 51.

The Audit Committee's primary responsibilities are to monitor the integrity of the financial affairs and statements of the Group, to ensure that the financial performance of the Group and any subsidiary is properly measured and reported, and to review reports from the Group'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 Audit Committee also plays a key role in supporting the Board with the ongoing risk assessment and management framework for the Group.

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 Audit Committee comprises of Brian Phillips, who acts as Chairman of the Committee, Trevor Phillips and Jonathan Glenn.



Details of the perceived risk appetite of the Board is available on pages 38 to 43.

The Remuneration Committee Report

The Remuneration Committee report is available on pages 58 to 59.

The Remuneration Committee comprises of Trevor Phillips, who acts as Chairman of the Committee, Brian Phillips and Shervanthi Homer-Vanniasinkam.



The roles of the Board

Jonathan Glenn – 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, and Company management, to ensure effective communications

Daniel Lee – CEO

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

David Cocke – CFO

- ▶ Working with the CEO, responsible for the strategic vision of the Group
- ▶ Act as an onsite sounding board for the CEO, providing advice on operational matters
- ▶ Responsible for the oversight of the overall financial management of the Group, including establishing budgets and forecasts
- ▶ Monitors the Group's performance against budgets and forecasts and reports on those to the Board
- ▶ Responsible for clear communications with providers of capital, both debt and equity
- ▶ Advises the Board on funding strategies for the Group as well as the appropriate capital structure to promote corporate growth

Kirsten Lund – Company Secretary

- ▶ Responsible to the Board and ensuring compliance with all statutory regulations
- ▶ Responsible for advising the Board on Corporate Governance matters
- ▶ Responsible under the direction of the CEO, for ensuring that the Board receives accurate and timely information

CORPORATE GOVERNANCE

CONTINUED

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 of communication 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 provide reasonable, but not absolute assurance against material misstatement or loss. The Board confirms that it has established a sound system of internal controls. 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
- ▶ 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 Group to follow is the Quoted Company Alliance Corporate Governance Code, which the Group implemented in September 2018. Below is an overview as to how the Group addresses the 10 principles 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 16 to 19 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 and social media 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 CFO 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 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. In September 2020, the Group undertook its first 'Investor meet' retail investor presentation as part of the interim results investor roadshow, with 58 individuals attending live via video conferencing and a further 44 receiving the presentation on demand.

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.

A key stakeholder in the success of the Group is a well-supported and motivated employee base. We have set out a clear Company culture, vision, mission and values which we believe are important in establishing and ensuring a healthy working environment. More information can be found in the sustainability report on pages 44 to 45.

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.

We actively audit our organ procurement organisation partners and tissue suppliers on a regular basis, to ensure that donations 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. As part of this we ensure to track each donation, and wherever requested, by either regulatory bodies or next of kin, are in a position to provide further information around the use of donation.

We consider our environmental sustainability in every aspect of the business and have taken a number of steps to reduce our carbon footprint, energy consumption and improve our waste management; these initiatives were even more important during 2020 as we commenced the capacity expansion programme in San Antonio and undertook the relocation of the UK facility. Further details of our corporate social responsibility strategy are set out at page 45 of this report.

The Board considers feedback from its advisers and stakeholders formally at 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 the Tissue Regenix Group, and endeavours to minimise the impact of weaknesses and risks by employing the necessary mitigating 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 wound care, urogynaecology and trauma), Orthopaedics and Dental, and Ophthalmology. 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; the Board ensures to review a detailed risk matrix on a rolling basis as part of the formal Board meetings. Details of the risk framework and prominent risks identified are set out on pages 38 to 43 of this report.

Tissue Regenix maintains a central finance team, with three team members based in the UK and three 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 CFO 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. The regulatory and quality teams at each facility ensure to implement and maintain a comprehensive quality management system with each employee having a personal training record.

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.

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

The Board is comprised of three independent Non-Executive Directors, the Non-Executive Chairman, and two Executive Directors, the Chief Executive Officer and the Chief Financial Officer. The Non-Executive Directors bring a mix of financial, clinical, operational and commercial experience to the Board. During 2020, there were a number of changes to the Board following the resignation of the Executive Chairman, CEO and latterly, two Non-Executive Directors. After reviewing the requirements of the Group and the proposed corporate and commercial strategy, new appointments to the Board were made and the Board believes that its size, composition and skillset is now suitable for the Company requirements.

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

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 their own Terms of Reference to govern how they are run. The Audit Committee meets at least twice per year and is chaired by Brian Phillips who is a Chartered Accountant and has relevant financial experience. The Remuneration

CORPORATE GOVERNANCE

CONTINUED

Committee meets no fewer than twice per year and is chaired by Trevor Phillips who has many years of relevant operational and commercial industry experience. Further details of these Committees can be found on page 53 of this Annual Report.

For senior level appointments the Board may engage the expertise of a relevant recruitment consultant to assist with the search and hiring of a relevant individual, as per the process to appoint the Chief Executive Officer in 2020.

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.

During 2020, two new Non-Executive Directors; Trevor Phillips and Brian Phillips, were appointed to the Board following the resignations of Alan Miller and Randeep Grewal. These appointments were undertaken due to the relevant skills and experience that both Brian and Trevor could bring to the business at this stage of development, and to advise the Group in order to successfully execute the corporate and commercial strategy.

The Board members have complementary skillsets and bring different experience to the Board which is pivotal in the success of the Group. Daniel Lee and Trevor Phillips and David Cocke have significant industry and operational experience whilst Jonathan Glenn has commercial, industry and financial experience. Shervanthi Homer-Vanniasinkam

is a respected vascular surgeon and brings extensive clinical expertise, Brian Phillips is a chartered accountant and experienced investment professional.

The Board members maintain their skillsets through their day-to-day roles and use external advisers to enhance 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 nominated adviser, 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. 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.

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

The CEO and CFO 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. The Board undertook a review of corporate governance practices during 2020 and as part of this, intends to begin Board member appraisals and a formal Board appraisal process during 2021.

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 and ethically responsible Company.

The Group, led by the 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, and to ensure that employees are aware of Company developments and successes.

Operating in an industry based upon the 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 53, and the Company's website.

In addition to this, the Group operates a clear list of matters which are reserved for the Board, and terms of reference for each of the committees.

For senior level appointments the Board will look to engage the expertise of a relevant recruitment consultant to assist with the search and hiring of a relevant individual. To supplement the Board, the Group maintains a team of senior management who 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: Tina Trimble, VP Donor Services, Gerald Sharpe, VP Strategic Partnerships, Lance Johnson, VP Quality/Regulatory, Kirsten Lund, Group Finance Director, and Christine Rowley, Technical and Operations Director, UK, 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.

Further details on risk in the remuneration policy is available on pages 58 to 59.

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 2020 Remuneration Committee comprises Trevor Phillips as Chair of the Committee, Brian Phillips and Shervanthi Homer-Vanniasinkam. 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.

The Committee also approves the level of the pool for salary reviews for all staff.

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.

Long term incentive plan

The Company has chosen to replace the existing deferred annual bonus (DAB) plan, with a new Long Term Incentive Plan (LTIP) for Executive Directors and senior management. Though this is a post year event the Company can confirm that the DAB plan was not utilised during 2020.

The LTIP awards will be made annually, starting in 2021, to the Executive Directors and those senior management members recommended to participate by the Executive Directors and approved by the Board.

Awards will be based upon a predetermined percentage of an individual's annual salary and will vest over a period of three years. The final vesting of the awards will be determined by performance against vesting criteria, set by the Remuneration Committee at the time of grant, and adjudged by the Remuneration Committee in the period prior to the nominated vesting date. The goals will be set against key aspects of Company performance, defined to be Total Shareholder Return (TSR), Revenue Growth and Profitability and individual performance against personal performance goals. Weighting has been set at 80% of the vesting directed at Company performance over the period against the three corporate goals and 20% against personal performance goals. As part of the LTIP rules the Executive Directors will be required to use vested LTIPs to build a shareholding in the Company to a level of 100% of base salary over a period of six years. It is anticipated that the first awards will be granted post annual results in April 2021.

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 2020 was:

	Salary and fees £000	Bonus £000	Benefits £000	Total December 2020 £000	Total December 2019 £000
John Samuel (resigned 20/03/20)	24	-	-	24	111
Steven Couldwell (resigned 30/07/2019)	-	-	-	-	203
Gareth Jones ~ (resigned 17/11/2020)	347	120	23	490	250
Randeep Grewal (resigned 4/12/2020)	51	-	-	51	35
Jonathan Glenn	30	-	-	30	30
Alan Miller (resigned 4/12/2020)	58	-	-	58	35
Shervanthi Homer- Vanniasinkam	30	-	-	30	30
Daniel Lee (appointed 16/11/20)	28	-	-	28	-
Michael Barker (appointed on 28th August and resigned 18th November 2019)	-	-	-	-	40
Total	568	120	23	711	734

Within 2019 the total bonus payments were £110k and benefits were £16k.

~ Included within this salary is £49k for loss of office and £84k in lieu of notice.

Directors' shareholdings

Directors' interests in the shares of the Company, including family interests at 31 December 2020 were:

	31 December 2020 Number	31 December 2020 %	31 December 2019 Number	31 December 2019 %
Jonathan Glenn	40,600,000	0.58%	600,000	0.06%
Shervanthi Homer-Vanniasinkam	1,628,222	0.02%	250,000	0.02%

On behalf of the Board

Trevor Phillips

Chairman of the Remuneration Committee

27 April 2021

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 2020.

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 principally a holding company incorporated and domiciled in the UK and is listed on the London Stock Exchange Alternative Investment Market. The subsidiary undertakings of the Group are listed in note C4 of the Company's financial statements.

Business model

A description of the Group's business model is included on pages 14 to 15. Explanations of activities and how it seeks to add value are included in the Chairman's statement on page 04 to 07 and the CEO operational review on pages 28 to 33 as well as the KPI report on pages 22 to 23 and future milestones on pages 20 to 21.

Business review and results

A review of the Group's performance and future prospects is included in the Chairman's statement on pages 04 to 07 and CEO operational report on pages 28 to 33, as well as the future milestones on pages 20 to 21 and KPIs set out on pages 22 to 23. A review of the Group's financial performance is within the financial overview on pages 34 to 35. The loss for the 12 months attributable to equity holders of the parent was (£10,139k) (2019: £7,697k). The Directors do not recommend the payment of a dividend (2019: nil).

Share capital and funding

Full details of the Group and Company's share capital movements during the year are given in note 20 to the financial statements.

Directors and their interests

The following Directors held office in the year:

John Samuel –
resigned 20 March 2020

Gareth Jones –
resigned 17 November 2020

Jonathan Glenn

Shervanthi Homer-Vanniasinkam

Alan Miller –
resigned 4 December 2020

Randeep Singh Grewal –
resigned 4 December 2020

Daniel Lee –
appointed 16 November 2020

Directors' interests in the shares of the Company, including family interests, are included in the remuneration report on pages 58 to 59.

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 52 to 57.

Substantial shareholders

As at 31 December 2020, shareholders holding more than 3% of the share capital of Tissue Regenix Group plc were:

Name of shareholder	Number of shares	% of voting rights
Lombard Odier	1,109,400,001	15.77
IP Group (London)	960,837,567	13.66
Mr Richard Griffiths (UK)	711,250,000	10.11
Premier Miton Investments (London)	709,029,653	10.08
Harwood Capital (London)	487,500,000	6.93

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 44 to 45.

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 38 to 43 and in note 15 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.

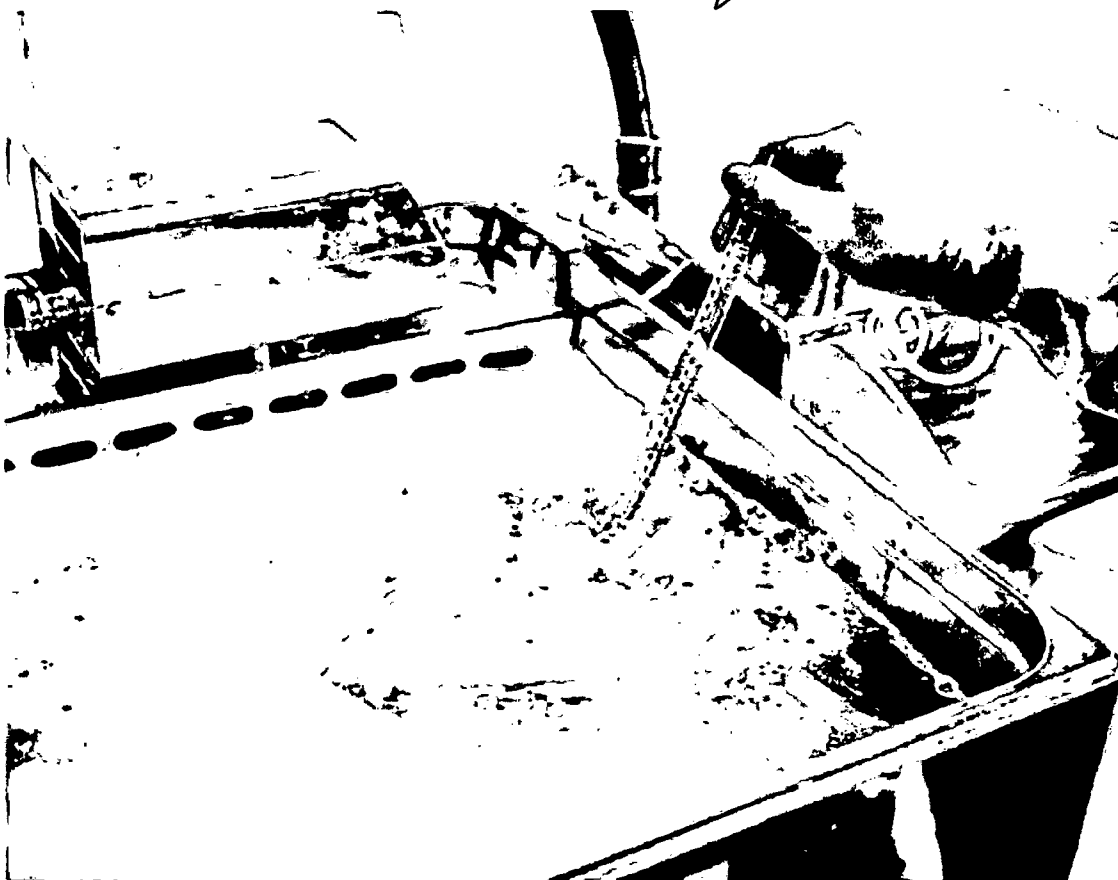
Strategic report

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

The Directors Report was approved by the Board on 27 April 2021.

On behalf of the Board

Mark Turner
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, 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. The directors have elected under company law to prepare the group financial statements in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and have elected under company law to prepare the company financial statements in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and applicable law.

The Group and company financial statements are required by law and international accounting standards, in conformity with the requirements of the Companies Act 2006, to present fairly the financial position of the Group, the company and the financial performance of the Group. The Companies Act 2006, provided in relation to such financial statements, references the relevant part of that Act to the financial statements that gives a true and fair view and references the achievement of 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:

- select suitable accounting policies and then apply them consistently
- make judgements and accounting estimates that are reasonable and prudent
- state whether they have been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006
- 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 requirements of 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 plc 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 2020 which comprise the Consolidated Statement of Comprehensive Income, the Consolidated and Parent Company Statement of Financial Position, the Consolidated and Parent Company Statement of Changes in Equity, the Consolidated and Parent Company Statement of Cash Flows and notes to the financial statements, including significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and International Accounting Standards in conformity with the requirements of the Companies Act 2006 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 2020 and of the group's loss for the year then ended;
- ▶ the group financial statements have been properly prepared in accordance with International Accounting Standards in conformity with the requirements of the Companies Act 2006;
- ▶ the parent company financial statements have been properly prepared in accordance with International Accounting Standards in conformity with the requirements of the Companies Act 2006 and as applied in accordance with the Companies Act 2006; and
- ▶ the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our

report. We are independent of the group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to SME listed entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the group's and parent company's ability to continue to adopt the going concern basis of accounting included obtaining and reviewing management's going concern assessment for the period to 31 December 2022, assessing the results and appropriateness of management's sensitivity testing, reviewing the key terms of debt facilities, and reviewing going concern disclosures included in the financial statements.

We have observed that the group continues to experience disruption in the USA due primarily to the Coronavirus pandemic and the deferral of elective surgery. However, the Group has significant cash reserves at 31 December of £9.6m following the fundraising in June 2020 and even in downside scenarios which take account of slow sales growth management's forecasts indicate significant cash at the end of the forecast period.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's or the parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Summary of our audit approach

Key audit matters	Group
	▶ Goodwill impairment
	Parent Company
	▶ Impairment of intercompany receivables
Materiality	Group
	▶ Overall materiality: £290,000 (2019: £297,000)
	▶ Performance materiality: £217,000 (2019: £222,000)
	Parent Company
	▶ Overall materiality: £222,000 (2019: £169,000)
	▶ Performance materiality: £166,000 (2019: £127,000)
Scope	Our audit procedures covered 100% of revenue, 98% of total assets and 98% of loss before tax.

INDEPENDENT AUDITOR'S REPORT

To the members of Tissue Regenix Group PLC

CONTINUED

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.

Goodwill impairment

Key audit matter description	<p>The non-current assets of the CellRight Technologies LLC ("CellRight") cash generating unit (CGU) includes goodwill of £8.6m (after a current year impairment charge of £6.1m) and this CGU is subject to annual impairment testing. The CellRight CGU is a legal entity in its own right and forms part of the Orthopaedics and Dental operating segment. Management have disclosed details relating to their impairment test in note 12.</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. 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>
How the matter was addressed in the audit	<p>Management provided us with an impairment model for the CellRight CGU. We performed audit work on this impairment test, which included:</p> <ul style="list-style-type: none"> ▶ Checking the calculation of the impairment charge arising by reperforming the comparison of Recoverable Amount with carrying amount, including agreeing the carrying amount to the accounting records. ▶ Using a specialist to check the appropriateness of the method and the mathematical calculation of value in use within the model and to obtain an independent estimate of an appropriate weighted average cost of capital (WACC). ▶ Challenging management to support key assumptions within the model, particularly forecast revenue growth. ▶ Reviewing the disclosures made in the financial statements to ensure that they were in accordance with the applicable financial reporting framework.
Key observations	<p>We identified a significant mechanical error in the impairment model initially presented by management which reduced the calculation of value in use significantly. We also identified that the key assumption within the model was future revenue growth and we challenged management on whether sector growth rates used previously adequately reflected the uncertainty created by the Coronavirus pandemic. In response to these findings, management revised their assessment, resulting in an impairment charge of £6.1m.</p>

Impairment of intercompany receivables (parent company only)

Key audit matter description	<p>The parent company has loans due from subsidiary undertakings that are currently loss making. The loans are repayable on demand and the subsidiary undertakings do not have sufficient liquid assets to make repayment should the parent company call in the loans.</p> <p>One of the most significant matters in the current year audit of the parent company is that 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 and estimation 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 the loan balances we considered this matter to be one of the matters of most significance in the current year audit.</p> <p>At the 31 December 2020, the carrying value of amounts due from group undertakings amounted to £11.8m after recording an ECL provision of £64.1m (see note C2).</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 the latest Board approved forecasts. ▶ 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	£290,000 (2019: £297,000)	£222,000 (2019: £169,000)
Basis for determining overall materiality	2.3% of total revenue	0.6% 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 focus on revenue growth. The group is still in relatively early phase of development and revenue growth is critical to reducing operating losses.	Net assets selected as the parent company is purely a holding company and no income statement is presented.
Performance materiality	£217,000 (2019: £222,000)	£166,000 (2019: £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 £11,000 and misstatements below that threshold that, in our view, warranted reporting on qualitative grounds.

INDEPENDENT AUDITOR'S REPORT

To the members of Tissue Regenix Group PLC

CONTINUED

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	Loss before tax
Full scope audit	8	84%	98%	96%
Specific audit procedures	2	16%	–%	2%
Total	10	100%	98%	98%

Specific audit procedures were performed on two components: one contained the Borrowings of the group and related finance costs and the other contained significant revenue. Analytical procedures at group level were performed for the remaining 1 component.

Of the above, specific audit procedures for the component containing significant revenue were undertaken by component auditors.

Other information

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. 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.

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 course of 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 this gives rise to a material misstatement in the financial statements themselves. 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 Statement of Director's Responsibilities, 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.

The extent to which the audit was considered capable of detecting irregularities, including fraud

Irregularities are instances of non-compliance with laws and regulations. The objectives of our audit are to obtain sufficient appropriate audit evidence regarding compliance with laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements, to perform audit procedures to help identify instances of non-compliance with other laws and regulations that may have a material effect on the financial statements, and to respond appropriately to identified or suspected non-compliance with laws and regulations identified during the audit.

In relation to fraud, the objectives of our audit are to identify and assess the risk of material misstatement of the financial statements due to fraud, to obtain sufficient appropriate audit evidence regarding the assessed risks of material misstatement due to fraud through designing and implementing appropriate responses and to respond appropriately to fraud or suspected fraud identified during the audit.

However, it is the primary responsibility of management, with the oversight of those charged with governance, to ensure that the entity's operations are conducted in accordance with the provisions of laws and regulations and for the prevention and detection of fraud.

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud, the group audit engagement team:

- ▶ obtained an understanding of the nature of the industry and sector, including the legal and regulatory frameworks that the group and parent company operate in and how the group and parent company are complying with the legal and regulatory frameworks;
- ▶ inquired of management, and those charged with governance, about their own identification and assessment of the risks of irregularities, including any known actual, suspected or alleged instances of fraud;
- ▶ discussed matters about non-compliance with laws and regulations and how fraud might occur including assessment of how and where the financial statements may be susceptible to fraud.

INDEPENDENT AUDITOR'S REPORT

To the members of Tissue Regenix Group PLC

CONTINUED

The most significant laws and regulations were determined as follows:

Legislation / Regulation	Additional audit procedures performed by the Group audit engagement team included:
IFRS and Companies Act 2006	<ul style="list-style-type: none"> Review of the financial statement disclosures and testing to supporting documentation; Completion of disclosure checklists to identify areas of non-compliance.
Tax compliance regulations	<ul style="list-style-type: none"> Inspection of advice received from internal and external tax advisors Input from a tax specialist was obtained regarding management's calculation of Research and Development tax credit claims made under the UK SME scheme during the year.
FDA Medical device regulations in the USA	<ul style="list-style-type: none"> Inquiry of management and those charged with governance as to whether the group is in compliance with these laws and regulations and inspection of correspondence with the regulatory authority.

The areas that we identified as being susceptible to material misstatement due to fraud were:

Risk	Audit procedures performed by the audit engagement team:
Revenue recognition	<ul style="list-style-type: none"> Testing a sample of revenue transactions, either side of the balance sheet date, to determine whether they have been recognised in the correct financial period; and Testing of revenue recognised on a Bill and Hold basis to ensure compliance with the Group's stated accounting policy in this area including: <ul style="list-style-type: none"> confirming existence by substantiating outstanding invoices at the year-end to subsequent cash receipt, and checking cut-off by ensuring that revenue for a sample of these transactions were recorded in the correct period by confirming key terms of the sale to the customer purchase order and by checking that the related inventory movement was recorded in the same period.
Management override of controls	<ul style="list-style-type: none"> Testing the appropriateness of journal entries and other adjustments; Assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and Evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

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

27 April 2021

RSM UK Audit LLP

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the year ended 31 December 2020

	Notes	2020 £000	2019 £000
Revenue	3	12,829	13,033
Cost of sales		(6,933)	(7,014)
Gross profit		5,896	6,019
Administrative expenses before exceptional items	3	(10,066)	(13,198)
Exceptional items	4	(6,483)	(21)
Total administrative expenses		(16,549)	(13,219)
Grant Income	4	855	-
Operating loss		(9,798)	(7,200)
Finance income	6	2	17
Finance charges	7	(445)	(477)
Loss before taxation		(10,241)	(7,660)
Tax	8	533	554
Loss for year		(9,708)	(7,106)
Attributable to:			
Equity holders of the parent	9	(9,709)	(6,973)
Non-controlling interests	22	1	(133)
		(9,708)	(7,106)
Other comprehensive income:			
Foreign currency translation differences – foreign operations		(764)	(724)
Total comprehensive expense for the year		(10,472)	(7,830)
Attributable to:			
Equity holders of the parent		(10,473)	(7,697)
Non-controlling interests	22	1	(133)
		(10,472)	(7,830)
Loss per share			
Basic and diluted loss attributable to equity holders of parent	9	(0.22)p	(0.60)p

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

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At 31 December 2020

	Notes	2020 €000	2019 €000
Assets			
Non-current assets			
Property, plant and equipment	10	3,252	2,357
Right of use assets	11	2,458	-
Intangible assets	12	10,931	17,999
Total non-current assets		16,641	20,356
Current assets			
Inventory	13	7,072	4,185
Trade and other receivables	14	2,643	2,539
Corporation tax receivable		825	1,035
Cash and cash equivalents	15	9,550	2,380
Total current assets		20,090	10,139
Total assets		36,731	30,495
Liabilities			
Non-current liabilities			
Borrowings	17	(2,790)	(2,115)
Deferred tax	18	(560)	(670)
Lease liability	19	(2,271)	-
Total non-current liabilities		(5,621)	(2,785)
Current liabilities			
Trade and other payables	16	(3,007)	(2,944)
Borrowings		-	(17)
Lease liability	19	(256)	-
Total current liabilities		(3,263)	(3,115)
Total liabilities		(8,884)	(5,900)
Net assets		27,847	24,595
Equity and reserves			
Share capital	20	11,720	5,859
Share premium	20	94,290	86,399
Merger reserve	20	10,884	10,884
Reverse acquisition reserve	20	(7,148)	(7,148)
Reserve for own shares	20	(831)	(831)
Share based payment reserve	21	955	983
Retained earnings deficit	20	(81,409)	(70,336)
Equity attributable to equity holders of parent		28,461	25,210
Non-controlling interests	22	(614)	(615)
Total equity		27,847	24,595

The consolidated financial statements were approved by the Board of Directors on 27 April 2021 and were signed on its behalf by

Daniel Lee
Chief Executive Officer

Company number: 3536327



CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 31 December 2020

	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 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 income	-	-	-	-	-	-	(724)		(724)	-	(724)
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(7,697)		(7,697)	(133)	(7,830)
Contributions by and distributions to owners											
Exercise of share options	-	1	-	-	-	-	-		1	-	1
Share based payments	-	-	-	-	-	(146)	-		(146)	-	(146)
At 31 December 2019	5,859	86,399	10,884	(7,148)	(831)	983	(70,936)		25,210	(615)	24,595
Loss for the period	-	-	-	-	-	-	(9,709)		(9,709)	1	(9,708)
Other comprehensive expense	-	-	-	-	-	-	(764)		(764)	-	(764)
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(10,473)		(10,473)	1	(10,472)
Contributions by and distributions to owners											
Issue of shares	5,860	8,790	-	-	-	-	-		14,650	-	14,650
Cost of issue of new Equity	-	(899)	-	-	-	-	-		(899)	-	(899)
Exercise of share options	1	-	-	-	-	-	-		1	-	1
Share based payments	-	-	-	-	-	(28)	-		(28)	-	(28)
At 31 December 2020	11,720	94,290	10,884	(7,148)	(831)	955	(81,409)		28,461	(614)	27,847

CONSOLIDATED STATEMENT OF CASH FLOWS

For the year ended 31 December 2020

	Notes	2020 £000	2019 £000
Operating activities			
Loss before taxation		(10,241)	(7,660)
Adjustment for:			
Depreciation of property, plant, equipment and right of use asset	10	192	476
Amortisation of intangible assets	12	570	570
Impairment of intangible assets and property, plant and equipment	10/12	6,130	1,311
Share based payments	21	(28)	(146)
Interest receivable	6	(2)	(17)
Interest payable	7	445	477
Operating cash outflow before working capital movements		(2,934)	(4,989)
(Increase) in inventory	13	(2,887)	(1,855)
(Increase)/decrease in trade and other receivables	14	(11)	1,076
(Decrease) in trade and other payables	16	(46)	(1,567)
Cash outflows from operations		(5,878)	(7,335)
Research & development tax credit received		649	653
Net cash outflow from operations		(5,229)	(6,682)
Investing activities			
Interest received	6	2	17
Purchases of property, plant and equipment	10	(1,158)	(438)
Capitalised development expenditure	12	(215)	(213)
Net cash outflow from investing activities		(1,371)	(634)
Financing activities			
Interest paid	7	(245)	(384)
Proceeds from exercise of share options		2	1
Gross proceeds from issue of shares		14,650	-
Cost of issue of equity		(899)	-
Proceeds from new loans		504	6,479
Repayment of loans		-	(4,193)
Lease liability payments	19	(41)	-
Lease interest payments		(200)	-
Net cash inflow from financing activities		13,771	1,903
Increase/(decrease) in cash and cash equivalents		7,171	(5,413)
Foreign exchange translation movement		(1)	(23)
Cash and cash equivalents at start of period		2,380	7,816
Cash and cash equivalents at end of period		9,550	2,380

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

1) Basis of preparation

The financial statements of Tissue Regenix Group plc are audited consolidated financial statements for the year ended 31 December 2020. These include audited comparatives for the year ended 31 December 2019.

The consolidated financial statements are prepared in accordance with international accounting standards in conformity with the Companies Act 2006 ('IFRS').

The Company is incorporated and domiciled in the United Kingdom and its registered number is 05969271. The address of the registered office is Unit 3 Phoenix Court, Lotherton Way, Garforth LS25 2GY. 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

The Group financial statements have been prepared on a going concern basis based on cash flow projections approved by the Board for the Group for the period to 31 December 2022 (the "Cash Flow Projections").

Funding requirements are reviewed on a regular basis by the Group's Chief Executive Officer and Chief Financial Officer and are reported to the Board at each Board meeting, as well as on an ad hoc basis, if requested. The Cash Flow Projections show that the group will continue to consume cash over the forecast period. Until sufficient cash is generated from its operations, the Group remains reliant on cash reserves of £9.6m at 31 December 2020 and the ongoing support of MidCap Financial Trust ("MidCap") (borrowings of £2.8m at 31 December 2020) to meet its working capital requirements, capital investment programme and other financial commitments.

The COVID-19 pandemic has affected most businesses during 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 the Cash Flow Projections, has considered a downside scenario 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 there

will not be a significant long-lasting impact on the capability of the business to carry out its commercial activities. The Cash Flow Projections prepared by the board, including the downside scenario, indicate that the Group will still have cash reserves at the end of the forecast period.

The Group's Cash Flow Projections also assume that the MidCap facilities are available throughout the forecast period as they are repayable in 2024. The availability of these facilities is dependent upon compliance with a rolling twelve month revenue covenant which is measured on a monthly basis. The Cash Flow Projections indicate compliance with this covenant throughout the forecast period. The scenario reflecting very low growth indicates that this covenant may be breached in the second half of 2022. That scenario also shows that the MidCap facility could be repaid from cash reserves in the event that repayment was demanded by MidCap.

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 have reviewed the Cash Flow Projections. On the basis of their assessment, they have concluded that the going concern basis remains appropriate for use in these financial statements.

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.

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

2) Significant accounting policies CONTINUED

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
- ▶ The Group cannot have the ability to use the product, or to direct it to another customer

Grant Income

Grant income is recognised as earned based on contractual conditions and is presented as Grant income on the face of the Statement of comprehensive income.

Foreign Currencies

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

Pounds Sterling, which is the functional and presentational currency of the Company and 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 operations are recorded in other comprehensive incomes 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
- ▶ 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.

2) Significant accounting policies CONTINUED

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.

Property, Plant, Equipment and Right of Use assets

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.

A Right of Use asset is recognised at commencement of the lease and initially measured at the amount of the lease liability, plus any incremental costs of obtaining the lease and any lease payments made at or before the leased asset is available for use by the Group. The Right of Use asset is subsequently measured at cost less accumulated depreciation and any accumulated impairment losses. Right of Use assets are depreciated on a straight-line basis over the lease term (39 years).

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, Intangible and Right of Use 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 five-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.

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

2) Significant accounting policies CONTINUED

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

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 six 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 12 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 dependent 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.

2) Significant accounting policies CONTINUED

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 judgements that have the most significant effects on the carrying amounts of the assets and liabilities in the financial information are discussed below:

Judgements

Leases

As disclosed in note 19, the Group recorded a lease liability during the year in respect of property adjacent to the owned facility at San Antonio, Texas. This lease includes the option to purchase the facility within 60 months of lease commencement for a fixed sum. The Directors have assumed that this option will be exercised in calculating the lease liability and the corresponding right of use asset on the basis that they are reasonably certain to exercise the option as the property is adjacent to the currently owned facility and there will be significant investment in fitting out the facility to a very high specification for the purpose of manufacturing the group's products. The assumption that the option will be exercised is considered to be a critical judgment given that there is no absolute certainty that the option will be exercised.

Grant Income

As described in note 4, the Group received loans during the year totalling £815,000 under the US Government's Paycheck Protection Program ("PPP"). These loans may be forgiven if used for permitted purposes. The Directors believe that they have fulfilled all of the necessary conditions and have commenced the process of applying for forgiveness. The forgiveness of the loan has been recorded within these financial statements as Grant Income, which is considered to be a critical judgement as there remains some uncertainty around the forgiveness process and outcome.

Estimates

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 recognised no impairment, other than in respect of the annual goodwill impairment testing as described below

(2019, an impairment charge of £972k against intangible assets and £339k against property, plant and equipment). In accordance with IFRS, management have performed an annual impairment test of the goodwill relating to CellRight Technologies LLC and an impairment charge of £6,130k has been recognised (2019:nil), further details are provided in note 12. By its very nature, impairment testing involves a high degree of estimation uncertainty due to the extent that assumptions have to be made regarding likely future trading performance.

New accounting standards and amendments adopted in the year

During the year, the Company adopted no new standards effective from the 1st January 2020. The Company has not adopted any new or amended standards early.

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 2020:

Amendments to References to the Conceptual Framework in IFRS Standards

Definition of a Business (Amendments to IFRS 3)

Definition of Material (Amendments to IAS 1 and IAS 8)

Interest Rate Benchmark Reform (Amendments to IFRS 9, IAS 39, IFRS 16, IFRS 4 and IFRS 7)

Standards, Amendments, Improvements & Interpretations issued 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:

Applying IFRS 9 'Financial Instruments' with IFRS 4 'Insurance Contracts' (Amendments to IFRS 4)

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2

Covid-19-Related Rent Concessions (Amendment to IFRS 16)

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.

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3) Segmental reporting

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

	2020 £000	2019 £000
USA	10,695	10,679
Rest of world	2,134	2,354
	12,829	13,033

Analysis of revenue by customer

During the year ending 31 December 2020, the Group had one customer who individually exceeded 10% of revenue. This customer generated 13% of revenue (2019: no customers).

Operating segments

The Group is organised into BioSurgery, Orthopaedics & Dental, GBM-V & Cardiac (recently merged due to size) divisions for internal management, reporting and decision making, based on the nature of the products of the Group's businesses. Managers within these divisions report to the Chief Executive Officer. These are the reportable operating segments in accordance with IFRS 8 "Operating Segments". The Directors recognise that the operations of the Group are dynamic and therefore, this position will be monitored as the Group develops.

In accordance with IFRS 8, the Group has derived the information for its operating segments using the information used by the Chief Operating Decision Maker. The Group has identified the 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.

3) Segmental reporting CONTINUED

	BioSurgery		Orthopaedics & Dental		GBM-v & Cardiac		Central		Total	
	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000
Revenue	3,308	4,233	7,446	6,724	2,075	2,076	-	-	12,829	13,033
Cost of sales	(1,849)	(2,535)	(3,848)	(3,076)	(1,236)	(1,403)	-	-	(6,933)	(7,014)
Gross Profit	1,459	1,698	3,598	3,648	839	673	-	-	5,896	6,019
Administrative costs	(2,660)	(3,729)	(4,977)	(4,553)	(1,104)	(991)	(1,325)	(3,925)	(10,066)	(13,198)
Exceptional costs:										
Contingent consideration	-	-	-	1,523	-	-	-	-	-	1,523
Impairment of assets	-	(983)	(6,130)	-	-	(152)	-	(176)	(6,130)	(1,311)
Restructuring costs	-	(72)	(14)	-	(101)	-	(238)	(92)	(353)	(164)
Litigation costs	-	(69)	-	-	-	-	-	-	-	(69)
Grant Income	325	-	490	-	-	-	40	-	855	-
Operating (loss)/profit	(876)	(3,155)	(7,033)	618	(366)	(470)	(1,523)	(4,193)	(9,798)	(7,200)
Finance (expense)	-	-	(443)	-	-	-	-	(460)	(443)	(460)
(Loss)/profit before taxation	(876)	(3,155)	(7,476)	618	(366)	(470)	(1,523)	(4,653)	(10,241)	(7,660)
Taxation	(22)	159	426	283	129	80	-	32	533	554
(Loss)/profit for the year	(898)	(2,996)	(7,050)	901	(237)	(390)	(1,523)	(4,621)	(9,708)	(7,106)

Revenue from all operating segments derives from the sale of biologic medical devices.
Administrative expenses are broken down as follows

	BioSurgery		Orthopaedics & Dental		GBM-v & Cardiac		Central		Total	
	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000
Staff costs	(2,106)	(2,862)	(2,607)	(2,931)	(423)	(483)	(527)	(889)	(5,663)	(7,165)
Sales and marketing - costs	(306)	(395)	(13)	(136)	-	(20)	(16)	(204)	(335)	(755)
Research and development	(118)	(256)	(257)	(530)	(164)	(172)	(7)	(409)	(546)	(1,367)
Depreciation and amortisation	-	(15)	(756)	(276)	(3)	(17)	(3)	(739)	(762)	(1,047)
Establishment and administration costs	(130)	(201)	(1,344)	(680)	(514)	(299)	(772)	(1,684)	(2,760)	(2,864)
Administrative costs	(2,660)	(3,729)	(4,977)	(4,553)	(1,104)	(991)	(1,325)	(3,925)	(10,066)	(13,198)

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3) Segmental reporting CONTINUED

The balance sheet can be analysed segmentally as follows:

	BioSurgery		Orthopaedics & Dental		GBM-v & Cardiac		Central		Total	
	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000	2020 £000	2019 £000
Non-current assets										
Intangible assets	-	-	10,931	17,999	-	-	-	-	10,931	17,999
Property, Plant & Equipment	-	-	3,214	2,357	4	-	34	-	3,252	2,357
Right of use asset	-	-	2,292	-	-	-	166	-	2,458	-
Total non-current assets	-	-	16,437	20,356	4	-	200	-	16,641	20,356
Current assets										
Inventory	1,308	345	5,530	3,661	150	122	84	57	7,072	4,185
Trade & other receivables	578	1,078	2,142	1,666	504	293	244	537	3,468	3,574
Cash & cash equivalents	181	495	143	87	141	41	9,085	1,757	9,550	2,380
Total current assets	2,067	1,918	7,815	5,414	795	456	9,413	2,351	20,090	10,139
Total assets	2,067	1,918	24,252	25,770	799	456	9,613	2,351	36,731	30,495
Liabilities										
Trade & other payables	(287)	(586)	(2,007)	(2,163)	(174)	(154)	(539)	(882)	(3,007)	(3,785)
Borrowings	-	-	(2,790)	(2,115)	-	-	-	-	(2,790)	(2,115)
Lease liability	-	-	(2,367)	-	-	-	(160)	-	(2,527)	-
Total liabilities	(287)	(586)	(7,164)	(4,278)	(174)	(154)	(699)	(882)	(8,324)	(5,900)
Net assets/(liabilities)	1,780	(1,332)	17,088	21,492	625	302	8,914	1,469	28,407	24,595
Capital expenditure	-	6	3,789	349	-	-	224	83	4,013	438
Additions to intangible assets	-	213	215	-	-	-	-	-	215	213

4) Loss from operations

	2020 £000	2019 £000
Loss from operations is stated after charging/(crediting):		
Depreciation of plant and equipment (see note 10)	192	476
Amortisation of intangible asset (see note 12)	570	571
Rentals subject to "short lease" exemption	116	213
Expensed inventory	5,990	5,803
Staff costs (see note 5)	5,663	7,165
Foreign exchange losses/(gains)	53	(1)
Research and development (exclusive of research and development staff costs)	546	1,368
Sales and marketing costs (exclusive of sales and marketing staff costs and commissions)	335	755
Exceptional items:		
Restructuring costs	353	164
Remeasurement of contingent consideration	-	(1,523)
Impairment of non-current assets	6,130	1,311
Litigation costs	-	69
	6,483	21
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	70	53
Other services:		
- fees in relation to cyber attack	108	-
- fees in relation to corporation tax	-	43
Total auditor's remuneration	198	116

Grant Income

	2020 £000	2019 £000
USA	815	-
Rest of world	40	-
	855	-

During the year the US subsidiaries of the Group were successful in their applications for two US Government PPP loans. The Loans have a two year term and carry a 1% annual interest rate deferred for 6 months, however, under the Loan agreement, the total amount of the Loan will not require repayment if the funds are used to support employee payroll, healthcare, utilities and rent payments within the US during the six months following inception. The Group believes they have met the above conditions and is presenting the loans in the Financial statements as grant income.

The UK companies applied for and received £40k under the UK government furlough scheme in 2020.

Grant income is presented within Operating activities within the cashflow statement.

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5) Staff costs

	2020 No.	2019 No.
The average monthly number of persons (including Directors) employed by the Group during the period was:		
Directors	5	7
Laboratory and administration staff	73	92
	78	99

	2020 £000	2019 £000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	4,717	6,178
Share based payments (see note 21)	(60)	(194)
Social security, pension & healthcare costs	1,006	1,181
	5,663	7,165
Directors' remuneration included above comprised:		
Emoluments for qualifying services	711	734

Social security, pension and healthcare costs include pension contributions of £98k (2019: £71k).

Directors' emoluments disclosed above include £490,000 paid to the highest paid Director (2019: £250,000). The share-based payments charge for Directors was nil (2019: £nil).

6) Finance income

	2020 £000	2019 £000
Bank interest receivable	2	17

7) Finance charges

	2020 £000	2019 £000
Imputed interest on deferred consideration	-	(93)
Interest on bank loans	(245)	(384)
Interest on lease liabilities	(200)	-
	(445)	(477)

8) Taxation

Tax on loss on ordinary activities

	2020 £000	2019 £000
Current tax:		
UK R&D tax credit	(440)	(488)
US corporation tax payable	-	29
	(440)	(459)
Deferred tax:		
Origination and reversal of temporary timing differences	(93)	(95)
Tax credit on loss on ordinary activities	(533)	(554)

8) Taxation CONTINUED

Factors affecting the current tax charges

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

	2020 £000	2019 £000
Loss on ordinary activities before tax	(10,241)	(7,660)
Tax at the standard rate of corporation tax 19% (2019: 19%)	(1,946)	(1,456)
Effects of:		
Research and development tax credits received	(314)	(468)
Surrender of research and development relief for repayable tax credit including enhancement	432	305
Unutilised tax losses	1,295	1,064
Tax credit for the period	(533)	(554)

Unrecognised deferred tax

	2020 £000	2019 £000
Tax losses		
Losses available to carry forward against future trading profits	51,104	43,533
*Deferred tax asset – at 19% (2019: 17%)	9,710	7,404

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

The enacted UK corporation tax rate of 19% forms the basis for the UK element of the deferred tax calculation, following the UK budget in 2021 the chancellor announced an increase to the main rate of corporation tax in the UK to 25% from April 2023, if applied this would significantly increase the value of the unrecognised deferred tax asset.

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.

	2020 £000	2019 £000
Total loss attributable to the equity holders of the parent	(9,709)	(6,973)

	No.	No.
Weighted average number of ordinary shares in issue during the year	4,447,666,932	1,171,867,216
Loss per share		
Basic and diluted loss for the year	(0.22)p	(0.60)p

As set out in note 21 the Company has options issued over 50,803,039 (2019: 19,553,729) ordinary shares and there are 16,112,800 (2019: 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.

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

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10) Property, plant and equipment

	Building & land £000	Laboratory equipment £000	Fixtures & fittings £000	Computer equipment £000	Total £000
Cost					
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)
At 31 December 2019	1,931	2,004	767	606	5,308
Exchange Adjustment	(32)	(34)	(12)	(3)	(81)
Additions	1,059	84	-	15	1,158
At 31 December 2020	2,958	2,054	755	618	6,385
Depreciation					
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 12)	-	123	179	37	339
At 31 December 2019	122	1,536	729	564	2,951
Exchange Adjustment	(3)	(5)	-	(2)	(10)
Charge for the period	48	124	8	12	192
At 31 December 2020	167	1,655	737	574	3,133
Net book value					
At 31 December 2020	2,791	399	18	44	3,252
At 31 December 2019	1,809	468	38	42	2,357
At 31 December 2018	1,923	537	253	115	2,828

11) Right of use assets

	Land and Buildings £000	Total £000
Cost		
At 31 December 2019	-	-
Additions	2,518	2,518
At 31 December 2020	2,518	2,518
Depreciation		
At 31 December 2019	-	-
Exchange adjustment	6	6
Charge for the period	(66)	(66)
At 31 December 2020	60	60
Net Book Value		
At 31 December 2020	2,458	2,458
At 31 December 2019	-	-

12) Intangible assets

	Development costs £000	Goodwill £000	Customer relationships £000	Trademarks £000	Process Tech £000	Supplier agreements £000	Total £000
Cost							
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
Additions*	215	-	-	-	-	-	215
Exchange adjustment	-	(522)	(71)	(19)	(35)	(14)	(661)
At 31 December 2020	1,187	14,740	1,999	533	1,000	400	19,859
Amortisation							
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
Charge for the period	-	-	234	125	117	94	570
Impairment (see below)	-	6,130	-	-	-	-	6,130
Exchange adjustment	-	-	(33)	(17)	(15)	(13)	(78)
At 31 December 2020	972	6,130	749	401	375	301	8,928
Net book value							
At 31 December 2020	215	8,610	1,250	132	625	99	10,931
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

*Additions in both years arose from internal development.

Goodwill, customer relationships, trademarks, process technology and supplier agreement all relate 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: 6.8 years, Trade marks: 1.8 years, Process Tech: 6.8 years, Supplier agreements: 1.8 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 14.6% (2019: 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 CellRight CGU is part of the Orthopaedics and Dental segment disclosed in note 3 and is the group's human tissue production and sales business in San Antonio, Texas.

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% (2019: 2%). Due to the uncertainty created by the Covid-19 pandemic the Directors have taken a cautious approach to the forecasts used in the calculation of value in use and in particular the assumption disclosed below in respect of future revenue growth.

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12) Intangible assets CONTINUED

The key inputs to the cash flow forecasts are:

- revenues (based on estimates of revenue growth with both new and existing customers based on an understanding of the needs of those customers and having regard to independent market assessments of market growth);
- gross margin and overheads (based on existing gross margins and adapted for appropriate increases base on the anticipated growth of the business);
- future anticipated capital expenditure (adjusted based on expected future growth); and
- movements in working capital.

The key assumption within the cash flow forecasts relates to sales growth which is inherently difficult to forecast in light of the pandemic. Across the five-year forecast period the compound annual growth rate (CAGR) is 18% which is significantly lower than the CAGR used in the prior year of 26% reflecting the uncertainty present in the group's markets at 31 December 2020.

The impairment test prepared by the Directors indicates a recoverable amount based on value in use of £22,412,000 compared to a CGU carrying amount of £28,542,000. The Directors have therefore recorded an impairment charge of £6,130,000 in these financial statements which has been allocated in full against the goodwill that arose on the original acquisition of CellRight. The Directors attribute the reason for this impairment to be the uncertainty created by the Covid-19 pandemic.

13) Inventory

	2020 £000	2019 £000
Raw materials and consumables	1,991	1,199
Work in progress	3,522	2,271
Finished goods including goods for resale	1,559	715
Total	7,072	4,185

Inventory is presented net of a provision of £271k (2019: Enil).

14) Trade and other receivables

	2020 £000	2019 £000
Trade debtors	1,785	1,719
Other receivables	95	341
Prepayments and accrued income	763	479
	2,643	2,539

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

	2020 £000	2019 £000
Trade receivables	1,817	1,813
Less: Allowance for expected credit losses	(32)	(94)
	1,785	1,719

14) Trade and other receivables CONTINUED**Allowance for expected credit losses**

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

	Expected credit loss rate	Carrying amount 2020 £000	Allowance for expected credit losses 2020 £000	Carrying amount 2019 £000	Allowance for expected credit losses 2019 £000
not overdue	0%	975	-	1,565	-
0 to 3 months overdue	0%	820	-	131	-
3 to 4 months overdue	25%	14	10	30	8
4 to 5 months overdue	50%	20	13	1	-
over 5 months overdue	100%	(12)	9	86	86
		1,817	32	1,813	94

The average Credit terms with customers is 40 days (2019: 40 days). Trade receivables are analysed by the currencies of settlement below:

	2020 £000	2019 £000
US Dollars	1,564	1,601
Euros	211	118
Sterling	10	-
Trade debtors	1,785	1,719

Movements in the impairment allowance for trade receivables are as follows:

	2020 £000	2019 £000
Opening provision for impairment of trade receivables	94	245
Increase during the year	27	135
Receivables written off during the year as uncollectable	-	-
Unused amounts reversed	(89)	(474)
At 31 December 2020	32	94

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15) Risk management of financial assets and liabilities

The Group's activities expose it to a variety of financial risks: Market risks, specifically interest rate risk, credit risk, liquidity risk, capital risk and foreign currency exchange rates. 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 due to little movement on deposit interest rates. Interest on the debt is at a fixed rate above LIBOR.

Accordingly, no sensitivity analysis has been presented as this is immaterial.

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 (see note 14).

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

	2020 £000	2019 £000
Cash and cash equivalents		
AA-	317	-
A+	515	1,000
A	8,498	1,380
A-	79	-
BBB+	141	-
	9,550	2,380

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.

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.

With the exception of borrowings detailed in note 17 and leases in note 19, all of the Group's financial liabilities mature within less than six months (2019: all within six months). At 31 December 2020 the Group was in compliance with all terms relating to the MidCap facilities and undrawn committed facilities of £702k were available to draw down. The maturity of borrowings was as follows:

	2020 £000	2019 £000
Less than 6 months	-	-
6 months to 1 year	-	171
1 year to 2 years	-	342
2 years to 5 years	2,790	1,773
	2,790	2,286

15) Risk management of financial assets and liabilities *CONTINUED*

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 20 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:

	2020 \$000	2019 \$000	2020 €000	2019 €000
Financial assets	1,564	1,601	195	121
Financial liabilities	(7,052)	(4,118)	(148)	(67)
Short-term exposure	(5,488)	(2,517)	47	54

The Group has exposure to the movements in the exchange rates in the Dollar and Euro at 31 December 2020. 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 £745k (2019: £311k) against the Dollar and gain £5k (2019: £5k) against the Euro.

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 2020				
Trade and other receivables	1,880	–	–	1,880
Cash and cash equivalents	9,550	–	–	9,550
Borrowings	–	(2,790)	–	(2,790)
Lease liabilities	–	(2,527)	–	(2,527)
Trade and other payables	–	(2,897)	–	(2,897)
	11,430	(8,214)	–	3,216

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)
Lease liabilities	–	–	–	–
Trade and other payables	–	(2,868)	–	(2,868)
	4,440	(5,154)	–	(714)

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16) Trade and other payables

	2020 £000	2019 £000
Current:		
Trade payables	975	1,650
Taxes and social security	110	76
Accruals	1,922	1,218
	3,007	2,944

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:

	2020 £000	2019 £000
Sterling	129	310
US Dollars	735	1,273
Euros	111	67
Trade payables	975	1,650

17) Borrowings

At 31 December 2020	Interest rate %	Maturity	Current £000	Non-current £000
Term Loan	LIBOR RATE +6.75%	Jun 2024	–	1,473
Revolving Credit	LIBOR RATE +4.5%	Jun 2024	–	1,507
Gross borrowings			–	2,980
Less capitalised debt issue costs			–	(190)
Borrowings			–	2,790

At 31 December 2019	Interest rate %	Maturity	Current £'000	Non-current £'000
Term Loan	LIBOR RATE +6.75%	Jun 2024	171	1,627
Revolving Credit	LIBOR RATE +4.5%	Jun 2024	–	761
Gross borrowings			171	2,388
Less capitalised debt issue costs			–	(273)
Borrowings			171	2,115

17) Borrowings CONTINUED

A US dollar denominated revised bank facility was signed by the Group in June 2019 with MidCap Financial Trust ("MidCap"). The bank loans outstanding at 31 December 2020 are represented by the following:

Term Loan: 5 years to June 2024. \$2m current facility. Interest maximum 6.75% above LIBOR RATE. Repayments of \$167,000 per month from July 2023. Maturity analysis as detailed in note 15.

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

As part of these facilities, MidCap hold security over the Group's freehold property in San Antonio and IP in respect of the Term Loan. The carrying amount of these assets pledged as security was £2.8m and £nil at 31 December 2020 (2019: £1.8m and £nil). The MidCap debt facility is subject to revenue covenants.

Also as part of these facilities, a warrant equating to 3% of the value of term loan was granted to MidCap in 2019 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 in 2019 as detailed in note 21.

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

The movement in total borrowings during the year was as follows:

	2019 £000	Cashflows £000	Non-cash changes Additions £000	Non-cash changes Foreign exchange movement £000	Non-cash changes Other £000	2020 £000
Borrowings	2,115	528	-	93	54	2,790
Lease liabilities	-	-	2,527	-	-	2,527
Total Liabilities from financing activities	2,115	528	2,527	93	54	5,317

	2018 £000	Cashflows £000	Non-cash changes Additions £000	Non-cash changes Foreign exchange movement £000	Non-cash changes Other £000	2019 £000
Borrowings	-	(4,193)	6,479	102	(273)	2,155
Total Liabilities from financing activities	-	(4,193)	6,479	102	(273)	2,155

18) Deferred tax liabilities

	Total £'000
As at December 2019	670
Release to the income statement	(93)
Exchange adjustment	(17)
As at December 2020	560

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

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

19) Lease liabilities

Lease liabilities, excluding short-term and low value leases, included in the Statement of Financial Position were as follows:

	2020 £000	2019 £000
Current Lease liabilities	(256)	-
Non-current liabilities	(2,271)	-
	(2,527)	-

Maturity analysis of lease liabilities

The maturity of the gross contractual undiscounted cashflows due on the Group's lease liabilities (excluding short-term and low value leases) is set out below based on the period between 31 December 2020 and the contractual maturity date.

	2020 £000	2019 £000
Land and buildings		
Less than 6 months	133	-
6 months to 1 year	133	-
1 year to 2 years	287	-
2 years to 5 years	2,948	-
5 or more years	-	-
	3,501	-

Disclosure of the carrying amounts of right of use assets by class and additions to right of use assets has been provided in note 11.

Effect of leases on financial performance

	2020 £000	2019 £000
Depreciation charge for the year:		
Administrative expenses	477	-
Interest expenses for the year on lease liabilities recognised in 'finance costs'	200	-
Total effect of leases on financial performance	677	-

Lease terms

The Group leases properties used for its operations in the UK and US. Lease terms are 5 years.

Terms on specific property leases also include:

UK Property: 5 year fixed lease and includes a break clause in 2023

US property: 5 year fixed and includes the option to purchase up to 2025

The Group average effective borrowing rate for leases at 31 December 2020 was 9%.

20) Share capital

	2020 £000	2019 £000
Ordinary shares of 0.1 pence	7,033	–
Deferred shares of 0.4 pence	4,687	–
Ordinary shares of 0.5 pence	–	5,859
	11,720	5,859

Movements on share capital during the period were as follows:

	Ordinary shares Number	£000	Deferred shares Number	£000
At 31 December 2018	1,171,730,823	5,859	–	–
Issued on exercise of share options	240,499	–	–	–
At 31 December 2019	1,171,971,322	5,859	–	–
Sub-division of shares		(4,687)	1,171,971,322	4,687
Issued on exercise of share options	1,479,965	1	–	–
Issue of shares	5,859,626,212	5,860	–	–
At 31 December 2020	7,033,077,499	7,033	1,171,971,322	4,687

All shares are ordinary shares which are fully paid and entitle the holder to full voting rights. The shares may be considered by the Directors when considering dividends from time to time. On 9 June 2020, a special resolution was passed at the general meeting for the 1,171,971,322 Ordinary Shares of 0.5 pence each in the issued share capital of the Company to be sub-divided into 1,171,971,322 Ordinary Shares of 0.1 pence each in the capital of the Company and 1,171,971,322 Deferred Shares of 0.4 pence each in the capital of the Company. The sub-division of shares was undertaken in order to facilitate the fundraising described below. The Deferred shares have no rights other than to a return of capital in the event of a winding up (and only after the holders of the Ordinary Shares have received the sum of £1m per share).

On 9 June 2020, the Company also completed a successful fundraising of £14.6m gross (£13.8m net).

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 a reverse 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 21)

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 21, there were employee related share options outstanding at 31 December 2020 of 66,915,839 over shares (2019: 32,569,731 shares) and options issued to providers of borrowings over 3,096,798 shares (2019: 3,096,798).

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

21) 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 0.3p to 22.5p and a vesting period between one and three 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 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
Exercised in the period	-	(1,479,965)	-	-	(1,479,965)	0.0008
Lapsed during year	(4,047,279)	(1,435,293)	-	(6,430,483)	(11,913,055)	0.0615
Issued in the year	-	-	-	47,739,128	47,739,128	0.0028
At 31 December 2020¹	1,220,437	1,843,474	16,112,800	47,739,128	66,915,839	0.0180

Excluding the EBT shares, there were 573,381 share options outstanding at 31 December 2020 (2019: 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 2020. The range of exercise prices applicable to share options is between 0.3p and 22.5p and the remaining options eligible to be exercised for 12p.

There were 16,112,800 of the jointly held EBT shares which were eligible to vest as at 31 December 2020.

21) Share based payments CONTINUED

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 following table lists the inputs to the models used:

	Options Granted year to 31 December 2020	Options Granted year to 31 December 2019
Dividend yield	-	-
Expected volatility (%)	63	47
Risk free interest rate (%)	0.9	1.0
Expected vesting life of EBT shares and options (years)	3	3
Weighted average fair value (£)	0.0180	0.0596

Share options issued under the Deferred Annual Bonus scheme (which is within the unapproved options) which are not exercised within four years from the date of grant will expire. Any other share options and employee interests in jointly owned EBT shares which are not exercised within 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 5.2 years (2019: 5.8 years). Expected volatility is based on historic share prices as published on LSE website.

Other Share Options

Warrants were issued in 2019 to MidCap 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 has been recognised in the statement of comprehensive income for the year as follows:

	Share based payment reserves £000
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
Credit in respect of employment related share options	(28)
At 31 December 2020	955

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

22) Non-controlling interest

	2020 £000	2019 £000
As at 31 December 2019	(615)	(482)
Attributable loss for the period	1	(133)
As at 31 December 2020	(614)	(615)

The non-controlling interest has 50% (2019: 50%) equity holding. GBM-V GmbH contributed revenue of £2,075k (2019: £2,076k) and a profit before tax of £2k (2019: loss £142k) for the year. Further financial information relating to GBM-V GmbH can be found in the segmental analysis in note 3.

23) Related party transactions

Transactions with key management personnel

During the year the Group entered into the following transactions in which the Directors and senior management also had an interest:

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

	2020 £000	2019 £000
Short-term employment benefits	971	836

24) Ultimate controlling party

The Directors believe that there is no ultimate controlling party.

25) Post balance sheet events

The Group carried out in January 2021 restructuring of the US Operations, this is estimated to save approximately \$700k on an annualised basis.

COMPANY STATEMENT OF CHANGES IN EQUITY

For the year ended 31 December 2020

	Share capital £000	Share premium £000	Merger reserve £000	Share based payment reserve £000	Retained earnings reserve £000	Total £000
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)
Contributions by and distributions to owners						
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
Total expense and other comprehensive loss for the period	-	-	-	-	(15,048)	(15,048)
Contributions by and distributions to owners						
Issue of shares	5,860	8,790			-	14,650
Costs of issue of new equity		(899)			-	(899)
Share options exercised	1	-	-	-	-	1
Share based payment credit	-	-	-	(3)	-	(3)
At 31 December 2020	11,720	94,290	10,884	907	(78,514)	39,287

COMPANY STATEMENT OF FINANCIAL POSITION

At 31 December 2020

	Notes	2020 £000	2019 £'000
Assets			
Non-current assets			
Investments	C4	18,813	18,594
Intercompany loan receivables	C6	11,754	3,860
Total non-current assets		30,567	22,454
Current assets			
Trade and other receivables	C5	35	218
Intercompany loan receivables	C6	-	16,757
Cash and cash equivalents	C8	9,039	1,669
Total current assets		9,074	18,644
Total assets		39,641	41,098
Liabilities			
Current liabilities			
Trade and other payables	C7	(354)	(512)
Total liabilities		(354)	(512)
Net assets		39,287	40,586
Equity and reserves			
Share capital	20	11,720	5,859
Share premium		94,290	86,399
Merger reserve		10,884	10,884
Share based payment reserve	C9	907	910
Retained earnings deficit		(78,514)	(63,466)
Total equity		39,287	40,586

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 2020 was a loss of £15,048k (2019: £50,001k).

The Company financial statements were approved by the Board of Directors and authorised for issue on 27 April 2021 and were signed on its behalf by

Daniel Lee
Chief Executive Officer

Company number: 0596927



COMPANY STATEMENT OF CASH FLOWS

For the year ended 31 December 2020

	Notes	2020 £000	2019 £000
Operating activities			
Loss before interest and tax		(15,594)	(50,646)
Adjustment for non-cash items:			
Share based payments		(222)	(146)
Impairment of intercompany loan receivables		14,222	48,600
Operating cash outflow		(1,594)	(2,192)
Decrease in trade and other receivables		183	35
(Decrease)/increase in trade and other payables		(159)	39
Net cash absorbed by operations		(1,570)	(2,118)
Investing activities			
Loan to subsidiary undertaking	C10	(5,359)	(4,021)
Interest received		546	645
Net cash used in investing activities		(4,813)	(4,021)
Financing activities			
Gross proceeds from equity raise		14,650	–
Cost of issue of new equity		(899)	–
Proceeds from exercise of share options		2	1
Net cash generated from financing activities		13,753	646
Increase/(decrease) in cash and cash equivalents		7,370	(5,493)
Cash and cash equivalents at start of period		1,669	7,162
Cash and cash equivalents at end of period		9,039	1,669

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December 2020

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 accounting standards in conformity with the Companies Act 2006 ('IFRS'). 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 has not adopted any new or amended standards early.

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 and judgements

Estimates and judgements are continually evaluated 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:

Estimates:

Recoverability of receivables from subsidiaries and impairment of financial assets

The gross loan advanced by the Company to its subsidiary undertakings is £75,866,000 (2019: £70,699,000). In accordance with IFRS 9 Financial Instruments, as the subsidiary undertakings cannot repay the loans 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 £64,132,000 has been recognised at 31 December 2020 (2019: £49,910,000).

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 scenarios 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 2020, 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 2020 is disclosed in note C10 to the financial statements.

C3. Staff costs

	2020 no.	2019 no.
The average monthly number of persons (including Directors) employed by the Company during the period was:		
Directors	5	7
Administration staff	2	1
	7	8
	£000	£000
The aggregate remuneration, including Directors, comprised:		
Wages and salaries	631	941
Social security, pension & healthcare costs	141	144
	772	1,085

Social security, pension and healthcare costs include pension contributions £33k (2019: £20k).

C4. Investment in subsidiary companies

	£000	£000
Cost at 1 January	18,594	18,594
Push down of share based payment charges	219	-
Carrying value at 31 December 2020	18,813	18,594

At 31 December 2020, the Company held the following investments in subsidiaries:

Undertaking	Sector	Share of issued capital and voting rights	
		2020	2019
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%
TRX 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 3, Phoenix Court, Lotherton Way, Garforth, Leeds LS25 2GY.

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

For the year ended 31 December 2020

CONTINUED

C5. Trade and other receivables

	2020 £000	2019 £000
Prepayments & accrued income	31	22
Other debtors	4	196
	35	218

C6. Intercompany loan receivables

	2020 £000	2019 £000
Gross intercompany loan receivables	75,886	70,527
Less: Expected credit losses	(64,132)	(49,910)
	11,754	20,617
Comprising:		
Non-current assets	11,754	3,860
Current assets	–	16,757
	11,754	20,617

Intercompany loans includes £828,000 gross (2019: 828,000) before provision of £740,889 due from the Group's EBT (2019: £642,889) (see note C10). No interest was receivable 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 at 4% above the Bank of England base rate and repayable in 2024. Intercompany loans are classified as non-current on the basis that they are not expected to be repaid within 12 months.

C7. Trade and other payables

	2020 £000	2019 £000
Trade creditors	–	124
Taxes & social security	110	30
Accruals	244	358
	354	512

C8. Risk management of financial assets and liabilities

The Company's 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.

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 (see C2.).

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

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

	2020 £000	2019 £000
Cash and cash equivalents		
A+	515	1,000
A	8,445	669
A-	79	-
	9,039	1,669

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.

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.

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 20 and in the Statement of Changes in Equity.

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 2020			
Trade and other receivables	4	-	4
Cash and cash equivalents	9,039	-	9,039
Intercompany loans	11,754	-	11,754
Trade and other payables	-	(244)	(244)
	20,797	(244)	20,553

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

NOTES TO THE COMPANY FINANCIAL STATEMENTS

For the year ended 31 December 2020

CONTINUED

C9. Share based payments

Other Share Options

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

	Share based payment reserves £000
At 31 December 2019	910
Credit in respect of employment related share options	(3)
At 31 December 2020	907

C10. Related party transactions

Remuneration received by the key management personnel which includes directors and senior management (including Employers NI) from the Group is set out below:

	2020 £000	2019 £000
Short-term employment benefits	946	836

Intercompany loans during and at the end of the year, before provisions for expected credit losses of £64,132k (2019: £49,910k) 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
At 31 December 2019	47,459	174	3,436	18,630	69,699
(Repayment)/Advance in the year	5,598	(18)	(145)	(76)	5,359
At 31 December 2020	53,057	156	3,291	18,554	75,058

Impairment provision:

At 31 December 2018	(1,310)	–	–	–	(1,310)
At 31 December 2019	(39,267)	–	–	(10,000)	(49,267)
At 31 December 2020	(50,765)	–	–	(12,626)	(63,391)

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 £828,000 (2019: £828,000) against which an impairment provision of £741,000 has been recorded (2019: £643,000). This is included as a debtor as there is a contractual loan agreement between the Company and the Trust.

NOTICE OF ANNUAL GENERAL MEETING

TISSUE REGENIX GROUP PLC IMPORTANT INFORMATION REGARDING COVID-19 AND THE AGM

The COVID-19 pandemic and the related guidelines and measures implemented by governmental authorities will clearly impact the ability of shareholders to attend the AGM.

Our preference had been to welcome shareholders in person to the AGM, particularly given the constraints we faced in 2020 due to the COVID-19 pandemic. However, at the time of writing of this Notice, it is expected that there will still be limitations on our ability to host shareholders at the AGM. We therefore strongly recommend that shareholders do not attend the AGM in person and instead appoint the Chairman of the meeting to act as their proxy. Due to the expected restrictions applicable at that time, shareholders may not be permitted to attend the physical location for the AGM in person or, if attendance at the venue is permissible at the relevant time, it is likely to be restricted in terms of numbers. We would therefore still encourage shareholders not to attend the venue in person and instead appoint the Chairman of the meeting to act as their proxy. If any shareholders do intend to attend the meeting in person, the Company strongly encourages them to advise the Company at least 48 hours in advance of the AGM by using the contact details below. Any such communication shall not provide a guarantee that admittance to the AGM will be permitted where to do so would be in breach of rules governing public gatherings and/or the need to protect the health and safety of those already in the meeting.

The Board's instructions are subject to change, depending on guidelines and measures implemented by governmental authorities, and any changes to such instructions will be communicated to shareholders.

TISSUE REGENIX GROUP PLC NOTICE OF ANNUAL GENERAL MEETING

Notice is given that the 2021 Annual General Meeting of Tissue Regenix Group plc ("Company") will be held at DLA Piper, Princes Exchange, Princes Square, Leeds LS1 4BY on 3 June 2021 at 12.00 p.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 2020.
2. To reappoint Jonathan Glenn who retires by rotation, as a director of the Company.
3. To reappoint Shervanthi Homer-Vanniasinkam who retires by rotation, as a director of the Company.
4. To reappoint Daniel Lee as a director of the Company, who has been appointed by the Board since the last Annual General Meeting, as a director of the Company.
5. To reappoint David Cocke as a Director of the Company, who has been appointed by the Board since the last Annual General Meeting, as a director of the Company.
6. To reappoint Brian Phillips as a Director of the Company, who has been appointed by the Board since the last Annual General Meeting, as a director of the Company.
7. To reappoint Trevor Phillips as a Director of the Company, who has been appointed by the Board since the last Annual General Meeting, as a director of the Company.
8. To reappoint RSM UK Audit LLP as Auditors of the Company.
9. To authorise the directors to determine the remuneration of the Auditors.

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10. That, pursuant to section 551 of the Companies Act 2006 ("Act"), the directors be generally and unconditionally authorised to allot Relevant Securities:

- 10.1 Up to an aggregate nominal amount of £2,344,359; and
- 10.2 Comprising equity securities (as defined in section 560(1) of the Act) up to a further aggregate nominal amount of £2,344,359 in connection with an offer by way of a rights issue:

10.2.1 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

10.2.2 to holders of other equity securities in the capital of the Company, as required by the rights of those securities or, subject to such rights, as the directors otherwise consider necessary,

but subject to such exclusions or other arrangements as the directors may deem necessary or expedient in relation to treasury shares, fractional entitlements, record dates or any legal or practical problems under the laws of any territory or the requirements of any regulatory body or stock exchange, provided that these authorities shall expire at the conclusion of the next Annual General Meeting of the Company after the passing of this resolution or on 27 August 2022 (whichever is the earlier), save that, in each case, the Company may make an offer or agreement before the authority expires which would or might require Relevant Securities to be allotted after the authority expires and the directors may allot Relevant Securities pursuant to any such offer or agreement as if the authority had not expired.

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

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

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

11. That, subject to the passing of resolution 10 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 10 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:

- 11.1 In connection with an offer of equity securities (whether by way of a rights issue, open offer or otherwise, but, in the case of an allotment pursuant to the authority granted by paragraph 10.2 of resolution 10, such power shall be limited to the allotment of equity securities in connection with an offer by way of a rights issue):

11.1.1 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

11.1.2 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

- 11.2 Otherwise than pursuant to paragraph 1.1 of this resolution up to an aggregate nominal amount of £703,307,

and this power shall expire at the conclusion of the next Annual General Meeting of the Company after the passing of this resolution or on 27 August 2022 (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).

12. That, pursuant to section 701 of the Act, the Company be and is generally and unconditionally authorised to make market purchases (within the meaning of section 693(4) of the Act) of ordinary shares of 0.1p each in the capital of the Company ("**Shares**"), provided that:

- 12.1 The maximum aggregate number of Shares which may be purchased is 703,307,749;
- 12.2 The minimum price (excluding expenses) which may be paid for a Share is 0.1p;
- 12.3 The maximum price (excluding expenses) which may be paid for a Share is an amount equal to 105% of the average of the middle market quotations for a Share as derived from the Daily Official List of the London Stock Exchange plc for the five business days immediately preceding the day on which the purchase is made;

and (unless previously revoked, varied or renewed) this authority shall expire at the conclusion of the next Annual General Meeting of the Company after the passing of this resolution or on 27 August 2022 (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

26 April 2021

Registered office: Unit 3, Phoenix Court,
Lotherton Way, Garforth, Leeds, England,
LS25 2GY

Registered in England and Wales No.
05969271

Notes

Entitlement to attend and vote

1. The right to vote at the meeting is determined by reference to the register of members. Only those shareholders registered in the register of members of the Company as at the close of business on 25 May 2021 (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. You can vote either:
- ▶ by logging on to www.signalshares.com and following the instructions;
 - ▶ You may request a hard copy form of proxy directly from the registrars, Link Group (previously called Capita), on Tel: 0371 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. Lines are open between 09:00 - 17:30, Monday to Friday excluding public holidays in England and Wales).
 - ▶ in the case of CREST members, by utilising the CREST electronic proxy appointment service in accordance with the procedures set out below.

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In order for a proxy appointment to be valid a form of proxy must be completed. In each case the form of proxy must be received by Link Group at 10th Floor, Central Square, 29 Wellington Street, Leeds, LS1 4DL by 10.00am on 1 June 2021.

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 Group (ID RA10) no later than 10.00 a.m. on 1 June 2021 (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 Group 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.

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 50 and 51 of the enclosed Annual Report and Accounts.

Share capital

9. As at 27 April 2021 (the last practicable business day prior to the date of this notice), the Company's issued share capital comprised 7,033,077,499 ordinary shares of 0.1 pence each and 1,171,971,322 deferred shares of 0.4 pence each. Each ordinary share carries the right to vote at a general meeting of the Company. The deferred shares carry no voting rights. Therefore, the total number of voting rights as at the date of this document is 7,033,077,499.

DIRECTORS AND OFFICERS

DIRECTORS

Jonathan Glenn

Daniel Lee

David Cocke

Shervanthi Homer-Vanniasinkam

Trevor Phillips

Brian Phillips

Non-Executive Chairman

Chief Executive Officer

Chief Financial Officer

Non-Executive Director

Non-Executive Director

Non-Executive Director

COMPANY SECRETARY

Kirsten Lund

COMPANY WEBSITE

www.tissueregenix.com

COMPANY NUMBER

05969271 (England & Wales)

REGISTERED OFFICE

Unit 3
Phoenix Court
Lotherton Way
Garforth
LS25 2GY

REGISTRAR

Link Group
PXS 1
Link Group
Central Square
29 Wellington Street
Leeds
LS1 4DL

AUDITOR

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

LEGAL ADVISERS

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

Squire Patton Boggs UK LLP
6 Wellington Place
Leeds
LS1 4AP

NOMINATED ADVISER AND BROKER

Stifel Nicolaus Europe Ltd
150 Cheapside
London
EC2V 6ET



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Phoenix Court,
Lotherton Way,
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LS25 2GV**

www.tissueregenix.com