15 March 2022



# Tissue Regenix Group plc

("Tissue Regenix" or "the Group")

# Final year results for the year ended 31 December 2021 Annual Report and Notice of AGM

Tissue Regenix Group (AIM:TRX), the regenerative medical devices company, announces its final results for the year ended 31 December 2021.

# **Financial Highlights**

- Returned to double digit revenue growth up 20% to US\$19.7m (2020: US\$16.5m) due to a strong performance in the US
  - BioRinse<sup>®</sup> (orthopaedics and dental) revenue of US\$12.7m, up 33% (2020: US\$9.5m)
  - Joint venture GBM-v increased revenue of US\$2.8m, up 5% (2020: US\$2.6m)
  - o **dCELL**<sup>®</sup> (DermaPure<sup>®</sup>) sales remained consistent at US\$4.2m (2020: US\$4.2m)
- Gross Profit increased to US\$8.5m (2020: US\$7.5m)
- Operating Loss reduced to US\$4.9m (2020: US\$12.4m)
- Cash balance at 31 December 2021 of US\$7.7m, supports current business growth plan

# **Operational Highlights**

- Completion of the Phase 1 facility expansion at the San Antonio, Texas facility, in June 2021 on time and on budget
- Launch of **dCELL**<sup>®</sup> product line extensions; DermaPure<sup>®</sup> Meshed, VNEW<sup>™</sup> and MatrixND<sup>™</sup>
- Reorganisation of the **dCELL**<sup>®</sup> commercial operations to reinvigorate sales growth
- Successfully secured several new strategic partners and distributors resulting in a 36% increase in units shipped during 2021
- ISO 13485 accreditation for the Garforth, Leeds facility received in February 2021
- Completion of restructuring of the **dCELL**<sup>®</sup> operations in January 2021 which will reduce the overhead cost base by c. US\$700k on an annualised basis
- Sales for DermaPure<sup>®</sup> products to ARMS Medical were up 24%

# Post balance sheet events

- Exercised option to increase the current revolving credit facility from US\$3.0m to US\$5.0m; provides financial flexibility
- Distribution agreement signed with Geistlich Biomaterials Italia for the distribution of OrthoPure XT in Italy

**Daniel Lee, Chief Executive Officer of Tissue Regenix, commented:** "Our organisation continued to demonstrate success despite all the ongoing challenges associated with the pandemic. Our positive financial performance during such uncertain circumstances have set our trajectory to be even greater in 2022 as our Group and our partners emerge from under the pandemic's cloud that has limited our growth. With our focus on the 4S's - Supply, Sales Revenue, Sustainability and Scale - these will serve us in building shareholder value as we expand our opportunities and global growth in regenerative medicine. 2021 represented the first full year of my responsibilities as CEO of the Tissue Regenix Group and I am delighted by the progress the organisation has made."

#### Annual Report and Accounts and Notice of AGM

As part of the Company's move to electronic reporting, the Annual Report and Accounts, notice of AGM and accompanying form of proxy, will be available later this morning on the Company's website, <u>www.tissueregenix.com</u>, in accordance with AIM Rule 20. For those who opted to receive hard copies of the Annual Report, these will be posted today.

The AGM will be held at DLA Piper, 160 Aldersgate St, Barbican, London EC1A 4HT, on Tuesday 26 April 2022 at 1.00pm. At the time of writing there are no restrictions in place that would prevent us from holding a physical meeting and inviting all of our shareholders to attend, so we are proceeding on the assumption that we will be able to do so. The Board will, however, monitor developments closely in case the position changes and, if it does, we will notify you of any changes in our plans for the AGM both by a regulatory news service announcement and via our website at <u>https://www.tissueregenix.com/</u>. Shareholders are invited to submit any question to the Board about the Annual Report and Accounts or the AGM by contacting Walbrook PR at <u>TissueRegenix@walbrookpr.com</u>.

The results of the votes on the proposed resolutions will be announced by RNS as soon as practicable after the conclusion of the AGM.

For more information:

### **Tissue Regenix Group plc**

Daniel Lee, Chief Executive Officer David Cocke, Chief Financial Officer

**Stifel Nicolaus Europe Limited (Nominated Adviser and Broker)** Ben Maddison / Nick Harland

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#### About Tissue Regenix (www.tissuergenix.com)

Tissue Regenix is a leading medical devices company in the field of regenerative medicine. The company's patented decellularisation ('dCELL<sup>®</sup>') technology removes DNA and other cellular material from animal and human soft tissue leaving an acellular tissue scaffold which is not rejected by the patient's body and can then be used to repair diseased or damaged body structures. Current applications address many critical clinical needs such as in sports medicine, foot and ankle, and wound care.

In August 2017 Tissue Regenix acquired CellRight Technologies<sup>®</sup>, a biotech company that specializes in regenerative medicine and is dedicated to the development of innovative osteoinductive and wound care scaffolds that enhance healing opportunities of defects created by trauma and disease. CellRight's human osteobiologics may be used in spine, trauma, general orthopaedic, dental, and ophthalmological surgical procedures.

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# Chairman's statement

### Introduction

Despite the ongoing challenges posed by the COVID-19 pandemic, in 2021 we saw continued positive momentum in creating long-term sustainable shareholder value. The Group returned to double digit revenue growth, thanks largely to an exceptionally strong performance in the US.

I would like to extend my thanks to the Executive team and all our employees for what has been achieved over the last year. The Group has delivered robust financial and operational performances and ended the period in a strong financial position that supports the current business growth plan.

### **Clear strategy**

Our ambition is to create a commercially focused global regenerative medicine company addressing soft tissues and bone, operating in a high-growth sector with a multi-billion-dollar addressable market. Through its platform technologies, the Group can commercialise its regenerative medicine products, helping to transform the treatment of patients in key surgical applications. The main focus of the Group's strategy is the commercialisation of its product portfolio.

2021 has seen significant delivery of our strategy within our four key areas of focus (Supply, Sales Revenue, Sustainability and Scale), providing clear strategic direction of the Group's ambitions and delivering shareholder value - The following are notable achievements in the period:

- Accelerated market penetration in the US, the largest healthcare market in the world:
  - The BioRinse<sup>®</sup> division performed strongly in 2021, aided by the completion of the first phase of the manufacturing expansion
  - The Group saw a strong comparative sales performance due to its diverse surgical specialties
- New partnership agreements:
  - During the year we identified and signed additional opportunities and distribution agreements that target products and therapeutic areas which are complementary to our current processing activities to diversify the Group's sales portfolio further
  - The Group was successful in signing new strategic partners and expanded its customer base following the acquisition of three of the Group's existing strategic partners by larger organisations, where we benefit from greater market penetration
  - $\circ$   $\;$  The Group also secured additional donor sourcing agreements in the US
  - Phase 1 manufacturing facility expansion in San Antonio, Texas:
  - Completed on time and on budget
  - The completion of the manufacturing expansion increases the Group's revenue generation potential and processing efficiency as well as providing additional donor storage capacity
- Reorganisation of US dCELL<sup>®</sup> divisional operations:
  - The Group completed restructuring of the operational and commercial activities for the dCELL<sup>®</sup> division which will provide an opportunity to increase new customer wins as well as increased penetration and upsell of existing accounts.
- Expansion of product portfolio and additional product line extensions:
  - During the year the Group successfully launched product line extensions in its dCELL<sup>®</sup> division; DermaPure<sup>®</sup> Meshed, VNEW<sup>™</sup> and MatrixND<sup>™</sup>.

#### Board

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With confirmation of my appointment as Non-Executive Chairman in February 2021 and other Board appointments announced in the first quarter of 2021, we now have a strong, commercially focused Board and executive leadership in Danny Lee and David Cocke, collectively committed to creating long-term sustainable value and growth of the Group through an increased portfolio offering and market penetration.

In January 2021, Trevor Phillips and Brian Phillips (no relation) were appointed to the Board as Non-Executive Directors. Brian and Trevor bring a wealth of experience particularly regarding operations and corporate development in the life sciences industry and financial management, which have been key in driving the Group's success during 2021. Brian Phillips is Chair of the Audit Committee and Trevor Phillips is Chair of the Remuneration Committee.

Shortly following these appointments in January, David Cocke was appointed CFO of the Group alongside Danny Lee, CEO, based in San Antonio, Texas. David has 30 years' experience in senior finance and operations roles having previously been CFO at Aperion Biologics, Inc. and founding NuPak Medical, Ltd. in 1997 which was later acquired by Katena Products, Inc. in 2017.

#### **Financial overview**

Trading in the year was robust with a return to double digit revenue growth and in line with management expectations despite the challenges of the COVID-19 pandemic. A particularly strong growth performance was seen by the BioRinse<sup>®</sup> division aided by the completion of the Phase 1 of the manufacturing expansion project. The Group's cash position at year end supports our current business growth plan.

# 2022 Outlook

Despite another year with continuing challenges posed by the pandemic and the postponement of elective surgeries across all specialties, we continue to make encouraging progress on our strategy, deliver revenue growth, expand our product portfolio and deliver operational efficiency. Importantly, while we recognise the ongoing challenges of COVID-19, we continue to see strong demand for our products and the Board is optimistic as we see a return to pre-pandemic conditions, this demand will drive sales revenue growth as the Group moves towards profitability.

On behalf of the Board, I would like to thank Danny and David for their excellent leadership along with the rest of our management team and employees for their hard work to achieve a strong recovery despite the external challenges over the year. We would also like to thank our shareholders, our business partners and suppliers for their continued support throughout 2021 and we look forward with optimism for the year ahead.

Jonathan Glenn Chairman 14 March 2022

# **Chief Executive Officer's statement**

In my first full year as CEO of the Group, we have established a clear strategy, accelerated market penetration in the US and expanded our customer base and product portfolio whilst increasing our processing efficiency and donor storage capacity. These full year results reflect the progress we have made as we drive towards profitability.

I am pleased to report that the Group performed admirably during 2021 despite the ongoing global challenges posed by the pandemic when hospitals, governments and healthcare providers postponed elective surgeries across all specialties. Despite these challenges we continued to make progress and reinvigorate commercial growth. As our products experienced broader adoption, this growth was supported by the Group's dedicated and resilient employees.

### Strategy

The tissue engineering market is anticipated to grow significantly and is projected to reach \$6.8bn by 2027, growing at a 14% Compound Annual Growth Rate (CAGR) from 2020 owing to increases in the prevalence of chronic diseases and trauma emergencies, increased awareness of tissue engineering, and potential pipeline products.

In 2021, we announced our 4S strategy as the foundation of how we operate and drive our growth:

- **Supply** highlighted by the fundamental ability to source donor tissue and having the capacity to produce various graft products
- **Sales Revenue** to distribute the finished grafts to the clinicians and institutions that need these products to treat patients
- **Sustainability** to manage sales revenue along with expenses to be a profitable entity that does not need additional external capital to operate
- **Scale** to utilise the first three S's to continue to invest and grow the business, license or acquire new products, technologies and companies

Our focus on the 4S's across all divisions and departments provides a 360-degree approach and strategic direction for our future success. We believe this focus will allow the Group to achieve above-market growth rates, as we have demonstrated in 2021 with a 20% growth rate over 2020.

# BioRinse<sup>®</sup> (Bone)

Orthopaedics and dental markets in the US reported a strong performance in 2021 and our 33% year-on-year growth we experienced in 2021 surpassed many others in this space. This is indicative of the continued confidence in our products, strong performance of our distributors and strategic partners, our participation in diverse surgical specialties and the addition of new distributors.

#### dCELL® (Soft Tissue)

A strategic review was performed on the dCELL<sup>®</sup> division with the objective of driving increased sales revenue momentum. This review indicated that a flatter, more customer-facing commercial organisation could yield enhanced customer penetration. As a result, we compressed three layers of management into one, pushing our commercial management closer to the end users and sales channel partners. In addition, in January 2021 we restructured the operations of this segment to become more efficient and reduce the overhead cost base by c. \$700k on an annualised basis.

As the pandemic continued into 2021, distributors faced numerous challenges with the dCELL<sup>®</sup> product line due to the postponement of elective surgical procedures. As a result, sales in this division were flat year-on-year. However, the demand for our DermaPure<sup>®</sup> products increased in the urological/gynaecological sector driven by orders from ARMS Medical, which were up 24% from the previous year.

The EU and its member countries experienced volatility throughout 2021, especially in elective surgeries. OrthoPure<sup>®</sup> XT, the first non-human biologic graft available to the market, is used in the reconstruction of the Anterior Cruciate

Ligament (ACL) and can be used 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. In mid-2020 we received the CE Mark for OrthoPure<sup>®</sup> XT and in November 2020 launched the product into a limited number of European markets. However, the pandemic caused postponement of many elective ACL procedures, so we plan to relaunch in 2022 when more normal conditions resume. We expect to gain market traction in the UK and EU and remain confident that OrthoPure<sup>®</sup> XT will begin to add revenues in 2022.

The pandemic delayed our plans to expand the geographic outreach of our dCELL<sup>®</sup> and BioRinse<sup>®</sup> portfolios into new territories and we anticipate demand for our dCELL<sup>®</sup> products will resume as surgical procedures return to prepandemic levels. In 2022 we plan to establish a logistical partner and distributors in select European markets for our human tissue products which will be made possible by our increased processing capacity.

### dCELL<sup>®</sup> product line extensions

We continued to pursue the commercialisation of products which utilise our core technology platforms, provide product line extensions that are fast to market and address a specific clinical or commercial need.

In 2021 we introduced three new products which utilise our dCELL® technology platform:

- **DermaPure® Meshed**; used to treat wounds where additional surface area coverage and wound drainage is needed (approximately 70,000 procedures in the US per annum) and eliminates time consuming manual meshing in the operating room. Targeted for use by general, plastic and trauma surgeons who treat patients with conditions that result in loss of integumental tissue (skin), requiring replacement, repair, or reconstruction
- **VNEW**<sup>™</sup>; a pre-cut dermal allograft that can be used in pelvic organ prolapse procedures (approximately 300,000 procedures in the US per annum) which are frequently performed in women post childbirth. ARMS Medical, our exclusive distributor for this product, placed their initial stocking order in August and re-ordered in December
- Matrix ND<sup>™</sup>; a dermal allograft designed for use in dental or oral and maxillofacial procedures for soft tissue repair coverage and augmentation which was developed to meet the need of our dental partners (approximately 400,000 procedures in the US per annum). A dental membrane is frequently used in conjunction with dental bone grafting procedures

Additional product line extensions and product improvements are anticipated during 2022 which will contribute to our organic growth and support the commercial efforts of our organisation and strategic partners.

#### GBM-v

Our controlled joint venture in Germany, GBM-v, grew 6% in 2021 despite continued impacts from the pandemic on elective procedures, specifically for corneal transplants in Germany. The demand for corneal tissue continues to outpace supply, but the market has been suppressed due to the postponement of elective surgeries with many patients electing to defer to avoid entering healthcare institutions. We expect this growth to continue and accelerate as more normalised conditions return.

# New strategic partners and distributors

Despite the challenges of the pandemic, we continued to be successful in securing new strategic partners and distributors and saw a 36% increase in the units shipped in 2021. One partial explanation for this increase in shipments was the consolidation of several of our strategic partners. Three of these were acquired by larger entities that have a more significant presence in the marketplace and importantly more distribution outlets. As an example, one of our BioRinse<sup>®</sup> customers was acquired in 2021, and orders increased by 142% year-on-year under the new ownership. We also signed new agreements with four strategic partners and distributors who target specialty markets such as spinal and dental.

### Manufacturing facilities

In February 2021, San Antonio experienced an unprecedented snowstorm and freeze which impacted electrical and water services throughout the state of Texas. This temporarily affected our ability to process at the facility in San Antonio, but the power loss did not impact materials in storage in the ultra-low temperature freezers. We were unable to service customer demand the following week as delivery services had also been impacted and had limited capacity. During the weeks that followed, the team worked to catch up with demand and service all our customers. In the future, any impact to the Group due to a power grid failure will be partially addressed through a battery back-up system to be implemented in 2022.

The relocation in October 2020 of our operations in the UK to Garforth, Leeds and reinitiating the processing of the OrthoPure<sup>®</sup> XT product, required the product to be recertified for the CE Mark. The recommendation for certification of the facility to ISO 13485 was received in February 2021.

In mid-2021 we completed our Phase 1 capacity expansion programme in San Antonio on time and on budget. The Phase 1 expansion comprised of fitting out approximately half of a 21,000 sq. ft. building that is adjacent to our existing facility in San Antonio to provide improvements in key areas: donor storage, processing, production, and distribution. We moved the bulk of our storage freezer space to the new facility in mid-March and added capacity through the purchase of new, more efficient ultra-low temperature freezers to triple our donor tissue storage capabilities which will meet demand over the next 3-5 years. The expansion also included a new distribution facility which consolidated this function and its personnel to one location. The anticipated labour and time savings in processing orders was realised in 2021 as we increased unit shipments by 36% with only one additional member of staff.

The move of freezer storage and personnel into the new building freed up space for processing and production in the existing facility. Two sterile packaging rooms were added in the existing facility, which brought the total number of clean rooms to seven. The new sterile packaging rooms and installation of additional processing equipment increased our BioRinse<sup>®</sup> portfolio processing capacity by c.50%. Space created by the move to the new building was also utilised to set up additional workspace for downstream production activities such as final product boxing and labelling.

When the Phase 1 expansion is up and running at full capacity, the Group's revenue generation potential will be c.\$30m per year within the existing facility footprint. For Phase 2, it is our intention to build an additional ten clean rooms in the new facility, which will meet our capacity needs for the next 5–7 years as we grow our portfolio, markets, customer base and global presence.

#### The impact of COVID-19

The pandemic continued to stunt the surgical marketplace when hospitals, governments and health care providers halted elective procedures across all specialties. A partial return to normality occurred in the second quarter of 2021 before the Delta variant affected elective procedures in the third and early fourth quarter of 2021. These disruptions led to unpredictable demand for our products, however a healthy inventory meant we could respond as needed to changes in the marketplace.

We remained diligent at all our facilities and implemented the initiatives and guidelines necessary to minimise disruption. We had already expanded our donor sourcing efforts in 2020 and in 2021 these efforts were further expanded to other tissue processors for the procurement or disbursement of donor tissue. Tissue processors have the responsibility to be the stewards of the gift of tissue donation, so we need to consider all avenues for donor tissue to be utilised in meeting the donor families' wishes.

#### Outlook

Our positive financial performance during such uncertain circumstances has set our trajectory to be even greater in 2022 as the Group and our partners expect to emerge from the pandemic. In 2021 we saw particularly strong growth in BioRinse<sup>®</sup> and with the completion of the manufacturing expansion we expect this solid performance to continue.

As markets start to return to pre-pandemic levels the Group is well positioned to meet the demand now that we have the capacity and inventory in place to do so.

The implementation of a new commercialisation strategy for the dCELL<sup>®</sup> products is expected to enable greater market penetration and we look forward to increasing sales revenue momentum from this segment as well as our additional product line extensions in 2022.

I am confident in our growth strategy, our products and their potential to benefit patients in what will hopefully be a less unsettled year ahead. With the changes we have made in 2021 the business is well positioned to service our customers and drive shareholder value. I look forward to the continuing success of the Group in the coming year and as we move towards profitability.

Daniel Lee Chief Executive Officer 14 March 2022

#### **Financial review**

With effect from 1 January 2021, the Group's presentation currency changed from pounds sterling (" $\pounds$ ") to United States dollar (" $\ddagger$ ") as the Directors considered the USD to be more representative of the geography in which the Group primarily operates.

#### Revenue

In the year ended 31 December 2021 revenue increased by 20% to \$19,746k (2020: \$16,473k).

The financial performance for the year was impacted at times by the ongoing coronavirus pandemic, as Q1 saw ongoing effects of the initial wave of the pandemic before widespread vaccine rollouts took place in the US, and the Q3 and early Q4 sales were affected by the Delta variant, before rebounding positively in November and December 2021.

The BioRinse<sup>®</sup> segment performed strongly in 2021, aided by the completion of the first phase of the expansion of the Group's manufacturing capacity in San Antonio, TX. This unit successfully grew top line sales by 33%, to \$12,711k (2020: \$9,562k) as the BioRinse<sup>®</sup> division used its strong relationships with strategic partners to take market share in the US. Revenue from DermaPure<sup>®</sup>, under the DCell<sup>®</sup> division, was slower to respond to the easing of the pandemic and associated restrictions with 2021 sales flat at \$4,246k (2020: \$4,247k).

The Group's joint venture, GBM-v, based in Rostock, increased revenues 5% to \$2,789k (2020: \$2,664k) despite continued market disruptions from the pandemic that continued throughout 2021.

#### Cost of sales and gross profit

Gross profit for the year was \$8,476k (2020: \$7,570k). Gross margin percentage decreased to 43% (2020: 46%). In 2021 the Group transferred certain excess tissues at a reduced margin in order to honour the gift of tissue donation and prudently manage the statement of financial position by reducing slow moving inventory. Those transfers will not recur in future periods. In addition, the Group experienced supply chain driven price increases in the period. A price increase was put in place in the BioRinse<sup>®</sup> division to address the cost pressures.

Included in costs of sales is cost of product \$10,348k (2020: \$7,699k) and third-party commissions \$922k (2020: \$1,204k).

#### Administrative expenses

During 2021 administrative expenses before exceptional items decreased by \$351k to \$12,574k (2020: \$12,925k).

#### **Exceptional items**

Exceptional items decreased by \$7,969k to \$355k primarily driven by the impairment charge in 2020 (2020: \$8,324k). Restructuring costs of \$52k related to a redundancy in the Central segment were charged in the year.

Restructuring costs of \$183k were charged to the DCell<sup>®</sup> division as a result of a restructuring of that division in January 2021.

The February 2021 winter storm event in Texas resulted in a charge of \$120k at the BioRinse<sup>®</sup> division relating to non-productive time and spoilage.

#### Finance income/charges

Finance income of \$3k (2020: \$3k) represented interest earned on cash deposits. Finance charges for the year were reported at \$692k (2020: \$571k) and related primarily to interest charges and associated costs for the MidCap loan arrangement.

#### Loss for the year

The loss for the year was \$4,985k (2020 loss: \$12,465k) resulting in a basic loss per share of (0.07 cents) (2020 loss: 0.28 cents).

### Taxation

The Group continues to invest in developing its product offering, and as such is eligible to submit enhanced research and development tax claims, enabling it to exchange tax losses for a cash refund. In the year to December 2021, a refund of \$534k was receivable (2020: \$1,120k). The year-on-year reduction was a result of the business continuing to move its resources away from research and development to more commercial activities.

Corporation tax payable in the US amounted to \$0k (2020: \$0k). A corporation tax credit of \$157k (2020: \$684k) was recognized in the period. Gross tax losses carried forward in the UK were \$73,643k (2020: \$69,399k). 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.

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

At December 2021, the Group had net assets of \$33,392k (2020: \$37,817k) of which cash in hand totalled \$7,709k (2020: \$12,968k).

Inventory remained stable at \$9,719k (2020: \$9,604k) as the BioRinse<sup>®</sup> and DCell<sup>®</sup> segments managed stock levels closely to increase inventory turnover while also keeping adequate stock levels to meet customer demand.

Intangible assets increased slightly to \$15,064k (2020: \$14,845k) in the year. A further \$497k of development costs were capitalised in the year. The balance of movements in this account relate to amortisation.

A full impairment test was performed on each of the Group's CGUs to determine whether the property, plant and equipment, right-of-use, or intangible assets have suffered an impairment loss. This assessment resulted in no indication of impairment and no charges were recognized for the year.

Working capital increased slightly in the year to \$9,992k (2020: \$9,882k), driven by an increase to inventory from continued growth in manufacturing activities. The statement of financial position included corporation tax receivable of \$534k (2020: \$1,120k) in respect of UK research and development tax credits.

#### Borrowings/Lease liability

Non-current liabilities include the \$4,465k debt facility through MidCap and the \$3,072k lease liability related to the Group's leasehold in San Antonio, TX (2020: \$3,788k and \$3,084k respectively). The MidCap debt facility includes \$2,000k of the term loan and \$2,465k of the revolving credit facility, net of \$184k of capitalised debt issue costs.

#### Dividend

No dividend has been proposed for the year to 31 December 2021 (2020: Nil).

#### **Accounting policies**

Following the departure from the EU, the Group's consolidated financial information has been prepared in accordance with UK adopted international accounting standards (UK adopted IAS).

#### **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 2023 (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 \$7.7m at 31 December 2021 and the ongoing support of MidCap Financial Trust ("MidCap") (borrowings of \$4.5m at 31 December 2021) to meet its working capital requirements, capital investment programme and other financial commitments. Repayment on the MidCap borrowings is scheduled to begin in July 2023.

The COVID-19 pandemic continued to affect most healthcare businesses in 2021, as the emergence of the Delta and Omicron variants extended the timeline for a return to normal healthcare procedure volumes. 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 ability 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 the repayment is not due to start until H2 2023. 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. 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.

#### Subsequent development

In January 2022 the Group elected to exercise its option to increase its current revolving credit facility from \$3.0m to \$5.0m. Although this financing is not dictated by the current business plan, which is fully funded by the Group's year end cash position, the additional liquidity is a prudent measure to provide additional cash resources in the face of future risks posed by COVID-19.

#### **Future development**

The emergence of the Omicron variant in late 2021 has caused disruptions in the US healthcare system and supply chains worldwide. Although Omicron appears to have milder complications than prior variants, it remains difficult to predict at what pace a return to pre-pandemic procedural levels will occur.

#### **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 Cocke Chief Financial Officer 14 March 2022

# **Financial Statements Consolidated Statement of Income** For the year ended 31 December 2021

	2021	2020
	USD	USD
	'000	'000
Revenue	19,746	16,473
Cost of sales	(11,270)	(8,903)
Gross profit	8,476	7,570
Administrative expenses before exceptional items	(12,574)	(12,925)
Exceptional items	(355)	(8,324)
Total administrative expenses	(12,929)	(21,249)
Grant Income	-	1,098
Operating loss	(4,453)	(12,581)
Finance income	3	3
Finance charges	(692)	(571)
Loss on ordinary activities before taxation	(5,142)	(13,149)
Taxation	157	684
Loss for the year	(4,985)	(12,465)
Loss for the year attributable to:		
Equity holders of the parent company	(4,792)	(12,466)
Non-controlling interest	(193)	1
	(4,985)	(12,465)
Loss per ordinary share attributable to equity holders of the parent		
company		
Basic and diluted, cents per share	(0.07)	(0.28)

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

# Consolidated Statement of Comprehensive Income

For the year ended 31 December 2021

	2021	2020
	USD	USD
	'000	'000
Loss for the year	(4,985)	(12,465)
Other comprehensive income		
Items that may be subsequently reclassified to profit or loss:		
Foreign currency translation differences	(4)	970
Total comprehensive loss for the year	(4,989)	(11,495)
Total comprehensive loss for the year attributable		
to:		
Equity holders of the parent company	(4,796)	(11,496)
Non-controlling interest	(193)	1
	(4,989)	(11,495)

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

As at 31 December 2021

	2021	2020
	USD	USD
	'000	'000
Assets		
Non-current assets		
Property, plant and equipment	5,708	4,417
Right-of-use assets	3,388	3,337
Intangible assets	15,064	15,299
	24,160	23,053
Current assets		
Inventory	9,719	9,604
Trade and other receivables	4,101	3,589
Corporation tax receivable	534	1,120
Cash and cash equivalents	7,709	12,968
	22,063	27,281
Total assets	46,223	50,334
Liabilities		
Non-current liabilities		
Loans and borrowings	(4,465)	(3,788)
Deferred tax	(640)	(760)
Lease liability	(3,364)	(3,084)
	(8,469)	(7,632)
Current liabilities		
Trade and other payables	(4,244)	(4,084)
Lease liability	(118)	(347)
	(4,362)	(4,431)
Total liabilities	(12,831)	(12,063)
Net assets	33,392	38,271
Equity		
Share capital	15,947	15,947
Share premium	134,173	134,173
Merger reserve	16,441	16,441
Reverse acquisition reserve	(10,798)	(10,798)
Reserve for own shares	(1,257)	(1,257)
Share-based payment reserve	1,573	1,463
Cumulative translation reserve	(1,305)	(1,301)
Retained deficit	(120,432)	(115,640)
Equity attributable to equity holders of the parent company	34,342	39,028
Non-controlling interest	(950)	(757)
Total equity	33,392	38,271

The consolidated financial statements were approved by the Board of Directors and authorised for issue on 14 March 2022 and were signed on its behalf by:

Daniel Lee

Chief Executive Officer Company number: 05969271

# Consolidated Statement of Changes in Equity

For the year ended 31 December 2021

	Share capital USD'000	Share premium USD'000	Merger reserve USD'000	Reserve acquisition reserve USD'000	Reserve for own shares USD'000	Share based payment reserve USD'000	Cumulative translation reserve USD'000	Retained Deficit USD <sup>4</sup> 000	Total USD <sup>^</sup> 000	Non-controlling interest USD'000	Total equity USD <sup>^</sup> 000
At 31 December 2019	8,478	124,118	16,441	(10,798)	(1,257)	1,500	(2,271)	(103,174)	33,037	(758)	32,27
Transactions with owners in their capacity as owners: Issue of equity shares	7,467	11,200	-	-		-			18,667		18,66
Expenses of issue of equity shares	-	(1,145)	-	-	-	-	-	-	(1,145)	-	(1,14
Exercise of share options Share-based payments	2	-	-	-	-	- (37)	-	-	2 (37)	-	(3
Total transactions with owners in their capacity as owners											
Loss for the year	7,469	10,055	-	-	-	(37)	-	- (12,466)	17,487 (12,466)	- 1	17,48 (12,46
Other comprehensive income: Currency translation differences	-	-	_		-	-	970	-	970	-	97
Total other comprehensive income for the year	-	-	-	-	-	-	970	-	970	-	97
Total comprehensive income for the year	-	-	-	-	-	-	970	(12,466)	(11,496)	1	(11,49
At 31 December 2020	15,947	134,173	16,441	(10,798)	(1,257)	1,463	(1,301)	(115,640)	39,028	(757)	38,27
Transactions with owners in their capacity as owners: Share-based payments											
Total transactions with owners in their capacity as owners	-	-		-	-	110 110			110 110	-	11
Loss for the year	-	-	-	-	-	-	-	(4,792)	(4,792)	(193)	(4,98
Other comprehensive income: Currency translation differences	-	-	-	-	-	-	(4)	-	(4)	-	()
Total other comprehensive income for the year	-	-	-	-	-	-	(4)	-	(4)	-	(
Total comprehensive income for the year	-	-	-	-	-	-	(4)	(4,792)	(4,796)	(193)	(4,98
At 31 December 2021	15,947	134,173	16,441	(10,798)	(1,257)	1,573	(1,305)	(120,432)	34,342	(950)	33,39

# Attributable to equity holders of parent

# **Consolidated Statement of Cash Flows**

For the year ended 31 December 2021

	2021	2020
	USD '000	USD '000
Operating activities	000	000
Loss before taxation	(5,142)	(13,149)
Adjustments for:	(0))	(10)1 (0)
Finance income	(3)	(3)
Finance charges	692	571
Depreciation of property, plant and equipment	258	245
Depreciation of right-of-use assets	103	78
Amortisation of intangible assets	730	730
Impairment of intangible assets	-	7,871
Share-based payments	110	(37)
Amortisation of debt cost	75	75
Unrealised foreign exchange loss	55	834
Operating outflow before working capital movements	(3,122)	(2,785)
Increase in inventory	(115)	(4,115)
Increase in trade and other receivables	(512)	(1)113)
Increase in trade and other payables	159	223
Cash used in operations	(3,590)	(6,936)
Research & development tax credits received	615	881
Net cash used in operating activities	(2,975)	(6,055)
	(2,573)	(0,000)
Investing activities		
Interest received	3	3
Purchase of property, plant and equipment	(1,550)	(1,573)
Capitalised development expenditure	(497)	(293)
Net cash used in investing activities	(2,044)	(1,863)
		( ) )
Financing activities		
Proceeds from issue of shares	-	18,667
Expenses of issue of shares	-	(1,146)
Proceeds from exercise of share options	-	2
Proceeds from new borrowings	602	715
Interest paid on loans and borrowings	(391)	(317)
Lease liability payments	(102)	-
Lease interest payments	(301)	(237)
Net cash (used in)/generated from financing activities	(192)	17,684
Net (decrease)/increase in cash and cash equivalents	(5,211)	9,766
Cash and cash equivalents at beginning of year	12,968	3,121
Effects of movement in exchange rates on cash held	(48)	81
Cash and cash equivalents at end of year	7,709	12,968

### Notes to the financial statements

For the year ended 31 December 2021

#### 1) Significant accounting policies

#### **Basis of preparation**

These financial statements have been prepared and approved by the directors in accordance with UK- adopted International Accounting Standards (IAS).

The financial statements have been prepared on the historical basis, other than certain financial assets and liabilities which are stated at their fair value. Historical cost is generally based on the fair value of the considerations given in exchange for assets.

As described below, the Directors continue to adopt the going concern basis in preparing the consolidated financial statements.

The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods presented in these financial statements.

#### Restatement

With effect from 1 January 2021, the Group's presentation currency changed from pounds sterling (" $\pm$ ") to United States dollar ("USD") as the Directors considered the USD to be more representative of the sector in which the Group primarily operates. The functional currency of the Group is pounds sterling (" $\pm$ ").

In accordance with International Accounting Standards, this change has been applied retrospectively and comparatives for the year ended 31 December 2020 were translated, for all statement of financial position items except equity, using USD:£ exchange spot rate at that date, being USD 1.358, for the income statement using the average USD:£ exchange rate during the year, being USD 1.284, and for the opening balances as at 1 January 2020, except equity, using the USD spot rate on that date, being USD 1.3116. Share capital, share premium and other reserves were translated at the historic rates prevailing at the dates of transactions.

Historical differences arising from the retranslation to USD up to 1 January 2020 have been taken directly to the foreign currency translation reserve.

The Directors have not presented a third statement of financial position and associated notes to reflect the change in presentation currency as they do not believe this additional disclosure is material. The rate used to confirm the net assets has been included above and the Statement of Changes in Equity represents the equity elements of the statement of financial position on a converted basis. Notes 12, 13, and 14 disclose the impact on the non-current assets.

All amounts have been rounded to the nearest thousand, unless otherwise indicated.

#### **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 2023 (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 USD 7.8 million at 31 December 2021 and the ongoing support of MidCap Financial Trust ("MidCap") (borrowings of USD 4.5 million at 31 December 2021) to meet its working capital requirements, capital investment programme and other financial commitments.

The COVID-19 pandemic continued to affect most healthcare businesses in 2021, as the emergence of the Delta and Omicron variants extended the timeline for a return to normal healthcare procedure volumes. 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 ability 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 repayment is not due to start until July 2023. 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.

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.

#### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and its subsidiary undertakings (together "the Group") made up to 31 December each year.

Subsidiary undertakings are those entities controlled directly or indirectly by the Company. Control is achieved when the Company 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 results 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 to have a deficit balance.

#### 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.

#### Non-controlling interest

Non-controlling interests are measured at their proportionate share of the acquiree's identifiable net assets at the date of acquisition. Changes in the Group's interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions. Losses applicable to the non-controlling interests are allocated to the non-controlling interests even if doing so causes the non-controlling interests to have a deficit balance.

#### **Controlled Joint Venture**

In January 2016, the Group entered a joint venture establishing GBM-V GmbH, a company incorporated in Germany. The Group controls the majority of the voting rights and consequently the results for this entity are consolidated in full

within these financial statements with the recognition of a non-controlling interest within equity.

#### 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 Consolidated Statement of 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 United States dollar, which is the presentation currency for the consolidated financial statements.

In preparing the financial statements of the individual companies, transactions in currencies other than the functional currency of each group company ("foreign currencies") are translated into the functional currency at the rates of exchange prevailing on the dates of the transactions. At each reporting date, monetary assets and liabilities that are denominated in foreign currencies are retranslated into the functional currency at the rates prevailing on the reporting date. Non-monetary assets and liabilities carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Foreign exchange differences are recognised in the profit or loss in the period in which they arise, except for foreign exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned nor likely to occur and which, therefore, form part of the net investment in the foreign operation. Foreign exchange differences arising on the translation of the Group's net investment in foreign operations are recognised as a separate component of Shareholders' equity via the statement of other comprehensive income. On disposal of foreign operations and foreign entities, the cumulative translation differences are recognised in the income statement as part of the gain or loss on disposal.

For the purpose of presenting company and consolidated financial statements, the assets and liabilities of the Company, and the Group's operations which have a functional currency other than United States dollar, are translated

using exchange rates prevailing at the end of each reporting period. Income and expense items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transactions are used. Foreign exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity. Equity items are translated at the exchange rates at the date of transactions arising, if any, are recognised in other comprehensive income and accumulated in equity. Equity items are translated at the exchange rates at the date of transactions and foreign exchange differences arising, if any, are accumulated directly in equity.

On the disposal of a foreign operation (i.e. a disposal of the Group's entire interest in a foreign operation, a disposal involving loss of control over a subsidiary that includes a foreign operation or loss of joint control over a jointly controlled entity that includes a foreign operation), all of the accumulated exchange differences in respect of that operation attributable to the Group are reclassified to profit or loss. Where there is no change in the proportionate percentage interest in an entity then there has been no disposal or partial disposal and accumulated exchange differences attributable to the Group are not reclassified to profit or loss.

Fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the rate of exchange prevailing at the end of each reporting period. Exchange differences arising are recognised in equity.

### **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.

#### **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, Right-of-use and intangible assets

At each reporting date, the Group reviews the carrying amounts of its property, plant and equipment and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash generating units).

Discounted cash flow valuation techniques are generally applied for assessing recoverable amounts using Board approved 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. Historically, the fair value of the options granted have been measured using the Binomial model, however, the fair value of the options issued in the current year have been measured using the Monte Carlo model. The performance conditions of previous grants were generally market based whereas current grants are now issued with multiple performance conditions and therefore the Monte Carlo model is considered to be a more appropriate 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 consolidated statement of comprehensive income, with a corresponding entry in equity.

The grant by the Company of options and share-based compensation plans over its equity instruments to the employees of subsidiary undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognised over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity in the parent entity accounts.

### Jointly held shares

Where an employee acquires an interest in shares in the Company jointly with the Tissue Regenix Employee Share Trust, the fair value of the option at the purchase date is recognised on a straight-line basis over the vesting period. The fair value benefit is measured using a binomial valuation model, taking into account the terms and conditions upon which the jointly owned shares were purchased.

#### **Financial Assets and Liabilities**

#### Trade and other receivables

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

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

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

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

0% of aged receivables
0% of aged receivables
25% of aged receivables
50% of aged receivables
100% of aged receivables overdue

#### 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

An equity instrument is any contract that evidences a residual interest in the assets of the Group after deducting all of its liabilities. Equity instruments issued by the Group are recognised at the proceeds received, net of direct issue costs. The costs of an equity transaction are accounted for as a deduction from equity to the extent they are incremental costs directly attributable to the equity transaction that would otherwise have been avoided.

#### 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 USD 5,000 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 statement of financial position 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 statement of financial position date.

#### Segmental reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker, who is responsible for allocating resources and assessing performance of the operating segments and making strategic decisions, has been identified as the Board of Directors.

# 2) Critical Accounting Judgements and Key Sources of Estimation Uncertainty

In the application of the Group's accounting policies, the Directors are required to make judgements, estimates and assumptions about the carrying value of the assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both the current and future periods.

The following are the critical judgements and estimations that the Directors have made in the process of applying the Group's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

### Recoverability of non-current assets

Determining whether an asset is impaired requires an assessment of whether there are any indicators of impairment. If there is any indication of potential impairment, an impairment test is required based on the recoverable amount of the asset.

At 31 December 2021, the Directors determined that there were indicators of impairment in respect of the Group's non-current assets and that there was a requirement to perform an impairment test. The assets were assessed for impairment based on value in use which requires the Group to estimate the future cash flows expected to arise from the cash-generating unit using a suitable discount rate in order to calculate present value. The future cash flows expected to arise was calculated using a discount rate of 14.6% based on the weighted average cost of capital. The impairment test indicated that the recoverable amount was at least equal to the carrying amount of the assets and no provision for impairment was required (2020: USD 7.9 million impairment of Goodwill).

The carrying amount of non-current assets at the 31 December 2021 was USD 24.2 million (2020: USD 23.1 million) and the Directors did not consider that it was appropriate to make a provision for impairment in respect of these assets.

# 3) Segmental reporting

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

	2021	2020
	USD	USD
	'000	
USA	16,883	
Rest of world	2,863	
	19,746	
	-, -	-, -

#### Analysis of revenue by customer

During the year ending 31 December 2021, the Group had one customer who individually exceeded 10% of revenue. This customer generated 14% of revenue (2020: one customer who generated 13% of revenue).

#### **Operating segments**

At 31 December 2020, the Group was organised into 3 operating divisions for internal management, reporting and decision-making purposes. These divisions were, BioSurgery, Orthopaedics & Dental, and GBM-V & Cardiac and were the operating segments reported in accordance with IFRS 8 "Operating Segments".

The Directors have now determined that it would be more appropriate to the Group's operations to disclose its divisions as, dCELL (formerly BioSurgery and now including Cardiac and the UK side of the Ortho & Dental segment), BioRinse (formerly the US side of the Ortho & Dental segment), and GBM-V.

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 who has been identified as the Board of Directors.

Central overheads, which primarily relate to operations of the Group function, are not allocated to the business unit. Segmental information about these divisions is presented below. We have not restated the prior year with the changes as the information was not readily available and the value added was considered to be minimal.

Income Statement	dCELL	BioRinse	GBM-V	Central	Total
	2021	2021	2021	2021	2021
	USD	USD	USD	USD	USD
	'000	'000	'000	<b>'</b> 000	<b>'</b> 000
Revenue	4,246	12,711	2,789	-	19,746
Gross Profit	1,720	5,852	904	-	8,476
Exceptional items	(183)	(120)	-	(52)	(355)
Depreciation	(18)	(305)	(3)	(35)	(361)
Amortisation	-	(730)	-	-	(730)
Operating loss	(1,236)	(1,118)	(154)	(1,945)	(4,453)
Net Finance charges	1	(682)	-	(8)	(689)
Loss before taxation	(1,235)	(1,800)	(154)	(1,953)	(5,142)
Taxation	37	120	-	-	157
Loss for the year	(1,198)	(1,680)	(154)	(1,953)	(4,985)

Income Statement	Biosurgery	Ortho & dental	GBM-V &	Central	Total
			Cardiac		
	2020	2020	2020	2020	2020
	USD	USD	USD	USD	USD
	<b>'</b> 000	<b>'</b> 000	<i>'</i> 000	'000	'000
Revenue	4,247	9,562	2,664	-	16,473
Cost of sales	(2,374)	(4,942)	(1,587)	-	(8 <i>,</i> 903)
Gross Profit	1,873	4,620	1,077	-	7,570
Administrative expenses	(3,415)	(6,390)	(1,418)	(1,702)	(12,925)
Exceptional items:					
Impairment of intangible assets	-	(7,871)	-	-	(7,871)
Restructuring costs	-	(18)	(129)	(306)	(453)
Grant Income	417	629	-	52	1,098
Operating loss	(1,125)	(9,030)	(470)	(1,956)	(12,581)
Net Finance charges	-	(568)	-	-	(568)
Loss before taxation	(1,125)	(9,598)	(470)	(1,956)	(13,149)
Taxation	(28)	547	166	_	684
Loss for the year	(1,153)	(9,051)	(304)	(1,956)	(12,465)

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

Statement of Financial Position	dCELL	BioRinse	GBM-V	Central	Total
	2021	2021	2021	2021	2021
	USD	USD	USD	USD	USD
	'000	'000	<b>'</b> 000	'000	<b>'</b> 000
Non-current assets	808	23,005	5	342	24,160
Current assets	3,326	11,310	706	6,721	22,063
Total assets	4,134	34,315	711	7,063	46,223
Non-current liabilities	-	(8,056)	-	(121)	(8,177)
Current liabilities	(428)	(3,421)	(249)	(556)	(4,654)
Total liabilities	(428)	(11,477)	(249)	(677)	(12,831)
Net assets	3,706	22,838	462	6,386	33,392
Capital expenditure	2	1,594	3	105	1,704
Additions to intangible assets	-	497	-	-	497

Statement of Financial Position	Biosurgery	Ortho & dental	GBM-V	Central	Total
	2020	2020	2020	2020	2020
	USD	USD	USD	USD	USD
	<b>'</b> 000'	'000	<b>'</b> 000	'000	<b>'</b> 000
Non-current assets	-	22,322	5	272	22,599
Current assets	2,807	10,613	1,079	12,782	27,281
Total assets	2,807	32,935	1,084	13,054	49,880
Non-current liabilities	-	(7,415)	-	(217)	(7,632)
Current liabilities	(390)	(3,073)	(236)	(732)	(4,431)
Total liabilities	(390)	(10,488)	(236)	(949)	(12,063)
Net assets	2,417	22,447	848	12,105	37,817
Capital expenditure	13	4,692	4	278	4,987
Additions to intangible assets	-	293	-	-	293

#### 4) Taxation

Tax on loss on ordinary activities

	2021	2020
	USD	USD
	<b>'</b> 000	'000
Current tax:		
UK R&D tax credit	(37)	(564)
	(37)	(564)
Deferred tax:		
Origination and reversal of temporary timing differences	(120)	(120)
Tax credit on loss on ordinary activities	(157)	(684)

The credit for the year can be reconciled to the loss per the income statement as follows:

	2021	2020
	USD	USD
	<b>'</b> 000	'000
Loss on ordinary activities before tax	(5,142)	(13,149)
Tax at the standard rate of corporation tax 19% (2020: 19%)	(977)	(2,499)
Effects of:		
Research and development tax credits received	(124)	(403)
Surrender of research and development relief for repayable tax	74	555
credit including enhancement		
Unutilised tax losses	870	1,663
Tax credit for the period	(157)	(684)

Unrelieved tax losses carried forward have not been recognised as a deferred tax asset as there is currently insufficient evidence that the asset will be recoverable in the foreseeable future. The losses must be utilised in relation to the same operations.

	2021	2020
	USD	USD
	<b>'</b> 000	<b>'</b> 000'
Tax losses		
Losses available to carry forward against future trading profits	73,643	69,399
Unrecognised deferred tax asset – at 25% (2020: 19%)	18,411	13,186

The enacted UK corporation tax rate of 25% forms the basis for the UK element of the deferred tax calculation, following the UK budget in 2021 when the chancellor announced an increase to the main rate of corporation tax in the UK to 25% from April 2023.

# 5) Loss per ordinary share

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

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

The calculation of the basic and diluted loss per ordinary share is based on the following data:

	2021	2020
	USD	USD
	'000	'000
Total loss attributable to the equity holders of the parent	(4,792)	(12,466)
	No.	No.
Weighted average number of ordinary shares in issue during the year	7,033,077,499	4,447,666,932
Loss per ordinary share		

The Company has options issued over 106,832,872 (2020: 50,803,039) ordinary shares and there are 16,112,800 (2020: 16,112,800) jointly owned shares which are potentially dilutive.

Due to the losses incurred from continuing operations in the years reported, there is no dilutive effect from the existing share options and jointly owned shares.

# 6) Lease liabilities

		2020
	2021	USD
	USD	<b>'</b> 000
	<b>'</b> 000	
Current Lease liabilities	118	347
Non-current liabilities	3,364	3,084
	3,482	3,431

# Maturity analysis of lease liabilities

The maturity of the gross contractual undiscounted cashflows due on the Group's lease liabilities is set out below based on the period between 31 December 2021 and the contractual maturity date.

	2021	2020
	USD	USD
	<b>'</b> 000	<b>'</b> 000
Land and buildings		
Less than 6 months	202	181
6 months to 1 year	208	181
1 year to 2 years	420	390
2 years to 5 years	3,518	4,002
5 or more years	-	-
	4,348	4,754

# Effect of leases on financial performance

	2021	2020
	USD	USD
	<b>'</b> 000'	<b>'</b> 000'
Depreciation on right-of-use assets	103	78
Interest expense	301	254
Total effect of leases on financial performance	404	332

The Group leases properties used for its operations in the United Kingdom ("UK") and United States ("US").

UK Property: 5-year fixed lease which includes a break clause in 2023.

US property: 5-year fixed which includes an option to purchase up to 2025.

The Group average effective borrowing rate for leases at 31 December 2021 was 9% (2020: 9%).