RNS Number : 3255H
Tissue Regenix Group PLC
19 March 2024

Tissue Regenix Group plc
('Tissue Regenix', the 'Group', or the 'Company')

Final results for the year ended 31 December 2023
Annual Report and Notice of AGM

Tissue Regenix Group plc (AIM: TRX), the regenerative medical devices company, announces its audited final results for the year ended 31 December 2023, with record revenues and a positive adjusted EBITDA* for the full year, a first for Tissue Regenix.

Financial Highlights

- Top line revenue growth for the Group of 20%
  - This performance marks the sixth consecutive period of half-on-half, double digit revenue growth (averaging over 20% for the last three years)
  - BioRinse® revenues increased by 25% to USD20.1m (2022: USD16.0m), driven by growth in our flagship products and Released Donor Tissue
  - dCELL® revenues increased by 17% to USD6.2m (2022: USD5.3m) as the commercial reorganisation implemented in 2022 continued to mature
  - The Group's joint venture, GBM-V, grew modestly by 2% to USD3.2m (2022: USD3.1m)
- Positive adjusted EBITDA of USD925k (2022 loss: USD626k), a first for Tissue Regenix
  - Driven by increased sales revenue and improved gross margin; aided by management of administrative expenses
- Gross profit of USD14.0m (2022: USD11.3m)
  - Gross margin increased to 48% (2022: 46%)
- Cash position at 31 December 2023 of USD4.7m (2022: USD5.9m)
  - Cash balance increased from H1 2023

Operational Highlights

- Received approval from the Irish Health Products Regulatory Authority (IHPRA), allowing the Company to distribute tissue within the European Union from its third-party logistics partner in the Republic of Ireland
- Announced an agreement with Spineart España SLU to distribute allograft tissue into Spain
- Signed BioRinse agreements with five new strategic partners and six stocking distributors targeting the spinal and dental markets
- Added 66 new distributors for dCELL in 2023, 206% greater than targeted
- Signed an exclusive distribution agreement with Kingsung Medical Group, for the distribution of OrthoPure® XT in China and initiated the regulatory approval process for China
- Signed distribution agreements for OrthoPure XT in the United Kingdom and Australia
- Sourced 31% more musculoskeletal and dermis donors and released 38% more donors versus 2022

Jonathan Glenn, Chair of Tissue Regenix, commented *"2023 was another year of solid progress for the Group. We have seen record revenues, Tissue Regenix's first full year positive adjusted EBITDA, improved cash conversion and many operational highlights including further regulatory approvals, and new and improved relationships with our many partners. The diligent focus of our highly motivated team is allowing us to broaden the Group's capacity, continue to grow the business at an impressive rate and, importantly, build shareholder value. The Board of Tissue Regenix is confident and excited about the future and looks forward to further significant progress in 2024."*

*Adjusted EBITDA: profit before interest, taxes, depreciation, amortisation, and share based payments

Annual Report and Accounts and Notice of Annual General Meeting (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, www.tissueregenix.com, in accordance with AIM Rule 20. For those who opted to receive hard copies of the Annual Report, these will be posted today.

The Company's AGM will be held at DLA Piper 160 Aldersgate St, Barbican, London EC1A 4HT on 25 April 2024 at 11.00am. Shareholders are invited to ask the Board questions about the Annual Report and Accounts or the

AGM by email emailing Walbrook PR at TissueRegenix@walbrookpr.com.

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

Investor Briefing

Daniel Lee, Chief Executive Officer, and David Cocke, Chief Financial Officer, will host a live online presentation relating to the final results via the Investor Meet Company platform at 11.00am today. The presentation is open to all existing and potential shareholders.

Investors can sign up to Investor Meet Company for free and register for the presentation here:
https://www.investormeetcompany.com/tissue-regenix-group-plc/register-investor

For more information:

Tissue Regenix Group plc www.tissueregenix.com
David Cocke, Chief Financial Officer via Walbrook PR

Cavendish Capital Markets Limited (Nominated Adviser and Broker)
Emily Watts/Geoff Nash/George Dollemore - Corporate Finance
Nigel Birks/Harriet Ward - ECM

Walbrook PR (Financial PR and IR) Tel: +44 (0)20 7933 8780
Alice Woodings/Charlotte Edgar TissueRegenix@walbrookpr.com

About Tissue Regenix (www.tissueregenix.com)
Tissue Regenix is a leading medical device company in regenerative medicine. The Company's patented decellularisation technology (dCELL®) removes DNA and other cellular material from animal and human soft tissue, leaving an acellular tissue scaffold not rejected by the patient's body that can be used to repair diseased or damaged body structures. Current applications address many crucial clinical needs in sports medicine, foot and ankle injuries, and wound care.

In August 2017, Tissue Regenix acquired CellRight Technologies®. This biotech company specialises in regenerative medicine and is dedicated to developing high-quality, innovative tissue scaffolds to enhance healing opportunities in defects created by trauma and disease. CellRight's human tissue products may be used in spine, trauma, general orthopaedic, dental and ophthalmological surgical procedures.

Chief Executive Officer's Statement

2023 performance
The Group's performance continued the positive trajectory set over the past three years, achieving numerous milestones over the reporting period. We saw record revenues for the Group, with top-line revenue growth of 20% during FY2023. This faster than market growth was driven by the continued adoption of our products through our strategic partners as well as our direct distribution activities. The combination of sales growth and a tight focus on overheads translated into positive adjusted EBITDA* for the year - a first for Tissue Regenix - and contributed to an increase in our cash balance over the second half of 2023. These results could not have happened without the hard work and dedication of all the employees of the Group. We are proud of what we have achieved so far and believe that a bright future lies ahead for Tissue Regenix.

*(Earnings before interest, taxes, depreciation and amortisation and adjusted for share-based payments)

Strategy
Our focus on the 4S strategic elements of ***Supply, Sales Revenue, Sustainability*** and ***Scale*** continues to provide the foundation of how we operate, execute and drive growth.

The continued investment that we are making and the focus we are placing on tissue ***Supply*** has enabled us to sustain and grow in line with our business needs as well as manage the inventories more efficiently and provide tissue to other tissue processors. Processing capacity, another key element in Supply, has kept pace with the Group's growth despite resource-related headwinds, as experienced more broadly across numerous industries.

Our focus on ***Sales Revenue*** and ***Sustainability*** has been realised in revenue growth and a positive adjusted EBITDA for the year. Our ability to increase our cash balance in the second half of 2023 was a milestone for the organisation and a further demonstration of Sustainability.

Obtaining the regulatory approvals for our third-party logistics partner provides us the opportunity and flexibility to ***Scale*** our allograft business in markets outside the U.S. ('OUS').

The Group's solid 4S foundation enables us to continue growth plans for Tissue Regenix and deliver shareholder value.

Growth pillars
The 4S strategy enables us to support defined tactical activities moving forward. In 2023, we implemented clearly defined growth pillars to provide further direction and help sustain the growth trajectory for the Group.

The four growth pillars are:

1. **Base Business**
We will continue to grow our core businesses with our existing and new partners/distributors through the BioRinse and dCELL product lines. This base business includes existing specialities and geographic markets. We will support this growth with logical new product enhancements and clinical- or market-related activities. This growth will also be supported by our current infrastructure and planned capacity enhancements.

2. **Tissue Partnerships**

Our focus on tissue supply is at the core of our growth as it drives our capacity. We have built supply volumes that exceed our internal needs, so we have the opportunity to provide donor tissue to other tissue processors ('Released Donor Tissue'). We also have the responsibility of meeting the donor's desire to have their tissue utilised to help others in a safe and expeditious manner. Our tissue supply operation adds value by performing the medical reviews and chart releases required for tissue suitable for immediate processing by other domestic and OUS partners. These activities help us to manage our recovery partner relationships and provide opportunities for tissue that we currently do not utilise in our processing operations.

3. Market Expansion

We will continue to broaden the markets for our products via a two-pronged approach. The need for tissue-based products in the surgical marketplace is substantial, and we currently participate in limited segments. We intend to expand into additional surgical specialities by first generating clinical experience at institutions where we have an existing base business. This will serve as the stepping stone for expansion with additional customers and institutions.

We also plan to expand into markets that have a need for allograft tissue-based products but currently have limited availability. Our establishment and receipt of approval to distribute tissue through a third-party logistics partner provides the conduit for opportunities into the EU. OrthoPure XT, our xenograft tissue product, received a CE Mark in 2020, and we continue to identify opportunities to distribute this product in markets that recognise the CE Mark.

4. Regulatory Evolution

The bulk of our revenue comes from allograft tissue-based products, which are regulated as Section 361 HCTP (Human, Cell and Tissue Products) in the U.S. The requirements mandated for Section 361 products place limits on changes to the allograft tissue; if one works beyond these limits then the product will need to be regulated as a medical device. Our facility in San Antonio has been established to meet the requirements of producing Section 361 products. We intend to evolve and change this facility to become one that is capable of meeting medical device requirements. This evolution will give us the opportunity to innovate with human tissue and broaden opportunities for Tissue Regenix to distribute tissue into certain international markets that regulate human tissue allografts as medical devices.

BioRinse

The BioRinse portfolio was our top performer over the financial year, reporting sales of USD20,133k (2022: USD16,049k), driven by the U.S. orthopaedics, wound care and dental markets. The 25% year-on-year growth was led by confidence in our Concelltrate, AmnioWorks and other demineralised bone matrix ('DBM') products in addition to our Released Donor Tissue relationships. Our ability to supply these products in 2022 translated into 2023 through the conviction of our strategic partners to increase their orders and grow their respective businesses. Our customers expect a level of service, and we remain flexible and responsive to our customers' needs.

We continue to grow at above-market rates due to the superior performance of our products, excellent customer service and adaptability to customer needs. Our growth rate is above market for the period, but there is still opportunity for additional growth. We saw greater than 20% growth from the prior year within our top five product families.

Our focus on supply ensures an adequate and continuous supply of donated human tissue. As stewards of the gift of human tissue donation, we use every effort to ensure that the tissue is utilised to produce our high-quality products. Our management of human tissue donation and the processing of the tissue to meet product demands can result in excess tissue in our inventories. We have been able to utilise these inventories, complete the medical review and release process and provide these value-added tissues to other processors for their own needs. This ultimately meets our obligation to make sure that the donated human tissue is used efficiently.

In 2023, after some unanticipated regulatory delays, we received approval to distribute tissue from our third-party logistics partner in the Republic of Ireland. This approval has opened up additional markets within the EU. We also announced our agreement with SpineArt España to distribute allograft tissue into Spain. Other markets and agreements are still in the discussion phase as our plan is to explore opportunities for focused commercial distribution in the Europe, Middle East and Africa ('EMEA') markets.

dCELL

In 2023, the commercial reorganisation of the dCELL business continued to provide growth opportunities for this division. dCELL is a direct business with a regional sales management team managing distributors in their respective territories. This business is highly impacted by Group Purchasing Organization ('GPO') approvals for our products, which we currently have with the top five GPOs. As a result, we have placed management in areas that align with our approvals and will continue to pursue opportunities to help us achieve coverage over the entire U.S. market. To increase our coverage footprint, we have targeted areas where we have already established business. In 2023, our aim was to add 32 new distributors over the year. Pleasingly, we more than doubled that goal by adding 66 distributors by 31 December 2023, and, as a result, revenue growth for this division increased 17% year on year to USD6,183k (2022: USD5,301k).

The OrthoPure® XT product is the only non-human biologic tissue graft available for certain ligament reconstruction procedures. In 2022, we introduced this product into two new markets and added the UK in 2023. Our efforts to expand distribution into Australia were impacted by regulatory approval delays. Additional markets were temporarily put on hold as we resolved inventory issues in Leeds. Efforts to expand distribution opportunities will resume this year.

In 2023, clinical use and traction of the OrthoPure XT device continued to gain momentum in Italy, and we expect the initial positive Italian experiences of the OrthoPure XT in broader clinical use to be presented at the European Society of Sports Traumatology, Knee Surgery and Arthroscopy ('ESSKA') meeting in 2024.The manuscript on the five-year clinical experience from the initial regulatory approval study is in final preparation and planned for submission to a major European publication. During 2023, we also conducted a retrospective study reviewing DermaPure® use in addressing Achilles tendinopathy. A poster has been presented at the 2024 American College of Foot and Ankle Surgeons meeting, and a manuscript is to be submitted for publication soon after.

GBM-V

The GBM-V joint venture operates in a GMP (Good Manufacturing Practice) level facility that has been producing commercial corneal products since 2016. In 2023, the joint venture faced supply issues in Germany due to customers requiring the donor tissue to be sourced from donors who not only were COVID free but also had no history of COVID infection. While this impacted the growth of tissue supply, the joint venture realised USD3,177k (2022: USD3,126k) of revenue, which was marginally up on the prior year. Demand for corneal tissue continues to outpace supply, and efforts to minimise COVID concerns, alongside efforts by our tissue recovery partner to increase supply, will continue in 2024.

New strategic partners and distributors

During 2023, we achieved commercial milestones for the Group as we saw record revenue months across all our human tissue product families - musculoskeletal, dermis and amnion. These milestones were achieved through the growth of our

commercial partners and securing additional strategic partnerships/distributor relationships.

For BioRinse, our top customers remained consistent from the prior year. We saw a 13% increase in the number of units shipped but a 2% decrease in the number of orders we processed due to a trend towards larger orders. In 2023, we signed BioRinse agreements with five new strategic partners and six stocking distributors who target specialities such as the spine and dental markets.

For dCELL, the number of distributors added by the end of the year was 206% greater than targeted. Overall revenue was up 17% versus the prior year, which represented record annual revenue for this division. The number of products invoiced for dCELL products increased by 3% versus the prior year, and the revenue increase was due in large part to our product mix shifting to those with higher Average Selling Prices ('ASPs'). Our meshed DermaPure products helped to drive this revenue increase, and this sales traction is expected to continue into 2024.

We continued to pursue the commercialisation of products that utilise our core technology platforms, provide product line extensions that are faster to market, address a specific clinical or commercial need and have a customer in place. In 2023, due to customer requests, we introduced a smaller DermaPure Mesh product. To address market expectations for our sports medicine tendon grafts, we implemented new processing protocols and reagents to improve product safety and implemented a low-dose sterilisation process.

We added UK distribution of the OrthoPure XT in 2023. Further adoption of this unique product into select European markets was impacted by mid-year production issues related to a bioburden spike within the processing line at our Leeds facility. The temporary halt to production affected inventory availability, so we paused market expansion during this period as we needed existing inventory to service current customers. Despite this brief setback, we look forward to the resumption of discussions with additional EU distribution partners.

During 2023, we continued to pursue our global commercialisation plans for our tissue-based products. We have already described how our third-party logistics partner in the Republic of Ireland will be central to our human allograft tissue opportunities in the EMEA region. We signed an agreement with a Chinese distributor for our OrthoPure XT product and have initiated the regulatory approval process for China, which required a regulatory submission, and a human clinical evaluation in China is planned. The resources needed for this involved process are being shared with our distribution partner. Another notable example of the global market demand for our OrthoPure XT product was adding a distributor in Australia. The CE mark for this product is recognised in Australia, although additional regulatory approvals are required there before marketing. The review process in Australia has been slower than anticipated due to the volume of submissions within the Therapeutic Goods Administration.

Expanding demand for our existing products with new and existing partners as well as product line extensions and product improvements are anticipated to drive our continued organic growth in 2024 and further utilise our facility and tissues.

Operations
2023 was another year of growth for the Group as we continued operations throughout the year at all our locations without significant impacts from any external influences.

For our allograft tissue business, the supply of donor tissue is directly linked to our growth plans. To meet the need of our commercial partners and our focus on Supply, in 2023, we sourced 31% more musculoskeletal and dermis donors and released 38% more donors versus the prior year. These shifts reflected the demand for our processing of musculoskeletal donors and demand from other tissue processors for our Released Donor Tissue.

In 2022, we implemented a programme to help us manage the inventory of Released Donor Tissue by making some of it available to other processing companies. All tissue we receive needs to go through an internal review and release process to ensure the safety and quality of the tissue before it is processed. We continue to expand our relationships with other tissue processors located domestically or outside the U.S. who wish to have access to this tissue. This segment of our business has grown dramatically over the prior year and has become one of the growth pillars for our organisation. This programme aligns with our responsibility to honour the gift of tissue donation through utilisation in a timely manner into products that can help patients.

The addition of two sterile packaging rooms in the existing San Antonio facility from our Phase 1 expansion in 2021 brought the total number of clean rooms to seven and provided additional capacity and flexibility. We continue to identify ways in which we can be more efficient with the flexibility we now have with room utilisation and processing scheduling. As a result, we have been able to respond to orders or unanticipated changes in almost half the amount of time prior to the Phase 1 expansion. These rooms effectively provide approximately USD40m of revenue generation potential and delayed our need for the Phase 2 expansion and its 8-10 additional clean rooms until 2025, and we do not anticipate the need for additional equity funding for this further expansion.

In late 2023, we implemented Sage X3, an enterprise resource planning ('ERP') system, in our U.S. operations. This ERP product is used to manage financial aspects of the business, and we believe that this investment will significantly increase efficiencies for the Group. The transition from our legacy system has been smooth, and we continue to refine the system to meet the needs of all groups within the organisation. The implementation of Sage X3 was a multi-year effort involving all segments of the business and two consulting groups and is a strong strategic investment for the Group that will support our growth plans.

We believe that the contribution of increased processing efficiency, increased capacity and state-of-the-art systems will allow us to enjoy improved gross margins over time.

The pandemic is behind us
In the U.S., the issues of healthcare institution staff shortages still exist in some geographic areas. We have seen elective procedure volumes improve. Supply chain issues have been improved, but costs across all aspects of our operations have increased since the pandemic. We will absorb most of these increases through efficiencies in our operation. We began the year with issues related to labour shortages, but by year end we saw some normalisation with respect to candidates applying for open positions at our U.S. business.

Organisational changes
We will continue to invest in resources that will grow our organisation across all divisions. Additions and adjustments to our commercial team in BioRinse and dCELL will seek to bring additional commercial opportunities to our organisation and spread Tissue Regenix's footprint in the U.S. and OUS.

Outlook

Sales Revenue and Sustainability will continue to be the priorities of the 4S's in 2024. We will continue to build on this base to provide a more solid foundation for the future. Our four growth pillars are the tactical areas of focus that will be built on this foundation.

The BioRinse products will continue to be the dominant revenue contributor in 2024. Growth will come from existing and new partners as well as new products. Our dCELL business is also expected to show further growth as we expand into new domestic territories where we historically have not had much presence. We will also use our current footholds to expand into other surgical specialities, such as oncology and colorectal surgery, as clinicians become familiar with our practise areas. The inventory of Released Donor Tissue will be distributed to other processors who have a need for tissue that is ready to be processed. Our GBM-V joint venture will continue to identify opportunities to increase their tissue supply and address any issues that have impacted their growth.

Our geographic outreach with our human tissue dCELL and BioRinse portfolios is only just beginning as we have our registered logistics partner, which provides the opportunity to move into numerous EU markets. We will also seek registrations and distribution partners in other OUS markets for our human allograft. Interim supply challenges are behind us, and OrthoPure XT will be introduced into additional EU and other markets in 2024.

Our evolution into a medical device manufacturer will provide us the flexibility to be more innovative with our products versus 361 HCTP products. A medical device registration is rare for a tissue processor of our size but positions us well to consider not only novel products but also entry into markets that regulate allograft tissue as a medical device.

In 2024, we will begin some of the preliminary planning activities to build our Phase 2 capacity expansion. In addition to our organic growth plans, we will continue to examine acquisition opportunities that would allow us to scale the business for additional longer-term growth.

In 2021, the Board of Tissue Regenix set in place our 4S strategy. It has been a highly successful strategy for the Group and continues to provide structure and clear direction for everything that we do. Three years later, we are in a strong position, with market-leading products that are distributed globally, production facilities that allow us to fulfil our current growth ambitions, a balance sheet to support these growth opportunities and a team of people that are motivated, talented and driven with a very clear idea of where we are taking the business. I am proud to be a part of the Tissue Regenix Group and excited for its future prospects in 2024 and beyond.

Daniel Lee
Chief Executive Officer
18 March 2024

Financial Review

Statement of Comprehensive Income
Revenue
During the year ended 31 December 2023, revenue increased by 20% to USD29,493k (2022: USD24,476k).

The Group experienced growth across all three key business segments for the year, as more fully described below:

- The BioRinse segment increased top-line sales by 25% to USD20,133k (2022: USD16,049k), driven by growth in Released Donor Tissue and continued growth across the allograft segments, led by the AmnioWorks and Concelltrate 100 product families.
- Revenue from the dCELL division increased by 17% to USD6,183k (2022: USD5,301k) as the commercial reorganisation implemented in 2022 continued to mature.
- The Group's joint venture, GBM-V, based in Rostock, Germany, grew modestly by 2% to USD3,177k (2022: USD3,126k).

Cost of sales and gross profit
Gross profit for the year was USD14,040k (2022: USD11,258k). Gross margin percentage increased to 48% (2022: 46%).

Included in costs of sales is cost of product - USD13,750k (2022: USD12,013k) - and third-party commissions - USD1,703k (2022: USD1,205k).

Administrative expenses
During 2023, administrative expenses increased by USD1,166k, or 9%, to USD14,434k (2022: USD13,268k), driven primarily by additional staffing costs.

Adjusted EBITDA
During 2023, the Group reported adjusted EBITDA of USD925k (2022 loss: USD626k). This shift into positive adjusted EBITDA was driven by increased sales revenue and gross margin percentage and aided by management of administrative expenses to achieve operating leverage. In 2023, EBITDA was USD583k (2022 loss: USD875k) and is adjusted for share based payments of USD342k (2022: USD249k).

Finance income/charges
Finance income of USD26k (2022: USD8k) primarily represented interest earned on cash deposits. Finance charges for the year were reported at USD1,301k (2022: USD826k) and related primarily to interest charges and associated costs in respect of the MidCap Financial Trust ('MidCap') loan arrangement. Included in finance charges for 2023 is USD248k relating to a financing fee associated with the former MidCap loan termination.

Loss for the year
The loss for the year was USD1,657k (2022: loss: USD2,596k), resulting in a basic loss per share of 2.43 cents (2022: loss per share: 3.83 cents). The reduction in the loss for the year was driven by the increases in sales revenue and gross margin percentage.

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 2023, a refund of USD352k was receivable (2022: USD401k). The year-on-year reduction was a result of the collection of aged research and development credits during 2023.

Income tax payable in the U.S. amounted to USD310k (2022: USD nil). Gross tax losses carried forward in the UK were USD60,361k (2022: USD58,900k). 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
As at December 2023, the Group had net assets of USD29,355k (2022: USD30,401k), of which cash in hand totalled USD4,650k (2022: USD5,949k).

Inventory levels decreased 5% against the 20% sales revenue increase at USD10,358k (2022: USD10,882k) as the BioRinse and dCELL segments managed stock levels closely to increase inventory turnover while also keeping adequate stock levels to meet customer demand. The Released Donor Tissue offering of the BioRinse segment turns over more rapidly than processed grafts.

Intangible assets increased slightly to USD15,135k (2022: USD15,061k) in the year. A further USD450k of development costs, relating primarily to clinical research, were capitalised in the year (2022: USD709k). The balance of movements in this account relate to amortisation and exchange adjustments.

The Directors carried out the annual impairment review, as required by IAS 36, to determine whether there was any requirement for an impairment provision in respect of goodwill as at 31 December 2023.

The results of the test indicated that the recoverable amount of the Group's non-current assets was at least equal to the carrying amount of those assets and, therefore, no provision for impairment was required as at 31 December 2023 (2022: USD nil).

Working capital increased slightly in the year to USD9,9,705k (2022: USD9,442k), driven by a decrease in payables made possible by improved debtor collections and lower inventory investment. As mentioned above, the Released Donor Tissue offering of the BioRinse segment turns over more rapidly, which speeds up the sales cycle, allowing for faster cash generation. The Statement of Financial Position includes income tax receivable of USD352k (2022: USD401k) in respect of UK research and development tax credits.

Loans and borrowings and lease liability
Borrowings include the USD5,985k debt facility through MidCap and the USD3,410k lease liability related to the Group's leasehold in San Antonio (2022: USD6,258k and USD3,350k, respectively). The MidCap debt facility includes USD2,000k in respect of the term loan and USD4,148k in respect of the revolving credit facility, net of USD163k of capitalised debt issue costs. In January 2023, the Group elected to increase its current revolving credit facility from USD5,000k to USD10,000k and extend the maturity until 2028. Repayment of the term loan in equal instalments commenced in February 2024.

Dividend
No dividend has been proposed for the year to 31 December 2023 (2022: nil).

Accounting policies
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 2025 (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. Until sufficient cash is generated from its operations, the Group remains reliant on cash reserves of USD4,650k at 31 December 2023 and the ongoing support of MidCap (borrowings of USD5,985k at 31 December 2023) and other lending institutions to meet its working capital requirements, capital investment programme and other financial commitments. Repayment on the MidCap borrowings commenced in February 2024.

In compiling the Cash Flow Projections, the Board has considered a downside scenario regarding the effect of reduced and delayed revenues due to slower market uptake of the Group's product offerings. 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 assume that the MidCap revolving credit facility is available throughout the forecast period and that the term loan repayment begins in 2024. The availability of these facilities is dependent upon compliance with a rolling 12-month revenue covenant that is measured on a monthly basis. The Cash Flow Projections, including the downside scenario, 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 the preparation of the financial statements of the Group and have reviewed the Cash Flow Projections, including the downside scenario. On the basis of their assessment, they have concluded that the going concern basis remains appropriate for use in the financial statements.

Cautionary statement
The strategic report, containing the strategic and financial reports of the Group, contains 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
18 March 2024

Consolidated Statement of Income
For the year ended 31 December 2023

	2023 USD'000	2022 USD'000

Revenue	29,493	24,476
Cost of sales	(15,453)	(13,218)
Gross profit	14,040	11,258
Administrative expenses	(14,434)	(13,268)
Operating loss	(394)	(2,010)
Finance income	26	8
Finance charges	(1,301)	(826)
Loss on ordinary activities before taxation	(1,669)	(2,828)
Taxation	12	232
Loss for the year	(1,657)	(2,596)
Loss for the year attributable to:		
Owners of the parent company	(1,713)	(2,695)
Non-controlling interest	56	99
	(1,657)	(2,596)
Loss per Ordinary Share		
Basic and diluted, cents per share	(2.43)	(3.83)*

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

*Restated to reflect the share consolidation that became effective on 28 April 2023.

Consolidated Statement of Comprehensive Income

For the year ended 31 December 2023

	2023 USD'000	2022 USD'000
Loss for the year	(1,657)	(2,596)
Other comprehensive income		
Items that may be subsequently reclassified to profit or loss:		
Foreign currency translation differences	195	(653)
Total comprehensive loss for the year	(1,462)	(3,249)
Total comprehensive loss for the year attributable to:		
Owners of the parent company	(1,518)	(3,348)
Non-controlling interest	56	99
	(1,462)	(3,249)

Consolidated Statement of Financial Position

As at 31 December 2023

	2023 USD'000	2022 USD'000
Assets		
Non-current assets		
Property, plant and equipment	5,748	5,740
Right-of-use assets	3,270	3,203
Intangible assets	15,135	15,061
	24,153	24,004
Current assets		
Inventory	10,358	10,882
Trade and other receivables	3,730	4,803
Corporation tax receivable	352	401
Cash and cash equivalents	4,650	5,949
	19,090	22,035
Total assets	43,243	46,039
Liabilities		
Non-current liabilities		
Loans and borrowings	(5,527)	(5,258)
Deferred tax	(400)	(520)
Lease liability	(3,226)	(3,216)
	(9,153)	(8,994)
Current liabilities		
Trade and other payables	(3,783)	(5,510)
Taxation payable	(310)	-
Loans and borrowings	(458)	(1,000)
Lease liability	(184)	(134)
	(4,735)	(6,644)

Total liabilities	(13,888)	(15,638)
Net assets	29,355	30,401
Equity		
Share capital	15,950	15,950
Share premium	134,253	134,179
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	1,088	824
Cumulative translation reserve	(1,763)	(1,958)
Retained deficit	(123,764)	(122,129)
Equity attributable to owners of the parent company	30,150	31,252
Non-controlling interest	(795)	(851)
Total equity	29,355	30,401

Consolidated Statement of Changes in Equity

For the year ended 31 December 2023

	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	Share- based payment reserve USD'000	Retained deficit USD'000	Total USD'000	Non-controlling interest USD'000	Total equity USD'000
At 31 December 2021	15,947	134,173	16,441	(10,798)	(1,257)	1,573	(1,305)	(120,432)	34,342	(950)	33,392
Transactions with owners in their capacity as owners:											
Exercise of share options	3	6	-	-	-	-	-	-	9	-	9
Transfer to retained deficit in respect of lapsed, expired and exercised options	-	-	-	-	-	(998)	-	998	-	-	-
Share-based payments	-	-	-	-	-	249	-	-	249	-	249
Total transactions with owners in their capacity as owners	3	6	-	-	-	(749)	-	998	258	-	258
Loss for the year	-	-	-	-	-	-	-	(2,695)	(2,695)	99	(2,596)
Other comprehensive income: Currency translation differences	-	-	-	-	-	-	(653)	-	(653)	-	(653)
Total other comprehensive income for the year	-	-	-	-	-	-	(653)	-	(653)	-	(653)
Total comprehensive income for the year	-	-	-	-	-	-	(653)	(2,695)	(3,348)	99	(3,249)
At 31 December 2022	15,950	134,179	16,441	(10,798)	(1,257)	824	(1,958)	(122,129)	31,252	(851)	30,401
Transactions with owners in their capacity as owners:											
Exercise of share options	-	74	-	-	-	-	-	-	74	-	74
Transfer to retained deficit in respect of exercised and expired options	-	-	-	-	-	(78)	-	78	-	-	-
Share-based payments	-	-	-	-	-	342	-	-	342	-	342
Total transactions with owners in their capacity as owners	-	74	-	-	-	264	-	78	416	-	416
Loss for the year	-	-	-	-	-	-	-	(1,713)	(1,713)	56	(1,657)
Other comprehensive income: Currency translation differences	-	-	-	-	-	-	195	-	195	-	195
Total other comprehensive income for the year	-	-	-	-	-	-	195	-	195	-	195
Total comprehensive income for the year	-	-	-	-	-	-	195	(1,713)	(1,518)	56	(1,462)
At 31 December 2023	15,950	134,253	16,441	(10,798)	(1,257)	1,088	(1,763)	(123,764)	30,150	(795)	29,355

Consolidated Statement of Cash Flows

For the year ended 31 December 2023

	2023 USD'000	2022 USD'000
Operating activities		
Loss on ordinary activities before taxation	(1,669)	(2,828)
Adjustments for:		
Finance income	(26)	(8)

Finance income	(20)	(8)
Finance charges	1,301	826
Depreciation of property, plant and equipment	395	353
Depreciation of right-of-use assets	132	164
Amortisation of intangible assets	450	618
Share-based payments	342	249
Unrealised foreign exchange loss/(gain)	84	(239)
Operating cash inflow/(outflow) before movements in working capital	1,009	(865)
Decrease/(increase) in inventory	524	(1,163)
Decrease/(increase) in trade and other receivables	1,073	(702)
(Decrease)/increase in trade and other payables	(1,836)	1,249
Net cash generated from/(used in) operations	770	(1,481)
Research and development tax credits received	270	187
Net cash generated from/(used in) operating activities	1,040	(1,294)
Investing activities		
Interest received	26	8
Purchase of property, plant and equipment	(413)	(381)
Capitalised development expenditure	(450)	(709)
Net cash used in investing activities	(837)	(1,082)
Financing activities		
Proceeds from exercise of share options	74	9
(Repayment of)/proceeds from loans and borrowings	(238)	1,708
Interest paid on loans and borrowings	(567)	(450)
Fees paid on loans and borrowings	(355)	-
Lease liability payments	(140)	(66)
Lease interest payments	(284)	(291)
Other interest payments	(2)	-
Net cash (used in)/generated from financing activities	(1,512)	910
Net decrease in cash and cash equivalents	(1,309)	(1,466)
Cash and cash equivalents at beginning of year	5,949	7,709
Effect of movements in exchange rates on cash held	10	(294)
Cash and cash equivalents at end of year	4,650	5,949

Notes to the Consolidated Financial Statements
For the year ended 31 December 2023

1. Material accounting policies

Basis of preparation

The financial information set out herein does not constitute statutory accounts as defined in Section 434 of the Companies Act 2006.

The financial information for the year ended 31 December 2023 has been extracted from the Company's audited financial statements which were approved by the Board of Directors on 18 March 2024 and which, if adopted, will be delivered to the Registrar of Companies for England and Wales.

The financial information for the year ended 31 December 2022 has been extracted from the Company's audited financial statements which were approved by the Board of Directors on 20 March 2023.

Statutory accounts for the years ended 31 December 2023 and 31 December 2022 have been reported on by the auditor. Their reports for both years (i) were unqualified; (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their audit report and (iii) did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006.

The information in this preliminary statement has been extracted from the audited financial statements for the year ended 31 December 2023 and as such, does not contain all the information required to be disclosed in the financial statements prepared in accordance with UK adopted International Accounting Standards ('IAS').

The Company is a public limited company incorporated and domiciled in England and whose shares are quoted on AIM, a market operated by The London Stock Exchange.

The address of the registered office is Unit 3, Phoenix Court, Lotherton Way, Garforth LS25 2GY.

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 2025 (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. Until sufficient cash is generated from its operations, the Group remains reliant on cash reserves of USD4.7 million at 31 December 2023 and the ongoing support of MidCap (borrowings of USD6.0 million at 31 December 2023) and other lending institutions to meet its working capital requirements, capital investment programme and other financial commitments. Repayment of the MidCap borrowings commenced in February 2024.

In compiling the Cash Flow Projections, the Board has considered a downside scenario regarding the effect of reduced and delayed revenues due to slower market uptake of the Group's product offerings. 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 assume that the MidCap revolving credit facility is available throughout the forecast period and that the term loan repayment begins in 2024. The availability of these facilities is dependent upon compliance with a rolling 12-month revenue covenant that is measured on a monthly basis. The Cash Flow Projections, including the downside scenario, 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 the preparation of the financial statements of the Group and have reviewed the Cash Flow Projections, including the downside scenario. On the basis of their assessment, they have concluded that the going concern basis remains appropriate for use in this financial information.

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 amounts 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 ongoing basis. Revisions to accounting estimates are recognised 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

The Directors are required by IAS 36 *Impairment of assets* to carry out an annual impairment review in respect of goodwill to determine whether there was any requirement for an impairment provision in respect of the Group's goodwill at 31 December 2023.

The carrying amount of non-current assets at 31 December 2023 was USD24.2 million (2022: USD24.0 million).

Critical judgements

The Group's non-current assets include intangible assets and goodwill arising on the acquisition of CellRight Technologies LLC, plus certain property, plant and machinery and right-of-use assets. It is the Directors judgement that the recoverable amount of these assets cannot be determined individually and that this is the smallest identifiable group of assets whose output has an active market and which generate largely independent cash flows from other assets or group of assets. It is, therefore, the Directors judgement that these assets should be considered to be a single cash generating unit ('CGU'). Only the assets included in the CGU are subject to impairment review.

Estimations

The aggregate carrying value of the CGU was assessed for impairment based on value in use, which requires the Directors to estimate the future cash flows expected to arise from the CGU using a suitable discount rate in order to calculate present value. The future cash flows expected to arise were calculated using a discount rate of 18.3% (2022: 18.3%) 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, therefore, no provision for impairment was required at 31 December 2023 (2022: nil).

The key inputs to the cash flow forecast are revenues, gross margin and overheads, future anticipated capital expenditure and movements in working capital. The key estimation relates to sales growth, which is inherently difficult to forecast in a rapidly growing market, and it is possible that any or all of these key assumptions may change, which may then impact the estimated recoverable amount of the CGU and require a material adjustment to the carrying value of the assets in future periods.

material adjustment to the carrying value of the assets in future periods.

Leases

Critical judgements

Determining the term of a lease that includes an option to purchase requires the Directors to use their judgement in determining whether the option is reasonably certain to be exercised. The Directors' assessment will impact both the determination of the lease term and the useful economic life of the asset.

In determining the term of a lease, the Directors consider all facts and circumstances that create an economic incentive to exercise an option to purchase a leased asset. Periods after the date of the option to purchase are not included in the lease term if the option to purchase is reasonably certain to be exercised.

In making their assessment, the Directors considered the potential cash outflow arising as a result of financing the option to purchase against the potential cost of ongoing lease payments, the potential market value of the property, which an independent appraisal indicated would be in excess of the fixed option exercise price, and the commercial advantages of taking ownership and control of the property.

The Directors concluded that the option to purchase is reasonably certain to be exercised, therefore, the lease term has been determined on this basis, and the USD3 million cash outflow on exercise of the option has been included in the lease liability.

Estimations

Right-of-use assets are depreciated over the shorter of the useful life of the asset and the lease term, unless the title to the asset transfers at the end of the lease term, in which case it is depreciated over the useful life. As a result of the Directors assessment that the Group will exercise the option to purchase, the assets are being depreciated over an estimated useful life of 39 years.

3. Segmental information

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

	2023 USD'000	2022 USD'000
US	25,327	20,711
Rest of World	4,166	3,765
	29,493	24,476

Analysis of revenue by customer

During the year ended 31 December 2023, the Group had one customer who individually exceeded 10% of revenue. This customer generated 13% of revenue (2022: one customer who generated 13% of revenue).

Operating segments

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.

The Board of Directors has determined that the Group has three operating segments for internal management, reporting and decision-making purposes, namely dCELL, BioRinse and GBM-V.

Central overheads, which primarily relate to operations of the Group function, are not allocated to an operating segment.

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

	dCELL 2023 USD'000	BioRinse 2023 USD'000	GBM-V 2023 USD'000	Central 2023 USD'000	Total 2023 USD'000
Statement of Income					
Revenue	6,183	20,133	3,177	-	29,493
Gross profit	2,839	10,141	1,060	-	14,040
Depreciation	(4)	(423)	(16)	(84)	(527)
Amortisation	-	(450)	-	-	(450)
Operating profit/(loss)	340	1,838	220	(2,792)	(394)
Net finance					

Net finance income/(charges)	4	(1,296)	-	17	(1,275)
Profit/(loss) before taxation	344	542	220	(2,775)	(1,669)
Taxation	202	(190)	-	-	12
Profit/(loss) for the year	546	352	220	(2,775)	(1,657)

	dCELL 2022 USD'000	BioRinse 2022 USD'000	GBM-V 2022 USD'000	Central 2022 USD'000	Total 2022 USD'000
Statement of Income					
Revenue	5,301	16,049	3,126	-	24,476
Gross profit	1,829	8,258	1,171	-	11,258
Depreciation	(10)	(394)	-	(113)	(517)
Amortisation	-	(618)	-	-	(618)
Operating (loss)/ profit	(994)	678	409	(2,103)	(2,010)
Net finance charges	-	(818)	-	-	(818)
(Loss)/profit before taxation	(994)	(140)	409	(2,103)	(2,828)
Taxation	112	120	-	-	232
(Loss)/profit for the year	(882)	(20)	409	(2,103)	(2,596)

	dCELL 2023 USD'000	BioRinse 2023 USD'000	GBM-V 2023 USD'000	Central 2023 USD'000	Total 2023 USD'000
Statement of Financial Position					
Non-current assets	1,946	21,987	6	214	24,153
Current assets	5,030	12,649	807	604	19,090
Total assets	6,976	34,636	813	818	43,243
Non-current liabilities	-	(9,123)	-	(30)	(9,153)
Current liabilities	(693)	(3,345)	(200)	(497)	(4,735)
Total liabilities	(693)	(12,468)	(200)	(527)	(13,888)
Net assets	6,283	22,168	613	291	29,355
Capital expenditure	165	167	9	54	395
Additions to intangible assets	334	116	-	-	450

	dCELL 2022 USD'000	BioRinse 2022 USD'000	GBM-V 2022 USD'000	Central 2022 USD'000	Total 2022 USD'000
Statement of Financial Position					
Non-current assets	1,376	22,382	13	233	24,004
Current assets	3,571	14,998	806	2,660	22,035
Total assets	4,947	37,380	819	2,893	46,039
Non-current liabilities	-	(8,921)	-	(73)	(8,994)
Current liabilities	(736)	(5,171)	(255)	(482)	(6,644)
Total liabilities	(736)	(14,092)	(255)	(555)	(15,638)
Net assets	4,211	23,288	564	2,338	30,401
Capital expenditure	124	230	9	36	399
Additions to intangible assets	549	160	-	-	709

4. Taxation

	2023 USD'000	2022 USD'000
Current tax:		

Current tax:		
UK R&D tax credit	(202)	(112)
Foreign taxation	310	-
	108	(112)
Deferred tax:		
Origination and reversal of temporary differences	(120)	(120)
Tax credit for the year	(12)	(232)

The credit for the year can be reconciled to the loss per the Consolidated Statement of Income as follows:

	2023 USD'000	2022 USD'000
Loss on ordinary activities before tax	(1,669)	(2,828)
Loss multiplied by the standard rate of corporation tax for UK companies of 23.52% (2022: 19%)	(393)	(537)
Effects of:		
Research and development tax credits received	-	(80)
Surrender of tax losses for R&D tax credit refund	233	104
Deduction for R&D expenditure	(115)	(59)
Remeasurement of deferred tax for changes in tax rates	(22)	-
Adjustments in respect of prior period current and deferred tax	122	(154)
Movement in deferred tax not recognised on unutilised tax losses	175	(366)
Expenses not deductible for tax purposes	108	980
Origination and reversal of timing differences	(120)	(120)
Tax credit on loss for the year	(12)	(232)

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.

Unrelieved tax losses carried forward, as detailed below, 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 are related to UK operations and must be utilised in relation to the same operations.

	2023 USD'000	2022 USD'000
Tax losses		
Losses available to carry forward	60,361	58,900
Unrecognised deferred tax asset at 25% (2022: 25%)	15,090	14,725

5. Loss per Ordinary Share

Basic loss per Ordinary Share is calculated by dividing the net loss for the year attributable to owners 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 Ordinary Share is calculated by dividing the net loss for the year attributable to owners of the parent company by the weighted average number of Ordinary Shares in issue during the year adjusted for the dilutive effect of potential Ordinary Shares arising from the Company's share options and jointly owned shares.

The calculation of the basic and diluted loss per Ordinary Share is based on the following data:

	2023 USD'000	2022 USD'000
Losses		
Losses for the purpose of basic and diluted loss per Ordinary Share being net loss for the year attributable to owners of the parent company	(1,713)	(2,695)
	Number	**Number**

Number of shares		
Weighted average number of Ordinary Shares for the purpose of basic and diluted loss per Ordinary Share	70,426,760	70,345,218
Basic and diluted, cents per share	(2.43)	(3.83)

The Company has options issued over 2,585,537 (2022: 2,009,293) Ordinary Shares and warrants issued over 30,968 (2022: 30,968) Ordinary Shares, and there are 161,128 (2022: 161,128) jointly owned shares that 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.

The information shown above has been restated to reflect the share consolidation, that became effective on 28 April 2023, in all periods presented.

6. Lease liabilities

	2023 USD'000	2022 USD'000
Current lease liabilities	184	134
Non-current lease liabilities	3,226	3,216
At 31 December	3,410	3,350

Maturity analysis of leases

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 2023 and the contractual maturity date.

	2023 USD'000	2022 USD'000
Less than 6 months	236	203
6 months to 1 year	236	203
1 year to 2 years	3,147	412
2 years to 5 years	138	3,107
	3,757	3,925

The movement in lease liabilities during the year was:

	2023 USD'000	2022 USD'000
At 1 January	3,350	3,482
Cash flows - financing activities - lease repayments	(140)	(66)
Non-cash movements - additions to right-of-use-assets	195	-
Non-cash movements - net effect of foreign exchange	5	(66)
At 31 December	3,410	3,350

Effect of leases on financial performance

	2023 USD'000	2022 USD'000
Depreciation of right-of-use assets	132	164
Interest expense	284	291
	416	455

The Group leases properties used for its operations in the UK and the US.

- UK land and buildings: Five-year fixed lease, which included a break clause in 2023 not exercised.
- US land and buildings: Ten-year fixed lease, which includes an option to purchase within the first five years, being up to November 2024.
- US property, plant and equipment: Five-year fixed leases.

The Group's average effective borrowing rate for leases at 31 December 2023 was 9% (2022: 9%).

END

FR EAADPFLXLEAA