



Building a Leading Regenerative Medicines Business Interim results for the period ended 30 June 2024 September 2024

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## **Presenters**





**DANIEL LEE**Chief Executive Officer
Joined Jan 2019, appointed to CEO in Nov 2020

- Over 30 years' experience in medical device and biologics
- Former President of US Operations at CellRight Technologies and Former CEO of Scaffold Biologics and Aperion Biologics
- B.E.S in Materials Science and Engineering from the Johns Hopkins University and M.S. in Biomedical Engineering from the University of Alabama











DAVID COCKE
Chief Financial Officer
Joined Jan 2021

- Over 30 years' experience in the medical device industry
- Founding partner of NuPak Medical, contract manufacturer of sterile disposable medical devices, former CFO at Aperion Biologics (2008-2017) and experience at Salomon Brothers and GE Capital
- B.B.A. in Business Honors from the University of Texas at Austin and M.B.A. from the University of Virginia









# **Company Overview**





Pioneering medical technology company in the field of **regenerative medicine** 



dCELL® & BioRinse®- two platform technologies utilising bone and soft tissues for the treatment of numerous surgical and non-surgical indications



**International manufacturing capabilities** – US, UK & Germany



**Extensive and expanding product portfolio** 



Strategic partnerships with industry leaders and market distributors



Multi-billion-dollar addressable market, transforming patient care and delivering favourable health economic outcomes



## H1 2024 Highlights



## **Financial Highlights**



Group revenues **increased by 16%** to \$16.4m (H1 2023: \$14.1m)



Gross profit for the year **increased to 53%** (H1 2023: 49%)



Adjusted EBITDA profit of \$1.1m (H1 2023: \$0.4m)



The **cash position** as at 30 June 2024 of \$3.5m (H1 2023: \$4.1m)



**Eighth consecutive reporting period of growth** and the seventh consecutive period of double-digit, half-on-half growth

### **Divisional Revenue Highlights**



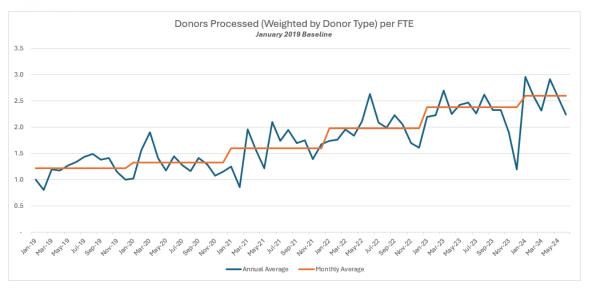
#### To \$10.5m (H1 2023: \$9.4m)

result of continued and increased demand for the diversified product portfolio with existing and new customers



#### To \$4.2m (H1 2023: \$3.1m)

driven by the Group's DermaPure® products



# H1 2024 Highlights



### **H1 2024 Commercial and Operational Highlights**



**29% year-on-year increase in donor processing throughput in H1 2024**, as a result of additional efficiencies realized from the Phase 1 capacity expansion



Impressive growth for the dCELL division due in part to the addition of 24 new distributors and shipping of 17% more units in H1 2024 versus the same period in 2023



OrthoPure XT® sales initiated in the **Swiss market** with the Group's distribution partner, Geistlich Pharma

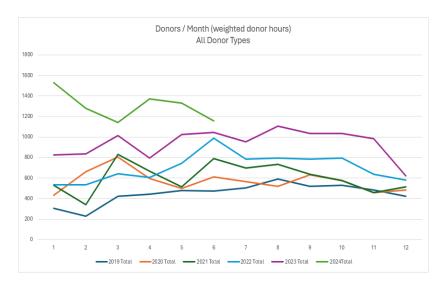


**Building purchase in San Antonio of existing facility** as part of the Phase 1 and 2 expansion plans



**"4S" Strategy & the Company's Growth Pillars continue** to drive the Group's strategy





# Core Product Portfolio and Line Extensions High Growth Product Lines Focused On Bone, Soft and Birth Tissues



| Processing Platform             | BIORINSE (bone and birth tissue)  | dCELL® (soft tissue)  |  |
|---------------------------------|---|---|--|
| By revenue (USD)                | \$10.5m in H1 2024  | \$4.2m in H1 2024   |  |
| Flagship / high growth Products | ConCelltrate® AmnioWorks™   | DermaPure®  |  |
| New product line extensions     | <ul> <li>Expansion of private label opportunities</li> <li>Sports medicine grafts</li> <li>Expansion of private label opportunities</li> </ul>  | <ul> <li>DermaPure® Mesh 4 x 6</li> <li>VNEW® M</li> </ul>  |  |
| Applications                    | <ul> <li>Foot / Ankle</li> <li>Spine</li> <li>Dental</li> <li>Orthopaedics</li> <li>Onthopaedics</li> </ul>   | <ul> <li>Wound care</li> <li>Hernia</li> <li>Plastic surgery</li> <li>Urogynaecology</li> <li>Sports medicine</li> </ul>      |  |
| Differentiators                 | <ul> <li>✓ 100% Demineralized Bone Matrix</li> <li>✓ Sterile</li> <li>✓ Each lot verified for osteoinductivity</li> <li>✓ Handling and use properties</li> <li>✓ Aesthetics</li> <li>✓ Clinical outcomes</li> <li>✓ Stored at room temperature</li> </ul> | <ul> <li>✓ Take – 99% DNA removal</li> <li>✓ Integration</li> <li>✓ Handling</li> <li>✓ Stored at room temperature</li> </ul> |  |

## Multi-Billion-Dollar Addressable Market



#### Global Bone Graft Substitutes market projected to grow at 6.1% CAGR to c. \$6.0 billion by 2029

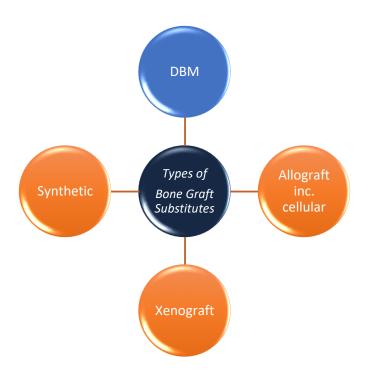
- Increase in prevalence of spinal fusion or other chronic diseases and trauma emergencies
- Market demand and growth returning to pre-pandemic levels
- Rise in awareness related to tissue engineering in global markets
- Key competitors include MTF, LifeNet, RTI Surgical, CTS, AlloSource and XTANT

### U.S. Skin Substitute market projected to grow at 2.2% CAGR to c. \$2.0 billion by 2028

- Focus areas are wound management, sports related injuries and uro-gynaecology (through partnership with ARMS Medical)
- Key competitors include Integra, Organogenesis, MiMedx and ColoPlast

#### Global Soft Tissue Biologics market projected to grow at 5.0% CAGR to \$3.9 billion by 2028

- Focus area is ligament repair
- Key competitors are MTF, LifeNet, RTI Surgical, CTS, AlloSource and Corin Group



Growing faster than the markets we compete in due to superior product performance, responsive customer service and adaptability to client needs

# **Building on the 4S Foundation**

Our Growth Pillars



Supply Sales Revenue 45's Sustainability Scale









- Base Business
  Growth of our
  - Growth of our base business with existing and new customers

Tissue Partnerships

Growth of our unique capacity to provide donor and in-process tissue

**3** Market Expansion

Growth into additional surgical specialties and geographic regions globally

Regulatory Evolution

Growth into markets requiring device approvals or with products classified as devices

## **Growth from the 4S and Growth Pillars**



#### **Base Business**



#### **Tissue Partnerships**



#### **Market Expansion**



#### **Regulatory Evolution**



## **2024 Objectives**

- Increase in donors and processing to meet commercial demand
- Continued increase in processing efficiencies
- Planning and commitments for Phase 2 expansion
- Support continued growth of base business
- Expand RDT opportunities

- Distribute allograft tissue products in markets outside the US
- Distribute xenograft tissue in markets outside of the EU

- Regulatory approval in new markets
- Evolution of organization with medical device capabilities

## **2024** Accomplishments

- 34% increase in 2024 dCELL business vs prior year
- Increase 2024 DBM base business with lead partner (+87%)
- Two additional recovery partners and two for partially processed tissue
- RDT new domestic (amnion) and international (dermis) outlets
- Initiated distribution in EU
- Signed agreements in other markets for allograft and xenograft
- Organizational changes completed to be a US medical device manufacturer if needed
- Changes needed for ISO 13485 in process for completion in 2025
- Approvals in new markets or with new strategic partners

# **Acquired Building in San Antonio for Expansion Plans**



#### **Building features**

- Occupied in H1 2021 as part of Phase 1 expansion
- 3X donor storage capacity
- Centralised and efficient distribution function
- Added office space for Finance, Human Resources, Donor Services and Senior Management
- Building block for Phase 2 expansion for added operational capacity; has space for ten additional clean rooms and support activities

#### **Option to Purchase Terms**

- Lease signed in 2019 provided option to purchase the building at a pre-set price up to November 2024.
- Pre-set purchase price lower than current fair market value for the property.
- No cash down payment required.
- Fixed rate mortgage payments are on par with current lease payments and will result in cost savings in later years.



## **Financials**

# Condensed Consolidated Statement of Income | For the six months ended 30 June 2024



|  | Six months<br>ended 30<br>June 2024<br><sub>Unaudited</sub> | Six months<br>ended 30<br>June 2023<br><sub>Unaudited</sub> |
|--|---|---|
|  | USD'000   | USD'000   |
| Revenue  | 16,402  | 14,098  |
| Cost of sales                                    | (7,784)   | (7,174)   |
| Gross Profit                                     | 8,618   | 6,924   |
| Administrative expenses before exceptional items | (8,095)   | (7,158)   |
| Operating loss                                   | 523   | (234)   |
| Finance income                                   | 5   | 16  |
| Finance charges                                  | (395)   | (704)   |
| Profit (Loss) before taxation                    | 133   | (922)   |
| Taxation   | (316)   | 61  |
| Loss for the period                              | (183)   | (861)   |

- Group revenues increased by 16% to \$16.4m (H1 2023: \$14.1m) driven by:
  - **BioRinse** up 12% to \$10.5m (H1 2023: \$9.4m)
  - dCELL up 34% to \$4.2m (H1 2023: \$3.1m)
- **Gross profit** increased to 53% (H1 2023: 49%)
- Eighth consecutive reporting period of growth and seventh consecutive period of double-digit, half-on-half growth
- Adjusted EBITDA profit of \$1.1m (H1 2023: \$0.4m)
- Maiden Profit before taxation of \$0.1m (H1 2023: \$0.9m loss)

# Financials Consolidated statement of financial position | As at 30 June 2024



|                               | As at 30 June 2024 Unaudited | As at 30 June 2023<br>Unaudited |
|-------------------------------|------------------------------|---------------------------------|
|                               | USD'000                      | USD'000                         |
| Assets                        |                              |                                 |
| Property, plant and equipment | 8,753                        | 5,755                           |
| Right-of-use assets           | 230                          | 3,144                           |
| Intangible assets             | 15,207                       | 15,129                          |
| Non-current assets            | 24,190                       | 24,028                          |
| Inventory                     | 12,712                       | 11,358                          |
| Trade and other receivables   | 4,582                        | 5,343                           |
| Corporation tax receivable    | 178                          | 145                             |
| Cash and cash equivalents     | 3,461                        | 4,064                           |
| Current assets                | 20,933                       | 20,910                          |
| Total assets                  | 45,123                       | 44,938                          |
| Liabilities                   |                              |                                 |
| Non-current liabilities       |                              |                                 |
| Loans and borrowings          | (9,702)                      | (5,958)                         |
| Deferred tax                  | (340)                        | (460)                           |
| Lease liability               | (144)                        | (3,147)                         |
|                               | (10,186)                     | (9,565)                         |
| Current liabilities           |                              |                                 |
| Trade and other payables      | (4,569)                      | (5,148)                         |
| Taxation Payable              | (400)                        | -                               |
| Loans and borrowings          | (543)                        | (250)                           |
| Lease liability               | (83)                         | (143)                           |
|                               | (5,595)                      | (5,541)                         |
| Total liabilities             | (15,781)                     | (15,106)                        |
| Net assets                    | 29,342                       | 29,832                          |

- Strong cash position of \$3.5m (H1 2023: \$4.1m)
  - Sufficient to fund existing business plans
- Inventory levels increased to support business growth
- Trade receivables collections improved 26% from prior year levels
- 2023 revision to MidCap Financial facility extends maturity to 2028 and Revolving credit facility increased from \$5m to \$10m. \$1m increase in facility taken down in June 2024 to support working capital growth.

# **Summary and Outlook**





**Continued progress on executing '4S' strategy** with the addition of four Growth Pillars to focus activities within the Group



**Increased capacity** and **improvements in efficiency** have given the Group much more operational flexibility



Continued progress to profitability with positive profit before taxation for H1 2024



**Obtaining regulatory approvals outside the US** to scale our business by entering into markets with a lack of access to tissue products



**Group revenues increased by 16%** to \$16.4m (H1 2023: \$14.1m) with Group positioned to continue its growth trajectory



Cash balance supports the current growth plan





# **Appendix**

## Focussing on the Four S's



UPPLY



ALES



USTAINABILITY





- Tissue Regenix benefits from having strong relationships with tissue suppliers, which is fundamental for growth
- Strategy centres around growth of tissue supply for existing and new customers
- Once tissue has been procured, there must be adequate capacity to transform it into finished products
- Tissue has delivered this with the expansion of facility and the increase in donor sourcing agreements

- Sales revenue is the result supply in conjunction with concerted commercial and product development efforts
- Diversified portfolio and customer partners generate Company's revenues
- To ensure long-term objectives are met

- Sustainability occurs when the growth in sales revenue, made possible by supply, funds the Company's existence without reliance on external capital
- Laser focus on revenue growth critical to realising operational leverage and profitability
- Tight expense management with an emphasis towards commercial needs, should accelerate transition to sustainability

- Driven by sustainability, scale allows the Group to pursue strategic growth alternatives which further enhance supply, sales revenue and sustainability
- The Group continue to look at opportunities to invest in cost reductions, acquire companies and new technologies
- Execution of further strategic partnerships can help with long term growth opportunities

# **Significant Shareholders**



As of 31 August 2024, shareholders holding more than 3% of the share capital of Tissue Regenix Group Plc are:

| Inthallo Limited                        | 15.01% |
|---|--------|
| Harwood Capital                         | 14.82% |
| Lombard Odier Asset Management          | 12.09% |
| Richard Griffiths & Controlled entities | 9.60%  |
| IP Group                                | 9.15%  |

# **Experienced Management and Board**





DANIEL LEE
Chief Executive Officer
• Bio on slide 3



JONATHAN GLENN

#### Chairman

- Former Chief Executive Officer at Consort Medical plc December 2007 – January 2020
- Chairman of Surgical Innovations plc
- Chairman of Torbay Pharmaceuticals Ltd.



**BRIAN PHILLIPS** 

#### **NED**

- Entrepreneurial investment professional with over 25 years' experience
- Current Principal of Ethos partners, which he co-founded in 2018



DAVID COCKE
Chief Financial Officer
• Bio on slide 3



SHERVANTHI HOMER-VANNIASINKAM

#### **NED**

- Graduated from Mysore University, India in 1981
- Became a Fellow of the Royal College of Surgeons, Edinburgh in 1989
- Appointed Consultant Vascular Surgeon at Leeds General Infirmary in 1995



**TREVOR PHILLIPS** 

#### **NED**

- Extensive listed experience in the UK & US corporate development, M&A in pharma and life sciences industry
- Held positions as Executive Chairman of hVIVO (2017-2020), COO of Vectura Group plc (2011-2017)