



Building a Leading Regenerative Medicines Business Interim results for the period ended 30 June 2023 September 2023

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### **Presenters**





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

- 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 John Hopkins University and M.S. in Biomedical Engineering from the University of Alabama











DAVID COCKE
Chief Financial Officer
Joined Jan 2021

- 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 2023 Highlights



### **2023** Commercial and Operational Highlights



**15% year-on-year increase in processing throughput** during H1 2023, as a result of the Phase 1 capacity expansion



Addition of **new BioRinse® product line** for all sports medicine allografts



Distribution agreements for OrthoPure® XT in the UK, China and Australia



37% increase in finished product availability for the OrthoPure ® XT product in H1 2023



**"4S" Strategy continues** to drive the Group in accomplishing each pillar: Supply, Sales Revenue, Sustainability and Scale

### **Financial Highlights**



Group revenues increased by 19% to \$14.1m (H1 2022: \$11.8m)



Gross profit for the period increased to 49% (H1 2022: 46%)



**Adjusted EBITDA profit** of \$0.4m against an adjusted EBITDA loss of \$0.5 m in H1 2022

• Profitable on an adjusted EBITDA basis for the last twelve months



The cash position as at 30 June 2023 of \$4.1m (30 June 2022: \$6.2m)

### **Divisional Revenue Highlights**



To \$9.4m (H1 2022: \$7.8m)

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



To \$3.1m (H1 2022: \$2.4m)

due to the increased commercial activity

## Multi-Billion-Dollar Addressable Market



### Global Bone Graft Substitutes market projected to grow at 6.1% CAGR to c. \$5.7 billion by 2028

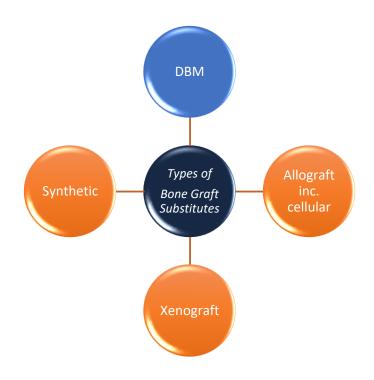
- Increase in prevalence of spinal fusion or other chronic diseases and trauma emergencies
- Market demand and growth returning to pre-pandemic levels
- Rise in awareness related to tissue engineering in global markets
- Key competitors include MTF, LifeNet, RTI Surgical and XTANT

### Soft Tissue market projected to grow at 5.0% CAGR to c. \$15.5 billion by 2027

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

### Tissue Regenix is helping to transform the treatment of patients in key surgical applications

- Strong competitive performance; taking market share
- Significant momentum for continued growth



Focused on increased commercialisation of existing product lines and launch of product line extensions addressing growing clinical demands

# **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)	\$9.4m in H1 2023	\$3.1m in H1 2023	
Flagship / high growth Products	ConCelltrate® AmnioWorks™	DermaPure®	
New product line extensions	<ul> <li>Expansion of private label opportunities</li> <li>Expansion of private label opportunities</li> </ul>	<ul> <li>OrthoPure® XT (relaunch)</li> <li>DermaPure® Meshed</li> <li>VNEW™</li> <li>Matrix ND™</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>	

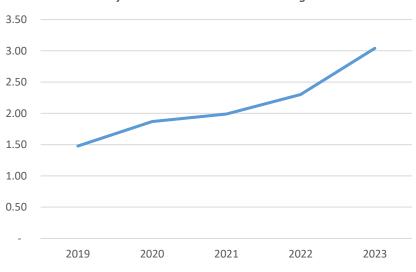
## **BioRinse- Strong Sales Growth in US market**



- BioRinse US exceptionally strong performance 20% growth from H1 2023
  - Growth and acceptance of DBM and amnion membrane products in orthopaedics, ophthalmology and wound care markets and Released Donor Tissue
- Indicative of the continued confidence in our products
  - Participation in diverse surgical specialties
- Strong performance of distributors and strategic partners
  - Successful addition of new partnerships
  - Outperforming competitors and taking market share
- San Antonio, Texas: Increased efficiencies continue in Phase 1 expansion
  - c.\$10m additional sales revenue potential through a c. 33% increase from existing footprint
  - Provides the ability to respond rapidly to shifts in market demand







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

## dCELL – US Reorganisation Continues to Reinvigorate Sales Growth



- dCell (tissue) US reorganisation and commercialisation strategy providing an opportunity to reinvigorate sales growth
  - Commercial reorganization shows results—sales up 29% for H1 2023
  - 25 new distributors in H1 2023 hired and trained against a plan for 32 new hires for the year
  - Three layers of commercial management compressed into one
    - Flattening the organisational structure to get closer to the customer and sales channel partners
- OrthoPure XT preparation for the reintroduction of the only commercially available xenograft for sports medicine indications
  - Signing of a UK distributor and distribution agreements for China and Australia which will require additional regulatory and clinical approvals
  - H1 2023 Sales growth aided by contributions from OrthoPure XT







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

## **New Product Line Launch**







Comprehensive change to our complete line of sports medicine soft tissue allografts

New processing protocols designed to minimize processing effects to produce sterile soft tissue products

Aligns this product line with market expectations and enables us to be more competitive in the market

US market for sports medicine allografts is estimated to be over \$300m\*

\*Independent market research estimates by GR Consulting

First order received in Q3 2023. Products requested by our strategic partners will enable to us to continue to enhance our growth potential in the near term

## Focusing on the Four S's





### **SALES REVENUE**



### **SUSTAINABILITY**



### **SCALE**



## **Accomplishments** H1 2023

Future objectives

- 15% year-on-year increase in processing throughput in US operations
- 37% increase in finished product availability for OrthoPure XT
- Signed one **new donor supply** contract for BioRinse in the H1 2023
- BioRinse division returned 20% growth in the period, continuing to take market share
- · Commercial reorganisation of dCELL division continues to show benefits with 29% sales growth in the H1 2023
- Positive Adjusted EBITDA for the last twelve months due to sales growth and tight expense management
- Increased capacity from Phase One expansion allows Phase Two capital expenditure to be pushed out
- Cash position supports current business plan
- · Continue tight monitoring and control of operational and capital expenses
- Continue to identify opportunities to be more capital efficient across all aspects of the organisation

- Identified and are in the process of establishing a third-party logistics provider to provide distribution services to the European Union and the UK
- · Increased credit facility with MidCap from \$5.0m to \$10.0m to support future working capital growth
- Distribute allograft tissue products in markets outside the US

- Construction of Phase 2 expansion has been pushed to 2025 as a result of the capacity created by Phase 1
- Phase 2 will include an additional ten clean rooms
- Continue taking market share with above-market, double digit growth rates

## **Processing Efficiencies**



## Phase 1 Expansion has capacity for over \$40m in sales revenue

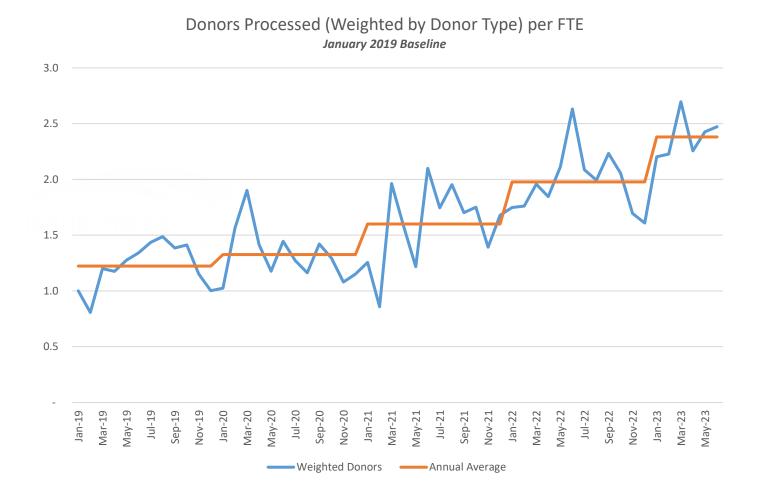
- c.\$10m more than originally estimated (33%)
- Allows demand spikes to be met within 30 days—c.50% of the previous lead time

### **Increased capacity driven by:**

- Scheduling optimisation
- Streamlined documentation
- Re-engineered processes for efficiency
- Cross training technicians

### Phase 2 expansion

 Initiation can now be pushed out to 2025 while still meeting sales objectives



# Financials Consolidated statement of comprehensive income | For the full year to 30 June 2023



		Unaudited six months ended 30 June 2022
	USD'000	USD'000
Revenue	14,098	11,836
Cost of sales	(7,174)	(6,415)
Gross Profit	6,924	5,421
Administrative expenses before exceptional items	(7,158)	(6,669)
Operating loss	(234)	(1,248)
Finance income	16	2
Finance charges	(704)	(401)
Loss before taxation	(922)	(1,647)
Taxation	61	60
Loss for the year	(861)	(1,587)

- Group revenues increased by 19% to \$14.1m (H1 2022: \$11.8m) driven by:
  - **BioRinse** up 20% to \$9.4m (H1 2022: \$7.8m)
  - dCELL up 29% to \$3.1m (H1 2022: \$2.4m)
- **Gross profit** increased to 49% (H1 2022: 46%)
- Sixth consecutive reporting period of growth and the fifth consecutive period of doubledigit half-on-half growth
- Adjusted EBITDA profit of \$0.4m (H1 2022: \$(0.5)m)
- Profitable on an adjusted EBITDA basis for the last twelve months

# Financials Consolidated statement of financial position | for the six months ended 30 June 2023



	As at 30 June 2023 Unaudited	As at 30 June 2022 Unaudited
	USD'000	USD'000
Assets		
Property, plant and equipment	5,755	5,701
Right-of-use assets	3,144	3,232
Intangible assets	15,129	15,001
Non-current assets	24,028	23,934
Inventory	11,358	10,066
Trade and other receivables	5,343	4,020
Corporation tax receivable	145	294
Cash and cash equivalents	4,064	6,172
Current assets	20,910	20,552
Total assets	44,938	44,486
Liabilities		
Loans and borrowings	(5,958)	(5,154)
Deferred tax	(460)	(580)
Lease Liability	(3,147)	(3,287)
Non-current liabilities	(9,565)	(9,021)
Trade and other payables	(5,148)	(4,315)
Loans and borrowings	(250)	-
Lease liability	(143)	(123)
Current liabilities	(5,541)	(4,438)
Total liabilities	(15,106)	(13,459)
Net assets	29,832	31,027

- Strong cash position of \$4.1m (H1 2022: \$6.2m)
- Inventory levels increased 13% as sales increased 19%. Turnover remained consistent to 2022 levels
- Trade receivables collections improved 12% from prior year levels
- Revised MidCap Financial facility extends maturity to 2028; interest only until January 2024. Revolving credit facility increased from \$5m to \$10m; not required by current business plan but provides flexibility for growth

## **Summary and Outlook**





**Continued progress on executing '4S' strategy** with increased production capacity, sales revenue growth, product portfolio expansion, and improved operational efficiency



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



Continued progress to profitability with positive adjusted EBTIDA for the last twelve months



**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 19%** to \$14.1m (H1 2022: \$11.8m) with Group positioned to continue its growth trajectory



Cash balance supports the current growth plan, supported by significant commercial momentum and improving margins





# **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 2023, shareholders holding more than 3% of the share capital of Tissue Regenix Group Plc are:

Harwood Capital	15.16%
Inthallo Limited	13.00%
Richard Griffiths & Controlled entities	9.71%
IP Group	9.25%
Lombard Odier Asset Management	8.34%

## **Experienced Management and Board**





DANIEL LEE
Chief Executive Officer
• Bio on slide 3



JONATHAN GLENN

### Chairman

- Held position of Group Finance Director of Consort Medical plc from September 2006 to December 2007
- Former Chief Executive Officer at Consort Medical plc December 2007 – January 2020



**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)