



Building a Leading Regenerative Medicines Business

September 2020

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# **Executive Biographies**

# **Experienced Management and Board**



#### **Senior Management Team**



GARETH JONES
Interim Chief Executive Officer
Joined Nov 2018

- Joined as CFO November 2018
- Became interim CEO in August 2019
- CFO, Applied Graphene Materials plc 2016-2018
- Qualified Chartered Accountant with PWC
- 25 years' industry experience predominantly within UK and US listed businesses



KIRSTEN LUND
Group Finance Director<sup>(1)</sup>
Joined Jan 2010

- Qualified as Chartered Certified Accountant in 2015
- Group Financial Controller at Tissue Regenix 2017 – 2019
- 10 year's experience in the health care sector and Tissue Regenix

#### Supported by an experienced and well balanced Board



#### Jonathan Glenn, Interim Non-Executive Chairperson

- 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.



#### Alan Miller, NED

- CIO and a Founding Partner of SCM Direct.
- Formerly Chief Investment Officer and founding shareholder of New Star Asset Management.
- Qualified accountant; alumni of London Business School.



#### Randeep Singh Grewal, NED

- 20 years' experience in institutional investing having worked at Trium Capital LLC, F&C Asset Management, ICAP Equities and Tudor Capital.
- Chairman of BB Healthcare Investment Trust, listed on the London Stock Exchange since December 2016.



#### 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.

# **Core Product Portfolio**

# Two high growth product lines focused on bone and skin



Healthcare Area	Bone	Skin	
Product Name	BioRinse®	dCELL®	
H1 2020 Revenue	£3.4m	£1.7m	
Products	ConCelltrate®	DermaPure®	
Applications	Foot / Ankle	Open wound	
	• Spine	Hernia	
	• Dental	• Plastics	
	Orthopaedics	Urogynaecology	
		Sports medicine	
Differentiators	✓ Induces new bone growth	✓ Faster healing	
	✓ Faster healing	✓ No second graft	
	✓ Superior handling	✓ Stored at room temperature	
	✓ Reduced flush out	✓ Superior handling	

# **Company Overview**



## **Overview**



Commercial, high growth regenerative medtech company focused on **skin** and **bone** 



**£6.1million** revenue H1 2020<sup>(1)</sup> **Overheads reduced by £1.7million**<sup>(2)</sup> **to £5.5million** 



£13.7million cash at 30 June 2020(3)



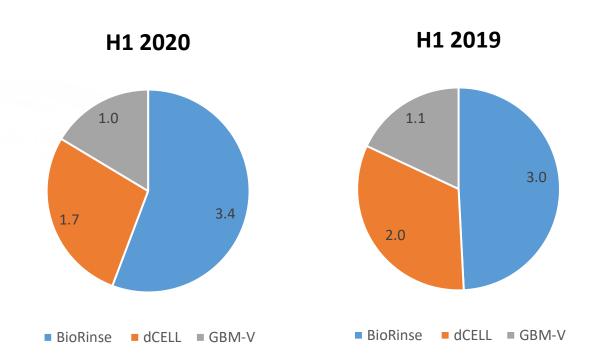
US capacity expansion programme commenced to capitalise on significant commercial opportunities



Strategic collaborations and distribution agreements entered for new products and geographies

# Revenue growth by product year-on-year

£m



(1) (3) 2020 unaudited interim results (2) Excludes exceptionals

# **Tissue Regenix's Four Strategic Growth Areas**











# **Achievements**

Focus

# Milestones

#### **US Market Penetration**

Drive growth in US sales of current products through current direct and indirect distribution channels and increasing GPO relationships

- Secure funding to allow investment into US capacity expansion
- Number of new accounts secured
- Commence Phase 1 of capacity expansion build out

#### **Geographic Expansion**

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

- √ Target additional territories for distribution and licensing opportunities - Latin America, **Cyprus, Taiwan**
- Launch OrthoPure® XT into the UK market
- Secure additional distribution agreements for OrthoPure® XT in Europe

Commence supply of OrthoPure®

XT into Continental Europe

## **Strategic Partnerships**

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

- Sign up additional strategic partnerships for OEM and product collaboration opportunities
- Increase licensing and strategic partnerships

New strategic partner / major

### **Strengthen Portfolio**

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

- OrthoPure® XT CE Mark for launch into European markets
- Launch new product with top 10 **Global healthcare Company**
- OrthoPure® XT 2 year clinical data publicly available

- Phase 1 of capacity expansion comes on stream
- Review timeline for commencement of Phase 2

- expansion with strategic partner
- Urogyn product line extension
- Dermis product line extension
- Clinical data publications

# **COVID-19 US Industry trends**

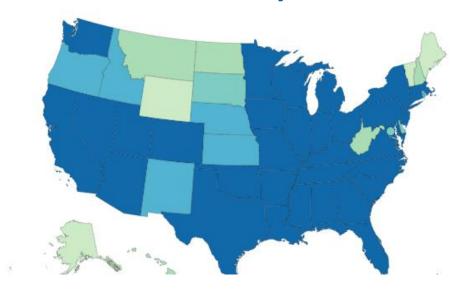


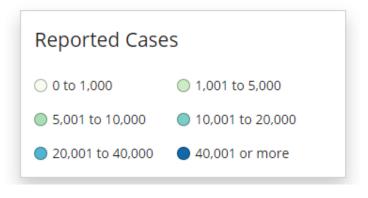


# The industry impact

- Elective procedures postponed and recommenced on a county-by-county, not state-by-state basis
- US not successfully dealt with Phase 1
  - Elective procedures recommenced and then halted in a number of areas
  - North-East region particularly hard hit during Q2 2020
  - Affected the South and Western regions later than the North And East
- Value Analysis Committees slowed approval of new products in hospitals
- New distribution agreements delayed until normalised level of procedures returns
- Complex landscape at a local level:
  - Speed of recovery complex due to a number of factors
  - Decisions taken county-by-county, not by state
  - Healthcare provider departmental by departmental
  - Differing levels of patient confidence
- Ability of healthcare providers to make up for delayed procedures

# **US COVID-19 cases by State**

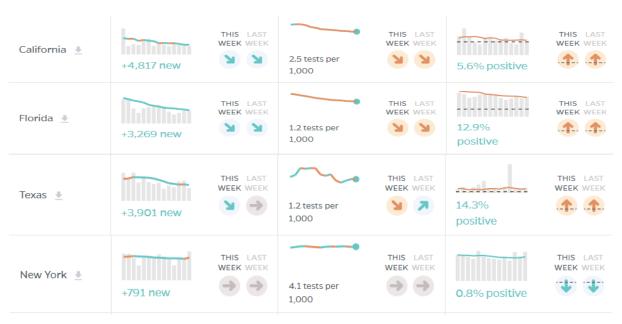




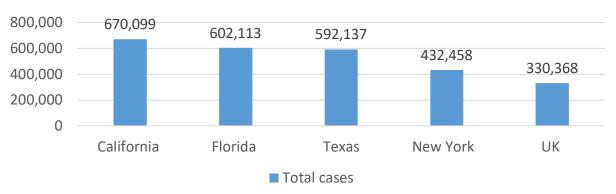
# The ongoing impact of COVID-19 US States significantly impacted



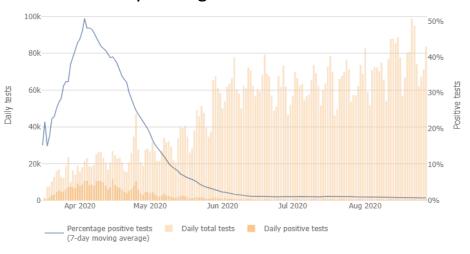
#### Testing trends as a State overview<sup>(1)</sup>



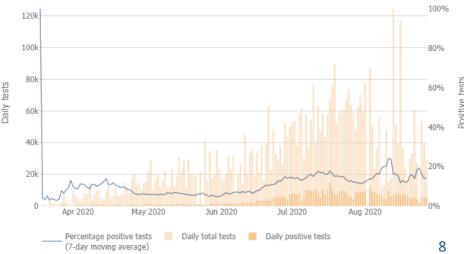
#### Total COVID-19 cases<sup>(4)(5)</sup>



#### New York daily testing trends(2)



### Texas daily testing trends<sup>(3)</sup>



# How has TRX navigated the COVID-19 landscape?





### **US Business**



- Supply chain not affected
- Target 120 days supply of all key PPE
- Increased number of recovery agency relationships to ensure continued donor availability

#### Production

- Updated operating procedures
- Commenced flexible working patterns to:
- Reduce employee interaction
- Reduce on-site attendance for certain employees
- New protocols have contributed to no reported COVID-19 related incidents

# Customers

- A number of elective procedures postponed
- Urogynecology and dental procedures significantly affected initially
- North- East region of US particularly badly affected in initial wave
- Ongoing dialogue with customer base
- Enhanced monitoring of credit lines

### **UK Business**

- UK facility closed and operational & technical staff furloughed April – July
- Office based staff commenced working form home
- Operational procedures and health and safety guidelines updated to allow facility to re-open July 2020
- All staff re-engaged July 2020
- Business ensured sufficient level of PPE and has experienced no impact on supply chain
- Processing recommenced to facilitate launch of OrthoPure®XT
- Staff have commenced a staggered day rota to minimize number of individuals on-site

# **Product portfolio**Two new products launched during 2020



#### OrthoPure® XT

- Xenograft (pig) tendon for the reconstruction of knee ligaments to restore knee function and stability
- Potential to be disruptive in the market
- Processed in-house at UK facility
- CE Mark approval granted June 2020
- Distribution agreement for the UK market entered August 2020
- Initial delivery of product expected Q4 2020

#### **Soft Tissue Orthopaedic product**

- New product launched with top 10 global healthcare company
- Result of R&D collaboration between both companies
- Expected to make a material impact over the next 2 years



Further product line extensions and distribution agreements expected in the next 12 months

# Revenue and Capacity Capacity expansion programme commenced July 2020



# **Capabilities in San Antonio Facility**

### **Existing Capabilities:**

- 4 clean rooms dedicated to BioRinse production, processing 22 donors per month
- \$1.1m per month based on average revenue of \$50k per donor

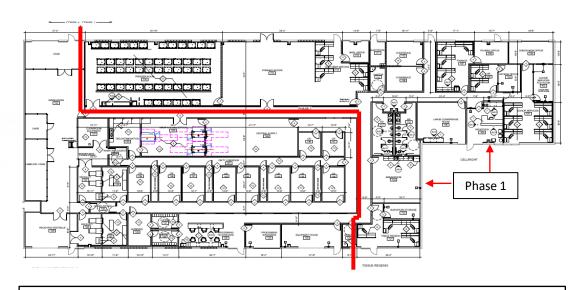
#### Phase 1 Expansion:

- Planned expansion provides 2 additional sterile packaging clean rooms in existing building
- Enables additional 11 donors per month
- Total estimated cost of \$1.2m, with six months build time

#### **Expanded Revenue Potential:**

- To bring total capacity to 33 donors per month
- Following completion of the Phase 1 facility build out, it is estimated that the maximum serviceable revenue for BioRinse, based on the increased capacity, would be c.\$19.8m

# **Phase 1 and 2 Expansion Project**



Phase 1 of capacity expansion programme commenced in July 2020. This will involve the moving of freezer and distribution functions into the new facility which will in turn allow space for two additional sterile packaging clean rooms to be installed in the existing facility.

Currently, programme is running on time.

# Core strategic priorities to deliver break-even





	Achieved	Further Improvements
Revenue Ensuring that there is sufficient capacity and opportunity to increase top line growth in a post-COVID market	<ul> <li>Commenced capacity expansion plan</li> <li>Top 10 global healthcare company collaboration opportunity</li> <li>Launch of OrthoPure XT into European market</li> </ul>	<ul> <li>Additional strategic partnerships</li> <li>Product line extension opportunities</li> </ul>
COGs  Driving increased efficiency with the manufacturing facilities	<ul> <li>San Antonio efficiency programme</li> <li>CTS yields showing notable improvement (outsourcing partner for DermaPure)</li> <li>Non-Oriented DermaPure utilises previously un-used donor tissue improving yields and product availability</li> </ul>	<ul> <li>San Antonio efficiency programme</li> <li>Processing efficiencies to drive COGs improvements</li> </ul>
Overhead Cost Management Appropriately sizing the overhead cost base to reduce non-critical spend and focus on return on investments	<ul> <li>Q4 2019 employee headcount reduced by 18</li> <li>Relocation of UK facility – annualized savings of over £400k</li> <li>Review of Corporate overheads</li> </ul>	<ul> <li>Ongoing review of Corporate overhead spend</li> <li>Challenging R&amp;D and clinical spend</li> <li>Capital expenditure focused on improving efficiencies for continued reduction in overhead spend</li> </ul>

# **Financials**



	6 months 30 Jun 2020 (Unaudited) £'000	6 months 30 Jun 2019 (Unaudited) £'000	Year 31 Dec 2019 Audited £'000
Revenue	6,085	6,069	13,033
Cost of sales	(3,150)	(3,225)	(7,014)
Gross Profit	2,935	2,844	6,019
Administrative expenses before exceptional items	(5,355)	(7,024)	(13,198)
Exceptional items	(106)	(40)	(21)
Total administrative expenses	(5,461)	(7,064)	(13,219)
Operating loss	(2,526)	(4,220)	(7,200)
Net finance charges	(170)	(172)	(460)
Loss before tax	(2,696)	(4,392)	(7,660)
Taxation	297	311	554
Loss after tax	(2,399)	(4,081)	(7,106)

**Revenue** remained flat Y-O-Y despite cyber security incident and COVID-19 (-2% constant currency).

Margins improvement by 100bps from 47% to 48% due to:

- Product mix with greater contribution from the BioRinse business
- Upside from the newer products
- Efficiency gains

Overheads have decreased Y-O-Y by £1.7m

A small proportion of the savings relate to reduced travel and delays to clinical programmes due to COVID-19.

**Exceptional items** are related to the cyber security incident.

# **Financials**



	30 June 2020 £'000	30 June 2019 £'000	31 Dec 2019 £'000
Non-current assets			
Property, plant and equipment	2,456	2,917	2,357
Intangible assets	17,865	19,614	17,999
Total non-current assets	20,321	22,531	20,356
Current assets			
Inventory	6,288	2,738	4,185
Trade and other receivables	2,628	3,041	2,539
Corporation tax receivable	684	900	1,035
Cash and cash equivalent	13,667	10,076	2,380
Total current assets	23,267	16,755	10,139
Total assets	43,588	39,286	30,495
Total non-current liabilities	(2,936)	(6,545)	(2,785)
Total current liabilities	(4,242)	(4,112)	(3,115)
Net assets	36,410	28,629	24,595

- Cash of £13.7m which includes \$2m from the Midcap term loan and \$1m drawn on the revolver.
- Inventory increase is driven by:
  - COVID-19 impact on customer sales.
  - Supply chain ramp up.
- Midcap terms renegotiated to extend repayment period to start in 2023.
- US government loan of £850k (c.\$1m) expected to become a grant once the banks open the forgiven application process.
- Fundraise with gross proceeds of £14.6m from an equity placing (£13.8m net).
- Phase 1 of the fit out of the new building initiated on 24<sup>th</sup> July.

# **Conclusions and Near-Term Strategic Goals**



#### During 2020 we have...

- Secured required financing to support investment and working capital
- Reduced overhead burden and restructured the business
- Signed new collaboration for white label manufacturing with a leading top 10 global healthcare company bringing to market a newly developed product line
- Received CE Mark approval for OrthoPure®
   XT
- Signed distribution agreement for UK distribution of OrthoPure® XT
- Managed issues arising due to the pandemic whilst maintaining production at our US facility



#### In the near-term, we intend to:

- Complete phase one of the new manufacturing facility
- Increase availability of current products and launch new products to the market
- Develop new strategic partnerships
- Ensure business is positioned to capitalize on opportunities in a post-COVID market
- Continue to actively manage overhead base



# **Appendix**

# **Executive Biographies**

# **Experienced Top Tier Management Team**



#### **Senior Management Team**



MIKE IZON R&D Director Joined Nov 2014

- -10 year's experience as a management consultant with expertise in R&D, for start ups
- Former CE mark reviewer and auditor
- Previous operational leadership roles with Proctor & Gamble, Clairol and Sanofi Aventis



**DANIEL LEE**President of US Operations, Joined
Jan 2019

- -Nearly 30 year's experience in medical devices and biologics
- -Prior to joining CellRight, Danny was CEO of Scaffold Biologics and Aperion Biologics
- -B.E.S. degree in Materials Science and Engineering from John Hopkins University and M.S. in Biomedical Engineering from the University of Alabama at Birmingham



JOEL PICKERING
President, TRX BioSurgery, Joined
Oct 2015

- -Joel joined Tissue Regenix Wound Care Inc in October 2015
- -He became president of the division in Jan 2017
- -Over 20 year's experience in wound care marketing
- -Worked for: J&J Medical, Lifecell, Convatec and KCI

# **Significant Shareholders**



# **Significant shareholders**

As at 2 September 2020, shareholders holding more than 3% of the share capital of Tissue Regenix Group Plc are:

Lombard Odier Asset Management	15.03%
IP Group	13.66%
Richard Griffiths & Controlled entities	10.11%
Premier Miton Group plc	10.08%
Spreadex Ltd	6.46%
Jupiter Asset Management	4.86%
Directors and Related Holdings	3.90%