

Building a Leading Regenerative Medicines Business

September 2018

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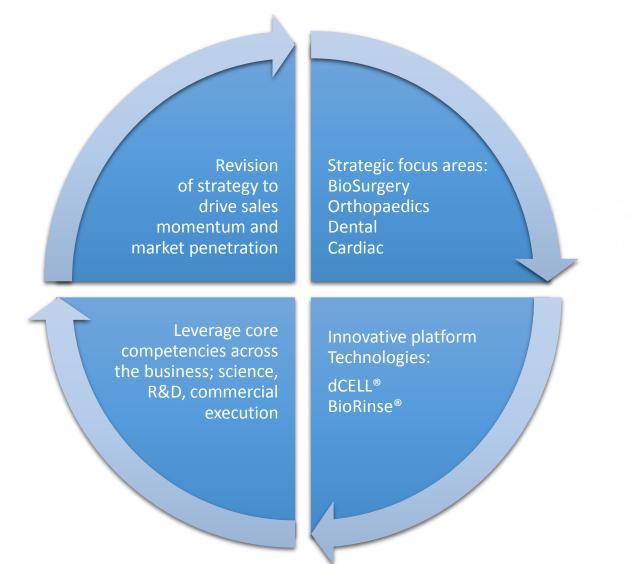
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"To establish Tissue Regenix as a leader in the science and innovation of regenerative medicine and become our clinicians' partner of choice to meet growing clinical needs, transform patient care and deliver favourable health economic outcomes."

### **Executive Summary** Commercial execution remains key to access c.7bn enterprise opportunity





- Two proven regenerative medical technology platforms
- Proven strategy to execute growth ambitions
- ✓ Differentiated product offering
- ✓ Multiple future pipeline opportunities
- ✓ Growing global distribution network
- ✓ Poised for further product launches in EU and US

### **Financial Summary** Group sales increased to £5.6m

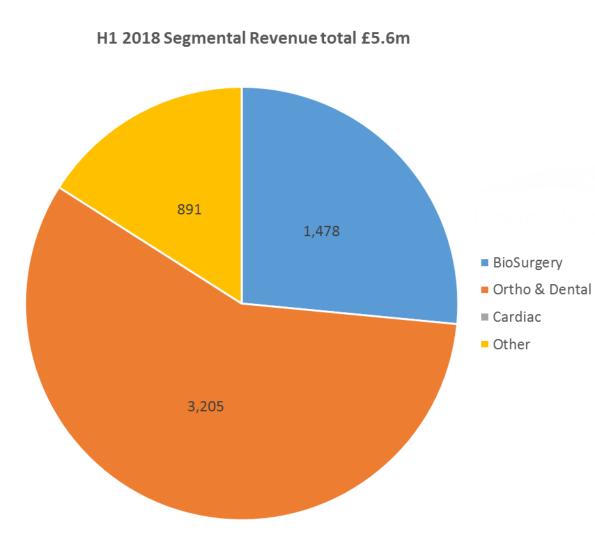


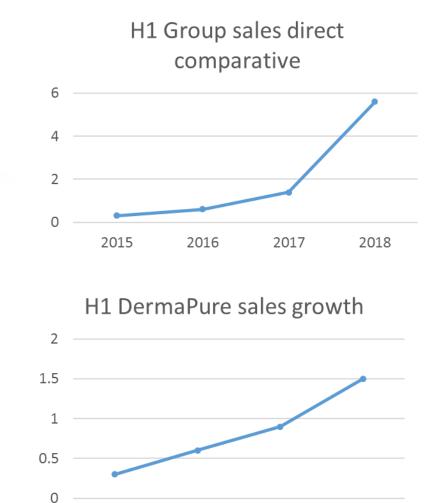
	6 months 30 June 2018 (Unaudited) £000	6 months 30 June 2017 (Unaudited) £000	Change £000	Change %
REVENUE	5,574	1,343	4,231	315%
Cost of Sales	(2,451)	(754)	(1,697)	225%
GROSS PROFIT	3,123	589	2,534	430%
Other Operating Costs	(6,597)	(5,687)	(910)	16%
ADJUSTED LBITDA	(3,474)	(5,098)	1,624	-32%
Depreciation	(283)	(209)	(74)	35%
Amortisation	(267)	_	(267)	0%
Share-based payment	(212)	(135)	(77)	57%
Finance income	42	17	25	0%
Finance charges	(146)	_	(146)	0%
ADJUSTED LOSS BEFORE TAX	(4,340)	(5,425)	1,085	-20%
Taxation – payable	(47)	_	(47)	0%
Taxation – R&D credits	352	660	(308)	-47%
ADJUSTED LOSS AFTER TAX	(4,035)	(4,765)	730	-15%
Exceptional items	(500)	_	(500)	0%
STATUTORY LOSS	(4,535)	(4,765)	230	-5%

- Group sales increased to £5.6m (H1 2017: £1.3m)
  +61 % pro forma, driven by:
  - DermaPure<sup>®</sup> sales grew by 73% on a reported basis, 96% in constant currency, to £1.5m (H1 2017: £0.9m)
  - CellRight contribution of £3.2m under orthopaedics and dental, +46% pro forma
  - Increased sales from GBM-V by 70% to £0.9m (H1 2017: £0.5m)
- Gross margin increased by 12.1 percentage points to 56%
- Significantly narrowed Group EBITDA loss for the period £3.5m (£5.1m)
- Cash balance at 30 June 2018 £12.2m
- Overall cash outflow reduced £4.3m (H1 2017: £4.6m)

### **Financial Summary** Segmental Review







## **Highlights** Major H1 milestones achieved



# Strategic Partnerships signed – Arthrex, ARMS, Pennine

✓ A number of further strategic opportunities identified and discussions commenced

#### **HTA** License

 Granted for the import of BioRinse products into the UK and a gateway for Europe

#### **Integration** activities

- ✓ In house manufacturing of DermaPure
- Global employee engagement programme launched - Verto

#### DermaPure

- ✓ Further GPO agreements signed
  - Premier 3 year extension
  - ✓ Premier Supplier Horizon award
- DermaPure Commercial 'Accelerator' programme established

### Clinical data programme under consideration

- 100 patient prospective observational clinical trial for DermaPure in orthopaedic trauma
- DermaPure clinical trial for urogynaecology in partnership with ARMS medical

### **Cost structure reviewed**

- ✓ Efficiency initiative within our R&D portfolio
- ✓ Biosurgery infrastructure reorganisation
- ✓ Leeds operational site manufacturing enhancements

### Management appointment

✓ CFO appointed, Gareth Jones to join in Q4 2018

### **R&D**, **Product** pipeline

- Ongoing discussions with significant R&D partners, initial projects chartered
- ✓ SurgiPure XD commercial manufacturing commenced
- ✓ Launch pathway for OrthoPure XT established

### **Operational Overview - BioSurgery**



H1 Revenue - £ 1.5m (H1 2017: £0.9m) 73% year on year growth on a reported basis, 96% in constant currency

#### H1 Achievements

- Implementation of DermaPure commercial 'Accelerator' programme building significant momentum - execution
- Increased traction in the Urogyn market under distribution agreement with ARMS medical - over 300 patients treated
- ✓ Additional agreement signed with GPO Premier, Inc.
- Granted Supplier Horizon Award for 'exceptional local customer service and engagement, value creation through clinical excellence and commitment to lower costs' voted on by Premier, Inc. members

#### H2 Milestones

- Additional product sizes being brought onstream to address clinical requirements
- Significant approvals expected for access within hospital Groups
- 100 patient prospective observational clinical study commencing in Ortho-trauma
- US launch of SurgiPure XD for hernia repair

# **Divisional Overview - Orthopaedics and Dental**



H1 Revenue - £ 3.2m (H1 2017: £3.0m pro forma) 46% year on year growth Dental +31% Orthopaedics +51%

### **Orthopaedics**

#### **H1 Achievements**

- Significant distribution agreements signed leading to increased sales traction
- HTA license allows for import of BioRinse portfolio into the UK market with additional EU approvals processing

#### H2 Milestones

- First UK sales through Pennine agreement
- Additional distribution agreements
- Completion of OrthoPure XT 2 year clinical data

#### **Dental**

#### **H1 Achievements**

- ✓ Increased demand for BioRinse portfolio
- ✓ Clinical advisors appointed
- ✓ Scoping for the use of DermaPure in dental procedures

#### **H2** Milestones

- Identify potential market opportunities outside of US
- Bring on board significant US distribution partner

# **Divisional Overview - Cardiac (GBM-V)**



H1 Revenue - £ 0.9m (H1 2017: 0.5m) +70% year on year growth

#### **Future Milestones**

- Regulatory submission remains on track for 2019 manufacturing licence for CardioPure
- Marketing authorisation on track for 2020
- Processing of alternative tissues
- Determine commercialisation pathway
  - □ Potential for strategic partners under review

# **GBM-V,** ROSTOCK, GERMANY



# **Summary and Milestones** Strong foundations from which to deliver



Strong first half of the year H1 Revenue - £ 5.6m + 61% pro forma

- Strategic Partnerships signed Arthrex, ARMS, Pennine
- HTA License for UK (European) distribution
- Integration progressing on track
- DermaPure growth very encouraging
- Clinical data programme under consideration
- Cost structure reviewed
- Management focus realigned
- Pipeline 'Stage & Gate' process established

#### **Future Milestones**

- Additional strategic partnerships
- Geographic expansion into new territories
- First sales under Pennine distribution agreement for BioRinse portfolio
- First SurgiPure XD sales in US
- Completion of OrthoPure XT 2 year clinical data
- Initial expansion of capacity capabilities
- Roll out of employee engagement initiatives

### Outlook 2019 / 2020 Building on momentum



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Pursue licencing opportunities in different territories

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Increase number of strategic partners for distribution opportunities and R&D projects



Multiple organic development opportunities innovative product portfolio and pipeline

Extensive geographical opportunities - China



Capacity expansion to scale business

## **Summary** Commercial execution remains key to access c.7bn enterprise opportunity





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- Differentiated product offering
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- ✓ Poised for further product launches in EU and US



