

# **Highlights**

### Financial

- Group sales increased to £6.1m (H1 2018: £5.6m)
  - DermaPure increased sales by 33% to £2.0m (H1 2018: £1.5m)
  - GBM-v revenue growth of 19% to £1.1m (H1 2018: £0.9m)
  - Orthopaedics & Dental sales were affected by a realigning of manufacturing to address capacity in H2 but still delivered sales of £3.0m (H1 2018: £3.2m)
- Group EBITDA\* loss of £3.6m (H1 2018: £3.5m)
- Cash balance of £10.1m (H1 2018: £12.2m), post-\$7.5m drawdown under a credit facility secured for up to \$20m to invest in meeting growing demand for products

#### Commercial

- Accelerating US market penetration
  - Expanded Group Purchasing Organisation coverage for DermaPure®
  - o Commissioned SurgiPure® XD post marketing clinical data collection trial
- Continue to exploit global market potential
  - Entered Latin America for the first time through a distribution agreement for BioRinse® products in Chile
- Working towards strengthened portfolio
  - Submitted positive two-year clinical data for OrthoPure<sup>™</sup> XT to the notified body

# Operational

- Commenced second shift for BioRinse® products
- Appointed US President of Operations
- Supply chain improvement to deliver efficiencies

#### Post period

 John Samuel resumed position of Executive Chairman, Gareth Jones appointed Interim Chief Executive Officer and Mike Barker appointed Chief Financial Officer following the resignation of Steve Couldwell as Chief Executive Officer due to a recurrence of his illness.

<sup>\*</sup>EBITDA is a non-IFRS measure that the Group uses to assess its performance. It is defined as earnings before interest, taxation, depreciation and amortisation



### **Executive Chairman, John Samuel**

"We have strong global demand for our products, which allowed us to deliver continued revenue growth, demonstrated by DermaPure, which increased sales by 33% in the first half. We remain focused on short and medium term initiatives to increase capacity and alleviate supply constraints."

During the first half of the year, we streamlined our supply chain activities and enhanced our operational procedures. These initiatives have enabled us to increase production capabilities within the San Antonio facility, the benefits of which will come to fruition in the second half of the year. Longer term, having secured a credit facility of up to \$20m with MidCap Financial LLP, this will support our ambitious growth plans, by adding further processing capacity to the San Antonio facility and expanding our commercial footprint.

We anticipated that the year would be significantly weighted towards the second half, as announced on the 4 June 2019, at the time of the Company's results for the year ended 31 December 2018. We continue to expect that this will be the case, and, against a background where we see the ever growing demand for our products as the business looks to increase its manufacturing capabilities, the ability to bring this on stream during the second half of the year will be key in determining the year end outcome.

## **Business Review**

#### **BioSurgery**

The BioSurgery division (DermaPure®,) grew revenue 33% year-on-year to £2.0m, as the repositioning in the hospital space continues to gain traction.

We received a further Group Purchasing Organisation (GPO) approval in April, and now have access to circa 95% of all hospitals covered under GPOs in the US. With the increasing use of the product in uro-gyneacology procedures, where we have a specialist distribution partner, ARMS Medical, and the commencement of use in maxilliofacial and dental applications, we expect continued strong demand for the BioSurgery products in the second half of the year. To satisfy growing demand we have reinstated the processing agreement with Community Tissue Services for the production of DermaPure® in order to increase capacity and have received the first products under this agreement.

The business continues to make good inroads into premium medical institutions within the US market and this, coupled with additional product line extensions, is anticipated to create opportunities in the near future.

# **Orthopaedics and Dental**

As we realigned manufacturing capacity for further growth in the second half of the year there was a slight dip in revenue performance during the first half of the year for the Orthopaedics and Dental division, primarily comprising of the BioRinse® portfolio.

We introduced a second shift during the first quarter, which has increased processing capacity, and, in conjunction with supply chain improvements, we expect to see these changes drive revenue

performance in the second half of the year. The relationship with our BioRinse® strategic distribution partner, Arthrex, Inc. continues to develop as we look to explore additional market opportunities.

Positive two-year clinical data for OrthoPure™ XT (porcine tendon) has been submitted to the notified body and we remain optimistic that we will be awarded the CE mark during 2019

#### **GBM-V**

Our controlled joint venture GBM-V is now largely self-sustainable and during the period increased revenue by 19% though the sale of corneal implants, whilst it also manages the regulatory process for the CardioPure products in Germany, which remains on track for a launch during 2020.

# **Operations and Management**

Daniel Lee, appointed as President of US Operations in January 2019, has initially focused on developing the manufacturing capabilities and re-alignment of our supply chain processes at the San Antonio facility, with the introduction of a second shift, and in March 2019 the hiring of a Head of Donor Services.

On the orthopaedic / dental side of the business (BioRinse®), the lead-time for final products to become available is 3 months. This means that manufacturing in Q3 will be increased, following these initiatives, and this will be key in determining our final revenues for 2019.

#### Post balance sheet events

As announced on 15 August 2019, we have entered into an agreement for a 10-year lease, with an option to purchase, on a 21,000sq ft manufacturing facility, adjacent to our current building in San Antonio which allows for the first phase of the expansion project to begin. Initially, the office space and warehousing will be transferred into the new facility allowing for further clean rooms to be installed in the original building. Over time, this will allow for further clean rooms to be brought on stream as required.

Steve Couldwell, Chief Executive Officer (CEO), informed the Board of a recurrence of his illness, and resigned his position with immediate effect in order to concentrate on his recovery. John Samuel resumed the position of Executive Chairman, Gareth Jones, Chief Operating Officer, has taken up the position of interim-CEO. Mike Barker, who has supported the Group since January was appointed as Chief Finance Officer and Director on the Board.

# Financial Overview

During the first half of 2019, we have achieved a number of milestones in order to help secure our future success. Pivotal to this was the credit agreement with MidCap Financial LLP, which has allowed us access of up to \$20m of debt financing, meaning we can begin to implement our ambitious growth plans.

# Revenue

Revenue has increased to £6.1m (H1 2018: £5.6m). BioSurgery has increased by 33% and our joint venture, GBM-V, has increased by 19% on a reported basis. As a result of manufacturing capacity constraints in the first half, Orthopaedics and Dental revenues decreased by 5%.

#### Margin

Margin decreased in H1 from 56% to 47% reflecting short term higher cost absorption as the second shift was brought up to full efficiency and an adverse sales mix as lower BioRinse® product volumes (generally our higher margin products) contributed less to the overall total.

## Loss for the year

Operating loss in the six months ended 30 June 2019 improved to £4,220K (H1 2018: £4,736K).

R&D tax credits of £352K (H1 2018: £353K) represent the estimated tax credit receivable, together with a premium of 40%, on development costs.

Exceptional costs of £40k represent the costs of the MidCap Financial Trust (MidCap) loan facility.

#### Cash position

Cash position for the Group at 30 June 2019 is £10.1m (H1 2018: £12.2m). The Group received the first tranche of the MidCap loan at \$7.5m in June 2019, and has available the initial revolving credit facility of up to \$3.0m.

#### **Current trading and Outlook**

During the first half of the year, we made significant operational progress, both in terms of our production and supply chain capabilities, investment in key appointments, and secured further funding to underpin the development of the business and to allow for our continued expansion. With this now in place, the long-term outlook for our product portfolio remains positive and our focus will be on executing against our strategic focus areas to drive forward commercial momentum.

We continue to look at ways to develop relationships with our strategic partners and have entered investigational discussions for geographic expansion through licensing or distribution agreements with a number of additional potential partners.

Demand for our products is strong, evidenced by our healthy order book from key customers, which we expect to fulfil as the operational improvements come to fruition. As capacity is increased, it will allow us greater flexibility to pursue the varied commercial opportunities we see for the products in the market.

We anticipated that the year would be significantly weighted towards the second half, as announced on the 4 June 2019, at the time of the Company's results for the year ended 31 December 2018. We continue to expect that this will be the case, and, against a background where we see the ever growing demand for our products as the business looks to increase its manufacturing capabilities, the ability to bring this on stream during the second half of the year will be key in determining the year end outcome.

# CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED) FOR THE SIX MONTHS TO 30 JUNE 2019

	Notes	6 months 30 Jun 2019 (Unaudited) £'000	6 months 30 Jun 2018 (Unaudited) £'000	Year 31 Dec 2018 Audited £'000
Revenue		6,069	5,574	11,619
Cost of sales		(3,225)	(2,451)	(5,702)
Gross Profit		2,844	3,123	5,917
Administrative expenses before exceptional items		(7,024)	(7,359)	(14,183)
Exceptional items		(40)	(500)	(423)
Total administrative expenses		(7,064)	(7,859)	(14,606)
Operating loss		(4,220)	(4,736)	(8,689)
Finance income		11	42	72
Finance charges		(183)	(146)	(262)
Loss before tax		(4,392)	(4,840)	(8,879)
Taxation	4	311	305	620
Loss after tax		(4,081)	(4,535)	(8,259)
Attributable to:		(4.055)	(4.446)	(0.400)
Equity holders of the parent Non-controlling		(4,055) (26)	(4,446) (89)	(8,186) (73)
Non-controlling		(4,081)	(4,535)	(8,259)
		(4,001)	(4,000)	(0,200)
Other comprehensive income/(expense): Foreign currency translation differences –				
foreign operations		122	531	1,360
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR		(3,959)	(4,004)	(6,899)
Attributable to:				
Equity holders of the parent		(3,933)	(3,915)	(6,826)
Non-controlling interests		(26)	(89)	(73)
		(3,959)	(4,004)	(6,899)
Loss per share				
Basic and diluted on loss attributable to equity holders of the parent	5	(0.35p)	(0.38)p	(0.70)p

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

# CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (UNAUDITED) FOR THE SIX MONTHS TO 30 JUNE 2019

# Attributable to equity holders of parent

	Share Capital £000	Share Premium £000	Merger Reserve £000	Reverse Acquisition Reserve £000	Reserve For Own Shares £000	Share Based Payment Reserve £000	Retained Earnings Deficit £000	Total £000	Non- controlling Interests £000	Total Equity £000
At 31 December 2017	5,855	86,398	10,884	(7,148)	(831)	1,186	(56,413)	39,931	(409)	39,522
Loss for the period Other comprehensive	-	-	-	-	-	-	(4,446)	(4,446)	(89)	(4,535)
expense	-	-	-	-	-	-	531	531	-	531
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(3,915)	(3,915)	(89)	(4,004)
Exercise of share options	4	-	-	-	-	-	-	4	-	4
Share based payment expense	-	-	-	-	-	212	-	212	-	212
At 30 June 2018	5,859	86,398	10,884	(7,148)	(831)	1,398	(60,328)	36,232	(498)	35,734
Loss for the period Other comprehensive	-	-	-	-	-	-	(3,740)	(3,740)	16	(3,724)
expense	-	-	-	-	-	-	829	829	-	829
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(2,911)	(2,911)	16	(2,895)

At 30 June 2019	5,859	86,398	10,884	(7,148)	(831)	1,147	(67,172)	29,137	(508)	28,629
expense										
payment										
Share based	-	-	-	-	-	18	-	18	-	18
period										
expense for the										
comprehensive							•			•
Loss and total	-	-	-	-	-	-	(3,933)	(3,933)	(26)	(3,959)
expense	-	-	-	-	-	-	122	122	-	122
comprehensive										
Other										
period							,	,	,	( , ,
Loss for the	-	-	-	-	-	-	(4,055)	(4,055)	(26)	(4,081)
2018										
At 31 December	5,859	86,398	10,884	(7,148)	(831)	1,129	(63,239)	33,052	(482)	32,570
expense										
payment										
Share based	-	-	-	-	-	(269)	-	(269)	-	(269)

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED) AS AT 30 JUNE 2019

	Notes	30 June 2019 £'000	30 June 2018 £'000	31 Dec 2018 £'000
Non-current assets				
Property, plant and equipment		2,917	2,879	2,828
Intangible assets		19,614	19,486	19,938
Total non-current assets		22,531	22,365	22,766
Current assets				
Inventory		2,738	2,540	2,330
Trade and other receivables		3,041	3,554	3,551
Corporation tax receivable		900	925	1,200
Cash and cash equivalent		10,076	12,215	7,816
Total current assets		16,755	19,234	14,897
Total assets		39,286	41,599	37,663
Non-current liabilities				_
Long term debt		(5,790)	(3,713)	-
Deferred tax		(755)	(797)	(791)
Total non-current liabilities		(6,545)	(4,510)	(791)
Current liabilities				
Trade and other payables		(4,112)	(1,355)	(4,302)
Total current liabilities		(4,112)	(1,355)	(4,302)
Total liabilities		(10,657)	(5,865)	(5,093)
Net assets		28,629	35,734	32,570
Equity				
Share capital	6	5,859	5,859	5,859
Share premium	6	86,398	86,398	86,398
Merger Reserve	6	10,884	10,884	10,884
Reverse acquisition reserve	6	(7,148)	(7,148)	(7,148)
Reserve for own shares		(831)	(831)	(831)
Share based payment reserve		1,147	1,398	1,129
Retained earnings deficit	7	(67,172)	(60,328)	(63,239)
Equity attributable to equity holders of		29,137	36,232	33,052
parent				
Non-controlling interests		(508)	(498)	(482)
Total equity		28,629	35,734	32,570

Approved by the Board and authorised for issue on 10 September 2019

# CONDENSED CONSOLIDATED CASH FLOW STATEMENT (UNAUDITED) FOR THE SIX MONTHS ENDED 30 JUNE 2019

	Notes	6 months to 30 June 2019 £'000	6 months to 30 June 2018 £'000	12 months to 31 Dec 2018 £'000
Operating Activities				
Operating loss		(4,220)	(4,736)	(8,689)
Adjustment for non-cash items:				
Depreciation of property, plant & equipment		273	283	598
Amortisation of intangible assets		282	267	575
Share based payment		18	212	(57)
Research tax credit received		653	1,047	1,225
Finance Charges		(183)	(28)	-
Operating cash outflow		(3,177)	(2,955)	(6,348)
Increase/ decrease in inventory		(408)	399	542
Increase/ decrease in trade & other		468	(603)	(1,188)
receivables				
Increase/ decrease in trade & other payables		(482)	(1,007)	156
Net cash outflow from operations		(3,599)	(4,166)	(6,838)
Investing activities				
Interest received		11	42	72
Purchase of property, plant & equipment		(366)	(113)	(290)
Capitalised development expenditure		-	(24)	(116)
Acquisition of subsidiary		-	-	(1,564)
Net cash outflow from investing activities		(355)	(95)	(1,898)
Financing activities				
Proceeds from issue of share capital		-	-	-
Proceeds from exercised share options		-	4	4
Proceeds from loan		6,114	-	-
Net cash inflow from financing activities		6,114	4	4
Increase/ (decrease) in cash and cash equivalents		2,160	(4,257)	(8,732)
Foreign exchange translation movement		100	49	125
Cash and cash equivalents at start of period		7,816	16,423	16,423
Cash and cash equivalents at end of		10,076	12,215	7,816
period		-		•

# NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) FOR THE SIX MONTHS ENDED 30 JUNE 2019

### 1. Basis of preparation

The condensed financial statements are not statutory accounts, have not been audited and, as permitted under the AIM Rules, do not comply with IAS 34 "Interim Financial Reporting".

The accounting policies adopted are in accordance with International Financial Reporting Standards and are consistent with those expected to be applied in the preparation of the audited financial statements for the year ending 31 December 2019, including the adoption of the following new standard with effect from 1<sup>st</sup> January 2019:

#### IFRS 16 Leases

The comparative figures for the year ended 31 December 2018 are from the statutory accounts. Those accounts have been reported on by the Company's Auditor and delivered to the Registrar of Companies. The report of the Auditor was unqualified, did not include reference to any matters by way of emphasis and did not contain a statement under section 498 of the Companies Act 2006.

This is the first set of results since the adoption of IFRS 16 which has caused no material impact to the Group's financial statements as the Group has been able to benefit from the exemption for leases with less than 12 months left to run.

# 2. Segmental reporting

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

	6 months to	6 months to	12 months
	30 June	30 June	to
Notes	2019	2018	31 Dec
	£'000	£'000	2018
			£'000
USA	4,961	4,559	9,434
Rest of world	1,108	1,015	2,185
	6,069	5,574	11,619

6 months to 30	BioSurgery	Orthopaedics & Dental	Cardiac	Other	Central	Total
June 2019	£'000	£'000	£'000	£'000	£'000	£'000
Revenue	1,963	3,049	-	1,057	-	6,069
Cost of sales	(1,095)	(1,430)	-	(700)	-	(3,225)
<b>Gross Profit</b>	868	1,619	-	357	-	2,844
Administrative costs	(2,018)	(2,319)	(193)	(289)	(2,205)	(7,024)
Exceptional costs	-		-	-	(40)	(40)
Operating loss	(1,150)	(700)	(193)	68	(2,245)	(4,219)
Finance income	-	-	-	-	11	11
Finance charges	-	-	-	-	(183)	(183)
Loss before taxation	(1,150)	(700)	(193)	68	(2,417)	(4,392)
Taxation	-	-	-	-	311	311
Loss for the year	(1,150)	(700)	(193)	68	(2,106)	(4,081)

6 months to 30	BioSurgery	Orthopaedics & Dental	Cardiac	Other	Central	Total
June 2018	£'000	£'000	£'000	£'000	£'000	£'000
Revenue	1,478	3,205	-	891	-	5,574
Cost of sales	(732)	(1,115)	-	(604)	-	(2,451)
<b>Gross Profit</b>	746	2,090	-	287	-	3,123
Administrative costs	(2,042)	(2,835)	(224)	(272)	(1,986)	(7,359)
Exceptional costs	-	-	-	-	(500)	(500)
Operating loss	(1,296)	(745)	(224)	15	(2,486)	(4,736)
Finance income	-	-	-	-	42	42
Finance charges	-	-	-	-	(146)	(146)
Loss before taxation	(1,296)	(745)	(224)	15	(2,590)	(4,840)
Taxation	(6)	259	52	-	-	305
Loss for the year	(1,302)	(486)	(172)	15	(2,590)	(4,535)

12 months to 31 December	BioSurgery	Orthopaedics & Dental	Cardiac	Other	Central	Total
2018	£'000	£'000	£'000	£'000	£'000	£'000
Revenue	3,381	6,396	-	1,842	-	11,619
Cost of sales	(1,769)	(2,676)	-	(1,257)	-	(5,702)
<b>Gross Profit</b>	1,612	3,720	-	585	-	5,917
Administrative costs	(4,169)	(4,992)	(428)	(551)	(4,043)	(14,183)
Exceptional costs	-	-	-	-	(423)	(423)
Operating loss	(2,557)	(1,272)	(428)	34	(4,466)	(8,689)
Finance income	-	-	-	-	(190)	(190)
Finance charges	-	-	-	-	-	-
Loss before taxation	(2,557)	(1,272)	(428)	34	(4,656)	(8,879)
Taxation	73	543	102	-	(98)	620
Loss for the year	(2,484)	(729)	(326)	34	(4,754)	(8,259)

#### 3. Taxation

	6 months to 30 June 2019 £'000	6 months to 30 June 2018 £'000	12 months to 31 Dec 2018 £'000
Current Tax:			
UK corporation tax credit on research and	(353)	(352)	(790)
development costs in the period			
US corporation tax	42	47	72
	(311)	(305)	(718)
Deferred tax:			
Origination and reversal of temporary timing			
differences	-	-	98
Tax credit on loss on ordinary activities	(311)	(305)	(620)

The Group has accumulated losses available to carry forward against future trading profits.

# 4. Loss per share (basic and diluted)

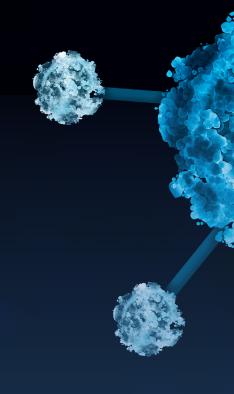
Basic loss per share is calculated by dividing the loss attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period excluding own shares held jointly by the Tissue Regenix Employee Share Trust and certain employees. Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares in issue during the period to assume conversion of all dilutive potential ordinary shares.

	6 months to 30 June 2019 £'000	6 months to 30 June 2018 £'000	12 months to 31 Dec 2018 £'000
Total loss attributable to the equity	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		
holders of the parent	(4,055)	(4,446)	(8,186)
	No.	No.	No.
Weighted average number of ordinary shares in issue during the period	1,171,534,448	1,171,534,448	1,171,633,442
Loss per share			
Basic and diluted on loss for the period	(0.35)p	(0.38)p	(0.70)p

The Company has issued employees options over 23,786,780 ordinary shares and there are 16,940,386 jointly owned shares which are potentially dilutive. There is, however, no dilutive effect of these issued options as there is a loss for each of the periods concerned.

# 5. Interim financial report

A copy of this interim report is available on the Company's website at www.tissueregenix.com in accordance with AIM Rule 20.



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