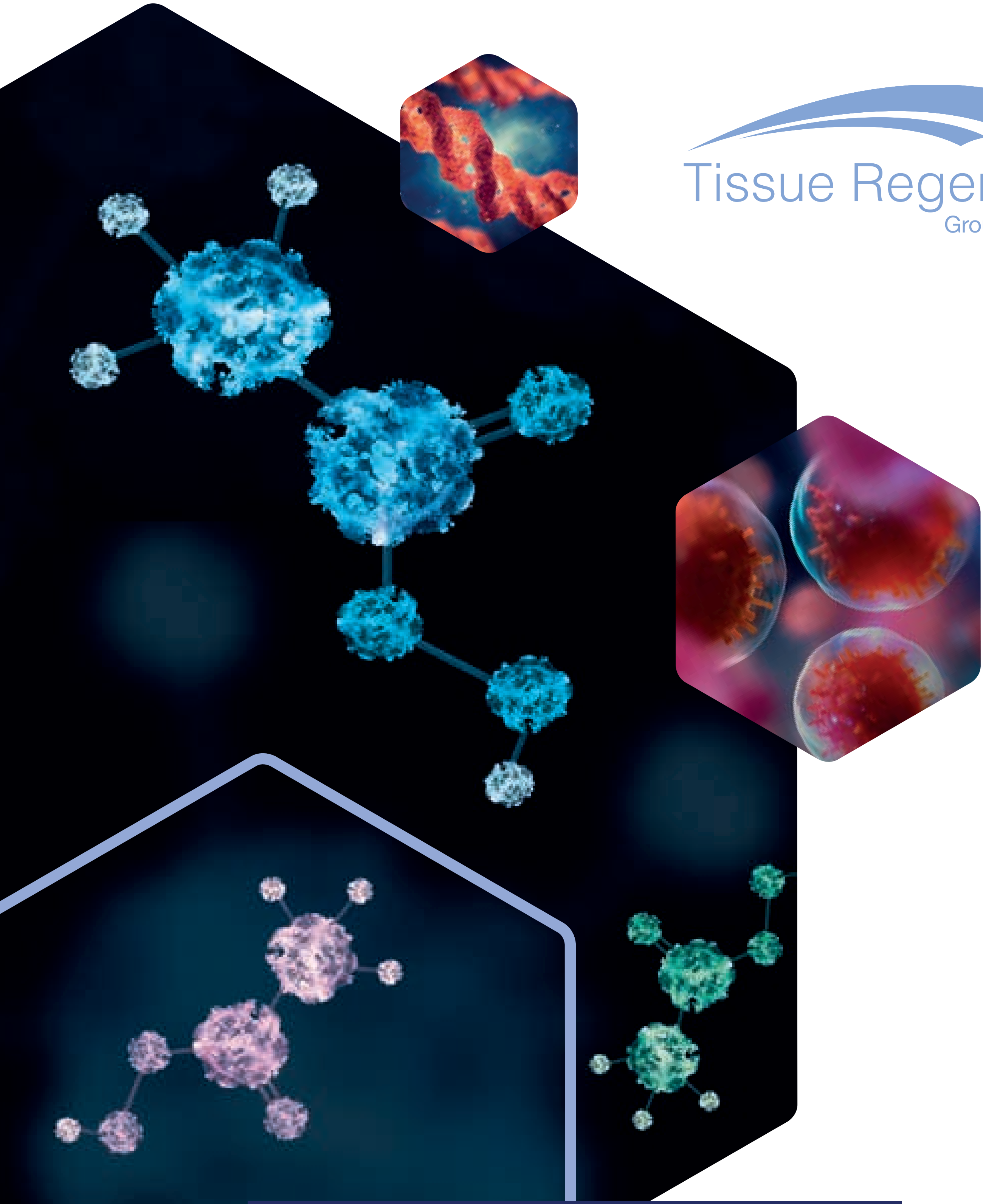
Tissue Regenix Group plc



Unaudited Interim Financial Report

For the six months up to June 30 2020

Stock Code: TRX

Contents

Interim Non-Executive Chairman, Jonathan Glenn

Despite the unprecedented backdrop of the COVID-19 pandemic and the additional challenges that this presented, during the first six months of 2020 the Group achieved a number of operational and commercial milestones and it is encouraging to see progress on a number of fronts.

Throughout this period, where lockdown restrictions were in place in both the US and Europe, our US facility remained fully operational enabling us to continue to supply our customer base. Although, the postponement of elective surgical procedures has been felt across the industry, encouragingly we have delivered revenues for the first half of the year which are in line with the comparative 2019 period.

We remain focused on our programme to rationalise the Company's cost base, which was initiated in 2019. This process has continued into 2020, including the plan to relocate the UK head office and manufacturing facility and, in conjunction with careful management of costs across the Group, we have continued to make significant reductions to our overall cash requirements and overhead base.

In June 2020, the Group secured £13.8m (net) of funding via an equity placing to support the Group's expansion plans and working capital requirements. Capacity constraints have historically restricted the ability of the business to meet customer demand and these additional funds will enable the Group to implement a capacity expansion programme at its US facility. I am happy to report that the first phase of this commenced in July 2020 and it is anticipated to come on-stream in H1 2021. I would like to take this opportunity to thank both our existing and new shareholders who have supported us in the fundraise.

Outlook

Having secured the required financing to support the capacity expansion project and working capital requirements, the business is focussed on delivering the additional production capabilities in a timely manner and, once operational, we will be positioned to achieve future growth potential as markets stabilise following the COVID-19 pandemic.

Given the uncertainty around the current COVID-19 situation, the potential for a second wave and the time it will take for postponed surgeries to be undertaken, it is difficult for the Board to provide forward looking guidance for the second half of 2020 and beyond. However, in spite of this uncertainty, the Board is encouraged by the progress we have made in the first half of the year, with the start of the expansion programme at the San Antonio facility, attaining the CE mark certification for OrthoPure® XT and a reduction in the overhead base whilst maintaining revenues, and as such remain confident about the future prospects for the Group.

Business Review, Gareth Jones, Interim Chief Executive Officer

Revenue

During H1 the Group continued to make operational and commercial progress, despite the backdrop of COVID-19, ending the first half with year-on-year sales maintained in-line with the first six months of the prior year at £6.1m (H1 2019: £6.1m).

The BioRinse portfolio, under the Orthopaedics and Dental division, returned sales of £3.4m (H1 2019: £3.0m) a £0.4m year-on-year increase (£0.3m at constant currency), despite the challenging market conditions; highlighting the demand for our product portfolio and its potential once more normalised market conditions return.

DermaPure sales, under the BioSurgery division, were impacted by the postponement of elective surgical procedures in the US as a result of the COVID-19 pandemic. This was primarily related to urogynecology procedures and the North East region of the US which was particularly badly affected during H1. Overall sales for the first 6 months of the year were down by £0.3m year-on-year to £1.7m (H1 2019: £2.0m, £2.0.m at constant currency).

In Germany, our business was impacted by the lockdown restrictions imposed early in the pandemic. Although a more normalised level of business has now returned, the impact of this lockdown was still felt with sales of £1.0m (H1 2019: £1.1m) for the first six months of the year.

During this period, the business was also able to secure a number of additional customers and as restrictions implemented as part of the pandemic are relaxed, in conjunction with enhanced operational capabilities coming on stream, the Group will be well placed to capitalise on these opportunities.

Commercial development

During the first half of the year, the Group achieved a number of commercial milestones which will support our strategic growth drivers and provide the basis for additional opportunities in the future.

In May 2020, we announced a strategic collaboration with a top 10 global healthcare company for white label manufacturing of a new soft tissue orthopaedic product, which was the result of an R&D collaboration between the two companies. We have seen a positive market response to this launch and anticipate that this product line will make a material contribution to our top line revenue growth across the next two years.

In addition, we received the CE mark for OrthoPure® XT in June 2020, and in August 2020 we announced our first distribution agreement with a specialist supplier of orthopaedic and biologic products covering the UK market. The first modest order has been received and we expect that the initial delivery will take place during Q4 2020.

Operations

Throughout the first six months of the year we were able to fully maintain operations at our San Antonio facility. During this time, we were also granted US Government backed loans of c.$1m to support the employee payroll, healthcare, utilities and rent payments in the US. As these funds were used in the required manner, under the terms of the loans, we anticipate that the loans will be forgiven and will not require repayment. In the UK, operations and technical staff were furloughed for a period in line with the UK Government advice. With the UK business gearing up its operational capabilities to ensure the supply of OrthoPure® XT and recommencing various clinical programmes, all furloughed staff were re-engaged in July.

Having identified the need to expand our processing facility in San Antonio, TX, to meet the increasing demand for our products, a second shift was implemented in the current facility during 2019 and we began to see the benefits of this during Q4 2019 and into H1 2020. Furthermore, in August 2019, additional operational capabilities were secured via a lease with an option to buy on a 21,000 sq. ft facility adjacent to the current plot. Proceeds from the £13.8m equity fundraise completed in June 2020 will enable this facility to be fitted out, with the first phase of the expansion programme initiated in July 2020.

This capacity expansion project will be undertaken in phases in order to deploy the investment capital in the most efficient manner and bring the new capacity onstream in a staged process to meet the increasing demand. Phase one will involve moving freezer and distribution functions into the new facility which will in turn allow space for additional sterile packaging clean rooms to be installed in the existing facility. Phase two of the project will provide a further 10 additional clean rooms in the new facility.

Funding and cost savings

In June 2020, the Group raised net funds of £13.8m through an accelerated book build and PrimaryBid offering. This capital will be used to fund the required investment programme and to provide working capital to support the business.

During 2019, the business commenced a review of its cost base with a view to appropriately sizing its overhead expenditure whilst continuing to support operational and commercial activities. This has continued into 2020 the latest results of which are considered in the post balance sheet events section. Overall, in the first six months of the year this programme has contributed to the business being able to report a reduction in overheads, excluding exceptional costs, of £1.7m in comparison to the first six months of 2019.

Financial Overview

Revenue

During the first six months of the year revenue remained in line with the first six months of 2019 at £6.1m (H1 2019: £6.1m, £6.2m on a constant currency basis).

The Orthopaedic and Dental division recorded an increase in revenues at £3.4m (H1 2019: £3.0m, £3.1m at constant currency), as the delays in elective surgeries caused by the pandemic, particularly in the dental sector, were more than offset by demand elsewhere. In contrast, the BioSurgery division recorded a decrease in revenues to £1.7m (H1 2019: £2.0m, £2.0m at constant currency) also caused by the impact of the COVID-19 pandemic on elective surgeries, particularly in urogynaecology and the North East region of the USA. The impact of the pandemic also affected output in Germany where revenues were reported at £1.0m (H1 2019: £1.1m, £1.1m at constant currency).

Margin

Margin has increased slightly for the period from 47% to 48% largely due to product mix as BioRinse products from the Orthopaedics and Dental division made up a greater proportion of revenues.

Loss for the year

Operating loss in the six months ended 30 June 2020 reduced to £2.5m (H1 2019: £4.5m). The cost restructuring programme commenced at the end of 2019 reduced administrative expenses by £1.7m (excluding exceptionals) during the first six months compared with the comparable period in 2019. Whilst a small part of the reduction was COVID-19 related given travel restrictions and furloughed staff, the majority of these reductions are permanent and anticipated to continue into the second half of the year.

R&D tax credits of £0.2m (H1 2019: £0.4m) represent the estimated tax credit receivable, together with a premium of 40%, on development costs. The anticipated decrease is expected to arise as more resources are directed away from the development phase and the business looks to commercialise more products.

Exceptional costs of £0.1m for 2020 represent the costs incurred in relation to the cyber security incident in the USA.

Cash position

Cash position for the Group at 30 June 2020 was £13.7m (H1 2018: £10.1m). The Group raised net proceeds of £13.8m through a placing in June 2020.

Post balance sheet events

Phase one of the capacity expansion project was commenced in July 2020 and it is expected to take approximately six months to complete. We expect to see the first uplift to the output in processing from this investment in Q2 2021, following the three-month lead time for the osteoinductive testing required for the BioRinse products.

In August 2020, we announced that the UK head office and manufacturing facility will be relocated to Garforth, Leeds in November 2020 from the current site in Swillington, Leeds. This decision was made as part of the ongoing initiatives to appropriately size the overhead cost base. This move is expected to reduce the Group's overhead costs by over £0.4m on an annualised basis from 2021. As part of the relocation programme, the Group will outsource elements of the production cycle, including testing and packaging. It will retain its processing functions, including the processing of OrthoPure® XT, enabling the Group to meet its initial order due in Q4 2020, and future demand following the agreement signed in August 2020 for UK distribution.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED)
FOR THE SIX MONTHS TO 30 JUNE 2020

	Notes	6 months 30 Jun 2020 (Unaudited) £'000	6 months 30 Jun 2019 (Unaudited) £'000	Year 31 Dec 2019 Audited £'000
Revenue	2	**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)**
Finance income		3	11	17
Finance Charges		(173)	(183)	(477)
Loss before tax		**(2,696)**	**(4,392)**	**(7,660)**
Taxation	3	297	311	554
Loss after tax		**(2,399)**	**(4,081)**	**(7,106)**
Attributable to:				
Equity holders of the parent		**(2,345)**	**(4,055)**	**(6,973)**
Non-controlling		**(54)**	**(26)**	**(133)**
		(2,399)	**(4,081)**	**(7,106)**
Other comprehensive income/(expense):				
Foreign currency translation differences – foreign operations		**444**	**122**	**(724)**
TOTAL COMPREHENSIVE EXPENSE FOR THE YEAR		**(1,955)**	**(3,959)**	**(7,830)**
Attributable to:				
Equity holders of the parent		**(1,901)**	**(3,933)**	**(7,697)**
Non-controlling interests		**(54)**	**(26)**	**(133)**
		(1,955)	**(3,959)**	**(7,830)**
Loss per share				
Basic and diluted on loss attributable to equity holders of the parent	4	**(0.16p)**	**(0.35p)**	**(0.60)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 2020

	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 2018	5,859	86,398	10,884	(7,148)	(831)	1,129	(63,239)	33,052	(482)	32,570
Loss for the period	-	-	-	-	-	-	(4,055)	(4,055)	(26)	(4,081)
Other comprehensive expense	-	-	-	-	-	-	122	122	-	122
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(3.933)	(3,933)	(26)	(3,959)
Share based payment expense	-	-	-	-	-	18	-	18	-	18
At 30 June 2019	5,859	86,398	10,884	(7,148)	(831)	1,147	(67,172)	29,137	(508)	28,629
Loss for the period	-	-	-	-	-	-	(2,918)	(2,918)	(107)	(3,025)
Other comprehensive expense	-	-	-	-	-	-	(846)	(846)	-	(846)
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(3,764)	(3,764)	(107)	(3,871)
Exercise of share options	-	1	-	-	-	-	-	1	-	1
Share based payment expense	-	-	-	-	-	(164)	-	(164)	-	(164)
At 31 December 2019	5,859	86,399	10,884	(7,148)	(831)	983	(70,936)	25,210	(615)	24,595
Loss for the period	-	-	-	-	-	-	(2,345)	(2,345)	(54)	(2,399)

Other comprehensive expense	-	-	-	-	-	-	444	444	-	444
Loss and total comprehensive expense for the period	-	-	-	-	-	-	(1,901)	(1,901)	(54)	(1,955)
Issue of shares	5,860	8,790	-	-	-	-	-	14,650	-	14,650
Expenses on issue of shares		(899)					-	(899)	-	(899)
Exercise of share options	1	-	-	-	-	-	-	1	-	1
Share based payment expense	-	-	-	-	-	18	-	18	-	18
At 30 June 2020	**11,720**	**94,290**	**10,884**	**(7,148)**	**(831)**	**1,001**	**(72,837)**	**37,079**	**(669)**	**36.410**

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION (UNAUDITED)
AS AT 30 JUNE 2020

	Notes	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**
Non-current liabilities				
Borrowings		(2,222)	(5,790)	(2,115)
Deferred tax		(714)	(755)	(670)
Total non-current liabilities		**(2,936)**	**(6,545)**	**(2,785)**
Current liabilities				
Borrowings		(850)	-	(171)
Trade and other payables		(3,392)	(4,112)	(2,944)
Total current liabilities		**(4,242)**	**(4,112)**	**(3,115)**
Total liabilities		**(7,178)**	**(10,657)**	**(5,900)**
Net assets		**36,410**	**28,629**	**24,595**
Equity				
Share capital	5	11,720	5,859	5,859
Share premium	5	94,290	86,398	86,399
Merger Reserve	5	10,884	10,884	10,884
Reverse acquisition reserve	5	(7,148)	(7,148)	(7,148)
Reserve for own shares		(831)	(831)	(831)
Share based payment reserve		1,001	1,147	983
Retained earnings deficit		(72,837)	(67,172)	(70,936)
Equity attributable to equity holders of parent		**37,079**	**29,137**	**25,210**
Non-controlling interests		**(669)**	**(508)**	(615)
Total equity		**36,410**	**28,629**	**24,595**

Approved by the Board and authorised for issue on 2 September 2020

Gareth Jones (Interim Chief Executive Officer)

CONDENSED CONSOLIDATED CASH FLOW STATEMENT (UNAUDITED)
FOR THE SIX MONTHS ENDED 30 JUNE 2020

	6 months to 30 June 2020 £'000	6 months to 30 June 2019 £'000	12 months to 31 Dec 2019 £'000
Operating Activities			
Loss before Tax	**(2,696)**	**(4,392)**	**(7,660)**
Adjustment for:			
Depreciation of property, plant & equipment	101	273	476
Amortisation of intangible assets	319	282	570
Impairment of intangible and property, plant and equipment	-	-	1,311
Share based payment	18	18	(146)
Interest receivable	(3)	(11)	(17)
Interest payable	173	194	477
Operating cash outflow	**(2,088)**	**(3,636)**	**(4,989)**
(Increase) in inventory	(2,103)	(408)	(1,855)
(Increase)/decrease in trade & other receivables	(90)	258	1,076
Increase/(decrease) in trade & other payables	665	(466)	(1,567)
Cash outflows from operations	**(3,616)**	**(4,252)**	**(7,335)**
Research and Development Tax Credits received	649	653	653
Net cash outflow from operations	**(2,967)**	**(3,599)**	**(6,682)**
Investing activities			
Interest received	3	11	17
Purchase of property, plant & equipment	(53)	(366)	(438)
Capitalised development expenditure	-	-	(213)
Net cash outflow from investing activities	**(50)**	**(355)**	**(634)**
Financing activities			
Interest paid	(173)	-	(384)
Proceeds from issue of share capital	13,752	-	-
Proceeds from exercised share options	-	-	1
Proceeds from new loans	850	6,114	6,479
Repayment of loans	(237)	-	(4,193)
Net cash inflow from financing activities	**14,192**	**6,114**	**1,903**
Increase/(decrease) in cash and cash equivalents	**11,175**	**2,160**	**(5,413)**
Foreign exchange translation movement	112	100	(23)
Cash and cash equivalents at start of period	2,380	7,816	7,816
Cash and cash equivalents at end of period	**13,667**	**10,076**	**2,380**

1. Basis of preparation

The unaudited condensed consolidated interim financial information does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. The interim financial statements, which are unaudited and have not been reviewed by the Company's auditors, have been prepared in accordance with the policies set out in the 2019 Annual Report and Accounts.

The comparative figures for the year ended 31 December 2019 do not constitute full financial statements and have been abridged from the full accounts for the year ended on that date, on which the auditors gave an unqualified report, but did contain an emphasis of matter paragraph in respect of the Group's ability to continue as a going concern due to the fundraise being conditional on shareholder approval. They did not contain any statement under Section 498 of the Companies Act 2006. The 2019 accounts have been delivered to the Registrar of Companies. The Company has chosen not to adopt IAS 34 'Interim Financial Statements'.

2. Segmental reporting

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

	Notes	6 months to 30 June 2020 £'000	6 months to 30 June 2019 £'000	12 months to 31 Dec 2019 £'000
USA		**5,050**	4,961	10,679
Rest of world		**1,035**	1,108	2,354
		6,085	**6,069**	**13,033**

6 months to 30 June 2020	BioSurgery £'000	Orthopaedics & Dental £'000	Cardiac £'000	GBM-V £'000	Central £'000	Total £'000
Revenue	1,710	3,418	-	957	-	6,085
Cost of sales	(1,021)	(1,569)	-	(560)	-	(3,150)
Gross Profit	689	1,849	-	397	-	2,935
Administrative costs	(1,417)	(2,112)	(164)	(320)	(1,342)	(5,355)
Exceptional costs	(22)	(84)	-	-	-	(106)
Operating profit/(loss)	(750)	(347)	(164)	77	(1,342)	(2,526)
Finance income	-	-	-	-	3	3
Finance charges	-	-	-	-	(173)	(173)
Profit/(loss) before taxation	(750)	(347)	(164)	77	(1,512)	(2,696)
Taxation	27	163	59	-	48	297
Profit/(loss) for the period	(723)	(184)	(105)	77	(1,464)	(2,399)

6 months to 30 June 2019	BioSurgery £'000	Orthopaedics & Dental £'000	Cardiac £'000	GBM-V £'000	Central £'000	Total £'000
Revenue	1,963	3,049	-	1,057	-	6,069
Cost of sales	(1,095)	(1,430)	-	(700)	-	(3,225)
Gross Profit	868	1,619	-	357	-	2,844
Administrative costs	(2,018)	(2,319)	(193)	(289)	(2,205)	(7,024)
Exceptional costs	-		-	-	(40)	(40)
Operating profit/(loss)	(1,150)	(700)	(193)	68	(2,245)	(4,220)
Finance income	-	-	-	-	11	11
Finance charges	-	-	-	-	(183)	(183)
Profit/(loss) before taxation	(1,150)	(700)	(193)	68	(2,417)	(4,392)
Taxation	80	191	40	-	-	311
Profit/(loss) for the period	(1,070)	(509)	(153)	68	(2,417)	(4,081)

12 months to 31 December 2019	BioSurgery £'000	Orthopaedics & Dental £'000	Cardiac £'000	GBM-V £'000	Central £'000	Total £'000
Revenue	4,233	6,724	-	2,076	-	13,033
Cost of sales	(2,535)	(3,076)	-	(1,403)	-	(7,014)
Gross Profit	1,698	3,648	-	673	-	6,019
Administrative costs	(3,729)	(4,553)	(328)	(663)	(3,925)	(13,198)
Exceptional costs	(1,124)	1,523	-	(152)	(268)	(21)
Operating profit/(loss)	(3,155)	618	(328)	(142)	(4,193)	(7,200)
Finance income	-	-	-	-	17	17
Finance charges	-	-	-	-	(477)	(477)
Profit/(loss) before taxation	(3,155)	618	(328)	(142)	(4,653)	(7,660)
Taxation	159	283	80	-	32	554
Profit/(loss) for the period	(2,996)	901	(248)	(142)	(4,621)	(7,106)

3. Taxation

	6 months to 30 June 2020 £'000	6 months to 30 June 2019 £'000	12 months to 31 Dec 2019 £'000
Current Tax:			
UK corporation tax credit on research and development costs in the period	(249)	(353)	(488)
US corporation tax	-	42	29
	(249)	**(311)**	**(459)**
Deferred tax:			
Origination and reversal of temporary timing differences	(48)	-	(95)
Tax credit on loss on ordinary activities	**(297)**	**(311)**	**(554)**

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 2020 £'000	6 months to 30 June 2019 £'000	12 months to 31 Dec 2019 £'000
Total loss attributable to the equity holders of the parent	**(2,345)**	**(4,055)**	**(6,973)**

	No.	No.	No.
Weighted average number of ordinary shares in issue during the period	**1,493,073,354**	**1,171,534,448**	**1,171,867,216**
Loss per share			
Basic and diluted on loss for the period	(0.16)p	(0.35)p	(0.60)p

The Company has issued employees options over 10,419,817 ordinary shares and there are 16,112,800 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. Share capital

	30 June 2020 £'000	30 June 2019 £'000	31 Dec 2019 £'000
Ordinary shares of 0.1 pence	7,033	-	-
Deferred shares of 0.4 pence	4,687	-	-
Ordinary shares of 0.5 pence	-	5,859	5,859
	11,720	**5,859**	**5,859**

Movements on share capital during the period were as follows:

	Ordinary shares		Deferred shares	
	Number	**£'000**	**Number**	**£'000**
At 31 December 2018	**1,171,730,823**	**5,859**	**-**	**-**
Issued on exercise of share options	-	-	-	-
At 30 June 2019	**1,171,730,823**	**5,859**	**-**	**-**
Issued on exercise of share options	240,499	-	-	-
At 31 December 2019	**1,171,971,322**	**5,859**	**-**	**-**
Sub-division of shares	1,171,971,322	(4,687)	1,171,971,322	4,687
Issued on exercise of share options	1,388,222	1	-	-
Issue of shares	5,859,626,212	5,860	-	-
At 30 June 2020	**7,032,985,756**	**7,033**	**1,171,971,322**	**4,687**

On the 9th June a special resolution was passed at the general meeting for the 1,171,971,322 Ordinary Shares of 0.5 pence each in the issued share capital of the Company be sub-divided into 1,171,971,322 Ordinary Shares of 0.1 pence each in the capital of the Company and 1,171,971,322 Deferred Shares of 0.4 pence each in the capital of the Company.

On the 9th June the Company also completed a successful fundraise of £14.6m gross.

6. Interim financial report

A copy of this interim report will be available on the Company's website at www.tissueregenix.com.