



6 December 2019

AIM: RENE

**ReNeuron Group plc**  
("ReNeuron" or "the Company")

### **Interim Results for the six months ended 30 September 2019**

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to announce its interim results for the six months ended 30 September 2019.

#### **Operational highlights**

##### hRPC stem cell therapy candidate for retinal disease:

- Positive top-line efficacy data presented from Phase 2a patients in ongoing US Phase 1/2a clinical trial in retinitis pigmentosa
- Ongoing Phase 2a study to be expanded to allow for subsequent potential single pre-approval clinical study and shorter route to market
- Further top-line efficacy data from expanded Phase 2a study expected to be presented during 2020

##### CTX stem cell therapy candidate for stroke disability:

- Clinical trial protocol amendments and other initiatives in place to accelerate patient recruitment in ongoing US Phase 2b clinical trial
- Significant increase planned in overall number of patients to receive CTX therapy as opposed to placebo procedure in Phase 2b study
- Overall size of Phase 2b study increased from 110 to 130 patients, with top line data expected in mid-2021

##### Exosome and iPS cell technologies:

- Grant-funded collaboration initiated with European Cancer Stem Cell Research Institute to enable delivery of therapeutic nucleic acids using CTX-derived exosomes
- New data presented, supporting use of CTX-derived iPSCs (induced pluripotent stem cells) to develop new immortalised cell lines as potential therapeutic agents for subsequent licensing to third parties

##### Increased business development activity:

- Exclusive out-licence agreement signed with Fosun Pharma to develop and commercialise hRPC and CTX programmes in China
  - ReNeuron to receive upfront, near term and estimated success-based milestone payments of £80.0 million plus double-digit royalties on sales
- Discussions ongoing with other commercial third parties regarding potential out-licence deals across all of ReNeuron's programmes

## Financial highlights

- Reduced loss for the period of £3.90 million (2018: loss of £5.36 million)
- Reduced cash consumed by operations of £5.15 million (2018: £7.54 million)
- Upfront payment of £5.40 million, net of withholding tax, received pertaining to licence agreement with Fosun Pharma
- Cash, cash equivalents and bank deposits at 30 September 2019 of £21.27 million (31 March 2019: £26.39 million)

## Commenting on the results, Olav Hellebø, Chief Executive Officer, said:

“The period under review has been marked by significant progress across our various clinical and research programmes. During the period, and subsequent to it, we presented very encouraging positive efficacy data from the Phase 2a patients in the ongoing US Phase 1/2a clinical trial of our hRPC cell therapy candidate in retinitis pigmentosa. We have taken advantage of these early results to amend our clinical development strategy with the aim of shortening the overall time to market approval application for this therapeutic candidate.

“During the period, we have instigated a number of protocol amendments and other initiatives to accelerate patient recruitment into the ongoing US Phase 2b clinical trial of our CTX cell therapy candidate in chronic stroke disability. These amendments will result in a greatly increased number of CTX-treated patients in the study. Additionally, we have been very encouraged to see the potential of our exosome and iPS cell technologies emerge further during the period.

“We are pleased to be working with Fosun Pharma as our partner for China, following the signing of the exclusive licence agreement for both our CTX and hRPC programmes in that territory during the period. We hope to be able to announce further deals with commercial third parties across our various programmes in the months ahead.”

## Analyst meeting and webcast:

A meeting for analysts will be held at 9.30am today at the offices of Buchanan, 107 Cheapside, London, EC2V 6DN.

For a webcast of the analyst presentation, please log on to the following web address approximately 10 minutes before 9.30am:

<https://webcasting.buchanan.uk.com/broadcast/5dcc32879535b1405a05b0bd>

For further details please contact Buchanan on 020 7466 5000 or email [reneuron@buchanan.uk.com](mailto:reneuron@buchanan.uk.com). A recording of the webcast will be made available on ReNeuron's website, [www.reneuron.com](http://www.reneuron.com).

## Enquiries:

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*This announcement contains inside information. The person responsible for arranging for the release of this announcement on behalf of the Company is Olav Hellebø, Chief Executive Officer.*

## **About ReNeuron**

ReNeuron is a global leader in cell-based therapeutics, harnessing its unique stem cell technologies to develop 'off the shelf' stem cell treatments, without the need for immunosuppressive drugs. The Company's lead clinical-stage candidates are in development for the blindness-causing disease, retinitis pigmentosa, and for disability as a result of stroke. ReNeuron is also advancing its proprietary exosome technology platform as a potential delivery system for drugs that would otherwise be unable to reach their site of action. ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. For further information visit [www.reneuron.com](http://www.reneuron.com).

*This announcement contains forward-looking statements with respect to the financial condition, results of operations and business achievements/performance of ReNeuron and certain of the plans and objectives of management of ReNeuron with respect thereto. These statements may generally, but not always, be identified by the use of words such as "should", "expects", "estimates", "believes" or similar expressions. This announcement also contains forward-looking statements attributed to certain third parties relating to their estimates regarding the growth of markets and demand for products. By their nature, forward-looking also statements involve risk and uncertainty because they reflect ReNeuron's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of factors could cause ReNeuron's actual financial condition, results of operations and business achievements/performance to differ materially from the estimates made or implied in such forward-looking statements and, accordingly, reliance should not be placed on such statements.*

## **Review of clinical programmes**

### ***hRPC (human retinal progenitor cells) for retinal disease***

During the period under review, and thereafter, we have made significant progress with our ongoing Phase 1/2a clinical trial in retinitis pigmentosa (RP). RP is a group of hereditary diseases of the eye that lead to progressive loss of sight due to cells in the retina becoming damaged and eventually dying.

The Phase 1/2a clinical trial is an open-label study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in patients with advanced RP. The Phase 2a segment of the study, which uses a cryopreserved hRPC formulation, enrolls subjects with some remaining retinal function and is being conducted at two clinical sites in the US – Massachusetts Eye and Ear in Boston and Retinal Research Institute in Phoenix, Arizona.

In April 2019, initial data from the first cohort of three patients in the Phase 2a segment of the study were presented at the sixth annual Retinal Cell and Gene Therapy Innovation Summit in Vancouver, Canada. The data demonstrated a sustained improvement in visual acuity compared with baseline in these patients, as measured by the number of letters read on the ETDRS chart (the standardised eye chart used to measure visual acuity in clinical trials).

In October 2019, further positive efficacy data from the study were presented at the American Academy of Ophthalmology Annual Meeting (AAO) in San Francisco. At this point, 22 patients had been treated in the study, consisting of 12 patients in the Phase 1 segment of the study and 10 patients in the Phase 2a segment of the study. Eight out of the ten Phase 2a patients treated had reached at least the one month follow up time point.

The visual acuity data presented at the AAO conference from the patients treated in the Phase 2a segment of the study continued to show the hRPC therapy's ability to deliver clinically meaningful signals of efficacy in a patient population where inexorable disease progression is the norm. The clinical trial data also continued to show a good overall safety profile for the hRPC therapy, with no immune or cell-related serious adverse events reported and isolated episodes of surgically related adverse events consistent with those expected for a sub-retinal injection procedure.

Taking advantage of the positive clinical data generated thus far, we intend to expand the ongoing Phase 2a segment of the study to generate further and longer-term follow up efficacy data in a larger group of RP patients during 2020. Our aim is to use this expanded data set, assuming it continues to be positive, to design and agree with the regulatory authorities a protocol for a subsequent single pre-approval clinical study for the hRPC therapy in RP. We believe that this strategy should lead to a shorter overall time to market approval application for the therapy than the clinical development strategy we were previously pursuing in this indication.

Our hRPC cell therapy candidate offers a number of potential advantages over alternative approaches to the treatment of RP. Firstly, our cell therapy candidate is independent of the many specific genetic defects that collectively define RP as a disease, thereby allowing a much broader potential patient population to be eligible for the treatment. Secondly, the cells are cryopreserved, enabling on-demand shipment and use at local surgeries and hospitals. Finally, the cells are injected directly to the site of retinal degeneration, allowing a greater chance of anatomic restoration of photoreceptor function.

Our RP clinical programme has been granted Orphan Drug Designation in both Europe and the US, as well as Fast Track designation from the FDA in the US. Orphan Drug Designation provides the potential for a significant period of market exclusivity once the therapy is approved in those territories. Fast Track designation provides eligibility for an accelerated approval and priority review process by the FDA.

### ***CTX for stroke disability***

During the period, we have continued to progress the clinical development of our CTX cell therapy candidate for stroke disability. This candidate is currently being evaluated in our PISCES III clinical study, a randomised, placebo-controlled, Phase 2b clinical trial being undertaken in the US.

Patients in the study are treated between 6 and 12 months after their stroke and are randomised to receive either CTX therapy or placebo treatment. The primary end-point of the PISCES III study is the proportion of patients showing a clinically important improvement (at least one point) on the modified Rankin Scale (mRS) at six months post-treatment compared with baseline. The mRS is a global measure of disability or dependence upon others in carrying out activities of daily living and is accepted by regulatory authorities as an appropriate end-point for marketing approval in stroke disability.

During the period and thereafter, we have pursued a number of initiatives to increase the rate of patient recruitment into the PISCES III clinical trial. These include various initiatives to better target eligible patients for the study as well as potential amendments to the clinical trial protocol itself. In particular, the clinical trial protocol has been amended to change the treatment randomisation ratio from 1:1, to 2:1 (that is, two out of three patients recruited into the study will now receive the CTX cell therapy as opposed to a placebo procedure). This amendment will increase the number of patients in the study who will be randomised to receive the CTX therapy from 55 to approximately 85 patients. We expect this to accelerate patient recruitment into the study as well as providing a broader data set of CTX-treated patients overall.

Further, the treatment window in the PISCES III clinical trial protocol has been increased from six to twelve months post-stroke, to six to 24 months post-stroke, thereby allowing for recruitment into the study from a larger pool of potentially eligible stroke survivors.

In order to maintain the statistical integrity of the study as a result of these protocol changes, the total number of patients to be treated in the PISCES III study will increase from 110 to

130 patients. As a result, we anticipate that top-line data from the PISCES III clinical trial will be available in mid-2021.

### **Exosome and iPSC cell technologies**

Our exosome technology is being exploited as a novel vector for delivering third party biological drugs. In July 2019, we announced the grant of a number of key patents in Europe, Japan, China and South Korea covering our neural stem cell-derived exosomes and their methods of production. In August 2019, we announced a new grant-funded collaboration with the European Cancer Stem Cell Research Institute at Cardiff University to develop novel systems to enable the delivery of therapeutic nucleic acids across the blood brain barrier using our CTX stem cell-derived exosomes.

In October 2019, we presented new data demonstrating the stability and scalability of new stem cell lines derived from the Company's CTX human neural stem cells following re-programming to an embryonic stem cell-like state. We have designated these reprogrammed CTX stem cells as CTX-iPSCs (or CTX-derived, induced pluripotent stem cells). In essence, this means that we are able to take our CTX neural stem cells back to being stem cells that are able to differentiate into any other type of stem cell, including bone, nerve, muscle and skin. Further, we showed that the new stem cell lines generated could be grown at scale by virtue of the Company's conditional immortalisation technology, enabling the efficient production of clinical-grade, allogeneic ("off the shelf") cell therapy candidates.

As a result of the above findings, we are currently exploring the potential of our CTX-iPSC technology to be utilised to develop further new, immortalised allogeneic cell lines of varying types as potential therapeutic agents in diseases of unmet medical need for subsequent licensing to third parties. For example, the production of allogeneic haematopoietic stem cells from our CTX-iPSCs could potentially provide an alternative approach to those cancer immunotherapies currently in development that rely on the use of the patient's own T-cells.

### **Business development activities**

In April 2019, we announced the signing of an exclusive licence agreement with Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. ("Fosun Pharma") for the development, manufacture and commercialisation of both our CTX and hRPC cell therapy programmes in the People's Republic of China ("China").

Under the terms of the licence agreement, Fosun Pharma will fully fund the development of our CTX and hRPC cell therapy programmes in China, including clinical development and subsequent commercialisation activities. Fosun Pharma has also been granted rights to manufacture the licensed products in China. In return, ReNeuron received £6.0 million (before withholding tax) on entering into the agreement and will receive up to £6.0 million in near-term operational milestones and up to £8.0 million in future regulatory milestone payments. In addition, ReNeuron will receive post-launch profit threshold milestone payments derived from the licensed products, leading to total estimated milestone payments of £80.0 million provided all milestones and profit thresholds are successfully met,

as well as tiered royalties at rates between 12% and 14% on sales of the licensed products in the Chinese market.

We are working closely with Fosun Pharma as it pursues the development, manufacture and commercialisation of our cell therapy programmes in the People's Republic of China, with the CTX programme being the initial focus of activities.

We remain in active discussions with other commercial third parties regarding potential collaboration and/or out-licensing deals across all of our programmes.

### **Other activities**

In August 2019, we were delighted to announce the appointment of Professor Robert MacLaren, Dr Sally Temple and Dr José-Alain Sahel to ReNeuron's Scientific Advisory Board. ReNeuron's Scientific Advisory Board is composed of leading academics and industry executives with a world-class breadth of expertise across the Company's areas of operation.

Professor Robert MacLaren is Professor of Ophthalmology at the University of Oxford, where he directs research into developing new clinical treatments for blindness, using stem cells, gene therapy and electronic retinal implants. In 2014, he co-founded Nightstar Therapeutics, a biotechnology company developing gene therapy treatments for patients with retinal diseases, which was acquired for \$800 million by Nasdaq-listed Biogen, Inc. in June 2019.

Dr Sally Temple is the Scientific Director of the Neural Stem Cell Institute in New York. She leads a team of 30 researchers focused on using neural stem cells to develop therapies for eye, brain, and spinal cord disorders.

Dr José-Alain Sahel is the chair of the Department of Ophthalmology at the University of Pittsburgh School of Medicine, of the UPMC Eye Center, and the Eye and Ear Foundation Endowed Chair of Ophthalmology. Dr Sahel founded Fovea Pharmaceuticals, which later became the Ophthalmology Division of Sanofi Aventis. He is also a scientific co-founder of GenSight Biologics, Pixium Vision and Sparing Vision.

### **Financial review**

In the six months to 30 September 2019, revenues were £6,030,000 (2018: £27,000), including an initial gross licence fee of £6.00 million received from Fosun Pharma in May 2019. Grant income of £64,000 was received and is shown as other operating income (2018: £508,000). In 2018, other operating income also included £1,893,000 in respect of an exclusivity fee received during licensing negotiations.

IFRS 16 was adopted during the period and the comparative figures for prior periods have been restated accordingly. Details are set out in note 16 to these Interim Financial Statements.

Total operating costs increased in the period to £11.80 million (2018: £10.12 million). Research and development expenditure increased to £9.23 million (2018: £7.54 million),

reflecting costs incurred in progressing the PISCES III clinical trial. General and administrative expenses remained constant at £2.58 million (2018: £2.58 million).

Finance income represents income received from the Group's cash and investments and gains from foreign exchange. Finance income was £0.59 million in the period (2018: £0.89 million) and included foreign exchange gains of £0.42 million (2018: £0.75 million). The Group holds cash and investments in foreign currencies in order to hedge against operational spend and the strengthening of the US Dollar against sterling during the period has resulted in a relative appreciation of the Group's foreign currency deposits. Finance expense comprises finance lease interest of £22,000 (2018: £19,000). The total tax credit for the period was £1.85 million (2018: £1.46 million). This was offset by overseas taxes paid of £0.60 million (2018: £Nil).

As a result of the above, the total comprehensive loss for the period reduced to £3.90 million (2018: £5.36 million).

Cash consumed by operations in the period reduced to £5.15 million (2018: £7.54 million), broadly reflecting the operating expenses incurred during the period, net of the initial licence fee of £5.40 million (after withholding tax) received from Fosun Pharma. The Group had cash, cash equivalents and bank deposits totalling £21.27 million as at 30 September 2019 (31 March 2019: £26.39 million).

## **Summary and outlook**

The period under review has been marked by significant progress across our various clinical and research programmes. During the period, and subsequent to it, we presented very encouraging positive efficacy data from the Phase 2a patients in the ongoing US Phase 1/2a clinical trial of our hRPC cell therapy candidate in retinitis pigmentosa. We have taken advantage of these early results to amend our clinical development strategy with the aim of shortening the overall time to market approval application for this therapeutic candidate.

During the period, we have instigated a number of protocol amendments and other initiatives to accelerate patient recruitment into the ongoing US Phase 2b clinical trial of our CTX cell therapy candidate in chronic stroke disability. These amendments will result in a greatly increased number of CTX-treated patients in the study. Additionally, we have been very encouraged to see the potential of our exosome and iPS cell technologies emerge further during the period.

We are pleased to be working with Fosun Pharma as our partner for China, following the signing of the exclusive licence agreement for both our CTX and hRPC programmes in that territory during the period. We hope to be able to announce further deals with commercial third parties across our various programmes in the months ahead.

**Olav Hellebø**

Chief Executive Officer

6 December 2019

## Interim Financial Statements

### Unaudited Consolidated Statement of Comprehensive Income for the six months ended 30 September 2019

		Six months ended 30 September 2019 £'000	Restated <sup>1</sup> Six months ended 30 September 2018 £'000	Restated <sup>1</sup> Year ended 31 March 2019 £'000
	Note			
Revenue	4	6,030	27	49
Other operating income	6	64	2,401	2,671
Research and development costs		(9,227)	(7,543)	(16,240)
General and administrative costs		(2,575)	(2,576)	(4,779)
<b>Operating loss</b>		<b>(5,708)</b>	(7,691)	(18,299)
Finance income	7	588	893	1,103
Finance expense	8	(22)	(19)	(39)
<b>Loss before income taxes</b>		<b>(5,142)</b>	(6,817)	(17,235)
Taxation	9	1,245	1,457	2,887
<b>Total comprehensive loss for the period</b>		<b>(3,897)</b>	(5,360)	(14,348)
<b>Total comprehensive loss attributable to equity owners of the Company</b>		<b>(3,897)</b>	(5,360)	(14,348)
<b>Basic and diluted loss per share</b>	10	<b>(12.3p)</b>	(16.9p)	(45.3p)

<sup>1</sup>For further details on the restatement of the reported results for IFRS 16 in the 6 months ended 30 September 2018 and the year ended 31 March 2019, see notes 2 and 16.

## Unaudited Consolidated Statement of Financial Position as at 30 September 2019

		30 September	Restated <sup>1</sup> 30 September	Restated <sup>1</sup> 31 March
	Note	2019 £'000	2018 £'000	2019 £'000
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment		557	727	632
Right-of-use-assets	11	654	707	704
Intangible assets		186	186	186
		<b>1,397</b>	1,620	1,522
<b>Current assets</b>				
Trade and other receivables		924	1,054	834
Corporation tax receivable		4,618	4,467	2,768
Investments – bank deposits		2,500	5,951	5,954
Cash and cash equivalents		18,771	24,722	20,432
		<b>26,813</b>	36,194	29,988
<b>Total assets</b>		<b>28,210</b>	37,814	31,510
<b>Equity</b>				
<b>Equity attributable to owners of the Company</b>				
Share capital	12	318	316	316
Share premium	12	97,888	97,704	97,704
Capital redemption reserve		40,294	40,294	40,294
Merger reserve		2,223	2,223	2,223
Accumulated losses		(120,499)	(108,781)	(117,293)
<b>Total equity</b>		<b>20,224</b>	31,756	23,244
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		7,038	5,046	7,261
Finance lease liability		154	108	141
		<b>7,192</b>	5,154	7,402
<b>Non-current liabilities</b>				
Finance lease liability		794	904	864
		<b>794</b>	904	864
<b>Total liabilities</b>		<b>7,986</b>	6,058	8,266
<b>Total equity and liabilities</b>		<b>28,210</b>	37,814	31,510

<sup>1</sup>For further details on the restatement of the reported results for IFRS 16 in the 6 months ended 30 September 2018 and the year ended 31 March 2019, see notes 2 and 16.

## Unaudited Consolidated Statement of Changes in Equity for the six months ended 30 September 2019

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
<b>As at 1 April 2018 (previously reported)</b>	316	97,704	40,294	2,223	(103,868)	36,669
Change in accounting policy <sup>1</sup>	—	—	—	—	(117)	(117)
<b>As at 1 April 2018 (restated)</b>	316	97,704	40,294	2,223	(103,985)	36,552
Share-based credit	—	—	—	—	564	564
Loss for the period	—	—	—	—	(5,360)	(5,360)
<b>As at 30 September 2018 (restated)</b>	<b>316</b>	<b>97,704</b>	<b>40,294</b>	<b>2,223</b>	<b>(108,781)</b>	<b>31,756</b>
Share-based credit	—	—	—	—	476	476
Loss for the period	—	—	—	—	(8,988)	(8,988)
<b>As at 31 March 2019 (restated)</b>	316	97,704	40,294	2,223	(117,293)	23,244
Exercise of share options	2	184	—	—	—	186
Share-based credit	—	—	—	—	691	691
Loss for the period	—	—	—	—	(3,897)	(3,897)
<b>As at 30 September 2019</b>	<b>318</b>	<b>97,888</b>	<b>40,294</b>	<b>2,223</b>	<b>(120,499)</b>	<b>20,224</b>

<sup>1</sup>For further details on the restatement of the reported results for IFRS 16 in the 6 months ended 30 September 2018 and the year ended 31 March 2019, see notes 2 and 16.

## Unaudited Consolidated Statement of Cash Flows for the six months ended 30 September 2019

		Six months ended 30 September 2019 £'000	Restated' Six months ended 30 September 2018 £'000	Restated' Year ended 31 March 2019 £'000
<b>Cash consumed by operations</b>	13	<b>(5,145)</b>	(7,535)	(15,037)
Overseas taxes paid		<b>(605)</b>	-	-
Income tax credit received		-	-	3,129
Interest paid		<b>(22)</b>	-	(39)
<b>Cash outflow from operating activities</b>		<b>(5,772)</b>	(7,535)	(11,947)
<b>Cash flows from investing activities</b>				
Capital expenditure		<b>(81)</b>	(133)	(239)
Interest received		<b>185</b>	188	342
<b>Net cash generated in investing activities</b>		<b>104</b>	55	103
<b>Cash flows from financing activities</b>				
Proceeds from exercise of employee share options		<b>186</b>	-	-
Bank deposits matured		<b>3,878</b>	4,297	4,359
Lease payments		<b>(69)</b>	(6)	(45)
Lease finance		<b>12</b>	-	51
<b>Net cash generated by financing activities</b>		<b>4,007</b>	4,291	4,365
<b>Net decrease in cash and cash equivalents</b>	14	<b>(1,661)</b>	(3,189)	(7,479)
Cash and cash equivalents at the start of period		<b>20,432</b>	27,911	27,911
<b>Cash and cash equivalents at the end of period</b>	15	<b>18,771</b>	24,722	20,432

<sup>1</sup>For further details on the restatement of the reported results for IFRS 16 in the 6 months ended 30 September 2018 and the year ended 31 March 2019, see notes 2 and 16.

## **Notes to the interim financial statements**

for the six months ended 30 September 2019

### **1. General information and basis of preparation**

ReNeuron Group plc is an AIM listed company incorporated and domiciled in the United Kingdom under the Companies Act 2006. The Company's registered office and its principal place of business is Pencoed Business Park, Pencoed, Bridgend CF35 5HY.

These Interim Financial Statements were prepared by the Directors and approved for issue on 6 December 2019. They have not been audited.

These Interim Financial Statements do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 March 2019 were approved by the Board of Directors on 18 July 2019 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified and did not contain statements under 498 (2) or (3) of the Companies Act 2006 and did not contain any emphasis of matter.

As permitted, these Interim Financial Statements have been prepared in accordance with UK AIM rules and the IAS 34, 'Interim financial reporting' as adopted by the European Union. They should be read in conjunction with the Annual Financial Statements for the year ended 31 March 2019, which have been prepared in accordance with IFRS as adopted by the European Union.

### **2. Accounting policies**

Following the signature of the licensing agreement with Fosun Pharma in April 2019, the Group has expanded its revenue recognition policy under IFRS 15 'Revenue from Contracts with Customers', as set out below. Otherwise, the accounting policies applied are consistent with those of the Annual Financial Statements for the year ended 31 March 2019, as described in those Annual Financial Statements. Where new standards or amendments to existing standards have become effective during the year, with the exception of IFRS 16 – Leasing, there has been no material impact on the net assets or results of the Group.

#### **Revenue**

Revenue is accounted for in line with the principles of IFRS 15 'Revenue from Contracts with Customers'. It is measured at the fair value of the consideration received or receivable, net of discounts and sales-related taxes.

Licensing agreements may contain a number of elements and provide for varying consideration terms, such as initial fees, sales, development and regulatory milestones together with sales-based royalties and similar payments. Such arrangements are within the scope of IFRS 15 and are assessed under its five-step model to determine revenue recognition. The distinct performance obligations within the contract and the arrangement transaction price are identified. The fair value of the arrangement transaction price is allocated to the different performance obligations based upon the relative stand-alone selling price of those obligations together with the performance obligation activities to which the terms of the payments specifically relate. The allocated transaction price is recognised over the respective performance period of each performance obligation.

Initial fees relating to the immediate transfer of intellectual property are recognised as revenue upon signature of the contract.

Development and regulatory approval milestone payments are recognised as revenue when the respective milestones are achieved.

Sales based royalty income and related milestone payments are recognised in the period when the related sales occur or when the relevant milestone is achieved.

Income which is related to on-going development activity or technology transfer is recognised as the activity is undertaken, in accordance with the contract.

### **IFRS 16 'Leases'**

IFRS 16 'Leases' replaces IAS 17 'Leases' and IFRIC 4 'Determining whether an arrangement contains a lease', SIC-15 'Operating Leases-Incentives' and SIC 27 'Evaluating the Substance of Transactions Involving the Legal Form of a Lease'. The standard applies a single recognition and measurement approach for all applicable leases under which the Group is the lessee.

The Group has lease contracts for property and equipment. Prior to the adoption of IFRS 16, these were classified as operating leases under IAS 17 and the lease payments were recognised as rental costs in the Consolidated Income Statement. Any pre-paid rent and accrued rent were recognised under prepayments and accruals respectively.

The Group has applied IFRS 16 for the first time for the 6 months ended 30 September 2019 using the retrospective method. Therefore, the Group has applied IFRS 16 at the date of initial application as if it had already been effective at the commencement date of existing lease contracts. Accordingly, the comparative information in these Interim Financial Statements has been restated. The impact of the implementation of IFRS 16 is described in note 16 below.

At transition, the Group used the practical expedient allowing IFRS 16 to be applied only to contracts that were previously classified as leases under IAS 17 and IFRIC 4.

For leases where the Group is a lessee, IFRS 16 requires the recognition of a right of use asset and a corresponding lease liability at the lease commencement date.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed lease payments, less any incentives received. The lease payments are discounted at the rate implicit in the lease.

Each lease payment is allocated between the liability and finance cost. The finance cost is charged to the Income Statement over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right of use assets are initially measured at cost which comprises the following:

- the amount of the initial measurement of the lease liability;
- any lease payments made at or before the commencement date, less any lease incentives received;
- any initial direct costs; and
- restoration costs.

Right of use assets are depreciated on a straight-line basis over the shorter of the lease period or the useful economic life of the asset.

### **Forward looking statements**

Certain statements within this report are forward looking. The expectations reflected in these statements are considered reasonable. However, no assurance can be given that they are correct. As these statements involve risks and uncertainties, the actual results may differ materially from those expressed or implied by these statements.

### 3. Going concern

The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development. The operations of the Group are currently being financed from funds that have been raised from share placings, commercial partnerships and grants and the Directors are currently considering a number of options for further funding of the Company's ongoing clinical programmes.

The Group actively seeks business development and fundraising opportunities in order to support its ongoing development programmes. The Board places considerable emphasis on communication with shareholders, potential investors and other commercial organisations in order to maximise the chances of success in exploiting these opportunities. However, there is a risk that the Group may not be able raise sufficient funds as needed which could have a negative impact on its financial condition and ability to pursue all of its ongoing development programmes.

After making enquiries, the Directors expect that the Group's current financial resources can, where appropriate, be managed such that they will be sufficient to support the business for at least the next 12 months from the date of this announcement. The Group therefore continues to adopt the going concern basis in the preparation of these financial statements.

### 4. Revenue

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
Royalty income	30	27	49
Initial licence fee	6,000	-	-
	<b>6,030</b>	27	49

On 9 April 2019, ReNeuron Limited signed an exclusive licensing agreement ("the Agreement") with Shanghai Fosun Pharmaceutical Development Co. Ltd ("Fosun Pharma"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co. Ltd. for the development, manufacture and commercialisation of ReNeuron's CTX and hRPC cell therapy programmes ("the Licensed Products") in the People's Republic of China ("China").

Under the terms of the Agreement, Fosun Pharma will fully fund the development of ReNeuron's CTX and hRPC cell therapy programmes in China including clinical development and subsequent commercialisation activities. Fosun Pharma has also been granted rights to manufacture the Licensed Products in China. ReNeuron retains the rights to the Licensed Products in the rest of the world.

In May 2019, ReNeuron received an initial licensing fee of £6.00 million (before withholding tax). Only the initial licensing fee has been included in the transaction price. It has been determined that the development, regulatory and sales milestones should be included in the transaction price when each performance obligation is met.

Under the terms of the Agreement, ReNeuron is entitled to further payments based upon the achievement of development, regulatory and sales milestones. The Agreement also entitles ReNeuron to royalty payments based upon future net sales of the Licensed Products in China.

## 5. Segment information

The Group has identified the Chief Executive Officer as the Chief Operating Decision Maker (CODM). The CODM manages the business as one segment, the development of cell-based therapies. Since this is the only reporting segment, no further information is included. The information used internally by the CODM is the same as that disclosed in the Interim Financial Statements. The Group's revenue derives wholly from assets located in the United Kingdom. Revenue is analysed in note 4 above. Analysed by location of customer all royalty income is derived from the United States of America. The initial license fee is derived from the People's Republic of China.

## 6. Other operating income

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
Government grants	64	508	778
Exclusivity fee	-	1,893	1,893
	<b>64</b>	<b>2,401</b>	<b>2,671</b>

## 7. Finance income

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
Interest received	164	146	291
Foreign exchange gains	424	747	812
	<b>588</b>	<b>893</b>	<b>1,103</b>

## 8. Finance expense

	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Finance lease interest	22	19	39

## 9. Taxation

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
R & D tax credit	1,850	1,457	2,887
Foreign taxation	(605)	-	-
	<b>1,245</b>	<b>1,457</b>	<b>2,887</b>

## 10. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £3,897,000 (September 2018: £5,360,000, March 2019: £14,348,000) by 31,789,724 shares (September 2018 and March 2019: 31,646,186 shares), being the weighted average number of ordinary 1p shares in issue during the period. Potential ordinary shares are not treated as dilutive as the entity is loss making.

## 11. Right-of-use-asset

	30 September 2019 £'000	30 September 2018 £'000	31 March 2019 £'000
At beginning of the period	704	755	755
Additions	12	-	51
Depreciation charge	(62)	(48)	(102)
<b>At end of the period</b>	<b>654</b>	<b>707</b>	<b>704</b>

The net book value of the underlying assets is as follows:

	30 September 2019 £'000	30 September 2018 £'000	31 March 2019 £'000
Land and buildings	612	707	659
Computer and office equipment	42	-	45
<b>At end of the period</b>	<b>654</b>	<b>707</b>	<b>704</b>

## 12. Share capital and share premium

	Number of shares	Share capital £'000	Share premium £'000	Total £'000
As at 30 September 2018 and 1 April 2019	31,646,186	316	97,704	98,020
Share options exercised	186,084	2	184	186
<b>As at 30 September 2019</b>	<b>31,832,270</b>	<b>318</b>	<b>97,888</b>	<b>98,206</b>

## 13. Cash consumed by operations

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
<b>Loss before income tax</b>	<b>(5,142)</b>	<b>(6,817)</b>	<b>(17,235)</b>
Adjustment for:			
Finance income	(588)	(893)	(1,103)
Finance expense	22	19	39
Depreciation of tangible fixed assets	206	185	384
Share-based payment charge	691	564	1,040
Changes in working capital:			
Receivables	(110)	186	397
Payables	(224)	(779)	1,441
<b>Cash consumed by operations</b>	<b>(5,145)</b>	<b>(7,535)</b>	<b>(15,037)</b>

## 14. Reconciliation of net cash flow to movement in net funds

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
Decrease in cash and cash equivalents	(1,661)	(3,189)	(7,479)
Non-cash inflow from increase in finance lease liability	(12)	-	(51)
Finance lease repayments	91	6	84
Finance lease interest	(22)	(19)	(39)
Net funds at start of period	19,427	26,912	26,912
<b>Net funds at end of period</b>	<b>17,823</b>	<b>23,710</b>	<b>19,427</b>

## 15. Analysis of net funds

	Six months ended 30 September 2019 £'000	Six months ended 30 September 2018 £'000	Year ended 31 March 2019 £'000
Cash and cash equivalents	18,771	24,722	20,432
Finance lease liabilities	(948)	(1,012)	(1,005)
<b>Net funds</b>	<b>17,823</b>	<b>23,710</b>	<b>19,427</b>

## 16. Implementation of IFRS 16

The Group has adopted the fully retrospective approach to transition for IFRS 16 and accordingly, the opening consolidated balance sheet at 1 April 2018 and the comparative consolidated balance sheets at 30 September 2018 and 31 March 2019 have been restated. Details are set out below.

### *Impact on the Consolidated Income Statement*

The implementation of IFRS 16 has resulted in the following changes to the Consolidated Income Statement:

	Year ended 31 March 2019 £'000	Six months ended 30 September 2018 £'000
<b>Result as previously stated</b>	(14,292)	(5,325)
Research and development costs – lease payment	15	-
General and administration costs:		
Rent charged	70	32
Depreciation of right of use asset	(102)	(48)
	(32)	(16)
Finance cost – lease interest	(39)	(19)
<b>Result adjusted for IFRS 16</b>	<b>(14,348)</b>	<b>(5,360)</b>

The adjustments arise from the replacement of the operating lease rentals charged under IAS 17, with charges in respect of depreciation of the right of use asset and also finance lease interest.

### *Impact on the Consolidated Statement of Financial Position*

Upon adoption of IFRS 16, the Group recognised right-of-use assets and lease liabilities for lease payments on the discounted future obligations.

The impact of IFRS 16 on the relevant lines in the Consolidated Statement of Financial Position as at 31 March 2019, 30 September 2018 and 1 April 2018 is illustrated below:

	31 March 2019 £'000	30 September 2018 £'000	1 April 2018 £'000
<b>Assets</b>			
<b>Non-current assets</b>			
Right-of-use-asset	704	707	755
	704	707	755
<b>Current assets</b>			
Trade and other receivables	(41)	(3)	(3)
	(41)	(3)	(3)
<b>Total assets</b>	<b>663</b>	<b>704</b>	<b>752</b>
<b>Equity</b>			
<b>Equity attributable to owners of the Company</b>			
Accumulated losses	(172)	(152)	(117)
<b>Total equity</b>	<b>(172)</b>	<b>(152)</b>	<b>(117)</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	(170)	(156)	(130)
Lease liabilities	141	108	31
	(29)	(48)	(99)
<b>Non-current liabilities</b>			
Lease liabilities	864	904	968
	864	904	968
<b>Total liabilities</b>	<b>835</b>	<b>856</b>	<b>869</b>
<b>Total equity and liabilities</b>	<b>663</b>	<b>704</b>	<b>752</b>

The above adjustments to the Consolidated Statement of Financial Position reflect:

- The recognition of a right-of-use asset;
- The writing back of prepaid rent;
- The writing back of accrued lease incentives;
- The creation of a lease creditor, initially corresponding to the right-of-use asset; and
- A reduction in reserves representing the cumulative impact of the above.

#### *Impact on the Consolidated Cash Flow Statement*

The adoption of IFRS 16 has no impact upon the net cash flows of the Group. However, the presentation of the Consolidated Statement of Cash flows is amended because lease payments that were previously recognised within cash consumed by operations are now split between the interest element, which remains within cash consumed by operations and the capital element that is now presented within cash flows from financing activities as a reduction in the lease creditor. This is illustrated below:

	Year ended 31 March 2019 £'000	Six months ended 30 September 2018 £'000
<b>Cash consumed by operations</b>	84	6
<b>Interest paid</b>	(39)	-
<b>Cash consumed by operations</b>	45	6
<b>Cash flows from investing activities</b>		
Capital expenditure	(51)	-
<b>Cash outflow from investing activities</b>	(51)	-
<b>Cash flows from financing activities</b>		
Repayment of lease obligations	(45)	(6)
Lease finance	51	-
<b>Cash inflow/(outflow) from financing activities</b>	6	(6)
<b>Net movement in cash and cash equivalents</b>	-	-

The above adjustments reflect:

- The effect on working capital of adjustments to accruals and prepayments arising from the implementation of IFRS 16;
- The split of lease payments into interest and capital elements as described above; and
- The creation during the year ended 31 March 2019 of a right of-use asset and a corresponding lease creditor of £51,000 in respect of IT equipment acquired under an arrangement previously treated as an operating lease under IAS 17.