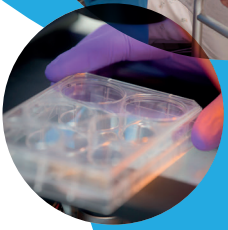
ReNeuron

Changing patients' lives



ReNeuron Group plc
Interim Report 2018

Welcome to our 2018 interim report

Our vision is to deliver life-changing therapies to patients

We are an AIM-listed company developing cell-based therapies for the treatment of stroke disability and inherited retinal diseases. We are also developing our exosome technology platform as a novel system for delivering complex biological drugs.

Our multiple assets are in varying stages of development with our most advanced programme targeting stroke disability in a Phase IIb clinical trial in the US.

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CTX stem cell therapy candidate for stroke disability:

Patient screening and enrolment commenced in Phase IIb clinical trial in the US

Top line data from Phase IIb study expected in early 2020

hRPC stem cell therapy candidate for retinal diseases:

Optimised formulation of the hRPC drug product developed and approved for use in ongoing Phase I/II clinical trial in retinitis pigmentosa in the US

Patient dosing recommenced in Phase I/II study using optimised hRPC formulation

Top line data from Phase I/II study expected in mid-2019

Exosome platform:

Programme to be refocused on use of ExoPr0 as drug delivery vehicle, providing greater scope for potential near-term partnering deals

Increased business development activity in the period reflecting third party interest in the Company's core therapeutic programmes

Active and well progressed discussions ongoing with commercial third parties

Financial Highlights

Reduced loss for the period of

£5.32 million

(2017: loss of £9.57 million)

Reduced cash consumed by operations of

£7.54 million

(2017: £9.22 million)

Cash, cash equivalents and bank deposits at 30 September 2018 of

£30.67million

(31 March 2018: £37.41 million)

Find out more at
www.reneuron.com

Review of therapeutic programmes

CTX for stroke disability

During the period under review, we have progressed our CTX cell therapy candidate for stroke disability into a Phase IIb clinical trial in the US. The study, PISCES III, is a placebo-controlled clinical trial and will involve 110 patients across 40 clinical trial sites in the US.

Patients in the study will be treated between 6 and 12 months after their stroke and will be randomised to receive either the CTX therapy or placebo treatment. The primary end-point of the PISCES III study is the proportion of patients in the treated and placebo arms showing a clinically important improvement 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.

To date, 33 out of the 40 sites targeted for participation in the PISCES III study have been identified and the first sites have now been opened, with patient screening and recruitment underway. We expect the first patient in the study to be randomised shortly and, subject to meeting patient recruitment targets, we expect top-line data from the study in early 2020. We expect the PISCES III clinical trial to be one of two pivotal studies required to support a marketing authorisation for the therapy in this indication.

hRPC for retinal diseases

During the period, we successfully developed a new cryo-preserved formulation of the hRPC drug product to optimise the sub-retinal implantation of the cells and to extend the shelf life of the drug product. Following the requisite regulatory approvals for this new hRPC formulation, we have recommenced patient dosing in the ongoing Phase I/II study in the US in retinitis pigmentosa (RP). The Phase I/II study, which is being undertaken at Massachusetts Eye and Ear Infirmary in Boston, is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in patients with advanced RP.

The clinical trial protocol for the Phase I/II study has been amended to allow for a larger patient population to be treated in the study and for a further study centre to be added, which will be open for patient enrolment shortly. Based on this, we expect short term read-outs from the Phase I/II study in mid-2019, with a Phase IIb study planned to commence thereafter. As also reported previously, we intend to seek approval to commence a Phase II clinical trial with our hRPC cell therapy candidate in patients with cone-rod dystrophy (CRD) to begin shortly after the start of Phase IIb testing of this candidate in RP. CRD is a group of rare eye disorders associated with a loss of cone cells in the retina resulting in deterioration of central visual acuity and colour vision.

Exosome platform

Pre-clinical development work has continued during the period with ExoPr0, our first CTX-derived exosome therapeutic candidate. Exosomes are nanoparticles secreted from cells including our proprietary CTX stem cell line. Exosomes play a key role in cell-to-cell signalling and early research with ExoPr0 has demonstrated its potential as both a novel therapeutic candidate and as a drug delivery vehicle.

We have recently reassessed how best to exploit our CTX cell-based exosome platform to maximise potential near-term commercial opportunities. In this regard, we intend to devote greater resource to the application of ExoPr0 as a vector for delivering biological drugs since this is where we see the greatest near-term opportunity for value-generating business development deals. We will therefore devote less internal resource to the pursuit of ExoPr0 as a therapeutic agent in its own right, preferring instead to pursue this application in collaboration with other academic and commercial third parties under existing grant-funded programmes. As a result, we do not now expect to undertake the previously planned oncology clinical trial with ExoPr0 in 2019.

Other activities

During October, we presented data demonstrating for the first time that our lead CTX cell line can be successfully reprogrammed to an embryonic stem cell-like state and then differentiated along a different path from the original cell line. Importantly, ReNeuron's immortalisation technology remained functional in the reprogrammed cells. These results, albeit early stage, are particularly encouraging as they demonstrate that our CTX cell line could be used to produce new conditionally immortalised allogeneic (i.e. non-donor-specific) cell lines from any of the three germ layers: ectoderm, mesoderm and endoderm. We are now working to develop further new allogeneic cell lines, including NK and T-cells (the cells that can be modified to attack cancer cells), as potential therapeutic agents for out-licensing to third parties.

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Our technologies and therapeutic programmes have increasingly attracted the interest of commercial third parties as they have progressed through pre-clinical and clinical development. As a result, we are in active and well-progressed discussions with commercial third parties relating to all of our platform technologies and programmes, with a view to potential collaboration and/or out-licensing deals in due course. These potential deals, if successfully concluded, will provide strong third-party validation to our technologies and programmes as well as an important source of potential non-dilutive funding to the Company.

During the period, an exclusivity fee of $2.5 million was received from one such third party relating to a potential out-license of our hRPC retinal stem cell technology. Although this particular potential licensee withdrew from the deal for reasons unrelated to ReNeuron's technology, we remain confident of securing an initial out-licence deal in the near term.

Financial review

In the six months to 30 September 2018, revenues were £27,000 (2017: £24,000) in addition to which grant income of £508,000 was received and is shown as other operating income (2017: £240,000). Other operating income also includes £1,893,000 (2017: £Nil) in respect of the exclusivity fee received during out-licensing negotiations.

Total operating costs reduced in the period to £10.10 million (2017: £10.81 million). Research and development expenditure reduced to £7.54 million (2017: £8.60 million). The higher cost in the prior period reflects heightened manufacturing process development activity ahead of the commencement of the ongoing clinical trials in stroke disability and retinitis pigmentosa.

Review of therapeutic programmes continued

General and administrative expenses increased to £2.56 million (2017: £2.21 million) as a result of increased costs associated with higher levels of business development activity.

Finance income represents income received from the Group's cash and investments and gains from foreign exchange, with losses from foreign exchange shown in finance expense. Finance income was £0.89 million in the period (2017: £0.19 million) including foreign exchange gains of £0.75 million. In 2017, the movement in foreign exchange rates led to a foreign exchange loss of £0.62 million. The Group holds cash and investments in foreign currencies in order to hedge against operational spend in those currencies. The strengthening of sterling against the US dollar during the period has resulted in a relative appreciation of the Group's foreign currency deposits. The total tax credit for the period was £1.46 million (2017: £1.40 million).

As a result of the above, the total comprehensive loss for the period reduced to £5.32 million (2017: £9.57 million).

Cash consumed by operations in the period reduced to £7.54 million (2017: £9.22 million), broadly reflecting the receipt of the £1.9m exclusivity fee in the period and lower operating costs, offset by a reduction in working capital compared with the prior period. The Group had cash, cash equivalents and bank deposits totalling £30.67 million as at 30 September 2018 (31 March 2018: £37.41 million).

Summary and outlook

Our therapeutic development programmes have continued to progress well during the period. We are particularly excited to have opened the placebo-controlled Phase IIb clinical trial in the US for CTX in chronic stroke disability. We remain encouraged by the progress made in partnering discussions across all of our technologies and programmes and we hope to be able to conclude an initial out-licensing agreement in the near term.

We have continued to maintain tight control over our operating costs, reflected in the financial statements for the period. Our cash position remains robust and we are positioned to deliver significant clinical milestones in our stroke and retinitis pigmentosa programmes over the next 18 months.

Olav Hellebø
Chief Executive Officer
14 December 2018

Unaudited Consolidated Statement of Comprehensive Income

for the six months ended 30 September 2018

	Note	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Revenue		27	24	43
Research and development costs		(7,543)	(8,599)	(16,657)
General and administrative costs		(2,560)	(2,210)	(4,616)
Other operating income	5	2,401	240	854
Operating loss		(7,675)	(10,545)	(20,376)
Finance income	6	893	188	320
Finance expense	7	–	(616)	(911)
Loss before income taxes		(6,782)	(10,973)	(20,967)
Tax credit on loss on ordinary activities		1,457	1,404	3,352
Total comprehensive loss for the period		(5,325)	(9.569)	(17,615)
Total comprehensive loss attributable to:				
– Equity owners of the Company		(5,325)	(9.569)	(17,615)
Basic and diluted loss per share	8	(16.8)	(30.2p)	(55.7p)

Unaudited Consolidated Statement of Financial Position

as at 30 September 2018

	30 September 2018 £'000	30 September 2017 £'000	31 March 2018 £'000
Assets			
Non-current assets			
Property, plant and equipment	**727**	685	726
Intangible assets	**186**	186	186
	913	871	912
Current assets			
Trade and other receivables	**1,057**	812	1,285
Corporation tax receivable	**4,467**	3,529	3,010
Investments – bank deposits	**5,951**	23,923	9,500
Cash and cash equivalents	**24,722**	21,359	27,911
	36,197	49,623	41,706
Total assets	**37,110**	50,494	42,618
Equity			
Equity attributable to owners of the Company			
Share capital	**316**	31,646	316
Share premium	**97,704**	97,704	97,704
Capital redemption reserve	**40,294**	8,964	40,294
Merger reserve	**2,223**	2,223	2,223
Accumulated losses	**(108,629)**	(96,381)	(103,868)
Total equity	**31,908**	44,156	36,669
Liabilities			
Current liabilities			
Trade and other payables	**5,202**	6,338	5,949
Total liabilities	**5,202**	6,338	5,949
Total equity and liabilities	**37,110**	50,494	42,618

Unaudited Consolidated Statement of Changes in Equity

for the six months ended 30 September 2018

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2017	31,646	97,704	8,964	2,223	(87,380)	53,157
Share-based credit	–	–	–	–	568	568
Loss for the period	–	–	–	–	(9,569)	(9,569)
As at 30 September 2017	**31,646**	**97,704**	**8,964**	**2,223**	**(96,381)**	**44,156**
Effect of share consolidation	(31,330)	–	31,330	–	–	–
Share-based credit	–	–	–	–	559	559
Loss for the period	–	–	–	–	(8,046)	(8,046)
As at 31 March 2018	316	97,704	40,294	2,223	(103,868)	36,669
Share-based credit	–	–	–	–	564	564
Loss for the period	–	–	–	–	(5,325)	(5,325)
As at 30 September 2018	**316**	**97,704**	**40,294**	**2,223**	**(108,629)**	**31,908**

Unaudited Consolidated Statement of Cash Flows

for the six months ended 30 September 2018

	Note	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Cash consumed by operations	9	**(7,541)**	(9,221)	(19,244)
Income tax credit received		**–**	1,890	4,357
Cash outflow from operating activities		**(7,541)**	(7,331)	(14,887)
Cash flows from investing activities				
Capital expenditure		**(133)**	(72)	(235)
Interest received		**188**	240	383
Net cash generated in investing activities		**55**	168	148
Cash flows from financing activities				
Bank deposits matured		**4,297**	397	14,525
Net cash generated by financing activities		**4,297**	397	14,525
Net decrease in cash and cash equivalents		**(3,189)**	(6,766)	(214)
Cash and cash equivalents at the start of period		**27,911**	28,125	28,125
Cash and cash equivalents at the end of period		**24,722**	21,359	27,911

Notes to the Interim Financial Statements

for the six months ended 30 September 2018

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 14 December 2018. 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 2018 were approved by the Board of Directors on 19 July 2018 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 2018, which have been prepared in accordance with IFRS as adopted by the European Union.

2. Accounting policies

The accounting policies applied are consistent with those of the Annual Financial Statements for the year ended 31 March 2018, as described in those Annual Financial Statements. Where new standards or amendments to existing standards have become effective during the year, there has been no material impact on the net assets or results of the Group.

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 operation of the Group is currently being financed from funds that have been raised from share placings and grants.

The Directors expect that the Group's current financial resources will be sufficient to support operations for at least the next 12 months from the date of this report. The Directors are currently considering a number of options for further funding and believe that sufficient funding will be available beyond current cash resources in order to continue with the Group's ongoing clinical programmes. Consequently, the going concern basis has been adopted in the preparation of these interim financial statements.

Notes to the Interim Financial Statements

for the six months ended 30 September 2018 continued

4. 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, and assets are predominantly based in the UK. 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. Analysed by location of customer all revenue is derived from the United States of America.

5. Other operating income

	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Government grants	508	240	854
Exclusivity fee	1,893	–	–
	2,401	240	854

6. Finance income

	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Interest received	146	188	320
Foreign exchange gains	747	–	–
	893	188	320

7. Finance expense

	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Foreign exchange losses	–	616	911

8. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of 5,325,000 (September 2017: £9,569,000, March 2018: £17,615,000) by 31,646,186 shares (September 2017: 31,646,186 shares and March 2017: 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. The comparative for 30 September 2017 has been adjusted to reflect the 1 for 100 share consolidation which took place in January 2018.

9. Cash consumed by operations

	Six months ended 30 September 2018 £'000	Six months ended 30 September 2017 £'000	Year ended 31 March 2018 £'000
Loss before income tax	**(6,782)**	(10,973)	(20,967)
Adjustment for:			
Finance income	**(893)**	(188)	(320)
Depreciation of tangible fixed assets	**137**	110	232
Share-based payment charge	**564**	568	1,127
Finance expense	**–**	616	911
Changes in working capital			
Receivables	**186**	196	(289)
Payables	**(753)**	450	62
Cash consumed by operations	**(7,541)**	(9,221)	(19,244)

Directors and advisers

Directors

John Berriman, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt ACA, Chief Financial Officer
Simon Cartmell OBE, Non-executive Director
Dr Tim Corn, Non-executive Director
Dr Claudia D'Augusta, Non-executive Director
Professor Sir Chris Evans OBE, Non-executive Director
Dr Mike Owen, Non-executive Director

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