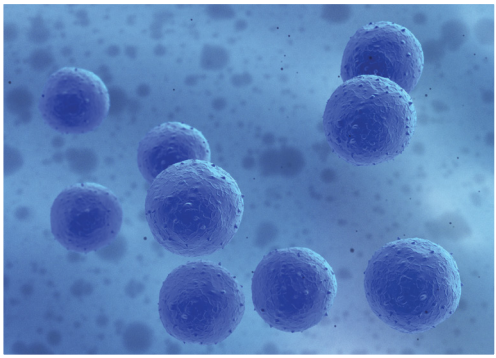
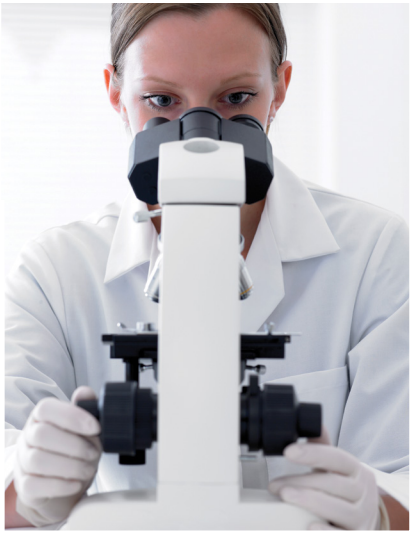
ReNeuron

pioneering stem cell therapeutics



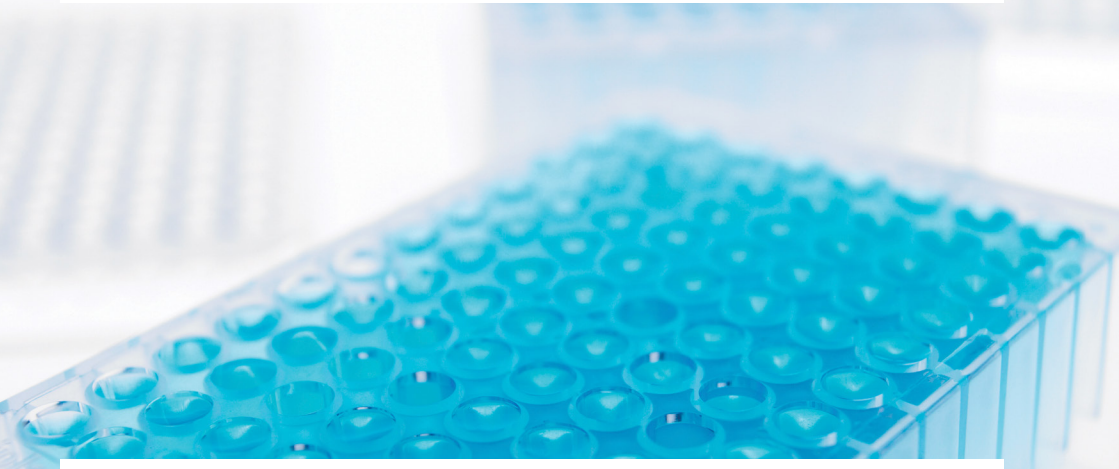


INTERIM REPORT 2015

ReNeuron Group plc

WHO WE ARE

We are a leading, clinical-stage stem cell business. Our primary objective is the development of novel stem cell therapies targeting areas of significant unmet or poorly met medical need.



CTX cells for Stroke Disability

Our lead therapeutic candidate is our CTX stem cell therapy for the treatment of patients left disabled by the effects of a stroke. This treatment is currently in mid-stage clinical development.

CTX cells for Critical Limb Ischaemia

Our second CTX stem cell candidate is for the treatment of critical limb ischaemia, a serious and common side effect of diabetes. This treatment is in early-stage clinical development.

hRPCs for Retinitis Pigmentosa

Our hRPC stem cell candidate is for the treatment of retinitis pigmentosa, a blindness-causing disease of the retina. This treatment is in early-stage clinical development.

CTX-derived Exosomes

Exosomes are nanoparticles released by cells containing a number of active proteins and microRNAs. Our exosomes nanomedicine platform is generating promising early pre-clinical data in cancer.

Head to **reneuron.com/products/products-technologies** to read more on our products and technologies >

Highlights in the period

- CTX stem cell therapy candidate for motor disability as a result of stroke:
  - Phase II clinical trial ongoing – data expected during H1 2016
  - Pivotal Phase II/III clinical trial planned to commence in H2 2016
- CTX stem cell therapy candidate for critical limb ischaemia:
  - Phase I clinical trial ongoing – data expected in H1 2016
  - Phase II clinical trial planned to commence in H2 2016
- hRPC stem cell therapy candidate for retinitis pigmentosa:
  - First patients consented for treatment in Phase I/II clinical trial
  - ReNeuron's first US clinical study
  - Pivotal Phase II/III clinical trial planned to commence in 2017
- Exosome nanomedicine platform:
  - Promising early pre-clinical data in cancer
  - Research collaboration extended with Benitec Biopharma utilising exosomes as a delivery system for gene therapy
- Placing completed to raise £68.4 million, before expenses, funding all therapeutic programmes through mid or late-stage clinical development
- Loss for the period of £4.48 million (2014: loss of £4.13 million); cash outflow from operations of £5.26 million (2014: outflow of £4.83 million); cash, cash equivalents and bank deposits at 30 September 2015 of £72.28 million (31 March 2015: £12.38 million)

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"During the period under review, we gained regulatory approval to commence our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. The first patients have been consented for treatment and we look forward to reporting progress with this important study over the coming year. We also expect to report data from our ongoing clinical trials in critical limb ischaemia and disability as a result of stroke during 2016, representing further significant milestones in the clinical development of our CTX cell therapy candidates. The development of our emerging exosome technology platform continues to progress well, both as a potential new nanomedicine targeting cancer and as a potential new delivery system in gene therapy. Finally, the substantial £68.4 million fundraising completed in the period has provided us with a very robust balance sheet with which to pursue the above programmes through to key clinical milestones over the next two to three years."

Olav Hellebø
Chief Executive Officer

Operational Review

Therapeutic programmes

We have continued to make considerable progress during the period across our therapeutic programmes and it highlights the increasing breadth of the Company's pipeline that we now have two clinical trials in progress in the UK, a clinical trial now open for enrolment in the US and an exciting early-stage exosome nanomedicine programme.

During the period under review, we obtained regulatory approval from the US FDA to commence a Phase I/II clinical trial in the US with our Human Retinal Progenitor Cell (hRPC) therapy candidate for 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 FDA has also granted Fast Track designation to our hRPC programme targeting RP. This designation provides eligibility for an accelerated approval and priority review process by the FDA and the Orphan Drug Designation already granted for our RP programme in both the US and Europe provides the potential for a significant period of market exclusivity once approved in these major territories.

The Phase I/II clinical trial in RP patients is now open for enrolment and, importantly, marks the initiation of clinical trial activity in the US with our therapeutic programmes. The study is being conducted at Massachusetts Eye and Ear Infirmary in Boston, a world-renowned clinical centre for the treatment of retinal diseases. The trial design is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in 15 patients with advanced RP. The first patients have been recruited to the study and initial safety and tolerability data from the study are expected in the second half of 2016.

Subject to the outcome of the Phase I/II study, we are planning to file an application to commence a pivotal Phase II/III clinical trial with our therapy for RP in 2017. This trial is expected to be the basis for subsequent marketing authorisation filings in both the US and Europe.

During the period, the clinical team from Glasgow's Southern General Hospital presented long-term follow-up data from the PISCES Phase I clinical trial with our CTX stem cell therapy candidate for motor disability as a result of stroke. There continued to be no cell-related or immunological adverse events reported in any of the eleven patients treated in the study out to at least 24 months post-treatment, with improvements in neurological status and limb function maintained throughout long-term follow-up compared with pre-treatment baseline performance.

A UK multi-site Phase II clinical trial (PISCES II) is ongoing to examine the efficacy of CTX in patients with motor disability as a result of ischaemic stroke. Sufficient suitable patients have been identified to complete the first cohort in the study, with data expected in the first half of 2016. At this point, and subject to an overall assessment of the collective data from the Phase I and Phase II studies, we are planning to curtail the Phase II study and file an application to commence a controlled, pivotal Phase II/III clinical trial in patients with motor disability as a result of ischaemic stroke.

Our CTX cell therapy candidate for critical limb ischaemia (CLI) is currently in a Phase I clinical trial in the UK. CLI is a condition that results in loss of blood flow to the lower limb, is common in diabetics and can ultimately lead to amputation. We expect safety data from this study in the first half of 2016, sufficient to enable us to initiate a Phase II placebo-controlled clinical trial later that year.

During the period, we continued to advance our exosome nanomedicine programme. Exosomes are lipid-based nanoparticles secreted from all cells and which are believed to play a key role in the transfer of beneficial proteins and particularly non-coding RNAs from one cell to another. We aim to exploit the therapeutic potential of exosomes derived from our own proprietary stem cell lines and we have filed multiple patent applications covering the composition, manufacture and therapeutic use of our exosome nanomedicine platform.

We have identified a novel mechanism by which exosomes from our CTX stem cells may inhibit the growth and migration of cancer cells in pre-clinical models of the disease. We are continuing to investigate the mechanism of action and utility of our exosome nanomedicine platform in a range of potential cancer indications. Alongside this, we are also optimising the process of harvesting exosomes from CTX cell production as a prelude to selecting the most suitable clinical development candidate.

During the period, we extended our research collaboration with Australia-based Benitec Biopharma (Benitec), a leader in the field of therapeutics focused on gene silencing. Following positive results in early studies,

the collaboration is investigating the potential of our CTX-derived exosomes as a delivery system for Benitec's proprietary gene silencing technology, targeting cancer as well as ophthalmic and neurologic diseases.

Other activities

During the period, we completed a Placing to raise £68.4 million, before expenses. This financing provides funding into the second half of 2018 and will enable us to take all of our current programmes into early or mid-stage clinical development and, subject to future clinical data and regulatory approvals, will enable us to take our therapeutic programmes in retinitis pigmentosa and motor disability as a result of stroke through late-stage clinical development to the point of application for marketing authorisation.

We remain on track to relocate our existing business operations to our new facility in South Wales in the early part of next year, with cell production suites planned to come on-stream at a later date, once qualified for use and licensed for clinical and commercial manufacture.

Last week, we announced the appointment of Dr Michael Owen as a Non-executive Director of the Company. Mike brings a wealth of scientific and commercial biotech and pharmaceutical experience to the Board and will also chair the Company's Scientific Advisory Board.

Financial review

In the six months to 30 September 2015, revenues were £11,000 (2014: £11,000) in addition to which grant income of £244,000 was received and is shown as other operating income (2014: £265,000).

Research and development expenditure was at a similar level to the equivalent prior period at £3.72 million (2014: £3.75 million). This expenditure will increase during the remainder of the financial year as clinical trial activity and associated cell manufacturing spend continues to increase. General and administrative expenses increased to £1.83 million (2014: £1.43 million). This increase is consistent with the increase seen in the second half of the previous financial year and is largely a result of the strengthening of the senior management team as well as project management and other costs associated with the upcoming relocation of the business to South Wales.

Interest received increased in the period to £59,000 (2014: £40,000) as a result of higher levels of cash deposits following the fund raise. The total tax credit for the period was £756,000 (2014: £739,000).

As a result of the above, the total comprehensive loss for the period increased to £4.48 million (2014: £4.13 million), in line with both internal and consensus analyst forecasts.

Cash outflow from operations in the period increased to £5.26 million (2014: £4.83 million), reflecting the increase in operating costs in the period. The Group had cash, cash equivalents and bank deposits totalling £72.28 million as at 30 September 2015 (31 March 2015: £12.38 million). As mentioned above, in August 2015, the Company issued 1,367,411,939 new ordinary shares at 5.0p per share to raise £68.37 million before expenses, by means of a placing with new and existing investors. Net proceeds were £65.12 million.

Summary and outlook

During the period under review, we gained regulatory approval to commence our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. The first patients have been consented for treatment and we look forward to reporting progress with this important study over the coming year. We also expect to report data from our ongoing clinical trials in critical limb ischaemia and disability as a result of stroke during 2016, representing further significant milestones in the clinical development of our CTX cell therapy candidates. The development of our emerging exosome technology platform continues to progress well, both as a potential new nanomedicine targeting cancer and as a potential new delivery system in gene therapy. Finally, the substantial £68.4 million fundraising completed in the period has provided us with a very robust balance sheet with which to pursue the above programmes through to key clinical milestones over the next two to three years.

Olav Hellebø
Chief Executive Officer

Michael Hunt
Chief Financial Officer

7 December 2015

Unaudited Consolidated Statement of Comprehensive Income for the six months ended 30 September 2015

	Note	**Six months ended 30 September 2015 £'000**	Six months ended 30 September 2014 £'000	Year ended 31 March 2015 £'000
Revenue		**11**	11	30
Research and development costs		**(3,716)**	(3,750)	(7,250)
General and administrative costs		**(1,834)**	(1,433)	(3,693)
Other operating income	3	**244**	265	519
Operating loss		**(5,295)**	(4,907)	(10,394)
Finance income		**59**	40	91
Loss before income taxes		**(5,236)**	(4,867)	(10,303)
Tax credit on loss on ordinary activities		**756**	739	1,397
Total comprehensive loss for the period		**(4,480)**	(4,128)	(8,906)
Total comprehensive loss attributable to:				
– Equity owners of the Company		**(4,480)**	(4,128)	(8,906)
Basic and diluted loss per share	4	**(0.2p)**	(0.2p)	(0.5p)

Unaudited Consolidated Statement of Financial Position as at 30 September 2015

	30 September 2015 £'000	30 September 2014 £'000	31 March 2015 £'000
Assets			
Non-current assets			
Property, plant and equipment	**145**	184	161
Intangible assets	**1,591**	1,272	1,591
Other non-current assets	**281**	275	281
	2,017	1,731	2,033
Current assets			
Trade and other receivables	**832**	674	400
Corporation tax receivable	**2,028**	1,493	1,272
Investments – bank deposits	**49,993**	6,000	–
Cash and cash equivalents	**22,283**	10,101	12,382
	75,136	18,268	14,054
Total assets	**77,153**	19,999	16,087
Equity			
Equity attributable to owners of the Company			
Share capital	**31,567**	17,888	17,888
Share premium	**97,704**	46,267	46,267
Capital redemption reserve	**8,964**	8,964	8,964
Merger reserve	**2,223**	2,223	2,223
Accumulated losses	**(66,428)**	(57,536)	(62,206)
Total equity	**74,030**	17,806	13,136
Liabilities			
Non-current liabilities			
Provisions	**605**	364	605
Financial liabilities: finance leases	**1**	2	1
	606	366	606
Current liabilities			
Trade and other payables	**2,516**	1,826	2,344
Financial liabilities: finance leases	**1**	1	1
	2,517	1,827	2,345
Total liabilities	**3,123**	2,193	2,951
Total equity and liabilities	**77,153**	19,999	16,087

Unaudited Consolidated Statement of Changes in Equity for the six months ended 30 September 2015

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2014	**17,888**	**46,267**	**8,964**	**2,223**	**(53,625)**	**21,717**
Share-based credit	–	–	–	–	217	217
Loss for the period	–	–	–	–	(4,128)	(4,128)
As at 30 September 2014	**17,888**	**46,267**	**8,964**	**2,223**	**(57,536)**	**17,806**
Share-based credit	–	–	–	–	108	108
Loss for the period	–	–	–	–	(4,778)	(4,778)
As at 31 March 2015	**17,888**	**46,267**	**8,964**	**2,223**	**(62,206)**	**13,136**
Issue of new ordinary shares	13,679	54,696	–	–	–	68,375
Costs of share issue	–	(3,259)	–	–	–	(3,259)
Share-based credit	–	–	–	–	258	258
Loss for the period	–	–	–	–	(4,480)	(4,480)
As at 30 September 2015	**31,567**	**97,704**	**8,964**	**2,223**	**(66,428)**	**74,030**

Unaudited Consolidated Statement of Cash Flows for the six months ended 30 September 2015

	Note	**Six months ended 30 September 2015 £'000**	Six months ended 30 September 2014 £'000	Year ended 31 March 2015 £'000
Cash consumed by operations	5	**(5,263)**	(4,834)	(9,124)
Income tax credit received		**–**	–	879
Cash outflow from operating activities		**(5,263)**	(4,834)	(8,245)
Cash flows from investing activities				
Capital expenditure		**(18)**	(22)	(61)
Purchase of intangible asset		**–**	–	(319)
Interest received		**59**	40	91
Net cash generated in investing activities		**41**	18	(289)
Cash flows from financing activities				
Finance lease principal payments		**–**	–	(1)
Proceeds from issuance of ordinary shares		**68,375**	–	–
Costs of share issue		**(3,259)**	–	–
Bank deposits (placed)/matured		**(49,993)**	–	(6,000)
Net cash generated by financing activities		**15,123**	–	5,999
Net increase/(decrease) in cash and cash equivalents	6	**9,901**	(4,816)	(2,535)
Cash and cash equivalents at the start of period		**12,382**	14,917	14,917
Cash and cash equivalents at the end of period	7	**22,283**	10,101	12,382

Notes to the Interim Financial Statements for the six months ended 30 September 2015

1. Accounting policies and basis of preparation

1.1 Basis of preparation

The Group's unaudited interim financial statements for the half year ended 30 September 2015 have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU including those applicable to accounting periods ending 31 March 2016 and the accounting policies set out in ReNeuron Group plc's Annual Report for the year ended 31 March 2015. They do not include all the statements required for full annual financial statements, and should be read in conjunction with the consolidated financial statements of the Group as at 31 March 2015.

This condensed consolidated interim financial information has not been audited or reviewed and does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory financial statements for the year ended 31 March 2015 were approved by the Board of Directors on 24 August 2015, have been filed with the Registrar of Companies for England and Wales and have been reported on by the Group's auditors. The report of the auditors on those accounts was unqualified, did not contain an emphasis-of-matter paragraph and did not contain any statement under section 498 of the Companies Act 2006.

1.2 Accounting policies

The accounting policies applied by the Group in this interim report are the same as those applied by the Group in the financial statements for the year ended 31 March 2015 subject to the following amendments to existing standards which are now effective and have been adopted by the Group. The financial statements of the Group are not materially impacted by these changes:

- Annual Improvements 2011-2013 (effective 1 July 2014) (endorsed for 1 January 2015)

There are a number of new standards, interpretations and amendments to existing standards that are not yet effective and have not been adopted early by the Group. The future introduction of these standards is not expected to have a material impact on the financial statements of the Group.

1.3 Going concern

The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development. During the period, the Company completed a Placing to shareholders to raise £68.4 million, before expenses. Following completion of the Placing, the Directors expect that the Group's financial resources will be sufficient to support operations into the second half of 2018. Consequently, the going concern basis has been adopted in the preparation of these interim financial statements.

2. Segment information

Following the adoption of IFRS8 Segment Reporting, 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. Analysed by location of customer all revenue is derived from the United States of America.

3. Other operating income

Other operating income comprises Government grants from Innovate UK (Technology Strategy Board) in relation to the Group's programmes.

4. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £4,480,000 (September 2014: £4,128,000, March 2015: £8,906,000) by 2,058,105,458 shares (September 2014 and March 2015: 1,788,827,700 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.

5. Cash consumed by operations

	Six months ended 30 September 2015 £'000	Six months ended 30 September 2014 £'000	Year ended 31 March 2015 £'000
Loss before income tax	**(5,236)**	(4,867)	(10,303)
Adjustment for:			
Interest received	**(59)**	(40)	(91)
Depreciation of tangible fixed assets	**34**	63	125
Provisions	**–**	–	241
Share-based payment charge	**258**	217	325
Changes in working capital			
Receivables	**(432)**	2	270
Payables	**172**	(209)	309
Cash consumed by operations	**(5,263)**	(4,834)	(9,124)

Notes to the Interim Financial Statements for the six months ended 30 September 2015 continued

6. Reconciliation of net cash flow to movement in net debt

	Six months ended 30 September 2015 £'000	Six months ended 30 September 2014 £'000	Year ended 31 March 2015 £'000
Net funds at start of period	**12,380**	14,914	14,914
Increase /(decrease) in cash in the period	**9,901**	(4,816)	(2,535)
Cash inflow from decrease in debt	**–**	–	1
Net funds at end of period	**22,281**	10,098	12,380

7. Analysis of net funds

	Six months ended 30 September 2015 £'000	Six months ended 30 September 2014 £'000	Year ended 31 March 2015 £'000
Cash at bank and in hand	**22,283**	10,101	12,382
Finance leases	**(2)**	(3)	(2)
	22,281	10,098	12,380

Directors and Advisers

Directors

John Berriman, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt, Chief Financial Officer
Simon Cartmell, Non-executive Director
Dr Tim Corn, Non-executive Director
Professor Sir Chris Evans, Non-executive Director
Dr Paul Harper, Non-executive Director
Dr Mike Owen, Non-executive Director

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