



ReNeuron
pioneering stem cell therapeutics

INTERIM REPORT 2014





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.



Ischaemic Stroke

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.



Critical Limb Ischaemia

Our second application for our *CTX* cells is for the treatment of critical limb ischaemia, a serious and common side effect of diabetes. This treatment is in early-stage clinical development.



Retinitis Pigmentosa

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

Highlights in the period

- CTX stem cell therapy candidate for stroke disability:
 - Phase II clinical trial commenced
 - Encouraging long term Phase I data presented at leading stroke conference
- CTX stem cell therapy candidate for critical limb ischaemia:
 - Phase I clinical trial commenced
 - Phase II clinical trial application planned for mid-2015
- hRPC stem cell therapy candidate for retinitis pigmentosa:
 - Phase I/II clinical trial application planned for early 2015 in US
- Exosome therapeutic platform on track to generate further pre-clinical efficacy data ahead of choice of first clinical target in early 2015
- New CEO appointed with substantial pharmaceutical commercial and business development experience
- Loss for the period of £4.13 million (2013: loss of £3.17 million); cash outflow from operations was £4.83 million (2013: outflow of £3.42 million); cash, cash equivalents and bank deposits at 30 September 2014 of £16.10 million (March 2014: £20.92 million)



During the period under review, dosing of patients has commenced in two new clinical trials in stroke disability and critical limb ischaemia, representing further significant milestones in the clinical development of ReNeuron's CTX cell therapy candidates. We also remain on track to file an application in the US early next year to commence a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We look forward to moving into our new, world-class cell manufacturing and research facility in South Wales next year. As a prospective centre of excellence in automated cell therapy manufacture, we believe this facility will become a major element of ReNeuron's overall value proposition.

The business benefits from a strong balance sheet and the backing of high calibre institutional investors and a management team focused on the delivery of clinical proof-of-concept data and associated value generation across its programmes over the next two years.

Bryan Morton
Chairman



Contents

Highlights	1
Chairman's and Chief Executive Officer's Joint Statement	2
Unaudited Consolidated Statement of Comprehensive Income	4
Unaudited Consolidated Statement of Financial Position	5
Unaudited Consolidated Statement of Changes in Equity	6
Unaudited Consolidated Statement of Cash Flows	7
Notes to the Interim Financial Statements	8
Directors and Advisers	IBC

Chairman's and Chief Executive Officer's Joint Statement

Therapeutic programmes

During the period under review, we commenced patient dosing in the Phase II clinical trial of our *CTX* cell therapy candidate for stroke disability. This efficacy study, designated "PISCES II", is currently recruiting stroke patients at nine leading NHS hospitals across the UK. The primary endpoint is a clinically significant improvement in upper limb function at six months post-stroke, in disabled stroke patients across two treated cohorts. Data from the first cohort in the study are expected before the end of 2015, with second cohort data due shortly thereafter.

In May of this year, twelve month follow-up data from the PISCES Phase I clinical trial in stroke disability were presented at the European Stroke Conference, confirming findings seen earlier in the study; notably, an absence of cell-related or immunological adverse events and sustained reductions in neurological impairment and spasticity in most patients compared with their stable pre-treatment baseline performance. These data are now being compiled for publication in a leading peer-reviewed scientific journal.

During the period, we also commenced dosing in a Phase I clinical trial of our *CTX* cell therapy candidate for critical limb ischaemia (CLI), a condition resulting in loss of blood flow to the lower limb which is common in diabetics and which can ultimately lead to amputation. This Phase I clinical trial is a single centre dose escalation safety study in nine patients with lower limb ischaemia and is being conducted at Ninewells Hospital, Dundee, Scotland. Data from this study are expected in the first half of 2015, at which point we expect to be able to submit an application to commence a Phase II study in this indication.

We have continued to invest in developing our lead *CTX* stem cell line during the period. Our first generation *CTX* drug product, used in the PISCES Phase I study in stroke disability, was non-cryopreserved with a consequent short shelf life. We have since developed a cryopreserved variant of our *CTX* drug product, designated *CTXcryo*. This cryopreserved variant was approved by the UK regulatory authorities for clinical trial use earlier this year with a 28 day shelf life. During the period, we have generated further stability data supporting a three month shelf life for *CTXcryo* drug

product. We have recently received UK regulatory approval to use this longer shelf life drug product in our ongoing clinical trials in both stroke disability and CLI. We expect to increase the shelf life of our *CTXcryo* cells still further over the coming months as we garner further stability data from ongoing process development activities, thus adding to the attractiveness of *CTXcryo* from a clinical and commercial perspective.

The final pre-clinical work on our hRPC cell therapy candidate for retinitis pigmentosa (RP) has proceeded well during the period, with further pre-clinical safety and efficacy data generated in support of a planned IND application in early 2015 to permit the commencement of a Phase I/II clinical trial in the US. Financial and clinical advisory support for this programme is being provided from the leading US charity in this field, Foundation Fighting Blindness. Our hRPC cell therapy candidate for RP has already been granted Orphan Drug Designation in both Europe and the US, providing the potential for ten and seven year market exclusivity, respectively, post-approval in these territories.

During the period, we continued to progress the development of our *CTX* cell-derived exosome platform. Exosomes are nanoparticles containing key proteins and micro-RNAs. They play a key role in cell to cell communication, modulate cellular immunity and promote the activation of regenerative or repair programmes in diseased or injured cells. Our *CTX* stem cells release large amounts of exosomes when cultured and, consequently, these exosomes can be readily harvested as a by-product of our existing *CTX* cell manufacturing process. We are currently conducting pre-clinical efficacy studies in a number of disease models including glioblastoma and corneal ulceration. From these studies, we expect to be able to select our first disease target for clinical development with an exosome-based therapeutic candidate in early 2015, thus broadening our therapeutic pipeline into indications beyond those targeted by our cell-based programmes.

Other activities

We remain on track with our plans to relocate ReNeuron's operations to a state-of-the-art manufacturing and development facility at Pencoed, near Cardiff in South Wales, in the second quarter

of 2015, with full licensure for cell manufacturing activities expected in the first half of 2016. This facility will incorporate robotic cell culture technology and, when fully licensed, will give us full control over the supply of our CTX cell-based therapies, meeting late stage clinical trial and in-market demand for drug product at low cost of goods. As such, the Welsh facility represents a key value driver in ReNeuron's commercial development strategy.

In order to manage the increasing breadth of the Company's clinical, operational and commercial activities, the Board of the Company was reconfigured during the period with the appointment of Olav Hellebø, a highly experienced pharmaceutical executive, as the Company's new Chief Executive Officer. Olav has broad commercial experience gained at both major pharmaceutical and small biotechnology companies. He has particular experience of the clinical development, out-licensing, commercialisation and marketing of new therapeutics. Michael Hunt, who has held the position of Chief Executive Officer since July 2005, remains on ReNeuron's Board as Chief Financial Officer, with responsibilities covering finance, public and investor relations and overall commercial and financial strategy.

Financial review

In the six months to 30 September 2014, revenues were £11,000 (2013: £11,000) in addition to which grant income of £265,000 was received and is shown as other operating income (2013: £178,000).

Research and development expenditure increased in the period to £3.75 million (2013: £2.76 million) principally as a result of increased clinical research, cell manufacturing and process development costs. General and administrative expenses increased to £1.43 million (2013: £0.92 million) primarily due to increased staff recruitment activity and project management costs associated with the prospective relocation of the business to South Wales. The Company expects to subsequently defray the costs associated with the relocation of the business by virtue of the grant package awarded to the business by the Welsh Government in July 2013.

Interest received increased in the period to £40,000 (2013: £15,000) as a result of higher average levels

of cash deposits held over the period. The total tax credit for the period was £739,000, composed of an accrual of £614,000 for a research and development tax credit for the period (2013: £311,000) and a further credit of £125,000 agreed for the year to March 2014.

As a result of the above, the total comprehensive loss for the period increased to £4.13 million (2013: £3.17 million), in line with both internal and consensus analyst forecasts.

Cash outflow from operations in the period increased to £4.83 million (2013: £3.42 million), reflecting the increase in operating costs in the period. The Group had cash, cash equivalents and bank deposits totalling £16.10 million as at 30 September 2014 (March 2014: £20.92 million).

Summary and outlook

During the period under review, dosing of patients has commenced in two new clinical trials in stroke disability and critical limb ischaemia, representing further significant milestones in the clinical development of ReNeuron's CTX cell therapy candidates. We also remain on track to file an application in the US early next year to commence a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We look forward to moving into our new, world-class cell manufacturing and research facility in South Wales next year. As a prospective centre of excellence in automated cell therapy manufacture, we believe this facility will become a major element of ReNeuron's overall value proposition.

The business benefits from a strong balance sheet and the backing of high calibre institutional investors and a management team focused on the delivery of clinical proof-of-concept data and associated value generation across its programmes over the next two years.



Bryan Morton
Chairman



Olav Hellebø
Chief Executive Officer

17 November 2014

Unaudited Consolidated Statement of Comprehensive Income

for the six months ended 30 September 2014

		Six months ended 30 September 2014 £'000	Six months ended 30 September 2013 £'000	Year ended 31 March 2014 £'000
	Note			
Revenue		11	11	22
Research and development costs		(3,750)	(2,759)	(5,829)
General and administrative costs		(1,433)	(923)	(2,824)
Other operating income	3	265	178	662
Operating loss		(4,907)	(3,493)	(7,969)
Finance income		40	15	149
Loss before income taxes		(4,867)	(3,478)	(7,820)
Tax credit on loss on ordinary activities		739	311	754
Total comprehensive loss for the period		(4,128)	(3,167)	(7,066)
Total comprehensive loss attributable to:				
– Equity owners of the company		(4,128)	(3,167)	(7,066)
Basic and diluted loss per share	4	(0.2p)	(0.3p)	(0.5p)

Unaudited Consolidated Statement of Financial Position

as at 30 September 2014

	30 September 2014 £'000	30 September 2013 £'000	31 March 2014 £'000
Assets			
Non-current assets			
Property, plant and equipment	184	219	225
Intangible assets	1,272	1,272	1,272
Other non-current assets	275	135	275
	1,731	1,626	1,772
Current assets			
Trade and other receivables	674	730	676
Corporation tax receivable	1,493	1,025	754
Investments – bank deposit	6,000	–	6,000
Cash and cash equivalents	10,101	23,515	14,917
	18,268	25,270	22,347
Total assets	19,999	26,896	24,119
Equity			
Equity attributable to owners of the company			
Share capital	17,888	17,888	17,888
Share premium	46,267	46,267	46,267
Capital redemption reserve	8,964	8,964	8,964
Merger reserve	2,223	2,223	2,223
Accumulated losses	(57,536)	(49,945)	(53,625)
Total equity	17,806	25,397	21,717
Liabilities			
Non-current liabilities			
Provisions	364	150	364
Financial liabilities: finance leases	2	–	2
	366	150	366
Current liabilities			
Trade and other payables	1,826	1,349	2,035
Financial liabilities: finance leases	1	–	1
	1,827	1,349	2,036
Total liabilities	2,193	1,499	2,402
Total equity and liabilities	19,999	26,896	24,119

Unaudited Consolidated Statement of Changes in Equity

for the six months ended 30 September 2014

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2013	7,748	32,972	8,964	2,223	(46,999)	4,908
Issue of new ordinary shares	10,140	15,210	–	–	–	25,350
Costs of share issue	–	(1,915)	–	–	–	(1,915)
Share-based credit	–	–	–	–	221	221
Loss for the period	–	–	–	–	(3,167)	(3,167)
As at 30 September 2013	17,888	46,267	8,964	2,223	(49,945)	25,397
Share-based credit	–	–	–	–	219	219
Loss for the period	–	–	–	–	(3,899)	(3,899)
As at 31 March 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

Unaudited Consolidated Statement of Cash Flows

for the six months ended 30 September 2014

		Six months ended 30 September 2014 £'000	Six months ended 30 September 2013 £'000	Year ended 31 March 2014 £'000
	Note			
Cash consumed by operations	5	(4,834)	(3,422)	(6,718)
Income tax credit received		–	–	714
Cash outflow from operating activities		(4,834)	(3,422)	(6,004)
Cash flows from investing activities				
Capital expenditure		(22)	(59)	(121)
Interest received		40	15	61
Net cash generated/(consumed) by investing activities		18	(44)	(60)
Cash flows from financing activities				
Finance lease principal payments		–	(1)	(1)
Proceeds from issuance of ordinary shares		–	25,350	25,350
Costs of share issue		–	(1,915)	(1,915)
Bank deposit placed		–	–	(6,000)
Net cash generated by financing activities		–	23,434	17,434
Net (decrease)/increase in cash and cash equivalents	6	(4,816)	19,968	11,370
Cash and cash equivalents at the start of period		14,917	3,547	3,547
Cash and cash equivalents at the end of period	7	10,101	23,515	14,917

Notes to the Interim Financial Statements

for the six months ended 30 September 2014

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 2014 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 2015 and the accounting policies set out in ReNeuron Group plc's Annual Report for the year ended 31 March 2014. 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 2014.

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 2014 were approved by the Board of Directors on 17 June 2014, 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 2014 subject to the following standards, interpretations and amendments to existing standards which are now effective and have been adopted by the Group:

- Amendment to IAS 1 "Financial Statement Presentation" applies for periods beginning on or after 1 July 2013;
- IFRS 10, "Consolidated Financial Statements" applies for periods beginning on or after 1 January 2014;
- IFRS 11, "Joint Arrangements" applies for periods beginning on or after 1 January 2014;
- IFRS 12, "Disclosures of Interests in Other Entities" applies for periods beginning on or after 1 January 2014;
- IAS 27 (Revised 2011), "Separate Financial Statements", applies for periods beginning on or after 1 January 2014; and
- IAS 28 (Revised 2011), "Associates and Joint Ventures" applies for periods beginning on or after 1 January 2014.

The following standards, interpretations and amendments to existing standards are not yet effective, have not yet been endorsed by the EU and have not been adopted early by the Group:

- IFRS 9, "Financial Instruments", for periods beginning on or after 1 January 2015.

The directors anticipate that the future introduction of the standards, amendments and interpretations listed above will not have a material impact on the consolidated financial statements.

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 and as it establishes a cell manufacturing and development facility in South Wales. The Directors believe that the Group has sufficient cash resources available for its immediate programme of activities, taking into account also the grant awards made by the Technology Strategic Board and the Welsh government and for at least 12 months from the date of announcement of these interim results.

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 £4,128,000 (September 2013: £3,167,000, March 2014: £7,066,000) by 1,788,827,700 shares (September 2013: 1,068,658,481 shares, March 2014: 1,424,978,475 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 2014 £'000	Six months ended 30 September 2013 £'000	Year ended 31 March 2014 £'000
Loss before income tax	(4,867)	(3,478)	(7,820)
Adjustment for:			
Interest received	(40)	(15)	(149)
Depreciation of tangible fixed assets	63	53	112
Provisions	–	–	214
Share-based payment charge	217	221	440
Changes in working capital			
Receivables	2	(389)	(387)
Payables	(209)	186	872
Cash consumed by operations	(4,834)	(3,422)	(6,718)

Notes to the Interim Financial Statements

for the six months ended 30 September 2014 continued

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

	Six months ended 30 September 2014 £'000	Six months ended 30 September 2013 £'000	Year ended 31 March 2014 £'000
Net funds at start of period	14,914	3,546	3,546
(Decrease)/increase in cash in the period	(4,816)	19,968	11,370
Cash inflow/(outflow) from decrease in debt	–	1	(2)
Net funds at end of period	10,098	23,515	14,914

7. Analysis of net funds

	Six months ended 30 September 2014 £'000	Six months ended 30 September 2013 £'000	Year ended 31 March 2014 £'000
Cash at bank and in hand	10,101	23,515	14,917
Finance leases	(3)	–	(3)
	10,098	23,515	14,914

Directors and Advisers

Directors

Bryan Morton, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt, Chief Financial Officer
Dr John Sinden, Chief Scientific Officer
John Berriman, Non-executive Director
Simon Cartmell, Non-executive Director
Dr Tim Corn, Non-executive Director
Mark Docherty, Non-executive Director
Professor Sir Chris Evans, Non-executive Director
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