ReNeuron

pioneering stem cell therapeutics

INTERIM REPORT 2013

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ReNeuron in Summary

ReNeuron is a leading, clinical-stage cell therapy development business. Its primary objective is the development of novel cell-based therapies targeting areas of significant unmet or poorly met medical need.

ReNeuron has used its unique stem cell technologies to develop cell-based therapies for significant disease conditions where the cells can be readily administered "off-the-shelf" to any eligible patient without the need for additional immunosuppressive drug treatments. The Company's lead therapeutic candidate is its ReN001 stem cell therapy for the treatment of patients left disabled by the effects of a stroke. This treatment is currently in clinical development. The Company is also developing stem cell therapies for other conditions such as critical limb ischaemia, a serious and common side effect of diabetes, and blindness-causing diseases of the retina.

ReNeuron is also advancing a proprietary platform technology to exploit nanoparticles (exosomes) secreted by stem cells as potential new drug candidates targeting indications in tissue repair, fibrosis and cancer.

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IBC Directors and advisers

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Directors and Advisers

Directors

Bryan Morton, Non-executive Chairman
Michael Hunt, Chief Executive 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
Dr Paul Harper, Non-executive Director

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Highlights in the period

Transformational fundraising and strong progress across all programmes

- Equity fundraising of £25.35 million, before expenses, forecast to fund core therapeutic programmes to value-enhancing clinical milestones and commercial deals over next three years
- Further grant package totalling £7.80 million from Welsh Government to establish a cell manufacturing and development facility in South Wales for late stage clinical and commercial product requirements
- Additional non-dilutive £1.49 million grant awarded from UK Government, via Technology Strategy Board, to support Phase II clinical trial with ReN001 in stroke
- Encouraging interim data from Phase I clinical trial of ReN001 in stroke presented at leading stroke conference
- Orphan Drug Designation granted in both Europe and the US for ReN003 programme for retinitis pigmentosa
- Recent positive data drives accelerated development of proprietary, cryopreserved variant of lead CTX stem cell line with extended shelf life for future clinical trials and in-market use
- Earlier-than-planned switch to cryopreserved CTX drug product expected to lead to lower product costs and earlier market launch with limited impact on near-term programme timelines
- Fundraising enables acceleration of programme to isolate and purify nanoparticles (exosomes) secreted by CTX cells as potential new drug candidates targeting indications in tissue repair, fibrosis and cancer
- Loss for the period of £3.17 million (2012: loss of £2.88 million); cash consumed by operations was £3.42 million (2012: outflow of £3.52 million); cash and cash equivalents at 30 September 2013 of £23.52 million (2012: £6.67 million).

Commenting on the results, Bryan Morton, ReNeuron's Chairman, said:
"The past few months have been transformational for our business, both operationally and financially. We have taken significant steps in the period to build real future value in the business. The £33 million financing completed in the period provides us with the funding to both establish a world-class cell manufacturing facility and to realise value through the generation of solid clinical data and associated commercial deals over the next three years."

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Chairman's and Chief Executive Officer's Joint Statement

Review of operations

The Company's *CTX*-based therapeutic programmes continued to make good progress during the period under review. In May of this year, interim data from the first nine patients treated in the PISCES Phase I clinical trial with ReN001, the Company's stem cell therapy candidate for stroke disability, were presented at the 22nd European Stroke Conference in London. The data showed an absence of cell-related or immunological adverse events in all patients treated and sustained reductions in neurological impairment and spasticity in most patients compared with their stable pre-treatment baseline performance.

These encouraging observations in the PISCES study have continued subsequently, with nine of the eleven patients treated now through one-year follow-up and four of these through two-year follow-up. Further data from the PISCES study will be presented by the Glasgow clinical team in the middle part of next year, for subsequent publication in a peer-reviewed scientific journal.

During the period, and subsequently, we and one of our outsourced contract manufacturers generated positive cell manufacturing data with a proprietary, cryopreserved variant of the *CTX* drug product, demonstrating its equivalence to the existing non-cryopreserved variant. As a result, we intend to accelerate the development of this extended shelf-life cryopreserved *CTX* drug product variant, enabling it to be deployed in all future *CTX*-based clinical trials and for eventual in-market use.

This second-generation *CTX* product variant will provide the business with major commercial and competitive advantages in terms of the availability of a genuine off-the-shelf, low cost-of-goods cell-based treatment with a shelf life enabling shipping to, and storage at, clinical sites on a global basis. The earlier-than-planned deployment of the cryopreserved product will also avoid the need for potential future bridging clinical studies and will enable ongoing clinical trial needs to be served much more efficiently and cost-effectively.

The contract manufacturer is currently completing the remaining validation runs necessary for GMP manufacture of cryopreserved *CTX* drug product, ahead of final regulatory approvals to utilise this enhanced product variant in both the forthcoming Phase II clinical trial with ReN001 in stroke and the Phase I clinical trial with ReN009 in critical limb ischaemia (for which all other regulatory and ethical review points have been cleared in both cases). Subject to these final approvals, both of these studies are expected to commence in the first half of 2014. Phase II data for ReN001 is anticipated in the second half of 2015 and for ReN009 in early 2016 (assuming a successful Phase I outcome next year), both well before the fourth quarter of 2016 into which the Company is now forecast to be financed.

Ahead of the final ReN001 Phase II approvals we will commence a planned non-interventional, observational study in stroke patients, initially at a selection of the clinical sites that will participate in the interventional Phase II study with ReN001. The observational study will allow for the pre-screening of potentially eligible patients for the Phase II study at the sites concerned, enabling such patients to be identified in good time while still in acute stroke care at the hospital. The study will also monitor eligible stroke patients who do not ultimately participate in the Phase II study with ReN001 on the same end-point measures, thus enabling a broader and valuable clinical data set to be built around the stroke patient sub-population we are targeting with the ReN001 therapy.

Earlier positive pre-clinical efficacy studies conducted with the Company's ReN009 candidate for critical limb ischaemia were recently published in the prestigious American Heart Association Journal, Arteriosclerosis, Thrombosis and Vascular Biology. These pre-clinical studies show the dose-dependent positive effects of *CTX* cells in restoring microvasculature and blood flow to the limb extremities in animal models of lower limb ischaemia. The results of these studies have therefore provided the rationale, through our ReN009 programme, to target critical limb ischaemia as a major clinical indication for our *CTX* cell product.

Our ReN003 programme, based on the Company's human retinal progenitor (hRPC) cells, is also progressing well, initially targeting the blindness-causing disease, retinitis pigmentosa. During the period, our academic collaborators at the UCL Institute of Ophthalmology in London confirmed earlier pre-clinical data demonstrating that the hRPC cells are able to enhance visual acuity in a standard rodent model of blindness caused by the loss of photoreceptors in the retina. A key US patent also granted in the period, covering the process by which the hRPC cells are cultured to permit large-scale cell bank generation.

Importantly, the ReN003 therapy was granted Orphan Drug Designation in both Europe and the US during the period. Treatments with this designation benefit from significant commercial and regulatory advantages, such as market exclusivity for 10 years from approval in the disease concerned, against other treatments offering no greater therapeutic advantage. For this reason, orphan status diseases are an increasing area of therapeutic and commercial focus by the mainstream pharmaceutical industry.

The late pre-clinical development programme for ReN003 continues to plan. We are working with key opinion leaders and other advisers in the field in both the UK and US, with a view to filing for regulatory approvals for a Phase I/II clinical trial in the middle part of 2014.

The £33 million financing we completed during the period (and described in the financial review below) provides forecast funding for the business into the fourth quarter of 2016 and will enable us to take our core therapeutic programmes to value-enhancing clinical milestones and commercial deals within this period.

Included within this financing was a £7.8 million grant package from the Welsh Government to establish a world-class cell

manufacturing and development facility in South Wales for late stage clinical and commercial product requirements. This facility will enable us to secure manufacturing capability, and margin, as our therapeutic candidates move closer to market, and therefore represents a key value driver for the business. We have identified a preferred site in South Wales and we are working with the Welsh Government to secure the site and fit it out to our requirements over the coming year. We are targeting to relocate the business to this site by the end of 2014 and to have the site fully licensed for GMP cell manufacture in time to meet our late-stage clinical trial and subsequent commercial product requirements from 2016 onwards.

The financing has also enabled us to accelerate the development of an additional therapeutic platform for the business. We have identified that our *CTX* cells release nanoparticles, known as exosomes, containing key proteins and micro-RNA that appear to influence neighbouring cells to stimulate certain therapeutic mechanisms associated with tissue repair. We have purified and characterised these *CTX*-based exosomes and tested them at differing concentrations in a range of early pre-clinical disease models with positive results. During the period, some of these results were presented at a leading exosome scientific conference in the US.

We have filed multiple patent applications covering our technologies and their therapeutic use in this fast-emerging field. We are targeting our *CTX*-based exosomes as new drug candidates for indications in tissue repair, fibrosis and cancer. The Company is very well-placed to exploit the future therapeutic potential of this field because our *CTX* cells have the capacity to become an efficient and potentially very valuable "producer" cell line for exosome-based therapies.

Financial review

In July 2013 the Company issued 1,014 million new shares at 2.5p per share to raise £25.35m before expenses. The fundraising attracted new blue chip investors such as Invesco, Abingworth and the Wales Life Sciences Investment Fund, which has provided a stronger institutional base to the share register.

In parallel with the equity funding the Welsh Government has offered a grant package of up to £7.80 million to establish a cell manufacturing and development facility in South Wales. The grant has three components comprising funds to fit out and equip the facility, support for employment and support for R&D activities.

Further funding was obtained in the period with a £1.49 million grant from the Technology Strategy Board (TSB), an innovation agency of the UK Government under its Supporting Regenerative Medicines and Cell Therapies Competition. The grant will part-fund the Company's Phase II clinical trial of its ReN001 stem cell therapy for disabled stroke patients. The grant is the third to have been won from the TSB in the financial year, emphasising the significance of the Company's technology and clinical programmes to third party reviewers.

In the six months to 30 September 2013, revenues were £11,000 (2012: £12,000) in addition to which grant income of £178,000 was received and is shown as 'Other operating income' (2012: nil).

Net operating expenses were £3.68 million in the period (2012: £3.35 million) reflecting a similar level of general and administrative costs and an increase in research and development expenditure from clinical manufacture activity.

Interest received reduced in the period to £15,000 (2012: £19,000) as a result of lower average levels of cash deposits held over the period. The Group accrued a research and development tax credit of £311,000 during the period (2012: £439,000) reduced in part because of costs covered by grant income.

The total comprehensive loss for the period increased to £3.17 million (2012: £2.88 million).

Cash consumed by operations at £3.42 million was at a similar level to 2012 (£3.52 million). Given this and following the fundraising the Group had cash and cash equivalents totalling £23.52 million as at 30 September 2013 (2012: £6.67 million).

Summary and outlook

The past few months have been transformational for our business, both operationally and financially. We have highlighted a number of key developments in the period, notably the successful and earlier-than-planned development of a second-generation cryopreserved *CTX* drug product for our stroke and critical limb ischaemia programmes, our planned world-class cell manufacturing facility in South Wales, the granting of Orphan Drug Designation for our retinitis pigmentosa programme and the accelerated development of our *CTX* cell-based exosomes therapeutic platform. These developments represent significant steps to build real future value in the business and the £33 million financing completed in the period provides us with the funding to realise this value through the generation of solid clinical data and associated commercial deals over the next three years.

Bryan Morton
Chairman

Michael Hunt
Chief Executive Officer

2 December 2013

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Unaudited Consolidated Statement of Comprehensive Income
for the six months ended 30 September 2013

	Note	**Six months ended 30 September 2013 £'000**	Six months ended 30 September 2012 £'000	Year ended 31 March 2013 £'000
Revenue		**11**	12	17
Research and development costs		**(2,759)**	(2,365)	(4,786)
General and administrative costs		**(923)**	(982)	(2,319)
Other operating income	3	**178**	0	0
Operating loss		**(3,493)**	(3,335)	(7,088)
Finance income		**15**	19	30
Finance costs		**–**	(1)	(1)
Loss before income taxes		**(3,478)**	(3,317)	(7,059)
Tax credit on loss on ordinary activities		**311**	439	714
Total comprehensive loss for the period		**(3,167)**	(2,878)	(6,345)
Total comprehensive loss attributable to:				
– Equity owners of the company		**(3,167)**	(2,878)	(6,345)
Basic and diluted loss per share	4	**(0.3p)**	(0.4p)	(0.8p)

Unaudited Consolidated Statement of Financial Position
as at 30 September 2013

	30 September 2013 £'000	30 September 2012 £'000	31 March 2013 £'000
Assets			
Non-current assets			
Property, plant and equipment	**219**	239	213
Intangible assets	**1,272**	1,272	1,272
Other non-current assets	**135**	135	135
	1,626	1,646	1,620
Current assets			
Trade and other receivables	**730**	530	341
Corporation Tax Receivable	**1,025**	439	714
Cash and cash equivalents	**23,515**	6,673	3,547
	25,270	7,642	4,602
Total assets	**26,896**	9,288	6,222
Equity			
Equity attributable to owners of the company			
Share capital	**17,888**	7,748	7,748
Share premium	**46,267**	32,972	32,972
Capital redemption reserve	**8,964**	8,964	8,964
Merger reserve	**2,223**	2,223	2,223
Warrant reserve	**149**	108	149
Share-based credit reserve	**2,221**	1,790	2,000
Retained deficit	**(52,315)**	(45,681)	(49,148)
Total equity	**25,397**	8,124	4,908
Liabilities			
Non-current Liabilities			
Provisions	**150**	125	150
Financial liabilities: finance leases	–	–	–
	150	125	150
Current Liabilities			
Trade and other payables	**1,349**	1,035	1,163
Financial liabilities: finance leases	**–**	4	1
	1,349	1,039	1,164
Total liabilities	**1,499**	1,164	1,314
Total equity and liabilities	**26,896**	9,288	6,222

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Unaudited Consolidated Statement of Changes in Equity
for the six months ended 30 September 2013

	Share capital £'000	Share premium account £'000	Capital Redemption Reserve £'000	Merger reserve £'000	Warrant reserve £'000	Share-based credit reserve £'000	Retained deficit £'000	Total Equity £'000
As at 1 April 2012	**6,234**	**28,885**	**8,964**	**2,223**	**108**	**1,623**	**(42,803)**	**5,234**
Issue of new ordinary shares	1,514	4,543	–	–	–	–	–	6,057
Costs of share issue	–	(456)	–	–	–	–	–	(456)
Share-based credit	–	–	–	–	–	167	–	167
Loss for the period	–	–	–	–	–	–	(2,878)	(2,878)
As at 30 September 2012	**7,748**	**32,972**	**8,964**	**2,223**	**108**	**1,790**	**(45,681)**	**8,124**
Issue of new ordinary shares	–	–	–	–	–	–	–	0
Share-based credit	–	–	–	–	–	210	–	210
Issue of Warrants	–	–	–	–	41	–	–	41
Loss for the period	–	–	–	–	–	–	(3,467)	(3,467)
As at 31 March 2013	**7,748**	**32,972**	**8,964**	**2,223**	**149**	**2,000**	**(49,148)**	**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**	**149**	**2,221**	**(52,315)**	**25,397**

Unaudited Consolidated Statement of Cash Flows
for the six months ended 30 September 2013

	Note	**Six months ended 30 September 2013 £'000**	Six months ended 30 September 2012 £'000	Year ended 31 March 2013 £'000
Cash consumed by operations	5	**(3,422)**	(3,523)	(6,637)
Interest paid		**–**	(1)	(1)
Income tax credit received		**–**	616	616
Cash outflow from operating activities		**(3,422)**	(2,908)	(6,022)
Cash flows from investing activities				
Capital expenditure		**(59)**	(17)	(37)
Interest received		**15**	19	30
Net cash generated in investing activities		**(44)**	2	(7)
Cash flows from financing activities				
Finance lease principal payments		**(1)**	(5)	(8)
Proceeds from issuance of ordinary shares		**25,350**	6,057	6,057
Costs of share issue		**(1,915)**	(456)	(456)
Net cash generated by financing activities		**23,434**	5,596	5,593
Net increase/(decrease) in cash and cash equivalents	6	**19,968**	2,690	(436)
Cash and cash equivalents at the start of period		**3,547**	3,983	3,983
Cash and cash equivalents at the end of period	7	**23,515**	6,673	3,547

Notes to the interim financial statements
for the six months ended 30 September 2013

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 2013 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 2014 and the accounting policies set out in ReNeuron Group plc's Annual Report for the year ended 31 March 2013. 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 2013.

This condensed consolidated interim financial information has not been audited 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 2013 were approved by the Board of Directors on 9th August 2013, 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 2013 subject to the following standards, interpretations and amendments to existing standards which are now effective and have been adopted by the Group:

- Amendment to IFRS 7, "Financial instruments: Disclosures" on offsetting financial assets and financial liabilities for periods beginning on or after 1 January 2013.
- Amendment to IAS 12, "Income Taxes" applies for periods beginning on or after 1 January 2013.
- Amendment to IAS 19, "Employee Benefits", for periods beginning on or after 1 January 2013.
- IFRS 13, "Fair Value Measurement", applies for periods beginning on or after 1 January 2013.
- Amendment to IAS 32, "Financial Instruments: Presentation" applies to periods beginning on or after 1 January 2013.

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.
- 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.
- IAS 28 (Revised 2011), "Associates and Joint Ventures" applies for periods beginning on or after 1 January 2014.

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

1.3 Going concern

The Group is developing its technologies for the marketplace and as such absorbs cash until sufficient funds from either licensing or products sold are generated. The directors estimate that the cash held by the Group will be sufficient to support the current level of activities into the fourth quarter of 2016. Consequently, the going concern basis has been adopted in the preparation on these 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 TSB grants 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 £3,167,000 (September 2012: £2,878,000, March 2013: £6,345,000) by 1,068,658,481 shares (September 2012: 739,881,381 shares, March 2013: 748,685,036 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 2013 £'000	Six months ended 30 September 2012 £'000	Year ended 31 March 2013 £'000
Loss before income tax	**(3,478)**	(3,317)	(7,059)
Adjustment for:			
Interest received	**(15)**	(19)	(30)
Interest payable	**–**	1	1
Depreciation of tangible fixed assets	**53**	77	122
Provisions	**–**	–	25
Share-based payment charge	**221**	167	418
Changes in working capital			
Receivables	**(389)**	(73)	116
Payables	**186**	(359)	(230)
Cash consumed by operations	**(3,422)**	(3,523)	(6,637)

Notes to the interim financial statements
for the six months ended 30 September 2013 continued

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

	Six months ended 30 September 2013 £'000	Six months ended 30 September 2012 £'000	Year ended 31 March 2013 £'000
Net (debt)/funds at start of period	**3,546**	3,974	3,974
Increase/(decrease) in cash in the period	**19,968**	2,690	(436)
Cash inflow from decrease in debt	**1**	5	8
Net funds at end of period	**23,515**	6,669	3,546

7. Analysis of net funds

	Six months ended 30 September 2013 £'000	Six months ended 30 September 2012 £'000	Year ended 31 March 2013 £'000
Cash at bank and in hand	**23,515**	6,673	3,547
Finance leases	**–**	(4)	(1)
	23,515	6,669	3,546

8. Related party disclosures

During the period the Company contracted cell manufacturing services of £nil (September 2012: £307,000) from Angel Biotechnology plc, of which Dr Paul Harper was a director.

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