ReNeuron

pioneering stem cell therapeutics

4 December 2012 **AIM: RENE**

ReNeuron Group plc

("ReNeuron" or "the Company")

Interim Results for the six months ended 30 September 2012

Guildford, UK, 4 December 2012: ReNeuron Group plc (AIM: RENE), a leading UK-based stem cell company, is pleased to announce its interim results for the six months ended 30 September 2012.

Highlights

- ReN001 stem cell therapy for stroke:
  - Nine patients treated in PISCES Phase I clinical trial, with the three remaining patients on track to be dosed by March 2013
  - Phase II clinical trial application filed in UK – study expected to commence in mid-2013
- ReN009 stem cell therapy for critical limb ischaemia:
  - Pre-clinical development programme complete
  - Phase I clinical trial applications filed in UK and Germany – study expected to commence in mid-2013
- ReN003 stem cell therapy for retinitis pigmentosa:
  - Further pre-clinical efficacy data generated and late pre-clinical development programme underway
  - Phase I/II clinical trial applications planned for end of 2013 in US and UK
- Pre-clinical efficacy data published in *Cell Transplantation* and *PLOS ONE* demonstrating mechanisms by which lead *CTX* stem cell line may promote repair in stroke-damaged brain
- Share Placing and Open Offer completed in May 2012, raising £6.1 million, before expenses, providing funding for core therapeutic programmes to Q4 2013
- Significant non-dilutive grants applied for across all of the Company's core therapeutic programmes
- Loss for the period reduced to £2.9 million (2011: £3.0 million); cash outflow from operating activities reduced to £2.9 million (2011: £3.2 million); cash and cash equivalents at 30 September 2012 of £6.7 million (2011: £6.5 million)

Commenting on the results, Bryan Morton, Chairman, said:

"During the period under review, our therapeutic programmes have continued to progress to plan. We have well-defined and costed development plans for each of these programmes and we see a clear route to value inflection through commercial deals over the next two to three years if the potential of these therapies can be further demonstrated in the clinic. We have also sought to

reduce the Company's reliance on equity-based funding over this period by pursuing an increasing number of non-dilutive grant opportunities now available to us.

"We believe that our stem cell product candidates embody characteristics that are critical for the development of scalable and affordable off-the-shelf cell-based therapies that can address large unmet medical and patient needs. We therefore strongly believe in the commercial potential of these therapeutic candidates and we look forward to reporting future progress towards realising that potential."

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Notes to Editors

ReNeuron is a leading, clinical-stage stem cell business. Its primary objective is the development of novel stem cell 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 are intended to be readily administered "off-the-shelf" to any eligible patient without the need for additional immunosuppressive drug treatments. ReNeuron's lead candidate is its ReN001 stem cell therapy for the treatment of patients left disabled by the effects of a stroke. This therapy is currently in clinical development. The Company is also developing stem cell therapies for other conditions such as peripheral arterial disease, a serious and common side-effect of diabetes, and blindness-causing diseases of the retina.

ReNeuron has also developed a range of stem cell lines for non-therapeutic applications – its *ReNcell®* products for use in academic and commercial research. The Company's *ReNcell®CX* and *ReNcell®VM* neural cell lines are marketed worldwide under license by USA-based Merck Millipore.

ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. Further information on ReNeuron and its products can be found at www.reneuron.com.

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

Chairman's and Chief Executive Officer's Joint Statement

Review of Operations

During the six months ended 30 September 2012, the PISCES clinical trial in stroke disability continued to progress to plan. In this open label, dose-ranging Phase I safety study, taking place in Scotland, our ReN001 stem cell therapy is being administered in ascending doses to a total of 12 stroke patients who have been left disabled by an ischaemic stroke, the most common form of the condition.

To date, nine patients have been treated with ReN001. Of these, one patient has reached his final two-year follow-up point and four further patients are now beyond their one year follow-up points. There continue to be no cell-related adverse events reported in the trial to date and no reported post-treatment deterioration in any of the patients treated, based on the neuro-functional tests being deployed in the study.

In June, interim data from the PISCES study from the first five patients treated was presented by the Glasgow clinical team at the 10th Annual Meeting of the International Society for Stem Cell Research (ISSCR) in Yokohama, Japan. Reductions in neurological impairment and spasticity were observed in all five patients compared with their stable pre-treatment baseline performance and these improvements were sustained in longer term follow-up.

The remaining three, high-dose cohort patients to be treated in the PISCES study have been pre-screened as eligible for treatment, with patient enquiries continuing to come into the Glasgow clinical site and a number of patients consequently identified as reserve candidates for the study. Subject to Data Safety Monitoring Board approval, these final three patients are scheduled to be treated in January and March 2013.

Based on the above progress, we submitted an application to the UK regulatory authority during the period, to commence a multi-site Phase II clinical trial examining the efficacy of ReN001 in patients disabled by an ischaemic stroke. This trial is designed to recruit from a well-defined population of patients between two and four months after their stroke, which we and our clinical collaborators currently believe will be the optimum treatment window for the therapy. Subject to continuing positive progress with the PISCES study, and based on progress to date with the Phase II application, we maintain our objective to commence the proposed Phase II stroke study in mid-2013, following short-term follow-up of the remaining high-dose cohort in the PISCES study.

During the period, we completed the late-preclinical development programme for our ReN009 stem cell therapy for critical limb ischaemia (CLI). Critical limb ischaemia is the severe end-stage manifestation of peripheral arterial disease and is a common side-effect of diabetes. It is caused by chronic lack of blood supply to the leg due to obstruction of blood flow in the peripheral arteries. The condition is characterised by pain at rest and lesions of the leg. There are no effective therapeutics and as many as 50% of CLI patients currently have no treatment option other than limb amputation. This patient group represents the initial target patient population for the ReN009 therapy, which will be administered via straightforward intramuscular injection of the cells.

Subsequent to completion of pre-clinical testing, we have submitted applications to both the UK and German regulatory authorities to commence a first clinical trial with ReN009. This is planned to be a Phase I dose escalation study in 9 patients, ahead of a larger placebo-controlled Phase II efficacy study, the protocol for which is currently being finalised. The Phase I study will involve at least one site in the UK and a potential further site in Germany, to ensure swift recruitment and treatment of patients. Subject to regulatory and ethical approvals, we hope to be able to commence the Phase I study in mid-2013. We believe that the straightforward nature of the treatment and design of the initial ReN009 clinical trial should enable a relatively swift progression into the planned Phase II study, subject to the Phase I safety end-points being met.

Our ReN003 programme, based on our human retinal progenitor (hRPC) cells, also continues to progress to plan, initially targeting the blindness-causing disease, retinitis pigmentosa. A late

pre-clinical testing programme has now commenced with the ReN003 therapy, in collaboration with academic partners in both the US and at the UCL Institute of Ophthalmology in London. During the period, our US academic collaborators generated further pre-clinical efficacy 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.

We are currently developing the protocol for an initial Phase I/II clinical trial with our ReN003 therapy in the UK and US, in retinitis pigmentosa patients. We have recently engaged with the US FDA to seek pre-filing regulatory advice on this programme, with a view to filing for regulatory approvals for the initial clinical study by the end of 2013.

Post-period end, two important new papers regarding our lead *CTX* stem cell line were published in the leading peer-reviewed scientific journals, *Cell Transplantation* and *PLOS ONE*. The papers describe further non-clinical studies undertaken by ReNeuron researchers and our academic collaborators at King's College London, demonstrating the mechanisms by which the *CTX* cells may promote repair in a stroke-damaged brain. A substantial body of peer-reviewed published work now exists, providing clear and reproducible evidence of the efficacy of our *CTX* cell line in models of stroke damage and the ways in which the cells may promote recovery of function in these models. We believe that these collective mechanism-of-action data, together with the emerging clinical data, will serve us well as we seek to exploit the licensing and commercial potential of our *CTX*-based therapeutic candidates, including our ReN001 candidate for stroke disability.

During the period and thereafter, a number of important and positive broader developments have taken place in the UK regenerative medicine field. Firstly, the process by which stem cell clinical trial applications are reviewed in the UK has been improved, with more frequent review meetings and a clearer delineation of the respective remits of the regulatory and ethical review bodies. Secondly, the Government, through the Technology Strategy Board, has now established the Cell Therapy Catapult, one of a number of innovation centres focused on accelerating the UK's commercial capability in strategically important technology areas. The aim of the London-based Cell Therapy Catapult is to provide the technical infrastructure, knowledge base and funding to grow the UK's cell therapy industry at a clinical and commercial level. Finally, the influential House of Lords Select Committee on Science and Technology has launched an ongoing inquiry into regenerative medicine in the UK, focusing in particular on barriers to the UK's ability to translate its world-leading research capability in this field into treatments and to benefit from the commercial opportunities this presents.

ReNeuron's senior management has played a key advisory role in all of these initiatives and we hope and expect that the Company will ultimately benefit from them as one of the UK's foremost players in this field.

Financial Review

In the six months to 30 September 2012, revenues were £12,000 (2011: £28,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses were £3.3 million in the period (2011: £3.4 million). Research and development expenditure reduced in the period to £2.4 million (2011: £2.5 million), largely reflecting the completion of the pre-clinical work on the ReN009 critical limb ischaemia programme. General and administrative costs in the period increased to £1.0 million from £0.9 million, primarily as a result of an increase in professional fees.

Interest received reduced in the period to £19,000 (2011: £25,000) as a result of lower average levels of cash deposits held over the period.

The Group accrued a research and development tax credit of £439,000 during the period (2011: £344,000), the higher claim reflecting the removal of the PAYE/NI cap on R&D tax credit claims from 1st April 2012.

As a result of the above income statement movements, the total comprehensive loss for the period reduced to £2.9 million (2011: £3.0 million).

The basic and diluted loss per ordinary share in the period reduced to 0.4p (2011: 0.5p loss), reflecting a combination of a smaller post-tax loss and the effect of the increase in ordinary shares in issue following the completion of the Placing and Open Offer referred to below.

Cash consumed by operations reduced to £3.5 million (2011: £3.7 million) due to a combination of a £0.1 million lower loss before tax and a £0.1 million improvement in the Group's working capital position. During the period, the Company raised £6.1 million, before expenses, by means of a Placing and Open Offer to all shareholders.

As a result of the above cash flow movements in the period, the Group had cash and cash equivalents totalling £6.7 million as at 30 September 2012 (2011: £6.5 million).

The directors expect the Group's current financial resources to last into the fourth quarter of 2013. As previously reported, the Company is pursuing a range of future funding options, including the use of non-dilutive grants. To this end, the Company has recently applied for a number of both match-funded or fully funded grants relating to the future Phase II clinical costs of the ReN001 stroke programme, the future Phase I clinical costs of the ReN009 critical limb ischaemia programme and the late pre-clinical development costs of the ReN003 retinitis pigmentosa programme. If these grant applications are successful, they will, in aggregate, significantly reduce the Company's reliance on equity-based funding for its core therapeutic programmes over the next 24 to 36 months. Within this period, the directors anticipate that the Company will have generated sufficient clinical data to take the business to value inflection points across its core therapeutic programmes.

Based on the above, the going concern basis has been adopted in the preparation of these interim financial statements.

Outlook

During the period under review, our therapeutic programmes have continued to progress to plan. We have well-defined and costed development plans for each of these programmes and we see a clear route to value inflection through commercial deals over the next two to three years if the potential of these therapies can be further demonstrated in the clinic. We have also sought to reduce the Company's reliance on equity-based funding over this period by pursuing an increasing number of non-dilutive grant opportunities now available to us.

We believe that our stem cell product candidates embody characteristics that are critical for the development of scalable and affordable off-the-shelf cell-based therapies that can address large unmet medical and patient needs. We therefore strongly believe in the commercial potential of these therapeutic candidates and we look forward to reporting future progress towards realising that potential.

Bryan Morton
Chairman

Michael Hunt
Chief Executive Officer

4 December 2012

Unaudited Consolidated Statement of Comprehensive Income
for the six months ended 30 September 2012

	Note	**Six months ended 30 September 2012** £'000	Six months ended 30 September 2011 £'000	Year ended 31 March 2012 £'000
Revenue		**12**	28	40
Research and development costs		**(2,365)**	(2,538)	(4,865)
General and administrative costs		**(982)**	(894)	(2,059)
Operating loss		**(3,335)**	(3,404)	(6,884)
Finance income		**19**	25	40
Finance costs		**(1)**	(1)	(1)
Loss before income taxes		**(3,317)**	(3,380)	(6,845)
Tax credit on loss on ordinary activities		**439**	344	616
Total comprehensive loss for the period		**(2,878)**	(3,036)	(6,229)
Total comprehensive loss attributable to:				
- Equity owners of the company		**(2,878)**	(3,036)	(6,229)
Basic and diluted loss per share	3	(0.4p)	(0.5p)	(1.0p)

Unaudited Consolidated Statement of Financial Position
as at 30 September 2012

	Note	30 September 2012 £'000	30 September 2011 £'000	31 March 2012 £'000
Assets				
Non-current assets				
Property, plant and equipment		**239**	**367**	299
Intangible assets		**1,272**	**1,272**	1,272
Other non-current assets		**135**	**135**	135
		1,646	**1,774**	1,706
Current assets				
Trade and other receivables		**530**	**509**	457
Corporation Tax Receivable		**439**	**344**	616
Cash and cash equivalents		**6,673**	**6,466**	3,983
		7,642	**7,319**	5,056
Total assets		**9,288**	**9,093**	6,762
Equity				
Equity attributable to owners of the company				
Share capital		**7,748**	**6,199**	6,234
Share premium		**32,972**	**28,811**	28,885
Capital redemption reserve		**8,964**	**8,964**	8,964
Merger reserve		**2,223**	**2,223**	2,223
Warrant reserve		**108**	**108**	108
Share-based credit reserve		**1,790**	**1,461**	1,623
Retained deficit		**(45,681)**	**(39,610)**	(42,803)
Total equity		**8,124**	**8,156**	5,234
Liabilities				
Non-current Liabilities				
Provisions		**125**	**100**	125
Financial liabilities: finance leases			**4**	-
		125	**104**	125
Current Liabilities				
Trade and other payables		**1,035**	**824**	1,394
Financial liabilities: finance leases		**4**	**9**	9
		1,039	**833**	1,403
Total liabilities		**1,164**	**937**	1,528
Total equity and liabilities		**9,288**	**9,093**	6,762

Unaudited Consolidated Statement of Changes in Equity
for the six months ended 30 September 2012

	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 2011	**6,199**	**28,811**	**8,964**	**2,223**	**108**	**1,271**	**(36,574)**	**11,002**
Share-based credit	-	-	-	-	-	190	-	190
Loss for the period	-	-	-	-	-	-	(3,036)	(3,036)
As at 30 September 2011	**6,199**	**28,811**	**8,964**	**2,223**	**108**	**1,461**	**(39,610)**	**8,156**
Issue of new ordinary shares	35	74	-	-	-	-	-	109
Share-based credit	-	-	-	-	-	162	-	162
Loss for the period	-	-	-	-			(3,193)	(3,193)
As at 31 March 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**

Unaudited Consolidated Statement of Cash Flows
for the six months ended 30 September 2012

	Note	**Six months ended 30 September 2012 £'000**	Six months ended 30 September 2011 £'000	Year ended 31 March 2012 £'000
Cash consumed by operations	4	**(3,523)**	(3,686)	(6,276)
Interest paid		**(1)**	(1)	(1)
Income tax credit received		**616**	488	491
Cash outflow from operating activities		**(2,908)**	(3,199)	(5,786)
Cash flows from investing activities				
Capital expenditure		**(17)**	(22)	(30)
Interest received		**19**	25	40
Net cash generated in investing activities		**2**	3	10
Cash flows from financing activities				
Finance lease principal payments		**(5)**	(6)	(9)
Proceeds from issuance of ordinary shares		**6,057**	-	100
Costs of share issue		**(456)**	-	-
Net cash generated by financing activities		**5,596**	(6)	91
Net increase/(decrease) in cash and cash equivalents	5	**2,690**	(3,202)	(5,685)
Cash and cash equivalents at the start of period		**3,983**	9,668	9,668
Cash and cash equivalents at the end of period	6	**6,673**	6,466	3,983

Notes to the interim financial statements

for the six months ended 30 September 2012

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 2012 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 2013 and the accounting policies set out in ReNeuron Group plc's Annual Report for the year ended 31 March 2012. 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 2012.

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 2012 were approved by the Board of Directors on 9 July 2012, 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 2012.

The following new standards, amendments to standards or interpretations became effective for the current reporting period:

- Amendment to IFRS 7, Financial Instruments: Transfers of financial assets (effective 1 July 2011)
- Amendment to IFRS 1 on hyperinflation and fixed dates (effective 1 July 2011)
- Amendment to IAS 12, "Income taxes" on deferred taxation (effective 1 January 2012).

The application of these standards and interpretations has not had a material effect on the net assets, results and disclosures of the Group.

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 2013. Based on anticipated progress in the business in the near term, the directors expect to secure equity-based and other non-dilutive sources of financing sufficient to meet the Group's ongoing requirements thereafter. These circumstances nonetheless represent a material uncertainty, which may cast doubt on the Group's ability to continue as a going concern. Should the Group be unable to obtain further funding, adjustments would be required to reduce balance sheet values of assets to their recoverable amounts, to provide for further liabilities that might arise and to reclassify fixed assets as current assets.

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. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £2,878,000 (September 2011: £3,036,000, March 2012: £6,229,000) by 739,881,381 shares (September 2011: 619,881,967 shares, March 2012: 619,946,923 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.

4. Cash consumed by operations

	Six months ended 30 September 2012 £'000	Six months ended 30 September 2011 £'000	Year ended 31 March 2012 £'000
Loss before income tax	**(3,317)**	(3,380)	(6,845)
Adjustment for:			
Interest received	**(19)**	(25)	(40)
Interest payable	**1**	1	1
Depreciation of tangible fixed assets	**77**	74	150
Provisions	-	-	25
Share-based payment charge	**167**	190	352
Fees payable in shares		-	9
Changes in working capital			
Receivables	**(73)**	(148)	(100)
Payables	**(359)**	(398)	172
Cash consumed by operations	**(3,523)**	(3,686)	(6,276)

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

	Six months ended 30 September 2012 £'000	Six months ended 30 September 2011 £'000	Year ended 31 March 2012 £'000
Net (debt)/funds at start of period	**3,974**	9,649	9,649
Increase/(decrease) in cash in the period	**2,690**	(3,202)	(5,685)
Cash inflow from decrease in debt	**5**	6	10
Net funds at end of period	**6,669**	6,453	3,974

6. Analysis of net funds

	Six months ended 30 September 2012 £'000	Six months ended 30 September 2011 £'000	Year ended 31 March 2012 £'000
Cash at bank and in hand	**6,673**	6,466	3,983
Finance leases	**(4)**	(13)	(9)
	6,669	6,453	3,974

7. Related party disclosures

Transactions with Angel Biotechnology plc

During the period the Company contracted cell manufacturing services of £307,000 (September 2011: £436,000) from Angel Biotechnology plc, of whom Dr Paul Harper is a director.