



Guildford, UK: 28 November 2011

## **ReNeuron Group plc Interim Results for the six months ended 30 September 2011**

### **Highlights**

- ReN001 stem cell therapy for stroke:
  - Five patients treated in PISCES Phase I clinical trial, with all remaining patients expected to be treated in 2012
  - No cell-related adverse events or deteriorations in health reported
  - Phase II efficacy study planned for 2013
- ReN009 stem cell therapy for critical limb ischaemia:
  - Confirmatory pre-clinical efficacy studies completed with positive results
  - Long term pre-clinical safety studies approaching completion
  - Phase I/II clinical trial application planned for H2, 2012
- ReN003 stem cell therapy for retinitis pigmentosa:
  - Further pre-clinical efficacy studies underway following license agreement signed with Schepens Eye Research Institute
  - Retinal cell manufacturing process transferred to US-based contract manufacturer
  - Phase I/II clinical trial application planned for mid-2013
- Board strengthened by appointments of John Berriman and Simon Cartmell as non-executive directors
- Loss for the period of £3.0 million (2010: £2.5 million); cash outflow from operating activities of £3.2 million (2010: £2.0 million); cash and cash equivalents at 30 September 2011 of £6.5 million (2010: £3.5 million)

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

“During the period under review, we have made good progress towards our ambition of developing a clinical-stage pipeline of high value stem cell therapies targeting significant and unmet disease conditions and with high commercial potential. The PISCES stroke trial is making steady and encouraging progress, with our ReN001 therapy exhibiting a very good safety profile in the disabled stroke patients treated thus far. Our other therapeutic programmes are also progressing towards the clinic to plan.”

“We believe that our particular stem cell technologies and capabilities provide us with a real competitive advantage in the field and will stand us in good stead as we look to secure commercial development partnerships for our therapies in due course. We look forward to a very exciting period in ReNeuron’s development.”

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## Chairman's and Chief Executive Officer's Joint Statement

### Review of Operations

During the six months ended 30 September 2011, we completed dosing of the first dose cohort of patients, and commenced dosing of the second dose cohort, in the ground-breaking Phase I clinical trial of our ReN001 stem cell therapy for stroke disability. The PISCES study (Pilot Investigation of Stem Cells in Stroke) is the world's first fully regulated clinical trial of a neural stem cell therapy for disabled stroke patients. The trial is being conducted in Scotland at the Institute of Neurological Sciences, Southern General Hospital, Greater Glasgow and Clyde NHS Board. In this safety study, the 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, five patients have been treated in the study: all three patients in the first dose cohort and two patients in the second dose cohort. The first, second and third patients treated in the first dose cohort are through their 12 month, 9 month and 6 month follow-up points, respectively. The first patient treated in the second dose cohort is through his one month follow-up point. The independent Data Safety Monitoring Board (DSMB) for the trial last met in late October, when it reviewed verified data from the first four patients treated at nine, nine, three and one month follow-up points, respectively. No cell-related adverse events have been reported in any of the patients treated to date and neurological and other safety assessments reviewed by the DSMB show no deterioration in the health of any of the patients as a result of the ReN001 treatment.

We expect that all remaining patients in the PISCES clinical trial will be treated over the course of 2012. We draw considerable encouragement from the progress of the PISCES study thus far and we have commenced the planning and design of a Phase II efficacy study with ReN001. In particular, we hope to be able to set criteria for this efficacy study that will target patients who we believe will best respond to the treatment in terms of the type, size and location of the stroke infarct which has caused their disability. During 2012, we intend to seek advice and clarification from the UK and other regulatory authorities regarding our clinical development strategy for ReN001, with a view to commencing a Phase II study in 2013.

During the period and thereafter, our collaborators at the Bristol Heart Institute completed pre-clinical studies successfully confirming the positive results from earlier pre-clinical efficacy studies with our ReN009 treatment for critical limb ischaemia, the end stage of peripheral arterial disease. Long term pre-clinical safety studies with ReN009 are also approaching completion. With the benefit of support and advice from leading vascular clinicians both in the UK and the US, we are planning to file in mid-late 2012 for approval to commence a substantial multi-centre Phase I/II combined safety and efficacy study with ReN009 in critical limb ischaemia patients. The final choice of location for this study will be determined by further regulatory interactions and the availability of the number of clinical centres that are likely to be required.

Our ReN003 collaborative programme for diseases of the retina continues to make progress in partnership with the Schepens Eye Research Institute in Boston, US, the initial clinical target being the blindness-causing disease, retinitis pigmentosa. Having secured the relevant intellectual property rights from Schepens to develop and commercialise our human retinal precursor cells (hRPCs), we have commenced pivotal pre-clinical efficacy studies to confirm the functional effects of these cells in models of retinitis pigmentosa. During the period, we have also transferred our highly efficient and proprietary hRPC cell expansion process to a contract manufacturer in the US, ahead of GMP banking and long term pre-clinical safety studies. On this basis, we expect to be able to file an application in mid-2013 to commence a Phase I/II clinical trial with ReN003 in retinitis pigmentosa patients. We also hope to shortly announce the establishment of a Clinical Advisory Board of eminent clinicians to advise the Company on the clinical aspects of the ReN003 programme.

Subject to available funding, we are planning to test our lead CTX neural stem cell line pre-clinically in other diseases where we believe the properties of this cell line may confer benefit and where our existing CTX safety and quality data packages can be used in any consequent clinical

trial applications. We are also progressing further pre-clinical studies to explore the potential of ReN001 as a broader treatment to include patients in the earlier stages of recovery from their stroke, as well as testing differing routes of administration of the ReN001 cells.

During the period, we announced the appointment of John Berriman and Simon Cartmell as non-executive directors of the Company. We further announced that Bryan Morton, an existing non-executive director, was to become Chairman, which took effect from 1<sup>st</sup> August 2011. At that point, Professor Trevor Jones stepped down as Chairman in order to establish and chair the Company's Scientific and Strategic Advisory Group. The remit of this advisory group will be to advise and assist the Company on strategic matters relating to its scientific and commercial agenda, including links to academic and industrial organisations and relationships with government bodies, the media and the public. We are in the process of clearing the appointments of the remaining members of this advisory group and we look forward to making a further announcement shortly in this regard.

## **Financial Review**

In the six months to 30 September 2011, revenues were £28,000 (2010: £18,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses were £3.4 million in the period (2010: £2.9 million). Research and development expenditure increased in the period to £2.5 million (2010: £1.7 million), reflecting additional costs incurred in the treatment of patients in the PISCES clinical trial with ReN001, further investment in the manufacturing development of the Group's therapeutic stem cell products and the progression of pre-clinical work on the ReN003 retinal programme following the signing of the collaboration agreement with the Schepens Eye Research Institute. General and administrative costs in the period reduced to £0.9 million from £1.2 million, primarily as a result of the Group ceasing to incur legal fees in connection with an intellectual property dispute with a competitor business, which settled in January 2011.

Other operating income of £135,000 received in the prior period represented grant income received from the UK Government's Technology Strategy Board under its Regenerative Medicine funding programme. No grant income was received in the current period.

Interest received increased in the period to £25,000 (2010: £10,000) as a result of higher average levels of cash deposits held over the period.

The Group accrued a research and development tax credit of £344,000 during the period (2010: £236,000), the higher claim reflecting the increase in pre-clinical and clinical activity across the Group's core therapeutic programmes.

As a result of the above income statement movements, the total comprehensive loss for the period increased to £3.0 million (2010: £2.5 million).

The basic and diluted loss per share reduced to 0.5p per share (2010: 0.6p loss), reflecting both the increased loss and an increase in ordinary shares in issue in the period following the £10 million share placing completed in December 2010.

Cash outflow from operating activities increased in the period to £3.2 million (2010: £2.0 million), due to a combination of the increase in operating expenses in the period and an adverse working capital position following a comparative reduction in creditors since the 31 March 2011 financial year end.

As a result of the above cash flow movements in the period, the Group had cash and cash equivalents totalling £6.5 million as at 30 September 2011 (2010: £3.5 million).

The directors expect the Group's current financial resources to last into the fourth quarter of 2012. The directors are confident of securing equity-based and other sources of funding sufficient to meet the Group's ongoing requirements thereafter. 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, we have made good progress towards our ambition of developing a clinical-stage pipeline of high value stem cell therapies targeting significant and unmet disease conditions and with high commercial potential. The PISCES stroke trial is making steady and encouraging progress, with our ReN001 therapy exhibiting a very good safety profile in the disabled stroke patients treated thus far. Our other therapeutic programmes are also progressing towards the clinic to plan.

We believe that our particular stem cell technologies and capabilities provide us with a real competitive advantage in the field and will stand us in good stead as we look to secure commercial development partnerships for our therapies in due course. We look forward to a very exciting period in ReNeuron's development.

**Bryan Morton**  
Chairman

**Michael Hunt**  
Chief Executive Officer

28 November 2011

**Unaudited Consolidated Statement of Comprehensive Income**  
for the six months ended 30 September 2011

	Note	Six months ended 30 September 2011 £'000	Six months ended 30 September 2010 £'000	Year ended 31 March 2011 £'000
Revenue		28	18	29
Research and development costs		(2,538)	(1,728)	(3,763)
General and administrative costs		(894)	(1,161)	(3,067)
Other operating income		-	135	135
<b>Operating loss</b>		<b>(3,404)</b>	<b>(2,736)</b>	<b>(6,666)</b>
Finance income		25	10	29
Finance costs		(1)	(1)	(2)
<b>Loss before income taxes</b>		<b>(3,380)</b>	<b>(2,727)</b>	<b>(6,639)</b>
Tax credit on loss on ordinary activities		344	236	491
<b>Total comprehensive loss for the period</b>		<b>(3,036)</b>	<b>(2,491)</b>	<b>(6,148)</b>
<b>Total comprehensive loss attributable to:</b>				
- Equity owners of the company		(3,036)	(2,491)	(6,148)
<b>Basic and diluted loss per share</b>	3	<b>(0.5p)</b>	<b>(0.6p)</b>	<b>(1.3p)</b>

**Unaudited Consolidated Statement of Financial Position**  
as at 30 September 2011

	30 September 2011 £'000	30 September 2010 £'000	31 March 2011 £'000
Note			
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	367	488	419
Intangible assets	1,272	1,272	1,272
Trade and other receivables	135	135	135
	<b>1,774</b>	<b>1,895</b>	<b>1,826</b>
<b>Current assets</b>			
Trade and other receivables	509	724	358
Corporation Tax Receivable	344	236	491
Cash and cash equivalents	6,466	3,477	9,668
	<b>7,319</b>	<b>4,437</b>	<b>10,517</b>
<b>Total assets</b>	<b>9,093</b>	<b>6,332</b>	<b>12,343</b>
<b>Equity</b>			
<b>Equity attributable to owners of the company</b>			
Share capital	6,199	4,380	6,199
Share premium	28,811	21,324	28,811
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	1,461	1,058	1,271
Retained deficit	(39,610)	(32,917)	(36,574)
<b>Total equity</b>	<b>8,156</b>	<b>5,140</b>	<b>11,002</b>
<b>Liabilities</b>			
<b>Non-current Liabilities</b>			
Provisions	100	75	100
Financial liabilities: finance leases	4	10	9
	<b>104</b>	<b>85</b>	<b>109</b>
<b>Current Liabilities</b>			
Trade and other payables	824	1,095	1,222
Financial liabilities: finance leases	9	12	10
	<b>833</b>	<b>1,107</b>	<b>1,232</b>
<b>Total liabilities</b>	<b>937</b>	<b>1,192</b>	<b>1,341</b>
<b>Total equity and liabilities</b>	<b>9,093</b>	<b>6,332</b>	<b>12,343</b>

**Unaudited Consolidated Statement of Changes in Equity**  
for the six months ended 30 September 2011

	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
<b>As at 1 April 2010</b>	<b>4,377</b>	<b>21,310</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>876</b>	<b>(30,426)</b>	<b>7,432</b>
Issue of new ordinary shares	3	14	-	-	-	-	-	17
Share-based credit	-	-	-	-	-	182	-	182
Loss for the period	-	-	-	-	-	-	(2,491)	(2,491)
<b>As at 30 September 2010</b>	<b>4,380</b>	<b>21,324</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>1,058</b>	<b>(32,917)</b>	<b>5,140</b>
Issue of new ordinary shares	1,819	8,183	-	-	-	-	-	10,002
Costs of share issue	-	(696)	-	-	-	-	-	(696)
Share-based credit	-	-	-	-	-	213	-	213
Loss for the period	-	-	-	-	-	-	(3,657)	(3,657)
<b>As at 31 March 2011</b>	<b>6,199</b>	<b>28,811</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>1,271</b>	<b>(36,574)</b>	<b>11,002</b>
Share-based credit	-	-	-	-	-	190	-	190
Loss for the period	-	-	-	-	-	-	(3,036)	(3,036)
<b>As at 30 September 2011</b>	<b>6,199</b>	<b>28,811</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>1,461</b>	<b>(39,610)</b>	<b>8,156</b>



**Unaudited Consolidated Statement of Cash Flows**  
for the six months ended 30 September 2011

		Six months ended 30 September 2011 £'000	Six months ended 30 September 2010 £'000	Year ended 31 March 2011 £'000
	Note			
<b>Cash consumed by operations</b>	4	(3,686)	(2,024)	(5,515)
Interest paid		(1)	(1)	(2)
Income tax credit received		488	-	369
<b>Cash outflow from operating activities</b>		(3,199)	(2,025)	(5,148)
<b>Cash flows from investing activities</b>				
Capital expenditure		(22)	(26)	(32)
Interest received		25	10	29
<b>Net cash generated in investing activities</b>		3	(16)	(3)
<b>Cash flows from financing activities</b>				
Finance lease principal payments		(6)	(7)	(10)
Proceeds from issuance of ordinary shares		-	-	10,000
Costs of share issue		-	-	(696)
<b>Net cash generated by financing activities</b>		(6)	(7)	9,294
<b>Net (decrease)/increase in cash and cash equivalents</b>	5	(3,202)	(2,048)	4,143
Cash and cash equivalents at the start of period		9,668	5,525	5,525
<b>Cash and cash equivalents at the end of period</b>	6	6,466	3,477	9,668

## **Notes to the interim financial statements**

for the six months ended 30 September 2011

### **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 2011 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 2012 and the accounting policies set out in ReNeuron Group plc's Annual Report for the year ended 31 March 2011. 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 2011.

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 2011 were approved by the Board of Directors on 22 July 2011, 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 2011.

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

IAS 24 (revised) Related Party Disclosures.

IFRIC 14 (amendment) Prepayment of a Minimum Funding Requirement.

IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments.

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 2012. Based on anticipated progress in the business in the near term, the directors expect to secure equity-based and other 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 Board of Directors 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.

### 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 £3,036,000 (September 2010: £2,491,000, March 2011: £6,148,000) by 619,881,967 shares (September 2010: 437,945,013 shares, March 2011: 486,506,803 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 2011 £'000	Six months ended 30 September 2010 £'000	Year ended 31 March 2011 £'000
<b>Loss before income tax</b>	<b>(3,380)</b>	<b>(2,727)</b>	<b>(6,639)</b>
Adjustment for:			
Interest received	(25)	(10)	(29)
Interest payable	1	1	2
Depreciation of tangible fixed assets	74	79	154
Provisions	-	-	25
Share-based payment charge	190	182	395
Fees payable in shares	-	17	19
Changes in working capital			
Receivables	(148)	(74)	(77)
Payables	(398)	508	635
<b>Cash consumed by operations</b>	<b>(3,686)</b>	<b>(2,024)</b>	<b>(5,515)</b>

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

	Six months ended 30 September 2011 £'000	Six months ended 30 September 2010 £'000	Year ended 31 March 2011 £'000
Net funds at start of period	9,649	5,496	5,496
(Decrease)/increase in cash in the period	(3,202)	(2,048)	4,143
Cash inflow from decrease in debt	6	7	10
<b>Net funds at end of period</b>	<b>6,453</b>	<b>3,455</b>	<b>9,649</b>

### 6. Analysis of net funds

	Six months ended 30 September 2011 £'000	Six months ended 30 September 2010 £'000	Year ended 31 March 2011 £'000
Cash at bank and in hand	6,466	3,477	9,668
Finance leases	(13)	(22)	(19)
	<b>6,453</b>	<b>3,455</b>	<b>9,649</b>

## **7. Related party disclosures**

### **Transactions with Excalibur Fund Managers Limited**

Excalibur Fund Managers Limited, as investment advisor to Merlin General Partner II Limited, a substantial shareholder in the Company, recharged directors' fees of £nil in the period (September 2010: £7,500).

### **Transactions with Angel Biotechnology plc**

During the period the Company contracted cell manufacturing services of £436,000 (September 2010: £177,000) from Angel Biotechnology plc, of whom Dr Paul Harper is a director.

### **About ReNeuron**

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 can 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](http://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.*