

**ReNeuron Group plc  
Preliminary Results for the Year Ended 31 March 2012**

**Highlights**

- ReN001 stem cell therapy for stroke:
  - Six patients treated in PISCES Phase I clinical trial, with remaining patients expected to be recruited and dosed by early 2013
  - Interim data from first five patients in PISCES study presented at leading stem cell conference:
    - no cell-related adverse events
    - evidence of sustained reductions in neurological impairment and spasticity
  - Phase II clinical trial application planned for mid-2013
- ReN009 stem cell therapy for critical limb ischaemia:
  - Confirmatory pre-clinical efficacy and safety studies completed
  - Pre-clinical efficacy confirmed across a range of cell formulations
  - Phase I/II clinical trial application planned for H2, 2012
- ReN003 stem cell therapy for retinitis pigmentosa:
  - Pre-clinical efficacy data presented with confirmatory pre-clinical efficacy studies in progress
  - Retinal cell manufacturing process successfully transferred to US-based contract manufacturer
  - Phase I/II clinical trial application planned for late 2013
- Management and advisory functions strengthened by non-executive Board appointments and establishment of Scientific and Strategic Advisory Group
- Share Placing and Open Offer announced post year-end, raising £6.1 million, before expenses, providing pre-clinical and clinical development funding for core therapeutic programmes to Q3 2013
- Loss for the year of £6.2 million (2011: £6.1 million); cash used in operating activities of £5.8 million (2011: £5.1 million); cash and cash equivalents at 31 March 2012 of £4.0 million (2011: £9.7 million)

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

“During the period under review, our therapeutic programmes have continued to progress well. We are encouraged by the recently presented interim data from the PISCES clinical trial of our ReN001 therapeutic candidate for stroke and we remain on track to file an application, later this year, to commence clinical development of our ReN009 therapeutic candidate for critical limb ischaemia. The pre-clinical development of our ReN003 therapeutic candidate for retinitis pigmentosa also progresses to plan.

We and our academic collaborators have continued to generate and present a breadth of pre-clinical data demonstrating the potency, versatility and clinical and commercial potential of our lead CTX neural and hRPC retinal stem cell product candidates used in our therapeutic programmes. These are stem cell product candidates which demonstrate the characteristics that we believe are critical for the development of scalable and affordable off-the-shelf cell-based therapies addressing large unmet patient needs. We look forward to reporting further progress towards the realisation of that clinical and commercial potential in the year ahead.”

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

### **Review of Operations**

#### **ReN001 stem cell therapy for stroke**

During the financial year, and subsequently, dosing of the first two dose cohorts was completed in the Phase I clinical trial of our ReN001 stem cell therapy candidate 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 therapeutic candidate 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 cells are 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. The primary aim of the study is to test the safety and tolerability of the treatment in ascending doses of the ReN001 cells, in patients with moderate to severe functional neurological impairments resulting from their stroke. The secondary aim of the study is to evaluate efficacy measures for the design of future clinical trials with ReN001, including imaging measures as well as a number of tests of sensory, motor and cognitive functions.

To date, one patient is through 18 month follow-up, two are through 12 month follow-up, one is through 9 month follow-up, one is through 6 month follow-up and one is through one month follow-up. No cell-related adverse events or adverse immune-related responses have been reported in any of the patients treated to date.

Earlier this month, interim data from the PISCES study from the first five patients treated, at 2 x 12 month, 1 x six month and 2 x three month follow-up points, was presented by the clinical team at Glasgow at the 10<sup>th</sup> 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. Additionally, functional magnetic resonance imaging (fMRI) data, collected pre- and post-treatment to identify potential biomarkers of change in neurological function, showed some longitudinal changes in motor activation, consistent with the observed improvements in neurological measures.

During the period, the PISCES study was adopted by the National Institute for Health Research (NIHR) Stroke Research Network. The NIHR is the UK public body responsible for promoting and enabling clinical research through the UK's NHS infrastructure. Adopted studies benefit from a number of measures to streamline and coordinate the set-up and monitoring of clinical sites and patient recruitment.

We remain greatly encouraged by the progress of the PISCES study thus far as we continue to plan for a proposed Phase II efficacy study with ReN001. The Glasgow clinical site is scheduling surgery dates for the remaining dose cohorts and we intend to seek approval for at least one further UK clinical site to recruit patients into the PISCES study should this be necessary to meet the remaining recruitment timetable. We expect that, subject to a continuing lack of cell-related adverse events and affirmative Data Safety Monitoring Board advice, the remaining higher dose

cohorts in the PISCES study will have been recruited and treated by early 2013, leaving the Company on track to submit an application for a Phase II clinical study with ReN001 in mid-2013.

### **Other therapeutic programmes**

The Company's other therapeutic programmes continue to progress to plan. Our academic collaborators at the Bristol Heart Institute have now completed pre-clinical studies successfully confirming the positive results from earlier pre-clinical efficacy studies with the Company's ReN009 stem cell treatment candidate for critical limb ischaemia, the end stage of peripheral arterial disease. Long term pre-clinical safety studies with ReN009 have also now been successfully completed.

Earlier this month, we presented data at the ISSCR meeting from a pivotal pre-clinical study examining different formulations of the Company's lead CTX stem cell line (used in both the Company's ReN001 stroke and ReN009 critical limb ischaemia candidate therapies). The results of the study showed equivalent efficacy in a rodent model of critical limb ischemia, regardless of cell formulation. The cell formulations tested included freshly prepared CTX cells prior to treatment, formulations of cryopreserved CTX cells using differing freezing media (and thawed prior to treatment), and a formulation of CTX cells incorporating the luciferase gene which allows the cells to be tracked post-implantation. The apparent potency of the CTX cells in models of critical limb ischaemia across these differing cell formulations bodes well for future commercial scale-up and manufacturing of the CTX cells.

We remain on track, later this year, to file for approval to commence a European multi-centre Phase I/II combined safety and efficacy study with ReN009 in critical limb ischaemia patients.

Our ReN003 programme for diseases of the retina continues to make progress, the initial clinical target being the blindness-causing disease, retinitis pigmentosa. Confirmatory pre-clinical efficacy studies with our human retinal progenitor cells (hRPCs) are underway in conjunction with academic collaborators at the US Schepens Eye Research Institute, Massachusetts Eye and Ear and elsewhere. During the period, we transferred our highly efficient and proprietary hRPC cell expansion process to Wuxi AppTec, a leading contract manufacturer with operations in China and the US, ahead of GMP banking and long term pre-clinical safety studies scheduled to commence shortly.

Data from a number of pre-clinical studies with our hRPC cell technology were also presented at the ISSCR meeting earlier this month, demonstrating that the hRPCs differentiate into cells expressing the appropriate cell surface markers for photoreceptors, the cells lost in retinitis pigmentosa patients. The data presented also demonstrated that in rodent models of retinal degeneration, transplanted hRPCs migrate into the outer nuclear layer of the host retina whilst preserving the characteristics of mature photoreceptors.

Based on the above progress, we are targeting a clinical trial filing for ReN003 in late 2013 in patients with retinitis pigmentosa.

### **Other activities**

During the period, we announced the appointment of John Berriman and Simon Cartmell as non-executive directors of the Company. Also during the period, Professor Trevor Jones stepped down as Chairman in order to establish the Company's Scientific and Strategic Advisory Group. Bryan

Morton, an existing non-executive director, became Chairman at this point. The remit of this new Advisory Group is 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 pleased to announce that the membership of the Scientific and Strategic Advisory Group has now been established and that, consequently, Professor Jones has, as planned, stepped down from the Board of the Company in order to chair the Advisory Group. On behalf of the Board of the Company, we would like to thank Professor Jones for the enormous contribution he has made as a director and Chairman of the Board since 1999 and we look forward to his continuing contribution to the business as Chairman of the Advisory Group.

We also pleased to announce the appointment of Dr Tim Corn as a non-executive director of the Company.

With the above appointments, the business now benefits from senior management, Board members and other external advisers with the breadth and depth of technical, clinical, regulatory and commercial experience to guide the successful clinical and commercial development of the Company's programmes.

During the year, we were proud to both sponsor and present at the UK Stroke Association's 2011 Stroke Forum conference in Glasgow. The Stroke Association is the major stroke charity in the UK, working with stroke survivors and their families as well as researchers and medics in the field.

## **Funding**

Subsequent to the financial year end, we announced in April 2012 that the Company had raised £6.1 million, before expenses, by means of a Placing and Open Offer to shareholders. This funding, together with existing cash resources, will be utilised to support current operations, including treatment of the remaining patients in the ReN001 Phase I stroke clinical trial, progressing regulatory submissions for a Phase II clinical trial with ReN001, securing regulatory approval for the ReN009 critical limb ischaemia Phase I/II clinical trial and pre-clinical development of the ReN003 retinal programme. Additional funding will be required for future clinical development of the ReN001 and ReN009 therapeutic candidates beyond that point. Programme spend will therefore be managed such that any significant costs on either programme, beyond obtaining the necessary regulatory approvals to commence the ReN001 Phase II and ReN009 Phase I/II clinical trials, will be incurred once such funding is secured.

We are actively pursuing a range of future funding sources, including potentially non-dilutive sources such as grants. We are also exploring the potential to reduce longer term funding requirements by the partnering of certain of our stem cell technologies and therapeutic programmes to commercial development partners in due course. Early discussions with interested parties have commenced in this regard.

Following completion of the above-mentioned Placing and Open Offer, we expect that our existing cash resources will be sufficient to support current operations until the end of the third quarter of 2013. Consequently, the going concern basis has been adopted in preparation of these financial statements.

## Summary of results

In the year to 31 March 2012, revenues were £40,000 (2011: £29,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses in the year were £6.9 million (2011: £6.8 million). Research and development expenditure increased in the year to £4.9 million (2011: £3.8 million), reflecting the additional costs incurred in the treatment of patients in the ReN001 clinical trial, further investment in developing the manufacturing processes for the Company's cell product candidates, completion of the late pre-clinical work on the ReN009 critical limb ischaemia therapeutic candidate and the progression of pre-clinical work on the ReN003 retinal programme. General and administrative costs in the period reduced to £2.1 million from £3.1 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 income from grants. No grant income was received in the current period.

Interest received increased in the period to £40,000 (2011: £29,000) as a result of higher average levels of cash deposits held over the period.

The Group accrued a research and development tax credit of £0.6m during the year (2011: £0.5m), 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 post-tax loss for the year increased to £6.2 million (2011: £6.1 million). The basic and diluted loss per share reduced to 1.0p per share (2011: 1.3p loss), reflecting a combination of an increased loss and the full year effect of the increase in ordinary shares in issue following the completion of the placing in December 2010.

Cash used in operating activities increased in the year to £5.8 million (2011: £5.1 million), primarily due to legal fee accruals at 31 March 2011 associated with the prior year intellectual property dispute, being paid in the current financial year.

As a result of the above cash flow movements in the year, the Group had cash and cash equivalents totalling £4.0 million as at 31 March 2012 (2011: £9.7 million). Subsequent to the financial year end, and as mentioned above, the Company announced that it had raised £6.1 million, before expenses, by means of a Placing and Open Offer to shareholders.

## **Summary and outlook**

During the period under review, our therapeutic programmes have continued to progress well. We are encouraged by the recently presented interim data from the PISCES clinical trial of our ReN001 therapeutic candidate for stroke and we remain on track to file an application, later this year, to commence clinical development of our ReN009 therapeutic candidate for critical limb ischaemia. The pre-clinical development of our ReN003 therapeutic candidate for retinitis pigmentosa also progresses to plan.

During the year, we and our academic collaborators have continued to generate and present a breadth of pre-clinical data demonstrating the potency, versatility and clinical and commercial potential of our lead *CTX* neural and hRPC retinal stem cell product candidates used in our therapeutic programmes. These are stem cell product candidates which demonstrate the characteristics that we believe are critical for the development of scalable and affordable off-the-shelf cell-based therapies addressing large unmet patient needs. We look forward to reporting further progress towards the realisation of that clinical and commercial potential in the year ahead.

**Bryan Morton**  
Chairman

**Michael Hunt**  
Chief Executive Officer

28 June 2012

**Group Statement of  
Comprehensive Income for the  
year ended 31 March**

	Note	2012 £'000	2011 £'000
Revenue		40	29
Research and development costs	4	(4,865)	(3,763)
General and administrative costs		(2,059)	(3,067)
Other operating income		-	135
<b>Operating loss</b>		<b>(6,884)</b>	(6,666)
Finance income		40	29
Finance costs		(1)	(2)
<b>Loss before income tax</b>		<b>(6,845)</b>	(6,639)
Tax on loss on ordinary activities		616	491
<b>Loss and total comprehensive loss for the year</b>		<b>(6,229)</b>	(6,148)
<b>Total loss and total comprehensive loss attributable to:</b>			
- Equity owners of the Company		(6,229)	(6,148)
<b>Basic and diluted loss per ordinary share</b>	5	<b>(1.0p)</b>	(1.3p)

<b>Group Statement of Financial Position</b>		
<b>as at 31 March</b>	<b>2012</b>	<b>2011</b>
	<b>£'000</b>	<b>£'000</b>
<b>Assets</b>		
<b>Non-current assets</b>		
Property, plant and equipment	299	419
Intangible assets	1,272	1,272
Trade and other receivables	135	135
	<b>1,706</b>	<b>1,826</b>
<b>Current assets</b>		
Trade and other receivables	457	358
Corporation tax receivable	616	491
Cash and cash equivalents	3,983	9,668
	<b>5,056</b>	<b>10,517</b>
<b>Total assets</b>	<b>6,762</b>	<b>12,343</b>
<b>Equity</b>		
<b>Equity attributable to owners of the company</b>		
Share capital	6,234	6,199
Share premium account	28,885	28,811
Capital redemption reserve	8,964	8,964
Merger reserve	2,223	2,223
Warrant reserve	108	108
Share-based credit reserve	1,623	1,271
Retained deficit	(42,803)	(36,574)
<b>Total equity</b>	<b>5,234</b>	<b>11,002</b>
<b>Liabilities</b>		
<b>Non-current liabilities</b>		
Provisions	125	100
Financial liabilities: finance leases	-	10
	<b>125</b>	<b>110</b>
<b>Current Liabilities</b>		
Trade and other payables	1,394	1,222
Financial liabilities: finance leases	9	9
	<b>1,403</b>	<b>1,231</b>
<b>Total liabilities</b>	<b>1,528</b>	<b>1,341</b>
<b>Total equity and liabilities</b>	<b>6,762</b>	<b>12,343</b>



**Group Statement of Changes in Equity**

	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	1,822	8,197	-	-	-	-	-	10,019
Costs of share issue	-	(696)	-	-	-	-	-	(696)
Share-based credit	-	-	-	-	-	395	-	395
Loss for the year and total comprehensive loss	-	-	-	-	-	-	(6,148)	(6,148)
<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>
Issue of new ordinary shares	35	74	-	-	-	-	-	109
Share-based credit	-	-	-	-	-	352	-	352
Loss for the year and total comprehensive loss	-	-	-	-	-	-	(6,229)	(6,229)
<b>As at 31 March 2012</b>	<b>6,234</b>	<b>28,885</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>1,623</b>	<b>(42,803)</b>	<b>5,234</b>

**Group Statement of Cash Flows for the  
year ending 31 March**

	Note	2012 £'000	2011 £'000
<b>Cash used in operations</b>	6	<b>(6,276)</b>	(5,515)
Interest paid		(1)	(2)
Income tax credit received		491	369
<b>Cash used in operating activities</b>		<b>(5,786)</b>	(5,148)
<b>Cash flows from investing activities</b>			
Capital expenditure		(30)	(32)
Interest received		40	29
<b>Net cash generated from/(used in) investing activities</b>		<b>10</b>	(3)
<b>Cash flows from financing activities</b>			
Finance lease principal payments		(9)	(10)
Proceeds from issuance of ordinary shares		100	10,000
Costs of share issue		-	(696)
<b>Net cash generated from financing activities</b>		<b>91</b>	9,294
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>(5,685)</b>	4,143
Cash and cash equivalents at the start of year		9,668	5,525
<b>Cash and cash equivalents at the end of year</b>		<b>3,983</b>	9,668

## **Notes to the financial information for the year ended 31 March 2012**

### **1. General information**

ReNeuron Group plc (“the Company”) and its subsidiaries (together “the Group”) are engaged in the research and development of therapies using stem cells. The Company is a public limited company incorporated and domiciled in England with registered number 05474163 and its shares are listed on the AIM stock market.

The unaudited financial information included in this preliminary results announcement for the year ended 31 March 2012 and audited financial information for the year ended 31 March 2011 does not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006, but has been extracted from the statutory financial statements for the year ended 31 March 2012 which will be delivered to the Registrar of Companies in due course. Statutory accounts for the year ended 31 March 2011 were approved by the Board of directors and delivered to the Registrar of Companies.

### **2. Accounting policies and basis of preparation**

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union, the interpretations of International Financial Reporting Interpretations Committee (IFRIC) and the Companies Act 2006 applicable to companies reporting under IFRS.

Whilst the financial information included in this preliminary announcement has been prepared in accordance with (IFRSs), this announcement does not itself contain sufficient information to comply with IFRSs. The preliminary announcement should be read in conjunction with the annual financial statements for the year ended 31 March 2012, which have also been prepared in accordance with IFRSs as adopted by the European Union.

The financial statements have been prepared on a historical cost basis. The accounting policies used in the preparation of these unaudited financial statements are consistent with those used in the preparation of the audited financial statements for the year ended 31 March 2011, except as described below.

A number of new and amended standards became effective for periods beginning on or after 1 January 2011. The principal changes that are relevant to the Group are:

Revised IAS 24, ‘Related party disclosures’, issued in November 2009. It supersedes IAS 24, ‘Related party disclosures’, issued in 2003. The revised IAS 24 is required to be applied from 1 January 2011.

### **3. Going concern**

ReNeuron's lead therapeutic candidate for stroke is in clinical development and it has other therapeutic candidates in pre-clinical development. The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development.

Subsequent to the financial year end, in April 2012, the Company announced that it had raised £6.1 million, before expenses, by means of a Placing and Open Offer to shareholders. This funding, together with existing cash resources, will be utilised to support current operations, including treatment of the remaining patients in the ReN001 Phase I stroke trial, progressing regulatory submissions for a Phase II trial of ReN001, securing regulatory approval for the ReN009 critical limb ischaemia Phase I/II trial and pre-clinical development of the ReN003 retinal programme.

Following the completion of the Placing and Open Offer, the Directors estimate that the cash held by the Group will be sufficient to support the current clinical programme and pre-clinical development described above to the end of the third quarter of 2013. Additional funding will be required for future clinical development of the ReN001 and ReN009 therapeutic candidates beyond this point and the Group will only incur significant costs on either programme, beyond obtaining the necessary regulatory approvals to commence the ReN001 Phase II and ReN009 Phase I/II clinical trials, once such funding is secured.

Based on anticipated progress in the business in 2012, the Directors do expect to secure additional financing from a range of funding sources, including potentially non-dilutive sources such as grants, sufficient for the future needs of the business beyond the third quarter of next year. The Group has an established track record of successfully raising funding from a number of sources but there is no certainty that adequate resources will be available on a timely basis. In the event that further funding is not achieved, then the Group would have to curtail or defer its planned programme development.

After making enquiries, the Directors consider that the Company and the Group have adequate resources to continue in operations for the foreseeable future. Accordingly, they have adopted the going concern basis in preparing the financial statements.

### **4. Research and development costs**

All research and development costs incurred in the year have been charged directly to the income statement.

### **5. Basic and diluted loss per ordinary share**

The basic and diluted loss per share is calculated by dividing the loss for the financial year of £6,229,000 (2011: £6,148,000) by 619,946,923 shares (2011: 486,506,803 shares), being the weighted average number of ordinary 1p shares in issue during the year.

Potential ordinary shares are not treated as dilutive as the entity is loss making.

## 6. Cash used in operations

	Year ended 31 March 2012 £'000	Year ended 31 March 2011 £'000
<b>Loss before income tax</b>	<b>(6,845)</b>	(6,639)
Adjustment for:		
Interest received	(40)	(29)
Interest payable	1	2
Depreciation of property, plant and equipment	150	154
Provisions movement	25	25
Share-based payment charges	352	395
Fees payable in ordinary shares	9	19
Changes in working capital		
Receivables	(100)	(77)
Payables	172	635
<b>Cash used in operations</b>	<b>(6,276)</b>	(5,515)

### 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 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*<sup>®</sup> products for use in academic and commercial research. The Company’s *ReNcell*<sup>®</sup> CX and *ReNcell*<sup>®</sup> 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.*