

ReNeuron Group plc

Unaudited Preliminary Results for the Year Ended 31 March 2013

Guildford, UK, 22 July 2013: ReNeuron Group plc (“ReNeuron” or the “Company”), a leading UK-based stem cell company, is pleased to announce its preliminary results for the year ended 31 March 2013.

Highlights

- ReN001 stem cell therapy candidate for stroke:
 - Dosing complete in Phase I clinical trial
 - Encouraging Phase I interim data presented at European Stroke Conference
 - Phase II clinical trial expected to commence in UK later this year
- ReN009 stem cell therapy candidate for critical limb ischaemia:
 - Regulatory and ethical approvals received for Phase I clinical trial – study expected to commence in UK later this year
- ReN003 stem cell therapy candidate for retinitis pigmentosa:
 - Further positive pre-clinical efficacy data generated and late pre-clinical development programme underway
 - Phase I/II clinical trial application planned for mid-2014 in US and UK
- Share Placing announced today to raise £25.35 million, before expenses, fully funding core therapeutic programmes through Phase II clinical development over next three years (see separate release)
- Further grant package totalling £7.8 million from Welsh Government announced today
 - Grant funding will enable establishment of cell manufacturing and development facility in South Wales over next two years, for late stage clinical and commercial product requirements
- Non-dilutive grants and contributions in kind totalling £2.5 million awarded during the period from UK Government, via Technology Strategy Board and Cell Therapy Catapult

- Loss for the period of £6.3 million (2012: £6.2 million); cash outflow from operating activities of £6.0 million (2012: £5.8 million); cash and cash equivalents at 31 March 2013 of £3.5 million (2012: £4.0 million)

Commenting on the results and fundraising, Bryan Morton, ReNeuron’s Chairman, said:

“Our therapeutic programmes have made considerable progress during the period under review. The Phase I clinical trial of our stem cell therapy candidate for stroke has yielded encouraging data and a Phase II study is planned to commence shortly, as is a Phase I study with our therapeutic candidate for critical limb ischaemia. We expect our stem cell therapy candidate for the blindness-causing disease, retinitis pigmentosa, to enter the clinic next year.

“We have well-defined clinical development plans for these therapeutic programmes and process development plans to both enhance and take control over the manufacture of our stem cell therapy candidates as they get closer to market. Crucially, the business is now fully funded to pursue these plans through to value inflection and commercial deals over the next three years and we look forward to reporting further progress towards that end.”

Analyst meeting and webcast

A meeting for analysts will be held at 10.30am today at the offices of Buchanan, 107 Cheapside, London, EC2V 6DN.

For a webcast of the analyst presentation, please log on to the following web address about 10 minutes before 10.30am: <http://mediaserve.buchanan.uk.com/2013/reneuron220713/registration.asp>.

For further details please contact Buchanan on 020 7466 5000.

A recording of the webcast will be made available on ReNeuron’s and Buchanan’s websites, www.reneuron.com and www.buchanan.uk.com.

Enquiries:

ReNeuron Michael Hunt, Chief Executive Officer Pat Huggins, Head of Finance	+44 (0) 1483 302560
Buchanan Mark Court, Fiona Henson, Sophie Cowles	+44 (0) 20 7466 5000
Cenkos Securities Stephen Keys, Adrian Hargrave (NOMAD and Broker) Andy Roberts (Sales)	+44 (0) 20 7397 8900

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 critical limb ischaemia, a serious and common side-effect of diabetes, and blindness-causing diseases of the retina such as retinitis pigmentosa.

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

Therapeutic programmes

During the financial year, we made good progress with our ReN001 stem cell candidate for stroke disability. Interim data from the first nine patients treated in the PISCES Phase I clinical trial with ReN001 were presented by the clinical team from Glasgow's Southern General Hospital at the 22nd European Stroke Conference in London in May of this year. There were no cell-related or immunological adverse events reported in any of the patients treated and sustained reductions in neurological impairment and spasticity were observed in most patients compared with their stable pre-treatment baseline performance.

Since the above data were collated, the remaining patients in the PISCES study have been treated and are all now through their short term follow-up period, with no cell-related or immunological adverse events reported.

During the period, we cleared all points arising from the regulatory review of our proposed UK multi-site Phase II clinical trial to examine the efficacy of ReN001 in disabled stroke patients. This Phase II study has been adopted by the NHS National Institute for Health Research Stroke Research Network (SRN), enabling us to work closely with the SRN to optimise performance against defined targets regarding site set-up, patient recruitment and monitoring activities across the various sites participating in the study. The SRN has also adopted a separate non-interventional protocol to allow for the pre-screening of potentially eligible patients for the Phase II study at the sites concerned. This separate protocol will enable such patients to be identified in good time while still in acute stroke care at the hospital.

As planned, we are now preparing a data package including three month follow-up data on the final dose cohort in the PISCES study in order to obtain final regulatory and ethical approvals for the Phase II clinical trial with ReN001. Assuming approvals are granted, we expect to commence recruitment into the Phase II study later this year.

During the period, we received regulatory and ethical approvals to commence a Phase I clinical trial in the UK with our ReN009 stem cell therapy programme targeting the major unmet medical need, critical limb ischaemia (CLI). CLI represents the second major disease target after stroke for our lead CTX stem cell line and is based on a number of pre-clinical studies showing dose-dependent positive effects of the CTX cells in restoring microvasculature and blood flow to the limb extremities in animal models of lower limb ischaemia. Our ReN009 therapy therefore offers the potential for an allogeneic (non-donor specific) and cost-effective cell-based treatment for CLI patients with the aim of restoring sufficient blood flow in the affected lower limb to avoid amputation and the severe health consequences that typically result from such an amputation.

The Phase I clinical trial will be undertaken through NHS Tayside at Ninewells Hospital and Medical School, Dundee, Scotland. In this dose escalation safety study, the ReN009 cells will be administered via straightforward intramuscular injection into the affected lower limb of nine patients with peripheral arterial disease. Approval may be sought in due course for a further clinical site in Germany to participate in the study.

During the period, we were awarded a Late Stage Biomedical Catalyst grant of £0.4 million from the Technology Strategy Board, the UK Government's innovation agency, to be deployed towards the cost of the ReN009 Phase I study. We expect recruitment and dosing of patients in the clinical trial to commence later this year. The straightforward nature of both the ReN009 treatment and the design of the Phase I clinical trial is expected to lead to progression into a larger placebo-controlled Phase II efficacy study during the second half of 2014, assuming the Phase I primary safety end-point is met.

Our ReN003 programme, based on our human retinal progenitor (hRPC) cells, also made good progress during the period, 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.

During the period, we were awarded a further Early Stage Biomedical Catalyst grant of £0.8 million from the Technology Strategy Board to be deployed towards the cost of the late pre-clinical development of the ReN003 programme through to the clinic. 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 commenced our interactions with the US FDA regarding pre-filing regulatory advice on this programme, with a view to filing for regulatory approvals for the initial clinical study in the middle part of 2014.

Other activities

During the period, 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.

Earlier this month, the influential House of Lords Select Committee on Science and Technology published its findings and recommendations arising from an inquiry to identify potential barriers to the development and commercialisation of regenerative medicine therapies in the UK. ReNeuron gave both written and oral evidence to the Committee and the Company is widely referred to in the Committee's published report. As one of the UK's foremost players in the field, we hope and expect the Company to benefit from the recommendations in the report if they are fully implemented.

Transformational funding

During the period, and thereafter, we have been successful in transforming the financial position and future prospects of the Company. We have separately announced today a £33 million financing package for the Company, composed of a Placing to raise £25.35 million, before expenses, and a £7.8 million grant package from the Welsh Government to establish a cell manufacturing and development facility in South Wales for late stage clinical and commercial product requirements. The Company will move its principal operations to this facility as it is phased in over the next two years.

The above financing provides funding for the business over the next three years and will enable us to take all of our core therapeutic programmes through Phase II studies and to consequent value inflection through commercial development deals or a broader strategic transaction. It will also enable us to secure manufacturing capability, and margin, as our therapeutic candidates move closer to market.

We have previously stated our intention to make greater use of non-dilutive grants and similar funding sources that have become available over the last eighteen months. We have succeeded in this aim, having secured in excess of £10 million of such commitments in this calendar year alone, including the Welsh Government grant package announced today. As mentioned above, we were also awarded two separate grants, totalling £1.2 million, from the UK Biomedical Catalyst during the period to pursue the further development of our ReN009 and ReN003 stem cell therapy candidates. Further, during the period, we were the first UK cell therapy business to enter into a collaboration with the newly established Cell Therapy Catapult, one of a number of innovation centres established by the UK Government, through the Technology Strategy Board, to accelerate the UK's commercial capability in strategically important technology areas. The collaboration will focus on the development and optimisation of the processes required to scale up manufacture of our CTX cell line, as well as improving potency assays for the CTX cells, based on the characteristics of the cells and their potential mechanisms of action. The Catapult will contribute £1.3 million into the collaboration, to be provided in the form of expert knowledge, plus state-of-the-art laboratories, equipment and services.

The grant awarding bodies mentioned above, together with the specialist life science equity investors participating in the equity financing announced today, have subjected our programmes to considerable due diligence and expert peer review in arriving at their investment decisions. We therefore regard these investments into our business as representing a strong independent endorsement of our world-class stem cell development capabilities and our progress to date.

Summary of results

In the year to 31 March 2013, revenues were £17,000 (2012: £40,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses in the year were £7.1 million (2012: £6.9 million). Research and development expenditure reduced in the year to £4.8 million (2012: £4.9 million), reflecting lower clinical and manufacturing development costs. General and administrative costs in the year increased to £2.3 million (2012: £2.1 million), primarily as a result of an increase in professional fees.

Interest received reduced in the year to £30,000 (2012: £40,000) as a result of lower average levels of cash deposits held over the period.

The Group accrued a research and development tax credit of £0.7m during the year (2012: £0.6m), the higher claim reflecting the removal of the PAYE/NI cap in the financial year.

As a result of the above income statement movements, the post-tax loss for the year increased to £6.3 million (2012: £6.2 million). The basic and diluted loss per share reduced to 0.8p per share

(2012: 1.0p 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 April 2012.

Cash used in operating activities increased in the year to £6.0 million (2012: £5.8 million), due to a combination of a higher loss before tax and an adverse working capital position. During the year, the Company raised £6.1 million, before expenses, by means of a Placing and Open Offer to shareholders.

As a result of the above cash flow movements in the year, the Group had cash and cash equivalents totalling £3.5 million as at 31 March 2013 (2012: £4.0 million). Subsequent to the financial year end, and as mentioned above, the Company has announced that it expects to raise £25.35 million, before expenses, by means of a Placing to shareholders, together with a £7.8m grant package from the Welsh Government to establish a cell manufacturing and development facility in South Wales over the next two years. Following completion of the Placing, the directors expect that the Group's financial resources will be sufficient to support operations until the third quarter of 2016. Consequently, the going concern basis has been adopted in the preparation of these financial statements.

Summary and outlook

Our therapeutic programmes have made considerable progress during the period under review. The Phase I clinical trial of our stem cell therapy candidate for stroke has yielded encouraging data and a Phase II study is planned to commence shortly, as is a Phase I study with our therapeutic candidate for critical limb ischaemia. We expect our stem cell therapy candidate for the blindness-causing disease, retinitis pigmentosa, to enter the clinic next year.

We have well-defined clinical development plans for these therapeutic programmes and process development plans to both enhance and take full control over the manufacture of our stem cell therapy candidates as they get closer to market. Crucially, the business is now fully funded to pursue these plans through to value inflection and commercial deals over the next three years and we look forward to reporting further progress towards that end.

Bryan Morton
Chairman

Michael Hunt
Chief Executive Officer

22 July 2013

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

	Note	2013 £'000	2012 £'000
Revenue		17	40
Research and development costs	4	(4,786)	(4,865)
General and administrative costs		(2,319)	(2,059)
Operating loss		(7,088)	(6,884)
Finance income		30	40
Finance costs		(1)	(1)
Loss before income tax		(7,059)	(6,845)
Taxation		714	616
Loss and total comprehensive loss for the year		(6,345)	(6,229)
Total loss and total comprehensive loss attributable to:			
- Equity owners of the Company		(6,345)	(6,229)
Basic and diluted loss per ordinary share	5	(0.8p)	(1.0p)

**Unaudited Group Statement of
Financial Position as at 31 March**

	Note	2013 £'000	2012 £'000
Assets			
Non-current assets			
Property, plant and equipment		213	299
Intangible assets		1,272	1,272
Trade and other receivables		135	135
		1,620	1,706
Current assets			
Trade and other receivables		341	457
Corporation tax receivable		714	616
Cash and cash equivalents		3,547	3,983
		4,602	5,056
Total assets		6,222	6,762
Equity			
Equity attributable to owners of the company			
Share capital		7,748	6,234
Share premium account		32,972	28,885
Capital redemption reserve		8,964	8,964
Merger reserve		2,223	2,223
Warrant reserve		149	108
Share-based credit reserve		2,000	1,623
Retained deficit		(49,148)	(42,803)
Total equity		4,908	5,234
Liabilities			
Non-current liabilities			
Provisions		150	125
Financial liabilities: finance leases		-	-
		150	125
Current liabilities			
Trade and other payables		1,163	1,394
Financial liabilities: finance leases		1	9
		1,164	1,403
Total liabilities		1,314	1,528
Total equity and liabilities		6,222	6,762

Unaudited 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
As at 1 April 2011	6,199	28,811	8,964	2,223	108	1,271	(36,574)	11,002
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)
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	-	-	-	-	-	377	-	377
Issue of Warrants	-	-	-	-	41	-	-	41
Loss for the year and total comprehensive loss	-	-	-	-	-	-	(6,345)	(6,345)
As at 31 March 2013	7,748	32,972	8,964	2,223	149	2,000	(49,148)	4,908

Unaudited Group Statement of Cash Flows for the year ended 31 March

	Note	2013 £'000	2012 £'000
Cash used in operations	6	(6,637)	(6,276)
Interest paid		(1)	(1)
Income tax credit received		616	491
Cash used in operating activities		(6,022)	(5,786)
Cash flows from investing activities			
Capital expenditure		(37)	(30)
Loans provided to subsidiaries		-	-
Interest received		30	40
Net cash (used in)/generated from investing activities		(7)	10
Cash flows from financing activities			
Finance lease principal payments		(8)	(9)
Proceeds from issuance of ordinary shares		6,057	100
Costs of share issue		(456)	-
Net cash generated from financing activities		5,593	91
Net decrease in cash and cash equivalents		(436)	(5,685)
Cash and cash equivalents at the start of year		3,983	9,668
Cash and cash equivalents at the end of year		3,547	3,983

Notes to the financial information for the year ended 31 March 2013

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 2013 and audited financial information for the year ended 31 March 2012 does not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006, but has been extracted from the draft statutory financial statements for the year ended 31 March 2013 which will be delivered to the Registrar of Companies in due course. Statutory accounts for the year ended 31 March 2012 were approved by the Board of directors and delivered to the Registrar of Companies. The report of the Auditors on these accounts was unqualified with no emphasis of matter statements included.

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 draft annual financial statements for the year ended 31 March 2013, 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 2012.

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 the Company has announced that it has raised £25.35 million, before expenses, by means of a Placing to shareholders, together with a £7.8m grant package from the Welsh Government to establish a cell manufacturing and development facility in South Wales over the next two years. Following completion of the Placing, the directors expect that the Group's financial resources will be sufficient to support operations until the third quarter of 2016. Consequently, the going concern basis has been adopted in the preparation of these 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 £6,345,000 (2012: £6,229,000) by 748,685,036 shares (2012: 619,946,923 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 2013 £'000	Year ended 31 March 2012 £'000
Loss before income tax	(7,059)	(6,845)
Adjustment for:		
Interest received	(30)	(40)
Interest payable	1	1
Depreciation of property, plant and equipment	123	150
Provisions movement	25	25
Share-based payment charges	418	352
Fees payable in ordinary shares	-	9
Changes in working capital		
Receivables	116	(100)
Payables	(231)	172
Cash used in operations	(6,637)	(6,276)