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ReNeuron Group plc

Preliminary Results for the Year Ended 31 March 2014

Guildford, UK, 18 June 2014: 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 2014.

Highlights

- ReN001 stem cell therapy candidate for stroke:
  - Phase II clinical trial open for recruitment
  - Encouraging long term Phase I data presented at leading stroke conference

- ReN009 stem cell therapy candidate for critical limb ischaemia:
  - Phase I clinical trial open for recruitment

- ReN003 stem cell therapy candidate for retinitis pigmentosa:
  - Orphan Drug Designation granted in both Europe and the US
  - Phase I/II clinical trial application planned for early 2015 in US

- Cryopreserved variant of lead *CTX* stem cell line with extended shelf life approved for use in stroke and critical limb ischaemia clinical trials

- *CTX*-derived exosome platform generating promising early pre-clinical data across a range of further indications in tissue repair, inflammation and cancer

- Share Placing in July 2013 raised £25.35m, before expenses, funding core therapeutic programmes through key Phase II clinical trials over next two years

- Grant package totalling £7.80m from Welsh Government to enable establishment of cell manufacturing and development facility in South Wales for late stage clinical and commercial product requirements

- Additional non-dilutive £1.49 million grant awarded from UK Government, via Technology Strategy Board, to support Phase II clinical trial with ReN001 in stroke

- Loss for the year of £7.07m (2013: £6.35m); cash outflow from operating activities of £6.00m (2013: £6.02m); cash, cash equivalents and bank deposits at 31 March 2014 of £20.92m (2013: £3.55m).

Commenting on the results, Bryan Morton, ReNeuron's Chairman, said:

"The past year has been transformational for our business, both operationally and financially. Our cell therapy candidate for stroke has entered Phase II clinical development and we have commenced clinical development of our cell therapy candidate for critical limb ischaemia. In both cases, and earlier-than-planned, we have gained regulatory approval to use a second-generation cryopreserved variant of our lead *CTX* stem cell line, providing the potential for significant commercial and competitive advantages for our business. We remain on track to move into our world-class cell manufacturing facility in South Wales in the early part of next year, which we believe will become a major element of ReNeuron's overall value proposition. We are also on track to file an IND application in the US early next year seeking FDA approval to start a Phase I/II clinical trial of our retinitis pigmentosa cell therapy, and we are greatly encouraged by the progress and potential of our emerging *CTX* cell-derived exosome therapeutic platform.

"These developments represent significant steps to building real future value in the business and the £34.6 million equity and grant financing completed in the year provides us with a robust balance sheet to reach further key clinical milestones in the business. We look forward to the future with great confidence.''

Analyst meeting and webcast

A meeting for analysts will be held at 10.00am 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 10.00am:
http://mediaserve.buchanan.uk.com/2014/reneuron180614/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 Richard Moulson, Interim CFO	+44 (0) 1483 302560
Buchanan Mark Court, Fiona Henson, Sophie Cowles	+44 (0) 20 7466 5000
Cenkos Securities Stephen Keys, Chris Golden (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 and Chief Executive Officer's Joint Statement

Overview

The last financial year has seen ReNeuron make very substantial progress in its development as a world-class regenerative medicine business. In August, a major fundraising was completed which has allowed us to plan and resource clinical programmes which will provide proof of concept data in multiple indications, and to invest in our exosome programme, a fast-developing field in which we are at the forefront.

In March of this year, we signed an agreement to lease a new manufacturing and R&D facility in South Wales. Construction and fit out of the facility is being funded by the Welsh Government. When finished, it will provide us with the means to refine our manufacturing processes and supply product for Phase III trials and early in-market sales.

Regulatory approval was obtained during the financial year for two clinical trials: a Phase II trial in stroke and a Phase I trial in critical limb ischaemia. Both have since commenced and each will use the new CTXcryo variant of our lead CTX stem cell line - a cryopreserved variant which we believe will transform the commercial opportunities open to us following market authorisations.

Review of programmes

ReN001 for ischaemic stroke disability

In May of this year, twelve month follow-up data on all 11 patients treated in the PISCES Phase I trial of ReN001 were presented at the European Stroke Conference, confirming findings seen earlier on in the study; notably, an absence of cell-related or immunological adverse events and sustained reductions in neurological impairment and spasticity in most patients compared with their stable pre-treatment baseline performance.

The above Phase I data were presented alongside the opening for recruitment of a Phase II clinical trial with ReN001. This new efficacy study, which received final regulatory approval in March, will recruit up to 41 patients at up to 10 sites across the UK. We anticipate that six month follow-up data from all patients treated will be available by the end of 2015. The primary endpoint is a meaningful improvement in upper limb function in disabled stroke patients to a degree that would support reimbursement of the therapy by healthcare payers on a Quality Adjusted Life Year basis. In parallel, we have commenced a non-interventional, observational study in stroke patients, initially at a selection of the clinical sites that will participate in the interventional Phase II clinical trial. The observational study will allow for the pre-screening of potentially eligible patients for the Phase II study and also provide a broader and valuable clinical data set against which outcomes in treated patients can be compared.

ReN009 for critical limb ischaemia

During the financial year, positive data from pre-clinical efficacy studies conducted with the Company's ReN009 candidate for critical limb ischaemia were published in the prestigious American Heart Association's Journal, *'Arteriosclerosis, Thrombosis and Vascular Biology'*. These pre-clinical studies show the dose-dependent positive effects of *CTX* cells in restoring

microvasculature and blood flow to the limb extremities in animal models of lower limb ischaemia. The results of these studies have therefore provided the rationale, through our ReN009 programme, to target critical limb ischaemia as a major clinical indication for our *CTX* cell product.

Recruitment is now open for a Phase I trial with ReN009 in patients with lower limb ischaemia, following final UK regulatory approval in March. The trial will take place at Ninewells Hospital, Dundee, Scotland and is a dose escalation safety study in 9 patients. Assuming a clean safety profile for ReN009 in this study, a Phase II efficacy study is planned to commence in mid-2015.

ReN003 for retinal diseases

Our ReN003 programme, based on the Company's human retinal progenitor cells (hRPCs), is undergoing a final set of pre-clinical studies which will support an IND filing in the US for an initial Phase I/II clinical trial targeted for early 2015. Financial and clinical advisory support for this programme is being provided from the leading US charity in this field, Foundation Fighting Blindness.

Data published in the Journal of Biological Chemistry in January of this year showed that ReNeuron's hRPCs protected visual function when transplanted into a well-established rat model of retinal degeneration. The hRPC-grafted eyes had significantly superior visual acuity compared with vehicle controls in the study. Long term pre-clinical safety studies with ReN003 have successfully completed their in-life phase, with no adverse results reported.

The ReN003 therapy was granted Orphan Drug Designation in both Europe and the US during the year, providing the potential for 10 year market exclusivity post-approval of the therapy in these territories.

Technology development

During the period, and in collaboration with one of our outsourced contract manufacturers, we generated positive cell manufacturing data with a proprietary, cryopreserved variant of our lead *CTX* stem cell line, demonstrating its equivalence to the existing non-cryopreserved variant. As a result, we have accelerated the development of this extended shelf-life, cryopreserved *CTX* drug product (designated *CTXcryo*), enabling it to be deployed in all current and future *CTX*-based clinical trials and for eventual in-market use.

We believe that the *CTXcryo* product will provide the business with major commercial and competitive advantages in terms of the availability of a genuine off-the-shelf, low cost-of-goods cell-based treatment with a shelf life enabling shipping to, and storage at, clinical sites on a global basis. The earlier-than-planned deployment of *CTXcryo* in our clinical development programmes will also avoid the need for potential future bridging clinical studies and will serve ongoing clinical trial needs much more efficiently and cost-effectively.

As the financial year progressed, we became increasingly excited by the therapeutic potential of our *CTX* cell-derived exosome platform. Exosomes are nanoparticles containing key proteins and micro-RNAs. They play a key role in cell to cell communication, modulate cellular immunity and promote the activation of regenerative or repair programs in diseased or injured cells. Our *CTX* cells release large amounts of exosomes when cultured and we have purified and characterised

these, testing them at differing concentrations in a range of early *in vitro* pre-clinical disease models with positive results. We are now conducting various *in vivo* studies to assess the disease areas to target for clinical development and have currently generated early pre-clinical data supporting the therapeutic potential of our exosomes in indications ranging from gliomas to wound healing, thus broadening our therapeutic pipeline beyond cell-based programmes.

Funding and relocation to South Wales

In July 2013, we announced a £33.2 million financing package for the Company, comprising a Placing to raise £25.4 million, before expenses, and a £7.8 million grant package from the Welsh Government to establish a state-of-the-art cell manufacturing and development facility in South Wales. This financing allows us to progress Phase II clinical trials in both stroke and CLI as well as a Phase I/II clinical trial in retinitis pigmentosa. We believe that positive data from these clinical studies and the potential such data provide for future commercial development deals, or a broader strategic transaction, will lead to a value inflection for our business.

In March of this year, we signed an Agreement for Lease with the Welsh Government for the manufacturing and development facility, to be located at Pencoed Technology Park, near Cardiff, South Wales. Work has commenced on the facility and we expect handover, and relocation of ReNeuron's operations, to occur in the Spring of 2015. We anticipate gaining full licensure for *CTX* therapeutic product manufacture around a year later. This will enable us to supply our stroke and CLI Phase III trials from in-house production, with substantial advantages in terms of security of supply, flexibility and cost. The facility will also supply early in-market product, providing cost of goods advantages and enabling us to retain full manufacturing margin. We believe the South Wales site, when operational, will house the UK's most advanced commercial cell manufacturing facility and represents a key value driver in ReNeuron's commercial development strategy.

Our focus on obtaining non-dilutive grants and similar funding sources continued to yield results during the financial year. In addition to the Welsh Government grant package and earlier, prior-period grants awarded to support our ongoing critical limb ischaemia and retinitis pigmentosa therapeutic programmes, we also received a further £1.5 million grant during the period from the UK Government, via the Technology Strategy Board, to support the recently-commenced Phase II clinical trial with ReN001 in stroke. We also continue to work closely with the UK Government-funded Cell Therapy Catapult on a programme to develop the processes required to scale up manufacture of our *CTX* stem cell line, and to improve potency release assays for the *CTX* cells. We are especially pleased to see, and to directly benefit from, the Government's ongoing commitment to supporting the cell therapy field exemplified by this valuable collaboration.

Other activities

Last December, 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 was 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 and we continue to play a role in this important initiative as an industry member of the Regenerative Medicine Expert Group established by the Department of Health to drive the implementation of the Committee's recommendations within the UK's NHS infrastructure.

In April of this year, we announced that, in order to manage the increasing breadth of the Company's clinical, operational and commercial activities, the Board of the Company was to be reconfigured with the appointment of a new Chief Executive Officer. The current CEO, Michael Hunt, will remain in that role until such time as a suitable candidate has been recruited, following which he will remain on the Board of Directors in the new role of Chief Financial Officer, with responsibilities covering finance, public & investor relations and overall commercial and financial strategy. The search for a new CEO is ongoing and further announcements will be made in due course.

Financial summary

Cash outflow from operating activities was £6.00 million (2013: £6.02 million). Capital expenditure was £0.12 million (2013: £0.03 million). The net proceeds from the fundraising in August 2013 amounted to £23.44 million and as a consequence cash, cash equivalents and bank deposits totalled £20.92 million at the year-end (2013: £3.55 million), an increase of £17.37 million.

Revenues in the year amounted to £22k (2013: £17k), being royalties from non-therapeutic licensing activities. Grant income of £0.66 million (2013: nil) was also recognised.

Research and development (R&D) costs rose to £5.83 million (2013: £4.79 million) as a result of increased clinical research, collaborations and manufacturing costs. General and administrative (G&A) expenses increased to £2.82 million (2013: £2.32 million).

Mainly as a consequence of the increase in R&D and G&A costs, the loss before income tax increased to £7.82 million (2013: £7.06 million) resulting in a net loss, after allowing for the tax credit, of £7.07 million (2013: £6.35 million), in line with consensus analyst forecasts.

Summary and outlook

The past year has been transformational for our business, both operationally and financially. Our cell therapy candidate for stroke has entered Phase II clinical development and we have commenced clinical development of our cell therapy candidate for critical limb ischaemia. In both cases, and earlier-than-planned, we have gained regulatory approval to use a second-generation cryopreserved variant of our lead *CTX* stem cell line, providing the potential for significant commercial and competitive advantages for our business. We remain on track to move into our world-class cell manufacturing facility in South Wales in the Spring of next year, which we believe will become a major element of ReNeuron's overall value proposition. We are also on track to file an IND application in the US early next year seeking FDA approval to start a Phase I/II clinical trial of our retinitis pigmentosa cell therapy, and we are greatly encouraged by the progress and potential of our emerging *CTX* cell-derived exosome therapeutic platform.

These developments represent significant steps to building real future value in the business and the £34.6 million equity and grant financing completed in the year provides us with a robust balance sheet to reach further key clinical milestones in the business. We look forward to the future with great confidence.

Finally, we would like to thank all our staff for their hard work and commitment to ReNeuron during this exciting and challenging period.

Bryan Morton
Chairman

Michael Hunt
Chief Executive Officer

18 June 2014

Group Statement of Comprehensive Income for the year ended 31 March

	2014	2013
	£'000	£'000
Revenue: royalty income	**22**	17
Other income: grants	**662**	-
Research and development costs (note 4)	**(5,829)**	(4,786)
General and administrative costs	**(2,824)**	(2,319)
Operating loss	**(7,969)**	(7,088)
Finance income	**149**	30
Finance costs	**-**	(1)
Loss before income tax	**(7,820)**	(7,059)
Income tax credit	**754**	714
Loss and total comprehensive loss for the year	**(7,066)**	(6,345)
Loss and total comprehensive loss attributable to equity owners of the Company	**(7,066)**	(6,345)
Basic and diluted loss per ordinary share (note 5)	**(0.5p)**	(0.8p)

Group Statement of Financial Position as at 31 March

	2014	2013
	£'000	£'000
Assets		
Non-current assets		
Property, plant and equipment	**225**	213
Intangible assets	**1,272**	1,272
Trade and other receivables	**275**	135
	1,772	1,620
Current assets		
Trade and other receivables	**676**	341
Income tax receivable	**754**	714
Investments – bank deposit	**6,000**	-
Cash and cash equivalents	**14,917**	3,547
	22,347	4,602
Total assets	**24,119**	6,222
Equity attributable to owners of the Company		
Share capital	**17,888**	7,748
Share premium account	**46,267**	32,972
Capital redemption reserve	**8,964**	8,964
Merger reserve	**2,223**	2,223
Accumulated losses	**(53,625)**	(46,999)
Total equity	**21,717**	4,908
Liabilities		
Non-current liabilities		
Provisions	**364**	150
Financial liabilities: finance leases	**2**	-
	366	150
Current liabilities		
Trade and other payables	**2,035**	1,163
Financial liabilities: finance leases	**1**	1
	2,036	1,164
Total liabilities	**2,402**	1,314
Total equity and liabilities	**24,119**	6,222

Group Statement of Changes in Equity

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2012	**6,234**	**28,885**	**8,964**	**2,223**	**(41,072)**	**5,234**
Issue of ordinary shares	1,514	4,543	-	-	-	6,057
Costs of share issue	-	(456)	-	-	-	(456)
Credit on share-based payment	-	-	-	-	418	418
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**	**(46,999)**	**4,908**
Issue of ordinary shares	10,140	15,210	-	-	-	25,350
Costs of share issue	-	(1,915)	-	-	-	(1,915)
Credit on share-based payment	-	-	-	-	440	440
Loss for the year and total comprehensive loss	-	-	-	-	(7,066)	(7,066)
As at 31 March 2014	**17,888**	**46,267**	**8,964**	**2,223**	**(53,625)**	**21,717**

Group Statement of Cash Flows for the year ended 31 March

	2014	2013
	£'000	£'000
Cash used in operations (note 6)	**(6,718)**	(6,637)
Interest paid	**-**	(1)
Income tax credit received	**714**	616
Cash used in operating activities	**(6,004)**	(6,022)
Cash flows from investing activities		
Capital expenditure	**(121)**	(37)
Interest received	**61**	30
Net cash used in investing activities	**(60)**	(7)
Cash flows from financing activities		
Finance lease principal payments	**(1)**	(8)
Proceeds from issuance of ordinary shares	**25,350**	6,057
Costs of share issue	**(1,915)**	(456)
Bank deposit placed	**(6,000)**	-
Net cash generated from financing activities	**17,434**	5,593
Net increase/(decrease) in cash and cash equivalents	**11,370**	(436)
Cash and cash equivalents at the start of year	**3,547**	3,983
Cash and cash equivalents at the end of year	**14,917**	3,547

Notes to the financial information for the year ended 31 March 2014

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. Its shares are listed on the Alternative Investment Market (AIM) of the London Stock Exchange.

2. Basis of preparation

The financial information included in this preliminary results announcement does not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. The information has been extracted from the statutory financial statements for the year ended 31 March 2014 approved by the Directors on 17 June 2014. The report of the auditors on these financial statements was unqualified and did not include an emphasis of matter paragraph. The financial statements will be delivered to the Registrar of Companies after the Annual General Meeting. Statutory financial statements for the year ended 31 March 2013 were approved by the Board of directors on 9 August 2013 and have been delivered to the Registrar of Companies. The report of the auditors on these financial statements was unqualified and did not include an emphasis of matter paragraph.

In preparing this financial information management has used the principle accounting policies set out in the Group's statutory financial statements for the year ended 31 March 2013. Whilst the financial information included in this preliminary announcement has been prepared in accordance with International Financial Reporting Standards (IFRS), this announcement does not contain sufficient information to comply with IFRS.

3. Going concern

The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development and as it establishes a cell manufacturing and development facility in South Wales. The Group has sufficient cash resources available for its immediate programme of activities, taking into account also the grant awards made by the Technology Strategy Board and the Welsh government and for at least 12 months from the balance sheet date.

4. Research and development costs

All research and development costs incurred in the year have been charged directly to the Group Statement of Comprehensive Income.

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 £7,066,000 (2013: £6,345,000) by 1,424,978,475 shares (2013: 748,685,036 shares), being the weighted average number of 1p Ordinary 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 for the year ended 31 March

	2014	2013
	£'000	£'000
Loss before income tax	**(7,820)**	(7,059)
Adjustment for:		
Interest received	**(149)**	(30)
Interest payable	**-**	1
Depreciation of property, plant and equipment	**112**	122
Provisions movement	**214**	25
Share-based payment charges	**440**	418
Changes in working capital		
Receivables	**(387)**	117
Payables	**872**	(231)
Cash used in operations	**(6,718)**	(6,637)