



For Immediate Release

AIM: RENE

ReNeuron Group plc

Preliminary Results for the Year Ended 31 March 2015

Guildford, UK, 10 July 2015: 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 2015.

Highlights

- CTX stem cell therapy candidate for stroke:
 - Long term Phase I data presented confirming good safety profile and sustained improvements in neurological status and limb function
 - Phase II clinical trial ongoing – data expected during H1 2016
 - Phase II/III clinical trial planned to commence in H2 2016
- CTX stem cell therapy candidate for critical limb ischaemia:
 - Phase I clinical trial ongoing – data expected during H1 2016
 - Phase II clinical trial planned to commence in mid 2016
- hRPC stem cell therapy candidate for retinitis pigmentosa:
 - Orphan Drug Designation granted in both Europe and the US
 - Fast Track Designation granted in the US
 - Regulatory approval obtained post year-end to commence Phase I/II clinical trial in the US
 - Phase II/III clinical trial planned to commence in 2017
- Exosome nanomedicine platform generating promising early pre-clinical data in cancer, and research collaboration extended with Benitec Biopharma to utilise exosomes as delivery system for gene therapy targeting cancer
- Olav Hellebø appointed as CEO, bringing substantial pharmaceutical, commercial and business development experience
- Strengthening of senior management team with appointments of Chief Medical Officer, Head of Regulatory Affairs, Head of Research and VP Development & General Manager, Wales.
- Placing announced today to raise £68.4 million, before expenses, funding lead therapeutic programmes through late-stage clinical development over next three years (see separate release)

- Loss for the year of £8.91m (2014: £7.07m); cash outflow from operating activities of £8.25m (2014: £6.00m); cash, cash equivalents and bank deposits at 31 March 2015 of £12.38m (31 March 2014: £20.92m).

Commenting on the results, Olav Hellebø, ReNeuron’s CEO, said:

“During the year under review, we have commenced dosing of patients in two new clinical trials in stroke disability and critical limb ischaemia, representing further significant milestones in the clinical development of ReNeuron’s CTX cell therapy candidates. Importantly, we have since gained regulatory approval to commence our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We are also encouraged by the early pre-clinical data generated with our exosome nanomedicine platform, targeting cancer.

“As the business continues to progress its therapeutic programmes towards commercialisation, we have also expanded senior management capability within the business to meet future operational needs. In this regard, we look forward to the relocation of the business to our new, world-class cell manufacturing and research facility in South Wales early next year.

“Finally, as a result of the fundraising announced today, the business benefits from a very strong balance sheet, the backing of high calibre institutional investors and an experienced management team focused on the delivery of clinical data and associated value generation across all of the Company’s therapeutic programmes over the next three years. We continue to look forward to the future with high 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://vm.buchanan.uk.com/2015/reneuron100715/registration.htm>

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.

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About ReNeuron

ReNeuron is a leading, clinical-stage cell therapy development company. Based in the UK, its primary objective is the development of novel cell-based 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. The Company’s therapeutic candidates for stroke disability and critical limb ischaemia are in clinical development and its cell-based treatment for the blindness-causing disease, retinitis pigmentosa, is about to commence clinical development in the US.

ReNeuron is also advancing a proprietary platform technology to exploit nanoparticles (exosomes) secreted by stem cells as potential new drug candidates targeting a range of cancers.

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

Review of programmes

CTX for stroke disability

In April of this year, the clinical team from Glasgow's Southern General Hospital presented long term follow-up data from the PISCES Phase I clinical trial with our CTX stem cell therapy candidate for stroke at the 2015 European Stroke Organisation Conference. There continued to be no cell-related or immunological adverse events reported in any of the eleven patients treated in the study out to at least 24 months post-treatment. The improvements in neurological status and limb function compared to pre-treatment baseline performance that were observed within three months of treatment were maintained throughout long term follow-up. These data are now being compiled for publication in a leading peer-reviewed scientific journal.

During the period, we commenced dosing in a UK multi-site Phase II clinical trial (PISCES II) to examine the efficacy of CTX in patients disabled by an ischaemic stroke. As a result of observed good safety profile of the treatment, the highest cell dose, 20 million cells, from the PISCES study is being used in the ongoing Phase II study. As with the PISCES study, the Phase II clinical trial involves a single injection of CTX cells into the brain, adjacent to the area damaged by the stroke.

Following a recent change to the study protocol and discussions with key opinion leaders in the field, we intend to curtail this study after the first patient cohort of 21 patients, where dosing is expected to have completed by the end of the year with a read out in the first half of 2016. At this point, and based on an overall assessment of the collective data from the Phase I and Phase II studies, we are planning to file an application to commence a controlled, pivotal Phase II/III clinical trial in the target stroke patient population.

hRPC for retinitis pigmentosa

In May of this year, we obtained regulatory approval from the US FDA to commence a Phase I/II clinical trial in the US with our Human Retinal Progenitor Cell (hRPC) therapy candidate for retinitis pigmentosa (RP). RP is a group of hereditary diseases of the eye that lead to progressive loss of sight due to cells in the retina becoming damaged and eventually dying. Pre-clinical studies carried out in disease models by our academic collaborators have demonstrated that, when transplanted into the retina, our hRPCs help to preserve pre-existing photoreceptors, potentially reducing or halting further deterioration of vision. In addition, some of the hRPCs had both matured into apparently functional photoreceptors and engrafted into the photoreceptor layer, raising the possibility of a degree of reversal of the decline in vision associated with RP.

Shortly after the Phase I/II clinical trial approval, the FDA granted Fast Track designation to our hRPC programme targeting RP. Fast Track designation is an FDA programme intended to expedite the development and review of new drugs or biological products targeting unmet medical need where the diseases concerned are serious or life threatening. This, together with the Orphan Drug Designation already granted for the programme in both the US and Europe, provides accelerated clinical development and marketing authorisation review processes for our RP therapy as well as the potential for a significant period of market exclusivity once approved in these major territories.

The Phase I/II clinical trial will be conducted at Massachusetts Eye and Ear Infirmary in Boston, a world-renowned clinical centre for the treatment of retinal diseases. The trial design is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in 15 patients with advanced RP. We expect to be able to commence the study before the end of this year. Subject to the outcome of the Phase I/II study, we are planning to file an application to commence a pivotal Phase II/III clinical trial with our therapy for RP in 2017. This trial is expected to be the basis for subsequent marketing authorisation filings in both the US and Europe.

CTX for critical limb ischaemia

During the period under review, we also commenced dosing in a Phase I clinical trial of our CTX cell therapy candidate for critical limb ischaemia (CLI), a condition resulting in loss of blood flow to the lower limb which is common in diabetics and which can ultimately lead to amputation. This Phase I clinical trial is a single centre dose escalation safety study in nine patients with lower limb ischaemia and is being conducted at Ninewells Hospital, Dundee, Scotland. Published pre-clinical studies have demonstrated the dose-dependent positive effects of our CTX cells in restoring microvasculature and blood flow to the limb extremities in animal models of lower limb ischaemia.

Based on a recent review of our clinical development strategy for this indication, we intend to curtail this study at the middle dose level of 50 million cells and focus our resources on initiating a Phase II placebo-controlled clinical trial. The Phase I study is expected to have completed dosing by the end of this year and we expect to commence the Phase II study towards the middle of 2016.

Exosome nanomedicine platform

During the period, we continued to advance our exosome nanomedicine programme. The field of nanomedicine is growing rapidly and ReNeuron is a first-mover in the field of exosome-based therapeutics. Exosomes are lipid-based nanoparticles secreted from all cells and which are believed to play a key role in the transfer of beneficial proteins and particularly non-coding RNAs from one cell to another. We aim to exploit the therapeutic potential of exosomes derived from our own proprietary stem cell lines and we have filed multiple patent applications covering the composition, manufacture and therapeutic use of our exosome nanomedicine platform.

We have identified a novel mechanism by which exosomes from our CTX stem cells may inhibit the growth and migration of cancer cells in pre-clinical models of the disease. Studies suggest that the most highly expressed micro-RNA found within CTX-derived exosomes may play a key role in the suppression of cancer cells by promoting cell differentiation into benign cell types, as well as cell cycle arrest. Based upon these promising preliminary findings, we aim to further investigate the mechanism of action and utility of our exosome nanomedicine platform in a range of potential cancer indications. Subject to further success with the pre-clinical development of this new therapeutic platform, we expect to be able to submit an application to commence an initial clinical trial with our first exosome nanomedicine candidate towards the end of 2016.

In June of this year, we extended our research collaboration with Australia-based Benitec Pharma, a leader in the field of therapeutics focused on gene silencing. Following positive results in early

studies, the collaboration is investigating the potential of our CTX-derived exosomes as a delivery system for Benitec's proprietary gene silencing technology, targeting lung cancer and other drug resistant cancers.

Other activities

During the period, work commenced on the fit-out of our state-of-the-art cell manufacturing and research facility at Pencoed, near Cardiff in South Wales. This facility will incorporate robotic cell culture technology and, when fully licensed, will give us control over the supply of our CTX cell-based therapies, meeting late stage clinical trial and in-market demand for drug product at low cost of goods. As such, the Welsh facility represents a key value driver in ReNeuron's commercial development strategy. We expect to be able to commence the phased relocation of the business to the new facility early next year. Our current outsourced cell manufacturing capacity remains sufficient for our clinical trial requirements until the Welsh facility comes on-stream.

In order to manage the increasing breadth of the Company's clinical, operational and commercial activities, we commenced a phased restructuring and broadening of the Company's executive and non-executive management during the period. In September 2014, Olav Hellebø, a highly experienced pharmaceutical executive, was appointed as the Company's new Chief Executive Officer. Olav has broad commercial experience gained at both major pharmaceutical and small biotechnology companies, with particular experience of the clinical development, out-licensing, commercialisation and marketing of new therapeutics. Michael Hunt, who held the position of Chief Executive Officer since the Company's flotation in July 2005, remains on ReNeuron's Board as Chief Financial Officer, with responsibilities covering finance, public and investor relations and overall commercial and financial strategy.

In April of this year, Bryan Morton, having served on the Board of the Company as a non-executive director since 2008 and as Chairman since 2011, stepped down from the Board and was replaced as Chairman by John Berriman, a non-executive director of the Company since 2011. Mark Docherty, a non-executive director of the business since the Company's flotation in 2005, will step down from the Board at the Annual General Meeting of the Company in September of this year. Dr John Sinden, Chief Scientific Officer, a co-founder of ReNeuron and a Board member since the inception of the business, will also step down from the Board at the Annual General Meeting. His continuing role as Chief Scientific Officer at ReNeuron will focus on the Company's third party research collaborations and other externally facing activities

During the period, and subsequently, we have significantly strengthened the senior management of the business, with the appointment of highly experienced executives into the positions of Chief Medical Officer, Head of Regulatory Affairs, Head of Research and VP Development & General Manager, Wales.

Funding

We have separately announced today a Placing to raise £68.4 million, before expenses. This financing, the largest ever secured by the Company, provides funding for the business for at least the next three years. It will enable us to take all of our current programmes into early or mid-stage clinical development and, subject to future clinical data and regulatory approvals, will enable us to take our therapeutic programmes in stroke and retinitis pigmentosa through late-stage clinical development to the point of application for marketing authorisation.

Financial review

Revenues in the year amounted to £30k (2014: £22k), being royalties from non-therapeutic licensing activities. Grant income of £0.52 million (2014: £0.66 million) was also recognised.

Research and development costs increased to £7.25 million (2014: £5.83 million) and accounted for 66% of net operating expenses (2014: 67%). Research and development costs include staff costs for personnel engaged on research and development activities; sub-contracted clinical research costs; clinical trial and regulatory affairs costs, and the costs of cell manufacturing, quality assurance, quality control and shipping activities. The increase of £1.42 million during the period was as a result of increased clinical trial costs, manufacturing process development costs and cell manufacturing costs. Pre-clinical research costs reduced in the period, reflecting the further progression of the Company's therapeutic programmes into their clinical development phase.

General and administrative (G&A) expenses increased to £3.69 million (2014: £2.82 million) primarily due to increased staff recruitment activity and project management costs associated with the prospective relocation of the business to South Wales.

The total tax credit for the period was £1.40 million, composed of an accrual of £1.27 million for a research and development tax credit for the period (2014: £0.75 million) and a further credit of £0.13 million agreed for the year to 31 March 2014.

As a result of the above, the total comprehensive loss for the year increased to £8.91 million (2014: £7.07 million) in line with both internal and consensus analyst forecasts.

Cash outflow from operating activities was £8.25 million (2014: £6.00 million), largely reflecting the operating costs incurred during the period, less tax credits received. Capital expenditure was £0.38 million (2014: £0.12 million). Cash, cash equivalents and bank deposits totalled £12.38 million at the year-end (2014: £20.92 million). Subsequent to the financial year end, and as mentioned above, the Company has announced that it expects to raise £68.4million, before expenses, by means of a Placing with new and existing institutional investors. Following completion of the Placing, the directors expect that the Group's financial resources will be sufficient to support operations for at least the next three years. Consequently, the going concern basis has been adopted in the preparation of these financial statements.

Summary and outlook

During the period under review, we have commenced dosing of patients in two new clinical trials in stroke disability and critical limb ischaemia, representing further significant milestones in the clinical development of ReNeuron's CTX cell therapy candidates. Importantly, we have since gained regulatory approval to commence our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We are also encouraged by the early pre-clinical data generated with our exosome nanomedicine platform, targeting cancer.

As the business continues to progress its therapeutic programmes towards commercialisation, we have also expanded senior management capability within the business to meet future operational needs. In this regard, we look forward to the relocation of the business to our new, world-class

cell manufacturing and research facility in South Wales early next year. As a prospective centre of excellence in automated cell therapy manufacture, we believe this facility will become a key part of ReNeuron's overall value proposition.

Finally, as a result of the fundraising announced today, the business benefits from a very strong balance sheet, the backing of high calibre institutional investors and an experienced management team focused on the delivery of clinical data and associated value generation across all of the Company's therapeutic programmes over the next three years. We continue to look forward to the future with high confidence.

John Berriman
Chairman

Olav Hellebø
Chief Executive Officer

10 July 2015

Group Statement of Comprehensive Income for the year ended 31 March

	2015	2014
	£'000	£'000
Revenue: royalty income	30	22
Other income: grants	519	662
Research and development costs (note 4)	(7,250)	(5,829)
General and administrative costs	(3,693)	(2,824)
Operating loss	(10,394)	(7,969)
Finance income	91	149
Loss before income tax	(10,303)	(7,820)
Income tax credit	1,397	754
Loss and total comprehensive loss for the year	(8,906)	(7,066)
Loss and total comprehensive loss attributable to equity owners of the Company	(8,906)	(7,066)
Basic and diluted loss per ordinary share (note 5)	(0.5p)	(0.5p)

Group Statement of Financial Position as at 31 March

	2015 £'000	2014 £'000
Assets		
Non-current assets		
Property, plant and equipment	161	225
Intangible assets	1,591	1,272
Trade and other receivables	281	275
	2,033	1,772
Current assets		
Trade and other receivables	400	676
Income tax receivable	1,272	754
Investments – bank deposit	-	6,000
Cash and cash equivalents	12,382	14,917
	14,054	22,347
Total assets	16,087	24,119
Equity attributable to owners of the Company		
Share capital	17,888	17,888
Share premium account	46,267	46,267
Capital redemption reserve	8,964	8,964
Merger reserve	2,223	2,223
Accumulated losses	(62,206)	(53,625)
Total equity	13,136	21,717
Liabilities		
Non-current liabilities		
Provisions	605	364
Financial liabilities: finance leases	1	2
	606	366
Current liabilities		
Trade and other payables	2,344	2,035
Financial liabilities: finance leases	1	1
	2,345	2,036
Total liabilities	2,951	2,402
Total equity and liabilities	16,087	24,119

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 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
Credit on share-based payment	-	-	-	-	325	325
Loss for the year and total comprehensive loss	-	-	-	-	(8,906)	(8,906)
As at 31 March 2015	17,888	46,267	8,964	2,223	(62,206)	13,136

Group Statement of Cash Flows for the year ended 31 March

	2015	2014
	£'000	£'000
Cash used in operating activities (note 6)	(9,124)	(6,718)
Income tax credit received	879	714
Cash used in operating activities	(8,245)	(6,004)
Cash flows from investing activities		
Capital expenditure	(380)	(121)
Interest received	91	61
Net cash used in investing activities	(289)	(60)
Cash flows from financing activities		
Finance lease principal payments	(1)	(1)
Proceeds from issuance of ordinary shares	-	25,350
Costs of share issue	-	(1,915)
Bank deposit matured/(placed)	6,000	(6,000)
Net cash generated from financing activities	5,999	17,434
Net (decrease)/increase in cash and cash equivalents	(2,535)	11,370
Cash and cash equivalents at the start of year	14,917	3,547
Cash and cash equivalents at the end of year	12,382	14,917

Notes to the financial information for the year ended 31 March 2015

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 unaudited financial information included in this preliminary results announcement for the year ended 31 March 2015 and audited financial information for the year ended 31 March 2014 does not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. The information has been extracted from the draft statutory financial statements for the year ended 31 March 2015 which will be delivered to the Registrar of Companies in due course. Statutory financial statements for the year ended 31 March 2014 were approved by the Board of directors on 17 June 2014 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.

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 International Financial Reporting Standards (IFRS), this announcement does not contain sufficient information to comply with IFRS. 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 2014.

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.

Subsequent to the financial year end the Company has announced that it has raised £68.4 million, before expenses, by means of a Placing to shareholders. Following completion of the Placing, the directors expect that the Group’s financial resources will be sufficient to support operations for at least the next three years. 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 Group Statement of Comprehensive Income with the exception of a milestone payment made to StemCells Inc. under the terms of the 2005 cross-licence which has been capitalised as an intangible asset.

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 £8,906,000 (2014: £7,066,000) by 1,788,827,700 shares (2014: 1,424,978,475 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 operating activities for the year ended 31 March

	2015	2014
	£'000	£'000
Loss before income tax	(10,303)	(7,820)
Adjustment for:		
Interest received	(91)	(149)
Depreciation of property, plant and equipment	125	112
Provisions movement	241	214
Share-based payment charges	325	440
Changes in working capital		
Receivables	270	(387)
Payables	309	872
Cash used in operating activities	(9,124)	(6,718)