



7 July 2016

AIM: RENE

**ReNeuron Group plc**  
(“ReNeuron” or “the Company”)

### **Preliminary Results for the Year Ended 31 March 2016**

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to announce its preliminary results for the year ended 31 March 2016.

#### **Highlights in the period**

- *CTX* cell therapy candidate for motor disability as a result of stroke:
  - Phase II clinical trial – recruitment completed, data expected in Q4 2016
  - Pivotal Phase II/III clinical trial planned to commence in H1 2017
- hRPC cell therapy candidate for retinitis pigmentosa:
  - Phase I/II clinical trial underway - ReNeuron’s first US clinical study
  - Pivotal Phase II/III clinical trial planned to commence in 2018
- *CTX* cell therapy candidate for critical limb ischaemia:
  - Phase I clinical trial ongoing – data expected in H2 2016
  - Phase II clinical trial planned to commence in H1 2017
- Exosome nanomedicine platform:
  - Promising early pre-clinical data in cancer
  - Glioblastoma multiforme selected as first clinical target
- Placing completed in August 2015 to raise £68.4 million, before expenses, funding all therapeutic programmes into mid or late-stage clinical development
- Loss for the period of £11.35 million (2015: loss of £8.91 million); cash outflow from operations of £11.92 million (2015: outflow of £8.25 million); cash, cash equivalents and bank deposits at 31 March 2016 of £65.71 million (2015: £12.38 million)

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

“Our last financial year was one of significant progress. During the period, we commenced our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We have also made progress with our ongoing clinical trials in stroke disability and critical limb ischaemia and we look forward to reporting data from these studies later this year. We have recently selected brain cancer as the first clinical target for our exosome nanomedicine platform, based on exciting pre-clinical data published during the period. Finally, the substantial £68.4 million fundraising completed in the period has provided us with a very robust balance sheet with which to pursue the above programmes through to key clinical milestones over the next two to three years.”

## **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/2016/reneuron070716/registration.htm>

For further details please contact Buchanan on 020 7466 5000.

A recording of the presentation will be made available on ReNeuron's and Buchanan's websites, [www.reneuron.com](http://www.reneuron.com) and [www.buchanan.uk.com](http://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 has therapeutic candidates in clinical development for motor disability as a result of stroke, for critical limb ischaemia and for the blindness-causing disease, retinitis pigmentosa.

ReNeuron is also advancing its proprietary exosome technology platform as a potential new nanomedicine targeting cancer and as a potential delivery system for gene therapy treatments.

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.*

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

### **Review of programmes**

We have made considerable progress during the period across our therapeutic programmes and it underlines the increasing breadth of the Company's pipeline that we now have two clinical trials in progress in the UK, a further clinical trial underway in the US and an exciting early-stage exosome nanomedicine programme targeting cancer.

#### ***CTX for stroke disability***

During the period, 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 motor disability as a result of stroke. 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, with improvements in neurological status and limb function maintained throughout long-term follow-up compared with pre-treatment baseline performance.

A UK, multi-site Phase II clinical trial (PISCES II) is ongoing to examine the efficacy of CTX in patients with motor disability as a result of ischaemic stroke. Subsequent to the period-end, we announced that patient recruitment had completed in the PISCES II study, with three-month follow-up data expected to be available in the fourth quarter of 2016. We also announced that we had commenced formal interactions with regulatory authorities in Europe and the US regarding plans for a randomised, controlled, pivotal Phase II/III clinical trial with CTX in stroke disability. Subject to the results of the Phase II study, we expect to file an application in the first quarter of 2017 to commence a Phase II/III clinical trial.

Further, we have appointed local representatives to assist ReNeuron in taking advantage of the recently enacted and favourable regulatory regime for cell therapy candidates in Japan. These new Japanese regulations offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development than in the West. We intend to pursue discussions with the Japanese regulatory authorities over the coming months, in order to advance our CTX cell therapy candidate for stroke disability in Japan under the new regulations.

#### ***hRPC for retinitis pigmentosa***

During the period under review, we commenced 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. The FDA has also granted Fast Track designation to our hRPC programme targeting RP. This designation provides eligibility for an accelerated approval and priority review process by the FDA and the Orphan Drug Designation already granted for our RP programme in both the US and Europe provides the potential for a significant period of market exclusivity once approved in these major territories.

The Phase I/II clinical trial in RP patients marks the initiation of clinical trial activity in the US with our therapeutic programmes. The study is being 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 fifteen patients with advanced RP.

Initial short-term safety and tolerability data from the Phase I part of the study in the first nine patients are expected in early 2017. Longer term safety data, as well as efficacy read-outs from the Phase II part of the study in a further six patients, are expected in the second half of 2017. Subject to the outcome of the Phase I/II study, we expect to be able to file an application in late 2017 or early 2018 to commence a pivotal Phase II/III clinical trial of hRPC in RP. A positive outcome from this study is expected to form the basis for subsequent marketing authorisation filings in both the US and Europe.

### ***CTX for critical limb ischaemia***

Our CTX cell therapy candidate for critical limb ischaemia (CLI) is currently in a Phase I clinical trial in the UK. CLI is a condition that results in loss of blood flow to the lower limb. The condition is common in diabetics and can ultimately lead to amputation. During the past few months, we have prioritised CTX cell batches towards the PISCES II stroke study in preference to the CLI safety study. Notwithstanding this prioritisation, we expect to have safety data available from the CLI study by the end of this calendar year, sufficient to enable this programme to move into Phase II clinical development.

### ***Exosome nanomedicine platform***

During the period, we continued to advance our exosome nanomedicine programme. Exosomes are lipid-based nanoparticles secreted from all cells, 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.

ReNeuron researchers have identified a unique mechanism by which exosomes expressed from CTX cells inhibit the growth and migration of glioblastoma cells in pre-clinical models of the disease. During the period, a paper was published in the scientific journal PLOS ONE describing work undertaken by ReNeuron researchers to identify a unique set of highly enriched miRNAs contained within CTX-derived exosomes. The research demonstrated that these miRNAs may have significant impact in regulating cell growth and apoptosis in cancer.

Based on the above findings, we recently announced that we had selected glioblastoma multiforme ("GBM") as the first clinical target for our selected exosome nanomedicine candidate, designated *ExoPrO*. GBM accounts for 16 per cent of all diagnosed brain cancers. Overall median survival for newly diagnosed disease is 12 to 15 months with 5 year survival rates of 4 to 6 per cent. The incidence rate in the US and Europe combined is around 25,000 patients per annum.

During the period, we were awarded a £2.1 million grant from Innovate UK for our exosome nanomedicine programme. In collaboration with the Cell and Gene Therapy Catapult and the Department of Biochemical Engineering at University College London, this grant will fund the development of robust manufacturing systems to enable the production of *ExoPrO* at a commercial scale, as well as product characterisation work and pre-clinical efficacy and toxicity testing of the *ExoPrO* candidate.

Assuming a successful outcome to the above pre-clinical development programme, we expect to be able to file an application to commence a first human clinical trial with *ExoPrO* in the second half of 2017.

## **Other activities**

In August 2015, we completed a placing to raise £68.4 million, before expenses. This financing has provided the business with an extremely robust balance sheet, enabling us to take all of our current programmes into mid or late-stage clinical development over the next two to three years.

In February 2016, we relocated our existing business operations to our new facility in South Wales, with cell production suites planned to come on-stream at a later date, once qualified for use and licensed for clinical and commercial manufacture.

Also in February this year, we announced that we had received a Notice of Allowance from the US Patent and Trademark Office for a key patent application covering our cell cryopreservation technology. We have deployed this patented technology to our lead *CTX* stem cell line to derive a cryopreserved, long shelf life cell therapy candidate, designated *CTXcryo*. We believe that *CTXcryo* will provide ReNeuron with significant commercial and competitive advantages in terms of the availability of a genuine off-the-shelf, low cost-of-goods cell therapy candidate with a shelf life enabling shipping to, and storage at, clinical sites on a global basis.

Equivalent patents to the allowed US cryopreservation patent have already issued in Europe, Japan and Australia. Overall, ReNeuron owns or has exclusively licensed more than 80 issued patents, providing protection for our technologies and therapeutic candidates in key potential markets across the globe.

During the period, we have continued to strengthen the senior management of the business, at both executive and non-executive levels. In December 2015, we announced the appointment of Dr Michael Owen as a Non-executive Director of the Company. Mike brings a wealth of scientific and commercial biotech and pharmaceutical experience to the Board and also chairs the Company's newly established Scientific Advisory Board (SAB). The inaugural meeting of the SAB took place in December 2015, comprising nine leading academics and industry executives with a world-class breadth of expertise across ReNeuron's areas of operation.

## **Financial review**

Revenues in the year amounted to £29k (2015: £30k), being royalties from non-therapeutic licensing activities. Grant income of £0.53 million (2015: £0.52 million) was recognised in Other income.

Research and development costs increased to £10.27 million (2015: £7.25 million) and accounted for 72% of net operating expenses (2015: 66%). The increase during the period was primarily due to increased clinical trial costs, manufacturing process development costs and cell manufacturing costs as a result of increasing clinical trial activity. 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 expenses increased to £4.02 million (2015: £3.69 million) primarily due to increased staff recruitment activity and costs associated with the relocation of the business to South Wales.

The total tax credit for the period was £1.49 million, relating to an accrual for a research and development tax credit for the period (2015: £1.40 million).

As a result of the above, the total comprehensive loss for the year increased to £11.35 million (2015: £8.91 million) in line with both internal and consensus analyst forecasts.

Cash outflow from operating activities was £11.92 million (2015: £8.25 million), largely reflecting the operating costs incurred during the period. Capital expenditure was £0.29 million (2015: £0.38 million). As mentioned above, in August 2015, the Company raised £68.4 million, before expenses, by means of a placing with new and existing institutional investors. As a result, cash, cash equivalents and bank deposits totalled £65.71 million at the year-end (2015: £12.38 million).

### **Summary and outlook**

Our last financial year was one of significant progress. During the period, we commenced our first clinical trial in the US, a Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa. We have also made progress with our ongoing clinical trials in stroke disability and critical limb ischaemia and we look forward to reporting data from these studies later this year. We have recently selected brain cancer as the first clinical target for our exosome nanomedicine platform, based on exciting pre-clinical data published during the period. Finally, the substantial £68.4 million fundraising completed in the period has provided us with a very robust balance sheet with which to pursue the above programmes through to key clinical milestones over the next two to three years.

**John Berriman**  
Chairman

**Olav Hellebø**  
Chief Executive Officer

7 July 2016

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

	<b>2016</b>	2015
	<b>£'000</b>	£'000
Revenue: royalty income	<b>29</b>	30
Other income: grants	<b>534</b>	519
Research and development costs	<b>(10,272)</b>	(7,250)
General and administrative costs	<b>(4,015)</b>	(3,693)
<b>Operating loss</b>	<b>(13,724)</b>	(10,394)
Finance income	<b>878</b>	91
<b>Loss before income tax</b>	<b>(12,846)</b>	(10,303)
Income tax credit	<b>1,492</b>	1,397
<b>Loss and total comprehensive loss for the year</b>	<b>(11,354)</b>	(8,906)
<b>Loss and total comprehensive loss attributable to equity owners of the Company</b>	<b>(11,354)</b>	(8,906)
<b>Basic and diluted loss per ordinary share</b>	<b>(0.4p)</b>	(0.5p)



## Group Statement of Financial Position as at 31 March

	2016 £'000	2015 £'000
<b>Assets</b>		
<b>Non-current assets</b>		
Property, plant and equipment	361	161
Intangible assets	1,591	1,591
Investments – bank deposit	5,000	–
Trade and other receivables	11	281
	<b>6,963</b>	<b>2,033</b>
<b>Current assets</b>		
Trade and other receivables	1,421	400
Income tax receivable	2,764	1,272
Investments – bank deposit	43,283	–
Cash and cash equivalents	17,426	12,382
	<b>64,894</b>	<b>14,054</b>
<b>Total assets</b>	<b>71,857</b>	<b>16,087</b>
<b>Equity</b>		
<b>Equity attributable to owners of the Company</b>		
Share capital	31,646	17,888
Share premium account	97,704	46,267
Capital redemption reserve	8,964	8,964
Merger reserve	2,223	2,223
Accumulated losses	(72,879)	(62,206)
<b>Total equity</b>	<b>67,658</b>	<b>13,136</b>
<b>Liabilities</b>		
<b>Non-current liabilities</b>		
Provisions	–	605
Financial liabilities: finance leases	–	1
	–	606
<b>Current liabilities</b>		
Trade and other payables	3,700	2,344
Provisions	498	–
Financial liabilities: finance leases	1	1
	<b>4,199</b>	<b>2,345</b>
<b>Total liabilities</b>	<b>4,199</b>	<b>2,951</b>
<b>Total equity and liabilities</b>	<b>71,857</b>	<b>16,087</b>

## 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
<b>As at 1 April 2014</b>	<b>17,888</b>	<b>46,267</b>	<b>8,964</b>	<b>2,223</b>	<b>(53,625)</b>	<b>21,717</b>
Credit on share-based payment	–	–	–	–	325	325
Loss for the year and total comprehensive loss	–	–	–	–	(8,906)	(8,906)
<b>As at 31 March 2015</b>	<b>17,888</b>	<b>46,267</b>	<b>8,964</b>	<b>2,223</b>	<b>(62,206)</b>	<b>13,136</b>
Issue of Ordinary shares	13,758	54,696	–	–	–	68,454
Costs of share issue	–	(3,259)	–	–	–	(3,259)
Credit on share-based payment	–	–	–	–	681	681
Loss for the year and total comprehensive loss	–	–	–	–	(11,354)	(11,354)
<b>As at 31 March 2016</b>	<b>31,646</b>	<b>97,704</b>	<b>8,964</b>	<b>2,223</b>	<b>(72,879)</b>	<b>67,658</b>

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

	<b>2016</b>	2015
	<b>£'000</b>	£'000
<b>Cash used in operating activities</b>	<b>(11,920)</b>	(9,124)
Income tax credit received	–	879
<b>Cash used in operating activities</b>	<b>(11,920)</b>	(8,245)
<b>Cash flows from investing activities</b>		
Capital expenditure	<b>(293)</b>	(61)
Purchase of intangible asset	–	(319)
Interest received	<b>345</b>	91
<b>Net cash generated/(used) in investing activities</b>	<b>52</b>	(289)
<b>Cash flows from financing activities</b>		
Finance lease principal payments	–	(1)
Proceeds from issuance of Ordinary shares	<b>68,454</b>	–
Costs of share issue	<b>(3,259)</b>	–
Bank deposit (placed)/matured	<b>(48,283)</b>	6,000
<b>Net cash generated from financing activities</b>	<b>16,912</b>	5,999
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>5,044</b>	(2,535)
Cash and cash equivalents at the start of year	<b>12,382</b>	14,917
<b>Cash and cash equivalents at the end of year</b>	<b>17,426</b>	12,382

## **Notes to the financial information for the year ended 31 March 2016**

### **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 2016 and audited financial information for the year ended 31 March 2015 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 2016 which will be delivered to the Registrar of Companies in due course. Statutory financial statements for the year ended 31 March 2015 were approved by the Board of directors on 24 August 2015 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 2015.

### **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 facility in South Wales.

In August 2015, the Company raised £68.4 million, before expenses, by means of a Placing to shareholders. The directors expect that the Group’s financial resources will be sufficient to support operations for at least the next two 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.

## 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 £11,354,000 (2015: £8,906,000) by 2,609,315,899 shares (2015: 1,788,827,700 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

	<b>2016</b>	2015
	<b>£'000</b>	£'000
<b>Loss before income tax</b>	<b>(12,846)</b>	(10,303)
Adjustment for:		
Interest received	<b>(345)</b>	(91)
Depreciation of property, plant and equipment	<b>92</b>	125
Provisions movement	<b>(107)</b>	241
Share-based payment charges	<b>681</b>	325
Changes in working capital		
Receivables	<b>(751)</b>	270
Payables	<b>1,356</b>	309
<b>Cash used in operating activities</b>	<b>(11,920)</b>	(9,124)