29 June 2017 **AIM: RENE**

ReNeuron Group plc
("ReNeuron" or "the Company")

Preliminary Results for the Year Ended 31 March 2017

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 2017.

Highlights in the period

- *CTX* cell therapy candidate for motor disability as a result of stroke:
  - Positive Phase II efficacy data in PISCES II clinical trial
  - Phase I clinical trial data from PISCES I study published in The Lancet
  - Pivotal Phase III clinical trial planned to commence in US in early 2018, following positive feedback from the FDA

- hRPC cell therapy candidate for retinal diseases:
  - Phase I/II clinical trial in retinitis pigmentosa ongoing in US with Phase I data expected later in 2017 and data from enlarged Phase II stage expected in H2 2018
  - Cryopreserved formulation of hRPC approved by FDA for use in clinical trials
  - Phase II clinical trial application planned later in 2017 in cone-rod dystrophy

- *CTX* cell therapy candidate for critical limb ischaemia:
  - Phase I clinical trial completed with no significant adverse safety events reported

- Exosome therapy platform:
  - Positive pre-clinical data with *ExoPr0* exosome therapy candidate presented at leading scientific conferences
  - Data indicate that *ExoPr0* can cross blood-brain barrier and has potential to target multiple diseases
  - Initial clinical trial application expected in late 2018 in cancer

- Loss for the period of £15.57 million (2016: loss of £11.35 million); cash outflow from operations of £12.64 million (2016: outflow of £11.92 million); cash, cash equivalents and bank deposits at 31 March 2017 of £53.06 million (2016: £65.71 million)

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

*"*Our therapeutic development programmes have continued to progress well during the period, the highlight being positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability. We are encouraged by the subsequent feedback we have received from the FDA regarding our planned US pivotal Phase III clinical trial with CTX for stroke disability. The unmet medical need in chronic stroke disability is enormous and we are ever closer to being able to offer a potential new therapeutic option to these patients.

"We have made significant advances with our hRPC cell therapy candidate, both in terms of progressing the ongoing US Phase I/II clinical trial in retinitis pigmentosa and obtaining FDA approval for the cryopreserved formulation of this therapeutic candidate, enabling us to expand our ophthalmology programmes into new indications. We have also generated and presented further encouraging pre-clinical data with our *ExoPr0* exosome therapy candidate targeting cancer.

"With our stroke programme moving into Phase III clinical development over the coming months and our retinal disease programmes moving into Phase II clinical development later this year, we expect to achieve significant clinical milestones during each of the next three years."

Analyst meeting and webcast

A meeting for analysts will be held at 9.00am 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 9.00am:
http://vm.buchanan.uk.com/2017/reneuron290617/registration.htm

For further details please contact Buchanan on 020 7466 5000.

A recording of the presentation will be made available on ReNeuron's website, www.reneuron.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 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 drugs that would otherwise lack adequate capacity to penetrate to their site of action.

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 programmes

CTX for stroke disability

During the period, we completed dosing and announced positive data in the Phase II clinical trial (PISCES II) of our CTX cell therapy candidate for stroke disability. PISCES II is a single arm, open-label study in patients living with disability resulting from ischaemic stroke. At the time of announcement of the initial data, all 21 patients in the study had completed three-month follow-up, with ten patients followed for six months and three for twelve months.

The study's primary endpoint was for two patients to reach a minimum two-point improvement in the grasping and lifting test, sub-test number 2, of the Action Research Arm Test (ARAT), at three months post-treatment. Three of the 21 patients achieved this at three, six or twelve months respectively after treatment and were within a group of four responders who also showed clinically relevant improvements on the total ARAT score of arm motor performance. Although the ARAT sub-test number 2 study endpoint was not met (as some responses came later than the three-month target), we believe the result is nonetheless highly encouraging.

Strongly positive results were also seen in the other endpoints of the study, with seven patients (33%) showing a clinically relevant improvement on the Modified Rankin Scale (a measure of disability and dependence) and eight patients (38%) showing a clinically relevant improvement on the Barthel Index (a measure of performance in activities of daily living). In total, 15 out of 21 patients had a clinically significant response on at least one efficacy measure. Improvements in the ARAT scores, Modified Rankin Scale and Barthel Index were all sustained throughout the follow up period.

The study also demonstrated that the CTX treatment was well tolerated, with no cell-related adverse events. Longer term safety and efficacy data from the study will be presented at forthcoming stroke and rehabilitation medical conferences. The PISCES II study was part-funded by a regenerative medicine and cell therapy development grant from Innovate UK.

The above PISCES II data was generated after the publication of long term follow up data from our PISCES I stroke clinical trial in *The Lancet*. The PISCES I study was the first clinical trial of our CTX cell therapy candidate for stroke disability. *The Lancet* paper describes two-year follow up clinical data relating to the eleven stroke patients treated in the study. Improvements in neurological status and limb function compared with pre-treatment baseline performance were observed in this study within three months of treatment and maintained throughout long term follow up. The CTX treatment was also well-tolerated by the patients in the PISCES I study, with no cell-related or immunological adverse events reported across the four ascending dose levels.

As a result of the positive data reported from both the PISCES I and PISCES II studies, we have consulted the FDA regarding our plans to conduct a randomised, placebo-controlled, pivotal Phase III clinical trial with CTX in the US, in patients with disability post-stroke. As we reported recently, the FDA has responded positively to our proposals regarding the design and conduct of the proposed Phase III clinical trial and, significantly, specifically recommended that we apply for a Special Protocol Assessment (SPA) for the Phase III study. The SPA process is exclusively reserved for studies considered potentially pivotal in support of product marketing label claims.

Based on the FDA's recommendation, we plan to apply for an SPA for our proposed Phase III clinical trial with CTX for stroke disability. As part of our US regulatory strategy, we also plan to apply for Regenerative Medicine Advanced Therapy (RMAT) designation for our CTX cell therapy candidate for stroke disability. The benefits of RMAT designation are similar to those of Breakthrough Therapy designation, including increased interactions with the FDA during development and eligibility for priority review and accelerated marketing approval.

We are now working to finalise the relevant data packages to enable us to submit both the SPA and RMAT designation applications within the broader IND application to commence a Phase III clinical trial with CTX for stroke disability in the US. We expect to make this combined submission in the final quarter of this year, with the study now expected to commence in early 2018, subject to the requisite regulatory approvals. Data from the study are expected about two years later, in early 2020.

Separately, we have consulted with the European Medicines Agency on our plans for the Phase III clinical trial and we have taken the advice received into account when developing our protocol for the study. In this regard, we intend to file a clinical trial application to regulatory authorities in Europe, shortly after the corresponding US submission. Meetings with the Japanese regulatory agency (PDMA) are also ongoing in order to advance our CTX cell therapy candidate for stroke disability in Japan under regulations that offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development.

hRPC for retinitis pigmentosa

During the period under review, we completed dosing of the second dose cohort of three patients in the Phase I element of the Phase I/II clinical trial of our human Retinal Progenitor Cell (hRPC) cell therapy candidate for the blindness-causing disease, retinitis pigmentosa (RP). This US study, which is being conducted at Massachusetts Eye and Ear Infirmary in Boston, 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.

During the period, we also successfully developed a cryopreserved formulation of the hRPC therapeutic candidate. The FDA has recently approved this formulation and we have now started treating patients with it in the ongoing US Phase I/II study clinical trial in RP patients. The ability to cryopreserve our retinal cell therapy candidate at drug product level represents a major step forward for our retinal disease programme and mirrors the earlier breakthrough we achieved with the cryopreservation of our CTX cell therapy candidate. The new proprietary formulation enables the hRP cells to be frozen for shipping and storage and easily thawed at the point of clinical use. This freeze-thaw modality provides a greatly enhanced shelf life for the product, lower prospective cost of goods and the capability to ship the cells for clinical and commercial application anywhere in the world.

The new hRPC cryopreserved formulation has also allowed an expansion of ReNeuron's clinical programmes in ophthalmology. Firstly, we will shortly file an application with the FDA to expand the Phase II element of the ongoing US Phase I/II clinical trial in RP from six to 20 patients. The expanded study is designed to provide the depth and quality of data that, if positive, will allow subsequent progression to a Phase II/III pivotal study in this indication. In order to maintain the pace of patient recruitment and reduce reliance on a single clinical site, we also intend to open up

further US clinical sites for this study. As a consequence of these changes, we expect safety and tolerability data from the Phase I part of the RP study in the first nine patients later this year, with longer term safety data as well as efficacy read-outs from the enlarged Phase II part of the study in the second half of 2018.

Secondly, we intend to expand our hRPC retinal disease programmes into a further disease indication, cone-rod dystrophy (CRD). In contrast to RP, where the initial impact is a loss of rods leading to a deterioration in peripheral vision and night vision, CRD is a group of rare eye disorders associated with a loss of cone cells in the retina that initially results in deterioration of central visual acuity and colour vision. CRD frequently affects patients in childhood and has no cure. It is an inherited orphan disease that affects roughly 1 in 40,000 people.

The expansion of our ophthalmology programmes into CRD is part of a broader strategy to evaluate the efficacy of our hRPC therapeutic candidate across a range of genetic diseases of the eye. We intend to file an application to commence a Phase II clinical trial later this year in patients with CRD, to be run alongside the Phase II part of the ongoing RP clinical trial. Data from the CRD study are expected in mid 2019.

CTX for critical limb ischaemia

In order to focus on the significant opportunity presented by our stroke disability programme, our expanded retinal disease programmes and our emerging exosome platform, we have decided to put our programme for critical limb ischaemia on hold for the time being. Patient dosing was recently completed in a Phase I safety study in this indication, with no significant adverse safety events reported post-administration of the CTX cells via intramuscular injection.

Exosome nanomedicine platform

During the period, and subsequently, we have continued to generate and present pre-clinical data relating to our exosome development programme. Exosomes are nanoparticles secreted from all cells including ReNeuron's proprietary CTX stem cell line. They play a key role in cell-to-cell signalling and early research with *ExoPr0,* our first CTX-derived exosome therapeutic candidate, has demonstrated that it may have a significant effect in regulating cell growth and apoptosis in cancer.

In conjunction with our academic collaborators at the Department of Biochemical Engineering, University College London (UCL), we have presented data relating to the upstream cell culture processes needed to generate our exosomes and the downstream purification methods that can be applied to remove protein and DNA-based impurities from the exosomes at commercially relevant scale. These new methods were shown to yield a three-fold increase in particle protein purity and a more than five-fold increase in particle DNA purity compared with previous purification processes.

In conjunction with UK's Cell and Gene Therapy Catapult, we have also presented data relating to the characterisation of our exosomes to ensure consistency and control during manufacture. The data demonstrated a robust approach to optimising and qualifying assays for micro-RNA components found in the exosomes. The application of robust characterisation and purification methods to our exosome populations will support their future development across multiple potential disease indications.

Finally, we recently presented data relating to the *in vivo* biodistribution of *ExoPr0*, using the most common and disease applicable routes of administration to deliver the exosomes. The studies showed that *ExoPr0* can be targeted to specific organs and tissues by either local or systemic administration and, most importantly, can penetrate the blood-brain barrier. These findings, together with earlier research results, suggest that there is significant potential to develop ExoPr0 for the treatment of multiple diseases, both as a novel therapeutic candidate and as a drug delivery vehicle.

On the basis of the above progress and subject to continued success with ongoing pre-clinical development work, we expect to be able to reach the clinic with *ExoPr0* in late 2018, targeting cancer.

Other activities

Subsequent to the period end, we were awarded a £1.8 million grant from Innovate UK to further advance our next generation commercial cell therapy manufacturing capabilities. The grant will fund key process development activities relating to up-scaled commercial manufacture of our cell therapy candidates, including the development of robust manufacturing processes utilising next generation technology and techniques that will enable the production of our therapeutic candidates at a commercial scale. The work will be undertaken by ReNeuron, as lead participant, and our collaborators on the grant, the Cell & Gene Therapy Catapult.

We are also pleased to be an industry participant in the recently launched Future Targeted Healthcare Manufacturing Hub. The Hub, led by UCL and funded by the Engineering and Physical Sciences Research Council, is an industry-academia consortium established to address the manufacturing, business and regulatory challenges to ensure that new targeted biological medicines can be developed quickly and manufactured at a cost affordable to society.

Financial review

Revenues in the year amounted to £46k (2016: £29k), being royalties from non-therapeutic licensing activities. Grant income of £0.85 million (2016: £0.53 million) was also recognised in other income.

Research and development costs increased to £16.65 million (2016: £10.27 million) and accounted for 80% of net operating expenses (2016: 72%). This increase is primarily due to the increased level of clinical trial activity and associated cell manufacturing and process development costs across the Group's therapeutic programmes. Pre-clinical research costs also increased in the period, reflecting the further progression of the Company's exosome programme.

General and administrative expenses increased slightly to £4.14 million (2016: £4.02 million).

Finance income, which represents income received from the Group's cash and investments and gains from foreign exchange, was £1.72 million in the period (2016: £0.88 million). The increase in finance income reflects the increase in average cash and investment balances compared with the equivalent prior period, as well as a favourable movement in exchange rates during the period on cash and investments held in foreign currency.

The total tax credit for the period was £2.59 million, relating to an accrual for a research and development tax credit for the period (2016: £1.49 million). The increase on the previous year reflects the increase in applicable costs.

As a result of the above, the total comprehensive loss for the year increased to £15.57 million (2016: £11.35 million).

Cash outflow from operating activities was £12.64 million (2016: £11.92 million), largely reflecting the operating costs incurred during the period. Capital expenditure was £0.53 million (2016: £0.29 million). The Group had cash, cash equivalents and bank deposits totalling £53.06 million at the year-end (2016: £65.71 million).

Summary and outlook

Our therapeutic development programmes have continued to progress well during the period, the highlight being positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability. We are encouraged by the subsequent feedback we have received from the FDA regarding our planned US pivotal Phase III clinical trial with CTX for stroke disability. The unmet medical need in chronic stroke disability is enormous and we are ever closer to being able to offer a potential new therapeutic option to these patients.

We have made significant advances with our hRPC cell therapy candidate, both in terms of progressing the ongoing US Phase I/II clinical trial in retinitis pigmentosa and obtaining FDA approval for the cryopreserved formulation of this therapeutic candidate, enabling us to expand our ophthalmology programmes into new indications. We have also generated and presented further encouraging pre-clinical data with our *ExoPr0* exosome therapy candidate targeting cancer.

With our stroke programme moving into Phase III clinical development over the coming months and our retinal disease programmes moving into Phase II clinical development later this year, we expect to achieve significant clinical milestones during each of the next three years.

John Berriman
Chairman
29 June 2017

Olav Hellebø
Chief Executive Officer

Group Statement of Comprehensive Income for the year ended 31 March

	2017	2016
	£'000	£'000
Revenue: royalty income	**46**	29
Other income: grants	**854**	534
Research and development costs	**(16,648)**	(10,272)
General and administrative costs	**(4,139)**	(4,015)
Operating loss	**(19,887)**	(13,724)
Finance income	**1,722**	878
Loss before income tax	**(18,165)**	(12,846)
Income tax credit	**2,592**	1,492
Loss and total comprehensive loss for the year	**(15,573)**	(11,354)
Loss and total comprehensive loss attributable to equity owners of the	**2**	
Company	**(15,573)**	(11,354)
Basic and diluted loss per ordinary share	**(0.5p)**	(0.4p)

Group Statement of Financial Position as at 31 March

	2017	2016
	£'000	£'000
Assets		
Non-current assets		
Property, plant and equipment	**724**	361
Intangible assets	**–**	1,591
Investments – bank deposit	**–**	5,000
Trade and other receivables	**–**	11
	724	6,963
Current assets		
Trade and other receivables	**1,060**	1,421
Income tax receivable	**4,015**	2,764
Investments – bank deposit	**24,936**	43,283
Cash and cash equivalents	**28,125**	17,426
	58,136	64,894
Total assets	**58,860**	71,857
Equity		
Equity attributable to owners of the Company		
Share capital	**31,646**	31,646
Share premium account	**97,704**	97,704
Capital redemption reserve	**8,964**	8,964
Merger reserve	**2,223**	2,223
Accumulated losses	**(87,380)**	(72,879)
Total equity	**53,157**	67,658
Liabilities		
Non-current liabilities		
Financial liabilities: finance leases	**1**	–
	1	–
Current liabilities		
Trade and other payables	**5,701**	3,700
Provisions	**–**	498
Financial liabilities: finance leases	**1**	1
	5,702	4,199
Total liabilities	**5,703**	4,199
Total equity and liabilities	**58,860**	71,857

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 2015	**17,888**	**46,267**	**8,964**	**2,223**	**(62,206)**	**13,136**
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)
As at 31 March 2016	**31,646**	**97,704**	**8,964**	**2,223**	**(72,879)**	**67,658**
Credit on share-based payment	–	–	–	–	1,072	1,072
Loss for the year and total comprehensive loss	–	–	–	–	(15,573)	(15,573)
As at 31 March 2017	**31,646**	**97,704**	**8,964**	**2,223**	**(87,380)**	**53,157**

Group Statement of Cash Flows for the year ended 31 March

	2017	2016
	£'000	£'000
Cash used in operations	**(13,976)**	(11,920)
Income tax credit received	**1,340**	–
Cash used in operating activities	**(12,636)**	(11,920)
Cash flows from investing activities		
Capital expenditure - Fixed Assets	**(532)**	(293)
Interest received	**520**	345
Net cash (used)/generated in investing activities	**(12)**	52
Cash flows from financing activities		
Finance lease principal payments		
Proceeds from issuance of Ordinary shares	**–**	68,454
Costs of share issue	**–**	(3,259)
Bank deposit matured/(placed)	**23,347**	(48,283)
Net cash generated from financing activities	**23,347**	16,912
Net increase in cash and cash equivalents	**10,699**	5,044
Cash and cash equivalents at the start of year	**17,426**	12,382
Cash and cash equivalents at the end of year	**28,125**	17,426

Notes to the financial information for the year ended 31 March 2017

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 2017 and audited financial information for the year ended 31 March 2016 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 2017 which will be delivered to the Registrar of Companies in due course. Statutory financial statements for the year ended 31 March 2016 were approved by the Board of directors on 22 July 2016 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 2016.

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 current financial resources will be sufficient to support operations for at least the next 12 months. 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 £15,573,000 (2016: £11,354,000) by 3,164,618,541 shares (2016: 2,609,315,899 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

	2017	2016
	£'000	£'000
Loss before income tax	**(18,165)**	(12,846)
Adjustment for:		
Interest received	**(520)**	(345)
Depreciation of property, plant and equipment	**170**	92
Impairment of intangible assets	**1,591**	–
Provisions movement	**(498)**	(107)
Share-based payment charges	**1,072**	681
Changes in working capital:		
Receivables	**372**	(751)
Payables	**2,002**	1,356
Cash used in operating activities	**(13,976)**	(11,920)