

Details are given below of an analyst meeting and webcast at 10.00am BST this morning



11 July 2019

AIM: RENE

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

Preliminary Results for the year ended 31 March 2019

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 2019.

Operational highlights

hRPC stem cell therapy candidate for retinal disease:

- Positive preliminary efficacy data from first three Phase 2a patients in ongoing US Phase 1/2a clinical trial in retinitis pigmentosa
- Top line results from all treated Phase 2a patients to be presented at the American Academy of Ophthalmology Annual Meeting in October 2019

CTX stem cell therapy candidate for stroke disability:

- Patient dosing commenced in placebo-controlled US Phase 2b clinical trial
- Top line data from Phase 2b study expected in late 2020

Exosome platform:

- Programme primarily focused on use of exosome technology as a drug delivery vehicle
- First collaboration agreement signed with US company to explore use of exosome technology as a delivery vehicle in gene therapy

Increased business development activity reflecting interest from third parties:

- Exclusive out-licence agreement signed post-year end with Fosun Pharma to commercialise hRPC and CTX programmes in China
 - ReNeuron to receive upfront, future near term and estimated success-based milestone payments of £80.0 million plus double-digit royalties on sales
- Discussions ongoing with other commercial third parties regarding potential out-licence deals

Financial highlights

- Reduced loss for the year of £14.3 million (2018: loss of £17.6 million)

- Reduced cash used in operating activities of £12.0 million (2018: £14.9 million)
- Cash, cash equivalents and bank deposits at 31 March 2019 of £26.4 million (2018: £37.4 million).
- Upfront payment of £5.4 million, net of withholding tax, received post-year end pertaining to licence agreement with Fosun Pharma

Commenting on the results, Olav Hellebø, Chief Executive Officer, said:

“The past year has been a transformational one for ReNeuron. During the period, we commenced patient dosing in the US placebo-controlled Phase 2b clinical trial of our CTX cell therapy candidate in chronic stroke disability. This was followed shortly afterwards by the announcement of strongly positive preliminary efficacy data from the first three Phase 2a patients in the ongoing US Phase 1/2a clinical trial of our hRPC cell therapy candidate in retinitis pigmentosa. We look forward to delivering further significant clinical data in our stroke and retinitis pigmentosa programmes over the next 18 months.

“We are pleased to be working with Fosun Pharma as our partner for China, following the signing of the exclusive licence agreement for both our CTX and hRPC programmes in that territory. We are also encouraged by the level of interest other potential collaborators are showing in all of our programmes, including our exosome technology which is being developed as a novel system for delivering third party drugs.

“We look forward to providing further updates on our clinical and commercial progress in the months ahead.”

Analyst meeting and webcast:

A presentation meeting for analysts will be held at 10.00am BST 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 approximately 5 minutes before 10.00am:

<https://webcasting.buchanan.uk.com/broadcast/5d011332221579216107d918>

For further details please contact Buchanan on 020 7466 5000 or email reneuron@buchanan.uk.com.

A recording of the webcast will be made available on ReNeuron's website, www.reneuron.com.

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This announcement contains inside information. The person responsible for arranging for the release of this announcement on behalf of the Company is Olav Hellebø, Chief Executive Officer.

About ReNeuron

ReNeuron is a global leader in cell-based therapeutics, harnessing its unique stem cell technologies to develop 'off the shelf' stem cell treatments, without the need for immunosuppressive drugs. The Company's lead clinical-stage candidates are in development for the blindness-causing disease, retinitis pigmentosa, and for disability as a result of stroke. ReNeuron is also advancing its proprietary exosome technology platform as a potential delivery system for drugs that would otherwise be unable to reach their site of action. ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. For further information visit 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 also 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 STATEMENT

I am pleased to introduce the Group's Preliminary Results for the year ended 31 March 2019.

The Company's programmes have continued to progress well during the period. The most notable milestone achieved was the announcement, and subsequent presentation in conference, of positive preliminary data in the Phase 2a element of the ongoing US Phase 1/2 clinical trial with our hRPC cell therapy candidate for retinitis pigmentosa. We remain highly encouraged by these early efficacy results, with all three subjects in the cohort reported on demonstrating a rapid improvement in vision compared with their pre-treatment baseline. We look forward to reporting further Phase 2a data from the study later this year.

Elsewhere, we commenced patient dosing during the period in the US Phase 2b study of our CTX cell therapy candidate for stroke disability. Top-line results from this study are expected in late 2020. We have also refocused our exosome technology programme towards value-generating business partnerships, in which our exosomes may be exploited as a novel vector for delivering third party biological drugs.

We have highlighted previously the interest our therapeutic programmes have attracted from commercial third parties. In April 2019, this interest culminated in the signing of an exclusive licence agreement with Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. ("Fosun Pharma") for the development, manufacture and commercialisation of both our CTX and hRPC cell therapy programmes in the People's Republic of China. We are delighted to be partnering with Fosun Pharma, a leading healthcare group in China with extensive healthcare business interests worldwide.

In June 2019, ReNeuron won the 'Breakthrough of the Year' award at the annual European Mediscience Awards in London, in recognition of the strong clinical development and commercial progress the Company has made over the past year. The European Mediscience Awards is one of the largest annual gatherings of private and publicly quoted healthcare, biotech and life sciences companies in Europe.

Despite the substantial progress we have made during the period, we have continued to maintain tight control over our operating costs, reflected in the Group's financial results for the year ended 31 March 2019.

ReNeuron continues to make sound progress across its therapeutic programmes and we look forward to reporting further progress in the year ahead. The Board and I would like to extend our thanks to our employees for their ongoing commitment and hard work during the year. I would also like to thank all of our shareholders for their continued support.

John Berriman
Chairman

CHIEF EXECUTIVE OFFICER'S REVIEW

Review of clinical programmes

hRPC for retinal disease

During the period under review, and subsequent to it, we have made significant progress advancing the clinical development of our human retinal progenitor cell (hRPC) therapy candidate in the blindness-causing disease, retinitis pigmentosa (RP). A Phase 1/2a open-label clinical trial is ongoing to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in patients with advanced RP. The Phase 2a element of the study, which uses a cryopreserved hRPC formulation, enrolls subjects with some remaining retinal function and is being conducted at two clinical sites in the US: Massachusetts Eye and Ear in Boston and Retinal Research Institute in Phoenix, Arizona.

In February 2019, we reported positive preliminary data in the first cohort of three patients in the Phase 2a element of the study, with all three subjects in the cohort demonstrating a rapid improvement in vision compared with their pre-treatment baseline.

In April 2019, further data from the first patient cohort in the study were presented at the sixth annual Retinal Cell and Gene Therapy Innovation Summit in Vancouver, Canada, which preceded the 2019 annual meeting of the Association for Research in Vision and Ophthalmology. In the presentation, it was reported that the first cohort of patients in the Phase 2a element of the study had demonstrated a sustained and further improvement in vision compared with baseline, with a mean improvement from baseline in visual acuity of + 23 letters on the ETDRS eye chart in the treated eye (the untreated control eyes did not show meaningful improvement). An improvement of + 23 letters is equivalent to reading an additional four lines of letters on the ETDRS eye chart, the standardised eye chart used to measure visual acuity in clinical trials. An improvement of at least + 15 letters from baseline is considered to be clinically meaningful by the US Food and Drug Administration (FDA), as stated in their recent guidance on gene therapy for retinal disorders. In addition to these objective measurements, all three subjects had also noted a subjective improvement in vision in their treated eye.

Dosing of the second cohort of three subjects in the Phase 2a element of the study is complete and dosing of the remaining two cohorts is in progress. These later cohorts comprise patients with a greater baseline level of visual acuity than those patients earlier in the study, as we seek to assess preliminary efficacy in patient groups with differing levels of remaining vision. The clinical protocol for the study allows for up to 12 patients (four cohorts of three patients each) to be treated in the Phase 2a element of the study.

We expect to treat the remaining patients in the study shortly and to report preliminary data from all treated Phase 2a subjects in October at the American

Academy of Ophthalmology 2019 Annual Meeting in San Francisco. These results will form the basis of our future interactions with the European and US regulatory authorities regarding the future clinical development path of hRPC for the treatment of RP. Our clinical programme in RP benefits from Orphan Drug Designation in both Europe and the US, as well as Fast Track designation from the US Food and Drug Administration (FDA).

CTX for stroke disability

During the period, we have continued to progress the clinical development of our CTX cell therapy candidate for stroke disability. In January 2019, we announced that patient dosing had commenced in PISCES III, a randomised, placebo-controlled, Phase 2b clinical trial in 110 patients at up to 40 clinical trial sites in the US.

Patients in the study are treated between 6 and 12 months after their stroke and are randomised to receive either CTX therapy or placebo treatment. The primary end-point of the PISCES III study is the proportion of patients showing a clinically important improvement (at least one point) on the modified Rankin Scale (mRS) at six months post-treatment compared with baseline. The mRS is a global measure of disability or dependence upon others in carrying out activities of daily living and is accepted by regulatory authorities as an appropriate end-point for marketing approval in stroke disability.

Based on current patient recruitment and resource planning, we expect to report top-line data from the PISCES III study late in late 2020. We expect the PISCES III clinical trial, if positive, to be one of two pivotal studies required to support marketing authorisations for CTX in stroke disability.

Exosome technology

During the period, we reassessed how best to exploit our CTX cell-based exosome platform to maximise potential near-term commercial opportunities. We are pursuing opportunities to capitalise on the significant scientific and life sciences industry interest in exosomes by forming value-generating business partnerships covering our exosome technology. In this regard, ExoPr0, our first CTX-derived exosome candidate arising from this technology, is being developed as a novel vector for delivering third party biological drugs.

In January 2019, we signed a collaboration agreement with a US-based biopharmaceutical company to explore the use of our exosome technology to create delivery vehicles for synthetic oligonucleotides used in gene therapy. We are in active early discussions with other commercial third parties regarding potential collaboration agreements for our exosome technology.

Also in January 2019, new data were presented in conference from a grant-funded collaboration between ReNeuron, University College London and the Cell and Gene

Therapy Catapult. The new data demonstrated the feasibility of scaling up the production of our CTX-derived exosomes utilising state-of-the-art bioreactor systems, representing a significant advance towards an industrial scale production process without affecting the quality and consistency of the final product.

Business development activities

Our technologies and therapeutic programmes have increasingly attracted the interest of commercial third parties. During the period, a non-refundable exclusivity fee of US\$2.5 million was received from one such third party relating to a potential out-license of our hRPC retinal stem cell technology. As previously announced, this potential licensee ultimately withdrew from the deal for reasons unrelated to ReNeuron's technology.

In April 2019, we announced the signing of an exclusive licence agreement with Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. ("Fosun Pharma") for the development, manufacture and commercialisation of both our CTX and hRPC cell therapy programmes in the People's Republic of China.

Under the terms of the licence agreement, Fosun Pharma will fully fund the development of our CTX and hRPC cell therapy programmes in China, including clinical development and subsequent commercialisation activities. Fosun Pharma has also been granted rights to manufacture the licensed products in China. In return, ReNeuron received £6.0 million (before withholding tax) on entering into the agreement and will receive up to £6.0 million in near-term operational milestones and up to £8.0 million in future regulatory milestone payments. In addition, ReNeuron will receive estimated post-launch profit threshold milestone payments of £80.0 million provided all milestones and profit thresholds relating to the licensed products are successfully met, as well as tiered royalties at rates between 12% and 14% on sales of the licensed products in the Chinese market.

We remain in discussions with other commercial third parties regarding potential collaboration and/or out-licensing deals across our programmes.

Other activities

In October 2018, we presented data demonstrating for the first time that our lead CTX cell line can be successfully reprogrammed to an embryonic stem cell-like state and then differentiated along a different path from the original cell line. Importantly, ReNeuron's immortalisation technology remained functional in the reprogrammed cells. These results demonstrate that our CTX cell line could be used to produce new conditionally immortalised allogeneic (i.e. non-donor-specific) cell lines from any of the three germ layers: ectoderm, mesoderm and endoderm. We are now working to develop further new allogeneic cell lines, including NK and T-cells (the cells that can be modified to attack cancer cells), as potential therapeutic agents for out-licensing to third parties.

Summary and outlook

The last year has been a transformational one for ReNeuron. During the period, we commenced patient dosing in the US placebo-controlled Phase 2b clinical trial of our CTX cell therapy candidate in chronic stroke disability. This was followed shortly afterwards by the announcement of strongly positive preliminary efficacy data from the first three Phase 2a patients in the ongoing US Phase 1/2a clinical trial of our hRPC cell therapy candidate in retinitis pigmentosa. We look forward to delivering further significant clinical data in our stroke and retinitis pigmentosa programmes over the next 18 months.

We are pleased to be working with Fosun Pharma as our partner for China, following the signing of the exclusive licence agreement for both our CTX and hRPC programmes in that territory. We are also encouraged by the level of interest other potential collaborators are showing in all of our programmes, including our exosome technology which is being developed as a novel system for delivering third party drugs.

We look forward to providing further updates on our clinical and commercial progress in the months ahead.

Olav Hellebø

Chief Executive Officer

FINANCIAL REVIEW

Revenues in the year amounted to £49k (2018: £43k), being royalties from non-therapeutic licensing activities. Grant income of £0.8 million (2018: £0.85 million) was also recognised in other income. In addition, £1.9 million (2018: £Nil) was recognised in other income relating to an exclusivity fee received during out-licensing negotiations.

Research and development costs were slightly reduced at £16.3 million (2018: £16.7 million) and accounted for 77% of operating expenses (2018: 78%). The higher cost in the prior period reflects increased manufacturing and process development activity ahead of the commencement of the ongoing clinical trials in retinitis pigmentosa and stroke disability.

General and administrative expenses have increased by £0.1 million (2%) to £4.7 million (2018: £4.6 million). This increase is primarily explained by higher legal and professional fees driven by an increase in business development and contracting activities.

Finance income represents income received from the Group's cash and investments and gains from foreign exchange with losses from foreign exchange shown in finance costs. Finance income was £1.1 million in the period (2018: £0.3 million). In 2019, finance income included foreign exchange gains of £0.8 million (2018: £Nil). In 2018, foreign exchange rate movements led to a foreign exchange loss of £0.91 million. The Group holds cash and investments in foreign currencies in order to hedge against operational spend in those currencies. The strengthening of sterling against the US dollar during the period has resulted in a relative appreciation of the Group's foreign currency deposits.

The total tax credit for the period was £2.9 million (2018: £3.35 million). The 2018 figure included £0.35 million received relating to 2017. The reduction in the accrual on the previous year reflects the reduction in applicable costs.

As a result of the above, the total comprehensive loss for the year reduced to £14.3 million (2018: £17.6 million).

Cash used in operating activities was £12.0 million (2018: £14.9 million), largely reflecting the operating costs incurred during the period, net of tax credits received. The Group had cash, cash equivalents and bank deposits totalling £26.4 million at the year-end (2018: £37.4 million). Post-year end, the Group has received £5.4 million, net of withholding tax, pertaining to the licence agreement with Fosun Pharma.

Michael Hunt

Chief Financial Officer

Group Statement of Comprehensive Income for the year ended 31 March 2019

	2019	2018
	£'000	£'000
Revenue: royalty income	49	43
Other income	2,671	854
Research and development costs	(16,255)	(16,657)
General and administrative costs	(4,747)	(4,616)
Operating loss	(18,282)	(20,376)
Finance income	1,103	320
Finance expense	–	(911)
Loss before income tax	(17,179)	(20,967)
Income tax credit	2,887	3,352
Loss and total comprehensive loss for the year	(14,292)	(17,615)
Loss and total comprehensive loss attributable to equity owners of the Company	(14,292)	(17,615)
Basic and diluted loss per ordinary share	(45.2p)	(55.7p)

Group Statement of Financial Position as at 31 March

	2019	2018
	£'000	£'000
Assets		
Non-current assets		
Property, plant and equipment	632	726
Intangible assets	186	186
	818	912
Current assets		
Trade and other receivables	875	1,285
Income tax receivable	2,768	3,010
Investments – bank deposit	5,954	9,500
Cash and cash equivalents	20,432	27,911
	30,029	41,706
Total assets	30,847	42,618
Equity		
Equity attributable to owners of the Company		
Share capital	316	316
Share premium account	97,704	97,704
Capital redemption reserve	40,294	40,294
Merger reserve	2,223	2,223
Accumulated losses	(117,120)	(103,868)
Total equity	23,417	36,669
Liabilities		
Current liabilities		
Trade and other payables	7,430	5,949
	7,430	5,949
Total liabilities	7,430	5,949
Total equity and liabilities	30,847	42,618

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 2017	31,646	97,704	8,964	2,223	(87,380)	53,157
Effect of share consolidation	(31,330)	–	31,330	–	–	–
Credit on share-based payment	–	–	–	–	1,127	1,127
Loss for the year and total comprehensive loss	–	–	–	–	(17,615)	(17,615)
As at 31 March 2018	316	97,704	40,294	2,223	(103,868)	36,669
Credit on share-based payment	–	–	–	–	1,040	1,040
Loss for the year and total comprehensive loss	–	–	–	–	(14,292)	(14,292)
As at 31 March 2019	316	97,704	40,294	2,223	(117,120)	23,417

Group Statement of Cash Flows for the year ended 31 March

	2019	2018
	£'000	£'000
Cash used in operations	(15,121)	(19,244)
Income tax credit received	3,129	4,357
Cash used in operating activities	(11,992)	(14,887)
Cash flows from investing activities		
Capital expenditure - Fixed Assets	(188)	(235)
Interest received	342	383
Net cash generated from investing activities	154	148
Cash flows from financing activities		
Bank deposit matured	4,359	14,525
Net cash generated from financing activities	4,359	14,525
Net decrease in cash and cash equivalents	(7,479)	(214)
Cash and cash equivalents at the start of year	27,911	28,125
Cash and cash equivalents at the end of year	20,432	27,911

Notes to the financial information for the year ended 31 March 2019

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 2019 and audited financial information for the year ended 31 March 2018 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 2019 which will be delivered to the Registrar of Companies in due course. Statutory financial statements for the year ended 31 March 2018 were approved by the Board of directors on 19 July 2018 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 2018.

3. Going concern

The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development. The operation of the Group is currently being financed from funds that have been raised from share placings, commercial partnerships and grants and the directors are currently considering a number of options for further funding of the Company’s ongoing clinical programmes.

After making enquiries, the directors expect that the Group’s current financial resources can, where appropriate, be managed such that they will be sufficient to support operations for at least the next 12 months from the date of this announcement. The Group therefore continues to adopt the going concern basis 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 £14,292,000 (2018: 17,615,000) by 31,646,186 shares (2018: 31,646,186 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

	Year ended 31-Mar 2019 £'000	Year ended 31-Mar 2018 £'000
Loss before income tax	(17,179)	(20,967)
Adjustment for:		
Finance income	(1,103)	(320)
Depreciation of property, plant and equipment	282	232
Share-based payment charges	1,040	1,127
Finance costs	–	911
Changes in working capital:		
Receivables	358	(289)
Payables	1,481	62
Cash used in operating activities	(15,121)	(19,244)