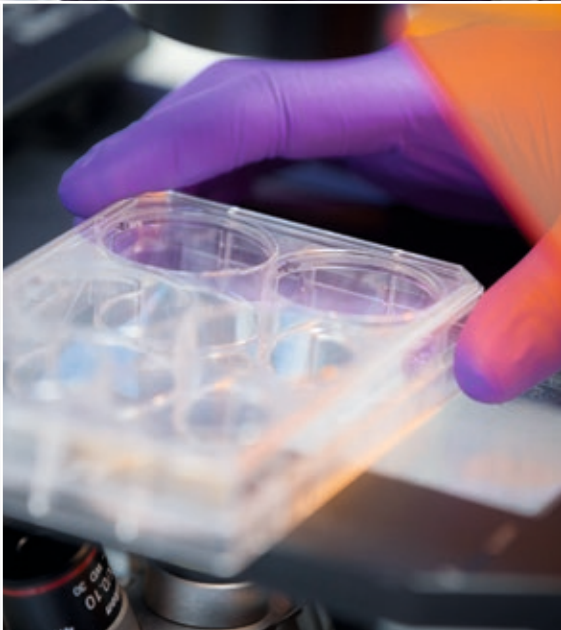
ReNeuron

Changing patients' lives

ReNeuron Group plc Interim Report 2017



ReNeuron

Our vision is to deliver life changing therapies to patients

- A leader in the cell therapy field
- Novel cell-based therapies targeting unmet needs
- At the forefront in our selected indications
- Secure intellectual property
- Manufacturing capability

Highlights

CTX stem cell therapy candidate for stroke disability:

- Long term data from Phase II clinical trial confirms positive results seen after 3 months post-treatment
- IND application approved to commence a Phase IIb, placebo-controlled clinical trial in the US in H1 2018

hRPC stem cell therapy candidate for retinal diseases:

- Dosing commenced in Phase II element of ongoing US Phase I/II clinical trial in retinitis pigmentosa
- Phase IIb clinical trial planned to commence in mid 2018 in retinitis pigmentosa alongside further Phase II clinical trial in cone-rod dystrophy

Exosome nanomedicine platform:

- Positive pre-clinical data with ExoPr0 exosome therapy candidate demonstrates potential of ExoPr0 to target multiple diseases
- Initial clinical trial application planned for 2019 in cancer

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- US office established in Boston, reflecting the Company's increasing clinical activity in the US
- Two further government grants awarded in the period, providing funding towards £3.5 million of collaborative work programmes to develop the Company's exosome therapy platform and its cell therapy manufacturing processes
- Loss for the period of £9.57 million (2016: loss of £7.70 million); cash consumed by operations of £9.22 million (2016: £6.99 million); cash, cash equivalents and bank deposits at 30 September 2017 of £45.28 million (31 March 2017: £53.06 million)

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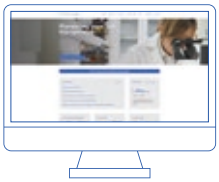


CTX for stroke disability

During the period under review, we have continued our preparations to move our CTX cell therapy candidate for stroke disability into the next stage of its clinical development in the US. These efforts have culminated in today's announcement that the FDA has approved our IND application to commence a Phase IIb study in the US. The study, designated PISCES III, is a randomised, placebo-controlled clinical trial involving 110 patients across 25 clinical trial sites in the US. Patients with stable post-stroke disability will be entered into the study 6 to 12 months after their stroke and will be randomised to receive either the CTX therapy or placebo treatment. The primary endpoint of the study will be a comparison of the proportion of patients in the treated and placebo arms showing a clinically important improvement on the modified Rankin Scale (mRS), a measure of disability and dependence, at 6 months post-treatment compared with baseline. Data from the study are expected in late 2019.

We also recently announced that the positive response rates in key measures reported at three months after treatment in the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability were sustained at 12 months after treatment. PISCES II is a single arm, open-label study in patients living with significant disability resulting from ischaemic stroke. We originally announced positive initial data from the study in December 2016, when all patients had been followed up for at least three months after treatment. Importantly, the mRS response rate was maintained at 12 months post-treatment, with 7 out of 20 patients (35%) showing a clinically relevant improvement. It is this measure of disability and dependence that has been carried forward as the primary endpoint in the PISCES III clinical trial.

hRPC for retinal diseases

During the period under review, we completed dosing in the Phase I element of the ongoing US Phase I/II clinical trial of our hRPC cell therapy candidate for the blindness-causing disease retinitis pigmentosa (RP). This 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 patients with advanced RP.

We recently announced that the study's Data Safety Monitoring Board had given approval for the study to progress into its Phase II element. This decision was based on short term data from the nine RP patients treated in the Phase I part of the study, which indicate that the hRPC cell therapy was safe and well tolerated at the three doses tested.

The final high-dose cohort of patients in the Phase I part of the study was treated with the newly developed cryopreserved formulation of our hRPC cell therapy candidate. Based on the short term safety data, this is the formulation and dose that will be utilised in the Phase II element of the study, where patient dosing has now commenced. This part of the study will recruit six RP patients with less impaired vision than those treated in the Phase I element and it is expected that this will lead to a larger, placebo-controlled Phase IIb clinical trial in similar patients in terms of the progression of their disease.

We expect read-outs from the Phase II part of the ongoing RP clinical trial in the second half of 2018, with efficacy data from the subsequent Phase IIb study in the first half of 2020.

The cryopreserved formulation of our hRPC cell therapy candidate has given us an opportunity to expand our clinical programmes in ophthalmology. To this end, and as previously announced, we intend to seek approval to commence a Phase II clinical trial with our hRPC cell therapy candidate in patients with cone-rod dystrophy ("CRD"), to run concurrently with the Phase IIb testing of this candidate in RP. CRD is a group of rare eye disorders associated with a loss of cone cells in the retina that results in deterioration of central visual acuity and colour vision.

Exosome nanomedicine platform

During the period, we continued to generate and present pre-clinical data relating to our exosome development programme in conjunction with our academic collaborators. Exosomes are nanoparticles secreted from cells including our 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 its potential as both a novel therapeutic candidate and as a drug delivery vehicle.

Data were presented during the period showing a significant reduction in proliferation of a number of tumour-derived cell lines when treated with ExoPr0, indicating that ExoPr0 may have a significant effect in regulating cell growth and apoptosis in cancer. Further biodistribution data were also presented during the period showing 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 suggest that there is significant potential to develop ExoPr0 for the treatment of multiple diseases, including solid tumours.

Finally, we and our collaborators have presented robust methodologies to characterise our CTX-derived exosomes to ensure consistency and control during manufacture as well as purification strategies to address 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.

On the basis of the above progress and subject to continued success with ongoing pre-clinical development work, we hope to be able to commence clinical development with ExoPr0 during 2019, targeting a solid tumour cancer indication.

Other activities

During the period and subsequent to the period end, we, along with our academic and commercial collaborators, have been awarded two further government grants. The first of these is a grant from Innovate UK funding a £2.3 million work programme to further advance our next generation commercial cell therapy manufacturing capabilities. The grant is funding 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 second grant has been awarded under the Welsh Government's SMARTExpertise scheme and will help fund a £1.2 million collaborative programme of work to advance our emerging exosome therapy platform.

The work programme will establish methods to refine and optimise the manufacturing process for generating our CTX-derived exosomes with the highest biological efficacy, methods to enhance the characterisation of the CTX-derived exosomes against solid tumours to identify new cancer targets, and methods to characterise exosomes with potential therapeutic benefit derived from ReNeuron's broader proprietary cell line library.

We recently announced that we have established an office in Boston, one of the US's most vibrant academic and commercial biotechnology hubs. This office will house our US-based clinical and medical staff and reflects our current and future focus on clinical development activities in the US across our therapeutic programmes.

During the period, Dr Paul Harper stepped down from the Board as a Non-executive Director. We thank Paul for the immense contribution he has made to the Company's success over his long tenure on the Board and wish him all the best in his future endeavours.

Other activities continued

Also during the period, we welcomed Dr Claudia D'Augusta as a new Non-executive Director of the Company. Dr D'Augusta will also chair the Company's Audit Committee and brings over 20 years' experience in Europe and US corporate finance, in particular in the cell therapy sector.

Financial review

In the six months to 30 September 2017, revenues were £24,000 (2016: £22,000) in addition to which grant income of £240,000 was received and is shown as other operating income (2016: £366,000).

Research and development expenditure increased in the period to £8.60 million (2016: £7.88 million). This increase in R&D expenditure, broadly consistent with the increase in spend seen in the second half of the previous financial year, reflects the increased level of clinical trial activity and associated cell manufacturing and process development costs across the Group's therapeutic programmes. General and administrative expenses increased to £2.21 million (2016: £2.14 million) in the period.

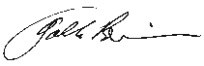
Finance income represents income received from the Group's cash and investments and gains from foreign exchange with losses from foreign exchange shown in finance costs. Finance income was £0.19 million in the period (2016: £1.00 million). In 2016, finance income included foreign exchange gains of £0.72 million. In 2017, the movement in exchange rates has led to a foreign exchange loss of £0.62 million. The Group holds cash and investments in foreign currencies in order to hedge against operational spend and the strengthening of Sterling against the US Dollar during the period has resulted in a relative devaluation of the Group's foreign currency deposits. The total tax credit for the period was £1.40 million (2016: £0.94 million).

As a result of the above, the total comprehensive loss for the period increased to £9.57 million (2016: £7.70 million).

Cash consumed by operations in the period increased to £9.22 million (2016: £6.99 million), broadly reflecting the increase in operating costs in the period. The Group had cash, cash equivalents and bank deposits totalling £45.3 million as at 30 September 2017 (31 March 2017: £53.1 million).

Summary and outlook

During the period, our therapeutic development programmes have continued to progress to plan. The subsequent FDA approval to commence a Phase IIb clinical trial in the US with our CTX cell therapy candidate for stroke disability marks another significant milestone with this programme. We have made significant advances with our hRPC cell therapy candidate, with dosing having commenced in the Phase II part of our ongoing US Phase I/II clinical trial in retinitis pigmentosa. We have also generated and presented further encouraging pre-clinical data with our ExoPr0 exosome therapy candidate targeting cancer. This progress positions us for the delivery of further significant clinical milestones across our therapeutic programmes during each of the next three years.



John Berriman
Chairman

Olav Hellebø
Chief Executive Officer
14 December 2017

Unaudited Consolidated Statement of Comprehensive Income

for the six months ended 30 September 2017

	Note	**Six months ended 30 September 2017 £'000**	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Revenue		**24**	22	46
Research and development costs		**(8,599)**	(7,883)	(16,648)
General and administrative costs		**(2,210)**	(2,137)	(4,139)
Other operating income	5	**240**	366	854
Operating loss		**(10,545)**	(9,632)	(19,887)
Finance income	6	**188**	997	1,722
Finance expense	7	**(616)**	—	—
Loss before income taxes		**(10,973)**	(8,635)	(18,165)
Tax credit on loss on ordinary activities		**1,404**	940	2,592
Total comprehensive loss for the period		**(9,569)**	(7,695)	(15,573)
Total comprehensive loss attributable to:				
– Equity owners of the Company		**(9,569)**	(7,695)	(15,573)
Basic and diluted loss per share	8	**(0.3p)**	(0.2p)	(0.5p)

Unaudited Consolidated Statement of Financial Position

as at 30 September 2017

	30 September 2017 £'000	30 September 2016 £'000	31 March 2017 £'000
Assets			
Non-current assets			
Property, plant and equipment	**685**	544	724
Intangible assets	**186**	1,272	—
Other non-current assets	**—**	11	—
	871	1,827	724
Current assets			
Trade and other receivables	**812**	787	1,060
Corporation tax receivable	**3,529**	2,363	4,015
Investments – bank deposits	**23,923**	39,659	24,936
Cash and cash equivalents	**21,359**	20,417	28,125
	49,623	63,226	58,136
Total assets	**50,494**	65,053	58,860
Equity			
Equity attributable to owners of the Company			
Share capital	**31,646**	31,646	31,646
Share premium	**97,704**	97,704	97,704
Capital redemption reserve	**8,964**	8,964	8,964
Merger reserve	**2,223**	2,223	2,223
Accumulated losses	**(96,381)**	(80,074)	(87,380)
Total equity	**44,156**	60,463	53,157
Liabilities			
Current liabilities			
Trade and other payables	**6,338**	4,446	5,703
Provisions	**—**	143	—
Financial liabilities: finance leases	**—**	1	—
	6,338	4,590	5,703
Total liabilities	**6,338**	4,590	5,703
Total equity and liabilities	**50,494**	65,053	58,860

Unaudited Consolidated Statement of Changes in Equity

for the six months ended 30 September 2017

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2016	31,646	97,704	8,964	2,223	(72,879)	67,658
Share-based credit	—	—	—	—	500	500
Loss for the period	—	—	—	—	(7,695)	(7,695)
As at 30 September 2016	31,646	97,704	8,964	2,223	(80,074)	60,463
Share-based credit	—	—	—	—	572	572
Loss for the period	—	—	—	—	(7,878)	(7,878)
As at 31 March 2017	31,646	97,704	8,964	2,223	(87,380)	53,157
Share-based credit	—	—	—	—	568	568
Loss for the period	—	—	—	—	(9,569)	(9,569)
As at 30 September 2017	**31,646**	**97,704**	**8,964**	**2,223**	**(96,381)**	**44,156**

Unaudited Consolidated Statement of Cash Flows

for the six months ended 30 September 2017

	Note	**Six months ended 30 September 2017 £'000**	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Cash consumed by operations	9	**(9,221)**	(6,992)	(13,976)
Income tax credit received		**1,890**	1,340	1,340
Cash outflow from operating activities		**(7,331)**	(5,652)	(12,636)
Cash flows from investing activities				
Capital expenditure		**(72)**	(255)	(532)
Interest received		**240**	274	520
Net cash generated from investing activities		**168**	19	(12)
Cash flows from financing activities				
Bank deposits matured		**397**	8,624	23,347
Net cash generated from financing activities		**397**	8,624	23,347
Net (decrease)/increase in cash and cash equivalents	10	**(6,766)**	2,991	10,699
Cash and cash equivalents at the start of period		**28,125**	17,426	17,426
Cash and cash equivalents at the end of period	11	**21,359**	20,417	28,125

1. General information and basis of preparation

ReNeuron Group plc is an AIM listed company incorporated and domiciled in the United Kingdom under the Companies Act 2006. The Company's registered office and its principal place of business is Pencoed Business Park, Pencoed, Bridgend CF35 5HY.

These Interim Financial Statements were prepared by the Directors and approved for issue on 14 December 2017. They have not been audited.

These Interim Financial Statements do not comprise statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 March 2017 were approved by the Board of Directors on 18 July 2017 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified and did not contain statements under Sections 498(2) or (3) of the Companies Act 2006 and did not contain any emphasis of matter.

As permitted these Interim Financial Statements have been prepared in accordance with UK AIM Rules and IAS 34, "Interim Financial Reporting" as adopted by the European Union. They should be read in conjunction with the Annual Financial Statements for the year ended 31 March 2017, which have been prepared in accordance with IFRS as adopted by the European Union.

2. Accounting policies

The accounting policies applied are consistent with those of the Annual Financial Statements for the year ended 31 March 2017, as described in those Annual Financial Statements. Where new standards or amendments to existing standards have become effective during the year, there has been no material impact on the net assets or results of the Group.

Certain statements within this report are forward looking. The expectations reflected in these statements are considered reasonable. However, no assurance can be given that they are correct. As these statements involve risks and uncertainties the actual results may differ materially from those expressed or implied by these statements.

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 Directors expect that the Group's financial resources will be sufficient to support operations into 2019. Consequently, the going concern basis has been adopted in the preparation of these Interim Financial Statements.

4. Segment information

Following the adoption of IFRS 8 "Segment Reporting", the Group has identified the Chief Executive Officer as the Chief Operating Decision Maker (CODM). The CODM manages the business as one segment, the development of cell-based therapies. Since this is the only reporting segment, no further information is included. The information used internally by the CODM is the same as that disclosed in the Interim Financial Statements. The Group's revenue derives wholly from assets located in the United Kingdom. Analysed by location of customer all revenue is derived from the United States of America.

5. Other operating income

Other operating income comprises government grants in relation to the Group's programmes.

Notes to the Interim Financial Statements *continued*

for the six months ended 30 September 2017

6. Finance income

	Six months ended 30 September 2017 £'000	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Interest received	**188**	274	520
Foreign exchange gains	**—**	723	1,202
	188	997	1,722

7. Finance expense

	Six months ended 30 September 2017 £'000	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Foreign exchange losses	**616**	—	—

8. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £9,569,000 (September 2016: £7,695,000; March 2017: £15,573,000) by 3,164,618,541 shares (September 2016 and March 2017: 3,164,618,541 shares), being the weighted average number of Ordinary 1p shares in issue during the period. Potential Ordinary shares are not treated as dilutive as the entity is loss making.

9. Cash consumed by operations

	Six months ended 30 September 2017 £'000	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Loss before income tax	**(10,973)**	(8,635)	(18,165)
Adjustment for:			
Finance income	**(188)**	(274)	(520)
Depreciation of tangible fixed assets	**110**	73	169
Impairment of intangible assets	**—**	319	1,591
Provisions	**—**	(355)	(498)
Share-based payment charge	**568**	500	1,072
Finance costs	**616**	—	—
Changes in working capital:			
Receivables	**196**	634	372
Payables	**450**	746	2,003
Cash consumed by operations	**(9,221)**	(6,992)	(13,976)

10. Reconciliation of net cash flow to movement in net debt

	Six months ended 30 September 2017 £'000	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Net funds at start of period	**28,125**	17,425	17,426
(Decrease)/increase in cash in period	**(6,766)**	2,991	10,699
Net funds at end of period	**21,359**	20,416	28,125

11. Analysis of net funds

	Six months ended 30 September 2017 £'000	Six months ended 30 September 2016 £'000	Year ended 31 March 2017 £'000
Cash at bank and in hand	**21,359**	20,417	28,125
Finance leases	**—**	(1)	—
	21,359	20,416	28,125

Directors and Advisers

Directors

John Berriman, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt ACA, Chief Financial Officer
Simon Cartmell OBE, Non-executive Director
Dr Tim Corn, Non-executive Director
Professor Sir Chris Evans OBE, Non-executive Director
Dr Claudia D'Augusta, Non-executive Director
Dr Mike Owen, Non-executive Director

Company Secretary and registered office

Michael Hunt
Pencoed Business Park
Pencoed
Bridgend
CF35 5HY

Principal banker

Barclays Bank plc
PO Box 326
28 Chesterton Road
Cambridge
CB4 3UT

Patent agents

Gill, Jennings & Every
Broadgate House
7 Eldon Street
London
EC2M 7LH

Nominated adviser and joint broker

Stifel Nicolaus Europe Limited
150 Cheapside
London
EC2V 6ET

Joint broker

Nplus1 Singer Advisory LLP
One Bartholomew Lane
London
EC2N 2AX

Financial PR consultants

Buchanan
107 Cheapside
London
EC2V 6DN

Registrars

Computershare Services plc
The Pavilions
Bridgwater Road
Bristol
BS13 8AE

Solicitors

Covington & Burling LLP
265 Strand
London
WC2R 1BH

Independent auditors

PricewaterhouseCoopers LLP
Chartered Accountants and Statutory Auditors
One Kingsway
Cardiff
CF10 3PW

Produced by
designportfolio

ReNeuron

ReNeuron Group plc
Pencoed Business Park, Pencoed
Bridgend CF35 5HY

t +44 (0) 203 8198400

e info@reneuron.com

www.reneuron.com