ReNeuron

Interim Report
2016

ReNeuron Group plc

Who We Are

We are a UK-based global leader in cell-based therapeutics. Our primary objective is the development of novel cell-based therapies targeting areas of significant unmet or poorly met medical need.

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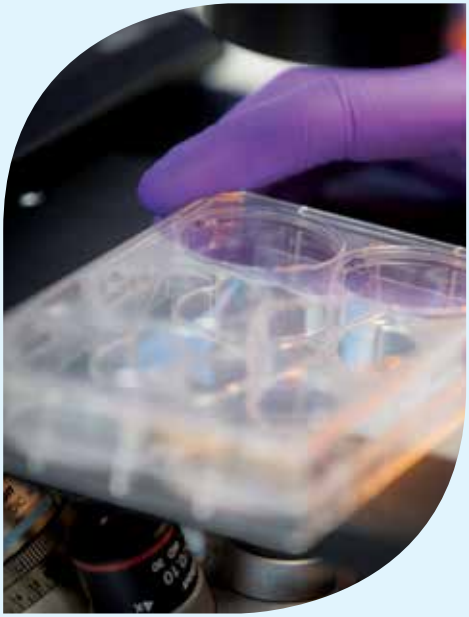

Highlights

CTX stem cell therapy candidate for motor disability as a result of stroke:

- Positive Phase II efficacy data in PISCES II clinical trial announced
- Phase I clinical trial data from PISCES I study published in The Lancet
- Clinical trial application for controlled, pivotal study planned for H1 2017 in US and UK

CTX stem cell therapy candidate for critical limb ischaemia:

- Phase I clinical trial ongoing – safety data expected in early 2017

hRPC stem cell therapy candidate for retinitis pigmentosa:

- Second dose cohort completed in US Phase I/II clinical trial
- Safety and efficacy data from Phase I/II study due during the course of 2017
- Pivotal clinical trial planned to commence in 2018

Exosome nanomedicine platform:

- Glioblastoma multiforme selected as first clinical target
- Pre-clinical development continues, supported by £2.1 million Innovate UK grant

Loss for the period of £7.70 million (2015: loss of £4.48 million); cash consumed by operations of £6.99 million (2015: £5.26 million)

Cash, cash equivalents and bank deposits at 30 September 2016 of £60.08 million (31 March 2016: £65.71 million)

Review of Therapeutic Programmes

CTX for stroke disability

During the period under review, we completed dosing in the Phase II clinical trial (PISCES II) of our CTX cell therapy candidate for stroke disability. We have subsequently announced positive data from this study. PISCES II is a single arm, open-label study in patients living with disability resulting from ischaemic stroke. All 21 patients in the study have 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, 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. 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 Phase II data follows the publication in August 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 intend to apply to the US and European regulatory authorities in early 2017 to commence a randomised, placebo-controlled, pivotal clinical trial in disabled stroke patients. As previously announced, we are also advancing our CTX cell therapy candidate for stroke disability in Japan under regulations in that territory which offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development than in the West.

hRPC for retinitis pigmentosa

During the period under review, the Phase I/II clinical trial of our human Retinal Progenitor Cell (hRPC) cell therapy candidate for the blindness-causing disease, retinitis pigmentosa (RP), has also progressed well. 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.

Subsequent to the end of the period under review, dosing of the second dose cohort of three patients in the Phase I/II study has been completed. Safety and tolerability data from the Phase I part of the study in the first nine patients are expected in the first half of 2017, with longer term safety data as well as efficacy read-outs from the Phase II part of the study in a further six patients 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 early 2018 to commence a pivotal 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. We expect to have safety data available from the CLI study slightly later than planned, in early 2017. We are encouraged that no adverse safety events have been reported thus far in the patients treated in the Phase I study. The study has been part-funded by a Biomedical Catalyst grant from Innovate UK.

Exosome nanomedicine platform

During the period under review, we have continued to advance our exosome nanomedicine 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 CTX-derived exosomes has demonstrated that they may have a significant effect in regulating cell growth and apoptosis in cancer. During the period under review, we announced that we had selected glioblastoma multiforme (GBM) as the first clinical target for ExoPr0, our first exosome nanomedicine candidate. GBM accounts for 16% of all diagnosed brain cancers, with 25,000 patients diagnosed per annum in the US and Europe combined.

Our exosome nanomedicine programme benefits from an Innovate UK grant to part-fund manufacturing process development as well as pre-clinical efficacy and toxicity testing of the ExoPr0 candidate. We see the optimisation of methods to harvest, characterise and purify CTX-derived exosomes, as well as further clarification of the mechanism of action of ExoPr0, as key research priorities ahead of late pre-clinical development of the ExoPr0 candidate. On this basis, and assuming a successful outcome to the above plan of work, we expect to be able to commence a first human clinical trial with ExoPr0 in 2018.

Financial review

In the six months to 30 September 2016, revenues were £22,000 (2015: £11,000) in addition to which grant income of £366,000 was received and is shown as other operating income (2015: £244,000).

Research and development expenditure increased in the period to £7.88 million (2015: £3.72 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 marginally to £2.14 million (2015: £1.93 million) in the period.

Finance income, which represents income received from the Group's cash and investments and gains from foreign exchange, was £1.00 million in the period (2015: £156,000). The increase in finance income reflects the increase in average cash and investment balances compared to 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 £940,000 (2015: £756,000).

As a result of the above, the total comprehensive loss for the period increased to £7.70 million (2015: £4.48 million), in line with internal forecasts.

Cash consumed by operations in the period increased to £6.99 million (2015: £5.26 million), broadly reflecting the increase in operating costs in the period. The Group had cash, cash equivalents and bank deposits totalling £60.08 million as at 30 September 2016 (31 March 2016: £65.71 million).

Summary and outlook

Our therapeutic development programmes have progressed well during the period, culminating in today's announcement of positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability. The results of this study represent the most important clinical milestone in ReNeuron's history and enable us to progress the CTX treatment into advanced clinical development in this indication. The unmet medical need in chronic stroke disability is enormous and we are delighted that we are now one step closer to being able to offer an effective therapy to these patients.

We are also very pleased with the pace of progress in the US Phase I/II clinical trial of our hRPC cell therapy candidate for retinitis pigmentosa during the period. ReNeuron remains well-funded to advance all of its therapeutic programmes through to further significant clinical milestones and we look forward to reporting further progress in the months ahead.

John Berriman
Chairman

Olav Hellebø
Chief Executive Officer

5 December 2016

Unaudited Consolidated Statement of Comprehensive Income for the six months ended 30 September 2016

	Note	**Six months ended 30 September 2016 £'000**	Six months ended 30 September 2015 £'000	Year ended 31 March 2016 £'000
Revenue		**22**	11	29
Research and development costs		**(7,883)**	(3,716)	(10,272)
General and administrative costs		**(2,137)**	(1,931)	(4,015)
Other operating income	5	**366**	244	534
Operating loss		**(9,632)**	(5,392)	(13,724)
Finance income		**997**	156	878
Loss before income taxes		**(8,635)**	(5,236)	(12,846)
Tax credit on loss on ordinary activities		**940**	756	1,492
Total comprehensive loss for the period		**(7,695)**	(4,480)	(11,354)
Total comprehensive loss attributable to:				
– Equity owners of the Company		**(7,695)**	(4,480)	(11,354)
Basic and diluted loss per share	6	**(0.2p)**	(0.2p)	(0.4p)

Unaudited Consolidated Statement of Financial Position as at 30 September 2016

	30 September 2016 £'000	30 September 2015 £'000	31 March 2016 £'000
Assets			
Non-current assets			
Property, plant and equipment	**544**	145	361
Intangible assets	**1,272**	1,591	1,591
Investments – bank deposit	**–**	–	5,000
Other non-current assets	**11**	281	11
	1,827	2,017	6,963
Current assets			
Trade and other receivables	**787**	832	1,421
Corporation tax receivable	**2,363**	2,028	2,764
Investments – bank deposits	**39,659**	49,993	43,283
Cash and cash equivalents	**20,417**	22,283	17,426
	63,226	75,136	64,894
Total assets	**65,053**	77,153	71,857
Equity			
Equity attributable to owners of the Company			
Share capital	**31,646**	31,567	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	**(80,074)**	(66,428)	(72,879)
Total equity	**60,463**	74,030	67,658
Liabilities			
Non-current liabilities			
Provisions	**–**	605	–
Financial liabilities: finance leases	**–**	1	–
	–	606	–
Current liabilities			
Trade and other payables	**4,446**	2,516	3,700
Provisions	**143**	–	498
Financial liabilities: finance leases	**1**	1	1
	4,590	2,517	4,199
Total liabilities	**4,590**	3,123	4,199
Total equity and liabilities	**65,053**	77,153	71,857

Unaudited Consolidated Statement of Changes in Equity for the six months ended 30 September 2016

	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 new ordinary shares	13,679	54,996	–	–	–	68,375
Costs of share issue	–	(3,259)	–	–	–	(3,259)
Share-based credit	–	–	–	–	258	258
Loss for the period	–	–	–	–	(4,480)	(4,480)
As at 30 September 2015	**31,567**	**97,704**	**8,964**	**2,223**	**(66,428)**	**74,030**
Issue of new ordinary shares	79	–	–	–	–	79
Share-based credit	–	–	–	–	423	423
Loss for the period	–	–	–	–	(6,874)	(6,874)
As at 31 March 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**

Unaudited Consolidated Statement of Cash Flows for the six months ended 30 September 2016

	Note	**Six months ended 30 September 2016 £'000**	Six months ended 30 September 2015 £'000	Year ended 31 March 2016 £'000
Cash consumed by operations	7	**(6,992)**	(5,263)	(11,920)
Income tax credit received		**1,340**	–	–
Cash outflow from operating activities		**(5,652)**	(5,263)	(11,920)
Cash flows from investing activities				
Capital expenditure		**(255)**	(18)	(293)
Purchase of intangible asset		**–**	–	–
Interest received		**274**	59	345
Net cash generated in investing activities		**19**	41	52
Cash flows from financing activities				
Finance lease principal payments		**–**	–	–
Proceeds from issuance of ordinary shares		**–**	68,375	68,454
Costs of share issue		**–**	(3,259)	(3,259)
Bank deposits (placed)/matured		**8,624**	(49,993)	(48,283)
Net cash generated by financing activities		**8,624**	15,123	16,912
Net increase in cash and cash equivalents	8	**2,991**	9,901	5,044
Cash and cash equivalents at the start of period		**17,426**	12,382	12,382
Cash and cash equivalents at the end of period	9	**20,417**	22,283	17,426

Notes to the Interim Financial Statements for the six months ended 30 September 2016

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 5 December 2016. 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 2016 were approved by the Board of Directors on 22 July 2016 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified and did not contain statements under 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 the 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 2016, 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 2016, 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 the second half of 2018. Consequently, the going concern basis has been adopted in the preparation of these Interim Financial Statements.

4. Segment information

Following the adoption of IFRS8 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 from Innovate UK (Technology Strategy Board) in relation to the Group's programmes.

6. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £7,695,000 (September 2015: £4,480,000, March 2016: £11,354,000) by 3,164,618,541 shares (September 2015: 2,058,105,458 shares and March 2016: 2,609,315,899 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.

7. Cash consumed by operations

	Six months ended 30 September 2016 £'000	Six months ended 30 September 2015 £'000	Year ended 31 March 2016 £'000
Loss before income tax	**(8,635)**	(5,236)	(12,846)
Adjustment for:			
Interest received	**(274)**	(59)	(345)
Depreciation of tangible fixed assets	**73**	34	92
Impairment of intangible assets	**319**	–	–
Provisions	**(355)**	–	(107)
Share-based payment charge	**500**	258	681
Changes in working capital			
Receivables	**634**	(432)	(751)
Payables	**746**	172	1,356
Cash consumed by operations	**(6,992)**	(5,263)	(11,920)

Notes to the Interim Financial Statements for the six months ended 30 September 2016 continued

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

	Six months ended 30 September 2016 £'000	Six months ended 30 September 2015 £'000	Year ended 31 March 2016 £'000
Net funds at start of period	**17,425**	12,380	12,380
Increase /(decrease) in cash in the period	**2,991**	9,901	5,044
Cash inflow from decrease in debt	**–**	–	1
Net funds at end of period	**20,416**	22,281	17,425

9. Analysis of net funds

	Six months ended 30 September 2016 £'000	Six months ended 30 September 2015 £'000	Year ended 31 March 2016 £'000
Cash at bank and in hand	**20,417**	22,283	17,426
Finance leases	**(1)**	(2)	(1)
	20,416	22,281	17,425

Directors and Advisers

Directors
John Berriman, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt, Chief Financial Officer
Simon Cartmell OBE, Non-executive Director
Dr Tim Corn, Non-executive Director
Professor Sir Chris Evans OBE, Non-executive Director
Dr Paul Harper, 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

Solicitors
Covington & Burling LLP
265 Strand
London
WC2R 1BH

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

Nominated adviser
Stifel Nicolaus Europe Limited
150 Cheapside
London
EC2V 6ET

Financial PR consultants
Buchanan
107 Cheapside
London
EC2Y 6DN

Registrars
Computershare Services plc
The Pavilions
Bridgwater Road
Bristol
BS13 8AE

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

ckd
Design & Production
www.carrkamasa.co.uk

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ReNeuron Group plc

ReNeuron
Pencoed Business Park
Pencoed
Bridgend
CF35 5HY

t +44 (0) 203 819 8400
e info@reneuron.com

www.reneuron.com