

# ReNeuron

*pioneering stem cell therapeutics*

Guildford, UK: 13 December 2010

## ReNeuron Group plc Interim Results for the six months ended 30 September 2010

### Highlights

- Commencement of landmark UK first-in-man clinical trial of ReN001 stem cell therapy for stroke:
  - First patient treated post-period end, with initial safety review to take place later this month
- Further positive pre-clinical efficacy data presented with ReN009 stem cell therapy for peripheral arterial disease:
  - Late pre-clinical development programme established and regulatory interactions commenced, leading to multi-centre first-in-man clinical trial planned for early 2012
- Pre-clinical development of ReN003 therapy for retinitis pigmentosa progressing to plan:
  - Development milestones on track to be met under first phase of third-party fully funded programme, ahead of initial clinical trial planned for 2012
- Share placing and share subscription announced today to raise £10 million, before expenses:
  - Provides pre-clinical and clinical development funding for core therapeutic programmes for the next two years, ahead of potential commercial partnering deals
- Loss for the period of £2.5 million (2009: £1.9 million); cash outflow from operating activities of £2.0 million (2009: £1.5 million); cash and cash equivalents at 30 September 2010 of £3.5 million (2009: £2.1 million).

Commenting on the results, Professor Trevor Jones, Chairman, said:

"The period under review has been one of very significant progress for our business, culminating last month in the treatment of the first patient in the PISCES clinical trial of our ReN001 stroke therapy. This takes our stroke programme into its clinical development stage and places ReNeuron in the forefront of the development of treatments for disabled stroke patients using neural stem cells.

"Our other core therapeutic programmes continue to progress to plan and we are pursuing further opportunities to exploit the therapeutic potential of our lead CTX stem cell line. Once the fundraising announced today has completed, the business will be funded to take its core therapeutic programmes through to meaningful clinical development milestones, setting the Company on its course as one of the world's leading clinical-stage stem cell therapy businesses."

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

### **Review of Operations**

During the six months ended 30 September 2010, we received the final local site approvals and device registrations required in order for us to commence patient recruitment in our landmark first-in-man clinical trial of our ReN001 stem cell therapy for stroke disability. The PISCES study (Pilot Investigation of Stem Cells in Stroke) is the world's first fully regulated clinical trial of a neural stem cell therapy for disabled stroke patients. ReNeuron is the first company to have received regulatory approval for any stem cell-based clinical trial in the UK.

After a pre-treatment evaluation period, the first patient in the PISCES clinical trial was treated with ReN001 in November, undoubtedly the most significant milestone in the Company's history. The patient was treated at the Institute of Neurological Sciences, Southern General Hospital, Greater Glasgow and Clyde NHS Board. He was safely discharged two days after the straightforward neurosurgical procedure used to administer the ReN001 cells. In line with the protocol for this clinical trial, an independent Data Safety Monitoring Board will review the first patient's progress later this month. Subject to the outcome of this review, and subject to patient consent and successful pre-treatment evaluations, the remainder of the first dose cohort in the trial will be treated shortly thereafter.

Subject to satisfactory safety data arising from the early patient cohorts in the trial, and as previously indicated, we intend to pursue an accelerated clinical development pathway with ReN001, focusing on particular stroke patient groups who are expected to most benefit from the therapy.

Our ReN009 stem cell therapy for peripheral arterial disease (PAD) continued to make good progress along its pre-clinical development pathway during the period. PAD is a chronic and debilitating disease that progressively restricts blood flow in the limbs, causing cramping, chronic pain and, in extreme cases, loss of limb. The disease is commonly associated with other conditions such as diabetes, obesity and stroke. At least 1 in 20 people over the age of 50 have some degree of PAD and it becomes more common with increasing age.

During the period, and in conjunction with our Clinical Advisory Board for ReN009, we established the late pre-clinical development pathway for the ReN009 programme and designed a protocol for a proposed multi-centre first-in-man clinical trial planned for early 2012. We have also commenced discussions with, and received guidance from, regulatory authorities in both the UK and the US. The rate-limiting, long-term pre-clinical safety studies required are well underway and will run alongside the remaining pre-clinical studies and cell manufacturing campaign necessary to complete the regulatory data package to be submitted for clinical trial approvals in due course.

In November, our academic collaborators on the ReN009 programme at the Bristol Heart Institute presented further positive pre-clinical efficacy data with ReN009 at the prestigious American Heart Association Scientific Sessions 2010 in Chicago. The study presented showed that our lead CTX stem cell line produced a significant and dose-dependent recovery of blood flow to the ischaemic limb in a recognised diabetic mouse model of hind limb ischaemia, a result consistent with that seen in earlier pre-clinical studies.

We are also greatly encouraged by the progress made in the period in the pre-clinical development of our ReN003 therapy for retinitis pigmentosa (RP), a blindness-causing disease caused by degeneration of the photoreceptor cells in the retina. This programme, conducted in collaboration with the Schepens Eye Research Institute at Harvard Medical School, is currently funded by an industrial grant from a major US specialty healthcare company.

Development work conducted during the period and subsequently means that we are now close to achieving the key milestones set out in the first phase of a two year programme to take human retinal precursor cells (hRPCs) to the clinic in the US in RP patients. We have optimised the cell culture process and yield for growing the hRPCs to the quantities required for clinical studies. We are also close to completing pre-clinical studies to demonstrate that injection of the hRPCs in rodent models of photoreceptor degeneration produces new photoreceptor-like cells in the retina which are functional in response to light.

Subject to regulatory advice and the results of further late pre-clinical efficacy and safety studies, we anticipate that the ReN003 programme will enter its clinical phase in 2012.

Based on what we have learned regarding how our CTX cells produce functional improvements in pre-clinical models of disease, we have instigated a number of new therapeutic programmes where these mechanisms of action may also be relevant, such as inflammatory diseases, depression and the earlier phases of ischaemic stroke damage. These programmes are initially being conducted in collaboration with academic institutions in the UK and in the US. We will provide further updates on these programmes as they progress.

In October, we were pleased to be given the opportunity to participate in a stem cell consortium round-table meeting, hosted by the California Institute of Regenerative Medicine, at which leading businesses and academics in the stem cell field came together with representatives from the FDA to share expertise and gain insights into the challenges involved in taking ground-breaking stem cell therapies through pre-clinical development and into the clinic.

## **Financial Review**

In the six months to 30 September 2010, revenues were £18,000 (2009: £14,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses were £2.9 million in the period (2009: £2.0 million). Research and development expenditure increased in the period to £1.7 million (2009: £1.1 million), reflecting an increase in pre-clinical development activity in the ReN009 peripheral arterial disease programme and an increase in costs relating to the ReN001 stroke programme arising from commencement of the PISCES clinical trial. General and administrative costs increased in the period to £1.2 million (2009: £0.9 million), due principally to increased professional adviser fees and an adverse exchange variance arising from cash balances held in US dollars.

Other operating income of £135,000 (2009: £nil) in the period represented grant income received from the UK Government's Technology Strategy Board under its Regenerative Medicine funding programme. No grant income was received in the prior period.

Interest received increased in the period to £10,000 (2009: £7,000) as a result of higher average levels of cash deposits held over the period. Interest costs decreased to £1,000 in the period (2009: £10,000), the 2009 comparative included interest accrued on convertible loan notes that were capitalised during that period.

The Group accrued a research and development tax credit of £236,000 during the period (2009: £154,000), the higher claim reflecting the increase in pre-clinical and clinical activity across the ReN009 and ReN001 therapeutic programmes.

As a result of the above income statement movements, the total comprehensive loss for the period increased to £2.5 million (2009: £1.9 million).

The basic and diluted loss per share remained unchanged at 0.6p per share, reflecting both the increased loss and an increase in ordinary shares in issue in the period due primarily to the share placing completed in March 2010.

Net cash outflow from operating activities increased in the period to £2.0 million (2009: £1.5 million), due to a combination of the increase in operating expenses in the period, partly mitigated by an improved working capital position.

As a result of the above cash flow movements in the period, the Group had cash and cash equivalents totalling £3.5 million as at 30 September 2010 (2009: £2.1 million).

## **Fundraising**

The Company has today announced that it has raised £10 million, before expenses, in a share placing to new and existing investors and a share subscription by the Directors of the Company. The proceeds of this fundraising, which was over-subscribed, are expected to fund the pre-clinical and clinical development costs of the Company's core therapeutic programmes and other general business costs for the next two years, beyond which the Company believes that out-license deals with commercial development partners will be possible for these programmes. The Company will also use the proceeds of the fundraising to complete manufacturing optimisation and scale-up of *CTXcryo<sup>TM</sup>*, the Company's long shelf-life variant of its lead *CTX* cell product. Further proceeds from the fundraising will be utilised to build out the Company's capabilities in clinical, manufacturing and business development, at both executive and non-executive level.

Based on the above, the going concern basis has been adopted in the preparation of these interim financial statements.

## **Outlook**

The period under review has been one of very significant progress for our business, culminating last month in the treatment of the first patient in the PISCES clinical trial of our ReN001 stroke therapy. This takes our stroke programme into its clinical development stage and places ReNeuron in the forefront of the development of treatments for disabled stroke patients using neural stem cells.

Our other core therapeutic programmes continue to progress to plan and we are pursuing further opportunities to exploit the therapeutic potential of our lead *CTX* stem cell line. Once the fundraising announced today has completed, the business will be funded to take its core therapeutic programmes through to meaningful clinical development milestones, setting the Company on its course as one of the world's leading clinical-stage stem cell therapy businesses.

**Professor Trevor Jones**  
Chairman

**Michael Hunt**  
Chief Executive Officer

13 December 2010

**Unaudited Consolidated Statement of Comprehensive Income**  
for the six months ended 30 September 2010

		Six months ended 30 September 2010 £'000	Six months ended 30 September 2009 £'000	Year ended 31 March 2010 £'000
	Note			
Revenue		18	14	31
Research and development costs		(1,728)	(1,138)	(2,078)
Research and development - exceptional costs	3	-	-	(2,291)
General and administrative costs		(1,161)	(901)	(1,914)
Other operating income		135	-	34
<b>Operating loss</b>		<b>(2,736)</b>	<b>(2,025)</b>	<b>(6,218)</b>
Finance income		10	7	11
Finance costs		(1)	(10)	(12)
<b>Loss before income taxes</b>		<b>(2,727)</b>	<b>(2,028)</b>	<b>(6,219)</b>
Tax credit on loss on ordinary activities		236	154	369
<b>Total comprehensive loss for the period</b>		<b>(2,491)</b>	<b>(1,874)</b>	<b>(5,850)</b>
<b>Total comprehensive loss attributable to:</b>				
- Equity owners of the company		(2,491)	(1,874)	(5,850)
<b>Basic and diluted loss per share</b>	4	<b>(0.6p)</b>	<b>(0.6p)</b>	<b>(1.8p)</b>

All revenues and expenses above were generated from continuing operations.

**Unaudited Consolidated Statement of Financial Position**  
as at 30 September 2010

	30 September 2010 £'000	30 September 2009 £'000	31 March 2010 £'000
Note			
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	488	755	541
Intangible assets	1,272	3,419	1,272
Other non-current assets	135	135	135
	<b>1,895</b>	<b>4,309</b>	<b>1,948</b>
<b>Current assets</b>			
Trade and other receivables	960	821	650
Cash and cash equivalents	3,477	2,146	5,525
	<b>4,437</b>	<b>2,967</b>	<b>6,175</b>
<b>Total assets</b>	<b>6,332</b>	<b>7,276</b>	<b>8,123</b>
<b>Equity</b>			
<b>Equity attributable to owners of the company</b>			
Share capital	4,380	3,396	4,377
Share premium	21,324	17,792	21,310
Capital redemption reserve	8,964	8,964	8,964
Merger reserve	2,223	2,223	2,223
Warrant reserve	108	113	108
Share-based credit reserve	1,058	682	876
Retained deficit	(32,917)	(26,563)	(30,426)
<b>Total equity</b>	<b>5,140</b>	<b>6,607</b>	<b>7,432</b>
<b>Liabilities</b>			
<b>Current Liabilities</b>			
Trade and other payables	1,095	584	587
Provisions	75	50	75
Financial liabilities: finance leases	22	35	29
	<b>1,192</b>	<b>669</b>	<b>691</b>
<b>Total liabilities</b>	<b>1,192</b>	<b>669</b>	<b>691</b>
<b>Total equity and liabilities</b>	<b>6,332</b>	<b>7,276</b>	<b>8,123</b>

**Unaudited Consolidated Statement of Changes in Equity**  
for the six months ended 30 September 2010

	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Warrant reserve £'000	Share- based credit reserve £'000	Retained deficit £'000	Total Equity £'000
<b>As at 1 April 2009</b>	<b>1,542</b>	<b>14,358</b>	<b>8,964</b>	<b>2,223</b>	<b>583</b>	<b>504</b>	<b>(24,689)</b>	<b>3,485</b>
Issue of new ordinary shares	1,697	3,396	-	-	-	-	-	5,093
Costs of share issue	-	(275)	-	-	-	-	-	(275)
Conversion of convertible loan to equity	157	313	-	-	(470)	-	-	-
Share-based credit	-	-	-	-	-	178	-	178
Loss for the period	-	-	-	-	-	-	(1,874)	(1,874)
<b>As at 30 September 2009</b>	<b>3,396</b>	<b>17,792</b>	<b>8,964</b>	<b>2,223</b>	<b>113</b>	<b>682</b>	<b>(26,563)</b>	<b>6,607</b>
Issue of new ordinary shares	981	3,989	-	-	-	-	-	4,970
Costs of share issue	-	(471)	-	-	-	-	-	(471)
Share-based credit	-	-	-	-	-	194	-	194
Issue of Warrants	-	-	-	-	108	-	-	108
Expiry of Warrants	-	-	-	-	(113)	-	113	-
Loss for the period	-	-	-	-	-	-	(3,976)	(3,976)
<b>As at 31 March 2010</b>	<b>4,377</b>	<b>21,310</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>876</b>	<b>(30,426)</b>	<b>7,432</b>
Issue of new ordinary shares	3	14	-	-	-	-	-	17
Share-based credit	-	-	-	-	-	182	-	182
Loss for the period	-	-	-	-	-	-	(2,491)	(2,491)
<b>As at 30 September 2010</b>	<b>4,380</b>	<b>21,324</b>	<b>8,964</b>	<b>2,223</b>	<b>108</b>	<b>1,058</b>	<b>(32,917)</b>	<b>5,140</b>

**Unaudited Consolidated Statement of Cash Flows**  
for the six months ended 30 September 2010

	Note	Six months ended 30 September 2010 £'000	Six months ended 30 September 2009 £'000	Year ended 31 March 2010 £'000
<b>Cash consumed by operations</b>	5	(2,024)	(1,518)	(3,328)
Interest paid		(1)	(2)	(4)
Income tax credit received		-	-	703
<b>Cash outflow from operating activities</b>		(2,025)	(1,520)	(2,629)
<b>Cash flows from investing activities</b>				
Capital expenditure		(26)	-	(8)
Interest received		10	7	11
<b>Net cash generated in investing activities</b>		(16)	7	3
<b>Cash flows from financing activities</b>				
Finance lease principal payments		(7)	(7)	(13)
Proceeds from issuance of ordinary shares		-	2,998	7,842
Costs of share issue		-	(275)	(621)
<b>Net cash generated by financing activities</b>		(7)	2,716	7,208
<b>Net increase/(decrease) in cash and cash equivalents</b>	6	(2,048)	1,203	4,582
Cash and cash equivalents at the start of period		5,525	943	943
<b>Cash and cash equivalents at the end of period</b>	7	3,477	2,146	5,525



## **Notes to the interim financial statements**

for the six months ended 30 September 2010

### **1. Accounting policies and basis of preparation**

#### **1.1 Basis of preparation**

The Group's unaudited interim results for the half year ended 30 September 2010 have been prepared in accordance with International Financial Reporting standards (IFRS). The comparative figures for the full year ended 31 March 2010 are an abridged version of the Group's audited financial statements and, together with other financial information contained in these interim results, do not constitute statutory financial statements of the Group within the meaning of section 434 of the Companies Act 2006.

This condensed consolidated interim financial information has not been audited and does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory financial statements for the year ended 31 March 2010 were approved by the Board of Directors on 30 July 2010, have been filed with the Registrar of Companies for England and Wales and have been reported on by the Group's auditors. The report of the auditors was not qualified, did not contain any statement under section 498 of the Companies Act 2006, but did contain an emphasis of matter paragraph relating to going concern.

#### **1.2 Accounting policies**

The accounting policies used in the preparation of these unaudited interim financial statements are consistent with those used in the preparation of the audited financial statements for the year ending 31 March 2010. No changes in accounting policies have occurred since then.

The following amended standard becomes effective for periods beginning on or after 1 January 2010:

#### **Amendments to IFRS 2, 'Share-based payments - group cash-settled transactions'**

The revised standard provides a clear basis to determine the classification of share-based payment awards in both consolidated and separate financial statements. There has been no effect on the reported results or previous financial position of the group as a result of this revised standard.

#### **1.3 Going concern**

The financial statements have been prepared on a going concern basis, which assumes that sufficient funds will be available for the Company and Group to continue in operational existence for the foreseeable future, by virtue of the fundraising referred to in Note 10, Post-balance sheet event.

### **2. Segment information**

Following the adoption of IFRS8 Segment Reporting, the Group has identified the Board of Directors 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.

## Notes to the interim financial statements continued

### 3. Exceptional items

The exceptional research and development costs expensed in the year ended 31 March 2010 arose following the completion of the cost-reduction programme instigated in mid-2008 and a consequent impairment review of the carrying values of research and development-related assets in the Group's Statement of Financial Position. The directors considered it appropriate to write down in full previously capitalised intangible assets, which were non-core to the future development of the Company's therapeutic programmes, together with a write-down of tangible assets following an operational review of ongoing laboratory space requirements.

This impairment review resulted in non-recurring, non-cash exceptional charges totalling £2.3 million in the Group's Statement of Comprehensive Income for the year ended 31 March 2010, of which £2.15 million related to intangible assets and £0.15 million related to tangible assets.

### 4. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £2,491,000 (September 2009: £1,874,000, March 2010: £5,850,000) by 437,945,013 shares (September 2009: 303,885,153 shares, March 2010: 327,168,945 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.

### 5. Cash consumed by operations

	Six months ended 30 September 2010 £'000	Six months ended 30 September 2009 £'000	Year ended 31 March 2010 £'000
Loss before income tax	(2,727)	(2,028)	(6,219)
Adjustment for:			
Interest received	(10)	(7)	(11)
Interest payable	1	10	12
Depreciation of tangible fixed assets	79	79	157
Exceptional items	-	-	2,291
Provisions	-	-	25
Share-based payment charge	182	178	480
Fees payable in ordinary shares	17	-	-
Changes in working capital			
Receivables	(74)	356	40
Payables	508	(106)	(103)
<b>Cash consumed by operations</b>	<b>(2,024)</b>	<b>(1,518)</b>	<b>(3,328)</b>

## 6. Reconciliation of net cash flow to movement in net debt

	Six months ended 30 September 2010 £'000	Six months ended 30 September 2009 £'000	Year ended 31 March 2010 £'000
Net funds / (debt) at start of period	5,496	(1,187)	(1,187)
(Decrease) / increase in cash in the period	(2,048)	1,203	4,582
Cash inflow from decrease in debt	7	2,095	2,101
<b>Net funds at end of period</b>	<b>3,455</b>	<b>2,111</b>	<b>5,496</b>

## 7. Analysis of net funds

	Six months ended 30 September 2010 £'000	Six months ended 30 September 2009 £'000	Year ended 31 March 2010 £'000
Cash at bank and in hand	3,477	2,146	5,525
Finance leases	(22)	(35)	(29)
	<b>3,455</b>	<b>2,111</b>	<b>5,496</b>

## 8. Contingent liability

A subsidiary of the Company is involved in a legal dispute with a US-based competitor who alleges misuse of confidential information relating to a collaboration undertaken between the parties in 2002. The competitor is seeking unquantified damages and an injunction preventing the subsidiary's alleged use of such confidential information. All claims against the subsidiary have been denied and the Company believes the claims can be successfully defended. Assuming the dispute is not settled or otherwise disposed of in the meantime, a trial date for the dispute has been set for April 2011.

## 9. Related party disclosures

### Transactions with Excalibur Fund Managers Limited

Excalibur Fund Managers Limited, as investment advisor to Merlin General Partner II Limited, a substantial shareholder in the Company, recharged directors' fees of £7,500 (September 2009: £7,500) in the period, in respect of services provided by Mark Docherty.

### Transactions with Biomedicon

Dr Paul Harper, trading as Biomedicon, recharged consultancy fees of £nil (September 2009: £1,650) in the period in respect of services provided, in accordance with a consultancy agreement between ReNeuron Limited and Dr Paul Harper, dated 4 August 2005, and recharged directors' fees of £10,000 (September 2009: £10,000) in respect of services provided by him.

### Transactions with Angel Biotechnology plc

During the period the Company contracted cell manufacturing services of £177,000 (September 2009: £91,000) from Angel Biotechnology plc, of whom Dr Paul Harper is a director.

## 10. Post-balance sheet event

On 13 December 2010, the Company announced that it had raised £10 million before expenses, by means of a placing with new and existing investors of 181,318,182 new ordinary shares of 1 pence each at a price of 5.5 pence per new Ordinary Share, together with a subscription by the Directors for 500,000 new ordinary shares also at a price of 5.5 pence per new Ordinary Share.

## Notes to Editors

ReNeuron is a leading, clinical-stage stem cell business. Its primary objective is the development of novel stem cell 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. ReNeuron's lead candidate is its ReN001 stem cell therapy for the treatment of patients left disabled by the effects of a stroke. This therapy is currently in early clinical development. ReNeuron's ReN009 stem cell therapy is being developed as a treatment for peripheral arterial disease, a serious and common side-effect of diabetes. The Company is also developing stem cell therapies for other conditions such as blindness-causing diseases of the retina.

ReNeuron has also developed a range of stem cell lines for non-therapeutic applications – its *ReNcell*<sup>®</sup> products for use in academic and commercial research. The Company's *ReNcell*<sup>®</sup>CX and *ReNcell*<sup>®</sup>VM neural cell lines are marketed worldwide under license by USA-based Millipore Corporation.

ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. Further information on ReNeuron and its products can be found at [www.reneuron.com](http://www.reneuron.com).

*This announcement contains forward-looking statements with respect to the financial condition, results of operations and business achievements/performance of ReNeuron and certain of the plans and objectives of management of ReNeuron with respect thereto. These statements may generally, but not always, be identified by the use of words such as "should", "expects", "estimates", "believes" or similar expressions. This announcement also contains forward-looking statements attributed to certain third parties relating to their estimates regarding the growth of markets and demand for products. By their nature, forward-looking statements involve risk and uncertainty because they reflect ReNeuron's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of factors could cause ReNeuron's actual financial condition, results of operations and business achievements/performance to differ materially from the estimates made or implied in such forward-looking statements and, accordingly, reliance should not be placed on such statements.*

*The terms 'ReNeuron', 'the Company' or 'the Group' used in this statement refer to ReNeuron Group plc and/or its subsidiary undertakings, depending on the context.*