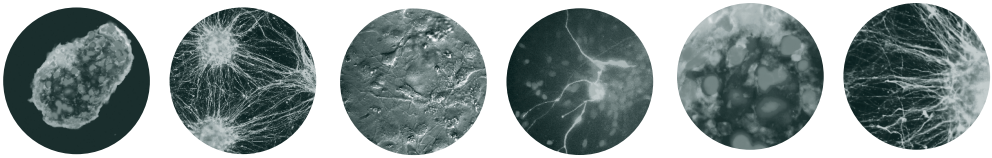
ReNeuron

pioneering stem cell therapeutics

Interim Report **2009**



ReNeuron is a leading, UK-based stem cell business. Our primary objective is the development of stem cell therapies targeting areas of significant unmet or poorly met medical need.

"During the six months to 30 September 2009, and subsequently, we have made significant progress across all areas of our operations. After a lengthy and exhaustive review process, our pioneering ReN001 therapy for stroke has received both UK regulatory and conditional ethical approvals for a first-in-man clinical study and we remain confident of meeting the remaining requirements to allow initiation of this clinical trial early in 2010.

"Our ReN009 therapy for peripheral arterial disease in diabetics is showing great promise pre-clinically, with an initial clinical trial targeted for 2011. Furthermore, we have developed a commercially attractive, second-generation formulation of our lead CTX cell line, our core therapeutic asset. We have a much reduced cost base reflected in the interim results for the period and we have also greatly enhanced the Group's financial position by way of a £3 million equity placing during the period and a further £5 million equity draw-down facility secured subsequently. We look forward to a period of further substantial progress over the coming year."

Professor Trevor Jones, Chairman

Contents

Operational Highlights

- ReN001 stem cell therapy for stroke:
  - Favourable ethical opinion, subject to conditions, given by UK ethics body for Phase I clinical trial, following earlier UK regulatory approval
  - Supplemental data package subsequently generated to meet remaining ethical approval condition
  - Five peer-reviewed papers published in the period regarding safety, efficacy, mechanism of action and manufacture of lead *CTX* stem cell line used in ReN001 programme
- Positive pre-clinical efficacy data presented with ReN009 stem cell therapy for peripheral arterial disease – initial clinical trial targeted to commence in 2011 using *CTX* stem cell line
- Long shelf-life, frozen formulation of *CTX* cell product developed, for subsequent clinical application in ReN001 and ReN009 programmes
- Three further peer-reviewed papers published in the period regarding positive pre-clinical data with ReN003 cell line for retinal diseases and research with *ReNcell*® product for non-therapeutic applications
- ReNeuron's Guildford facility granted full therapeutic application licence by UK Human Tissue Authority, following audit

Financial Highlights

- Share placing to raise £3.0 million, before expenses, completed in the period, together with capitalisation of outstanding £2.5 million convertible loan notes and accrued interest
- Further £5.0 million equity finance facility secured from the Company's joint broker, Matrix Corporate Capital LLP, post-period end, meeting funding requirements through to mid-2011, assuming facility is fully utilised
- Loss for the period reduced by 39% to £1.9 million (2008: £3.1million); net cash outflow from operating activities reduced by 5 to £1.5 million (2008: £3.0 million); cash and cash equivalents at 30 September 2009 of £2.1 million (2008: £0.8 million).

Chairman's and Chief Executive Officer's Joint Statement

Review of Operations

During the six months ended 30 September 2009, we received a final and favourable ethical opinion, subject to conditions, from the UK Gene Therapy Advisory Committee (GTAC) in respect of the proposed first-in-man clinical trial with ReN001, our stem cell therapy for stroke. GTAC acts as the national research ethics committee for gene therapy and stem cell therapy clinical trials in the UK. This final ethical opinion followed regulatory approval for the clinical trial granted by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) earlier in the year. This ground-breaking Phase I trial with ReN001 will take place in Scotland at Glasgow's Southern General Hospital, in patients who have been left disabled by a stroke.

In subsequent interactions with both GTAC and the MHRA, we have agreed appropriate amendments to the proposed clinical trial protocol. We are also finalising the supplemental pre-clinical data package requested by GTAC as a condition of their favourable ethical opinion, which we will submit for their review shortly. Assuming a swift and successful outcome, we expect the ReN001 Phase I clinical trial to commence in the first quarter of 2010.

During the period, a total of five peer-reviewed papers were published in separate scientific journals regarding the efficacy, safety, mechanism of action and manufacture of our lead *CTX* stem cell line and its application as our ReN001 therapeutic candidate for stroke. These papers describe work performed both by ReNeuron's own researchers and research undertaken in collaboration with UK and US academic institutions. We will continue to foster our relationships with academia and publish key findings with our various technologies and stem cell lines, in order to further exemplify the very significant therapeutic and commercial potential we believe they hold.

We made very encouraging progress with our ReN009 stem cell therapy for peripheral arterial disease (PAD) 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 55 have some degree of PAD and it becomes more common with increasing age. Pre-clinical efficacy testing of ReN009 is being conducted in collaboration with Professor Paolo Madeddu, Chair of Experimental Cardiovascular Medicine and colleagues at the Bristol Heart Institute, University of Bristol. Following the presentation of initial positive pre-clinical efficacy data with ReN009 in April of this year, the Bristol team recently presented further positive pre-clinical efficacy data in an award-winning poster at the American Heart Association Scientific Sessions in Orlando, Florida.

The ReN009 programme will utilise our well-characterised, lead *CTX* stem cell line as an allogeneic (non-patient specific) stem cell treatment candidate for late-stage PAD, or critical limb ischaemia, in diabetic patients for whom PAD is a side-effect of their diabetes. Further pre-clinical studies are currently in progress with ReN009 focusing on diabetic models, the results of which will be reported in early 2010. In the meantime, we have recently taken a scientific advice meeting with the MHRA, and we have scheduled a further meeting with GTAC shortly, in order to discuss and

agree certain aspects of the late pre-clinical development plan for the ReN009 therapy. Equivalent meetings are also planned with regulatory authorities in other territories, including the US, ahead of initial clinical trials expected to commence in 2011.

During the period, we successfully prototyped a second-generation, long shelf-life, frozen formulation of the *CTX* cells for subsequent pre-clinical and clinical use in the Company's ReN001 and ReN009 programmes. This new freeze-thaw formulation makes possible the scale-up and production of *CTX* cells for wide-scale use across the globe, both clinically and commercially. This scale-up capability should therefore provide the Company with a key advantage when seeking commercial development partners for its therapies. The technology is currently being transferred to our contract manufacturing partner, Angel Biotechnology in Scotland.

Two further peer-reviewed papers were published in the period regarding positive pre-clinical data generated with our ReN003 cell line for retinal diseases, by our collaborators at the Schepens Eye Research Institute at Harvard Medical School. A significant paper was also published by US researchers in the period, describing how ReNeuron's *ReNcell®VM* cell line was successfully re-programmed to generate stable human induced pluripotent stem cells (iPS cells), similar to human embryonic stem cells with the ability to differentiate into any type of cell in the body. We are encouraged by the increasing interest in our range of *ReNcell®* products for non-therapeutic applications by both academic and commercial researchers, since licensing them to Millipore Corporation for world-wide marketing and distribution.

We were also pleased to have met all the necessary conditions pertaining to the grant of a therapeutic application licence to ReNeuron by the UK Human Tissue Authority during the period, following their earlier audit of our Guildford research facility.

During the period, we announced the appointment of Daniel Stewart & Company plc as Nominated Adviser and joint broker, and Matrix Corporate Capital LLP ("Matrix") as joint broker, to the Company.

Summary of Results

In the six months to 30 September 2009, revenues were £14,000 (2008: £6,000), representing royalty income from the Group's non-therapeutic licensing activities.

Net operating expenses were £2.0 million in the period (2008: £3.1 million). Research and development expenditure decreased in the period to £1.1 million (2008: £1.9 million), due principally to the continuing effects of the cost reduction programme instigated in mid-2008, together with a further reduction in outsourced cell banking and testing costs in the ReN001 stroke programme. General and administrative costs also decreased in the period to £0.9 million (2008: £1.2 million), due principally to cost savings associated with the closure of the Company's US facility as part of the cost reduction programme.

Interest received decreased in the period to £7,000 (2008: £45,000) as a result of lower interest rates available on the Company's cash deposits over the period. Interest costs also decreased slightly to £10,000 in the period (2008: £14,000), relating to interest accrued on the outstanding convertible loan notes referred to below that were fully capitalised during the period.

The Group has accrued a research and development tax credit of £154,000 during the period. No equivalent accrual was made in the prior period due to uncertainty over the Group's ability to claim such credits at that time.

As a result of the above income statement movements, together with the effects of currency translation losses of £13,000 during the period (2008: £7,000 gain), the total comprehensive loss for the period decreased to £1.9 million (2008: £3.1 million).

Net cash outflow from operating activities decreased in the period to £1.5 million (2008: £3.0 million), due largely to the decrease in operating expenses in the period. During the period, the Group completed a further equity funding of £3.0 million before expenses, by way of a placing of new ordinary shares. In connection with this placing, a total of £2.5 million of outstanding convertible loan notes, together with accrued interest thereon, were capitalised.

As a result of the above cash flow movements in the period, the Group had cash and cash equivalents totalling £2.1 million as at 30 September 2009 (2008: £0.8 million).

In November 2009, the Group secured a further £5 million equity funding facility from Matrix, available for draw-down over a two year period. Draw-down amounts are calculated according to a formula based on the daily trading volume of the Group's ordinary shares, and their volume-weighted average price, over relevant trading periods. An over-allotment option also exists in the facility to enable larger draw-downs to be made should market conditions allow at the time. In the absence of any funding from other sources and allowing for the Group's existing cash resources, the Matrix equity facility will provide sufficient working capital to fund the Group's current operations through to mid-2011, if fully utilised over that period.

The directors expect the Group's current financial resources (excluding future funding available under the Matrix equity facility) to last into the second quarter of 2010. The directors are confident of raising further funds sufficient to meet the Group's ongoing requirements thereafter, both by draw-downs under the Matrix equity facility and by the issue of further equity or other financial instruments. The directors are also actively pursuing a number of non-dilutive governmental, regional and charitable translational funding sources. Based on the above, the going concern basis has been adopted in the preparation of these interim financial statements.

Outlook

During the period under review, and subsequently, we have made significant progress across all areas of our operations. After a lengthy and exhaustive review process, our pioneering ReN001 therapy for stroke has received both UK regulatory and conditional ethical approvals for a first-in-man clinical study and we remain confident of meeting the remaining requirements to allow initiation of this clinical trial early in 2010.

Our ReN009 therapy for peripheral arterial disease in diabetics is showing great promise pre-clinically, with an initial clinical trial targeted for 2011. Further, we have developed a commercially attractive, second-generation formulation of our lead *CTX* cell line, our core therapeutic asset. We have a much reduced cost base reflected in the interim results for the period and we have also greatly enhanced the Group's financial position by way of a £3 million equity placing during the

period and a further £5 million equity draw-down facility secured subsequently. We look forward to a period of further substantial progress over the coming year.

Professor Trevor Jones
Chairman

Michael Hunt
Chief Executive Officer

26 November 2009

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pioneering stem cell therapeutics

Unaudited Consolidated Statement of Comprehensive Income

for the six months ended 30 September 2009

	Note	**Six months ended 30 September 2009 £'000**	Six months ended 30 September 2008 £'000	Year ended 31 March 2009 £'000
Revenue		**14**	6	93
Research and development costs		**(1,138)**	(1,939)	(3,177)
General and administrative costs		**(888)**	(1,192)	(1,594)
Operating loss		**(2,012)**	(3,125)	(4,678)
Finance income		**7**	45	63
Finance costs		**(10)**	(14)	(62)
Loss before income taxes		**(2,015)**	(3,094)	(4,677)
Tax credit on loss on ordinary activities		**154**	–	1,000
Loss for the period		**(1,861)**	(3,094)	(3,677)
Other comprehensive income				
Currency translation differences		**(13)**	7	10
Total comprehensive loss for the period		**(1,874)**	(3,087)	(3,667)
Loss attributable to:				
– Equity owners of the company		**(1,861)**	(3,094)	(3,677)
Total comprehensive loss attributable to:				
– Equity owners of the company		**(1,874)**	(3,087)	(3,667)
Basic and diluted loss per share	3	**(0.6p)**	(2.0p)	(2.4p)

All revenues and expenses above were generated from continuing operations.

Unaudited Consolidated Statement of Financial Position

as at 30 September 2009

	Note	**30 September 2009 £'000**	30 September 2008 £'000	31 March 2009 £'000
Assets				
Non-current assets				
Property, plant and equipment		**755**	913	834
Intangible assets		**3,419**	3,419	3,419
Other non-current assets		**135**	135	135
		4,309	4,467	4,388
Current assets				
Trade and other receivables		**821**	432	1,024
Cash and cash equivalents		**2,146**	840	943
		2,967	1,272	1,967
Total assets		**7,276**	5,739	6,355
Equity				
Equity attributable to owners of the company				
Share capital		**3,396**	1,542	1,542
Share premium		**17,792**	14,358	14,358
Equity element of convertible loan note		**-**	184	-
Capital redemption reserve		**8,964**	8,964	8,964
Merger reserve		**2,223**	2,223	2,223
Warrant reserve		**113**	113	583
Share-based credit reserve		**682**	432	504
Retained deficit		**(26,563)**	(23,676)	(24,689)
Total equity		**6,607**	4,140	3,485
Liabilities				
Non-current liabilities				
Convertible loan	7	**-**	828	2,088
		-	828	2,088
Current Liabilities				
Trade and other payables		**634**	722	740
Financial liabilities: finance leases		**35**	49	42
		669	771	782
Total liabilities		**669**	1,599	2,870
Total equity and liabilities		**7,276**	5,739	6,355

Unaudited Consolidated Statement of Changes in Equity

for the six months ended 30 September 2009

	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
As at 1 April 2008	**1,542**	**14,358**	**8,964**	**2,223**	**113**	**329**	**(20,589)**	**6,940**
Equity element of convertible loan	–	–	–	–	184	–	–	184
Share-based credit	–	–	–	–	–	103	–	103
Loss for the period	–	–	–	–	–	–	(3,094)	(3,094)
Other comprehensive income:								
Currency translation differences	–	–	–	–	–	–	7	7
As at 30 September 2008	**1,542**	**14,358**	**8,964**	**2,223**	**297**	**432**	**(23,676)**	**4,140**
Equity element of convertible loan	–	–	–	–	286	–	–	286
Share-based credit	–	–	–	–	–	72	–	72
Loss on foreign exchange translation	–	–	–	–	–	–	(433)	(433)
Loss for the period	–	–	–	–	–	–	(590)	(590)
Other comprehensive income:								
Currency translation differences	–	–	–	–	–	–	10	10
As at 31 March 2009	**1,542**	**14,358**	**8,964**	**2,223**	**583**	**504**	**(24,689)**	**3,485**
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	–	–	–	–	–	–	(1,861)	(1,861)
Other comprehensive income:								
Currency translation differences	–	–	–	–	–	–	(13)	(13)
As at 30 September 2009	**3,396**	**17,792**	**8,964**	**2,223**	**113**	**682**	**(26,563)**	**6,607**

Unaudited Consolidated Statement of Cash Flows

for the six months ended 30 September 2009

	Note	**Six months ended 30 September 2009 £'000**	Six months ended 30 September 2008 £'000	Year ended 31 March 2009 £'000
Cash consumed by operations	4	**(1,518)**	(2,989)	(4,697)
Interest paid		**(2)**	(14)	(4)
Income tax credit received		**-**	-	300
Cash outflow from operating activities		**(1,520)**	(3,003)	(4,401)
Cash flows from investing activities				
Capital expenditure		**-**	(29)	(28)
Proceeds from sale of fixed assets		**-**	41	41
Interest received		**7**	45	63
Net cash generated in investing activities		**7**	57	76
Cash flows from financing activities				
Finance lease principal payments		**(7)**	(5)	(12)
Convertible loan note proceeds		**-**	1,000	2,500
Proceeds from issuance of ordinary shares	7	**2,998**	-	-
Costs of share issue		**(275)**	-	-
Net cash generated by financing activities		**2,716**	995	2,488
Net increase/(decrease) in cash and cash equivalents	5	**1,203**	(1,951)	(1,837)
Loss on foreign exchange translation		**-**	-	(11)
Cash and cash equivalents at the start of period		**943**	2,791	2,791
Cash and cash equivalents at the end of period	6	**2,146**	840	943

Notes to the interim financial statements

for the six months ended 30 September 2009

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 2009 have been prepared in accordance with International Financial Reporting standards (IFRS). The comparative figures for the full year ended 31 March 2009 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 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 2009 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 2009, except as described below.

A number of new and amended standards become effective for periods beginning on or after 1 January 2009. The principal changes that are relevant to the Group are:

IFRS 8 – Operating Statements

IFRS 8 is a disclosure standard only; there has been no effect on the reported results or previous financial position of the Group. The Group's reportable segments as reported under IAS 14 have remained unchanged following the adoption of this standard.

IAS 1 (revised 2007) – Presentation of Financial Statements

The revised standard has introduced a number of terminology changes (including revised titles for the condensed financial statements) and has resulted in a number of changes in presentation and disclosure. There has been no effect on the reported results or previous financial position of the Group.

1.3 Going concern

The Group is developing its technologies for the marketplace and as such absorbs cash until sufficient funds from either licensing or products sold are generated. The directors estimate that the cash held by the Group (excluding future funding available under the Matrix equity facility described in Note 8 below), will not be sufficient to support the current level of activities for the next twelve months.

However, in the absence of any funding from other sources but assuming full utilisation of the £5 million Matrix equity facility, the directors believe there will be sufficient working capital to fund the Group's current operations through to mid-2011. Based on this, the going concern basis has been adopted in the preparation of these interim financial statements. Furthermore, the directors are confident of raising additional funds by the issue of further equity or other financial instruments. The directors are also actively pursuing a number of non-dilutive governmental, regional and charitable translational funding sources.

If the directors considered that the going concern basis was no longer appropriate, adjustments would have to be made to revise the balance sheet value of assets to their realisable amounts and to provide for further liabilities that may arise.

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.

3. Basic and diluted loss per share

The basic and diluted loss per share is calculated by dividing the loss for the financial period of £1,874,000 (September 2008: £3,087,000, March 2009: £3,667,000) by 303,885,153 shares (September 2008: 154,167,534 shares, March 2009: 154,167,354 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.

Notes to the interim financial statements continued

4. Cash consumed by operations

	Six months ended 30 September 2009 £'000	Six months ended 30 September 2008 £'000	Year ended 31 March 2009 £'000
Loss before income tax	**(2,015)**	(3,094)	(4,677)
Adjustment for:			
Interest received	**(7)**	(45)	(63)
Interest payable	**10**	14	62
Currency translation differences	**(13)**	7	10
Depreciation of tangible fixed assets	**79**	117	197
Provisions	**-**	-	25
Share-based payment charge	**178**	103	175
(Profit) on sale of fixed assets	**-**	(39)	(39)
Changes in working capital			
Receivables	**356**	(21)	86
Payables	**(106)**	(31)	(473)
Cash consumed by operations	**(1,518)**	(2,989)	(4,697)

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

	Six months ended 30 September 2009 £'000	Six months ended 30 September 2008 £'000	Year ended 31 March 2009 £'000
Net (debt)/funds at start of period	**(1,187)**	2,737	2,737
Increase/(decrease) in cash in the period	**1,203**	(1,951)	(1,848)
Non cash movement	**-**	172	412
Cash inflow/(outflow) from decrease/(increase) in debt	**2,095**	(995)	(2,488)
Net funds/(debt) at end of period	**2,111**	(37)	(1,187)

6. Analysis of net funds

	Six months ended 30 September 2009 £'000	Six months ended 30 September 2008 £'000	Year ended 31 March 2009 £'000
Cash at bank and in hand	**2,146**	840	943
Finance leases	**(35)**	(49)	(42)
Convertible loan	**-**	(828)	(2,088)
	2,111	(37)	(1,187)

7. Share Placing and Conversion of Convertible Loan

In June 2008, the Group secured £2.5m of financing from its principal existing investors by way of a subscription for a series of new secured loan notes issued by the Group. As at 31 March 2009, this facility had been drawn down in full. On 12 March 2009, the Group announced its intention to raise up to £3 million, before expenses, via a placing of up to 100,000,000 new ordinary shares of 1 pence each credited as fully paid up at a price of 3 pence per ordinary share. The placing comprised four closings to enable certain placees to take advantage of UK Enterprise Investment Scheme tax treatment. On 18 May 2009, the Group announced the completion of the fourth and final closing of the placing, bringing the aggregate gross proceeds of the placing to the full £3 million. In connection with the placing, a further 85,526,648 ordinary shares were allotted and issued on capitalisation of the full £2.5 million of outstanding loan notes (together with accrued interest) at a price of 3 pence per ordinary share. Following the fourth and final closing of the Placing and the issue of ordinary shares on capitalisation of all outstanding loan notes (together with accrued interest), the issued share capital of ReNeuron Group plc comprised 339,627,516 ordinary shares.

8. Post-balance sheet event

In November 2009, the Group secured a two-year, gross £5 million equity funding facility from Matrix, the Group's joint broker. The Flexible Use Small Capital Increase Agreement will enable the Group to service its ongoing working capital requirements by drawing on this facility, as required, over the next two years. The Group will control the timing and amount of any draw-down and is under no obligation to make any such draw-down. If a draw-down is made, the Group will issue new Ordinary Shares to Matrix at a price per share calculated according to a formula based on the daily trading volume of the Group's Ordinary Shares, and their volume-weighted average price, over relevant trading periods. The facility also incorporates an over-allotment option to enable larger draw-downs to be made, should market conditions allow at the time.

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Directors and advisers

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