ReNeuron

pioneering stem cell therapeutics

Interim results for the six months ended 30 September 2013

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Highlights in the period

Fundraising success and strong progress across all programmes

- Equity raise of £25.4m at 2.5p per share with new blue chip investors participating
- Welsh Government grants totalling £7.8m to build production facility for late-stage clinical and commercial product requirements
- Additional £1.5m Government grant to support Phase II stroke clinical trial
- Encouraging interim data presented from Phase I clinical trial of ReN001 in stroke
- Orphan Drug Designation granted in US and EU for ReN003 programme for treatment of retinitis pigmentosa
- Acceleration in development of cryopreserved *CTX* drug product to reduce future clinical development times and product costs
- Acceleration of exosome programme as potential new drug candidates targeting tissue repair, fibrosis and cancer

Corporate strategy

To position ReNeuron as a leading, high-value business in the rapidly developing cell therapy industry, based on:

- leading stem cell technologies underpinned by a strong IP platform
- clinical efficacy data from therapeutic candidates
- commercial development deals based on clinical data generated

ReNeuron is now fully funded to deliver value-generating milestones over the next three years in pursuance of this strategy

Technology overview

- ***CTX*** neural stem cell line
  - Derived using proprietary, patented cell expansion technology
  - Off-the-shelf cell therapy product – no delays for collection, shipping and processing
  - Guaranteed product consistency – no batch-to-batch or patient-to-patient variation
  - Cost effective, scalable manufacturing to full GMP standards

- **hRPC** human retinal progenitor cells
  - Patented low oxygen expansion technology
  - Allogeneic approach
  - Scalable to GMP

- **Exosome** programme on therapies using purified nanoparticles secreted by *CTX* cells
  - Potential drug candidates in multiple new indications (positive pre-clinical data)
  - Multiple patents filed and published
  - *CTX* a potent producer cell line for exosomes

Therapeutic pipeline status

Indication / Product	Pre-clinical	Phase I	Phase II	Phase III
Stroke Disability (*CTX* cell line)		2014	2016	
Critical Limb Ischaemia (*CTX* cell line)		2014	2015	2016
Retinitis Pigmentosa (hRPC cell line)		2014	2016	2017
Exosomes (*CTX*-derived)		2015		

NB: Dates are trial commencement dates

Current status

In funded window

Funded to value inflection

- Equity placing completed in July to raise £25.4 million
    - Cornerstones include Invesco, Abingworth and Wales Life Science Investment Fund
- £7.8 million grant commitment from Welsh Government also received in July to establish cell manufacturing and development laboratory facility in South Wales
    - Secures control/margin over manufacture and builds capacity for late-stage clinical and market supply
- ReNeuron is now funded to:
    - Phase II data on core therapeutic programmes
    - Demonstrate potential of exosome technology
    - Bring manufacturing in-house

Cell manufacturing advances

- Technology transfer of *CTX* cell manufacture to 2 contract manufacturing organisations on-going
- US patent granted on production process for hRPCs (retinal programme), to permit large scale cell bank generation
- Positive recent data with proprietary cryopreservation process led to advancing the development of a cryopreserved *CTX* drug product variant ahead of plan
- Initial data show equivalence to non-cryopreserved *CTX* drug product in cell potency, viability and concentration
- Final GMP validation runs underway to enable use of cryopreserved product for planned Phase II stroke and Phase I CLI clinical trials

Benefits of cryopreserved *CTX* drug product

- Allows ship-and-store on extended shelf life
- Capitalises on allogeneic advantage of our cell lines
- Significant favourable impact on COGS
- Ease of use considerably improved – much closer to off-the-shelf pharmaceuticals/biologicals treatment paradigm
- Will reduce costs and timelines of Phase II and Phase III clinical trials and avoid future bridging studies

Cryopreserved *CTX* represents the in-market product formulation

Clinical – ReN001 for stroke

Interim Phase I data presented at 22nd European Stroke Conference – London, May 2013
(First nine patients treated – follow-up as at Jan 2013)

Efficacy evaluation measures (against stable pre-treatment baseline)

- National Institutes of Health Stroke Scale (neurological deficit):
  - improved by median 1 point at 1 mth post-treatment (n=9) and 3 points at 1 year (n=5)
- Barthel Index (functional outcome):
  - improved by median 1 point at 3 mths (n=8) and 4 points at 1 year (n=5)
- Modified Rankin Score (disability and handicap):
  - improved by median 1 grade at 1 year (n= 5)
- Summated Ashworth scores for affected limbs (spasticity)
  - improved by mean 4.5 at 3 mths (n=9) and 7.2 at 1 year (n=5)

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Phase II clinical development – ReN001

Market

- Single largest cause of adult disability
- No pharmaceutical treatment options beyond 4 hours
- Market for ReN001 estimated at $1.1bn - $2.3bn per year in US (independently analysed)

Target: Improve trajectory of recovery in disabled stroke survivors 8-12 weeks post-stroke

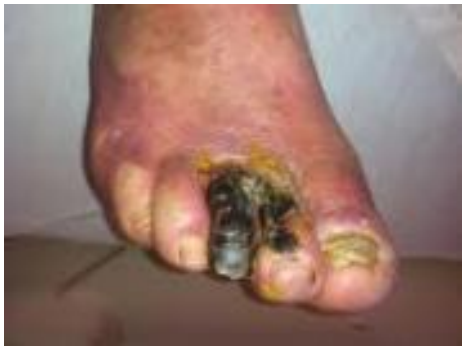
Phase II clinical development

- Phase II clinical trial design has UK regulatory approval – adopted by NHS Stroke Research Network
- Efficient clinical trial design in up to 41 patients to confirm efficacy signal ahead of larger pivotal efficacy study
- Inclusion: paretic arm 4 and 8 weeks after a stroke (<5% chance of recovering use of arm)
- End-points: ARAT, Barthel, Rankin, NIHSS (six months)
- Part funded by £1.5m UK TSB regenerative medicine grant
- Non-interventional, observational study to pre-screen patients for Phase II and build valuable clinical data set in target patient population

Clinical – ReN009 for critical limb ischaemia

Market

- The disease – loss of blood flow to lower limb, leading to gangrene and amputation
- Common in diabetics
- No current treatment options except surgery (20-50% ineligible for this)
- Market for ReN009 estimated at $1bn - $2bn in US (independently analysed)



Clinical development

Phase I study

- 9 patient IM dose-escalation safety study
- UK regulatory and ethical approvals in place
- Part-funded by £0.4m UK BioMedical Catalyst grant

Phase II study

- Double-blind, placebo-controlled study: 40 patients per arm
- Inclusion: CLI, rest pain, ischaemic ulcer
- Primary endpoint: reduction in death or amputation or ulcer doubling rate

Development plan – ReN003 for retinitis pigmentosa

Market

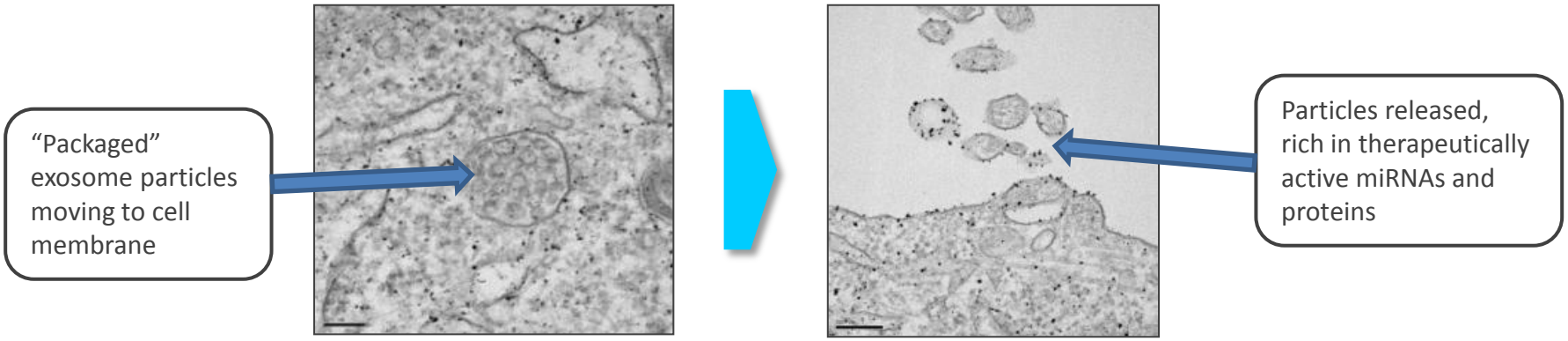
- Inherited blindness-causing disease
- Orphan Drug Designation received in EU and US – accelerated development/market exclusivity
- Target indication value: $200m - $400m p.a. in US
- Gateway to other retinal disease conditions, e.g. diabetic retinopathy

Development plan

- IND/CTA enabling studies underway
- Part-funded by £0.8m UK BioMedical Catalyst grant
- Phase I/II clinical trial application targeted for mid-2014
    - Primary endpoints: safety plus restore sight/prevent further deterioration

Research update – exosome platform

- *CTX* cell line shown to be highly efficient producer of biologically active nanoparticles known as exosomes
- Pre-clinical data shows therapeutic potential of exosomes in a range of assays, including wound healing, immune modulation, neuroprotection, cancer proliferation
- Multiple new patent applications filed describing composition, characterisation, manufacture and therapeutic uses
- Funding from Welsh Government awarded to support pre-clinical development



Relocation to Wales

- Control of manufacturing is a key asset in cell therapy:
  - Demonstrates security of supply chain to partners
  - Provides much greater control over development timelines
  - Underpins process development and maximises IP/know-how
  - Cost-effective vs. using CMOs

- Non-dilutive financing of £7.8 million enables ReNeuron to build capacity for all Phase III needs and initial in-market supply – an integrated cell therapy business

Relocation status

- Preferred building identified in South Wales (M4 corridor), subject to terms
- Detailed planning with Welsh Government and external contractors has commenced
- Allows for expansion space to meet peak in-market demand
- Target is full relocation by end-2014 and licensing of facility by end-2015, in time to supply Phase III trials from 2016 onwards

Interim results statement (unaudited) – Highlights

- Revenues include £178k of grant income
- R&D cost increase reflects increased cell manufacturing activity

(£'000)	Six months ended 30 Sept 2013	Six months ended 30 Sept 2012
Revenues and grant income	189	12
Research and development costs	(2,759)	(2,365)
General and administrative costs	(923)	(982)
Operating loss	(3,493)	(3,335)
Finance costs and tax credits	326	457
Loss for the period	(3,167)	(2,878)

Cash flow statement & cash position (unaudited)

(£'000)	Six months ended 30 Sept 2013	Six months ended 30 Sept 2012
Cash used in operations	(3,422)	(3,523)
Net finance income	14	13
Tax credit	-	616
Capital expenditure	(59)	(17)
Cash burn	(3,467)	(2,911)
Equity issue net of costs	23,435	5,601
Net cash flow	19,968	2,690
Cash at 1 April	3,547	3,983
Cash at 30 Sept	23,515	6,673

Future expected clinical milestones

	CTX programmes	hRPC programme (retinal)	Exosome programme
H1/2014	Stroke Phase I final data Stroke Phase II begins CLI Phase I begins	Completion of IND/CTA-enabling studies	
H2/2014	CLI Phase I data	Phase I/II begins	Pre-clinical validation 1st indication
H1/2015	CLI Phase II begins Stroke Phase II interim data		
H2/2015	Stroke Phase II final data		1st clinical trial approval
H1/2016	CLI Phase II data Stroke Phase III approval CLI Phase III approval	Interim Phase I/II data (safety)	

Summary

- Well-capitalised player in cell therapy development – a field set to play major role in addressing healthcare needs of ageing populations around the globe
- Clear focus on major market opportunities which play to technology strengths
- Clinical development programmes leading to multiple value inflection points and potential commercial deals over next three years
- Combination of IP-underpinned technology and maturing clinical programmes will be an attractive asset for partners wishing to enter regenerative medicine
- Experienced management/commercially-focused Board leadership
- Finances secured with support of major Government grants and leading cornerstone equity investors

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