

# REGEN THERAPEUTICS PLC AUTUMN PRESENTATION 2007

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This document and the presentation to which it relates includes forward-looking statements that relate to ReGen's objectives, estimates and goals. Any statements that are not statements of historical fact should be considered forward-looking statements. The Company's business is subject to numerous risks and uncertainties, including the necessity to conduct further clinical trials and related studies (such as toxicity and bio-equivalence), product testing and regulatory approval, efficacy and safety of Colostrinin™'s constituent peptides and zolpidem in the treatment of any disease or condition. These and other risks and uncertainties could cause ReGen's actual results and developments to be materially different from those expressed or implied by any of these forward-looking statements.

Key assumptions made in preparing this document and the presentation to which it relates include:

- Colostrinin<sup>™</sup> as a nutraceutical was launched in the professional channel in North America on 1 October 2007.
- There will not be a licensing deal for zolpidem before the end of 2008.
- The Company has a pre-clinical programme to develop the potential of Colostrinin<sup>™</sup> peptides as a treatment for Alzheimer's disease and other CNS illnesses. It is unlikely, however, that we will receive a milestone payment for Colostrinin<sup>™</sup> constituent peptides as a treatment for Alzheimer's disease, or other CNS illnesses before 2009.



### REGEN THERAPEUTICS PLC

Presentation by:
Percy Lomax
Chairman and Chief Executive



#### THE COMPANY

- ReGen Therapeutics Plc was founded in 1998 to acquire IP related to Alzheimer's disease.
- Floated on Ofex December 1998.
- AIM flotation March 2000.
- Capital raised so far £19.7m.
- Acquired Guildford Clinical Pharmacology Unit Limited (GCPUL) October 2004.
- US ADR programme established 4th December 2004.
- Sciencom Limited acquired February 2006 potential new use of zolpidem for treatment of secondary effects of stroke and other brain injury.



#### **OUR BUSINESS**

#### ReGen Therapeutics Plc has three business lines:

- Pharmaceutical drug development:
- a. Neurodegenerative diseases (Alzheimer's disease and Parkinson's disease market size approx \$6.6 billion in 2005\* and the estimate for the multiple sclerosis market in 2006 was \$4.9 billion\*)
- b. Brain trauma reversal of dormancy (market \$4.3 billion)\*\*
- Nutraceutical products (estimated \$210 billion global nutraceutical market (2006)\*\*\*
- Clinical Research Organization (revenues to half year June 2007 £117,000)



<sup>\*</sup>Source -Espicom

<sup>\*\*</sup>Source - ReGen estimates based on US Government data updated to 2006

<sup>\*\*\*</sup>Nutrition Business Journal

#### NUTRACEUTICAL COLOSTRININ™

- Original compound Colostrinin™ is a complex of low molecular weight proline-rich polypeptides well suited to the nutraceutical market.
- It has shown therapeutic activity in Alzheimer's disease when tested in over 150 human subjects.
- ReGen's Intellectual Property position is protected by granted use patents in USA, UK, Australia, New Zealand, South Africa, China, Turkey, Israel, Russia, Czech R. and South Korea - patents pending in Europe and other major countries.

# NUTRACEUTICAL COLOSTRININ™ COMMERCIAL PROSPECTS

- ReGen has licensed Metagenics Inc. to distribute Colostrinin<sup>™</sup> in North America and Australasia in the professional channel. A partner in the retail channel is being actively sought.
- In the USA Colostrinin<sup>™</sup> was launched as CogniSure<sup>™</sup> on 1
  October 2007 in the professional channel.
- Current peak production capability is around two million units\* per year – revenue per unit estimated at \$5. (Peak production will not be reached in 2007).
- Australasian launch July 2007.
- Negotiations with potential licensees in other territories are ongoing.

\* 30 tablets



## DRUG DEVELOPMENT PROGRAMME 1: COLOSTRININ™

- Research on Colostrinin<sup>™</sup> has shown potential utility in neurodegenerative disorders, in particular Alzheimer's disease and its precursor Mild Cognitive Impairment (MCI), and also in Parkinson's disease and Multiple Sclerosis.
- Clinical data Journal of Alzheimer's Disease, 2004:
  - 30-week trial of mild to moderate Alzheimer's disease treatment.
  - Evidence of early beneficial effects on cognitive symptoms and daily functions.
  - Statistically significant difference: ADAS-cog (p=0.02) and IADL (p=0.02).
  - No adverse side effects or safety issues arose from the 30week trial in 106 Alzheimer's disease sufferers.



## DRUG DEVELOPMENT PROGRAMME 1: COLOSTRININ™ (continued)

- Colostrinin's<sup>™</sup> individual constituents, as synthetic peptides or peptide mimetics, will address the pharmaceutical market. No safety or side effect issues have been raised with Colostrinin<sup>™</sup>.
- Two peptides NP Lis and NP Pol have shown activity in models predictive of Alzheimer's and Parkinson's respectively. Classical pharmaceutical pre-clinical candidate possible 2009.
- Despite sales of around \$11.8 billion (2006)\* the
  neurodegenerative markets shown above do not have
  satisfactory treatments. A new product with efficacy and a low
  side effect profile would be extremely attractive both on human
  and health economics grounds.

<sup>\*</sup>Source - Espicom



## DRUG DEVELOPMENT PROGRAMME 2: ZOLPIDEM

- "Open" clinical case observations have shown zolpidem can normalise brain dormancy secondary to a primary brain lesion.
- Brain dormancy secondary to stroke, traumatic brain injury, vascular dementia and Bells Palsy have shown response.
- Widely prescribed drug thus characteristics known.
- Usefulness of existing/generic (high dose tablets) limited by sedation and slow variable absorption.



#### **ZOLPIDEM: THE COMMERCIAL OPPORTUNITY**

- 2006/2007 clinical trial established that the 2.5mg sublingual spray dose is non-sedating.
- Sublingual spray formulation showed faster absorption compared to tablets in the trial.
- Further new formulations being evaluated for development and extensive scientific background work is being undertaken.
- Use patent filed 19/05/2004 cover to 2024 (if granted).
- Potential market \$4.3 billion\* totally unmet need. No alternative treatment.
- Further clinical trial expected to be undertaken with nonsedating low-dose formulations after more scientific evaluation.



<sup>\*</sup> ReGen estimates based on publicly available US government data updated to 2006.

# PHARMACEUTICAL LICENSING STRATEGY

- Initially to develop classical pharmaceuticals based on active principles within Colostrinin<sup>™</sup> to pre-clinical or Phase I.
- To develop a new use for zolpidem through Phase II.
- Pre clinical and Phase I deals have attracted upfront monies of \$20m in 2004, total deal value \$77m\*.

<sup>\*</sup> Source Windhover In-Vivo



#### **CONTRACT RESEARCH**

- GCPUL sales of £117,000 to half year June 2007.
- Wide ranging Phase I and Phase II expertise.
- Experienced management.





#### **SUMMARY**

#### Drug development:

- Zolpidem successfully completed clinical trial in June 2007 results announced August 2007.
- Colostrinin<sup>™</sup> peptide mimetic programme underway.
- One synthetic peptide (NP LIS) has shown improved memory/ cognitive function in rats.
- Another synthetic peptide (NP POL) has shown protection of cells from toxic insult in a model predictive of potential activity in Parkinson's disease.
   Both peptides prevent Aβ aggregation.

#### Colostrinin™ nutraceutical development:

- Metagenics Inc. launched Colostrinin™ as CogniSure™ in the professional channel in the USA on 1 October 2007.
- Australasian launch July 2007 further licensing deals being sought.
- ADR programme established December 2004.
- ReGen now anticipates achieving sustainable profitability end 2008.



#### FINANCIAL DATA

- Quoted AIM and proposed OTCQX
- Ticker symbols UK: RGT and USA: REGUY:PK – 1 ADR = 20 RGT\*.
- RGT: 60p\*\*.
- Shares in issue 10.26 million.
- Daily Trading Volume (AIM): 30,000\*\*\*.
- Revenues to half year June 2007 £117,000.
- R & D spend year end December 2006: £825,000.
- Market cap £6.15m (\$12.9m\*).

**NOTE**: This data has been prepared assuming the Consolidation goes through on 20/11/07 and ADR ratio, price, shares in issue, trading volume and market cap have been adjusted to reflect this.

<sup>\*\*\*</sup> Source house Broker



<sup>\*</sup> Subject to SEC confirmation

<sup>\*\*</sup> At 16.11.2007

### **POSSIBLE REVENUE STREAMS**

Product	2007	2008	2009
Colostrinin™	Australasian launch – July 2007	European launch Japanese launch	
	N American launch – October 2007		
Zolpidem		licensing deal end year	milestone
Colostrinin™-derived Synthetic Peptides			licensing deal



# RESEARCH APPENDIX



#### RESEARCH

### Science programmes at:

- University of Texas Medical Branch, Galveston, Texas, USA.
- Roswell Park Cancer Institute, Buffalo, NY, USA.
- Open University UK.
- Aston University UK.







#### **COLOSTRININ™ RESEARCH**

Primary Biological Effect: Improvement of Cognitive Function

- Colostrinin<sup>™</sup> was shown to facilitate learning and memory in old rats in a Morris Water Maze study.
- Colostrinin<sup>™</sup> was shown to enhance memory of avoidance learning in newly hatched chicks.
- Colostrinin<sup>™</sup> has shown evidence of early beneficial effects on cognitive symptoms and daily functions in humans.



#### **COLOSTRININ™ RESEARCH**

Primary Mode of Action: Reduction of oxidative stress

- Colostrinin<sup>™</sup> shown to reduce intracellular oxidative metabolism which is central to cell proliferation, differentiation and apoptosis. Specifically, the differentiation of primary cells into neuronal cells.
- Colostrinin<sup>™</sup> shown to increase lifespan of senescence accelerated mouse cells and normalise mitochondrial function (anti-ageing).
- Colostrinin<sup>™</sup> increases the lifespan of SAMP mice (Colostrinin<sup>™</sup> given in drinking water).
- Colostrinin<sup>™</sup> shown to reduce the frequency of spontaneous and induced mutations in Chinese hamster and human cells (cancer prevention and treatment).



# CLINICAL RESEARCH ON ALZHEIMER'S: SUMMARY

### Efficacy:

30-week trial of mild to moderate AD treatment. Statistically significant difference: ADAS-cog (p=0.02) and IADL (p=0.02).

### Safety:

No adverse side effects or safety issues from 106 AD patients. Three other trials have shown no adverse side effects/safety issues.



# PEPTIDE MIMETIC DEVELOPMENT PROGRAMME

- Programme underway to develop peptide mimetic pharmaceuticals to treat the neurodegenerative diseases where we have shown Colostrinin<sup>™</sup> and its constituent peptides to have activity.
- Based on initial research evidence the following disorders are in focus: Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, Amyotrophic Lateral Sclerosis.

