

# **REGEN THERAPEUTICS PLC**

## **DECEMBER 2006 PRESENTATION**

[www.regentherapeutics.com](http://www.regentherapeutics.com)

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## **Forward Looking Statements**

**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 in the treatment of any disease or condition in both the Colostrinin™ peptides and zolpidem. 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:**

- We do not expect sales of Colostrinin™ as a nutraceutical before mid year 2007.**
- There will not be a licensing deal for zolpidem before the second half of 2007.**
- The Company has a pre-clinical programme to develop the potential of Colostrinin™ peptides as a treatment for Alzheimer's disease and other CNS illnesses.**
- It is unlikely that we will receive a milestone payment for Colostrinin™ constituent peptides as a treatment for Alzheimer's disease, or other CNS illnesses before 2008.**



# 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 £17.1m.
- Acquired Guildford Clinical Pharmacology Unit Limited (GCPUL) October 2004.
- ADR programme established 4th December 2004, quotation March 2005.
- 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 (Neurodegenerative disorders sales \$10.2 billion end 2004\*).
- Nutraceutical products (part of \$170 billion global nutraceutical market).
- Clinical Research Organization (revenues 6 months ended June 2006: £55,000).

\*Source – IMS, Espicom and ReGen



# DRUG DEVELOPMENT PROGRAMME

- Scientific and clinical data on Colostrinin™ has shown potential utility in neurodegenerative disorders, in particular Alzheimer's disease and its precursor Mild Cognitive Impairment (MCI).
- Colostrinin™ as a complex of low molecular weight proline-rich polypeptides is well suited for the nutraceutical market, whereas the individual constituents, as synthetic peptides, will address the pharmaceutical market. Classical pharmaceutical pre-clinical candidate possible during 2008.
- Zolpidem – clinical study in South Africa for use in secondary effects of brain trauma.



# RESEARCH

Science programmes at:

- University of Texas Medical Branch, Galveston, Texas, USA.
- Roswell Park Cancer Institute, Buffalo, NY, USA.
- Open University – UK.
- William Harvey Research Institute – UK.
- Proximagen Plc – UK.





# COLOSTRININ™

- Proline-rich polypeptide complex derived from colostrum.
- Granted use patents in USA, UK, Australia, New Zealand, South Africa, China, Turkey, Israel, Russia and South Korea - patents pending in Europe and other major countries.
- Clinically tested in over 150 human subjects.



# COLOSTRININ™ RESEARCH

Primary Mode of Action: Reduction of oxidative stress

- Colostrinin™ 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™ shown to increase lifespan of senescence accelerated mouse cells and normalise mitochondrial function (anti-aging).
- Colostrinin™ shown to reduce the frequency of spontaneous and induced mutations in Chinese hamster and human cells (anti-cancer prevention and treatment).



# COLOSTRININ™ RESEARCH

## Primary Biological Effect: Improvement of Cognitive Function

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



# 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 mimetics for the neurodegenerative disorders where we have evidence of Colostrinin™ and its constituent peptides utility.
- Based on initial research evidence the following disorders are in focus: Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, Amyotrophic Lateral Sclerosis.



# NUTRACEUTICAL COLOSTRININ™

- ReGen has licensed Metagenics Inc. to distribute Colostrinin™ in North America in the professional channel. A partner in the retail channel is being actively sought.
- Revenues from a nutraceutical product are currently expected after mid year 2007.



# ZOLPIDEM

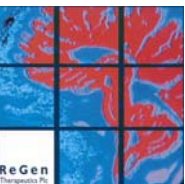
- Widely prescribed drug – thus characteristics known.
- “Open” clinical case observations have shown zolpidem can normalise brain dormancy secondary to a primary brain lesion.
- Brain dormancy secondary to stroke, traumatic brain injury, vascular dementia and Bells palsy have shown response.
- Usefulness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



# ZOLPIDEM - THE COMMERCIAL OPPORTUNITY

- Clinical trial to establish clinical feasibility of lower dose giving anti-dormancy effect but with less sedation.
- New orobuccal spray formulation to be compared to tablets in trial.
- Further new formulations to be developed.
- Use patent filed.
- Potential market \*\$4.3 billion.

\* ReGen estimates based on publicly available US government data.





# PHARMACEUTICAL LICENSING STRATEGY

- Initially to develop a classical pharmaceutical based on active principle within Colostrinin™ 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\*.

\* Source Windhover In-Vivo



# CONTRACT RESEARCH

- GCPUL is revenue generating.
- Wide ranging Phase I and Phase II expertise.
- Capable of significant expansion.
- Experienced management.



# SUMMARY

- Drug development:
  - Zolpidem entering clinical trials in Q4 2006.
  - Colostrinin<sup>TM</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 A $\beta$  aggregation.
- Colostrinin<sup>TM</sup> nutraceutical development:
  - First revenues from Metagenics Inc. deal expected after mid 2007.
  - Industrial scale process completed.
- ADR programme established December 2004 and quoted March 2005.



# THE OPPORTUNITY

- ReGen now anticipates achieving sustainable profitability in 2008.
- News flow over next year is anticipated to show further nutraceutical deals and nutraceutical sales.
- There could be further positive news on Colostrinin™ peptides.
- Zolpidem clinical trial results expected first half 2007 – deal possible that year.



# FINANCIAL DATA

- Quoted AIM and OTC (Pink Sheets).
- Ticker symbols – UK: RGT and  
USA: REGUY:PK – 1 ADR = 200 RGT.
- RGT: 1.15p\* – ADR: \$4.53\*.
- Shares in issue 694 million.
- Daily Trading Volume (AIM): 2.9 million\*\*.
- Revenues 6 months ended June 2006: £55,000.
- R & D spend 6 months ended June 2006: £360,000.

\* at 01.12.2006

\*\* source Hoodless Brennan data based on average for current year to 30.11.06

