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# Annual Report and Accounts 2009



### Chairman's statement



### **Highlights**

- Breakeven point of the Company has substantially reduced due to cost reduction. Administration costs down by 39% and development costs down by 81%.
- Major new licensees appointed.
- Improved balance sheet. Current liabilities reduced by 23% despite credit crunch.

#### **Financials**

We can take some significant positives for the future from 2009 despite showing a disappointing drop of 39% in sales. In particular these positives were as we spell out below – a dramatic reduction in costs, bringing the Company's breakeven point down significantly, an improved balance sheet and further distributors signed up.

The sales drop was primarily the result of the fact that we had received very large orders from our North American licensee in the first half of 2008, which satisfied its demand into 2009. As we then only had Metagenics and Golgi as distributors, clearly our sales pattern was significantly influenced by this. Since then, however, we have signed further contracts with new licensees and this makes us much less dependent on any one single distributor. As sales in the second half of 2009 were £46,000 (the fourth quarter were £26,000), and quarterly sales in the first quarter of 2010 are above that level, we may now have reached a situation where we have sufficient contracts to even out quarterly sales.

Most importantly, however, our loss before tax for the year was almost halved from £1.5 million to £758,000. This was achieved by significant

reduction in costs and allowed the Company to continue to operate on reduced parameters and also lowered the breakeven point for the Company. I would remind Shareholders that the loss in 2007 was £2.6 million. This fall in costs reflects the action taken in early 2008 to enable the Company to survive the very difficult funding conditions following the severe economic crisis. This continues although perhaps lessening in severity. In specific terms the items were:

- Administrative costs reduced by 39% from £1,176,224 to £719,569. Included within administrative costs are non-cash items of £238,774 so the cash expenditure on administration was actually £480,795. The largest reduction within this item was staff costs, which in cash terms were reduced from £457,056 to £262,271 in 2009.
- 2. Development costs reduced by 81% from £411,938 to £79,648. This reflected the slowing down of our development programme as we seek to exploit it commercially. As we show under Scientific Development there was actually some further development work taking place which was of no cost to ReGen.

Turning now to the balance sheet our total current liabilities have been reduced by 23% from £541,491 to £416,511. In view of the restricted capital markets during 2009 we regard this as a significant achievement and have plans in hand to reduce this still further. During 2009 we raised £691,185 and this enabled the Company to continue rolling out Colostrinin™ and improving its balance sheet to a limited extent.

### Commercial development Colostrinin™ roll out widens – New

Colostrinin™ roll out widens – New Developments:

### Cyprus

The agreement with Golgi Pharmaceuticals
Ltd of Cyprus under the brand name 'Cognase'
was extended on 25 March 2009 to allow them
to distribute Colostrinin<sup>TM</sup> in Greece and other
Balkan countries. On the same day a further
agreement was signed with Golgi to allow them
to tablet and package Colostrinin<sup>TM</sup> in Cyprus. As











part of this arrangement Golgi directly invested £28,000 in cash into ReGen in exchange for 700,000 shares priced at 4p per share. This represented at the time 3.4% of the enlarged share capital of the Company and was a 33% premium to the previous placing on 2 March 2009.

### **Poland**

Following the test marketing by Tagerr, a professional services and trading company established in Cologne, Germany, Tagerr has successfully launched Colostrinin™ in Poland and has been slowly increasing its demand.

### **Turkey**

On 29 January 2009 ReGen signed an agreement with Eczacibasi Ilac Pazarlama A.S., a leading Turkish industrials group, as the exclusive distributor of its nutraceutical product Colostrinin<sup>TM</sup>, under the brand name 'Dyna' in the Republic of Turkey. Eczacibasi is now launching 'Dyna' in Turkey and has paid ReGen a \$50,000 milestone payment. Net revenues to ReGen from Eczacibasi pursuant to the minimum annual purchase commitments in the distribution agreement are estimated to be \$52,000 in the first year after regulatory approval is obtained and \$104,000 in the second year.

### India

On 27 April 2010 ReGen signed a Supply Agreement with an Indian Company based in Mumbai, India.

The ReGen Board regards this as a crucial step for two reasons. Firstly, it provides entry into the second most heavily populated market in the world and one where self treatment is an integral part of healthcare. Secondly, India, along with China, is one of the two major growth drivers of the world economy. Thus, for these reasons a consumer launch in this market has significant potential for ReGen's long-term profitability.

### UK

PRG Nutraceuticals Limited launched 'MemoryAid' in the UK via the internet on the 1 October 2009.

#### China

China, with India, is a major potential market for ReGen, both because of its size and a tradition of self medication. We are currently engaging ICUK (a UK based British and Chinese Government Consultancy) to introduce us to key players in the Chinese market.

### **Existing Licensees**

Our major partner is still Metagenics Inc., who were taken over by Alticor during 2009. This takeover would have contributed to the fact that they did not reorder active material from us for almost one year. An additional problem was that for a period of time Colostrinin™ fell foul of a review of the Australian regulations relating to colostrum products which meant it could not be sold in Australia, by Metagenics's subsidiary company who order through the US. This problem has now been resolved. We now are led to believe there will be a relaunch of Colostrinin™ in the US in the latter half of 2010.

### Scientific development

Although ReGen has cut back its research spending, as it now believes it is time to capitalise on its research output, some research carried out in prior periods was reported in 2009. Also some of our former paid collaborators have continued to produce research out of their own funding.

### Colostrinin™:

In the autumn of 2007 we announced that a micro array analysis of peptides derived from Colostrinin™ at the University of Texas Medical Branch (UTMB) had shown that certain peptides had a capacity to change gene expression in areas involved in obesity and Alzheimer's disease. It was therefore decided to explore certain peptides further with a view to developing them to the status of pre-clinical pharmaceutical candidates. On 12 March 2009 we announced the successful completion of the first stage of this exercise.

### Alzheimer's disease:

In an *in vitro* study using neuronal cells two synthetic peptides (RG-01 and RG-018) have shown significant impact on expression of











### Chairman's statement continued

genes involved in beta-amyloid generation and degradation pathways. Controlling beta-amyloid generation could have important implications in Alzheimer's disease.

#### Anti-obesity:

In an *in-vivo* study on obesity Colostrinin<sup>TM</sup>, as well as three peptides in combination, have been shown to significantly reduce the body weight gain of mice when fed a high fat diet (HFD).

The obesity data could be used to create another nutraceutical product and indeed a large European food company is considering doing further work on this.

Backing up the work in Alzheimer's disease Professor Michael Stewart of the Open University has co-authored a paper showing further evidence of Colostrinin™ activity in reducing cytotoxicity related to Alzheimer's disease. Professor Stewart said:

"Alzheimer's disease is the most common form of dementia affecting 18 million people worldwide. It is characterised by extra cellular senile plaques consisting mainly of aggregated amyloid-beta and intracellular neurofibrillary tangles containing the cytoskeletal protein tau. A recent study by Froud et al. in Journal of Alzheimer's Disease¹ has demonstrated that Colostrinin™ significantly relieves amyloid-beta induced cytoxicity".

### Zolpidem:

A study confirming the zolpidem effect in brain damage was presented at the 4th International Congress on Brain and Behaviour on 3 – 6 December 2009 in Thessaloniki, Greece by Dr Ralf Clauss. 23 of 41 consecutive adult patients, at least 6 months after brain damage, were selected as neurologically disabled patients after scoring less than 100/100 on the Barthel Index. Causes of brain damage included stroke (12 subjects), traumatic brain injury (7 subjects), anaphylaxis (2 subjects), drug overdose (1

<sup>1</sup>J Alzheimers Dis. 2010 Feb 17. (Epub ahead of print) Colostrinin Alleviates Amyloid-beta Induced Toxicity in Rat Primary Hippocampal Cultures. Froud KE, Wardhaugh T, Banks D, Saffrey MJ, Stewart MG Department of Life Sciences, Open University, Walton Hall, Milton Keynes, UK. subject) and birth injury (1 subject). The selected 23 patients had a baseline SPECT scan before starting daily zolpidem therapy and a second within two weeks of therapy, performed 1 hour after receiving 10 mg oral zolpidem. Scans were designated as improved when at least two of three independent assessors detected improvement after zolpidem. The rest were designated non-improved.

After four months of daily zolpidem therapy, the clinical condition of subjects was rated on the Tinetti Falls Efficacy Scale (TFES) before and after zolpidem. The TFES ratings of all subjects and scan improvers and non-improvers were compared statistically.

Mean overall improvement after zolpidem on TFES was 11.3% from 73.4/100 (SD 25.4) to 62.1/100 (SD 28.8) (p=0.0006). 10/23 (43%) improved on SPECT scan after zolpidem. Their mean TFES improvement was 19.4% (SD 16.75) compared with 5.17% (SD 5.167) in 13/23 non-improvers (p=0.0081).

### Summary

The Company has survived the credit crunch by implementing a severe cost reduction programme, but as my review of the year shows the business side has been expanded despite this. We still continue to believe that during 2010 the Company will move to sustainable profitability.

I would like to thank the Shareholders and in particular our funders during 2009 for their very significant support at a time when money was very difficult to raise.

### Percy W Lomax

20 May 2010











### **Operational review**

### Introduction

ReGen Therapeutics Plc is commercialising its lead product Colostrinin™ on a world wide basis. Originally ReGen was formed to develop Colostrinin™ as a pharmaceutical compound for the treatment of Alzheimer's disease. For a number of reasons Colostrinin™ was finally assessed to be more suitable for development as a nutraceutical.

ReGen, however, has not lost its interest in pharmaceuticals. It is looking for development partners for Colostrinin™ peptides for the treatment of Alzheimer's disease and obesity and for zolpidem. ReGen continues to maintain the patents for these products.

To provide capital for the original programme the Company was floated on the Ofex market in December 1998 and on the Alternative Investment Market (AIM) of the London Stock Exchange in March 2000. In its public offerings and subsequent offerings the Company has raised approximately £22 million. We regard our ability to raise capital under difficult market conditions as crucial as it has enabled us to continue to carry out our programmes without interruption.

### **Objectives**

ReGen's core objective is to commercialise Colostrinin<sup>TM</sup> so that revenue from sales of this product will make ReGen profitable. Subsidiary objectives are to find development partners for the Colostrinin<sup>TM</sup> peptides and zolpidem.

### Key Historical Milestones Colostrinin™ World wide Commercial Roll out July 2007 to present day

### Turkey - April 2010

Eczacibasi Ilac Pazarlama A.S. – a leading Turkish industrials group launched Colostrinin™ in the Republic of Turkey under the brand name 'Dyna' in April 2010.

This generated immediate cash for ReGen as Eczacibasi paid ReGen a \$50,000 milestone payment on full approval being granted. Net Revenues to ReGen from Eczacibasi pursuant to the minimum annual purchase commitments in the distribution agreement are estimated to be \$52,000 in the first year after regulatory approval is obtained, and \$104,000 in the second year.

### UK - October 2009

PRG Nutraceuticals Limited launched Colostrinin™ under the brand name 'MemoryAid' in the UK over the internet on the 1 October 2009.

### Poland - April 2009

In April 2009 Tagerr gained approval to import and market Colostrinin™. Tagerr is a professional services and trading company established in Cologne, Germany. In operation since 1995, it has enjoyed a number of successes in the marketing and distribution of consumer products including food supplements in Central Europe and Germany.

### Cyprus - October 2008

Golgi Pharmaceuticals Ltd of Cyprus launched Colostrinin™ under the brand name of 'Cognase' in October 2008. This was the first launch in the European Union of the nutraceutical product.

### North America - October 2007

Metagenics Inc, a leading developer, manufacturer and marketeer of nutraceuticals, headquartered in San Clemente, California launched Colostrinin™ branded as 'Cognisure' in the North American market. This was a key launch for ReGen as the USA alone accounts for around one third of the world nutraceutical market

### Australia - July 2007

Healthworld Limited (a subsidiary of Metagenics Inc.) launched Colostrinin™ in the Australian market.











### Operational review continued

## Major Scientific Milestones Colostrinin™

### 2009

In March 2009 the Company reported that it had successfully completed the first stage of an evaluation of several Colostrinin™ derived peptides to modulate the expression of genes associated with obesity and Alzheimer's disease. This work was performed under a Sponsored Research Agreement with the University of Texas Medical Branch at Galveston.

#### Alzheimer's disease:

In an *in vitro* study using neuronal cells two synthetic peptides (RG-01 and RG-018) showed significant impact on expression of genes involved in beta-amyloid generation and degradation pathways. Controlling beta-amyloid generation could have important implications in Alzheimer's disease:

#### Anti-obesity:

In an *in vivo* study on obesity Colostrinin<sup>TM</sup>, as well as three peptides in combination, significantly reduced body weight gain in mice fed a high fat diet (HFD).

The obesity data could be used to create another nutraceutical product.

### 2008

In September of 2008 Dr. Marian Kruzel, the Company's Chief Scientific Advisor presented a paper at the 1st Clinical Trials in Alzheimer's Disease Conference, held in Montpellier, France. The paper provided a transcriptomal network analysis of gene expression in cells after exposure to Colostrinin™. Colostrinin™ favourably modulated the expression of several molecules involved in the pathology of Alzheimer's disease (upregulation of bleomycin hydrolase, downregulation of APP and effects on Tau phosphorylation). For the first time we were able to demonstrate how a low dose of Colostrinin™ could produce

significant medical benefits in AD patients. The presentation was published in the Journal of Nutrition Health and Aging (Szaniszlo P, German P, Hajas G, Saenz DN, Kruzel ML, Boldogh I. New insights into clinical trial for Colostrinin in Alzheimer's Disease. J Nutr Health Aging. 2009 Mar; 13(3):235-41).

In June of 2008 ReGen completed its work on gene expression in epithelial cell culture using both Colostrinin™ and specific synthetic peptides. This was published in the Journal of International Immunopharmacology in February 2009 (Szaniszlo P, German P, Hajas G, Saenz DN, Woodberry MW, Kruzel ML, Boldogh I. Effects of Colostrinin on Gene Expression – Transcriptomal Network Analysis. International Immunopharmacology. 2009;9(2):181-193).

In April of 2008 a review paper on Colostrinin™ and its constitutive peptides was published by Dr. Kruzel and Dr. Boldogh in the prestigious Journal of Alzheimer's Disease. It is considered to be the most comprehensive review regarding the potential utility of Colostrinin™ in neurodegenerative disorders. The paper also reviewed the novel mechanisms of action involved in neuroprotection and clearly demonstrates Colostrinin's™ biodiversity.

### 2007

In December 2007 ReGen announced that preliminary results of a study of Colostrinin™ in the treatment of dementia in ageing dogs looked encouraging. The dosing phase of the study had been completed and a preliminary report based on 22/23 subjects showed that Colostrinin™ was well tolerated and that '40% of owners felt that there had been signs of improvement' throughout the trial.

Also in December 2007 ReGen announced that several Colostrinin<sup>TM</sup>-derived peptides had been identified for further development. Two such synthetic peptides may have a potential utility in Alzheimer's disease and a further candidate potential utility in the management of obesity.











Further evidence of the diverse scientific potential of Colostrinin™ was presented in February 2007 when ReGen announced the results of an *in vivo* study that showed Colostrinin™ increases the lifespan of inbred mice predisposed to premature ageing.

In February 2005 the United States Patent and Trademark Office granted US Patent No. 6,852,700 for the use of Colostrinin™ as a medicament, particularly in the treatment of chronic disorders of the central nervous system and the immune system.

### 2006

In August an *in vitro* study published in the peerreviewed Journal of Experimental Therapeutics and Oncology showed that Colostrinin™ reduced the spontaneous or induced mutation frequency in the DNA of cells. This would suggest an impact on both the ageing process and the development of cancer.

In May 2006 formal safety studies started with the commercial form of Colostrinin™.

In January the full results of an *in vitro* study which showed that Colostrinin™ could cause precursor nerve cells to differentiate and proliferate was published in the peer-reviewed journal Cell and Molecular Neurobiology.

### 2005

In October 2005 ReGen presented an important paper regarding the effects of Colostrinin™ on life span in mice at the 21st International Conference of Alzheimer's Disease International in Istanbul.

In June 2005 the peer-reviewed journal 'Neuropeptides' published an article showing that Colostrinin™ can prevent the aggregation of beta amyloid – a toxic protein that builds up in the brains of Alzheimer's disease sufferers.

Also in June 2005 ReGen achieved production scale-up of Colostrinin™ using a proprietary industrial process

In April 2005 ReGen announced that Colostrinin™ and a nine amino-acid synthetic homolog of a Colostrinin™-derived peptide showed neuroprotection in a cell line model of Parkinson's disease.

### 2004

October 2004 at The Society for Neuroscience meeting, scientists at the Open University, showed that pre-treatment with Colostrinin™ in a chick model can limit the memory impairment induced by beta amyloid, a toxic protein involved in the pathology of Alzheimer's disease. Bovine-sourced Colostrinin™ made by ReGen's new production process was shown to have the same activity profile as the ovine-sourced material used in the clinical studies.

In July 2004 at the 9<sup>th</sup> International Conference on Alzheimer's Disease and Related Disorders scientists reported that the neuroprotective effects of Colostrinin™ can be due, in part, to a decrease in beta amyloid-induced apoptosis.

Also in July, at the Federation of European Neurological Societies meeting it was reported that Colostrinin™ was able to enhance memory when compared with control saline injections in young chicks.

In May 2004 at the 14<sup>th</sup> Alzheimer Europe Conference scientists presented two papers. In one they showed that Colostrinin<sup>™</sup> could prevent the aggregation of beta amyloid and reduce its toxic effect on neuroblastoma cells and in the other they showed that Colostrinin<sup>™</sup> could block the proliferation and promote the differentiation of primary cells into neuronal cells

In February 2004 ReGen's placebo-controlled clinical trial of Colostrinin™ given over 30 weeks (RG-010) to 106 Alzheimer's sufferers was published in the peer-reviewed Journal of Alzheimer's Disease. This study reached











### Operational review continued

statistical significance in its main clinical end-point of cognitive efficacy and its main secondary endpoint of Independent Activities of Daily Living (IADL).

### Zolpidem

### 2009

A study confirming the zolpidem effect in brain damage was presented at the 4th International Congress on Brain and Behaviour on 3 - 6 December 2009 in Thessaloniki, Greece by Dr Ralf Clauss. 23 of 41 consecutive adult patients, at least 6 months after brain damage, were selected as neurologically disabled patients after scoring less than 100/100 on the Barthel Index. Causes of brain damage included stroke (12 subjects), traumatic brain injury (7 subjects), anaphylaxis (2 subjects), drug overdoes (1 subject) and birth injury (1 subject). The selected 23 patients had a baseline SPECT scan before starting daily zolpidem therapy and a second within two weeks of therapy, performed 1 hour after receiving 10 mg oral zolpidem. Scans were designated as improved when at least two of three independent assessors detected improvement after zolpidem. The rest were designated non-improved.

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### 2008

In November, 2008, the preliminary findings from a study at the University of Pretoria, examining the use of zolpidem to reverse neurodormancy after brain damage were presented at the Asia Oceania Congress of Nuclear Medicine and Biology, Delhi, India.

In this prospective study, 40 patients with clinical and neurologically-confirmed brain damage due to various causes (mainly stroke and traumatic brain injury) were investigated by brain SPECT imaging before and after zolpidem. All patients underwent non-attenuation corrected Ceretec rest/zolpidem imaging. All testing was completed within a maximum period of a week. Three neuroimaging experts not directly involved in the study reviewed all of the images for each subject blinded to the treatment received. Concordance/discordance of brain SPECT and neurological assessment was determined. The results show that 72.5% of patients demonstrated an improvement in cerebral perfusion after zolpidem, which is significantly higher than the response rate based on clinical measurements only.

In June 2008, the Company announced that collaborators at Aston University, Birmingham UK had discovered new evidence of zolpidem's unique mode of action using pharmacomagneto-encephalography (MEG) brain imaging. They found that non-functioning areas of the brain within the stroke damaged area of a patient were being kept in a dormant state by excessive slow wave activity that zolpidem reversed. This effect could not be reproduced with either a placebo or another sedative with a similar pharmacological action (zopiclone). ReGen has filed a new patent application around this important discovery.

In 2008 further analysis of data from ReGen's first clinical study in patients with long-standing











brain damage established that the sublingual route of dosing is more consistent, faster in onset and more potent than existing tablets. Such characteristics will greatly help patients to control the effect of dosing when they need to avoid sedation. More importantly, the trial also demonstrated that 2.5 mg sublingually was non-sedative even when repeated. Since published reports have shown 2.5mg to be an effective dose in this new indication, this finding established a clear demarcation between ReGen's new indication and generic sedative formulations.

### 2007

In August 2007 the Company announced the successful completion of a Phase II trial in South Africa where it was established that a 2.5mg dose of a novel sublingual formulation of zolpidem is non-sedating. Two television documentaries on the effects of zolpidem in the treatment of brain trauma were screened in 2007. The most important one in scientific terms was screened in March on the Discovery Channel. This programme gave full prominence to ReGen's work in this area.

### 2006

Zolpidem was acquired in February 2006 as in a number of 'open' clinical case observations zolpidem had been shown to normalise areas of brain dormancy secondary to a primary lesion in brain damaged conditions.

# Our Market Place, Principal Risks and Uncertainties, Outlook

In summary the principal risks for ReGen are that:

- It will not be able to fund its development.
- It will not be able to do further licensing deals
- Revenues from licensing deals may not be sufficient to sustain the Company.
- It is a very small player in an international market.

ReGen is now primarily active in the commercial development of its nutraceutical product Colostrinin™. It is however seeking to capitalise on previous research done in the pharmaceutical field with the Colostrinin™ derived peptides and zolpidem.

The nutraceutical business is a different proposition in terms of risk/reward than pharmaceuticals, as generally it is easier to get a product to market because there the regulatory hurdles are less, but the returns will usually be lower. In terms of structure, the similarities are that ReGen is dependent on a marketeer to sell its end product, but it is able to get the product sufficiently developed so that it is ready to be marketed, unlike in pharmaceuticals. Although there are global nutraceutical marketeers such as Nestlé and Unilever there are a number of individual national or regional companies who are able to sell ReGen's product, which lowers its risk and this is shown by the number of deals it has done. We would, however, admit that there are still major deals to be done and the prime risk at this stage is not doing a licensing deal in the remaining key markets. We would also point out that we need to achieve the sales revenue necessary to sustain the Company once the product is launched.











### Operational review continued

ReGen has tried to guard against the licensing risk by initially employing an international licensing consultancy to introduce it to prospective licensees and advise it on the terms of appropriate licensing deals. ReGen now believes it has sufficient internal expertise built up to negotiate the licensing deals itself. To date, the efforts of the licensing consultancy and ourselves have resulted in the Company achieving licensing arrangements in North America, Australasia, parts of Europe, Turkey and India.

With regard to the problems of funding, ReGen has a long history of raising working capital and has now been on the AIM market since March 2000, having joined Ofex in December 1998.

The prime risk for ReGen is that we will not be able to do further deals or that we will not do particularly attractive deals. There is also a significant risk, before ReGen has done a deal, that we will run out of money, as we may not be able to attract further funding. Other risks are that, given the size of the Company, its competitive intelligence may both overestimate its opportunities and underestimate its difficulties. Essentially one must remember that ReGen is a very 'small fish in the nutraceutical and pharmaceutical sea'.

# American Depositary Receipt (ADR) Programme

Looking to the future development of the Company, we established an ADR programme in the US in March 2005. On the financial side, the US is by far the largest capital market, particularly for biotech. In consequence we believe that Shareholder value could be enhanced by having a US-based share trading facility as in time it could be used for capital raising and in the long-term for acquisition.











### ReGen management

### Percy Lomax BSc (Econ) FCSI

(Executive Chairman)

Percy Lomax joined the commercial intelligence department of Allen & Hanbury's, part of the Glaxo Group, in July 1967 and has been involved in the drug industry since then, either as an adviser or an employee. He was stockbroker in August 1987 to the flotation of Medirace Plc, which became Medeva Plc. As a healthcare analyst at Robert Fleming and Co he worked on the second fund raising for Wellcome in 1992. In 1995 he co-founded PolyMasc Pharmaceuticals Plc and was instrumental in its flotation in December of that year. In 1996 he was responsible for the rescue rights issue of Proteus Plc and the flotation of Oxford BioMedica plc. He joined the Board of ReGen prior to the Ofex flotation in 1998.

### **Norman Lott BSc ACA**

(Finance Director and Company Secretary)

Norman Lott qualified as a chartered accountant in 1980 with Ernst & Whinney and joined Peat Marwick Mitchell & Company in their Hong Kong office in 1981. From 1984 onwards he held a number of senior financial positions in commerce and industry before joining Tiger Books International Plc in 1993 as Finance Director and was subsequently appointed as Deputy Managing Director. He joined the Board of ReGen as Finance Director in June 1999.

### **Martin Small**

(New Projects Director)

Martin Small entered the international commodity trade in 1982, initially trading sugar in the Far Eastern and Middle Eastern markets, before moving to commodity broking in 1985. Working with clients in the Far East and West Africa, he gained an extensive knowledge of the oilseed industry and, in particular, the Hong Kong edible oil market. From the beginning of 1991, Martin developed various industrial business ventures in Scandinavia and Poland. In 1996 he met Jerzy Georgiades and learned of his work on a prospective therapy for Alzheimer's disease in Poland. The work with Dr Georgiades lead to their founding of The Georgiades Foundation Ltd and the acquisition of the ownership and development rights to Colostrinin™ from its original Polish inventors in October 1997. Following the sale of The Georgiades Foundation Ltd to ReGen in October 1998, Martin joined ReGen as General Manager and was appointed to the Board as New Projects Director on 10 December 2002.











### ReGen management continued

### **Timothy Shilton BSc Hons**

(Development Director)

Tim Shilton has been involved in the pharmaceutical industry for nearly 30 years. After completing his degree at Surrey University in 1979 Tim joined the Regulatory Affairs Department at Wellcome, where he was specifically involved in product registration and licensing. He later transferred to International Strategic Marketing/New Products, where he was part of the team responsible for establishing Wellcome as the market leader in antivirals with Zovirax (cyclovir) and Retrovir (AZT). After leaving Wellcome in 1995 Tim consulted for various pharmaceutical and healthcare communications companies, before joining Phairson Medical in 1996, as Product Development and Marketing Director. Tim joined ReGen in November 2000 as Development Manager and was appointed to the Board as Development Director on 10 December 2002.

### Dr Peter Garrod BDS, LDS

(Non-Executive Director)

Dr Garrod was educated at the London Hospital, part of the University of London. He graduated with a BDS and is a LDS of the Royal College of Surgeons. He has been the Senior Partner of the Bower Dental Centre, which specialises in advanced dental cosmetic surgery, for the last 18 years.

#### **Professor Marian L Kruzel PhD**

(Chief Scientific Officer)

Professor Kruzel is a faculty member of the Department of Integrative Biology and Pharmacology, The University of Texas Medical School at Houston. He is an internationally recognised immunologist with an established interest and expertise in inflammation and age-related pathophysiology. He is the recipient of numerous grants and a participant in NIH funded projects. Also, he serves as a reviewer on several scientific journals, including Clinical and Experimental Immunology and Cellular and Molecular Biology Letters. Recently, he has been elected as an Associate Editor of the Journal of Experimental Therapeutics and Oncology. In 1999 Prof. Kruzel founded PharmaReview Corporation, a consulting firm that provides guidance to bio-medical research companies in project design and development of clinical protocols. He is the former Chairman of the Board of Cancer Coalition of America. Through a consultancy agreement with ReGen, Prof. Kruzel is responsible to the Board for scientific research and development and management of the scientific aspects of future clinical development on behalf of the Company.











### **Report of the Directors**

for the year ended 31 December 2009

The Directors present their report together with the audited financial statements for the year ended 31 December 2009.

#### Results and dividends

The consolidated income statement is set out on page 19 and shows the loss for the year.

The Directors do not recommend the payment of an ordinary dividend (2008 - £nil).

### **Principal activities**

The principal activity of the Group was the development of healthcare products both nutraceutical and ethical pharmaceuticals.

### **Business performance**

The turnover for 2009 at £56,055 was 39% down on last year mainly as a result of an apparent drop in US sales. The main reason for this was a bulk order placed from the US distributor in 2008 to satisfy the expected demand for the professional market in 2009. Meanwhile sales arose during 2009 in two new territories, the UK and Poland.

Development costs at £79,648 were considerably less than last year's total of £411,938. With the ongoing difficulties we were facing in the financial markets in raising sufficient monies to justify our full commitment to the Peptide and Zolpidem programmes we continued to concentrate our efforts and financial resources on the Colostrinin<sup>TM</sup> roll out programme. Hence the drop in development spend with a view to conserving cash and pushing to accelerate our drive towards self sustainability by seeking to develop more licensing deals with Colostrinin<sup>TM</sup>.

Other administrative costs also reduced dramatically by 39% from £1,176,224 in 2008 to £719,569 for 2009. If you took out the non-cash items of depreciation, patent amortisation and the share-based option credit in 2008 and compared the costs on a cash basis the other administration costs have fallen by 47% from £971,843 in 2008 to £480,795 in 2009. As a result of these factors the loss after tax for the year decreased by 49% to £729,938.

The Group's net assets at 31 December 2009 are lower than 2008, mainly as a result of reduction in the patent carrying value by just over £195,000. However in these continuing difficult financial markets the Company has continued to raise regular smaller amounts of funds as opposed to the historical larger one off tranches. Indeed since the statement of financial position date further funds of £431,000 have been successfully raised.

The Group's key performance indicators are linked in with its commercial and scientific development. On the commercial side the key objectives are to progress further retail licensing deals in respect of Colostrinin™ on a global basis. During 2009 the Company has signed licensing deals with Eczacibasi in Turkey, PRG Nutraceuticals in the UK and Tagerr in Poland and are in discussions with various parties in respect of other territories. While sales have been recorded in both the UK and Poland in 2009 the Company has now fulfilled its initial order from Eczacibasi in Turkey in 2010. On 27 April 2010 ReGen has signed a Supply Agreement with a company in India. Further details are contained in the Chairman's statement. On the scientific and development front, although the Company has been constrained through the lack of available funding it has continued where possible to further explore certain peptides in relation to the treatment of obesity and Alzheimer's disease with a view to developing them to a status of pre-clinical candidates. It is the Company's objective to find development partners for the Colostrinin™ peptides and zolpidem.

### Principal risks, uncertainties and outlook

A review of the principal risks and outlook is contained in the operational review on pages 9 and 10.











### Report of the Directors continued

for the year ended 31 December 2009

#### **Financial Instruments**

Details of the use of financial instruments by the Group are contained in note 4 of the financial statements.

### Policy of the payment of creditors

Amounts due to suppliers are settled within their terms of payment where possible except in cases of dispute.

The number of days purchases of the Group represented by trade creditors at 31 December 2009 was 126 days (2008 117). The payment policy of the Group is to pay all invoices 30 days net, i.e. the end of the month following the date of issue, unless otherwise agreed.

### Corporate governance

The Directors acknowledge the importance of the revised Combined Code issued by the Financial Reporting Council (the Code) in 2008. Whilst compliance is not mandatory, they have applied the Code as appropriate to the Company given its size and nature.

A remuneration committee exists and is chaired by the Company's Non-Executive Director. It reviews the performance of Executive Directors and senior Executives, recommends the scale and structure of their remuneration and reviews the basis of their service agreements with due regard to the interests of Shareholders. No Director participates in decisions concerning his own remuneration.

An audit committee exists and is chaired by the Company's Non-Executive Director.

### Research and development

Research expenditure is recognised in the income statement in the year in which it is incurred. Development expenditure is recognised in the income statement in the year in which it is incurred unless it meets the recognition criteria of IAS 38 "Intangible Assets". Regulatory and other uncertainties generally mean that such criteria are not met. Where the recognition criteria are met, however, intangible assets are capitalised and amortised on a straight-line basis over their useful economic lives from product launch. This policy is in line with industry practise. All expenditure incurred in respect of the development of Colostrinin™ and zolpidem for 2009 has been charged to the consolidated income statement in accordance with this policy.

### **OTCQX**

The Company withdrew its American Depositary Receipt ("ADR") quotation from OTCQX International on 28 August 2009. The ADR's continue to trade in the United States on the Pink Sheets of the US over-the-counter (OTC) market.

### **Charitable Donations**

The Company made charitable donations amounting to £nil (2008 – £375).

#### Events after the balance sheet date

On 14 January 2010, the Company issued 8,333,333 ordinary shares of 0.01p each at a premium of 1.49p per share for a consideration of £125,000.

On 30 March 2010, the Company issued 5,000,000 ordinary shares of 0.01p each at a premium of 1.49p per share for a consideration of £75,000.

On 10 May 2010, the Company issued 11,550,000 ordinary shares of 0.01p each at a premium of 1.99p per share for a consideration of £231,000.

#### Directors

The Directors of the Company during the year and to the date of these financial statements were:

PWC Lomax

N A C Lott

M J Small

T S Shilton

P R Garrod - Non-Executive



#### **Directors' interests**

The Directors' interests in the shares of the Company at the year end were:

	Ordinary shares of 0.1p each 31 December 2009	Ordinary shares of 0.1p each 31 December 2008	Deferred A shares of 4.9p each 31 December 2008 & 2009	Deferred B shares of 9.99p each 31 December 2008 & 2009
P W C Lomax	219,787	53,787	1,448,736	53,787
N A C Lott	1,820	1,820	32,000	1,820
M J Small	58,320	58,320	1,348,736	58,320
T S Shilton	193,632	26,966	_	26,966
P R Garrod	882,500	882,500	3,715,000	882,500

Share options held by Directors are disclosed in note 7 to the financial statements.

### Directors' responsibilities

The Directors are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the Group, for safeguarding the assets of the Company, for taking reasonable steps for the prevention and detection of fraud and other irregularities and for the preparation of a Directors' Report which complies with the requirements of the Companies Act 2006.

The Directors are responsible for preparing the annual report and the financial statements in accordance with the Companies Act 2006. The Directors are also required to prepare financial statements for the Group in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs) and the rules of the London Stock Exchange for companies trading securities on the Alternative Investment Market. The Directors have chosen to prepare financial statements for the Company in accordance with UK Generally Accepted Accounting Practice.

### **Group financial statements**

International Accounting Standard 1 requires that financial statements present fairly for each financial year the Group's financial position, financial performance and cash flows. This requires the faithful representation of the effects of transactions, other events and conditions in accordance with the definitions and recognition criteria for assets, liabilities, income and expenses set out in the International Accounting Standards Board's 'Framework for the preparation and presentation of financial statements'. In virtually all circumstances, a fair presentation will be achieved by compliance with all applicable IFRSs. A fair presentation also requires the Directors to:

- consistently select and apply appropriate accounting policies;
- present information, including accounting policies, in a manner that provides relevant, reliable, comparable and understandable information;
- provide additional disclosures when compliance with the specific requirements in IFRSs is insufficient to enable users to understand the impact of particular transactions, other events and conditions on the entity's financial position and financial performance; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group will continue in business





### Report of the Directors continued

for the year ended 31 December 2009

### **Parent Company financial statements**

Company law requires the Directors to prepare financial statements for each financial year, which give a true and fair view of the state of affairs of the Company and of the profit or loss of the Company for that period. In preparing these financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business;
- make judgements and estimates that are reasonable and prudent; and
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements.

Financial statements are published on the Group's website in accordance with legislation in the United Kingdom governing the preparation and dissemination of financial statements, which may vary from legislation in other jurisdictions. The maintenance and integrity of the Group's website is the responsibility of the Directors. The Directors' responsibility also extends to the ongoing integrity of the financial statements contained therein.

#### Directors' indemnity

Subject to the conditions set out in the Companies Act 2006, the Company has arranged appropriate Directors' and Officers' insurance to indemnify the Directors against liability in respect of proceedings brought by third parties. Such provisions remain in force at the date of this report.

### Directors' statement as to disclosure of information to Auditors

Each of the Directors, who are all members of the Board at the time of approving the Directors' Report, confirms that having made enquiries of fellow Directors:

- so far as each of the Directors is aware, there is no relevant information of which the Company's Auditors are unaware;
   and
- he has taken all the steps that he ought to have taken as a Director in order to make himself aware of any relevant audit information and to establish that the Company's Auditors are aware of that information.

This confirmation is given and should be interpreted in accordance with the provision of section 234 of the Companies Act 2006.

### **Auditors**

Mazars LLP were appointed the Company's Auditors in May 2009 and a resolution to confirm their appointment will be proposed at the Annual General Meeting.

By order of the Board

### N Lott

Secretary

20 May 2010





### **Report of the independent Auditors**

### To the members of ReGen Therapeutics Plc

We have audited the Group and parent Company financial statements (the "financial statements") of ReGen Therapeutics Plc for the year ended 31 December 2009 which comprise the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of financial position, the parent Company balance sheet, the consolidated statement of cash flows, the consolidated statement of changes in equity and the related notes. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union for the consolidated financial statements and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) for the parent Company financial statements and, as regards the parent Company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

### Respective responsibilities of Directors and Auditors

As explained more fully in the Directors' Responsibilities Statements set out on page 15 the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's (APB's) Ethical Standards for Auditors. This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an Auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body for our audit work, for this report, or for the opinions we have formed.

### Scope of the audit of the financial statements

A description of the scope of an audit of financial statements is provided on the APB's website at www.frc.org.uk/apb/scope/UKNP.

### Opinion on the financial statements

In our opinion:

- the Group financial statements give a true and fair view of the state of the Group's affairs as at 31 December 2009 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the parent Company financial statements give a true and fair view of the state of the parent Company's affairs as at 31 December 2009 and of the parent Company's loss for the year then ended;
- the parent Company financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.





### Report of the independent Auditors continued

### Emphasis of matter - Going concern

In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures made in note 2 to the financial statements concerning the ability of the Group to continue as a going concern.

The financial statements have been prepared on the going concern basis, which depends on the outcome of future fund raising and the generation of revenues from licensing deals. These conditions indicate the existence of a material uncertainty, which may cast significant doubt on the ability of the Group to continue as a going concern. The financial statements do not include the adjustments that would result if the Group was unable to continue as a going concern.

### Opinion on the other matters prescribed by the Companies Act 2006

In our opinion the information given in the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

### Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent Company, or returns adequate for our audit have not been received from branches not visited by us;
- the parent Company financial statements are not in agreement with the accounting records and returns;
- certain disclosures of Directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Stephen Bullock (Senior statutory auditor)
for and on behalf of Mazars LLP, Chartered Accountants (Statutory auditor)
Tower Bridge House
St Katharine's Way
London
E1W 1DD

20 May 2010

Note: The maintenance and integrity of the ReGen Therapeutics Plc website is the responsibility of the Directors. The work carried out by the Auditors does not involve consideration of these matters and accordingly the Auditors accept no responsibility for any changes that may have occurred to the financial statements since they were originally presented on the website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.





### **Consolidated income statement**

for the year ended 31 December 2009

	Note	2009 £	2008 £
Continuing operations			
Revenue	5	56,055	91,716
Cost of sales		11,034	20,447
Gross profit		45,021	71,269
Research and development costs		79,648	411,938
Other administrative costs		719,569	1,176,224
Administrative expenses		799,217	1,588,162
Operating loss	6	(754,196)	(1,516,893)
Finance income	9	46	10,308
Finance costs	10	(4,138)	(3,436)
Loss before taxation		(758,288)	(1,510,021)
Taxation	11	28,350	80,590
Loss after taxation for continuing activities	26	(729,938)	(1,429,431)
Discontinued operations			
Loss after taxation from discontinued operations	12	_	(33,936)
Loss after taxation for the year		(729,938)	(1,463,367)
Attributable to:			
Equity holders of the parent		(729,938)	(1,463,367)
Basic and diluted loss per share	13	(2.67p)	(12.27p)
Basic and diluted loss per share on continuing operations		(2.67p)	(11.98p)
Basic and diluted loss per share on discontinued operations		-	(0.29p)



The notes on pages 24 to 49 form part of these consolidated financial statements.



### Consolidated statement of comprehensive income

for the year ended 31 December 2009

	Note	2009 £	2008 £
Loss for the year		(729,938)	(1,463,367)
Other comprehensive income for the year		_	-
Total comprehensive income for the year		(729,938)	(1,463,367)
Attributable to: Equity holders of the parent		(729,938)	(1,463,367)



The notes on pages 24 to 49 form part of these consolidated financial statements.



### Consolidated statement of changes in equity

for the year ended 31 December 2009

	Share capital	Share premium	Other reserves	Retained earnings	Total
	£	£	£	£	£
Opening equity as at 1 January 2008	6,323,835	13,969,394	265,745	(18,118,878)	2,440,096
Loss for the year				(1,463,367)	(1,463,367)
Total comprehensive income for the year	_	_	_	(1,463,367)	(1,463,367)
Issue of share capital	281,168	395,970	_	_	677,138
Share issue costs	_	(218,151)	_	_	(218,151)
Share-based payments/(credit)				(95,532)	(95,532)
Closing equity as at 31 December 2008	6,605,003	14,147,213	265,745	(19,677,777)	1,340,184
Loss for the year				(729,938)	(729,938)
Total comprehensive income for the year	_	_	_	(729,938)	(729,938)
Issue of share capital	2,163	689,022	_	_	691,185
Share issue costs		(88,340)	_		(88,340)
Closing equity as at 31 December 2009	6,607,166	14,747,895	265,745	(20,407,715)	1,213,091

Refer to note 26 for a description of each reserve.





### Consolidated statement of financial position

as at 31 December 2009

	Note	2009 £	2009 £	2008 £	2008 £
Assets					
Non-current assets					
Property, plant and equipment	14	177		1,017	
Intangible assets	15	1,564,205		1,759,250	
			1,564,382		1,760,267
Current assets					
Inventories	18	38,219		28,571	
Trade and other receivables	19	80,573		87,090	
Tax receivable		16,043		80,590	
Cash and cash equivalents	20	30,385		25,157	
Total current assets			165,220		221,408
Total assets			1,729,602		1,981,675
Liabilities					
Current liabilities					
Trade and other payables	21	367,805		489,699	
Loans and borrowings	22	48,706		51,792	
Total current liabilities			416,511		541,491
Non-current liabilities					
Provisions	23		100,000		100,000
Total liabilities			516,511		641,491
Total net assets			1,213,091		1,340,184
Equity					
Share capital	24		6,607,166		6,605,003
Share premium	26		14,747,895		14,147,213
Other reserves	26		265,745		265,745
Retained earnings	26		(20,407,715)		(19,677,777)
Equity attributable to equity holders of the parent			1,213,091		1,340,184

The financial statements were approved by the Board and authorised for issue on 20 May 2010 and were signed on its behalf by

### P W C Lomax

Director

The notes on pages 24 to 49 form part of these consolidated financial statements.

Registered Number: 3508592



### **Consolidated statement of cash flows**

for the year ended 31 December 2009

	Note	2009 £	2008 £
Operating activities		-	_
Loss after tax from continuing activities		(729,938)	(1,429,431)
Loss after tax from discontinued activities			(33,936)
Loss after tax for the financial year		(729,938)	(1,463,367)
Amortisation of intangible assets		237,934	298,256
Depreciation of property, plant and equipment		840	1,656
Share option credit		-	(95,532)
Finance costs		4,138	7,830
Finance income		(46)	(10,311)
Taxation credit		(28,350)	(80,590)
Taxation received		92,897	145,833
Operating cash flows before movements in working capital and provisions		(422,525)	(1,196,225)
Increase in inventories		(9,648)	(21,922)
Decrease in receivables		6,517	125,689
(Decrease)/increase in payables		(121,894)	178,064
Net cash flows from operating activities		(547,550)	(914,394)
Investing activities			
Interest received		46	10,311
Purchase of intangible assets		(42,889)	(110,947)
Net cash flows used in investing activities		(42,843)	(100,636)
Financing activities			
Proceeds from issue of share capital		691,185	677,138
Expenses paid on share issue		(88,340)	(218,151)
Interest paid		(4,138)	(7,830)
Net cash flows from financing activities		598,707	451,157
Net increase/(decrease) in cash and cash equivalents		8,314	(563,873)
Opening cash and cash equivalents	20	(26,635)	537,238
Closing cash and cash equivalents	20	(18,321)	(26,635)



The notes on pages 24 to 49 form part of these consolidated financial statements.



### Notes forming part of the financial statements

for the year ended 31 December 2009

#### 1 General information

The principal activity of ReGen Therapeutics Plc is the development of healthcare products both nutraceutical and ethical pharmaceuticals. The Company is registered in the UK and was incorporated on 11 February 1998 under the Companies Act. The address of its registered office is Suite 306, 73 Watling Street, London, EC4M 9BJ. The registered number of the Company is 03508592.

### 2 Accounting policies

### **Basis of preparation**

These financial statements have been prepared in accordance with International Financial Reporting Standards (IFRSs and IFRIC interpretations) issued by the International Accounting Standards Board (IASB) as adopted by European Union ("adopted IFRSs") and with those parts of the Companies Act 2006 applicable to companies preparing their accounts under IFRS.

### Going concern

The financial statements have been prepared on a going concern basis. However, the Group's ability to continue as a going concern is reliant upon successfully obtaining funds as it moves towards self sustainability and to finance its ongoing development. In considering the appropriateness of this basis of preparation the Directors have reviewed the Company's working capital forecasts. They believe that the funds raised recently, including new equity funds of £431,000 in aggregate raised between the statement of financial position date and the date of approval of these financial statements, together with further options being considered and taken in conjunction with revenues from licensing, will be sufficient for the Group's purposes for a minimum of 12 months from the date of the approval of the financial statements. If the Group was unable to secure sufficient funding to enable it to continue on a going concern basis then adjustments would be necessary to write down assets to their recoverable amounts, reclassify fixed assets and long-term liabilities as current and provide for additional liabilities.

#### Adoption of new standards during the year

In the current financial year, the Group has adopted IFRS 8 "Operating Segments" and IAS 1 Presentation of Financial Statements (revised).

IFRS 8 replaces IAS 14 "Segment Reporting" effective from 1 January 2009. The accounting policy for identifying operating segments is now based on internal management reporting information that is regularly reviewed by the chief operating decision maker. Previously IAS 14 required the Group to identify two sets of segments (business and geographical) based on risks and rewards of the operating segments. As a result of the application of IFRS 8, the Group's segmental information has been presented as discussed in note 2 and comparative information has been represented accordingly.

IAS 1 (revised) requires non-owner changes in equity to be presented separately from owner changes in equity within a performance statement. The Group have chosen to present two performance statements, the consolidated income statement and the consolidated statement of comprehensive income. The statement of changes in equity has been included as a primary statement and presents all owner changes in equity and non-owners changes in equity.

### Standards, amendments and interpretations to published standards not yet effective

The Directors anticipate that the adoption of IFRS 3, IFRS 9, IAS 17, IAS 31, IAS 32, IAS 39, IFRIC 14, IFRIC 17 and IFRIC 18 in future periods will have no material impact on the financial information of the Group or Company.





#### 2 Accounting policies continued

The Group will adopt the following as and when they become effective.

- IAS 7 Statement of Cash Flows, revised 2009 (effective 1 January 2010)
- IAS 24 Related Party Disclosures, revised 2009 (effective I January 2011)
- IAS 27 Consolidated and Separate Financial Statements arising from amendments to IFRS 3 (effective 1 July 2009)
- IAS 36 Impairment of Assets, revised 2009 (effective 1 January 2010)
- IFRC 19 Extinguishing Financial Liabilities with Equity Instruments (effective 1 July 2010)

The Group has already commenced the assessment of the impact to the Group and is not yet in a position to state whether these would have a significant impact on its results of operations and financial position.

The Directors also do not consider the adoption of the amendments resulting from the May 2008 and April 2009 Annual Improvement project will result in a material impact on the financial information of the Group.

Except as noted above, the following principal accounting policies have been applied consistently in the preparation of these financial statements:

### Research and development

Research expenditure is recognised in the income statement in the year in which it is incurred. Development expenditure is recognised in the income statement in the year in which it is incurred unless it meets the recognition criteria of IAS 38 "Intangible Assets". Regulatory and other uncertainties generally mean that such criteria are not met. Where, however the recognition criteria are met, intangible assets are capitalised and amortised on a straight-line basis over their useful economic lives from product launch. This policy is in line with industry practise.

#### Revenue

Revenue represents amounts invoiced during the year for goods and services provided in the normal course of business, exclusive of Value Added Tax.

Sales of Colostrinin™ are recognised when goods are delivered and title has passed.

#### **Operating loss**

Operating loss is stated after crediting all operating income and charging all operating expenses but before crediting/charging financial income/expense.

### Basis of consolidation

Where the Company has the power, either directly or indirectly, to govern the financial and operating policies of another entity or business so as to obtain benefits from its activities, it is classified as a subsidiary. The consolidated financial statements present the results of the Company and its subsidiaries ("the Group") as if they formed a single entity. Intercompany transactions and balances between Group companies are therefore eliminated in full.

### **Business combinations**

The consolidated financial statements incorporate the results of business combinations using the purchase method. In the consolidated balance sheet, the acquiree's identifiable assets, liabilities and contingent liabilities are initially recognised at their fair values at the acquisition date. The results of the acquired operations are included in the consolidated income statement from the date on which control is obtained.





### Notes forming part of the financial statements continued

for the year ended 31 December 2009

### 2 Accounting policies continued Goodwill

Goodwill represents the excess of the cost of a business combination over the interest in the fair value of the identifiable assets, liabilities and contingent liabilities acquired. Cost comprises the fair values of assets given, liabilities assumed and equity instruments issued, plus any direct costs of acquisition.

Goodwill is capitalised as an intangible asset with any impairment in carrying value being charged to the consolidated income statement. Where the fair value of identifiable assets, liabilities and contingent liabilities exceed the fair value of consideration paid, the excess is credited in full to the consolidated income statement on the acquisition date.

### Impairment of non-financial assets

Impairment tests on goodwill and other intangible assets with indefinite useful economic lives are undertaken annually on 31 December. Other non-financial assets are subject to impairment tests whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. Where the carrying value of an asset exceeds its recoverable amount (i.e. the higher of value in use and fair value less costs to sell), the asset is written down accordingly.

Where it is not possible to estimate the recoverable amount of an individual asset, the impairment test is carried out on the asset's cash-generating unit (i.e. the lowest group of assets in which the asset belongs for which there are separately identifiable cash flows). Goodwill is allocated on initial recognition to each of the Group's cash-generating units that are expected to benefit from the synergies of the combination giving rise to the goodwill (see note 16).

### Segment reporting

The Group has adopted IFRS 8 "Operating Segments" effective from 1 January 2009. IFRS 8 requires operating segments to be reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Board of Directors. The Board reviews the business from both a geographic and product perspective. The provision of clinical research services was effectively discontinued in 2008, but it was felt necessary to continue to report this as a segment for comparative purposes even though there was insignificant amounts involved in 2009. The Board assesses the performance of the operating segments based on revenues and profit before taxation for products and revenues only by geographical location. The Board do not review the information about total assets and total liabilities or capital expenditure for each reportable segment and therefore this information has not been separately provided.

### Property, plant and equipment

Items of property, plant and equipment are initially recognised at cost. As well as the purchase price, cost directly attributable costs and the estimated present value of any future unavoidable costs of dismantling and removing items.

All items of property, plant and equipment are carried at depreciated cost.

Depreciation is provided to write off the carrying value of items over their expected useful lives. It is applied at the following rate:

Office equipment - 25% per annum on cost.





### 2 Accounting policies continued

#### Inventories

Inventories are initially recognised at cost, and subsequently at the lower of cost and net realisable value. Cost comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition. In determining the cost of inventories sold, the batches are identified and the actual cost of the inventories is used.

### Foreign currency

Foreign currency transactions of individual companies are translated at the rates ruling when they occurred. Foreign currency monetary assets and liabilities are translated at the rates ruling at the statement of financial position dates. Any differences are taken to the profit and loss account.

The results of overseas operations are translated at the rate when the transaction took place and the statement of financial position translated into Sterling at the rate of exchange ruling on the statement of financial position date. Exchange differences, which arise from translation of the opening net assets and results of foreign subsidiary undertakings, are taken to reserves.

### **Financial instruments**

Financial assets and financial liabilities are recognised on the Group's balance sheet at fair value when the Group becomes a party to the contractual provisions of the instrument.

#### Trade receivables

Trade receivables represent amounts due from customers in the normal course of business. These are recognised at fair value and subsequently at amortised cost unless the effect of discounting is immaterial. Appropriate allowance is made for impairment.

### Cash and cash equivalents

Cash and cash equivalents include cash at hand and deposits held at call with banks with original maturities of three months or less.

### Trade payables

Trade payables are initially measured at fair value, and are subsequently measured at amortised cost, using the effective interest rate method.

### Internally generated intangible assets (research and development costs)

Research expenditure is recognised in the income statement in the year in which it is incurred. Development expenditure is recognised in the income statement in the year in which it is incurred unless it meets the recognition criteria of IAS 38 "Intangible Assets", namely:

- it is technically feasible to develop the product for it to be sold;
- adequate resources are available to complete the development;
- there is an intention to complete and sell the product;
- the Group is able to sell the product;
- sale of the product will generate future economic benefits; and
- expenditure on the project can be measured reliably.





### Notes forming part of the financial statements continued

for the year ended 31 December 2009

### 2 Accounting policies continued

Regulatory and other uncertainties generally mean that such criteria are not met. Where, however, the recognition criteria are met, intangible assets are capitalised and amortised on a straight-line basis over their useful economic lives from product launch.

### Externally generated intangible assets (Patents and trademarks)

Externally acquired intangible assets are initially recognised at cost and subsequently amortised on a straight-line basis over their useful economic lives. The amortisation expense is included within the administrative expenses line in the consolidated income statement.

The significant intangibles recognised by the Group and their useful economic lives are as follows:

Trademarks Indefinite

Patents Length of patent – up to 20 years

Costs to obtain patent rights for the use of Colostrinin<sup>™</sup> have been capitalised and will be amortised on a straight-line basis over the expected useful life of the patent from the date the patent is granted.

### **Deferred taxation**

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability in the statement of financial position differs from its tax base, except for differences arising on:

- the initial recognition of goodwill;
- the initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting or taxable profit; and
- investments in subsidiaries and jointly controlled entities where the Group is able to control the timing of the reversal of the difference and it is probable that the difference will not reverse in the foreseeable future.

Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the statement of financial position date and are expected to apply when the deferred tax liabilities/(assets) are settled/ (recovered).

### Leased assets

Where substantially all of the risks and rewards incidental to ownership are not transferred to the Group (an "operating lease"), the total rentals payable under the lease are charged to the consolidated income statement on a straight-line basis over the lease term. The aggregate benefit of lease incentives is recognised as a reduction of the rental expense over the lease term on a straight-line basis.

The land and buildings elements of property leases are considered separately for the purposes of lease classification and are classified as operating leases.





### 2 Accounting policies continued

### **Share-based payment**

Where share options are awarded to employees, the fair value of the options at the date of grant is charged to the income statement over the vesting period. Non-market vesting conditions are taken into account by adjusting the number of equity investments expected to vest at each statement of financial position date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of options that eventually vest. Market vesting conditions are factored into the fair value of the options granted. As long as all other vesting conditions are satisfied, a charge is made irrespective of whether the market vesting conditions are satisfied. The cumulative expense is not adjusted for failure to achieve a market vesting condition.

Where terms and conditions of options are modified before they vest, the increase in the fair value of the options, measured immediately before and after the modification, is also charged to the income statement over the remaining vesting period.

Where equity instruments are granted to persons other than employees, the income statement is charged with the fair value of goods and services received.

#### Cash and cash equivalents

For the purposes of the statement of cash flows, cash and cash equivalents are defined as cash available on demand and short-term deposits.

### **Provisions**

Provisions are recognised for liabilities of uncertain timing or amounts that have arisen as a result of past transactions.





### Notes forming part of the financial statements continued

for the year ended 31 December 2009

### 3 Critical accounting estimates and judgements

The Group makes certain estimates and assumptions regarding the future. Estimates and judgements are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

### (a) Impairment of goodwill

The Group is required to test, on an annual basis, whether goodwill has suffered any impairment. The recoverable amount is determined based on value in use calculations. The use of this method requires the estimation of future cash flows and the choice of a discount rate in order to calculate the present value of cash flows. Actual outcomes could vary from those projected, in particular the value in use is dependant on future revenue streams which are not certain. More information including carrying values is included in note 16.

### (b) Useful lives and carrying values of intangible assets

Intangible assets are amortised over their useful lives. Useful lives are based on the management's estimates of the period that the assets will generate revenue, which are periodically reviewed for continued appropriateness. The useful life of patents are determined by the length of the patents, which are 20 years from the application date, and they are amortised from the date the patent is granted. Changes to estimates can result in significant variations in the carrying value and amounts charged to the consolidated income statement in specific periods. More details including carrying values are included in note 15.

### (c) Research and development

Development expenditure was recognised in the income statement during the year. Management made the judgement not to capitalise this expenditure as it did not meet the recognition criteria of IAS 38 in that it related to costs incurred on the development of a product or products, which had not been approved from a regulatory point of view at that stage.

### (d) Share-based payment

The Group has an equity-settled share-based scheme for its employees. Employee services received, and the corresponding increase in equity, are measured by reference to the fair value of the equity instruments at the date of grant, excluding the impact of any non-market vesting conditions. The fair value of share options is estimated by using the Black-Scholes valuation model on the date of the grant based on certain assumptions. Those assumptions include, among others, the dividend growth rate, expected volatility, expected life of the options and number of options expected to vest. More details including carrying values are included in note 25.

### (e) Going concern

See note 2 for further details of the going concern risk.





#### 4 Financial Instruments - Risk Management

The Group is exposed through its operations to liquidity risk and credit risk, and is also exposed to market risk on interest on its borrowings. The Directors do not believe the Group has any significant currency risk. The Directors are of the opinion that there is no difference between the fair value and book value of financial instruments.

In common with all other businesses, the Group is exposed to risks that arise from its use of financial instruments. This note describes the Group's objectives, policies and processes for managing those risks and the methods used to measure them where appropriate. Further quantitative information in respect of these risks is presented throughout these financial statements.

There have been no substantive changes in the Group's exposure to financial instrument risks, its objectives, policies and processes for managing those risks or the methods used to measure them from previous periods unless otherwise stated in this note.

The list of financial instruments used by the Group, from which financial instrument risk arises are as follows:

- trade receivables
- cash and cash equivalents
- bank overdraft
- trade and other payables

	Loans, cash and cash equivalents and receivables held at amortised cost		and trade payables held at amortised cost	
	2009	2008	2009	2008
	£	£	£	£
Current financial assets				
Trade receivables	23,788	15,976	_	_
Cash and cash equivalents	30,385	25,157	-	_
Current financial liabilities				
Trade payables	_	_	309,770	419,308
Borrowings	-	_	48,706	51,792
Total	54,173	41,133	358,476	471,100

The Board has overall responsibility for the determination of the Group's risk management objectives and policies and it sets policies that seek to reduce risk as far as possible without unduly affecting the Group's competitiveness and flexibility. Further details regarding these policies are set out overleaf:





### Notes forming part of the financial statements continued

for the year ended 31 December 2009

### 4 Financial Instruments – Risk Management continued Liquidity risk

The principal risk to the Group is liquidity, which arises from the Group's management of working capital. It is a risk that the Group will encounter difficulty in meeting its financial obligations as they fall due. This aspect is kept under review by the Directors and in this respect the Board receives rolling 12 month cash flow projections on a monthly basis as well as information regarding cash balances. It is the Group's policy as regards liquidity to ensure sufficient cash resources are maintained to meet short-term liabilities. All financial liabilities at the year end are due within 180 days.

When the Group has surplus cash following capital raisings, the funds are placed on the money market in a mixture of short-term deposits and current accounts in order to obtain the best possible return on monies deposited, yet retaining the flexibility in terms of access to allow the Group to meet its liabilities when they become due.

The subsidiary company GCPUL has a bank overdraft outstanding and the Company have agreed to make regular repayments over a period of time. The bank overdraft is secured by way of a fixed and floating charge over the GCPUL's assets.

#### Credit risk

The Group's credit risk is primarily attributable to its trade receivables, which is represented by a small number of well-known and reputable customers. To help mitigate the exposure, credit worthiness checks are undertaken before entering into contracts with new customers in cases where it is deemed necessary. Amounts presented in the statement of financial position are stated net of allowances for doubtful recovery. There is no concentration of credit risk within trade receivables. The credit risk on liquid funds is limited as the funds are predominantly held at a reputable bank. The Group's maximum exposure to credit risk is £66,649 (2008 – £49,726).

### Market risk

The cash deposits are held in a mixture of short term deposits and current accounts at floating rates. There is a market risk arising from interest rates on the Group's borrowings but this is not considered to be material.

### Foreign exchange risk

Foreign exchange risk may arise when the Group enters into transactions denominated in a foreign currency. The Directors do not believe the Group has any significant currency risk. The Group is exposed to currency risk on purchases made from a small number of suppliers based in the USA. The Group also sells to a customer based in the USA and the US Dollar denominated receivables act as a partial hedge against US Dollar denominated payables. The Directors consider the appropriateness of the use of currency derivatives to hedge foreign exchange risk when they deem such risk to be material to the Group's operations. No material forward exchange contracts were entered into in either the current or comparative period. The remaining US Dollar exposure on suppliers should be covered by US Dollar receivables going forward as a natural hedge. It is therefore unlikely that the use of forward contracts will be necessary going forward in the short-term as it is not envisaged that there will be any significant exposure in this area. As all financial assets and liabilities are short-term in nature, this risk is not considered to be material.

### Capital

The Group considers its capital to comprise its ordinary share capital and share premium. The Group has historically considered equity funding as the most appropriate form of capital for the Group but keeps this under review bearing in mind the risks, costs and benefits to equity Shareholders of introducing debt finance. The Group's capital management objectives are to safeguard the entity's ability to continue as a going concern, so that it can continue to provide returns for Shareholders and benefits for other stakeholders and to provide an adequate return to Shareholders by pricing products and services commensurately with the level of risk.





5	Rev	enue
---	-----	------

	2009	2008
Revenue arises from:	£	£
Sale of Colostrinin™	56,055	91,716
	56,055	94,982
6 Loss from operations		
	2009	2008
	£	£
This has been arrived at after charging/(crediting):		
Inventory expense	23,364	20,447
Staff costs (see note 7)	262,110	356,079
Depreciation of property, plant and equipment	840	1,656
Amortisation of intangible non-current assets	237,934	298,256
Foreign exchange losses	8,538	2,657
Fees payable to the Company Auditor for the audit of the parent Company		
and the consolidated financial statements	15,000	18,000
Fees payable to the Company's Auditor for other services:		
– The audit of the Company's subsidiaries pursuant to legislation	3,000	6,000
<ul> <li>Other services relating to taxation</li> </ul>	7,450	_
Operating lease expense – property	44,031	116,418
Share-based (credit) (see note 25)	_	(95,532)

Included within the Group audit fee is an amount of £15,000 (2008 – £18,000) in respect of the Company.





### Notes forming part of the financial statements continued

for the year ended 31 December 2009

### 7 Staff costs

	2009	2008
	£	£
Staff costs (including Directors) comprise:	_	_
Wages and salaries	236,250	403,904
Social security costs	25,860	46,520
Other share-based payment (credit)/expense (see note 25)	-	(94,345)
	262,110	356,079
The average number of employees during the year, including Directors, was as follows:		
	Number	Number
Administration	5	6
Scientific	1	1
	6	7

Included in the share-based (credit) of £nil (2008 – (£95,532)) is £nil (2008 – (£94,345) relating to the share-based payments to employees and Directors, which is included in administrative expenses.

### **Directors' remuneration**

The remuneration of the Directors of the Company are set out below.

The formation of the Bhootore of the Company are content solow.	2009	2008
	£	£
Salaries	199,500	363,916
Private health benefit	_	8,175
Share-based payment expense (non-cash item)	-	(93,265)
	199,500	278,826



#### 7 Staff costs continued

Directors' emoluments by individual are as follows:

	2009	2009 Share-based payment expense	2009	2008	2008 Share-based payment expense	2008
•	ash items	(non-cash item)	Total	Cash items	(non-cash item)	Total
C	£	£	£	£	£	£
P W C Lomax	55,125	_	55,125	99,460	(28,066)	71,394
K B Corbin	_	-	_	14,791	(5,828)	8,963
N A C Lott	42,000	_	42,000	75,439	(17,272)	58,167
M J Small	42,000	_	42,000	75,250	(17,272)	57,978
T S Shilton	47,250	_	47,250	84,182	(19,430)	64,752
P R Garrod	13,125	_	13,125	22,969	(5,397)	17,572
- -	199,500		199,500	372,091	(93,265)	278,826

The share options of the Directors at the year-end under approved and unapproved share option schemes are set out below:

	1 January and 31 December		Date	
	2009	Exercise	from which	
	Number	price	exercisable	Expiry date
P W C Lomax	130,000	£1.25	31 December 2007	12 December 2016
N A C Lott	80,000	£1.25	31 December 2007	12 December 2016
M J Small	80,000	£1.25	31 December 2007	12 December 2016
T S Shilton	90,000	£1.25	31 December 2007	12 December 2016
P R Garrod	25,000	£1.25	31 December 2007	12 December 2016

No options were exercised during the year. These options have now lapsed and have now been forfeited. The market price of the shares at 31 December 2009 was 2.375p and the range during the financial year was 2.78p to 5.30p.





for the year ended 31 December 2009

#### 8 Segment information

The adoption of IFRS 8 has not resulted in any changes to the identification of the Group's reportable segments, the commercial development and sale of Colostrinin™ as a nutraceutical product and the provision of clinical research services. However as the Board do not review the information about total assets and total liabilities or capital expenditure for each reportable segment this information has not been separately provided. All non-current assets are held in the UK. The provision of clinical research services was discontinued in 2008.

phari de	eutical and maceutical velopment 2009 £	Provision of clinical research services (discontinued) 2009 £	Total 2009 £
Revenue Segment revenue	56,055	_	56,055
oegment revenue	30,033		30,033
Segment result			
Depreciation	(840)		(840)
Amortisation	(237,934)	_	(237,934)
Non-cash expenses Finance income	- 46	_	46
Finance income Finance costs	4,138	_	4,138
Loss before taxation	( <b>758,288</b> )	_	( <b>758,288</b> )
pha	ceutical and rmaceutical evelopment 2008 £	Provision of clinical research services (discontinued) 2008 £	Total 2008 £
Segment revenue	91,716	3,266	94,982
Segment result Depreciation Amortisation Non-cash expenses Finance income Finance costs	(1,656) (298,256) 95,532 10,308 (3,436)	- - - 3 (4,394)	(1,656) (298,256) 95,532 10,311 (7,830)
(Loss)/profit before taxation	(1,510,021)	(33,936)	(1,543,957)





#### 8 Segment information continued

Information on the Group's revenue by geographical area is set out below:

		by loc cust	l revenue ation of omers
		2009 £	2008 £
		_	L
	UK	17,564	3,266
	United States	21,446	66,196
	Australia	6,466	10,871
	Europe	10,579	14,649
		56,055	94,982
			0000
		2009	2008
	Customers representing over 10% of total revenue	£	£
	Customer a	27,912	77,067
	Customer b	17,564	77,007
	Customer c	7,000	14,649
	Other customers	3,579	-
		56,055	91,716
9	Finance income		
		2009	2008
		£	£
	Bank interest received – continuing operations	42	10,308
	Bank interest received – discontinued operations	4	3
		46	10,311
10	Finance expense		
	·	2009	2008
		£	£
	Interest expense on financial liabilities – continuing operations	2,120	3,436
	Interest expense on financial liabilities – discontinued operations	2,018	4,394
		4,138	7,830





for the year ended 31 December 2009

#### 11 Taxation

	2009	2008
	£	£
UK corporation tax credit in respect of current period	16,043	66,065
Adjustment in respect of prior years	12,307	14,525
Total current tax credit	28,350	80,590

The Group has unrecognised tax losses of approximately £14,000,000 (2008 – £13,500,000) for offset against future profits.

The rate of corporation tax changed to 28% with effect from April 2008. A deferred tax asset has not been recognised in relation to tax losses due to the uncertainty of future tax losses.

The tax for the year differs from the standard rate of corporation tax in the UK. The differences are explained below:

	2009 £	2008 £
	-	_
Loss before tax	758,288	1,543,957
Loss at the standard rate of corporation tax in the UK of 28% (2008 – 28.5%)	212,321	440,028
Effects of:		
Expenses not deductible for tax purposes	(1,152)	17,408
Expenditure qualifying for enhanced tax relief	13,751	46,990
Depreciation in excess of capital allowances	288	60
Difference in tax rate applying to R&D tax credit	(16,043)	(58,703)
Unrecognised deferred tax	-	_
Tax losses for which no deferred tax asset recognised	(193,122)	(379,718)
Adjustment to prior year tax charge	12,307	14,525
Total tax credit for the year	28,350	80,590





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#### 12 Discontinued operations

Due to the difficult market conditions and the very considerable competition in the UK Phase I/II clinical trials market the Board decided to close down the Guildford Clinical Pharmacology Unit Limited's offices in April 2008.

The results of the discontinued operations in this regard which have been included in the consolidated income statement, were as follows:

		2009	2008
		£	£
	Revenue	_	3,266
	Expenses	_	32,811
	Net finance costs	-	4,391
	(Loss)/profit before taxation		(33,936)
	Taxation		
	Net loss attributable to discontinued operations		(33,936)
	Net cash flows attributable to operating activities	_	3,163
	Net cash flows attributable to investing activities		3
	Net cash flows attributable to financing activities	_	(4,394)
13	Earnings per share		
		2009	2008
	Numerator	700 000	4 400 007
	Loss for the year	729,938	1,463,367
	Denominator		
	Weighted average number of shares	27,331,695	11,926,992

The Company has instruments that could potentially dilute basic earnings per share in the future, but that has not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented. These instruments are disclosed per note 25





for the year ended 31 December 2009

#### 14 Property, plant and equipment

	Office	Office
	equipment	equipment
	2009	2008
	£	£
Cost		
At 1 January	151,935	151,935
Additions	-	-
At 31 December	151,935	151,935
Depreciation		
At 1 January	150,918	149,261
Charge for the year	840	1,657
At 31 December	151,758	150,918
Carrying value at 31 December	177	1,017

The carrying value at 1 January 2008 was £2,674 (2007: £26,317).



#### ReGen Therapeutics Plc

#### 15 Intangible assets

<b>c</b>	rights £	marks £	Total £
_	_	_	_
1,952,236	1,191,623	4,681	3,148,540
	110,947	_	110,947
1,952,236	1,302,570	4,681	3,259,487
1,952,236	1,302,570	4,681	3,259,487
	42,889	_	42,889
1,952,236	1,345,459	4,681	3,302,376
986,831	215,150	_	1,201,981
_	-	_	-
	298,256	_	298,256
986,831	513,406	_	1,500,237
986,831	513,406	_	1,500,237
_	-	_	_
	237,934		237,934
986,831	751,340	_	1,738,171
965,405	976,473	4,681	1,946,559
965,405	789,164	4,681	1,759,250
965,405	594,119	4,681	1,564,205
	1,952,236  1,952,236  1,952,236  986,831  986,831  986,831  986,831  986,831	1,952,236	1,952,236       1,191,623       4,681         1,952,236       1,302,570       4,681         1,952,236       1,302,570       4,681         -       42,889       -         1,952,236       1,345,459       4,681         986,831       215,150       -         -       298,256       -         986,831       513,406       -         -       237,934       -         986,831       751,340       -         986,831       751,340       -         965,405       976,473       4,681         965,405       789,164       4,681

Patent costs will continue to be amortised over a maximum of 20 years from their filing dates. The amortisation charge is included in administration costs.





for the year ended 31 December 2009

#### 16 Goodwill and impairment

Details of goodwill allocated to each business unit are as follows:

G	Goodwill carrying amount	
	2009	2008
	£	£
Colostrinin™	819,146	819,146
Zolpidem (acquisition of Sciencom)	146,259	146,259
	965,405	965,405

The recoverable amounts of the different business units have been determined from value in use calculations based on cash flow projections from revenue and expenditure forecasts covering a five year period to 31 December 2014. Other major assumptions are as follows (Note: the growth rate applies only after 4 years, i.e. to the period beyond the initial forecasts of the launch phases of the individual projects, with the value in use calculation based on an extrapolation of the forecast cash flows from 2014 onwards):

	Colostrinin™ 2009 %	Zolpidem 2009 %
Discount rate	15	15
Growth rate	10	10
Wage inflation	5	5

Operating margins have been based on past experience and future expectations in the light of anticipated economic and market conditions. Discount rates are based on the Company's knowledge in terms of the cost of capital adjusted to reflect the management's assessment of the risk and uncertainty of future cash flows. Growth rates beyond the first 4 years are based on economic data pertaining to the growth of the global nutraceutical and pharmaceutical markets. Wage inflation has been based on recent trends and current future expectations.

If the sales growth over the first 4 years of forecasting were to be on average 50% lower than forecast, the carrying value of intangible assets would be in excess of recoverable value of the intangible assets of the Group.

If the discount rate and wage inflation were to be on average 30% lower than forecast, the carrying value of intangible assets would be in excess of recoverable value of the intangible assets of the Group.

Trademarks with carrying value of £4,681 (2008 – £4,681) are tested annually for impairments at business unit level and are incorporated in the goodwill impairment testing, as set out above.





#### 17 Subsidiaries

Information of the Group's subsidiaries is provided in note 4 of the Company financial statements.

#### 18 Inventories

		2009 £	2008 £
	Finished goods and goods for resale	38,219	28,571
19	Trade and other receivables		
		2009	2008
		£	£
	Trade receivables	23,788	15,976
	Less: provision for impairment of trade receivables	-	_
	Trade receivables – net	23,788	15,976
	Other receivables	12,476	8,593
	Prepayments	44,309	62,521
		80,573	87,090

This also represents the maximum credit risk exposure.

The number of days sales of the Group represented by trade receivables at 31 December 2009 was 54 days (2008 – 53 days). The high proportion of sales at the end of the year in comparison to the year's sales distorts the calculation of debtor days outstanding. In reality all but an immaterial amount of £2,568 of the total amount outstanding at 31 December 2009 are not past due. Provisions for impairment are made when it is no longer virtually certain that the debtor balance will be recovered.

The carrying values of the Group's trade receivables are denominated in the following currencies:

	2009	2008
	£	£
Pound Sterling	7,713	5,882
US Dollar	16,075	10,094
	23,788	15,976





for the year ended 31 December 2009

20	Cash	and	cash	equival	ents
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Cash and cash equivalents comprises:

	2009	2008
	£	£
Cash available on demand	29,406	7,682
Short-term deposits	979	17,475
	30,385	25,157
Overdraft	(48,706)	(51,792)
Cash and cash equivalents	(18,321)	(26,635)
All balances are denominated in pounds sterling.		

#### 21 Trade and other payables: current

nado ana otnor payablos, carrent	2009 £	2008 £
Trade payables	309,770	419,308
Other taxes and social security costs	11,376	6,886
Other payables	28,659	38,505
Accruals	18,000	25,000
	367,805	489,699

The number of days purchases of the Group represented by trade payables at 31 December 2009 was 126 days (2008 – 117 days).

#### 22 Loans and borrowings

	2009	2008
	£	£
Current		
Overdraft	48,706	51,792
Total borrowings	48,706	51,792

The bank overdraft is secured by a fixed and floating charge over the assets of Guildford Clinical Pharmacology Unit Limited. The Company have agreed to make regular repayments over a period of time.



#### 23 Provisions

	Deferred consideration	
	2009	2008
	£	£
At 1 January Movement	100,000 -	100,000
	100,000	100,000

Under the terms of the agreement to acquire Sciencom Limited there is contingent consideration of £100,000 following the demonstration, to the reasonable satisfaction of ReGen, of the efficacy of zolpidem, a new formulation, in the form of a clinically significant benefit. On the basis of the probable outcome of the studies taking place it is considered to be appropriate to provide for this sum at this stage. The Directors are unable to specify the payment date. The impact of discounting this provision is considered to be insignificant.

#### 24 Share capital

	2009	2008
	£	£
Authorised		
296,100,000 ordinary shares of 0.01p each		
(2008 – 296,100,000 ordinary shares of 0.01p each)	29,610	29,610
296,100,000 deferred B shares of 9.99p each	29,580,390	29,580,390
110,000,000 deferred A shares of 4.9p each	5,390,000	5,390,000
	35,000,000	35,000,000
Called up share capital issued and fully paid		
36,729,882 ordinary shares of 0.01p each		
(2008 – 15,107,050 ordinary shares of 0.01p each)	3,673	1,510
13,068,521 deferred B shares of 9.99p each	1,305,545	1,305,545
108,121,391 deferred A shares of 4.9p each	5,297,948	5,297,948
	6,607,166	6,605,003

Deferred shares do not carry voting rights and have no right to receive dividends. Deferred Shareholders are entitled to receive the amount paid up or credited as paid up on their respective holdings of deferred shares only after there has been paid on each ordinary share the nominal amount paid up on such share plus a further £1 per ordinary share. The holders of the deferred shares shall not be entitled to participate further in any distribution of the assets or the capital of the Company.

On 5 January 2009, the Company issued 350,000 ordinary shares of 0.01p each at a premium of 3.99p per share for a consideration of £14,000.

On 15 January 2009, the Company issued 400,000 ordinary shares of 0.01p each at a premium of 3.49p per share for a consideration of £14,000.





for the year ended 31 December 2009

#### 24 Share capital continued

On 18 February 2009, the Company issued 2,171,834 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £65,155.

On 18 February 2009, the Company issued 100,000 ordinary shares of 0.01p each at a premium of 9.99p per share for a consideration of £10,000.

On 19 February 2009, the Company issued 1,751,666 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £52,550.

On 25 March 2009, the Company issued 700,000 ordinary shares of 0.01p each at a premium of 3.99p per share for a consideration of £28,000.

On 7 April 2009, the Company issued 2,149,332 ordinary shares of 0.01p each at a premium of 3.99p per share for a consideration of £64,480.

On 15 April 2009, the Company issued 800,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £24,000.

On 24 April 2009, the Company issued 2,000,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £60,000.

On 4 June 2009, the Company issued 1,000,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £30,000.

On 12 June 2009, the Company issued 500,000 ordinary share of 0.01p each at a premium of 2.99p per share for a consideration of £15,000.

On 22 June 2009, the Company issued 1,000,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £30,000.

On 20 August 2009, the Company issued 3,200,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £96,000.

On 2 September 2009, the Company issued 3,000,000 ordinary shares of 0.01p each at a premium of 3.99p per share for a consideration of £120,000.

On 30 October 2009, the Company issued 2,500,000 ordinary shares of 0.01p each at a premium of 2.99p per share for a consideration of £75,000.

On 6 October 2008 a resolution was passed at a General Meeting of the Company whereby a sub-division of Share Capital was effected so that every Existing Ordinary Share in issue was sub-divided and reclassified into one new ordinary share having a nominal value of 0.01 pence ("New Ordinary Shares") and one deferred B share having a nominal value of 9.99 pence ("Deferred B Share") (the "Sub-division").

The number of New Ordinary Shares in issue following the Sub-division equated to the number of Existing Ordinary Shares previously in issue. The Sub-division did not affect the rights attaching to the Existing Ordinary Shares, other than to alter their nominal value and, in particular, did not affect the voting rights of the holders of Existing Ordinary Shares.

As all Existing Ordinary Shares were sub-divided, each Shareholder's percentage holding in the issued share capital of the Company immediately before and after the implementation of the Sub-division remained unchanged.





#### 24 Share capital continued

Share options

At 31 December 2009, total share options outstanding under the Company's approved and unapproved share option plan are as set out below:

		Date from		Exercise
	Number	which options are		price
Date of grant	of shares	first exercisable	Lapse date	per share
7 December 2000	2,000	1 December 2002	30 November 2010	£28
25 July 2002	893	25 July 2002	24 July 2010	£1.50
25 November 2003	11,500	25 November 2003	24 November 2010	£1.50
12 December 2006	415,500	31 December 2007	12 December 2016	£1.25

#### 25 Share-based payment

The Company operates a share-based remuneration scheme whereby options vest if certain performance conditions based on product launches and achieving certain revenue and profit targets over 2007, 2008 and 2009, are met. The performance criteria attached to these options were never met and did not vest. Consequently the 415,500 associated share options lapsed in 2008. A further 33,000 share options lapsed as they had expired.

	2009	2009	2008	2008
	Weighted		Weighted	
	average		average	
ех	ercise price	е	xercise price	
	(pence)	Number	(pence)	Number
Outstanding at the beginning of the year	593	20,643	157	469,143
Granted during the year	-	-	_	_
Exercised during the year	-	-	_	_
Lapsed during the year	600	(6,250)	436	(448,500)
Outstanding at the year end	518	14,393	593	20,643

Of the total number of options outstanding at the end of the year, 14,393 (2008 – 20,643) had vested and were exercisable at the end of the year.

	2009	2008
The share-based remuneration credit comprises:		
Equity-settled schemes	-	(95,532)





for the year ended 31 December 2009

#### 26 Reserves

	Share premium £	Other reserves	Retained earnings £	Total £
At 1 January 2008	13,969,394	265,745	(18,118,878)	(3,883,739)
Net income recognised directly in equity				
Loss for the year			(1,463,367)	(1,463,367)
Total comprehensive income				
for the year	_	_	(1,463,367)	(1,463,367)
Issue of share capital	177,819	_	_	177,819
Share-based payment/(credit)			(95,532)	(95,532)
Balance at 31 December 2008	14,147,213	265,745	(19,677,777)	(5,264,819)
Net income recognised directly in equity				
Loss for the year			(729,938)	(729,938)
Total comprehensive income				
for the year	_	_	(729,938)	(729,938)
Issue of share capital	689,022	_	_	689,022
Share issue costs	(88,340)			(88,340)
Balance at 31 December 2009	14,747,895	265,745	(20,407,715)	(5,394,075)

The following describes the nature and purpose of each reserve.

Reserve	Description and purpose
Share premium	Amount subscribed for share capital in excess of nominal value.
Other reserves	Share capital issued to finance acquisitions in excess of nominal value in accordance with Section 612 of Companies Act 2006.
Retained earnings	Cumulative net losses recognised in the consolidated income statement.





#### 27 Leases

Operating leases - lessee

The Company leases serviced offices, which can be cancelled at one months notice. The total future value of minimum lease payments are due as follows:

	2009	2008
	£	£
Not later than one year	3,669	3,669
Later than one year but not later than five years	-	_
Later than five years		

#### 28 Related party transactions

Details of Directors' remuneration are given in note 7 to the accounts and there are no additional key management personnel within the business. Other related party transactions are as follows:

			saction nount	Bala owed/(c	
Related party relationship	Type of transaction	2009 £	2008 £	2009 £	2008 £
P W C Lomax (Director)	Provision of services (Note 1)	8,389	12,032	60	273
P R Garrod (Director)	Sales of Goods (Note 2)	17,563	-	(5,145)	-
K B Corbin	Provision of Services (Note 3)	-	122	-	_

- Note 1 The provision of services through Lomax Pharmaceutical Consulting of which P W C Lomax is a partner.
- Note 2 The sale of MemoryAid (Colostrinin™) in the UK through PRG Nutraceuticals Limited of which P R Garrod is a Director.
- Note 3 The provision of services through Nerine Trust Company Limited to 9 July 2008, of which K B Corbin is a Director. K B Corbin was previously a Director of ReGen Therapeutics Plc and resigned on 9 July 2008.

#### 29 Events after the balance sheet date

On 14 January 2010, the Company issued 8,333,333 ordinary shares of 0.01p each at a premium of 1.49p per share for a consideration of £125,000.

On 30 March 2010, the Company issued 5,000,000 ordinary shares of 0.01p each at a premium of 1.49p per share for a consideration of £75,000.

On 10 May 2010, the Company issued 11,550,000 ordinary shares of 0.01p each at a premium of 1.99p per share for a consideration of £231,000.





# Company balance sheet as at 31 December 2009

	Note	2009	2009	2008	2008
Fixed assets		£	£	£	£
	2	42E 400		E02 270	
Intangible assets	2	425,480		582,370	
Tangible assets	3	177		1,017	
Investments in subsidiaries	4	2,904,852		2,905,823	
			3,330,509		3,489,210
Current assets					
Stock		38,219		28,571	
Debtors	5	93,947		163,054	
Cash and cash equivalents		30,248		24,994	
Total current assets		162,414		216,619	
Creditors: amounts falling due					
within one year	6	316,836		441,844	
Net current (liabilities)/assets			(154,422)		(225,225)
Total assets less current liabilities			3,176,087		3,263,985
Provision for liabilities	7		100,000		100,000
Net assets			3,076,087		3,163,985
Capital and reserves					
Share capital - Issued and fully paid	8		3,673		1,510
– Deferred A	8		5,297,948		5,297,948
<ul><li>Deferred B</li></ul>	8		1,305,545		1,305,545
Share premium	10		14,747,895		14,147,213
Retained earnings	10		(18,278,974)		(17,588,231)
Total equity			3,076,087		3,163,985

The financial statements were approved by the Board and authorised for issue on 20 May 2010 and were signed on its behalf by

#### P W C Lomax

Director

The notes on pages 51 to 56 form part of these company financial statements.



## Notes to the Company financial statements

for the year ended 31 December 2009

#### 1 Accounting policies

#### **Basis of preparation**

These financial statements present financial information for ReGen as a separate entity, and have been prepared in accordance with the Companies Act 2006 and United Kingdom Accounting Standards (UK Generally Accepted Accounting Practice). The principal accounting policies adopted in these Company financial statements are set out below and, unless otherwise indicated, have been consistently applied for all periods presented.

#### Going concern

The financial statements have been prepared on a going concern basis. However, the Company's ability to continue as a going concern is reliant upon successfully obtaining funds as it moves towards self sustainability and to finance ongoing development. In considering the appropriateness of this basis of preparation the Directors have reviewed the Company's working capital forecasts. They believe that the funds raised recently, including new equity funds of £431,000 in aggregate raised between the balance sheet date and the date of approval of these financial statements, together with further options being considered and taken in conjunction with revenues from licensing, will be sufficient for the Group's purposes for a minimum of 12 months from the date of approval of the financial statements. If the Company was unable to secure sufficient funding to enable it to continue on a going concern basis then adjustments would be necessary to write down assets to their recoverable amounts, reclassify fixed assets and long-term liabilities as current and provide for additional liabilities.

#### Loss for the financial year

The Company has taken advantage of Section 408(3) of the Companies Act 2006 and has not included its own Profit and Loss Account in these financial statements. The Company loss after tax for the year ended 31 December 2009 under UK GAAP was £690,743 (2008 – £1,355,865). Audit fees for the year were £15,000 (2008 – £18,000).

#### Related party transactions

The Company is exempt under the terms of FRS 8, related party disclosures, from disclosing related party transactions with entities that are part of the Group.

The principal accounting policies are summarised below.

#### **Share-based payment**

When shares and share options are granted to employees a charge is made to the profit and loss account and a credit to equity to record the fair value of the awards at the date of grant in accordance with FRS 20 "Share-based payment". This charge is spread over the vesting period.

#### Foreign currency

Foreign currency transactions of individual companies are translated at the rates ruling when they occurred. Foreign currency monetary assets and liabilities are translated at the rates ruling at the balance sheet dates. Any differences are taken to the profit and loss account.

#### **Patents**

Costs to obtain patent rights for the use of Colostrinin<sup>™</sup> have been capitalised and will be amortised on a straight-line basis over the expected useful life of the patent from the date the patent is granted.





## Notes to the Company financial statements

for the year ended 31 December 2009

#### 1 Accounting policies continued

#### Tangible assets

Tangible assets are carried at depreciated cost.

Depreciation is provided to write off the carrying value of items over their expected useful lives. It is applied at the following rate:

Office equipment - 25% per annum on cost.

#### Intangible assets

Intangible assets comprise patents and trademarks for the Company's products. These are initially recognised at the costs incurred to obtain rights. Intangible assets are amortised through the profit and loss account in equal instalments over the estimated useful life of the asset.

#### Investments in subsidiaries

Investments are stated at cost less any impairment considered necessary.

#### Stock

Stocks are stated at the lower of cost and net realisable value. In determining the cost of stocks sold, the batches are identified and the actual cost of the inventories is used.

#### **Deferred taxation**

Deferred tax balances are recognised in respect of all timing differences that have originated but not reversed by the balance sheet date except that the recognition of deferred tax assets is limited to the extent that the Company anticipates to make sufficient taxable profits in the future to absorb the reversal of the underlying timing differences.

Deferred tax balances are not discounted.



## ReGen Therapeutics Plc

2	Intangible assets	
		Patent
		rights
	Cost	£
	At 1 January 2009	926,657
	Additions	33,098
	At 31 December 2009	959,755
	Amortisation	
	At 1 January 2009	344,287
	Charge for the year	189,988
	At 31 December 2009	534,275
	At 01 December 2000	——————————————————————————————————————
	Net book value	
	At 31 December 2009	425,480
	At 31 December 2008	582,370
3	Tangible assets	
Ū		Office
		equipment
		£
	Cost	
	At 1 January 2009	66,367
	Additions	_
	At 31 December 2009	66,367
	At 31 December 2003	
	Depreciation	
	At 1 January 2009	65,350
	Charge for the year	840
	At 31 December 2009	66,190
	Net book value	
	At 31 December 2009	177

At 31 December 2008



1,017



## Notes to the Company financial statements continued

for the year ended 31 December 2009

#### 4 Investments in subsidiaries

Investments in subsidiary undertakings £	in subsidiary	•	Total
	£	£	
1,539,589	1,366,234	2,905,823	
_	2,848	2,848	
	(3,819)	(3,819)	
1,539,589	1,365,263	2,904,852	
	in subsidiary undertakings £ 1,539,589	in subsidiary undertakings  £  1,539,589  1,366,234  - 2,848  - (3,819)	

The investments at 31 December 2009 represent a 100% investment in ReGen Polska, a 100% interest in the ordinary shares of Guildford Clinical Pharmacology Unit Limited, a 100% interest in Sciencom Limited and a 100% interest in the ordinary 'A' shares of The Georgiades Foundation Limited and its wholly owned subsidiaries, ReGen Biotech Limited and Georgiades Biotech Limited. All of the above are unlisted companies.

Name	Country of registration	Nature of business
Guildford Clinical Pharmacology Unit Limited	Great Britain	Clinical Research
Sciencom Limited	Great Britain	Developer of zolpidem
ReGen Biotech Limited *	Great Britain	Dietary supplement licensee
The Georgiades Foundation Limited	British Virgin Islands	Developer of Colostrinin™
Georgiades Biotech Limited *	British Virgin Islands	Developer of Colostrinin™
ReGen Polska Sp. z o.o.	Poland	Developer of Colostrinin™

<sup>\*</sup> Interest held indirectly via The Georgiades Foundation Limited.

The investment in The Georgiades Foundation Limited is as follows:

Class of share	Number of shares in issue	Percentage held
10c ordinary 'A' shares	22,100	100
10c deferred shares	6,852	58
	28,952	

The share capital of The Georgiades Foundation Limited is denominated in US Dollars.



#### ReGen Therapeutics Plc

5	<b>Debtors</b>
•	DUDIUIS

		2009 £	2008 £
	Trade debtors	21,220	10,094
	Other debtors	12,375	9,849
	Prepayments	44,309	62,521
	Corporation tax	16,043	80,590
		93,947	163,054
6	Creditors: amounts falling due within one year		0000
		2009	2008
		£	£
	Trade creditors	283,506	396,158
	Other taxes and social security costs	11,376	6,886
	Other creditors	3,954	13,800
	Accruals	18,000	25,000
		316,836	441,844

#### 7 Provisions

(see note 23 to the consolidated accounts).

#### 8 Share Capital

(see note 24 to the consolidated accounts).

#### 9 Share Options

(see note 24 to the consolidated accounts).





## Notes to the Company financial statements continued

for the year ended 31 December 2009

#### 10 Share-based payment

(see note 25 to the consolidated accounts).

#### 11 Shareholders funds

	Share capital £	Share premium £	and loss account
At 1 January 2009	6,605,003	14,147,213	(17,588,231)
Shares issued	2,163	689,022	_
Share issue costs	_	(88,340)	_
Loss transferred to reserves	-	-	(690,743)
At 31 December 2009	6,607,166	14,747,895	(18,278,974)

#### 12 Post balance sheet events

(see note 29 to the consolidated accounts).





## Directors, officers and professional advisers

#### **Directors**

PWC Lomax (Chairman and Chief Executive)

N A C Lott (Finance Director)

M J Small (New Projects Director)
T S Shilton (Development Director)
P R Garrod (Non-Executive Director)

Secretary and registered office NAC Lott, Suite 306, 73 Watling Street, London, EC4M 9BJ.

Company number 3508592

**Business address** Suite 306, 73 Watling Street, London, EC4M 9BJ.

**Auditors** Mazars LLP, Tower Bridge House, St Katharine's Way, London, E1W 1DD.

Nominated Adviser Beaumont Cornish Limited, 2nd Floor, Bowman House, 29 Wilson Street,

London, EC2M 2SJ.

Broker Alexander David Securities Limited, 10 Finsbury Square, London, EC2A 1AD.

**Legal Advisers** Bird & Bird LLP, 15 Fetter Lane, London, EC4A 1JP.



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