

# ReGen

Therapeutics Plc

Nutraceuticals  
Pharmaceuticals  
Building a business



Annual Report and  
Accounts 2008





# Cognase colostrinin™

Support for Healthy Brain Aging & Cognition  
Υποστηρίζει για την υγιή γήρανση του εγκεφάλου  
Τα συμπληρώματα διατροφής δεν είναι απαραίτητα  
Dietary supplements are not essential

30 Μασώμενα δισκία  
Συμπλήρωμα  
διατροφής  
Chewable tablets  
Dietary  
Supplement



**Metagenics**  
Genetic Potential Through Nutrition

# CogniSure™

Support for Healthy Brain Aging & Cognition\*

Dietary Supplement

30 CHEWABLE TABLETS



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# Annual Report and Accounts 2008

## Chairman's statement



### Highlights

- Loss before tax from continuing operations reduced by £1.076 million to £1.510 million. Further £1 million reduction expected in 2009.
- Colostrinin™ sales up 44%. Worldwide roll-out proceeds.
- Intellectual Property portfolio still being enhanced.
- Sustainable profitability expected in 2010.

ReGen Therapeutics Plc ("ReGen" or "the Company" or "the Group") reacted quickly to the financial crisis, which engulfed the World in 2008. The Directors realised that as a small Company, mainly dependent upon the capital markets in the unfashionable biotechnology sector, it was particularly vulnerable to the freezing of liquidity. The Directors therefore took every step to cut costs and focus on the commercial development of Colostrinin™ so that the Company would be able to fund itself as quickly as possible.

The commercialisation of Colostrinin™, further described below, means that the Company will achieve earlier profitability than was formerly the case. We also achieved a number of significant scientific milestones, which we also detail later in this statement.

### Financials

Colostrinin™ sales rose 44% in 2008 to £91,982. Whilst these sales were over a full year for Metagenics in the USA, Canada and Australia the 2007 figures had been boosted by inventory building.

Research and Development costs fell during the year by £472,029 (59%) to £330,274. This reflected a number of items:

1. The largest fall was in the development cost of zolpidem, which finished its programme in 2008. Having reached a cost peak, including a successful clinical trial in 2007, zolpidem costs fell by £210,831 (45% of the total reduction). Whilst this project is now available for licensing to third parties we are pursuing external sources of funding which should give a chance of securing an enhanced licensing deal at no further cost to Shareholders.
2. The veterinary work on Colostrinin™ came to an end at the start of 2008 and costs in this area fell by £79,900 (17% of the total). We are attempting to license out the project and no further development work is planned.
3. Nutraceutical Colostrinin™ is now in the roll out stage so costs here have dramatically reduced. Pharmacology and toxicology fell from £88,812 to £892. Licensing expenditure was reduced by £25,812 as we took the commercial development in-house.
4. Colostrinin™ peptide research was also reduced by £45,803 as part of the Company's attempt to conserve cash. We did, however, complete the next stage of the Company's research programme. The results are now being evaluated by two global companies. We may, therefore, enter into a co-development partnership or licensing deal, which would enhance Shareholder value.



Other administration costs from continuing operations also showed a fall of 18% as we kept careful control of expenses. This figure, however, understates the fall in cash expenditure, as there was an increase in the amortisation of patents of £263,346, a non-cash item. Thus, taking this into account and changes in depreciation cash expenditure for continuing operations was just £994,542 of which staff costs were £458,705 (46% of total). These costs were down 32% on the previous period and in view of the actions taken during the year staff costs will approximately halve in 2009. Thus, the loss before taxation for continuing activities fell by 42% to £1.510 million.

Turning now to the Balance Sheet the deterioration in cash and cash equivalents of £563,873 is the result of the freezing of the capital markets, which meant that ReGen raised only £677,138 of new capital in 2008, compared to £2,486,875 in 2007. The Company had to react by savagely cutting costs, utilising the cash balances available, and extending its terms of trade where possible. This meant that Directors' salaries were halved, cash balances fell by £562,680, trade and other payables rose 57% (£178,063). During 2009, the Company has raised £367,000 so we believe that this deterioration has ceased and to some extent reversed.

## **Commercial development**

### **Colostrinin™ roll out accelerates:**

The roll out of Colostrinin™ as a nutraceutical, which has been developed to support healthy brain ageing and cognition is continuing in line with the Company's expectations.

The product is being sold (under the brand name CogniSure™) via healthcare professionals in the US, Canada and Australia through Metagenics, ReGen's licensing partner for those territories. Retail opportunities in the US market are being actively pursued.

At the beginning of March 2008, the Company announced its first European Union distribution agreement for Colostrinin™ with Golgi Pharmaceuticals Ltd of Cyprus and the launch of the nutraceutical product, under the brand name Cognase™, took place in October 2008.

The agreement with Golgi was extended on 25 March 2009 to allow them to distribute Colostrinin™ in Greece and other Balkan countries. On the same day a further agreement was signed with Golgi for them to tablet and package Colostrinin™ in the Republic of Cyprus. As part of this arrangement Golgi has 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.

On 26 November 2008 ReGen signed an agreement with Tagerr for the test marketing of Colostrinin™ in Poland. Tagerr is a professional services and trading company established in Cologne, Germany. In operation since 1995, Tagerr has enjoyed a number of successes in the marketing and distribution of consumer products including food supplements in Central Europe and Germany. In April 2009 it gained approval to import and market Colostrinin™ in Poland.

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™ in the Republic of Turkey.

This appointment is conditional upon Eczacibasi securing import and regulatory approval for the product. Should approval be forthcoming Eczacibasi will pay ReGen a \$50,000 milestone payment on approval being granted and then a fee per unit for the active ingredient component of the formulated product. 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.



## Chairman's statement continued

Whilst the main Colostrinin™ "use" patent expires in October 2016, we are pleased to announce that the EU patent, which protects our manufacturing process, has been granted and this expires in March 2024. The manufacture of Colostrinin™ is proprietary and complex so that this patent grant is of considerable commercial significance.

### **Scientific development** **Alzheimer's Conference on 17 September 2008**

Professor Marian Kruzel, the Company's Chief Scientific Advisor presented a poster reviewing how Colostrinin™ achieves its clinical effect at the first Clinical Trials in Alzheimer's Disease Conference, held in Montpellier, France, 17 September 2008.

Summarising the contents of his poster, Professor Kruzel said

"In this presentation I explained how such a low dose of Colostrinin™ can produce significant medical benefits in AD patients. I focussed on our findings from recent genomic microarray work, which shows that Colostrinin™ can favourably modulate the expression of several molecules involved in the pathology of Alzheimer's disease (upregulation of bleomycin hydrolase, downregulation of APP and effect on Tau phosphorylation). This enables the body's own multiple responses to reduce neuronal pathology and achieve homeostasis. The effect on Tau is said to be the reason for the response witnessed by the patients taking the drug Rember – product/trademark of TauRx. This data suggests that Colostrinin™, may be one of the first compounds with the potential to impact both Tau tangles and beta amyloid plaques, the two key pathologies of Alzheimer's disease."

### **Peer-reviewed International Immunopharmacology Journal**

On the 4 December 2008 the full results of the genomic microarray study were published on line ahead of availability in print by the peer-reviewed journal International Immunopharmacology.

We emphasise two key points of the article. Firstly, Colostrinin™ can favourably modulate the expression of several molecules involved in the pathology of Alzheimer's disease – upregulation of bleomycin hydrolase, downregulation of APP and effect on Tau phosphorylation. Given that Alzheimer's is a complex disease the multi-faceted action shown by Colostrinin™ is significant. Secondly, Colostrinin™ also modulates other molecules involved in biological pathways associated with other conditions such as obesity and allergy.

For a long time ReGen has had compelling experimental and clinical data that suggest Colostrinin™ can support healthy brain ageing and cognition. In discussions with potential licensing partners, investors and healthcare practitioners however, initially, there has always been a degree of scepticism that a small dose of peptides given orally could lead to significant clinical effects. ReGen's recent work, which suggests that Colostrinin™ absorbed in the lining of the mouth triggers the production of other molecules that lead to the final outcome, should go a considerable way to removing this as an issue and lead to greater use of the product.

### **Expert Opinion on Pharmacotherapy**

An article by Professor Mike Stewart of the Open University, Milton Keynes, UK, reviewing the benefits of Colostrinin™ has also recently been published on-line in the journal Expert Opinion on Pharmacotherapy, October 2008. Summarising his article, Professor Stewart, a former scientific consultant to ReGen, said:

'Neurodegenerative illnesses such as Alzheimer's disease and their debilitating effects pose a major problem as their incidence increases. Given that Colostrinin™ has efficacy in counteracting neural degradation, stimulating neural growth, reducing oxidative stress, preventing beta-amyloid aggregation and prolonging the lifespan of mice prone to premature ageing it would seem to have much to commend its use as a nutraceutical in the early stages of cognitive decline in ageing humans and companion animals'.



## Zolpidem

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.

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

Currently, and with advice from internationally respected experts in stroke rehabilitation, ReGen has planned a further, double-blind clinical trial in the UK designed to demonstrate the efficacy of repeated doses of zolpidem after stroke. This trial will only proceed if an application for outside funding is successful. This trial, if positive, will prove unequivocally that zolpidem works in this new indication.

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

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.

The findings of the MEG studies regarding the mechanism of the neurodormancy reversal and the preliminary findings of the Pretoria study were presented by Dr Ralf Clauss, a Scientific Advisor to ReGen, at the Ehrlich II Congress on 'Magic Bullets' in Nuremberg, Germany, at the beginning of October 2008.

There have been so many individual reports of a beneficial effect from zolpidem in a wide range of brain damage, from birth injury to trauma, stroke and others, that it is clear that zolpidem can help a considerable proportion of patients. The new Pretoria study suggests that the proportion of cases that might benefit from zolpidem could be much higher than expected from simple clinical responses. In some patients the benefit has been profound with recoveries of speech, continence, cognitive function and limb paralysis. Moreover, there has been no report of undue adverse effects other than the expected daytime sedation, all of which suggests that zolpidem should be tried in every case of brain injury.



## Chairman's statement continued

### OTCQX International

On 14 July 2008 ReGen announced the listing of its American Depositary Receipts (ADRs) on the OTC market's prestigious tier, International PrimeQX. Pink OTC Markets Inc., is the leading electronic inter-dealer quotation system, trading technology and financial information provider for over-the-counter (OTC) securities. International Prime QX changed its name to OTCQX International in 2009.

### People

**Keith Corbin** left the Board on 9 July 2008. He was the only person apart from myself who had been a Director of the Company since inception. During this period of time I found him to be a valuable source of advice and support and his comments were always perceptive at the Board meetings. We will miss him and wish him well with his demanding job running an International Trustee business.

**Nick Mills** died unexpectedly in 2008. Nick was our veterinary consultant whose idea it was to develop a veterinary use for Colostrinin™. He completed a successful veterinary trial for the Company, upon which we hope to be able to capitalise.

**Karl Kirwan** died at the young age of 44 in Dublin in 2008. He was the prime mover behind us going to the OTCQX, to which we were finally admitted in July 2008.

Both Nick and Karl will be sadly missed and we wish their families well.

### Summary

In the Report and Accounts for 2007 I commented that ReGen was getting to a stage where the nutraceutical product could take the Company into sustainable profitability. Indeed, up until quite recently it was our expectation that we would reach profitability in 2009. The credit crunch has had a severe impact on the business of our appointed and potential distributors and therefore on our development in the key markets of the USA and India. Consequently we now believe that we will not achieve sustainable profitability until 2010. Our losses until then, however, are expected to be significantly less than in 2008. In 2008 we lost £1.510 million before tax for continuing operations compared with £2.586 million in 2007, a reduction of £1.076 million. We expect losses to decrease by an even larger amount in 2009 with sustainable profitability being achieved during 2010.

### Percy W Lomax

18 June 2009



## Operational review

### Introduction

ReGen 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 as it is currently developing three of the Colostrinin™ peptides for the treatment of Alzheimer's disease and obesity. It has also developed zolpidem (an existing treatment for insomnia) for use in the reversal of brain dormancy.

To provide capital for the original programme the Company was floated on the Ofex (now trading as PLUS) market in December 1998 and on the AIM Market of the London Stock Exchange in March 2000. In its public offerings and subsequent offerings the Company has raised approximately £21 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™ so that revenue from sales of this product will make ReGen profitable. Subsidiary objectives are to find development partners for the Colostrinin™ peptides and zolpidem.

### Key Historical Milestones 2009/2008

#### Commercial Milestones

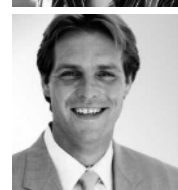
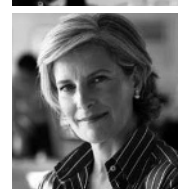
At the beginning of March 2008, the Company announced it had signed its first European Union distribution agreement for Colostrinin™ with Golgi Pharmaceuticals Ltd of Cyprus. The European Union launch of the nutraceutical product under the brand name Cognase™ took

place in October 2008. The agreement with Golgi was extended on 25 March 2009 to allow them to distribute Colostrinin™ in Greece and other Balkan countries. On the same day a further agreement was signed with Golgi for them to tablet and package Colostrinin™ in the Republic of Cyprus. As part of this arrangement Golgi has 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

On 26 November 2008 ReGen signed an agreement with Tagerr for the test marketing of Colostrinin™ in Poland. Tagerr is a professional services and trading company established in Cologne, Germany. In operation since 1995, Tagerr has enjoyed a number of successes in the marketing and distribution of consumer products including food supplements in Central Europe and Germany. In April 2009 it gained approval to import and market Colostrinin™ in Polish pharmacies.

In the first month of 2009 ReGen signed an important agreement in a major Eurasian market with Eczacibasi Ilac Pazarlama A.S. – a leading Turkish industrials group. Eczacibasi was given an exclusive right as the distributor of ReGen's nutraceutical product Colostrinin™ in the Republic of Turkey.

This appointment is conditional upon Eczacibasi securing import and regulatory approval for the product. Should approval be forthcoming Eczacibasi will pay ReGen a \$50,000 milestone payment on approval being granted and then a fee per unit for the active ingredient component of the formulated product. 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.



## Operational review continued

### Scientific Milestones

In 2008 ReGen extended a Sponsored Research Agreement with the University of Texas Medical Branch at Galveston for further development and efficacy testing of Colostrinin™-derived peptides in the management of both Alzheimer's disease and obesity. The research has focused on the potential impact of selected peptides on expression of genes that are involved in beta-amyloid generation, oligomerization, clearance, and degradation as well as expression of those genes, which may modify the disease, using human neural cells. During these studies we were able to select specific peptides for *in vivo* study using Alzheimer's disease and obesity mouse models.

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.

In June of 2008 ReGen completed its work on gene expression in epithelial cell culture using both Colostrinin™ and specific synthetic peptides. The data submitted for publication in the Journal of International Immunopharmacology were accepted and the manuscript was published 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 September of 2008 Dr. Kruzel, the Company's Chief Scientific Advisor presented a paper at the 1<sup>st</sup> Clinical Trials in Alzheimer's Disease Conference™, held in Montpellier, France. The paper provided a transcriptomal network analysis of gene expression upon Colostrinin™ treatment. It was demonstrated that Colostrinin™ can favourably modulate the expression of several molecules involved in the pathology of Alzheimer's disease (upregulation of bleomycin hydrolase, downregulation of APP and effect 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 has been recently 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 2009 ReGen continued to gain additional data from UTMB at Galveston regarding both *in vivo* and *in vitro* studies on Colostrinin™ and Colostrinin™-derived peptides.

### 2007

#### Commercial Milestones Colostrinin's™ first launch

The crucial commercial development of the year was in October 2007 when Colostrinin™ (branded as CogniSure™) was launched in the professional channel in the North American market by Metagenics Inc our licensee. This is a key development for ReGen as the USA alone accounts for around one third of the World nutraceutical market.



ReGen produces bulk Colostrinin™ in South Dakota. Currently production capacity is two million units per annum (a unit is thirty days supply) and a further extension of the manufacturing capacity to ten million units per annum is possible and within the financial resources of the Company. The license agreement provides Metagenics with the exclusive rights to market Colostrinin™ via healthcare professionals in its designated areas.

Metagenics subsidiary Health World Ltd launched Colostrinin™ in the Australasian market in July 2007 following a successful pre-launch conference in June.

### **Scientific Milestones** **Colostrinin™**

In December 2007 ReGen announced that several Colostrinin™-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 study that showed Colostrinin™ increases the lifespan of inbred mice predisposed to premature ageing.

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.

### **Zolpidem**

There were two television documentaries on the effects of zolpidem in the treatment of brain trauma 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, though, a second programme screened by the BBC in October 2007 was more disappointing giving no credit to ReGen and was not primarily a scientific programme.

Most importantly for ReGen 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.

## **2006**

### **Commercial Milestones**

2006 saw the start of Colostrinin™ commercial development when ReGen entered into an exclusive licence agreement with Metagenics Inc. for the marketing of Colostrinin™ as a human nutraceutical in North America, by far the World's largest nutraceutical market. Headquartered in San Clemente, California, Metagenics is a leading developer, manufacturer and marketer of nutraceuticals, dedicated to researching and evaluating the effects of natural ingredients on genetic expression and protein activity. Metagenics states that it serves over 30,000 healthcare practitioners in North America.

### **Sciencom acquired**

In February 2006 ReGen acquired Sciencom, following a successful feasibility study of its novel use for the existing drug zolpidem. The clinical effect discovered in a number of 'open' clinical case observations is that zolpidem can



## Operational review continued

normalise areas of brain dormancy secondary to a primary lesion in brain damage conditions. The clinical effects of the dormancy reversal have been the restoration of consciousness, swallowing, co-ordination and motor function after stroke and traumatic brain injury. Given that stroke alone is the largest single cause of severe disability in England and Wales, with over 450,000 people being affected at any one time, the Company believes that this represents a significant medical and commercial opportunity.

### Scientific milestones

There were two major scientific studies published in 2006. In August an *in vitro* study published in the peer-reviewed Journal of Experimental Therapeutics and Oncology showed that Colostrinin™ reduces 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. The diversity of Colostrinin's™ activity was further illustrated by the publication in January of the full results of an *in vitro* study which showed that Colostrinin™ could cause precursor nerve cells to differentiate and proliferate. This was published in the peer-reviewed journal Cell and Molecular Neurobiology. The potential to slow down or prevent the death of nerve cells in the brain has clear applicability to neurodegenerative diseases such as Alzheimer's, Parkinson's and Amyotrophic Lateral Sclerosis.

Further moves to full commercialisation of Colostrinin™ began in May 2006 when formal safety studies started with the commercial form of Colostrinin™.

### 2005

In 2005 ReGen produced three key scientific papers:

- 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.
- 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.

The first steps to full commercialisation of Colostrinin™ were announced in June 2005. ReGen achieved production scale-up of Colostrinin™ using a proprietary industrial process.

Another crucial milestone was achieved 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.

### 2004

The scientific programme put in place by the new management team at the end of 2002/2003 started to show real fruit in 2004 as the following publications show:

- 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 9th 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 the same month, 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 14th Alzheimer Europe Conference scientists presented two papers. In one they showed that Colostrinin™ can prevent the aggregation of beta amyloid and reduce its toxic effect on neuroblastoma cells and in the other they showed that Colostrinin™ can 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 statistical significance in its main clinical end-point of cognitive efficacy and its main secondary endpoint of Independent Activities of Daily Living (IADL).

## Pre-2004

October 2002 – Details on the potential mode of action of Colostrinin™ were first presented at the 18th International Conference on Alzheimer's disease in Barcelona, Spain. The presentation showed that Colostrinin™ had the ability to reduce intracellular levels of reactive oxygen species and therefore damage to proteins, depletion of the body's natural antioxidant defences and the production of enzymes involved in the process of apoptosis – programmed cell death.

1974 – Colostrinin™ was first isolated from ovine colostrum and characterised as a proline-rich polypeptide and suggested to have potential therapeutic utility by Dr Maria Janusz and her co-workers at the Ludwik Hirszfild Institute in

Wroclaw, Poland. The wide-ranging nature of its therapeutic efficacy meant that the definition of therapeutic goals took some time and had to be achieved on an extremely limited academic research budget.

## Our Market Place, Principal Risks and Uncertainties, Outlook

ReGen is active in two main areas; pharmaceutical development and the development of its nutraceutical product.

ReGen's original focus was as a researcher and developer of pharmaceuticals. Pharmaceuticals are medicines sold primarily through doctors and hospitals but can also be "over the counter" medicines (OTC). The primary factor in rewards from pharmaceuticals is that a patented compound will be able to enjoy a monopoly profit by virtue of its unique properties. A patent lasts for twenty years, from the date that the original patent application was filed, after which the product becomes a generic (i.e. anyone can manufacture and sell it and price and profits generally fall sharply). The objective of a pharmaceutical company is to deliver a product to market as rapidly as possible to take the full benefit of the monopoly profit whilst the product is patent protected.

ReGen has an original patent on the use of Colostrinin™ dating back to October 1996 and subsequent patents on a proprietary manufacturing process and the composition of its constituent peptides. The "use" patent on zolpidem was applied for in May 2004. ReGen therefore has a significant period of time in which to develop its compounds.



## Operational review continued

ReGen is, however, a tiny player within the international pharmaceutical market. The industry is dominated by global pharmaceutical companies like GlaxoSmithKline, the second largest global and the largest European pharmaceutical company – in 2008 revenues were £24,352 million of which pharmaceuticals was £20,381 million and consumer healthcare £3,971 million. The third largest global pharmaceutical company AstraZeneca had revenues in 2008 of £18,359 million. (Source *Edison Investment Research Limited*). These and global companies like them are totally integrated, having the ability to take a compound from initial concept straight to the market.

Biotechnology companies such as ReGen do not have either the capacity to market a product or generally the resources to carry out late stage clinical trials. Their object, therefore, is to get one of the global companies (or smaller companies with an international presence) to take on their compound and get it to market. As a result of this a biotechnology company will typically receive an upfront payment and payment milestones as the product development progresses. Finally, when and if the product is on the market it will earn a royalty.

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

Turning now to the nutraceutical business, this is a different proposition in terms of risk/reward than that of pharmaceuticals, as generally it is easier to get a product to market because 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.

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 built up sufficient internal expertise 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 and Turkey. 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.



In short the principal risks for ReGen are:

- That it will not be able to fund its development.
- That it will not be able to do a licensing deal.
- Even if we achieve licensing deals there is no certainty that revenues will be sufficient to sustain the Company.
- That it is a very small player in an international market.

### **American Depositary Receipt (ADR) Programme**

Looking to the future development of the Company, we established an ADR programme in the US in March 2005. We were listed on the new OTCQX International market on 14 July 2008. This is commercially relevant to ReGen as we carry out research, development and manufacturing in the US and 62% of central nervous system pharmaceutical sales are in the US, which is also the most developed nutraceutical market in the World. 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) FSI**

*(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 led 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.



**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 (acyclovir) 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 Marian 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 recognized 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 the Company 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 2008

The Directors present their report together with the audited financial statements for the year ended 31 December 2008.

### Results and dividends

The consolidated income statement is set out on page 22 and shows the loss for the year.

The Directors do not recommend the payment of an ordinary dividend (2007 – £Nil).

### Principal activities

The principal activity of the Group was the development of healthcare products both nutraceutical and ethical pharmaceuticals and, conducting pharmacokinetic and pharmacodynamic research.

### Business performance

The turnover for 2008 was generated almost entirely (96.5%) from the sales of CogniSure™ as a nutraceutical in Australia, the US professional market and at the back end of the year from sales of Cognase™ in Cyprus. Following the closure of Guildford Clinical Pharmacology Unit Limited ("GCPUL") revenue from that source dried up at the beginning of 2008 and contributed just £3,266. As a result of this the higher margins achieved by the Colostrinin™ sales helped increase the overall margin from 65% in 2007 to 76% in 2008.

Development costs at £330,274 were considerably less than last year's total of £802,303. With the difficulties we were facing in the financial markets in raising sufficient monies to justify our full commitment to the Peptide and Zolpidem programmes we decided to concentrate our efforts and financial muscle on the Colostrinin™ 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™.

Other administrative costs for continuing activities have fallen by some 18% from £1,525,728 in 2007 to £1,257,888 for 2008. While the share-based payment charge for 2007 amounted to £88,184 there was a credit to the income statement in 2008 of £95,532 representing a favourable swing of £183,716. However this was counteracted by a substantial write down of patent costs of £298,256 in 2008 compared with £34,910 the previous year representing an unfavourable swing of £263,346. When these two non-cash items are taken out of the equation administrative costs have still decreased by £347,470, some 33%, in cash terms. As a result of these factors the loss after tax for the year decreased by 39% to £1,463,367.

The Group's net assets at 31 December 2008 are materially down on 2007. The cash resources are over £560k down on the previous year and the patent carrying value has dropped by just under £180k. However in these credit crunch times the Company has been raising smaller amounts of funds more frequently as opposed to the larger one off tranches. Indeed since the balance sheet date further funds of £367,000 have been successfully raised. The Company still also has access to the Duke Holdings equity credit facility.

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 licensing deals in respect of Colostrinin™ globally and particularly in the US to achieve a retail deal. During 2009 the Company has signed licensing deals with Eczacibasi in Turkey and Tagerr in Poland and are in discussions with various parties in respect of other territories. Further details are contained in the Chairman's statement. On the scientific and development front, the Company is currently developing three of the Colostrinin™ peptides for the treatment of Alzheimer's disease and obesity. 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 11 to 13.

### 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 promptly within their terms of payment except in cases of dispute.

The number of days purchases of the Group represented by trade creditors at 31 December 2008 was 117 days (2007 – 39). 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 contracted.

**Corporate governance**

The Directors acknowledge the importance of the revised Combined Code issued by the Financial Reporting Council (2007 FRC Code) in June 2006. 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 2008 has been charged to the consolidated income statement in accordance with this policy.

**OTCQX**

The Company was listed on the new OTCQX International market on 14 July 2008. All announcements made on AIM are also made on the OTCQX exchange and all filings with AIM are also filed with OTCQX.

**Charitable Donations**

The Company made charitable donations amounting to £375 of which £350 was donated to the Alzheimer's Society (2007 – £350).

**Events after the balance sheet date**

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.

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 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.



## Report of the Directors continued

for the year ended 31 December 2008

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 shares of 0.01p each at a premium of 2.99p per share for a consideration of £15,000.

### Directors

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

P W C Lomax  
K B Corbin – Non-Executive (resigned 9 July 2008)  
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 2008	Ordinary shares of 10p each 31 December 2007	Deferred A shares of 4.9p each 31 December 2008	Deferred B shares of 9.99p each 31 December 2007	Deferred B shares of 9.99p each 31 December 2008
P W C Lomax	53,787	38,487	1,448,736	1,448,736	53,787
K B Corbin	–	31,050	–	105,000	–
N A C Lott	1,820	1,820	32,000	32,000	1,820
M J Small	58,320	45,820	1,348,736	1,348,736	58,320
T S Shilton	26,966	11,666	–	–	26,966
P R Garrod	882,500	757,500	3,715,000	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 1985.

The Directors are responsible for preparing the annual report and the financial statements in accordance with the Companies Act 1985. 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; and
- 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.

**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.

**Auditors**

All of the current Directors have taken all the steps that they ought to have taken to make themselves aware of any information needed by the Company's Auditors for the purposes of their audit and to establish that the Auditors are aware of that information. The Directors are not aware of any relevant audit information of which the Auditors are unaware.

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

18 June 2009



## Report of the independent auditors

### To the Shareholders 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 2008 which comprise the consolidated income statement, the consolidated and parent Company balance sheets, the consolidated cash flow statement, the consolidated statement of changes in equity and the related notes. These financial statements have been prepared under the accounting policies set out therein.

This report is made solely to the Company's members, as a body, in accordance with Section 235 of the Companies Act 1985. 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 auditors' 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.

### Respective responsibilities of Directors and Auditors

The Directors' responsibilities for preparing the Annual Report and the Group financial statements in accordance with applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union, and for preparing the parent Company financial statements in accordance with the applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice) are set out in the Statement of Directors' Responsibilities.

Our responsibility is to audit the financial statements in accordance with the relevant legal and regulatory requirements and International Standards on Auditing (UK and Ireland).

We report to you our opinion as to whether the financial statements give a true and fair view and whether the financial statements have been properly prepared in accordance with the Companies Act 1985. We also report to you whether in our opinion the information given in the Directors' Report is consistent with the financial statements.

In addition we report to you if, in our opinion, the Company has not kept proper accounting records, if we have not received all the information and explanations we require for our audit, or if information specified by law regarding Directors' remuneration and other transactions is not disclosed.

We read other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. The other information comprises only the Chairman's Statement and the Operational Review. We consider the implications for our report if we become aware of any apparent misstatements or material inconsistencies with the financial statements. Our responsibilities do not extend to any other information.

### Basis of audit opinion

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosure in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Directors in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Group's and Company's circumstances, consistently applied and adequately disclosed.

We planned and performed our audit so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or other irregularity or error. In forming our opinion we also evaluated the overall adequacy of the presentation of information in the financial statements.



**Opinion**

In our opinion:

- the Group financial statements give a true and fair view, in accordance with IFRSs as adopted by the European Union, of the state of the Group's affairs as at 31 December 2008 and of its loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with the Companies Act 1985;
- the parent Company financial statements give a true and fair view, in accordance with United Kingdom Generally Accepted Accounting Practice, of the state of the parent Company's affairs as at 31 December 2008;
- the parent Company financial statements have been properly prepared in accordance with the Companies Act 1985; and
- the information given in the Directors' Report is consistent with the financial statements.

**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.

**Mazars LLP**

*Chartered Accountants*

*Registered Auditors*

Tower Bridge House

St Katharine's Way

London, E1W 1DD

18 June 2009

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 2008

	Note	2008 £	2007 £
<b>Continuing operations</b>			
<b>Revenue</b>	5	<b>91,716</b>	63,810
Cost of sales		<b>20,447</b>	24,042
		<hr/>	<hr/>
<b>Gross profit</b>		<b>71,269</b>	39,768
<hr/>			
Research and development costs		<b>330,274</b>	802,303
Other administrative costs		<b>1,257,888</b>	1,525,728
Impairment of intangible assets		–	348,562
<hr/>			
<b>Administrative expenses</b>		<b>1,588,162</b>	2,676,593
<hr/>			
<b>Operating loss</b>	6	<b>(1,516,893)</b>	(2,636,825)
Finance income	9	<b>10,308</b>	56,534
Finance costs	10	<b>(3,436)</b>	(5,434)
<hr/>			
<b>Loss before taxation</b>		<b>(1,510,021)</b>	(2,585,725)
Taxation	11	<b>80,590</b>	168,517
<hr/>			
<b>Loss after taxation for continuing activities</b>	25	<b>(1,429,431)</b>	(2,417,208)
<hr/>			
<b>Discontinued operations</b>			
<b>(Loss)/profit after taxation from discontinued operations</b>	12	<b>(33,936)</b>	32,134
<hr/>			
<b>Loss after taxation for the year</b>		<b>(1,463,367)</b>	(2,385,074)
<hr/>			
Basic and diluted loss per share	13	<b>(12.27p)</b>	(25.71p)
Basic and diluted loss per share on continuing operations		<b>(11.98p)</b>	(26.07p)
Basic and diluted (loss)/profit per share on discontinued operations		<b>(0.28p)</b>	0.36p



The notes on pages 26 to 54 form part of these consolidated financial statements.

## Consolidated statement of changes in equity

for the year ended 31 December 2008

	Share capital £	Share premium £	Other reserves £	Retained earnings £	Total £
At 1 January 2007	5,992,251	11,991,836	265,745	(15,821,988)	2,427,844
Loss for the year	–	–	–	(2,385,074)	(2,385,074)
Total recognised income and expense for the year	–	–	–	(2,385,074)	(2,385,074)
Net issue of share capital	331,584	1,977,558	–	–	2,309,142
Recognition of share-based payments	–	–	–	88,184	88,184
Balance at 31 December 2007	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 recognised income and expense 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)
Recognition of share-based payments	–	–	–	(95,532)	(95,532)
Balance at 31 December 2008	<b>6,605,003</b>	<b>14,147,213</b>	<b>265,745</b>	<b>(19,677,777)</b>	<b>1,340,184</b>



The notes on pages 26 to 54 form part of these consolidated financial statements.

## Consolidated balance sheet

at 31 December 2008

	Note	2008 £	2008 £	2007 £	2007 £
<b>Assets</b>					
<b>Non-current assets</b>					
Property, plant and equipment	14	1,017		2,674	
Intangible assets	15	1,759,250		1,946,559	
			<b>1,760,267</b>		1,949,233
<b>Current assets</b>					
Inventories	18	28,571		6,649	
Trade and other receivables	19	87,090		212,779	
Tax receivable	19	80,590		145,833	
Cash and cash equivalents		25,157		587,837	
			<b>221,408</b>		953,098
<b>Total assets</b>			<b>1,981,675</b>		2,902,331
<b>Liabilities</b>					
<b>Current liabilities</b>					
Trade and other payables	20	489,699		311,636	
Loans and borrowings	21	51,792		50,599	
			<b>541,491</b>		362,235
<b>Non-current liabilities</b>					
Provisions	22	100,000		100,000	
<b>Total liabilities</b>			<b>641,491</b>		462,235
<b>Total net assets</b>			<b>1,340,184</b>		2,440,096
<b>Equity</b>					
Share capital	23	6,605,003		6,323,835	
Share premium	25	14,147,213		13,969,394	
Other reserves	25	265,745		265,745	
Retained earnings	25	(19,677,777)		(18,118,878)	
<b>Total equity</b>			<b>1,340,184</b>		2,440,096

The financial statements were approved by the Board and authorised for issue on 18 June 2009 and were signed on its behalf by

**P W C Lomax**

Director

18 June 2009

The notes on pages 26 to 54 form part of these consolidated financial statements.

# Consolidated cash flow statement

for the year ended 31 December 2008

	Note	2008 £	2007 £
<b>Loss after tax from continuing activities</b>		<b>(1,429,431)</b>	(2,418,208)
<b>(Loss)/profit after tax from discontinued activities</b>		<b>(33,936)</b>	33,134
<b>Loss after tax for the financial year</b>		<b>(1,463,367)</b>	(2,385,074)
Impairment of goodwill		–	348,562
Amortisation of intangible assets		<b>298,256</b>	34,910
Depreciation of property, plant and equipment		<b>1,656</b>	24,353
Share option (credit)/charge		<b>(95,532)</b>	88,184
Interest charged		<b>7,830</b>	8,581
Interest credited		<b>(10,311)</b>	(56,537)
Taxation credit		<b>(80,590)</b>	(168,517)
Taxation received		<b>145,833</b>	138,148
<b>Operating cash flows before movements in working capital and provisions</b>		<b>(1,196,225)</b>	(1,967,390)
(Increase)/decrease in inventories		<b>(21,922)</b>	13,482
Decrease in receivables		<b>125,689</b>	16,739
Increase/(decrease) in payables		<b>178,064</b>	(247,956)
<b>Net cash outflow from operating activities</b>		<b>(914,394)</b>	(2,185,125)
<b>Cash flows from investing activities</b>			
Interest received		<b>10,311</b>	56,537
Purchase of property, plant and equipment		–	(710)
Purchase of intangible assets		<b>(110,947)</b>	(69,630)
<b>Net cash used in investing activities</b>		<b>(100,636)</b>	(13,803)
<b>Cash flows from financing activities</b>			
Proceeds from issue of share capital		<b>677,138</b>	2,486,875
Expenses paid on share issue		<b>(218,151)</b>	(177,733)
Interest paid		<b>(7,830)</b>	(8,581)
<b>Net cash from financing activities</b>		<b>451,157</b>	2,300,561
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>(563,873)</b>	101,633
<b>Opening cash and cash equivalents</b>	26	<b>537,238</b>	435,605
<b>Closing cash and cash equivalents</b>	26	<b>(26,635)</b>	537,238

The notes on pages 26 to 54 form part of these consolidated financial statements.



# Notes forming part of the financial statements

for the year ended 31 December 2008

## 1 General information

The principal activity of ReGen is the development of healthcare products both nutraceutical and ethical pharmaceuticals and, conducting pharmacokinetic and pharmacodynamic research. The Company is registered in the UK and was incorporated on 11 February 1998. 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 1985 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 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 £367,185 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 30 June 2009. 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.

### Standards, interpretations and amendments to published standards effective in 2008 but which are not relevant to the Group

Certain new standards, amendments and interpretations to existing standards have been published that are mandatory for the Group's accounting periods beginning on or after 1 January 2008 or later periods and which the Group has decided not to adopt early. These are:

— *IFRS 8, Operating Segments* (effective for accounting periods beginning on or after 1 January 2009). This standard sets the requirements for the disclosure of information about an entity's operating segments and also about the entity's products and services, the geographical areas in which it operates, and its major customers. It replaces IAS 14, Segmental Reporting. The Group expects to apply this standard in the accounting period beginning on 1 January 2009. As this is a disclosure standard it will not have any impact on the results or net assets of the Group.

— *IAS 23, Borrowing Costs (revised)* (effective for accounting period beginning on or after 1 January 2009). The revised IAS 23 is still to be endorsed by the EU. The main change from the previous version is the removal of the option of immediately recognising as an expense borrowing costs that relate to qualifying assets, broadly being assets that take a substantial period of time to get ready for use or sale. The Group is currently assessing its impact on the financial statements.

— *IFRIC 13, Customer Loyalty Programmes* (effective for accounting periods beginning on or after 1 July 2008). IFRIC 13 is still to be endorsed by the EU. IFRIC 13 addresses sales transactions in which the entities grant their customers award credits that, subject to meeting any further qualifying conditions, the customers can redeem in future for free or discounted goods or services. IFRIC 13 is not relevant to the Group's operations due to absence of such arrangements.



– *IFRIC 14, IAS 19 – The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction* (effective for accounting periods beginning on or after 1 January 2008). IFRIC 14 is still to be endorsed by the EU. IFRIC 14 clarifies when refunds or reductions in future contributions should be regarded as available in accordance with paragraph 58 of IAS 19, how a minimum funding requirement might affect the availability of reductions in future contributions and when a minimum funding requirement might give rise to a liability. Management is currently assessing the impact of IFRIC 14 on the accounts.

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

— *Revised IFRS 3, Business Combination and complementary Amendments to IAS 27, 'Consolidated and separate financial statements* (both effective for accounting periods beginning on or after 1 July 2009). This revised standard and amendments to is still to be endorsed by the EU. The revised IFRS 3 and amendments to IAS 27 arise from a joint project with the Financial Accounting Standards Board (FASB), the US standards setter, and results in IFRS being largely converged with the related, recently issued, US requirements. There are certain very significant changes to the requirements of IFRS, and options available, if accounting for business combinations. Management is currently assessing the impact of revised IFRS 3 and amendments to IAS 27 on the accounts.

— *Amendment to IFRS 2, Share-based payments: vesting conditions and cancellations* (effective for accounting periods beginning on or after 1 January 2009). This amendment is still to be endorsed by the EU. The Amendment to IFRS 2 is of particular relevance to companies that operate employee shares save schemes. This is because it results in an immediate acceleration of the IFRS 2 expense that would otherwise have been recognised in future periods should an employee decide to stop contributing to the savings plan, as well as a potential revision to the fair value of the awards granted to factor in the probability of employees withdrawing from such a plan. Management is currently assessing the impact of the Amendment on the accounts.

— *Amendment to IFRS 5, Non-current assets held for sale and discontinued operations: amendments resulting from April 2009 annual improvements to IFRSs* (effective for accounting periods beginning on or after 1 January 2010). Management is currently assessing the impact of the Amendment on the accounts.

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.

Revenue arising from the sale of clinical trial services is recognised by reference to the stage of completion of the trial activity at the balance sheet date. The stage of completion is determined by reference to the milestones achieved and pertinent criteria such as the number of patients that have taken part at certain stages of the trial.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 2 Accounting policies (continued)

#### 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.

#### 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

A reportable segment, as defined by IAS 14 "Segment Reporting", is a distinguishable business or geographical component of the Group, that provides products or services, that are subject to risks and rewards that are different from those of other segments. The Group considers its primary reporting format to be business segments. A business segment is a distinguishable component of an enterprise that is engaged in providing an individual product or service and is subject to separate risks and rewards.

#### Property, plant and equipment

Items of property, plant and equipment are initially recognised at cost.



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.

### **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.

### **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.

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

### **Financial instruments**

In relation to the disclosures made in note 4:

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 2008

### 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:

Intangible asset	Useful economic life
Trademarks	Indefinite
Patents	Length of patent – up to 20 years

Costs to obtain patent rights for the use of Colostrinin™ have been capitalised and will be amortised over the expected useful life of the patent from the date the patent is filed.

#### Deferred taxation

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability in the balance sheet 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 balance sheet 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.

#### Retirement benefits: Defined contribution schemes

Contributions to defined contribution pension schemes are charged to the consolidated income statement in the year to which they relate.



**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 balance sheet 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 cash flow statement, 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 amount that have arisen as a result of past transactions.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 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. More details including carrying values are included in note 24.



#### 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 Group's financial instruments comprise principally cash and current asset investments. The main purpose of these financial instruments is to finance the Group's operations. 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

All financial assets are designated as loans and receivables and all financial liabilities are measured at amortised cost.

	Loans and receivables held at amortised cost		Borrowings and trade payables held at amortised cost	
	2008	2007	2008	2007
	£	£	£	£
<b>Current financial assets</b>				
Trade receivables	<b>15,976</b>	56,156	-	-
<b>Current financial liabilities</b>				
Trade payables	-	-	<b>419,308</b>	212,426
Borrowings	-	-	<b>51,792</b>	50,599
<b>Total</b>	<b>15,976</b>	56,156	<b>471,100</b>	263,025

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 2008

### 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 moneys 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 and the guarantors are currently in discussions with regard to its repayment.

#### 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 balance sheet 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.

#### Market risk

There is a market risk arising from interest rates on the Group's borrowings.

#### Foreign exchange risk

Foreign exchange risk may arise when the Group enters into transactions denominated in a foreign currency. 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 principal risk to the Group is liquidity and this is kept under review by the Directors. The Directors do not believe the Group has any significant currency risk. The cash deposits are held in a mixture of short-term deposits and current accounts at floating rates. The Directors are of the opinion that there is no difference between the fair value and book value of financial instruments.



**5 Revenue**

	<b>2008</b>	<b>2007</b>
	<b>£</b>	<b>£</b>
Revenue arises from:		
Sale of Colostrinin™ — continuing	<b>91,716</b>	63,810
Provision of clinical research services — discontinued	<b>3,266</b>	247,678
	<b>94,982</b>	311,488

**6 Operating loss**

	<b>2008</b>	<b>2007</b>
	<b>£</b>	<b>£</b>
This has been arrived at after charging:		
Inventory expense	<b>20,447</b>	24,042
Staff costs (see note 7)	<b>356,079</b>	816,985
Depreciation of property, plant and equipment	<b>1,656</b>	24,228
Goodwill impairment charge	–	348,562
Amortisation of intangible non-current assets	<b>298,256</b>	34,910
Foreign exchange differences	<b>2,657</b>	2,334
Research and development costs	<b>330,274</b>	737,076
Fees payable to the Company Auditor for the audit of the parent Company and the consolidated financial statements	<b>18,000</b>	43,600
Fees payable to the Company's Auditor for other services:		
– The audit of the Company's subsidiaries pursuant to legislation	<b>6,000</b>	4,500
– Other services pursuant to legislation	–	2,000
– Other services relating to taxation	–	11,500
– All other services	–	8,500
Operating lease expense – property	<b>116,418</b>	122,587
Share-based (credit)/payment (see note 24)	<b>(95,532)</b>	88,184

Included within the Group audit fee is an amount of £18,000 (2007 – £22,000) in respect of the Company.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 7 Staff costs

	2008 £	2007 £
Staff costs (including Directors) comprise:		
Wages and salaries	<b>403,904</b>	650,213
Social security costs	<b>46,520</b>	72,796
Other pension costs	–	5,792
Share-based payment (credit)/expense (see note 24)	<b>(94,345)</b>	88,184
	<b>356,079</b>	816,985

The average number of employees during the year, including Directors, was as follows:

	Number	Number
Administration	<b>6</b>	9
Scientific	<b>1</b>	2
	<b>7</b>	11

Included in the share-based (credit)/payments of (£95,532) (2007 – £88,184) is (£94,345) (2007 – £87,088) relating to the share-based payments to employees and Directors, this is included in wages and salaries.

### Directors' remuneration

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

	2008 £	2007 £
Salaries	<b>363,916</b>	409,084
Bonuses	–	10,000
Private health benefit	<b>8,175</b>	6,034
Share-based payment expense (non-cash item)	<b>(93,265)</b>	86,091
	<b>278,826</b>	511,209



Directors' emoluments by individual are as follows:

	2008	2008	2008	2007	2007	2007
	Cash items	Share-based payment expense (non-cash item)	Total	Cash items	Share-based payment expense (non-cash item)	Total
	£	£	£	£	£	£
P W C Lomax	99,460	(28,066)	71,394	119,437	25,907	145,344
K B Corbin	14,791	(5,828)	8,963	27,001	5,380	32,381
N A C Lott	75,439	(17,272)	58,167	81,640	15,943	97,583
M J Small	75,250	(17,272)	57,978	80,793	15,943	96,736
T S Shilton	84,182	(19,430)	64,752	91,247	17,936	109,183
P R Garrod	22,969	(5,397)	17,572	25,000	4,982	29,982
	<b>372,091</b>	<b>(93,265)</b>	<b>278,826</b>	425,118	86,091	511,209

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 2008	Exercise price	Date from which 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. The market price of the shares at 31 December 2008 was 5.75p and the range during the financial year was 4p to 56.5p.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 8 Segment information

The Group operated in two main business segments during the year, the commercial development and sale of Colostrinin™ as a nutraceutical product and the provision of clinical research services. The provision of clinical research services has now been discontinued. In addition ReGen continues to be active in progressing Colostrinin™ and its constituent peptides in terms of their development on the pharmaceutical front together with continuing to develop new formulations of zolpidem as a form of a clinically significant benefit.

The Group's primary reporting format for reporting segment information is business segments.

	Nutraceutical and pharmaceutical development	Provision of clinical research services (discontinued)	Total
	2008	2008	2008
	£	£	£

*Revenue*

<b>Segment revenue</b>	<b>91,716</b>	<b>3,266</b>	<b>94,982</b>
<i>Segment result</i>			
Depreciation	(1,656)	–	(1,656)
Amortisation	(298,256)	–	(298,256)
Non-cash expenses	95,532	–	95,532
Finance income	10,308	3	10,311
Finance costs	(3,436)	(4,394)	(7,830)
<b>Loss before taxation</b>	<b>(1,510,021)</b>	<b>(33,936)</b>	<b>(1,543,957)</b>
Taxation	80,590	–	80,590
<b>Loss for the year</b>	<b>(1,429,431)</b>	<b>(33,936)</b>	<b>(1,463,367)</b>

	Nutraceutical and pharmaceutical development	Provision of clinical research services (discontinued)	Total
	2007	2007	2007
	£	£	£

*Revenue*

<b>Segment revenue</b>	<b>63,810</b>	<b>247,678</b>	<b>311,488</b>
<i>Segment result</i>			
Depreciation	(2,789)	(21,439)	(24,228)
Amortisation	(34,910)	–	(34,910)
Non-cash expenses	(88,184)	–	(88,184)
Finance income	56,534	3	56,537
Finance costs	(5,434)	(3,147)	(8,581)
<b>(Loss)/profit before taxation</b>	<b>(2,586,725)</b>	<b>33,134</b>	<b>(2,553,591)</b>
Taxation	168,517	–	168,517
<b>(Loss)/profit for the year</b>	<b>(2,418,208)</b>	<b>33,134</b>	<b>(2,385,074)</b>

Segment assets and liabilities as at 31 December 2008 and capital expenditure for the year then ended are as follows:

	<b>Nutraceutical and pharmaceutical development 2008 £</b>	<b>Provision of clinical research services 2008 £</b>	<b>Total 2008 £</b>
<b>Total assets</b>	<b>1,976,988</b>	<b>4,687</b>	<b>1,981,675</b>
<b>Total liabilities</b>	<b>575,265</b>	<b>66,226</b>	<b>641,491</b>
<b>Capital expenditure</b>	<b>110,947</b>	<b>–</b>	<b>110,947</b>

	<b>Nutraceutical and pharmaceutical development 2007 £</b>	<b>Provision of clinical research services 2007 £</b>	<b>Total 2007 £</b>
Total assets	2,679,871	66,576	2,746,447
Total liabilities	356,940	93,016	449,956
Capital expenditure	70,341	–	70,341

The Group's secondary reporting format for reporting segment information is geographic segments.

	<b>External revenue by location of customers</b>		<b>Total assets by location of assets</b>		<b>Capital expenditure by location of assets</b>	
	<b>2008 £</b>	2007 £	<b>2008 £</b>	2007 £	<b>2008 £</b>	2007 £
UK	<b>3,266</b>	247,678	<b>1,901,085</b>	2,746,447	–	70,341
United States	<b>66,196</b>	52,990	–	–	–	–
Australia	<b>10,871</b>	10,820	–	–	–	–
Europe	<b>14,649</b>	–	–	–	–	–
	<b>94,982</b>	311,488	<b>1,901,085</b>	2,746,447	–	70,341



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 9 Finance income

	2008	2007
	£	£
<i>Finance income</i>		
Bank interest received	<b>10,311</b>	56,537

### 10 Finance expense

	2008	2007
	£	£
<i>Finance expense</i>		
Interest expense on financial liabilities	<b>7,830</b>	8,581

### 11 Taxation

	2008	2007
	£	£
UK corporation tax credit in respect of current period	<b>66,065</b>	145,833
Adjustment in respect of prior years	<b>14,525</b>	22,684
Total current tax credit	<b>80,590</b>	168,517

The Group has unrecognised tax losses of approximately £13,500,000 (2007 – £12,500,000) for offset against future profits.

The rate of corporation tax changed to 28% with effect from April 2008.

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

	2008	2007
	£	£
Loss before tax	<b>1,543,957</b>	2,553,591
Loss at the standard rate of corporation tax in the UK of 28.5% (2007 – 30%)	<b>440,028</b>	766,077
Effects of:		
Expenses not deductible for tax purposes	<b>17,408</b>	(165,192)
Expenditure qualifying for enhanced tax relief	<b>46,990</b>	–
Depreciation in excess of capital allowances	<b>60</b>	–
Difference in tax rate applying to R&D tax credit	<b>(58,703)</b>	(35,621)
Unrecognised deferred tax	–	13,510
Tax losses for which no deferred tax asset recognised	<b>(379,718)</b>	(432,941)
Adjustment to prior year tax charge	<b>14,525</b>	22,684
Total tax credit for the year	<b>80,590</b>	168,517

## 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:

	<b>2008</b>	2007
	<b>£</b>	£
Revenue	<b>3,266</b>	247,678
Expenses	<b>37,202</b>	215,544
(Loss)/profit before taxation	<b>(33,936)</b>	32,134
Taxation	-	-
Net loss attributable to discontinued operations	<b>(33,936)</b>	32,134
Net cash flows attributable to operating activities	<b>3,163</b>	24,787
Net cash flows attributable to investing activities	<b>3</b>	3
Net cash flows attributable to financing activities	<b>(4,394)</b>	(3,147)

## 13 Earnings per share

	<b>2008</b>	2007
<i>Numerator</i>		
Loss for the year	<b>1,463,367</b>	2,385,074
<i>Denominator</i>		
Weighted average number of shares of 0.01p/10p	<b>11,926,992</b>	9,276,893

The Company has instruments that could potentially dilute basic earnings per share in the future, but that have 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 23.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 14 Property, plant and equipment

	<b>Office equipment 2008 £</b>	Office equipment 2007 £
<i>Cost</i>		
At 1 January	<b>151,935</b>	151,225
Additions	–	710
At 31 December	<b>151,935</b>	151,935
<i>Depreciation</i>		
At 1 January	<b>149,261</b>	124,908
Charge for the year	<b>1,657</b>	24,353
At 31 December	<b>150,918</b>	149,261
Carrying value at 31 December	<b>1,017</b>	2,674

The carrying value at 1 January 2007 was £26,317.



**15 Intangible assets**

	<b>Goodwill</b>	<b>Patent</b>	<b>Trade</b>	<b>Total</b>
	<b>£</b>	<b>rights</b>	<b>marks</b>	<b>£</b>
		<b>£</b>	<b>£</b>	
<i>Cost</i>				
At 1 January 2007	1,952,236	1,121,992	4,681	3,078,909
Additions	–	69,631	–	69,631
At 31 December 2007	<b>1,952,236</b>	<b>1,191,623</b>	<b>4,681</b>	<b>3,148,540</b>
<i>Amortisation</i>				
At 1 January 2007	638,269	180,240	–	818,509
Impairment losses	348,562	–	–	348,562
Amortisation	–	34,910	–	34,910
At 31 December 2007	<b>986,831</b>	<b>215,150</b>	<b>–</b>	<b>1,201,981</b>
<i>Cost</i>				
At 1 January 2008	1,952,236	1,191,623	4,681	3,148,540
Additions	–	110,947	–	110,947
At 31 December 2008	<b>1,952,236</b>	<b>1,302,570</b>	<b>4,681</b>	<b>3,259,487</b>
<i>Amortisation</i>				
At 1 January 2008	986,831	215,150	–	1,201,981
Impairment losses	–	–	–	–
Amortisation	–	298,256	–	298,256
At 31 December 2008	<b>986,831</b>	<b>513,406</b>	<b>–</b>	<b>1,500,237</b>
<i>Carrying value</i>				
At 1 January 2007	1,313,967	941,752	4,681	2,260,400
At 31 December 2007	965,405	976,473	4,681	1,946,559
At 31 December 2008	<b>965,405</b>	<b>789,164</b>	<b>4,681</b>	<b>1,759,250</b>

Patent costs will continue to be amortised over a maximum of 20 years from their filing dates.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 16 Goodwill and impairment

As a result of the difficult market conditions and the very considerable competition in the UK Phase I/II clinical trials market it was decided to close down the operations of GCPUL, and, as a consequence the goodwill, which arose on the acquisition of GCPUL was fully impaired in 2007.

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

	Goodwill carrying amount	
	2008	2007
	£	£
Colostrinin™	819,146	819,146
Zolpidem (acquisition of Sciencom)	146,259	146,259
GCPUL	–	–
	<b>965,405</b>	<b>965,405</b>

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 2013. Other major assumptions are as follows (Note: the growth rate applies only after 3 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™	Zolpidem
	2008	2008
	%	%
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 3 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.

## 17 Subsidiaries

The principal subsidiaries of ReGen Therapeutics Plc, all of which have been included in these consolidated financial statements are as follows:

Name	Country of Incorporation	Proportion of ownership interest at 31 December	
		2008	2007
Guildford Clinical Pharmacology Unit Limited	Great Britain	100%	100%
Sciencom Limited	Great Britain	100%	100%
ReGen Biotech Limited*	Great Britain	100%	100%
The Georgiades Foundation Limited	British Virgin Islands	100%	100%
Georgiades Biotech Limited*	British Virgin Islands	100%	100%
ReGen Polska Sp. z o.o.	Poland	100%	100%

\* 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
	<b>28,952</b>	

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

## 18 Inventories

	2008	2007
	£	£
Finished goods and goods for resale	<b>28,571</b>	6,649



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 19 Trade and other receivables

	2008 £	2007 £
Trade receivables	15,976	56,156
Less: provision for impairment of trade receivables	–	–
	<hr/>	<hr/>
Trade receivables – net	15,976	56,156
Other receivables	8,593	58,012
Prepayments	62,521	98,611
Corporation tax	80,590	145,833
	<hr/>	<hr/>
	<b>167,680</b>	<b>358,612</b>

There is no difference between the fair value and book value of trade and other receivables. This also represents the maximum credit risk exposure.

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

	2008 £	2007 £
Pound Sterling	5,882	48,749
US Dollar	10,094	7,407
	<hr/>	<hr/>
	<b>15,976</b>	<b>56,156</b>

### 20 Trade and other payables: current

	2008 £	2007 £
Trade payables	419,308	212,426
Other taxes and social security costs	6,886	21,759
Other payables	38,329	24,529
Accruals	25,000	52,746
Minority interests	176	176
	<hr/>	<hr/>
	<b>489,699</b>	<b>311,636</b>

## 21 Loans and borrowings

	<b>Book value</b>	<b>Fair value</b>	Book value	Fair value
	<b>2008</b>	<b>2008</b>	2007	2007
	<b>£</b>	<b>£</b>	£	£
<b>Current</b>				
Overdraft	<b>51,792</b>	<b>51,792</b>	50,599	50,599
<b>Total borrowings</b>	<b>51,792</b>	<b>51,792</b>	50,599	50,599

The bank overdraft is secured by a fixed and floating charge over the assets of Guildford Clinical Pharmacology Unit Limited.

The Company also has in place an equity credit facility of up to £2,000,000, which is available if required based on trading volumes. This facility expires on 27 March 2010.

## 22 Provisions

	<b>Deferred consideration</b>	
	<b>2008</b>	2007
	<b>£</b>	£
At 1 January	<b>100,000</b>	100,000
Movement	-	-
	<b>100,000</b>	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.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 23 Share capital

	2008	2007
	£	£
<i>Authorised</i>		
296,100,000 ordinary shares of 0.01p each (2007 – 296,100,000 ordinary shares of 10p each)	<b>29,610</b>	29,610,000
296,100,000 deferred B shares of 9.99p each	<b>29,580,390</b>	–
110,000,000 deferred A shares of 4.9p each	<b>5,390,000</b>	5,390,000
	<b>35,000,000</b>	35,000,000
<i>Called up share capital issued and fully paid</i>		
15,107,050 ordinary shares of 0.01p each (2007 – 10,258,878 ordinary shares of 10p each)	<b>1,510</b>	1,025,887
13,068,521 deferred B shares of 9.99p each	<b>1,305,545</b>	–
108,121,391 deferred A shares of 4.9p each	<b>5,297,948</b>	5,297,948
	<b>6,605,003</b>	6,323,835

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 26 March 2008, the Company issued 629,685 ordinary shares of 10p each at a premium of 22.5p per share for a consideration of £204,648.

On 27 March 2008, the Company issued 130,000 ordinary shares of 10p each at a premium of 22.5p per share for a consideration of £42,250.

On 27 March 2008, the Company issued 138,889 ordinary shares of 10p each at a premium of 26p per share for a consideration of £50,000 representing the draw down fees payable upon entering in to an agreement with Duke Holdings Corporation Limited (“Duke”) under which Duke will make available to the Company an initial equity credit facility. The Company has an initial facility of £2,000,000, which is available for 24 months in two tranches of £1,000,000, with draw downs based on traded share volumes achieved by the Company.

On 17 April 2008, the Company issued 325,000 ordinary shares of 10p each at a premium of 13.8p per share for a consideration of £77,350.

On 12 August 2008, the Company issued 309,598 ordinary shares of 10p each at a premium of 6.15p per share for a consideration of £50,000.

On 13 August 2008, the Company issued 123,839 ordinary shares of 10p each at a premium of 6.15p per share for a consideration of £20,000.

On 15 September 2008, the Company issued 1,152,632 ordinary shares of 10p each with no premium per share for a consideration of £115,263.

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.

On 27 October 2008, the Company issued 709,570 ordinary shares of 0.01p each at a premium of 6.43p per share for a consideration of £45,691.

On 27 October 2008, the Company issued 123,707 ordinary shares of 0.01p each at a premium of 9.99p per share for a consideration of £12,371.

On 10 November 2008, the Company issued 305,252 ordinary shares of 0.01p each at a premium of 5.99p per share for a consideration of £18,315.

On 25 November 2008, the Company issued 350,000 ordinary shares of 0.01p each at a premium of 5.49p per share for a consideration of £19,250.

On 9 December 2008, the Company issued 550,000 ordinary shares of 0.01p each at a premium of 3.99p per share for a consideration of £22,000.

The issued shares rank *pari passu* with existing shares.

On 20 November 2007 there was a consolidation of the Company's share capital whereby a resolution was passed at an Extraordinary General Meeting of the Company at which every one hundred existing ordinary shares of 0.1p each were consolidated into one new ordinary share with a nominal value of 10p.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 23 Share capital (continued)

The movements during the year of issued share capital and share premium are set out below:

	Date	Nominal value £	Number of ordinary shares	Issued share capital £	Premium per share on issue £	Share premium £
At 1 January 2008	1 January 2008	0.10	10,258,878	1,025,887		13,969,394
Share issue	26 March 2008	0.10	629,685	62,969	0.225	141,679
Share issue	27 March 2008	0.10	130,000	13,000	0.225	29,250
Share issue	27 March 2008	0.10	138,889	13,889	0.26	36,111
Share issue	17 April 2008	0.10	325,000	32,500	0.138	44,850
Share issue	12 August 2008	0.10	309,598	30,960	0.0615	19,040
Share issue	13 August 2008	0.10	123,839	12,384	0.0615	7,616
Share issue	15 September 2008	0.10	1,152,632	115,263	0.00	–
			13,068,521	1,306,852		14,247,940
Capital sub-division	6 October 2008	0.0001	13,068,521	1,307		14,247,940
Share issue	27 October 2008	0.0001	709,570	71	0.0643	45,620
Share issue	27 October 2008	0.0001	123,707	12	0.0999	12,359
Share issue	10 November 2008	0.0001	305,252	31	0.0599	18,285
Share issue	25 November 2008	0.0001	350,000	35	0.0549	19,215
Share issue	9 December 2008	0.0001	550,000	55	0.0399	21,945
Less total share issue costs						(218,151)
At 31 December 2008			15,107,050	1,511		14,147,213

#### Share options

At 31 December 2008, total share options outstanding under the Company's approved and unapproved share option plan are as set out below:

Date of grant	Pre-Consolidation Number of shares	Date from which options are first exercisable	Lapse date	Pre-Consolidation Price per share
7 December 2000	200,000	1 December 2002	30 November 2010	28p
25 July 2002	89,285	25 July 2002	24 July 2010	1.5p
25 November 2003	1,150,000	25 November 2003	24 November 2010	1.5p
13 February 2004	400,000	13 February 2004	13 February 2009	6p
21 December 2004	225,000	21 December 2004	21 December 2009	6p
12 December 2007	41,550,000	31 December 2007	12 December 2016	1.25p

## 24 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. It is considered that the performance criteria attached to these options will never be met and therefore will not vest. Consequently the 415,500 associated share options are deemed to have lapsed.

	<b>2008</b>	<b>2008</b>	2007	2007
	<b>Weighted</b>		Weighted	
	<b>average</b>		average	
	<b>exercise price</b>	<b>Number</b>	exercise price	Number
	<b>(pence)</b>		(pence)	
Outstanding at the beginning of the year	<b>157</b>	<b>469,143</b>	1.57	46,914,285
Granted during the year	–	–	–	–
Forfeited during the year	<b>311</b>	<b>(33,000)</b>	–	–
Exercised during the year	–	–	–	–
Lapsed during the year	<b>125</b>	<b>(415,500)</b>	–	–
	<b>593</b>	<b>20,643</b>	1.57	46,914,285
Capital consolidation 20 November 2007	–	–	157	469,143
Outstanding at the year end	<b>593</b>	<b>20,643</b>	157	469,143

The exercise price of non-vesting options outstanding at the end of the year was £1.25 (2007 – £1.25) and their weighted average contractual life was 10 months (2007 – 1.75 years).

Of the total number of options outstanding at the end of the year, 20,643 (2007 – 26,643) had vested and were exercisable at the end of the year.

	<b>2008</b>	2007
The share-based remuneration (credit)/expense (note 6) comprises:		
Equity-settled schemes	<b>(94,345)</b>	88,184



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 25 Reserves

	Share premium £	Other reserves £	Retained earnings £	Total £
At 1 January 2007	11,991,836	265,745	(15,821,988)	(3,564,407)
Loss for the year	–	–	(2,385,074)	(2,385,074)
Total recognised income and expense for the year	–	–	(2,385,074)	(2,385,074)
Issue of share capital	1,977,558	–	–	1,977,558
Equity share options issued	–	–	88,184	88,184
Balance at 31 December 2007	13,969,394	265,745	(18,118,878)	(3,883,739)
Loss for the year	–	–	(1,463,367)	(1,463,367)
Total recognised income and expense for the year	–	–	(1,463,367)	(1,463,367)
Issue of share capital	177,819	–	–	177,819
Equity share options issued	–	–	(95,532)	(95,532)
Balance at 31 December 2008	<b>14,147,213</b>	<b>265,745</b>	<b>(19,677,777)</b>	<b>(5,264,819)</b>

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 131 of Companies Act 1985.
Retained earnings	Cumulative net losses recognised in the consolidated income statement.

### 26 Note supporting cash flow statement

Cash and cash equivalents comprises:

	2008 £	2007 £
Cash available on demand	<b>7,682</b>	18,579
Short-term deposits	<b>17,475</b>	569,258
Cash and cash equivalents	<b>25,157</b>	587,837
Overdraft	<b>(51,792)</b>	(50,599)
	<b>(26,635)</b>	537,238

## 27 Leases

*Operating leases – lessee*

The Company leases serviced offices. The total future value of minimum lease payments are due as follows:

	<b>2008</b>	2007
	<b>£</b>	£
Not later than one year	<b>3,669</b>	30,630
Later than one year but not later than 5 years	–	–
Later than 5 years	–	–
	<hr/>	<hr/>

## 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:

<b>Related party relationship</b>	<b>Type of transaction</b>	<b>Transaction amount</b>		<b>Balance owed/(owing)</b>	
		<b>2008</b>	2007	<b>2008</b>	2007
		<b>£</b>	£	<b>£</b>	£
P W C Lomax (Director)	Provision of services (Note 1)	<b>12,032</b>	13,456	<b>273</b>	397
K B Corbin	Provision of services (Note 2)	<b>122</b>	1,273	–	1,273

Note 1 – The provision of services through Lomax Pharmaceutical Consulting of which P W C Lomax is a partner.

Note 2 – The provision of services through Nerine Trust Company Limited to 9 July 2008, of which K B Corbin is a Director.



## Notes forming part of the financial statements continued

for the year ended 31 December 2008

### 29 Events after the balance sheet date

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.

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 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.



# Company balance sheet

at 31 December 2008

	Note	2008	2008	2007	2007
		£	£	Restated	Restated
				£	£
<b>Fixed assets</b>					
Intangible assets	2	582,370		693,539	
Tangible assets	3	1,017		2,674	
Investments in subsidiaries	4	2,905,823		2,917,420	
			<b>3,489,210</b>		3,613,633
<b>Current assets</b>					
Inventories		28,571		6,649	
Debtors	5	163,054		292,132	
Cash and cash equivalents		24,994		587,223	
<b>Total current assets</b>		<b>216,619</b>		886,004	
<b>Creditors: amounts falling due within one year</b>	6	<b>441,844</b>		243,241	
<b>Net current (liabilities)/assets</b>			<b>(225,225)</b>		642,763
<b>Total assets less current liabilities</b>			<b>3,263,985</b>		4,256,396
<b>Provision for liabilities</b>			<b>100,000</b>		100,000
<b>Net assets</b>			<b>3,163,985</b>		4,156,396
<b>Capital and reserves</b>					
Share capital – Issued and fully paid	7		1,510		1,025,887
– Deferred A	7		5,297,948		5,297,948
– Deferred B	7		1,305,545		–
Share premium	10		14,147,213		13,969,394
Retained earnings	10		(17,588,231)		(16,136,833)
<b>Total equity</b>			<b>3,163,985</b>		4,156,396

The financial statements were approved by the Board and authorised for issue on 18 June 2009 and were signed on its behalf by

**P W C Lomax**

Director

18 June 2009

The notes on pages 56 to 60 form part of these Company financial statements.



# Notes to the Company financial statements

for the year ended 31 December 2008

## 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 1985 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.

### Loss for the financial year

The Company has taken advantage of Section 230 of the Company's Act 1985 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 2008 under UK GAAP was £1,355,865 (2007 – £2,555,427).

Audit fees for the year were £18,000 (2007 – £22,000).

### 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™ and zolpidem have been capitalised and will be amortised over 20 years, the expected useful life of the patent from the date the patent is filed.

### 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.

### Investments in subsidiaries

Investments are stated at cost less any impairment considered necessary

### 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.



## 2 Intangible assets

	<b>Patent rights £</b>
<i>Cost</i>	
At 1 January 2008	826,861
Additions	99,796
	<hr/>
At 31 December 2008	<b>926,657</b>
	<hr/>
<i>Amortisation</i>	
At 1 January 2008	133,322
Charge for the year	210,965
	<hr/>
At 31 December 2008	<b>344,287</b>
	<hr/>
<i>Net book value</i>	
At 31 December 2008	<b>582,370</b>
	<hr/>
At 31 December 2007	693,539
	<hr/>

## 3 Tangible assets

	<b>Office equipment £</b>
<i>Cost</i>	
At 1 January 2008	66,367
Additions	–
	<hr/>
At 31 December 2008	<b>66,367</b>
	<hr/>
<i>Depreciation</i>	
At 1 January 2008	63,693
Charge for the year	1,657
	<hr/>
At 31 December 2008	<b>65,350</b>
	<hr/>
<i>Net book value</i>	
At 31 December 2008	<b>1,017</b>
	<hr/>
At 31 December 2007	2,674
	<hr/>



## Notes to the Company financial statements continued

for the year ended 31 December 2008

### 4 Investments in subsidiaries

	Investments in subsidiary undertakings Restated £	Loans to subsidiary undertakings Restated £	Total Restated £
At 1 January 2008 – at cost	1,539,589	1,377,831	2,917,420
Additions/(repayments)	–	(11,597)	(11,597)
Impairment charge	–	–	–
	<hr/>	<hr/>	<hr/>
At 31 December 2008 – at cost less impairment	1,539,589	1,366,234	2,905,823
	<hr/>	<hr/>	<hr/>

The investments at 31 December 2008 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™

\* 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
	<hr/>	
	28,952	
	<hr/>	

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

**5 Debtors**

	<b>2008</b>	2007
	<b>£</b>	£
Trade receivables	<b>10,094</b>	7,407
Other receivables	<b>9,849</b>	43,634
Prepayments	<b>62,521</b>	95,258
Corporation tax	<b>80,590</b>	145,833
	<hr/> <b>163,054</b> <hr/>	<hr/> 292,132 <hr/>

**6 Creditors: amounts falling due within one year**

	<b>2008</b>	2007
	<b>£</b>	£
Trade creditors	<b>396,158</b>	192,382
Other taxes and social security costs	<b>6,886</b>	21,759
Other creditors	<b>13,800</b>	–
Accruals	<b>25,000</b>	29,100
	<hr/> <b>441,844</b> <hr/>	<hr/> 243,241 <hr/>

**7 Share capital**

(See note 23 to the consolidated accounts).

**8 Share Options**

(See note 23 to the consolidated accounts).

**9 Share-based payment**

(See note 24 to the consolidated accounts).



## Notes to the Company financial statements continued

for the year ended 31 December 2008

### 10 Reserves

	Share premium £	Profit and loss account £
At 1 January 2008	13,969,394	(16,136,833)
Shares issued	395,970	–
Share issue costs written off	(218,151)	–
Loss transferred to reserves	–	(1,355,865)
Recognition of share-based payments	–	(95,532)
	<hr/>	<hr/>
At 31 December 2008	<b>14,147,213</b>	<b>(17,588,231)</b>

### 11 Prior year adjustment

The Directors have restated the prior year financial statements to incorporate a provision for the deferred consideration of one of the Company's subsidiaries, Sciencom Limited. The effect of this restatement is to increase the carrying value of the investments in subsidiaries and the provision for liabilities by £100,000. There is no impact on the profit and loss account for the years ended 31 December 2007 or 31 December 2008, or the net assets as at 31 December 2007 or 31 December 2008.



## Directors, officers and professional advisers

### Directors

P W C 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** N A C 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** Orrick, Herrington & Sutcliffe, Tower 42, Level 35, 25 Old Broad Street, London, EC2N 1HQ.



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