

## **REGEN THERAPEUTICS PLC**

### **Chairman's Statement and Preliminary Unaudited Results for the year ended 31 December 2008**

#### **PRELIMINARY STATEMENT**

##### **Highlights of 2008**

- Loss before tax from continuing operations reduced by £1.076m to £1.510m. Further £1m 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 £1.510m.

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, utilizing 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.

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<sup>th</sup> 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, 17th 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<sup>th</sup> 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 skepticism 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 pharmaco-magneto-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.

## 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 £1.510m before tax for continuing operations compared with £2.586m in 2007, a reduction of £1.076m. We expect losses to decrease by an even larger amount in 2009 with sustainable profitability being achieved during 2010.

Percy W Lomax  
Executive Chairman  
16 June 2009

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# **REGEN THERAPEUTICS PLC**

## **Consolidated income statement for the year ended 31 December 2008**

|  | <b>2008</b><br><b>£</b><br><b>(Unaudited)</b> | <b>2007</b><br><b>£</b><br><b>(Audited)</b> |
|--|---|---|
| <i><b>Continuing operations</b></i>                                  |   |   |
| <b>Revenue</b>   | <b>91,716</b>                                 | 63,810                                      |
| <b>Cost of sales</b>   | <b>20,447</b>                                 | 24,042                                      |
|  | <hr/>   | <hr/>                                       |
| <b>Gross Profit</b>  | <b>71,269</b>                                 | 39,768                                      |
| 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                                      | <b>-</b>                                      | 348,562                                     |
|  | <hr/>   | <hr/>                                       |
| <b>Administrative expenses</b>                                       | <b>1,588,162</b>                              | 2,676,593                                   |
|  | <hr/>   | <hr/>                                       |
| <b>Operating loss</b>  | <b>(1,516,893)</b>                            | (2,636,825)                                 |
| Finance income   | <b>10,308</b>                                 | 56,534                                      |
| Finance costs  | <b>(3,436)</b>                                | (5,434)                                     |
|  | <hr/>   | <hr/>                                       |
| <b>Loss before taxation</b>  | <b>(1,510,021)</b>                            | (2,585,725)                                 |
| Taxation   | <b>80,590</b>                                 | 168,517                                     |
|  | <hr/>   | <hr/>                                       |
| <b>Loss after taxation for continuing activities</b>                 | <b>(1,429,431)</b>                            | (2,417,208)                                 |
|  | <hr/>   | <hr/>                                       |
| <i><b>Discontinued operations</b></i>                                |   |   |
| <b>(Loss)/profit after taxation from discontinued operations</b>     | <b>(33,936)</b>                               | 32,134                                      |
|  | <hr/>   | <hr/>                                       |
| <b>Loss after taxation for the year</b>                              | <b>(1,463,367)</b>                            | (2,385,074)                                 |
|  | <hr/>   | <hr/>                                       |
| Basic and diluted loss per share                                     | Note 7 <b>(12.27)p</b>                        | (25.71)p                                    |
| 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                                       |

# **REGEN THERAPEUTICS PLC**

## **Consolidated Statement Of Changes In Equity for the year ended 31 December 2008**

|   | <b>Share<br/>capital<br/>£</b> | <b>Share<br/>premium<br/>£</b> | <b>Other<br/>reserves<br/>£</b> | <b>Retained<br/>earnings<br/>£</b> | <b>Total<br/>£</b> |
|---|--------------------------------|--------------------------------|---------------------------------|------------------------------------|--------------------|
| <b>Audited</b>                                      |                                |                                |                                 |                                    |                    |
| 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)        |
|   | <hr/>                          | <hr/>                          | <hr/>                           | <hr/>                              | <hr/>              |
| Total recognised income and<br>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             |
|   | <hr/>                          | <hr/>                          | <hr/>                           | <hr/>                              | <hr/>              |
| Balance at 31 December 2007                         | 6,323,835                      | 13,969,394                     | 265,745                         | (18,118,878)                       | 2,440,096          |
| <b>Unaudited</b>                                    |                                |                                |                                 |                                    |                    |
| Loss for the year                                   | -                              | -                              | -                               | (1,463,367)                        | (1,463,367)        |
|   | <hr/>                          | <hr/>                          | <hr/>                           | <hr/>                              | <hr/>              |
| Total recognised income and<br>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)           |
|   | <hr/>                          | <hr/>                          | <hr/>                           | <hr/>                              | <hr/>              |
| 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>   |
|   | <hr/>                          | <hr/>                          | <hr/>                           | <hr/>                              | <hr/>              |

# **REGEN THERAPEUTICS PLC**

## **Consolidated balance sheet at 31 December 2008**

|                                  | 2008<br>£<br>(Unaudited) | 2008<br>£<br>(Unaudited) | 2007<br>£<br>(Audited) | 2007<br>£<br>(Audited) |
|----------------------------------|--------------------------|--------------------------|------------------------|------------------------|
| <b>Non current assets</b>        |                          |                          |                        |                        |
| Property, plant and equipment    |                          | 1,017                    |                        | 2,674                  |
| Intangible assets                |                          | 1,759,250                |                        | 1,946,559              |
|                                  |                          | <u>1,760,267</u>         |                        | <u>1,949,233</u>       |
| <b>Current assets</b>            |                          |                          |                        |                        |
| Inventories                      | 28,571                   |                          | 6,649                  |                        |
| Trade and other receivables      | 87,090                   |                          | 212,779                |                        |
| Tax receivable                   | 80,590                   |                          | 145,833                |                        |
| Cash and cash equivalents        | 25,157                   |                          | 587,837                |                        |
|                                  | <u>221,408</u>           |                          | <u>953,098</u>         |                        |
| <b>Total current assets</b>      |                          | <u>221,408</u>           |                        | <u>953,098</u>         |
| <b>Total assets</b>              |                          | <u>1,981,675</u>         |                        | <u>2,902,331</u>       |
| <b>Liabilities</b>               |                          |                          |                        |                        |
| <b>Current liabilities</b>       |                          |                          |                        |                        |
| Trade and other payables         | 489,699                  |                          | 311,636                |                        |
| Loans and borrowings             | 51,792                   |                          | 50,599                 |                        |
|                                  | <u>541,491</u>           |                          | <u>362,235</u>         |                        |
| <b>Total current liabilities</b> |                          | <u>541,491</u>           |                        | <u>362,235</u>         |
| <b>Non current liabilities</b>   |                          |                          |                        |                        |
| Provisions                       |                          | 100,000                  |                        | 100,000                |
|                                  |                          | <u>641,491</u>           |                        | <u>462,235</u>         |
| <b>Total liabilities</b>         |                          | <u>641,491</u>           |                        | <u>462,235</u>         |
| <b>Total net assets</b>          |                          | <u>1,340,184</u>         |                        | <u>2,440,096</u>       |
| <b>Equity</b>                    |                          |                          |                        |                        |
| Share capital                    | Note 5                   | 6,605,003                |                        | 6,323,835              |
| Share premium                    |                          | 14,147,213               |                        | 13,969,394             |
| Other reserves                   |                          | 265,745                  |                        | 265,745                |
| Retained earnings                |                          | (19,677,777)             |                        | (18,118,878)           |
|                                  |                          | <u>1,340,184</u>         |                        | <u>2,440,096</u>       |
| <b>Total equity</b>              |                          | <u>1,340,184</u>         |                        | <u>2,440,096</u>       |

**REGEN THERAPEUTICS PLC****Consolidated cash flow statement for the year ended 31 December 2008**

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

|  |        |                 |             |
|--|--------|-----------------|-------------|
| <b>Opening cash and cash equivalents</b> |        | <b>537,238</b>  | 435,605     |
|  |        | <hr/>           | <hr/>       |
| <b>Closing cash and cash equivalents</b> | Note 8 | <b>(26,635)</b> | 537,238     |
|  |        | <hr/> <hr/>     | <hr/> <hr/> |

## **1 Basis of preparation**

The consolidated 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.

The financial information contained in this announcement does not constitute statutory financial statements within the meaning of Section 240 of the Companies Act 1985. Whilst the financial information included in this announcement has been prepared in accordance with International Financial Reporting Standards (IFRS), this announcement itself does not contain sufficient financial information to comply with IFRS. A copy of the statutory financial statements for the year ended 31 December 2008 will be issued to shareholders prior to the Company’s Annual General Meeting. The announcement has been agreed with the auditors and was approved by the Board of Directors on 16 June 2009. Whilst the auditors have not yet reported on the financial statements for the year ended 31 December 2008, they anticipate issuing an unqualified report which will not contain statements under section 237 (2) or (3) of the Companies Act 1985 but anticipate, however, including an explanatory paragraph dealing with a material uncertainty relating to going concern. The financial information for the year ended 31 December 2007 has been extracted from the statutory financial statements for that year, which have been filed with the Registrar of Companies. The audit report on those financial statements was unqualified and did not contain any statement under Sections 237 (2) or (3) of the Companies Act 1985. It did contain, however, an explanatory paragraph dealing with a material uncertainty relating to going concern

The directors do not recommend the payment of a dividend for the year.

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

### **3 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.

### **4 Accounting policies**

The financial information has been prepared in accordance with the accounting policies adopted by the Group which are consistent with those adopted in the financial statements for the year ended 31 December 2007 as well as applying the following key accounting policies.

#### *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.

## *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.

## **5 Share Capital**

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 there was 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.

## 6 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:

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

## 7 Loss per share

|  | 2008<br>£  | 2007<br>£ |
|--|------------|-----------|
| <i>Numerator</i>                               |            |           |
| Loss for the year                              | 1,463,367  | 2,385,074 |
| <i>Denominator</i>                             |            |           |
| Weighted average number of shares of 0.01p/10p | 11,926,992 | 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.

## 8 Note supporting cash flow statement

Cash and cash equivalents comprises:

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

## 9 Taxation

|  | 2008<br>£ | 2007<br>£ |
|--|-----------|-----------|
| UK corporation tax credit in respect of current period | 66,065    | 145,833   |
| Adjustment in respect of prior years                   | 14,525    | 22,684    |
| Total current tax credit                               | 80,590    | 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:

|   | <b>2008</b><br>£ | <b>2007</b><br>£ |
|---|------------------|------------------|
| Loss before tax   | <b>1,543,957</b> | 2,553,591        |
| Loss at the standard rate of corporation tax<br>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          |

The annual report and financial statements for the year ended 31 December 2008 will be sent to all shareholders in due course and copies will be available on the web site [www.regentherapeutics.com](http://www.regentherapeutics.com) and from the company's business address at 73 Watling Street, London, EC4M 9BJ.