

## **Preliminary Results For The Year Ended 30 September 2008**

**Porton Down, UK, 18 November 2008:** GW Pharmaceuticals plc (AIM: GWP), the developer and manufacturer of a range of new cannabinoid medicines, including Sativex<sup>®</sup>, announces its preliminary results for the year ended 30 September 2008.

### **OPERATIONAL HIGHLIGHTS**

- Patient recruitment completed in Sativex Phase III MS spasticity trial in October 2008. Results due late Q1 09, to be followed by regulatory submission in Q2 09
- Sativex Phase IIb/III cancer pain trial, funded by Otsuka as part of the US development programme, ongoing and due to complete in H2 09
- Positive results in Sativex MS pain placebo-controlled randomised withdrawal trial confirm long term maintenance of efficacy
- Sativex prescription use continues to rise – product now exported to 21 countries
- Otsuka cannabinoid research collaboration yielding promising new psychiatric and oncology drug candidates
- Phase II trial in planning on novel cannabinoid medicine for the treatment of dyslipidaemia in Type II diabetes patients

### **FINANCIAL HIGHLIGHTS**

- Turnover more than doubled to **£11.8m** (2007: **£5.7m**) reflecting revenue growth from Otsuka alliance and increased Sativex sales
- Net loss for the year reduced 22% to **£8.2m** (2007: **£10.6m**)
- Cash and short term deposits at 30 September 2008 of **£14.1m**

Dr Geoffrey Guy, GW's Chairman, said: "We are pleased to report financial results showing increased revenue, reduced net loss and a healthy cash position. In the last year, due in large part to the agreements signed with Otsuka in 2007 as well as growth in Sativex sales, GW has managed to increase its research activities whilst at the same time reducing its cash burn.

"Looking forward, we have completed patient recruitment into our Sativex Phase III MS spasticity trial and this is due to report results in late Q1 2009. We expect to submit a regulatory application in selected European countries very shortly thereafter with a view to obtaining approval by the end of 2009. We also continue to progress our development programme for Sativex in the US with the Phase II/III trial in cancer pain, which is due to complete next year, as well as our highly promising earlier stage cannabinoid pipeline. We have a large number of key newsflow events expected in 2009 and look forward to updating shareholders with news of our progress."

An analyst presentation of the interim results is being held today at 09.30 at Financial Dynamics, Holborn Gate, 26 Southampton Buildings, London WC2A 1PB. Please contact Juliet Edwards at Financial Dynamics on +44 20 7269 7125 for details. An audio webcast of the presentation will be available on GW's website at [www.gwpharm.com](http://www.gwpharm.com) later this afternoon.

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**GW Pharmaceuticals plc  
("GW" or "the Group")**

**Preliminary Results For The Year Ended 30 September 2008**

**INTRODUCTION**

This has been a year of intensive international research and commercial activity. We have achieved record recruitment rates in completing our Phase III Multiple Sclerosis (MS) spasticity trial in just ten months and look forward to results from this trial in late Q1 09. We expect a regulatory submission in selected European countries to be filed in Q2 09 and hope to achieve approval by the end of 2009. In parallel, we are progressing our Phase IIb/III cancer pain trial, conducted in collaboration with our US partner, Otsuka Pharmaceutical Co. Ltd. We are also working with Otsuka on a new pipeline of cannabinoid medicines targeting treatments for Central Nervous System (CNS) disorders and cancer, as well as progressing our in-house pipeline development in the field of diabetes.

The financial results highlight an encouraging picture of increasing revenues and decreasing cash burn. Sales of Sativex on prescription continues to grow, both under marketing approval in Canada and on a named patient basis elsewhere, and there is increasing awareness of the product's benefits, as demonstrated by the publication of the positive results in a programme conducted by the Government of Catalonia in Spain. In addition, the Otsuka relationship yields important financial benefits through their funding of both the US development of Sativex and our pipeline development in CNS and cancer. This financial picture reflects our ongoing strategy to increase investment in the product pipeline whilst decreasing GW's in-house expenditure by encouraging partners to fund such research activities.

With key Sativex data from two Phase III trials due next year, a major regulatory submission planned, partners for Sativex secured in key markets, a highly promising earlier stage pipeline beginning to emerge and a healthy financial position, GW is well positioned for success in 2009.

**SATIVEX REGULATORY STRATEGY**

The clinical and regulatory strategy for Sativex is focused on four specific therapeutic indications, each of which represents a distinct regulatory opportunity and each of which requires a distinct set of clinical efficacy data. These indications are as follows:

- MS spasticity
- Cancer pain
- MS neuropathic pain
- Peripheral neuropathic pain

Each of these target indications is supported by existing positive Phase II/III data and will continue to be supplemented by further late stage trials over the next few years in order to supplement globally approvable regulatory packages.

The lead indication for Sativex differs across different regions of the world. In Europe, the lead indication for approval is MS spasticity and in the US, cancer pain is the initial target indication for approval. In Canada, MS neuropathic pain was the first approved indication, and this has been successfully followed by the approval in cancer pain.

This clinical and regulatory programme has been designed to provide a series of opportunities over the next few years to obtain approvals for Sativex across the different indications in a number of territories.

## **MS Spasticity**

MS spasticity represents the nearest term regulatory opportunity for Sativex in Europe. In October 2008, GW announced that it had completed patient recruitment into its Phase III trial in this indication. This trial was requested by the UK regulator last year prior to obtaining approval for Sativex. The trial is due to report results in late Q1 09 and a regulatory submission is planned shortly thereafter.

In total, 575 patients have been recruited into the Phase III study, by far the largest study GW has ever undertaken. Recruitment was achieved in just ten months using 52 hospital sites in five countries – UK, Spain, Italy, Czech Republic and Poland.

This indication has been the sole focus of previous discussions with European regulatory authorities. The body of clinical evidence generated to date to support the efficacy of Sativex in MS spasticity includes two pivotal Phase III trials, a positive pooled analysis including over 600 patients, as well as supportive positive data from Phase II trials.

This most recent Phase III study was conducted in response to discussions with the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), which provided specific guidance on the route to approval in this indication. Their key outstanding requirement was to perform this additional Phase III clinical trial using an “enriched design”. This design first identifies responders over a four week period (Phase A), and then focuses on analysing the effect of Sativex vs placebo on those responders over a further period of 12 weeks (Phase B). The study enrolled 575 patients into Phase A and 248 patients have entered Phase B. The primary endpoint of the study is the difference in the severity of spasticity as assessed on the validated Numeric Rating Scale between the Sativex and placebo groups in Phase B of the study.

In September 2008, GW reported positive results from a placebo-controlled “randomized withdrawal” study of Sativex in patients with MS neuropathic pain, the design of which bears important similarities to the Phase III MS spasticity study (see below). If the difference between Sativex and placebo achieved in the MS pain trial are replicated in the Phase III MS spasticity study, this Phase III study will meet its objectives.

Separately, two recent papers have been published which validate GW’s clinical data and address an additional point raised in the previous regulatory submission requesting reassurance on the validity of the Numeric Rating Scale used in clinical trials as a measure of spasticity. The first paper<sup>1</sup>, authored by Professor John Farrar, an eminent statistician at the University of Pennsylvania, concludes that “the measurement of the symptom of spasticity using a patient-rated 0-10 numeric rating scale was found to be both reliable and valid”. The second paper<sup>2</sup>, reporting on a study carried out by Professor Mike Barnes in the UK, concludes “The spasticity NRS has been shown to be a valid and reliable tool in the assessment of spasticity with a moderate to high level of correlation with other clinician rated instruments used to assess spasticity.”

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<sup>1</sup> Farrar et al, Validity, Reliability and Clinical Importance of Change in a 0-10 Numeric Rating Scale Measure of Spasticity: A Post-Hoc Analysis of a Randomized Controlled Clinical Trial. *Clinical Therapeutics*, Vol 30, No 5, 2008

<sup>2</sup> Anwar K, Barnes MP, A Pilot Study of a Comparison Between a Patient Scored Numeric Rating Scale and Clinician Scored Measures of Spasticity in Multiple Sclerosis, *Neurorehabilitation* 2008 (in press)

## **Cancer Pain**

In 2007, GW obtained approval for Sativex in Canada in the indication of cancer pain. This approval was obtained under the Canadian Notice of Compliance with Conditions (NOC/c) policy on the basis of a single positive Phase II/III trial conducted in Europe. In this study, Sativex was significantly superior to placebo in reducing pain ( $p=0.014$ ). In addition, 43% of patients who received Sativex, while remaining on opioids, exhibited at least a 30% decrease in their pain score compared to 21% of patients receiving placebo and opioids (Odds Ratio = 2.8:  $p= 0.024$ ).

GW's ongoing cancer pain clinical programme is being funded by Otsuka who have licensed the US rights to this product. These trials are designed to obtain approval in this indication from the FDA, but it is also intended that they form the basis of a European regulatory application in this indication.

The FDA has permitted Sativex to enter directly into Phase III clinical development in the US for the treatment of pain in patients with advanced cancer, who experience inadequate analgesia during optimized chronic opioid therapy.

The first pivotal trial is now underway. This five-week, placebo-controlled study is a Phase IIb/III dose ranging study in 336 patients. The primary objective of the study is to evaluate the potential role and dose range of Sativex in these patients as an adjunct to their pre-existing pain medications. Whilst recruitment of patients is taking longer than we would ideally have liked, which is not untypical in cancer trials, we have taken steps, together with Otsuka, to expand this study to additional hospital sites and to additional countries. This study is now expected to complete in H2 09.

The current US development programme anticipates two further Phase III trials prior to a subsequent submission of a NDA to the FDA. All data generated in the US will also be available to GW for submission to regulatory authorities in Europe and elsewhere.

In addition to the large scale pivotal clinical trials in cancer pain required for submission to FDA, the US development programme for Sativex includes a number of clinical pharmacology studies. During the course of this year, four such studies have completed patient enrolment on track. Each of these studies has been agreed with the FDA as components of the Sativex US NDA and results to date emphasise the favourable safety profile of Sativex. The largest of these studies was a thorough QT (TQT) study which enrolled a total of 255 patients. TQT studies are mandated by the FDA for all regulatory applications and examine effects on cardiac conduction. The primary endpoint of this study shows that Sativex does not prolong the QT interval and therefore does not carry a risk of cardiac arrhythmia (abnormal heart rhythm). In addition, results of a 36 subject formal drug-drug interaction study showed Sativex not to have any clinically relevant interaction with other drugs.

## **MS Neuropathic Pain**

In 2005, GW obtained approval for Sativex in Canada in the indication of neuropathic pain in MS. This approval was obtained under the Canadian NOC/c policy on the basis of a single positive Phase III trial. This study, which was published in the peer-reviewed journal, *Neurology*<sup>3</sup>, showed that Sativex was significantly superior to placebo in reducing pain ( $p=0.005$ ) and sleep disturbance ( $p=0.003$ ).

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<sup>3</sup> D.J.Rog, T.J.Nurmikko, T.Friede, and C.A Young. Randomized, controlled trial of cannabis-based medicine in central pain in multiple sclerosis. *Neurology* 2005;65:812

In April 2008, GW announced preliminary results of a second Phase III trial in this indication which included 339 patients. In this study, 50% of Sativex patients experienced a pain reduction of at least 30%, the second largest response rate seen in any Sativex study and amongst the largest seen for any pain treatment in the published literature. However, although the difference between the Sativex and placebo groups was clearly in favour of Sativex, it narrowly failed to reach statistical significance in this trial due to an unexpectedly large placebo response.

In October 2008, GW announced positive results from Part B of this study. This part of the study followed a placebo-controlled “randomized withdrawal” design, a methodology described by regulators as being sufficient to demonstrate long-term efficacy.

This randomized withdrawal study evaluated 42 MS patients who had previously been in the Phase III MS neuropathic pain study and who continued to take Sativex on an open label basis for 12 weeks. They were then randomized to Sativex or placebo for a further 4 weeks in a double-blinded manner. During the randomized period, patients were not permitted to adjust their dose. The purpose of this blinded 4-week “randomized withdrawal” study was to assess the maintenance of pain control in patients who remain on Sativex versus those who switch to placebo.

In the patients who were randomized to Sativex pain scores remained stable. In the patients randomized to placebo, pain and sleep scores deteriorated. The prospectively defined primary efficacy endpoint of the study - the time to treatment failure - was statistically significantly in favour of Sativex ( $p=0.036$ ). The difference between Sativex and placebo was also significant for mean pain score ( $p=0.028$ ) and sleep quality ( $p=0.015$ ). The results of all other symptom-related endpoints showed that Sativex patients maintained or improved their response whilst the symptoms of those who switched from Sativex to placebo worsened in the 4 weeks following cessation of active treatment. During the randomized withdrawal period, there were 2 patients with adverse events on Sativex, and 5 on placebo. One patient on placebo withdrew from the study. There was no evidence of any withdrawal syndrome.

This is the first placebo-controlled study showing that Sativex provides long term efficacy for MS patients with neuropathic pain and supplements previously published open-label studies.

### **Peripheral Neuropathic Pain**

GW has generated positive results from clinical trials in a number of models of peripheral neuropathic pain. These data contribute to a future regulatory filing in this indication and GW intends to continue to add to this evidence base by conducting additional confirmatory trials in due course following the initial approval for Sativex in Europe.

### **New Zealand Regulatory Submission**

In late 2007, GW was invited by the New Zealand Ministry of Health to submit a regulatory application for Sativex to MedSafe, the New Zealand regulatory authority, under Section 23 of the Medicines Act 1981. This application was submitted in late December 2007. If successful, Sativex would be granted approval with a commitment to provide additional data post-market authorisation.

The regulatory submission process is ongoing. Questions were received and responses provided to the authorities earlier this year. Dialogue is continuing with the regulators and it is expected that an outcome should be known in 2009.

## **SATIVEX PRESCRIPTION USE**

Sativex is approved as a prescription medicine in Canada in the treatment of cancer pain and MS neuropathic pain. Sativex is approved under Health Canada's NOC/c policy, which requires the submission of confirmatory clinical data post-market authorisation.

Although Sativex awaits regulatory approval beyond Canada, the medicine can be prescribed by physicians in countries around the world as an unlicensed medicine. The basis on which Sativex may be prescribed is the clinical judgement of doctors in relation to specific nominated patients. No marketing or promotional activity is permitted for unlicensed medicines.

Sativex has now been exported from the UK to 21 countries either for named patient prescription use or for use in clinical trials. This heralds a growing awareness and appreciation of Sativex amongst the medical community and gives reason to be confident about eventual regulatory approvals abroad.

In the UK, Sativex continues to be prescribed to patients primarily with MS but also with other types of pain that is not adequately treated by other prescription medicines. New patients enter this named patient programme daily. Similarly, the number of UK physicians prescribing Sativex continues to grow and now totals over 1,700. Over 2,000 UK patients have received Sativex on prescription to date (including 400 ex-trial patients).

Experience of Sativex as a prescription medicine demonstrates that approximately half of patients who have failed to obtain benefit from current medication obtain meaningful improvements on Sativex and remain on the medicine long term. This is consistent with data from controlled clinical trials. The safety profile of Sativex in clinical practice is also reassuring with few adverse event reports received and no adverse comment from any regulatory authority.

### **Positive Outcome of Sativex Access Programme in Spain**

In April 2008, the Government of Catalonia in Spain published positive results of its pilot programme to evaluate Sativex as a treatment for high need patients suffering from a range of medical conditions. A total of 207 patients were included in the programme with the following therapeutic indications: MS (spasticity/pain), neuropathic pain, anorexia-cachexia syndrome due to cancer or AIDS, and nausea and secondary vomiting due to chemotherapy treatment.

Patients enrolled in the programme had severe symptoms, suffered from long term chronic diseases, were taking multiple medications to which they exhibited a poor response, and suffered from a poor quality of life. The published results show that Sativex provides important improvements in approximately half of high need patients who have otherwise failed to gain benefit from currently available medicines. As mentioned above, this is consistent with our experience of Sativex prescription use elsewhere.

## **OTSUKA CANNABINOID RESEARCH COLLABORATION**

In July 2007, GW signed a research collaboration agreement with Otsuka to research, develop and commercialise novel cannabinoid medicines in the therapeutic areas of CNS and oncology.

Under the GW-Otsuka collaboration, senior scientists from both companies are directing research into a range of GW cannabinoids as drug candidates within CNS and oncology. The research is being

carried out at GW's laboratories at Aberdeen University as well as other selected international academic centres with whom GW has developed a close relationship.

Otsuka fund all in-house and third party activities performed under the collaboration. At the time of signing of the agreement, Otsuka made available a research fund of US\$9m (£4.6m) to cover the initial three year term of the collaboration. In the GW financial year ended 30 September 2008, approximately £1.9m of funds contributed to GW core research and development expenditure.

The collaboration has to date focused on evaluating the pharmacology of six selected cannabinoid drug candidates within the CNS and oncology therapeutic fields. A wealth of novel pharmacology has already emerged and a number of patent filings have been made. In particular, promising new psychiatric and oncology drug candidates have become apparent and these are expected to be a principal focus for the next phase of the collaboration.

The collaboration has now entered its second year and a comprehensive research plan and budget for this second year has been agreed. This research plan identifies high priority candidate cannabinoids and therapeutic targets resulting from results generated in the first year. It has also been expanded to include the evaluation of a number of additional cannabinoid drug candidates within the GW portfolio.

## **DIABETES / METABOLIC DISEASE CLINICAL PROGRAMME**

GW has carried out extensive pre-clinical research on its cannabinoids in several models of diabetes. Results of this research show desirable effects on plasma insulin, leptin and adiponectin levels, hormones of particular relevance to the development and treatment of diabetes. In addition, we have seen a reduction in total cholesterol with an increase in the proportion of HDL (good) cholesterol.

GW's two leading cannabinoid candidates in this field are delta-9-tetrahydrocannabivarin (THCV) and cannabidiol (CBD). CBD has shown potential beneficial effects in hypercholesterolaemia and non-alcoholic fatty liver disease, while THCV has shown desirable effects notably in raising energy expenditure. Exploration of the effects of these two cannabinoids in combination confirms that a number of the components of the metabolic syndrome can potentially be addressed with a single medicine.

Both THCV and CBD have now successfully been the subject of Phase I clinical trials. GW is preparing to advance a combined THCV:CBD drug candidate into a Phase IIa multiple dose study in the treatment of dyslipidaemia and fatty liver in Type II diabetic patients. A decision on the timing of the start of this study will be taken next year.

GW believes that this exciting new field of research within its product pipeline offers significant commercial potential.

## **MANUFACTURING**

For several years, GW has been operating under Good Manufacturing Practice (GMP) licences granted by the MHRA which permit the company to manufacture pharmaceutical products for use in clinical trials and for named patient prescriptions. The most recent GMP inspection by the MHRA was held in late 2007 and led to a highly satisfactory outcome.

Sativex is manufactured in several stages, some of which are sub-contracted and others conducted in-house. Since 2001, GW has sub-contracted the final step in the bulk GMP manufacture of Sativex to a contract manufacturing partner. GW has in recent months chosen to expand its in-house GMP MHRA licences to include commercial manufacture and is now upgrading its in-house facility with this objective in mind. As a result, GW anticipates taking over the responsibility for GMP commercial finished product manufacture of Sativex from its sub-contracting partner around the end of 2009. The costs associated with implementing this new manufacturing strategy are expected to be no greater than that which GW was due to incur with its current sub-contracting partner.

## **FINANCIAL REVIEW**

The 2008 results show increased revenue, a reduced net loss and a healthy cash position. These results have been achieved in large part due to our strategy of seeking partners to fund research activities, in particular the Sativex US development programme and our early stage pipeline.

In 2008 our revenues more than doubled to £11.8m, while net losses reduced by £2.4m to £8.2m, a 22% improvement.

2008 is the first financial year to reflect a full twelve months' activity under both of the Otsuka agreements signed in 2007. This partnership approach to our research is now a core part of our strategy.

Total research and development expenditure in 2008 increased by 27% from £15.0m to £19.0m, in line with guidance. 45% of this research activity was funded by Otsuka (2007: 16%).

Net cash outflow for the year of £6.9m (2007: £1.1m inflow) resulted in closing cash reserves of £14.1m.

This is the first set of year end results prepared and presented in accordance with International Financial Reporting Standards "IFRS". The only significant change that has resulted to our accounting policies upon the transition from UK Generally Accepted Accounting Practice "UKGAAP" to IFRS is the elimination of the annual Goodwill amortisation charge that was required under UKGAAP. All prior year comparatives have been re-stated to reflect IFRS accounting policies. Full details of the financial effect of this transition are given in note 11.

### **Income statement**

Revenue has increased significantly from £5.7m in 2007 to £11.8m this year.

Total Sativex sales increased by 15% to £1.3m, the largest component of which, named patient sales, grew by 47% to £0.9m (2007: £0.6m). Sativex has now been prescribed to named patients in 13 different countries. Bayer, our marketing partner in Canada, has informed us that Canadian end sales are currently running at an annual rate of around C\$3m. GW's sales to Bayer Canada of £0.4m (2007: £0.5m) were marginally lower than the prior year due to the timing of despatch of orders to Bayer during the year.

Research and development fee revenues of £8.6m represent an increase of £6.1m over last year. These fees consist of research and development costs incurred by GW and charged to Otsuka under the Sativex US development agreement of £6.3m (2007: £2.2m) and the research collaboration agreement of £2.3m (2007: £0.3m).

The remainder of the revenue for the year of £1.9m represents income arising from the recognition of up-front signature fees from both the Almirall and Otsuka licence agreements (2007: £1.4m). In respect of Almirall, the £12.0m signature fee is being recognised at the rate of £0.8m per year over 15 years. For Otsuka, where the Group's obligations are weighted more towards the earlier years, the £9.2m signature fee is being recognised at the rate of £1.1m per year for the period to 30 September 2011 and at £0.3m per year for the following 15 years.

No milestone income was received in the year (2007: £0.7m in respect of the approval of cancer pain indication in Canada).

Research and development expenditure, which is expensed as incurred, was £19.0m (2007: £15.0m), of which £8.6m (2007: £2.5m) was funded by Otsuka. GW funded research reduced by £2.1m or 17% to £10.4m compared to the prior year expenditure of £12.5m.

Management and administration expenditure decreased marginally to £2.8m (2007: £2.9m) while the Share-based payment charge also decreased to £0.7m (2007: £1.1m).

The Group has claimed a research and development tax credit of £1.8m for the year (2007: £2.2m). This is subject to agreement with HM Revenue & Customs.

The Group loss for the year ended 30 September 2008 was £8.2m (2007: £10.6m).

Average headcount of the Group for the year was 113 (2007: 120).

## **Balance Sheet**

Capital expenditure of £0.4m (2007: £0.5m) consisted mainly of laboratory equipment for use in our early-stage pipeline research activity.

Debtors at 30 September 2008 were £2.6m (2007: £2.8m), consisting of £1.8m R&D tax credit (2007: £2.0m), £0.2m of trade debtors (from sales of Sativex) (2007: £0.2m) and £0.6m of other debtors and prepayments (2007: £0.6m).

At 30 September 2008 the Group had received £2.5m (2007: £1.6m) of advance payments for research activities to be carried out on behalf of Otsuka in the next six months. This has been disclosed as an advance payment received within deferred revenue due within one year.

Deferred signature fee revenue amounts to £17.3m (2007: £19.2m), of which £1.9m (2007: £1.9m) is shown as due within one year. £15.4m (2007: £17.3m) is shown as due after more than one year and represents the balance of non-refundable Sativex licence agreement signature fees. This will be recognised as revenue in future periods.

The Group's net funds comprise cash balances together with amounts held on short term deposit totalling £14.1m (2007: £21.0m).

## 2009 Financial Year

In 2009, we expect GW-funded research and development expenditure to reduce by approximately 30%. Partner-funded research and development expenditure will continue to rise.

A positive result from the Phase III MS spasticity trial due in late Q1 09 would result in a £2m milestone from Almirall. Subsequent UK and first mainland European approval, anticipated by the end of 2009, would result in a total of £13m of milestone payments from our partners.

## SUMMARY AND PROSPECTS

The 2008 financial results show increased revenue, reduced net loss and a healthy cash position. In the last year, due in large part to the agreements signed with Otsuka in 2007 as well as growth in Sativex sales, GW has managed to increase its research activities whilst at the same time reducing its cash burn.

Looking forward, we have completed patient recruitment into our Sativex Phase III MS spasticity trial and this is due to report results in late Q1 2009. We expect to submit a regulatory application in selected European countries very shortly thereafter with a view to obtaining approval by the end of 2009. We also continue to progress our development programme for Sativex in the US with the Phase II/III trial in cancer pain, which is due to complete next year, as well as our highly promising earlier stage cannabinoid pipeline. We have a large number of key newsflow events expected in 2009 and look forward to updating shareholders with news of our progress.

– Ends –

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*This news release may contain forward-looking statements that reflect the Group's current expectations regarding future events, including the clinical development and regulatory clearance of the Group's products. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of the Group's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies, including with respect to Sativex and the Group's other products, the uncertainties related to the regulatory process, and the acceptance of Sativex and other products by consumers and medical professionals*

GW Pharmaceuticals plc  
Consolidated income statement  
For the year ended 30 September 2008

	Notes	Year ended 30 September 2008 £000's	Year ended 30 September 2007 restated £000's
<b>Revenue</b>	3	11,774	5,677
Cost of sales		(249)	(254)
<b>Gross profit</b>		11,525	5,423
Research and development expenditure	4	(19,027)	(14,970)
Management and administrative expenses		(2,775)	(2,882)
Share-based payment		(726)	(1,130)
<b>Operating loss</b>		(11,003)	(13,559)
Interest income		809	958
<b>Loss before tax</b>		(10,194)	(12,601)
Tax credit	5	1,974	2,015
<b>Loss for the period</b>		<u>(8,220)</u>	<u>(10,586)</u>
<b>Loss per share - basic and diluted</b>	6	(6.8p)	(8.8p)

All activities relate to continuing operations.

The Group has no gains or losses other than those losses above and therefore no separate statement of recognised income and expense has been presented.

Results for the year ended 30 September 2007 have been restated to reflect the adoption of IFRS – see note 11

GW Pharmaceuticals plc  
Consolidated balance sheet  
30 September 2008

	Notes	30 September 2008 £000's	30 September 2007 £000's restated
<b>Non-current assets</b>			
Intangible assets - goodwill		5,210	5,210
Property, plant & equipment		1,107	1,082
		<u>6,317</u>	<u>6,292</u>
<b>Current assets</b>			
Inventories		503	535
Taxation recoverable	5	1,798	2,015
Trade and other receivables	7	774	800
Cash and cash equivalents		14,054	20,966
		<u>17,129</u>	<u>24,316</u>
<b>Total assets</b>		<u>23,446</u>	<u>30,608</u>
<b>Current liabilities</b>			
Trade and other payables	8	(5,363)	(4,186)
Deferred revenue	9	(4,411)	(3,460)
		<u>(9,774)</u>	<u>(7,646)</u>
<b>Non-current liabilities</b>			
Deferred revenue	9	(15,399)	(17,299)
		<u>(25,173)</u>	<u>(24,945)</u>
<b>Total liabilities</b>		<u>(25,173)</u>	<u>(24,945)</u>
<b>Net assets</b>		<u>(1,727)</u>	<u>5,663</u>
<b>Equity</b>			
Share capital	10	121	120
Share premium account	10	58,375	58,272
Other reserves	10	19,262	19,262
Retained earnings	10	(79,485)	(71,991)
		<u>(1,727)</u>	<u>5,663</u>
<b>Shareholders' funds</b>		<u>(1,727)</u>	<u>5,663</u>

The 2008 year end results were approved by the board of Directors on 17 November 2008.

GW Pharmaceuticals plc  
Consolidated cash flow statement  
For the year ended 30 September 2008

	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000's
<b>Operating loss</b>	(11,003)	(13,559)
Adjustments for:		
Depreciation of property, plant & equipment	415	370
Share-based payment charge	726	1,130
	<hr/>	<hr/>
<b>Operating cash flows before movements in working capital</b>	(9,862)	(12,059)
Decrease in inventories	32	160
Decrease in receivables	15	1,542
Increase in payables	227	8,904
	<hr/>	<hr/>
<b>Cash generated by operations</b>	(9,588)	(1,453)
Income tax credits received	2,191	2,022
	<hr/>	<hr/>
<b>Net cash (outflow)/inflow from operating activities</b>	(7,397)	569
<b>Investing activities</b>		
Interest received	821	960
Purchases of property, plant and equipment	(440)	(500)
	<hr/>	<hr/>
<b>Net cash from investing activities</b>	381	460
<b>Financing activities</b>		
Proceeds on issue of shares	104	62
	<hr/>	<hr/>
<b>Net cash from financing activities</b>	104	62
Net (decrease)/increase in cash and cash equivalents	(6,912)	1,091
Cash and cash equivalents at beginning of year	20,966	19,875
	<hr/>	<hr/>
<b>Cash and cash equivalents at end of the period</b>	<u>14,054</u>	<u>20,966</u>

## 1. General information

The financial information contained herein for the years ended 30 September 2007 and 30 September 2008 does not constitute statutory accounts as defined in section 240 of the Companies Act 1985. The statutory accounts for the year ended 30 September 2007, prepared in accordance with United Kingdom Generally Accepted Accounting Practice (UK GAAP), have been filed with the Registrar of Companies and the statutory accounts for the year ended 30th September 2008 will be delivered following the Company's Annual General Meeting. The auditors have reported on those accounts; their reports were unqualified and did not contain statements under section 237(2) or (3) of the Companies Act 1985.

The Board of Directors of the Company approved this statement on 17<sup>th</sup> November 2008.

The statutory accounts will be issued to shareholders shortly, together with the notice for the Annual General Meeting to be held at 11am on 14<sup>th</sup> January 2009 at Porton Down Science Park, Salisbury, Wiltshire.

## **2. Accounting policies**

### **a) Basis of accounting**

This statement has been prepared using accounting policies consistent with International Financial Reporting Standards (IFRS).

This statement has been prepared under the historical cost convention.

IFRS 1, First time adoption of IFRS, sets out the procedures that the Group must follow as it adopts IFRS for the first time. The Group is required to establish its accounting policies in accordance with the IFRS in force as at 30 September 2008 and, in general, apply these retrospectively to determine the IFRS opening balance sheet at its date of transition, 1 October 2006. The standard allows a number of exceptions to this general principal. The only exemption that affects the group is use of the exemption to IFRS 3, Business combinations, to only restate business combinations arising after 1 October 2006.

Note 11 provides the reconciliation of net assets and loss for the year from UK GAAP to IFRS as at and for the year ended 30 September 2007 together with the net assets at the date of transition, 1 October 2006

### **b) Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries) made up to 30 September each year. Subsidiaries are all entities over which the Group has the power to govern the financial and operating policies of the entity concerned, generally accompanying a shareholding of more than one half of the voting rights. All intra-group transactions, balances, income and expenses are eliminated on consolidation. Acquisitions are accounted for under the acquisition method.

### **c) Revenue**

Revenue is measured at the fair value of the consideration received or receivable and represents amounts receivable for goods and services provided in the normal course of business, net of trade discounts, VAT and other sales-related taxes.

Revenue is recognised only to the extent that the Group has performed its contractual obligations, principally as certain technical or clinical targets are reached, based on the fair value of the right to consideration for each component of the agreement.

Research and Development fee revenue is recognised in the period in which the related chargeable expenditure is incurred.

No revenue is recognised for consideration, the value or receipt of which is dependent on future events or future performance.

### **d) Research and Development**

Research and Development expenditure is recognised as an intangible asset only when the Group has achieved reasonable certainty that future economic benefits will flow to the Group and then only to the extent that the asset created is separately identifiable and the costs of which can be measured reliably.

All Research and development expenditure incurred prior to achieving regulatory approval is therefore expensed as incurred.

## 2. Accounting policies (continued)

### e) Taxation

The tax expense represents the sum of the tax currently payable or recoverable and deferred tax.

The tax payable or recoverable is based upon amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted or substantially enacted by the balance sheet date.

Deferred tax is the tax expected to be payable or recoverable on differences between carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the balance sheet liability method. Deferred tax liabilities are generally recognised for all taxable timing differences and deferred tax assets are recognised only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realised.

### f) Intangible Assets - Goodwill

Goodwill arising on the acquisition of the subsidiary undertakings, representing the excess of the fair value of the consideration given over the fair value of the identifiable assets and liabilities acquired, is recognised as an asset and shown separately on the face of the balance sheet. Goodwill is tested for impairment at least annually and, where appropriate, an impairment charge is reflected in the income statement.

### g) Property, plant and equipment

Fixtures and equipment are stated at cost, net of accumulated depreciation and any provision for impairment. Depreciation is provided on all tangible fixed assets, at rates calculated to write off the cost, less estimated residual value, of each asset on a straight-line basis over its expected useful life commencing upon the satisfactory completion of installation such that assets are ready for their intended use, as follows:

Plant and machinery	5 years
Motor vehicles	4 years
Lab equipment	4 years
IT equipment	4 years
Office equipment	4 years
Leasehold improvements	4 years or term of the lease if shorter

Residual value is calculated on prices prevailing at the date of acquisition.

### h) Inventories

Inventories are stated at the lower of cost and net realisable value. Cost includes materials, direct labour and an attributable proportion of manufacturing overheads based on normal levels of activity. Net realisable value is based on the estimated selling price, less further costs expected to be incurred to completion and disposal. Provision is made for obsolete, slow moving or defective items where appropriate.

### i) Financial instruments

Financial assets and financial liabilities are recognised in the group's balance sheet when the group becomes a party to the contractual provisions of the instrument.

## **2. Accounting policies (continued)**

### **Trade receivables**

Trade receivables are measured at initial recognition at fair value, and are subsequently measured at amortised cost, using the effective interest rate method where credit exceeds normal terms. Appropriate allowances for estimated irrecoverable amounts are recognised in the income statement when there is objective evidence that the asset is impaired. The allowance recognised is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the effective interest rate computed at initial recognition.

### **Trade payables**

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

### **Cash and cash equivalents**

Cash and cash equivalents comprise cash in hand and deposits held at call with banks and other short term highly liquid investments with an original maturity of three months or less.

### **j) Retirement benefit costs**

The Group does not operate any pension plans, but makes defined contributions to the personal pension arrangements of its executive Directors and employees. The amounts charged to the income statement in respect of pension costs are the contributions payable in the year. Differences between contributions payable in the year and contributions actually paid are shown as either accruals or prepayments in the balance sheet.

### **k) Foreign currency**

Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated at the rates of exchange prevailing at that date. Any gain or loss arising from a change in exchange rates subsequent to the date of the transaction is included as an exchange gain or loss in the income statement.

### **l) Provisions**

Provisions are recognised when the Group has a present obligation as a result of a past event, and it is probable that the Group will be required to settle that obligation. Provisions are measured at the Directors' best estimate of the expenditure required to settle the obligation at the balance sheet date, and are discounted to present value where the effect is material.

### **m) Share-based payment**

The Group has applied the requirements of IFRS 2, *Share-based payments*. In accordance with the transitional provisions, IFRS 2 has been applied to all grants of equity instruments after 7 November 2002 that were unvested as at 1 October 2005.

The Group issues equity-settled share-based payments to employees. Equity-settled share-based payments are measured at fair value (excluding the effect of non-market-based vesting conditions) at the date of grant. The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of non-market-based vesting conditions.

Fair value is measured by use of the Black-Scholes pricing model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations.

#### n) Leases

Rentals payable under operating leases are charged on a straight-line basis over the term of the relevant lease.

### 3. Business segments

The Directors consider that the Group operates within a single business segment, being pharmaceutical development.

Revenue:	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000's
Product sales	1,278	1,113
Research and development fees	8,596	2,464
Licensing fees:		
- signature fees	1,900	1,350
- development and approval fees	-	750
	<u>11,774</u>	<u>5,677</u>

Geographical analysis of revenue:

	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000s
UK	813	603
Europe (excluding UK)	906	822
North America	7,758	3,991
Asia	2,297	261
	<u>11,774</u>	<u>5,677</u>

All revenue and losses before taxation originated in the UK. All assets and liabilities are held in the UK.

### 4. Research and development expenditure

	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000s
GW-funded research	10,431	12,506
Development partner-funded research	8,596	2,464
Total	<u>19,027</u>	<u>14,970</u>

## 5. Tax credit

	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000's
UK Corporation tax – R&D tax credit:		
Prior year	176	-
Current period	1,798	2,015
Total credit for the period	<u>1,974</u>	<u>2,015</u>

The UK Corporation tax credits relate to research and development expenditure claimed under the Finance Act 2000.

The amounts are subject to the agreement of HM Revenue and Customs.

## 6. Loss per share

The calculations of loss per share are based on the following losses and numbers of shares.

	Year ended 30 September 2008 £000's	Year ended 30 September 2007 £000's
Loss for the period	<u>(8,220)</u>	<u>(10,586)</u>
	Number of shares	Number of shares
Weighted average number of shares	<u>120,514,879</u>	<u>120,138,669</u>

Since the Group reported a net loss, diluted loss per share is equal to basic loss per share.

## 7. Trade and other receivables

	30 September 2008 £000's	30 September 2007 £000's
<b>Amounts falling due within one year</b>		
Trade receivables	204	240
Other receivables	195	226
Prepayments and accrued income	375	334
	<u>774</u>	<u>800</u>

## 8. Trade and other payables

	30 September 2008 £000's	30 September 2007 £000's
Trade payables	2,954	2,048
Other taxation and social security	159	197
Accruals	2,209	1,895
Defined contribution pension scheme accruals	41	46
	<u>5,363</u>	<u>4,186</u>

## 9. Deferred revenue

	30 September 2008 £000's	30 September 2007 £000's
<b>Amounts falling due within one year</b>		
Deferred signature fee income	1,900	1,900
Advance payments received	2,511	1,560
	<u>4,411</u>	<u>3,460</u>
<b>Amounts falling due after one year</b>		
Deferred signature fee income	<u>15,399</u>	<u>17,299</u>

Deferred signature fee income represents the balance of the non-refundable signature fees received from Almirall and Otsuka. These amounts will be recognised as revenue in future periods.

For Almirall the £12m signature fee is being recognised at the rate of £0.8m per year over 15 years from December 2005. In the case of Otsuka, where the Group's obligations under the agreement are weighted towards the earlier years, the \$18m (£9.2m) signature is being recognised from 1 April 2007 to 30 September 2011 at the rate of £1.1m per year and at £0.28m per year for the following 15 years.

Advance payments received represents payments for research and development activities to be carried out in the next financial year on behalf of Otsuka. These amounts will be recognised as revenue in future periods.

## 10. Statements of changes in equity

### a) For the year ended 30 September 2008

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Retained earnings £000's	Total £000's
At 1 October 2007	120	58,272	19,262	(71,991)	5,663
Exercise of share options	1	103	-	-	104
Share-based payment	-	-	-	726	726
Retained loss for the period	-	-	-	(8,220)	(8,220)
At 30 September 2008	<u>121</u>	<u>58,375</u>	<u>19,262</u>	<u>(79,485)</u>	<u>(1,727)</u>

### b) For the year ended 30 September 2007

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Retained earnings £000's	Total £000's
At 1 October 2006	120	58,210	19,262	(62,535)	15,057
Exercise of share options	-	62	-	-	62
Share-based payment	-	-	-	1,130	1,130
Retained loss for the period	-	-	-	(10,586)	(10,586)
At 30 September 2007	<u>120</u>	<u>58,272</u>	<u>19,262</u>	<u>(71,991)</u>	<u>5,663</u>

## 11. Explanation of transition to IFRS

IFRS1 sets out the procedures that the Group must follow as it adopts IFRS for the first time as the basis for preparing its consolidated financial statements. The Group is required to establish its accounting policies as at 30 September 2008 and, in general, apply these retrospectively to determine the IFRS opening balance sheet at its date of transition, 1 October 2006. The standard allows a number of exceptions to this general principle. The only exemption that affects the Group is the use of the exemption to IFRS 3, *Business combinations*, to only restate business combinations arising after 1 October 2006.

The key change to accounting policies is related to goodwill, whereby goodwill will no longer be amortised under IFRS.

Reconciliations of the adjustments to the income statement and balance sheets for reported periods are shown below:

### a) Reconciliation of adjustments to the Income statement for the year ended 30 September 2007 (date of last UK GAAP financial statements)

	UK GAAP £000's	IFRS adjustments £000's	IFRS £000's
Revenue	5,677	-	5,677
Cost of sales	(254)	-	(254)
Gross profit	5,423	-	5,423
Research and development expenditure	(14,970)	-	(14,970)
Management and administration expenses	(3,239)	357	(2,882)
Share-based payment	(1,130)	-	(1,130)
Operating loss	(13,916)	357	(13,559)
Interest receivable	958	-	958
Loss before tax	(12,958)	357	(12,601)
Tax credit	2,015	-	2,015
Loss for the period	(10,943)	357	(10,586)

The adjustment of £357,000 represents the reversal of goodwill amortisation charged during the year to 30 September 2007 under UKGAAP.

**b) Reconciliation of adjustments to the balance sheet as at 30 September 2007  
(date of last UK GAAP financial statements)**

	UK GAAP	IFRS adjustments	IFRS
	£000's	£000's	£000's
Intangible assets – goodwill	4,853	357	5,210
Property, plant and equipment	1,082	-	1,082
<b>Total non-current assets</b>	<b>5,935</b>	<b>357</b>	<b>6,292</b>
Inventories	535	-	535
Trade and other receivables	2,815	-	2,815
Cash and cash equivalents	20,966	-	20,966
<b>Total current assets</b>	<b>24,316</b>	<b>-</b>	<b>24,316</b>
<b>Total assets</b>	<b>30,251</b>	<b>357</b>	<b>30,608</b>
Current liabilities	(7,634)	-	(7,634)
Non current liabilities	(17,311)	-	(17,311)
<b>Total liabilities</b>	<b>(24,945)</b>	<b>-</b>	<b>(24,945)</b>
<b>Net assets</b>	<b>5,306</b>	<b>357</b>	<b>5,663</b>
Equity			
Share capital	120	-	120
Share premium account	58,272	-	58,272
Other reserves	19,262	-	19,262
Retained earnings	(72,348)	357	(71,991)
<b>Shareholders' funds</b>	<b>5,306</b>	<b>357</b>	<b>5,663</b>

The adjustment of £357,000 represents the reversal of goodwill amortisation charged under UKGAAP in the year from 1 October 2006 (date of transition to IFRS) to 30 September 2007.

**c) Balance sheet as at 1 October 2006 (date of transition to IFRS)**

The transition from UKGAAP to IFRS did not result in any adjustments to the balance sheet as at 1 October 2006.

**12. Availability of information**

A copy of this statement is available from the Company Secretary at Porton Down Science Park, Salisbury, Wiltshire, SP4 0JQ.