

## **Interim Results For The Six Months Ended 31 March 2009**

**Porton Down, UK, 20 May 2009:** GW Pharmaceuticals plc (AIM: GWP), the developer and manufacturer of a range of new cannabinoid medicines, including Sativex<sup>®</sup>, announces its interim results for the six months ended 31 March 2009.

### **OPERATIONAL HIGHLIGHTS**

- Positive results in Sativex Phase III MS spasticity trial
- Sativex European regulatory submission filed (announced separately today) with outcome expected towards end of 2009 / early 2010
- Sativex European launch preparations underway
- Positive results in Sativex MS Spasticity randomised withdrawal study provide evidence of long term efficacy
- Sativex Phase IIb/III cancer pain trial, funded by Otsuka as part of the US development programme, ongoing and due to report results in Spring 2010
- Sativex named patient prescription use ongoing – product exported to 21 countries
- Otsuka cannabinoid research collaboration yielding promising new psychiatric, neurological and oncology drug candidates
- In-house metabolic research programme due to expand. Phase II trial in planning on novel cannabinoid medicine for the treatment of dyslipidaemia in Type II diabetes patients

### **FINANCIAL HIGHLIGHTS**

- Net profit for the period of £4.0m (H1 2008: £4.2m loss)
- Turnover increased to £16.1m (H1 2008: £5.7m) reflecting revenue growth from milestone income, Otsuka alliance and Sativex sales
- Cash and short term deposits at 31 March 2009 of £11.8m. A further £8m, in the form of a milestone payment from Almirall, was received in early April 2009.

Dr Geoffrey Guy, GW's Chairman, said: "We are pleased to report our maiden profit, significantly increased turnover and a robust cash position. Following the outstanding data in our recently reported Sativex Phase III trial and the regulatory submission announced today, GW is now making the transition from a late stage development company to an emerging pharmaceutical business with excellent growth prospects.

"Our focus for the remainder of 2009 will be on securing the first major regulatory approvals for Sativex in Europe, preparing for launch, and completing the Sativex cancer pain study in the United States. We will also continue to build on the promising data being generated in our cannabinoid pipeline. I am confident that GW has now entered its most exciting time since its foundation."

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")**

**Interim Results For The Six Months Ended 31 March 2009  
Interim Management Report**

**INTRODUCTION**

GW has made excellent progress during the last six months. Positive results in the Sativex Phase III study in Multiple Sclerosis (MS) spasticity, reported in March 2009, have now led to the filing of a regulatory submission. GW expects an outcome of this submission towards the end of this calendar year or early 2010. In anticipation of approval, launch preparations are underway in-house as well as at the Group's marketing partners, Bayer HealthCare in the UK, and Laboratorios Almirall S.A. elsewhere in Europe.

In recent months, GW has not only reported a positive Phase III study but also two other positive "randomised withdrawal" studies. Each of these studies incorporated a design modified from previous studies and it is very encouraging that this revised approach is producing such consistently positive results.

The financial results reflect the strong progress that the Group has made during the period and it is pleasing to be announcing our maiden profit. These results reflect the encouraging pattern which has emerged over recent years of increasing revenues and decreasing cash burn. This period includes £8m of revenue in the form of milestone income from Almirall. This milestone payment was increased by Almirall as part of a recently signed amendment to the licence agreement and we are delighted that this important partner recognises the significance of the recent Phase III data and shares our confidence that the regulatory submission should lead to approval.

GW's relationship with Otsuka Pharmaceutical Co. Ltd continues to yield important financial benefits through their funding of both the United States (US) development of Sativex and the company's pipeline development in Central Nervous System (CNS) and cancer. This reflects the Group's ongoing strategy to increase investment in the product pipeline and decrease GW's in-house expenditure by encouraging partners to fund such research activities.

In addition to Sativex for MS, GW continues to progress a major Phase IIb/III study of Sativex in cancer pain. This study, which is being funded by our US partner, Otsuka, and is targeted primarily at the US, is due to report results in Spring 2010. We are also encouraged by the progress being made in our research collaboration with Otsuka. This collaboration demonstrates the wealth of opportunity in our cannabinoid pipeline, highlighted by a number of promising new psychiatric, neurological and oncologic drug candidates which are emerging. We have also gained valuable new intellectual property as a direct consequence of this collaborative research. In addition, we continue to be excited by the promise of our in-house research programme in the field of diabetes and metabolic syndrome.

With the first potential major approval for Sativex in prospect, launch preparations underway, data from the US cancer pain Phase IIb/III trial due early next year, partners for Sativex secured in key markets, a highly promising earlier stage pipeline and a robust financial position, we are confident about the future prospects for GW.

## **SATIVEX REGULATORY STRATEGY**

Sativex has shown positive results in Phase II and III clinical trials across a range of potential indications, in particular in MS, cancer pain and neuropathic pain. Each of these indications represents a distinct regulatory opportunity and requires a distinct set of clinical efficacy data for inclusion in a regulatory submission.

We have chosen a different lead indication for Sativex in our various territories. The regulatory strategy in Europe is to first obtain approval for the indication of MS spasticity. Following initial European approval, regulatory approval for this indication will also be sought in certain other parts of the world. In the US, cancer pain has been selected as the initial target indication for approval. GW expects to expand the approval of Sativex in Europe and other territories to cancer pain in the future based on the data being generated in the US.

In Canada, MS neuropathic pain was the first approved indication, and this has been successfully followed by the approval in cancer pain. These early approvals were obtained with early stage data under the Notice of Compliance with conditions (NOC/c) policy.

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

### **MS Spasticity**

In March 2009, GW announced positive results from its pivotal Phase III double-blind randomised placebo-controlled study of Sativex in patients with spasticity due to MS, who have achieved inadequate relief with existing therapies. This study was requested by the UK regulator in order to gain approval in this indication. As announced separately today, the regulatory submission has been filed and validated, and both the UK and Spanish regulators are currently in the process of conducting their review.

This Phase III study used an enriched design whereby 572 patients initially received Sativex for 4 weeks in a single-blind manner (Phase A), following which eligible Sativex responders (n=241) were randomized to continue on Sativex or switch to placebo for a further 12 weeks in a double-blinded manner (Phase B). During the randomized period, patients were not permitted to adjust their dose. This study is the largest study GW has undertaken and recruitment was achieved in just ten months using 52 hospital sites in five countries – UK, Spain, Italy, Czech Republic and Poland.

The prospectively defined primary efficacy endpoint of the study - the difference between the mean change in spasticity severity of Sativex vs Placebo in Phase B - was highly statistically significantly in favour of Sativex ( $p=0.0002$ ). The numeric difference between the two groups as measured on a Numeric Rating Scale was 0.84 units from a baseline of 3.89, greater than that achieved in previous studies. The difference between Sativex and placebo was also significant for a number of secondary endpoints. 74% of Sativex patients compared with 51% of patients on placebo achieved an improvement of greater than 30% in their spasticity score over the entire study ( $p=0.0003$ ). In addition, statistically significant improvements were also seen in spasm frequency ( $p=0.005$ ), sleep disturbance ( $p<0.0001$ ), patient global impression of change ( $p=0.023$ ), physician global impression of change ( $p=0.005$ ) and the Barthel Activities of Daily Living Index ( $p=0.007$ ).

The study provides further evidence of Sativex's reassuring safety profile. The adverse event data in this study was superior to previous Sativex studies – an improvement which resulted from the

modified dose titration regimen employed in the study. The adverse event profile in Phase B (after the four weeks in Phase A) on Sativex was essentially similar to that of placebo.

### **MS Spasticity Regulatory Strategy**

As announced separately today, a regulatory submission has been filed in the UK and Spain under the decentralised procedure. We aim to secure approvals in these two countries towards the end of 2009 / early 2010. Following these initial approvals, we intend to seek wider approval during 2010 in additional European countries via the mutual recognition procedure. We also intend to file for approval in selected markets beyond Europe.

### **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 trial conducted in Europe. In this 177 patient study, Sativex was significantly superior to placebo in reducing average daily pain ( $p=0.014$ ). In addition, 43% of patients who received Sativex, while remaining on strong opioids, exhibited at least a 30% decrease in their pain score compared to 21% of patients receiving placebo and strong opioids (Odds Ratio = 2.8:  $p=0.024$ ).

GW's ongoing cancer pain clinical programme is being wholly funded by Otsuka who have the US rights to this product. These trials are designed to obtain approval in this indication from the Food & Drug Administration (FDA), but it is also intended that they form the basis of a future European regulatory application in this indication and we have taken scientific advice from the European Medicines Evaluation Agency (EMA).

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 due to report results in Spring 2010. This five-week, randomized, placebo-controlled study is a Phase IIb/III dose ranging study in 336 patients. The primary objective of the study is to evaluate the efficacy and optimum dose range of Sativex in these patients as an adjunct to their pre-existing pain medications. The study is recruiting in the US, certain European countries, and South Africa. Centres are also being set up in Latin America and India.

The current US development programme anticipates two further Phase III trials prior to a subsequent submission of a New Drug Application to the FDA. All data generated 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. In 2008, four such studies were successfully completed, including a 255 patient thorough QT (TQT) study. Each of these studies has been agreed with the FDA as components of the Sativex US Investigational Plan and results to date emphasise the satisfactory safety profile of Sativex.

## **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>1</sup>, showed that Sativex was significantly superior to placebo in reducing pain ( $p=0.005$ ) and sleep disturbance ( $p=0.003$ ). Subsequently Sativex has also been shown to maintain efficacy in the long-term in this condition.

In recent years, GW has generated positive results from clinical trials in a number of models of central and peripheral neuropathic pain. These data may contribute to future regulatory filings in these indications. Following the initial approval for Sativex in Europe, GW will consider adding to this evidence base by conducting additional confirmatory trials.

## **EUROPEAN LAUNCH PREPARATION**

For several years, GW has been operating under Good Manufacturing Practice (GMP) licences granted by the MHRA, which permit the Group to manufacture pharmaceutical products for use in clinical trials and for named patient prescriptions. Sativex is manufactured in several stages, some of which are sub-contracted. Since 2001 for example, GW has sub-contracted the final step in the bulk GMP manufacture of Sativex to a contract manufacturing partner. As reported at the time of the Group's 2008 preliminary results, GW has chosen to expand its in-house GMP MHRA licences to include commercial manufacture and we have nearly completed the upgrading of our own facility with this objective in mind. This upgrade has proceeded on time and on budget and, as a result, GW anticipates taking over the responsibility for GMP commercial finished product manufacture of Sativex from its sub-contracting partner in time for European commercial launch.

In parallel with manufacturing preparations, GW's marketing partners are preparing their launch plans. The marketing rights in the UK are held by Bayer HealthCare and the rights in Spain held by Almirall. Following the recent Phase III data, both companies have stepped up their launch preparations and are in the midst of finalising launch, promotional and sales force strategies.

## **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 depends upon clinical judgement of doctors in relation to specific nominated patients. No marketing or promotional activity is permitted for unlicensed medicines.

Sativex has now been used in 22 countries either on named patient prescription or in clinical trials. This demonstrates a growing awareness and appreciation of Sativex amongst the medical community and gives reason to be confident about eventual regulatory approvals abroad.

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<sup>1</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 the UK, Sativex continues to be prescribed to patients primarily with MS but also with other types of spasticity and pain that is not adequately treated by available 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 1,900. Over 2,200 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.

### **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.

Following the recent Phase III trial in MS spasticity, GW intends to supplement the regulatory submission with this new data. Hence, this activity will continue during 2009.

### **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 which GW has developed a close relationship.

Otsuka fund all in-house and third party activities performed under the collaboration.

The collaboration has to date focused on evaluating the pharmacology of eleven 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, neurological and oncologic drug candidates have been identified and these are expected to be a principal focus for the next phase of the collaboration.

### **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 later this year.

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

## **FINANCIAL REVIEW**

In the six months to 31 March 2009, GW recorded a profit before tax of £4.0m compared to a loss of £5.2m in the prior period. This is the first period since the Group's inception in which GW has recorded a profit.

Revenues increased substantially during the period to £16.1m (H1 2008: £5.7m) primarily as a result of the £8m of milestone revenue received from Almirall, coupled with £6.2m of research and development fees (H1 2008: £4.1m) representing research and development costs incurred by GW and charged to Otsuka under both the Sativex US licence agreement and the research collaboration agreement. Sativex sales increased by 57% to £1m (H1 2008: £0.6m). The remaining £0.95m relates to the recognition of deferred signature fees arising under the Almirall and Otsuka licence agreements.

Total research and development expenditure increased to £9.9m (H1 2008: £9.3m). This increase is driven by research activities funded by Otsuka in relation to Sativex US development and the research collaboration. This Otsuka-funded expenditure increased by £2.1m to £6.2m (H1 2008: £4.1m) whilst GW-funded expenditure decreased by £1.4m to £3.8m (H1 2008: £5.2m).

Management and administrative expenses increased marginally to £1.7m from £1.6m in H1 2008.

Capital expenditure of £0.6m (H1 2008 £0.3m) consisted mainly of enhancements to GW's manufacturing facilities in preparation for European commercial launch and the decision as outlined above to conduct a greater amount of in-house manufacturing in future.

In previous years GW has surrendered tax losses in order to claim a research and development tax credit cash payment. Due to the profitable performance in the first half of the year we have assumed that brought forward tax losses will be utilised to produce a nil tax charge for the period (H1 2008: £1m tax credit).

At 31 March 2009, GW had £11.8m of cash. A further £8m, in the form of milestone income due from Almirall, was received in early April 2009.

The net cash outflow for the period of £2.2m compares favourably to the outflow of £2.5m in the comparable period last year despite a reduction in R&D tax credit receipts to £1.8m (H1 2008: £2.2m) and reduced interest receipts of £0.1m (H1 2008 £0.4m) as a result of reduced interest rates.

Total deferred income of £18.2m represents the unrecognised balances of the non-refundable signature fees of £16.4m plus £1.8m of advance payments received from Almirall. These amounts will be recognised as revenue in future periods.

The headcount as at 31 March 2009 was 109 compared to 113 as at 30 September 2008.

Consistent with guidance provided at the beginning of this financial year, we expect GW-funded R&D expenditure for the 2009 financial year to be 30% lower than in 2008 and for total R&D expenditure to be marginally higher than that incurred in 2008, as a result of additional Otsuka-funded research activities.

Following the recent receipt of £8m in milestone income, the Board anticipates that the Group will see net outflows in the second half such as to be broadly P&L and cash flow neutral for the financial year as a whole.

In the event of regulatory approval in the UK and Spain, currently expected towards the end of 2009/early 2010, GW is expected to receive milestone payments from its partners totalling £12.5m, following which we will also start to generate commercial sales revenues from Sativex in Europe. We would also expect the 2010 financial year to show continued revenues from R&D fees.

## **SUMMARY AND OUTLOOK**

We are pleased to report our maiden profit, significantly increased turnover and a robust cash position. Following the outstanding data in our recently reported Sativex Phase III trial and the regulatory submission announced today, GW is now making the transition from a late stage development company to an emerging pharmaceutical business with excellent growth prospects.

Our focus for the remainder of 2009 will be on securing the first major regulatory approvals for Sativex in Europe, preparing for launch and completing the Sativex cancer pain study in the United States. We will also continue to build on the promising data being generated in our cannabinoid pipeline. We are confident that GW has now entered its most exciting time since its foundation.

## **RISKS AND UNCERTAINTIES**

GW continues to face a number of potential risks and uncertainties which could have a material impact on the Group's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results. The directors do not consider that the principal risks and uncertainties have changed since the publication of the annual report for the year ended 30 September 2008. A detailed explanation of the risks summarised below can be found on page 11 of the annual report which is available to download at [www.gwpharm.com](http://www.gwpharm.com).

The principal risks can be summarised as follows:

### **Clinical Risk**

Clinical trials may encounter delays or fail to achieve their endpoints.

### **Manufacturing Risk**

GW may encounter problems in its manufacturing process which may delay product development programmes or restrict the commercial quantities of product that can be made.

**Funding Risk**

The Group may require access to additional funding in future. If it fails to secure such funding the Group may need to delay or scale back some of its R&D programmes or the commercialisation of some of its products.

**Commercialisation Risk**

Following regulatory approval, GW's products may not achieve commercial success or may be subject to competition.

**Financial Risks**

The Group is subject to exchange rate risk, interest rate risk, credit risk, counterparty risk, market price and liquidity risks.

**Regulatory Risk**

Regulatory bodies around the world have different requirements for approval of therapeutic products. This may result in restriction of indication.

In the next six months, the key risk facing the Group relates to the recent submission of a marketing authorisation application for Sativex in the UK and Spain. Uncertainty exists over whether a marketing authorisation will be granted. Submission to the regulatory authorities may result in restriction of indication, denial of approval or demands for additional data.

***Related Party transactions***

The Group did not enter into any related party transactions during the period.

**Responsibility Statement**

The directors confirm that this condensed set of financial statements has been prepared in accordance with IAS34 as adopted by the European Union, and that the interim management report herein includes a fair review of the information required by DTR 4.2.7R (indication of important events during the first six months and description of the principal risks and uncertainties for the remaining six months of the year) and DTR 4.2.8R (disclosure of related party transactions and changes therein).

The directors of GW Pharmaceuticals plc are listed in the GW Pharmaceuticals plc Annual Report for the year ended 30<sup>th</sup> September 2008 and there has been no change in the interim period.

By Order of the Board

Dr Geoffrey Guy  
Chairman

Justin Gover  
Managing Director

GW Pharmaceuticals plc  
Condensed consolidated income statement  
Six months ended 31 March 2009

	Notes	Six months ended 31 March 2009 (Unaudited) £000's	Six months ended 31 March 2008 (Unaudited) £000's	Year ended 30 September 2008 (Audited) £000's
<b>Revenue</b>	3	16,086	5,695	11,774
Cost of sales		(269)	(136)	(249)
<b>Gross profit</b>		15,817	5,559	11,525
Research and development expenditure	4	(9,904)	(9,286)	(19,027)
Management and administrative expenses		(1,686)	(1,550)	(2,775)
Share-based payment		(298)	(372)	(726)
<b>Operating profit/(loss)</b>		3,929	(5,649)	(11,003)
Interest receivable		99	464	809
<b>Profit/(loss) on ordinary activities before taxation</b>		4,028	(5,185)	(10,194)
Tax credit on loss on ordinary activities	5	-	1,018	1,974
<b>Profit/(loss) on ordinary activities after taxation</b>		4,028	(4,167)	(8,220)
<b>Earnings/(loss) per share - basic and fully diluted</b>	6	3.3p	(3.5p)	(6.8p)

All amounts relate to continuing operations.

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

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Six months ended 31 March 2009

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Retained earnings £000's	Total £000's
<b>At 1 October 2007</b>	<b>120</b>	<b>58,272</b>	<b>19,262</b>	<b>(71,991)</b>	<b>5,663</b>
Exercise of share options	-	7	-	-	7
Share-based payment	-	-	-	372	372
Retained loss for the period	-	-	-	(4,167)	(4,167)
<b>Balance at 31 March 2008</b>	<b>120</b>	<b>58,279</b>	<b>19,262</b>	<b>(75,786)</b>	<b>1,875</b>
Exercise of share options	1	96	-	-	97
Share-based payment	-	-	-	354	354
Retained loss for the period	-	-	-	(4,053)	(4,053)
<b>Balance at 30 September 2008</b>	<b>121</b>	<b>58,375</b>	<b>19,262</b>	<b>(79,485)</b>	<b>(1,727)</b>
Exercise of share options	-	-	-	-	-
Share-based payment	-	-	-	298	298
Retained profit for the period	-	-	-	4,028	4,028
<b>Balance at 31 March 2009</b>	<b>121</b>	<b>58,375</b>	<b>19,262</b>	<b>(75,159)</b>	<b>2,599</b>

GW Pharmaceuticals plc  
Condensed consolidated balance sheet  
As at 31 March 2009

	Notes	31 March 2009 (Unaudited) £000's	31 March 2008 (Unaudited) £000's	30 September 2008 (Audited) £000's
<b>Non-current assets</b>				
Intangible assets – goodwill		5,210	5,210	5,210
Property, plant & equipment		1,500	1,183	1,107
		<u>6,710</u>	<u>6,393</u>	<u>6,317</u>
<b>Current assets</b>				
Inventories		599	608	503
Taxation recoverable		-	843	1,798
Trade and other receivables	7	9,010	1,092	774
Cash and cash equivalents		11,828	18,488	14,054
		<u>21,437</u>	<u>21,031</u>	<u>17,129</u>
<b>Total assets</b>		<u>28,147</u>	<u>27,424</u>	<u>23,446</u>
<b>Current liabilities</b>				
Trade and other payables	8	(7,396)	(5,212)	(5,363)
Deferred revenue	9	(3,703)	(3,988)	(4,411)
		<u>(11,099)</u>	<u>(9,200)</u>	<u>(9,774)</u>
<b>Non-current liabilities</b>				
Deferred revenue	9	(14,449)	(16,349)	(15,399)
<b>Total liabilities</b>		<u>(25,548)</u>	<u>(25,549)</u>	<u>(25,173)</u>
<b>Net assets/(liabilities)</b>		<u>2,599</u>	<u>1,875</u>	<u>(1,727)</u>
<b>Equity</b>				
Share capital		121	120	121
Share premium account		58,375	58,279	58,375
Other reserves		19,262	19,262	19,262
Retained earnings		(75,159)	(75,786)	(79,485)
		<u>2,599</u>	<u>1,875</u>	<u>(1,727)</u>
<b>Total Equity</b>		<u>2,599</u>	<u>1,875</u>	<u>(1,727)</u>

These interim results were approved by the board of Directors on 19 May 2009.

GW Pharmaceuticals plc  
Condensed consolidated cash flow statement  
For the six months ended 31 March 2009

	Six months ended 31 March 2009 (Unaudited) £000's	Six months ended 31 March 2008 (Unaudited) £000's	Year ended 30 September 2008 (Audited) £000's
<b>Operating profit/(loss)</b>	3,929	(5,649)	(11,003)
Adjustments for:			
Depreciation of property, plant & equipment	233	206	415
Share-based payment charge	298	372	726
	<hr/>	<hr/>	<hr/>
Operating cash in/(out)flows before movements in working capital	4,460	(5,071)	(9,862)
(Increase)/decrease in inventories	(96)	(73)	32
(Increase)/decrease in receivables	(8,229)	(271)	15
Increase in payables	375	604	227
	<hr/>	<hr/>	<hr/>
<b>Cash used by operations</b>	(3,490)	(4,811)	(9,588)
Income tax credits received	1,792	2,191	2,191
	<hr/>	<hr/>	<hr/>
<b>Net cash outflow from operating activities</b>	(1,698)	(2,620)	(7,397)
<b>Investing activities</b>			
Interest received	99	443	821
Purchases of property, plant and equipment	(627)	(308)	(440)
	<hr/>	<hr/>	<hr/>
<b>Net cash from investing activities</b>	(528)	135	381
<b>Financing activities</b>			
Proceeds on issue of shares	-	7	104
	<hr/>	<hr/>	<hr/>
<b>Net cash from financing activities</b>	-	7	104
Net (decrease) in cash and cash equivalents	(2,226)	(2,478)	(6,912)
Cash and cash equivalents at beginning of year	14,054	20,966	20,966
	<hr/>	<hr/>	<hr/>
<b>Cash and cash equivalents at end of the period</b>	11,828	18,488	14,054

## **1. General information and basis of preparation**

These interim financial statements are condensed financial statements that have been prepared in accordance with IAS34 – “Interim Financial Reporting” and were approved by the Board on 19 May 2009. They do not constitute statutory financial statements as defined in Section 435 of the Companies Act 2006.

The statutory accounts for the year ended 30 September 2008 have been filed with the Registrar of Companies. The auditors’ report on those financial statements was not qualified, did not draw attention to any matters by way of emphasis without qualifying their report and did not contain statements under section 237(2) or (3) of the Companies Act 1985.

At 31 March 2009 the Group had cash resources of £11.8 million and has received, since the balance sheet date, a further £8 million from Almirall. The Group is also generating revenues from Sativex sales, from Research and development activity that it carries out on behalf of Otsuka Pharmaceutical Ltd and has several opportunities to earn development milestones from these partners in the next year. The directors have reviewed the working capital and research and development funding requirements of the Group for the next twelve months and consider that the cash in hand, recurring revenues together with the strong development partner relationships that are in place mean that the Group is well placed to manage its business risks successfully despite the current economic outlook.

After making enquiries, the directors have a reasonable expectation that Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the financial information for the half year ended 31 March 2009.

Results for the six month periods ended 31 March 2009 and 31 March 2008 have not been audited.

## **2. Significant Accounting policies**

The significant accounting policies and methods of computation adopted in the preparation of these interim condensed financial statements are consistent with those used in the preparation of the Group’s financial statements for the year ended 30th September 2008.

### 3. Business and Geographical segments

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

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

The Directors do not consider the business to be seasonal or cyclical.

Revenues can be analysed as follows:

Revenue:	Six months ended 31 March 2009 £000's	Six months ended 31 March 2008 £000's	Year ended 30 September 2008 £000's
Product sales	974	619	1,278
Research and development fees	6,162	4,126	8,596
Licensing fees:			
- signature fees	950	950	1,900
- development and approval fees	8,000	-	-
	<u>16,086</u>	<u>5,695</u>	<u>11,774</u>

Geographical analysis of turnover: - by destination of customer

	Six months ended 31 March 2009 £000's	Six months ended 31 March 2008 £000's	Year ended 30 September 2008 £000's
UK	444	425	813
Europe (excluding UK)	8,508	404	906
North America	5,660	3,719	7,758
Asia	1,474	1,147	2,297
	<u>16,086</u>	<u>5,695</u>	<u>11,774</u>

### 4. Research and development expenditure

	Six months ended 31 March 2009 £000's	Six months ended 31 March 2008 £000's	Year ended 30 September 2008 £000's
GW-funded research	3,742	5,160	10,431
Development partner-funded research	6,162	4,126	8,596
Total	<u>9,904</u>	<u>9,286</u>	<u>19,027</u>

## 5. Tax credit

	Six months ended 31 March 2009 £000's	Six months ended 31 March 2008 £000's	Year ended 30 September 2008 £000's
UK Corporation tax – R&D tax credit:			
Prior year	-	175	176
Current period	-	843	1,798
	<hr/>	<hr/>	<hr/>
Total credit for the period	-	1,018	1,974

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. Earnings per share

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

	Six months ended 31 March 2009 £000's	Six months ended 31 March 2008 £000's	Year ended 30 September 2008 £000's
Profit/(loss) for the period – basic	4,028	(4,167)	(8,220)
Profit/(loss) for the period – fully diluted	<hr/> 4,030	<hr/> (4,167)	<hr/> (8,220)
	Number of shares	Number of shares	Number of shares
Weighted average number of shares – basic	120,785,335	120,304,949	120,514,879
Weighted average number of shares – fully diluted	<hr/> 123,248,756	<hr/> 120,304,949	<hr/> 120,514,879

In prior periods, since the Group reported a net loss, diluted loss per share is equal to basic loss per share.

## 7. Trade and other receivables

	31 March 2009 £000's	31 March 2008 £000's	30 September 2008 £000's
<b>Amounts falling due within one year</b>			
Trade receivables	8,138	278	204
Other receivables	169	301	195
Prepayments and accrued income	703	513	375
	<u>9,010</u>	<u>1,092</u>	<u>774</u>

The £8m milestone payment due from Almirall, included within trade receivables as at 31 March 2009, was received in full on 8<sup>th</sup> April 2009.

## 8. Trade and other payables

	31 March 2009 £000's	31 March 2008 £000's	30 September 2008 £000's
Trade payables	2,478	2,802	2,954
Other taxation and social security	151	189	159
Accruals and other payables	4,725	2,175	2,209
Defined contribution pension scheme accruals	42	46	41
	<u>7,396</u>	<u>5,212</u>	<u>5,363</u>

## 9. Deferred Revenue

	31 March 2009 £000's	31 March 2008 £000's	30 September 2008 £000's
<b>Amounts falling due within one year</b>			
Deferred signature fee income	1,900	1,900	1,900
Advance payments received	1,803	2,088	2,511
	<u>3,703</u>	<u>3,988</u>	<u>4,411</u>
<b>Amounts falling due after one year</b>			
Deferred signature fee income	<u>14,449</u>	<u>16,349</u>	<u>15,399</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 second half of the year on behalf of Otsuka. These amounts will be recognised as revenue in the second half of the year.

#### **10. Availability of information**

A copy of this statement is available from the Company Secretary at Porton Down Science Park, Salisbury, Wiltshire, SP4 0JQ. Full details can also be found on the Company's website at [www.gwpharm.com](http://www.gwpharm.com).

#### **Cautionary statement**

This Interim Management Report "IMR" has been prepared solely to provide additional information to shareholders to assess the Group's strategies and the potential for those strategies to succeed. The IMR should not be relied on by any other party for any other purpose.

The IMR contains certain forward-looking statements. These statements are made by the directors in good faith based on the information available to them up to the time of their approval of this report but such statements should be treated with caution due to the inherent uncertainties, including both economic and business risk factors, underlying any such forward-looking information.