



GW Pharmaceuticals plc

Interim Results

Porton Down, UK, 22 May 2012: GW Pharmaceuticals plc (AIM: GWP, “GW” or “the Group”), the specialty pharmaceutical company focused on cannabinoid science, announces its interim results for the six months ended 31 March 2012.

COMMERCIAL: STRONG PROGRESS

- Sativex[®] in-market sales grow to £5.4m (H1 2011: £1.9m). Fourteen additional European country launches being planned from the end of 2012 onwards
- Sativex European Mutual Recognition Procedure regulatory submission closes successfully with all ten countries recommending approval. A total of twenty one countries have now approved/recommended approval for Sativex
- Almirall licence agreement amended to include new milestone payment of €11.9m (£9.8m), received in May (after period end), and expanded Sativex commercial rights to Mexico

R&D: SIGNIFICANT CLINICAL ACTIVITY

- Two pivotal Sativex Phase III cancer pain trials recruiting on track. Third Phase III cancer pain trial now underway (see separate release today)
- Three Phase IIa clinical trials of novel cannabinoid medicines (GWP42003 and GWP42004) in diabetes/metabolic disease ongoing. First two trials fully recruited
- Phase IIa clinical trial of novel cannabinoid medicine (GWP42003) in ulcerative colitis commenced
- Initial clinical trial in glioma now in planning. Lead drug candidate GWP42006 identified in pre-clinical epilepsy programme

FINANCIALS: ROBUST FINANCIAL POSITION

- Total revenue of £11.1m (H1 2011: £16.6m, including £5.1m milestone payments). GW Sativex sales of £1.7m (H1 2011: £1.9m)
- Net loss before tax of £4.1m in line with expectations (H1 2011: £3.1m profit)
- Cash and short term deposits at 31 March 2012 of £26.2m (31 March 2011: £28.3m). Additional £9.8m milestone payment received in May, to be recognised as revenue in H2

Dr Geoffrey Guy, GW’s Chairman, said, “GW has made excellent progress in the first half of 2012. In-market sales of Sativex show strong growth and, with launches being planned in fourteen additional European countries, we expect this sales growth to continue. The market opportunity for Sativex is being expanded through three Sativex Phase III cancer pain trials, which constitute the largest clinical programme ever undertaken by GW and which are fully funded by our partner Otsuka. Success with

these trials would provide an opportunity to enter the important US market as well as significantly expand the market for Sativex in the rest of the world. In addition, with four Phase II trials now underway for novel cannabinoid drug candidates and further trials in planning, we are making significant steps towards realising the value of our cannabinoid pipeline. The company is underpinned by a strong financial position and we look forward to continued progress in the second half of the year.”

An analyst presentation is being held today at 9.30am at FTI Consulting, Holborn Gate, 26 Southampton Buildings, London WC2A 1PB. Please contact Jennifer Alves at FTI Consulting on +44 20 7269 7176 for details. An audio webcast of the presentation will be available on GW’s website at 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 2012

INTRODUCTION

In order to reflect the commercial progress of Sativex[®] as well as the Group's ongoing investment in its pipeline, GW's interim statement is structured to reflect the three key components to GW's business: Sativex Commercial; Sativex R&D; and Cannabinoid Platform/Pipeline R&D.

1. Sativex Commercial

With Sativex having now entered the early phase of its commercial life and with a large number of new markets due for launch, GW is increasingly a commercial business generating sales revenues through supply of commercial product to GW's marketing partners. In-market sales growth generated by marketing partners in currently approved markets, together with planned launches in a large number of new markets, are expected to drive GW revenue growth.

2. Sativex R&D

Sativex is currently approved /recommended for approval in 21 countries for spasticity due to Multiple Sclerosis (MS) but with three large Phase III studies in cancer pain ongoing, we believe that the MS indication represents only the start of Sativex's commercial potential. GW is seeking to maximise the potential of Sativex through these cancer pain trials which are funded by Otsuka Pharmaceutical Co. Ltd. This programme is targeted at the important United States (US) market but also provides an opportunity to address a major unmet need in other regions across the world.

3. Cannabinoid Platform / Pipeline R&D

GW occupies a world leading position in cannabinoid science. We believe that there is significant opportunity to leverage this strategic position to develop a number of new medicines with a view to seeking new licensing partners in due course. A programme of four Phase II trials is now underway in metabolic disease and in ulcerative colitis. In addition, following highly promising pre-clinical data in cancer and epilepsy, an initial clinical trial in glioma is in planning and a lead drug candidate for the epilepsy programme has been identified.

SATIVEX COMMERCIAL

In prior years, GW has entered into licensing agreements for the commercialisation of Sativex with Otsuka in the US, Almirall S.A. in Europe (excluding the United Kingdom), Bayer HealthCare AG in the UK and Canada, Novartis Pharma AG in Australasia, Asia (excluding Japan and China), Middle East (excluding Israel) and Africa, and Neopharm Group in Israel.

In March 2012, GW signed an amendment to its Sativex licence agreement with Almirall. As part of the revised agreement, Almirall's commercial rights have been extended beyond Europe to include Mexico, a country in which Almirall has had an affiliate in place for more than a decade. In addition, in return for Almirall agreeing to pay to GW a new milestone payment of €11.9m (£9.8m) based on a near term cancer pain trial recruitment target, GW agreed to reduce the Sativex supply price charged

by GW to Almirall over the next few years until the launch of Sativex in the cancer pain indication in Europe and agreed to cancel future cancer pain launch milestones of £5.5m.

This new milestone of €11.9m (£9.8m) was received in May 2012. Including this payment, GW has to date received £67m in signature fees, technical access fees and milestone payments from its various licence agreements. GW is entitled to receive up to a further £204m in additional milestone payments and also generates royalty/product supply income derived from sales by its existing commercial partners.

Regulatory Progress – MS Spasticity

In Europe, Sativex has now been approved / recommended for approval in eighteen countries for the treatment of spasticity (muscle stiffness/spasm) due to MS.

In prior years, GW achieved positive regulatory assessments in the UK, Spain, Germany, Italy, Denmark, Sweden, Austria and the Czech Republic. Earlier this month, GW announced that a further ten countries had now recommended approval under a Mutual Recognition Procedure (MRP). These countries are: Belgium, Finland, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovakia.

The next step in the regulatory process for these ten new markets involves separate national phases in each country to finalise local wording on product packaging and related documents and also to agree any other country-specific requirements. Following completion of the national step, each country is then expected to issue a national marketing authorisation. Launch timing in these ten new countries is dependent on national pricing and reimbursement procedures. Launches are anticipated from the end of 2012 onwards.

Beyond Europe, Sativex has received full regulatory approval for MS spasticity in Canada and New Zealand. Sativex has also now achieved approval in Israel for the two indications of MS Spasticity and MS neuropathic pain and, having secured reimbursement by a large private insurance provider, has started to be marketed by our partner, Neopharm. Within the Novartis licensed territory, a notice of rejection has recently been received from the Australian regulatory authority, which Novartis intend to appeal later this year. The application had been recommended for approval by the assessment team but this recommendation was subsequently declined by the authority's advisory committee on grounds of risk-benefit. Novartis has also initiated regulatory filings in selected countries in the Middle East with more to follow later this year. A regulatory filing is also underway in Switzerland.

Commercialisation in Europe

Sativex is the first new therapeutic solution to treat MS symptoms in over ten years and is designed to treat those patients who do not gain adequate benefit from existing anti-spasticity medication.

Total in-market sales in the period rose to £5.4m compared to £1.9m in the equivalent period last year. Almirall launched Sativex in Germany, Spain and Denmark in 2011 and recently reported that the product is evolving well and that they expect this positive trend to continue for the remainder of this year.

Germany

Sativex was launched in Germany by Almirall in early July 2011. With over 120,000 people with MS, Germany represents the largest potential European market opportunity for Sativex. During 2012, Almirall is not only deploying a dedicated in-house sales force but has also added a further team of sales representatives on a contract basis in order to drive awareness and uptake.

Market performance to date has been strong with Almirall's gross ex-factory sales in the first ten months reaching €4.45m. With significant activity planned for the remainder of this year, sales growth is expected to continue.

Under a revised German reimbursement/pricing system introduced last year for all new medicines, Almirall will be required to agree a long term price for Sativex with the German pricing authorities later this year. A recommendation as to the "added value" of Sativex is expected from the reimbursement body, the G-BA, during the summer and pricing discussions will then follow in the second half of the year.

Spain

In March 2011, Sativex was launched in Spain following a determination by the Spanish Ministry of Health that Sativex should be made available as a fully reimbursed medicine under Spain's National Health System. Having achieved this reimbursement status, since launch Almirall have focused efforts on securing hospital formulary listings for Sativex in the key relevant hospital centres across the country.

Although the economic climate in Spain presents challenges, GW and Almirall are pleased with initial sales performance since launch. Almirall's gross ex-factory sales since launch now total €2.3m. With formulary listings now achieved in the majority of key target hospitals, sales growth is expected to continue during the coming year.

Denmark

Sales to date in Denmark have been modest. With other launches in Scandinavia in planning, it is hoped that performance will start to improve in due course.

UK

Sativex was launched in the UK in the summer 2010 by GW's UK marketing partner, Bayer HealthCare. In-market sales in the last twelve months were £2.4m.

The pace of sales growth in the UK is expected to be determined by Bayer's efforts to secure NHS funding for Sativex from local Primary Care Trusts (PCTs). A significant body of work has been undertaken this year to demonstrate the positive budget impact that Sativex may have for PCTs in terms of the reduced cost burden on the NHS for patients who benefit from Sativex treatment. This new pharmaco-economic data is being introduced by Bayer next month and will be the focus of their strategy for the remainder of this year.

In addition, the National Institute for Clinical Excellence (NICE) is reviewing Sativex as part of a proposed updated set of NICE MS Treatment Guidelines. This review process is now underway.

Italy / Sweden / Austria / Czech Republic

These four countries all participated in the first successful MRP completed in 2011 and recommended approval of Sativex. In each country, Sativex requires pricing and reimbursement to be agreed with the national authorities prior to launch. Although this process is well underway for Sativex in all four markets, timelines for completion are generally becoming longer. As a result, launches in these countries should occur either towards the end of calendar 2012 or early 2013.

Ten newly approved European Countries

As discussed above, a further ten countries have recently recommended approval of Sativex: Belgium, Finland, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovakia. We now await national licences in each country, following which pricing and reimbursement procedures will then take place.

The length of time required for pricing/reimbursement varies considerably across countries and are more difficult to predict at present in light of the current macroeconomic environment. Hence, launches are likely to take place in certain markets around the end of calendar 2012 with other markets not launching until later in 2013.

SATIVEX R&D – Expanding the Sativex Label

Phase III Cancer Pain Trials Programme

The market potential for Sativex is being significantly enhanced through a comprehensive Phase III programme now underway to develop Sativex as a treatment for cancer pain. Studies suggest that more than one-third of patients with cancer, and more than three-quarters of those with advanced disease, suffer from chronic pain. Large surveys indicate that optimal opioid therapy does not yield adequate pain relief in a substantial proportion of these patients.

GW's cancer pain clinical programme is being wholly funded by Otsuka, which has licensed the US commercialisation rights to this product. The programme is the largest ever undertaken by GW and involves trial sites in Europe, North America, Latin America and Asia. The trials are designed to obtain approval in this indication from the Food & Drug Administration (FDA) in the US, and these data will also be used by GW for future regulatory applications in this indication in Europe and around the world.

Prior to commencing the Phase III programme, GW completed two Phase II studies with positive results including over 500 patients in total. Both of these have been published in peer-reviewed journals, the most recent being published last month in the Journal of Pain (1), the official journal of the American Pain Society.

Two Pivotal Phase III Trials

The pivotal Phase III programme comprises two randomised placebo-controlled multi-centre multinational trials as well as a long term extension study. Each Phase III trial is intended to recruit 380 patients and will evaluate the efficacy and safety of Sativex versus placebo over a 5 week treatment period. The primary efficacy analysis is the continuous response analysis, the same analysis that has yielded statistically significant results in both Phase II trials.

Patient recruitment for both studies is proceeding on track. Initial recruitment focused on European trial sites and operations have expanded over recent months to a large number of US sites which are

due to contribute significant patient numbers for the remainder of the studies. These two studies are expected to complete recruitment around the end of 2013. Regulatory filings are intended to be made upon completion of these two studies.

Professor Marie Fallon, Professor of Palliative Care, University of Edinburgh, is principal investigator of the first study. The principal investigator of the second study is Dr. Russell K. Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York City.

Third Phase III Trial

As announced separately today, a third supportive Phase III trial has now commenced. The purpose of this trial is to provide as needed supplementary data to that generated in the two pivotal studies.

The third Phase III trial differs in design from the first two studies, employing an “enriched study design” akin to that which was successfully employed in the MS spasticity trials programme. The study involves exposing patients to Sativex in a single blind phase of two weeks duration (“Phase A”), following which responders will be randomised either to stay on Sativex or switch to placebo in a double blind phase for a five week treatment period (“Phase B”). The primary efficacy analysis will be the mean change from baseline in Phase B. The study will aim to recruit 540 patients into Phase A and target 216 patients to enter Phase B.

New Sativex Indication/Sativex Investigator studies

Beyond MS and cancer pain, Sativex has also previously yielded positive results from clinical trials in a range of indications, including various types of pain, as well as other symptoms of MS. GW continues to evaluate these opportunities in conjunction with its marketing partners to determine whether a new target indication should be formally developed at this time. Discussions on this matter are ongoing.

As with any new medicine, the availability of Sativex has provoked interest in its potential for other neurological conditions, particularly motor disorders and neurodegenerative diseases. GW is working with a number of leading academic centres around Europe studying Sativex in conditions such as amyotrophic lateral sclerosis (motor neurone disease), Huntington’s Disease, cervical dystonia and Tourette’s syndrome.

CANNABINOID PLATFORM / PIPELINE R&D

GW occupies a world leading position in cannabinoid science. The company has developed a proprietary and validated cannabinoid technology platform and formed constructive collaborations with leading international scientists, universities and institutions in the field. GW’s research network now extends to over 25 academic institutions in 11 countries and involves research in a wide range of therapeutic areas, including oncology, neuroscience, metabolic disease, inflammatory disease, gastroenterology, and dermatology. The objective of this research effort is to progress a number of GW’s new cannabinoid pipeline candidates to full clinical development.

GW now has a programme of four Phase II studies underway in its non-Sativex cannabinoid pipeline.

GW’s understanding of the pure and applied pharmacology of new cannabinoids continues to be illuminated under the direction of two of the world’s most eminent cannabinoid scientists, Professor

Roger Pertwee at the University of Aberdeen and Professor Vincenzo di Marzo at Institute of Biomolecular Chemistry of the National Research Council, Naples. In December 2011, Professor Pertwee received the prestigious Wellcome Gold Medal, presented every two years by the British Pharmacological Society. In March 2012, GW announced that Professor Di Marzo has agreed to direct GW's global pre-clinical research programme and will assume the title of Research Director of GW Research Ltd and GW's Cannabinoid Research Institute.

In-House Funded Research

The principal areas of GW's investment are in diabetes/metabolic disease and inflammatory conditions. GW is selectively investing its resources to advance this part of the cannabinoid pipeline with a view to signing new out-licensing agreements in due course.

Diabetes/Metabolic Disease

GW has embarked on a programme of three Phase IIa clinical studies evaluating GW's cannabinoids as potential treatments in the field of metabolic syndrome and type 2 diabetes. This clinical programme seeks to build upon pre-clinical data which demonstrate the desirable effects of a number of GW cannabinoids on various features of the metabolic disease, notably insulin resistance, cholesterol and liver fat. These three studies are as follows:

- The first study is a multi-centre, randomised, double blind, placebo controlled, parallel group pilot study examining the effects on plasma lipid status of GWP42003 and GWP42004 at varying doses and at different ratios in patients with insulin resistance. This study is now fully recruited with a total of 62 patients.
- The second randomised controlled study is exploring the effect of GWP42003 on liver fat in 24 patients with Non-alcoholic Fatty Liver Disease. This study is now fully recruited.
- The third Phase IIa study is investigating whether GWP42003 and GWP42004 can prevent weight gain in 60 patients taking anti-psychotic therapy. Patient recruitment into this study is in its early stages.

In each of these studies, a range of secondary measures are also being investigated. The objective of this early exploratory clinical development programme is to define the optimal therapeutic role for cannabinoids in metabolic syndrome. As part of GW's research effort in this therapeutic area, GW is also working to set up clinical trials in the Gulf, a region with a high prevalence of diabetes.

Inflammation

Following pre-clinical research demonstrating that cannabinoids show potential in the treatment of Inflammatory Bowel Disease in standard in vivo models, GW has recently commenced a Phase IIa clinical study investigating the efficacy and safety of GWP42003 in the treatment of ulcerative colitis. This study aims to include 62 patient and the chief investigator is Dr Peter Irving at Guy's and St Thomas's Hospital, London.

Otsuka Funded Research

GW's research activities in the field of CNS disorders and oncology are supported by income from a global cannabinoid research collaboration with Otsuka. This collaboration was originally signed in July

2007 with a three year term, and was extended for a further three years to June 2013. To date, Otsuka's total investment in GW's research activities under this collaboration totals £18.5m.

Cancer

A major focus of the GW-Otsuka research collaboration lies in the area of cancer treatment. Pre-clinical studies are most advanced in the specific areas of glioma and breast cancer.

We have identified the putative mechanism of action for cannabinoids in glioma, where autophagy and programmed cell death are stimulated via inhibition of the akt/mTORC1 axis. In vivo studies have shown cannabinoids to have a synergistic effect with temozolomide, a standard treatment for glioma. In light of this promising pre-clinical research, GW has received interest from clinicians in conducting an early proof of concept clinical trial and a study is in advanced stages of planning which will evaluate GW cannabinoids in combination with temozolomide in patients with glioblastoma, the most common form of brain cancer. Meanwhile, efforts continue in the laboratory to define the most biologically active cannabinoids, to identify the most promising cancer targets, and to identify biomarkers for use in clinical trials.

In the area of breast cancer, the development by GW research collaborators of sophisticated new transgenic animal models means that we have been able to study the effect of cannabinoids both on local spread and distant spread of various types of therapy-resistant breast cancer. We have found a way to reduce the exposure of the tumour tissue to THC, without sacrificing anti-tumour efficacy, paving the way for effective cannabinoid treatments that minimise psychoactivity. Efforts are now focused on identifying the precise molecular mechanism of action of cannabinoids in breast cancer, and to define the optimum cannabinoid treatment regimen.

Neuroscience

The second major area of focus in the GW-Otsuka research collaboration lies in nervous system disorders, primarily epilepsy and psychiatric illness. GW compounds have shown promise in the area of epilepsy in standard models of seizure and a lead drug candidate, GWP42006, has been identified. An important recent development has been the demonstration that cannabinoids are able to reduce the expression of a series of epilepsy-related genes, in a way that correlates with the treatment effect. This finding may allow for the use of cannabinoids as personalised medicines in the field of epilepsy, whereby patients who are most likely to respond can be identified by the presence of a gene-related biomarker.

Work in psychotic disorders continues, with efforts targeted towards identifying the optimum combination of anti-psychotic agent not only to enhance symptom improvement, but also to reduce the unwanted motor effects of antipsychotic agents.

Neurodegenerative diseases are known to be associated with abnormalities of the endocannabinoid system. Studies in Huntington's Disease have shown that both the CB1 and CB2 receptors have a role in disease progression, and cannabinoids are neuroprotective in animal models of Huntington's Disease. A small preliminary clinical study programme looking at the impact of treatment with cannabinoids in Huntington's Disease has now completed recruitment.

FINANCIAL REVIEW

In the first half of the current financial year, we have seen encouraging signs of in-market Sativex

sales growth by our partners and have made positive steps towards achieving a full year profit. GW's cash position also remains strong.

Total in-market sales in the period by our partners rose to £5.4m compared to £1.9m in the equivalent period last year.

The reported loss before tax for the period of £4.1m (H1 2011: £3.1m profit) is in line with expectations, and reflects the fact that no major new Sativex country launches had been anticipated in the period nor had we expected to receive any milestone payments.

A key event during this first half was an amendment to the terms of the Sativex license agreement with Almirall, signed in March 2012. In return for a near-term reduction to the Sativex supply price to Almirall and in return for GW agreeing to waive entitlement to £5.5m of future cancer pain approval milestones, Almirall agreed to pay a near-term milestone of €11.9m (£9.8m), upon GW's achievement of a Phase III cancer pain recruitment target, as well as a €100,000 technical access fee for the addition of Mexico to the Almirall territory. The Phase III recruitment target was achieved in mid-April, with the result that the milestone has now been received and will be recognised in full as income in H2.

Total revenue for the six months to 31 March 2012 was £11.1m, £5.5m less than the prior period, in which £5.1m of milestone payments were received. No milestones were expected in this period.

We are encouraged by the growth of in-market sales achieved by our marketing partners as outlined above. GW's reported Sativex sales revenues are based upon the value of product shipped to our partners in the period. As such, they are not directly correlated with in-market sales, but vary from one period to the next in accordance with the volume of batches which are physically delivered. This means that GW's reportable Sativex revenues are subject to the stock holding policies of our partners, which is in turn determined by their expected needs for new territorial launches as well as demand in existing territories. As a result of this, and as guided previously, although we expect to see year on year growth in partner's in-market sales, this does not translate into straight line growth in GW's Sativex sales revenues. We therefore expect to see volatility from one period to the next, depending upon our partners' needs and the timing of our batch deliveries.

GW's Sativex sales in this period at £1.7m were slightly below the prior period (H1 2011: £1.9m). As noted in the 2011 results, sales last year were boosted by the delivery of £1.1m of German launch stock at the end of the financial year. This has had an impact upon sales recorded in H1 2012, a period in which stock previously shipped to Almirall has been utilised to supply product into the market.

In addition to the four European countries in which Sativex is already available, a further 14 European countries have approved/recommended approval and are due for launch from the end of calendar 2012 onwards.

Research and development fees increased marginally to £8.8m (H1 2011: £8.7m). These fees represent charges to Otsuka for research conducted under both the Sativex US licence agreement and the research collaboration agreements. The Phase III cancer pain programme is now gathering pace, with the third Phase III clinical trial having now started and can be expected to lead to increasing Otsuka-funded R&D spend in H2.

The remaining £0.6m (H1 2011:£0.95m) of revenue relates to the recognition of deferred signature fees and technical access fees arising under partner licence agreements.

Total research and development expenditure increased to £12.5m (H1 2011: £11.3m) of which the amount funded by GW increased to £3.7m (H1 2011: £2.7m), reflecting our investment in Phase II clinical activity.

Segmental analysis of the profit and loss account shows that the commercial Sativex business, despite not having received any milestones in this period, continued to generate a profit contribution of £2.2m in H1 (H1 2011: £7.4m – including £5.1m of milestones). Sativex R&D showed net expenditure of £2.3m (H1 2011: £1.5m) and the pipeline recorded net spend of £1.9m (H1 2011: £1.3m).

Management and administrative expenses increased to £1.8m (H1 2011: £1.4m).

The R&D tax credit of £0.9m (H1 2011: £0.2m) represents a £0.4m credit received from HMRC in respect of surrendered corporation tax losses for the year ended 30 September 2011 plus a further £0.5m which is expected to be claimed at year end in respect of the six months to 31 March 2012.

At 31 March 2012, GW had a strong cash position of £26.2m (31 March 2011: £28.3m, 30 Sept 2011 £28.3m). Net cash outflow for the period was £2.1m (H1 2011: £3.1m inflow).

Capital expenditure was £0.7m, consisting primarily of manufacturing equipment and leasehold improvements (H1 2011: £0.5m).

Inventory of £2.0m (31 March 2011: £0.9m) consists of finished goods, consumable items and work in progress and is stated net of a £3.0m realisable value provision (31 March 2011: £3.6m, 30 Sept 2011 £3.4m). During this period, the realisable value provision has reduced by £0.4m, resulting in a credit to the income statement, as our forward sales projections allow us to attribute a carrying value to a greater proportion of our work-in-progress.

Total deferred income of £16.1m (31 March 2011: £15.5m) represents the unrecognised balances of the non-refundable signature and technical access fees of £12.1m (31 March 2011: £12.5m) and £4.0m (31 March 2011: £3.0m) of advance payments received from Otsuka. These amounts will be recognised as revenue in future periods.

Average headcount for the period to 31 March 2012 was 173 (31 March 2011: 154).

2012 Full Year Guidance

Looking ahead to the full year ending 30 September 2012, with higher full year revenue now forecast as a result of the €11.9m milestone from Almirall and GW-funded R&D expenditure now expected to rise by 30% over 2011 (compared to previous guidance of 40-50%), we now anticipate making a small profit for 2012. Previous guidance provided at the time of the 2011 had anticipated a loss for this year.

With respect to Sativex sales, we expect to book Sativex revenues for 2012 of circa £2.5m. As outlined above, solid in-market sales growth by our partners is expected to continue but the effect on sales recorded by GW this financial year is likely to be muted by partner stock policies, the reduced Sativex supply price to Almirall following the recent amendment agreement, and the fact that we do

not envisage any new launches in this financial year. We do expect GW's Sativex sales growth to resume in the next financial year and to continue thereafter, reflecting continuing in-market sales growth coupled with normalized partner stock levels and a number of anticipated launches in further territories.

BOARD

In April, GW announced that, after ten years as Finance Director, David Kirk had informed the Company that he intends to stand down from the Board on 1st June 2012. David will be succeeded by Adam George, who has served as GW's Company Secretary and Group Financial Controller since 2007 and will take on the role of Finance Director and join the Board on 1st June 2012. The Board thanks David for his very significant contribution to GW and wishes him well for the future and is pleased to have in Adam George a well-qualified internal successor to David.

In addition, in view of the expansion of the Group's operations since the launch of Sativex, the Board has also decided that it intends to add a new executive role of Chief Operating Officer to the Board. A search for this new position has recently commenced.

SUMMARY

GW has made excellent progress in the first half of 2012. In-market sales of Sativex show strong growth and, with launches being planned in fourteen additional European countries, we expect this sales growth to continue. The market opportunity for Sativex is being expanded through three Sativex Phase III cancer pain trials, which constitute the largest clinical programme ever undertaken by GW and which are fully funded by our partner Otsuka. Success with these trials would provide an opportunity to enter the important US market as well as significantly expand the market for Sativex in the rest of the world. In addition, with four Phase II trials now underway for novel cannabinoid drug candidates and further trials in planning, we are making significant steps towards realising the value of our cannabinoid pipeline. The company is underpinned by a strong financial position and we look forward to continued progress in the second half of the year.

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 2011. A detailed explanation of the risks summarised below can be found on pages 23 and 24 of the annual report which is available to download at www.gwpharm.com.

The directors are satisfied that the Group has sufficient resources to continue in operation for the foreseeable future, a period of not less than 12 months from the date of this report. Accordingly, they continue to adopt the going concern basis in preparing the financial information for the half year ended 31 March 2012.

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, may be subject to competition, and may receive adverse decisions with respect to pricing and reimbursement.

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. Submissions to regulatory authorities may result in restriction of indication, denial of approval or demands for additional data.

In the next six months, the key risks facing the Group continue to relate to the continued commercialisation of Sativex by our commercial partners and the rate of progress with Phase III cancer pain trials recruitment. Having now achieved a series of national regulatory approvals, the key challenge is for our commercial partners, assisted by GW, to achieve pricing approval and reimbursement in each territory, and thereafter to encourage hospitals and funding bodies to add Sativex to their formulary listings so that prescribers can prescribe Sativex to their MS patients.

At the same time, GW is focussed upon recruiting the Phase III cancer pain studies, the success of which will determine the timeline for further regulatory approvals and the expansion of the patient population to which Sativex can be marketed.

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 IAS 34 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 30th September 2011 and there has been no change in the interim period.

By Order of the Board

Dr Geoffrey Guy
Chairman

Justin Gover
Managing Director

(1) [http://www.jpain.org/article/S1526-5900\(12\)00019-3/abstract](http://www.jpain.org/article/S1526-5900(12)00019-3/abstract)

GW Pharmaceuticals plc
Condensed consolidated income statement
Six months ended 31 March 2012

	Notes	Six months ended 31 March 2012 (Unaudited) £000's	Six months ended 31 March 2011 (Unaudited) £000's	Year ended 30 September 2011 (Audited) £000's
Revenue	3	11,078	16,576	29,627
Cost of sales		(522)	(570)	(1,347)
Gross profit		10,556	16,006	28,280
Research and development expenditure	4	(12,468)	(11,334)	(22,325)
Management and administrative expenses		(1,790)	(1,371)	(2,892)
Share-based payment		(500)	(378)	(795)
Operating (loss)/profit		(4,202)	2,923	2,268
Interest payable		-	(2)	(3)
Interest receivable		102	147	263
(Loss)/profit on ordinary activities before taxation		(4,100)	3,068	2,528
Tax credit	5	928	221	221
(Loss)/profit on ordinary activities after taxation		(3,172)	3,289	2,749
(Loss)/earnings per share – basic	6	(2.4p)	2.5p	2.1p
(Loss)/earnings per share – diluted	6	(2.4p)	2.4p	2.0p

All activities relate to continuing operations.

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

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Six months ended 31 March 2012
Unaudited

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Retained earnings £000's	Total; £000's
Balance at 1 October 2010	131	65,355	19,262	(72,075)	12,673
Exercise of share options	1	221	-	-	222
Share-based payment	-	-	-	378	378
Retained profit for the period	-	-	-	3,289	3,289
Balance at 31 March 2011	132	65,576	19,262	(68,408)	16,562
Exercise of share options	1	1,212	-	-	1,213
Share-based payment	-	-	-	417	417
Retained loss for the period	-	-	-	(540)	(540)
Balance at 30 September 2011	133	66,788	19,262	(68,531)	17,652
Exercise of share options	-	72	-	-	72
Share-based payment	-	-	-	500	500
Retained loss for the period	-	-	-	(3,172)	(3,172)
Balance at 31 March 2012	133	66,860	19,262	(71,203)	15,052

GW Pharmaceuticals plc
Condensed consolidated balance sheet
As at 31 March 2012

	Notes	31 March 2012 (Unaudited) £000's	31 March 2011 (Unaudited) £000's	30 September 2011 (Audited) £000's
Non-current assets				
Intangible assets – goodwill		5,210	5,210	5,210
Property, plant & equipment		2,227	1,742	1,868
		<u>7,437</u>	<u>6,952</u>	<u>7,078</u>
Current assets				
Inventories	7	1,997	871	1,424
Taxation recoverable		500	-	-
Trade and other receivables	8	1,306	1,177	2,281
Cash and cash equivalents		26,214	28,336	28,319
		<u>30,017</u>	<u>30,384</u>	<u>32,024</u>
Total assets		<u>37,454</u>	<u>37,336</u>	<u>39,102</u>
Current liabilities				
Trade and other payables	9	(6,264)	(5,240)	(6,562)
Obligations under finance leases		-	(27)	(7)
Deferred revenue	10	(5,330)	(4,448)	(3,459)
		<u>(11,594)</u>	<u>(9,715)</u>	<u>(10,028)</u>
Non-current liabilities				
Deferred revenue	10	(10,808)	(11,059)	(11,422)
Total liabilities		<u>(22,402)</u>	<u>(20,774)</u>	<u>(21,450)</u>
Net assets		<u>15,052</u>	<u>16,562</u>	<u>17,652</u>
Equity				
Share capital		133	132	133
Share premium account		66,860	65,576	66,788
Other reserves		19,262	19,262	19,262
Retained earnings		(71,203)	(68,408)	(68,531)
Shareholders' funds		<u>15,052</u>	<u>16,562</u>	<u>17,652</u>

These interim results were approved by the board of Directors on 21 May 2012.

GW Pharmaceuticals plc
Condensed consolidated cash flow statement
For the six months ended 31 March 2012

	Six months ended 31 March 2012 (Unaudited) £000's	Six months ended 31 March 2011 (Unaudited) £000's	Year ended 30 September 2011 (Audited) £000's
Operating (loss)/profit	(4,202)	2,923	2,268
Adjustments for:			
Depreciation of property, plant & equipment	379	275	589
Share-based payment charge	500	378	795
Operating cash flow before movements in working capital	(3,323)	3,576	3,652
(Increase)/decrease in inventories	(573)	(91)	(644)
Decrease(increase) in receivables	922	34	(1,043)
Increase/(decrease) in payables	959	(527)	168
Cash (used)/generated by operations	(2,015)	2,992	2,133
Income tax credits received	428	221	221
Net cash (out)/inflow from operating activities	(1,587)	3,213	2,354
Investing activities			
Interest received	155	154	244
Interest paid	(0)	(2)	(3)
Purchases of property, plant and equipment	(738)	(452)	(891)
Net cash from investing activities	(583)	(300)	(650)
Financing activities			
Proceeds on issue of shares	72	222	1,435
Expenses of share issue	-	-	-
Capital element of finance leases	(7)	(18)	(39)
Net cash from financing activities	65	204	1,396
Net (decrease)/increases in cash and cash equivalents	(2,105)	3,117	3,100
Cash and cash equivalents at beginning of year	28,319	25,219	25,219
Cash and cash equivalents at end of the period	<u>26,214</u>	<u>28,336</u>	<u>28,319</u>

1. General information and basis of preparation

These interim financial statements are condensed financial statements that have been prepared in accordance with IAS 34 – “Interim Financial Reporting” and were approved by the Board on 21 May 2012.

The information for the year ended 30 September 2011 does not constitute statutory accounts as defined in section 434 of the Companies Act 2006. The statutory accounts for the year ended 30 September 2011 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 498(2) or 498(3) of the Companies Act 2006.

At 31 March 2012 the Group had cash resources of £26.2 million. The Group is also generating revenues from Sativex sales, milestone payments and research and development fees receivable from pharmaceutical licensing partners. 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.

The directors are satisfied that the Group has sufficient resources to continue in operation for the foreseeable future, a period of not less than 12 months from the date of this report. Accordingly, they continue to adopt the going concern basis in preparing the financial information for the half year ended 31 March 2012.

Results for the six month periods ended 31 March 2012 and 31 March 2011 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 2011.

3. Operating and Geographical segments

Operating Segments

The Directors consider that GW’s business consists of three operating segments, being:

Sativex – Commercial operations
Sativex – Research and development
Pipeline – Research and Development

The management information used by the GW Board for monitoring performance and allocating resources focuses upon the financial results of these three segments.

The Board continues to make operational decisions and to assess performance against our strategic plan using cash flow and balance sheet information for the Group as a single operating entity. Therefore, no analysis of net assets nor cash flows by segment have been provided.

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.

Profit and Loss
For the Six Months Ended 31 March 2012
Unaudited

	Sativex Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Consolidated £'000
Product sales	1,652	–	–	1,652
Research and development fees	–	6,250	2,529	8,779
Licensing fees:				
– signature and technical access fees	647	–	–	647
– development and approval milestones	–	–	–	–
Total revenue	2,299	6,250	2,529	11,078
Cost of sales	(522)	–	–	(522)
Research and development expenditure	460	(8,546)	(4,382)	(12,468)
Segmental result	2,237	(2,296)	(1,853)	(1,912)
Management and administrative expenses				(1,790)
Share-based payment				(500)
Operating loss				(4,202)
Interest received				102
Loss before tax				(4,100)
Tax credit				928
Loss after tax				(3,172)

Profit and Loss
For the Six Months Ended 31 March 2011

	Sativex [®] Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Consolidated £'000
Product sales	1,878	–	–	1,878
Research and development fees	–	6,349	2,312	8,661
Licensing fees:				
– signature and technical access fees	950	–	–	950
– development and approval milestones	5,087	–	–	5,087
Total revenue	7,915	6,349	2,312	16,576
Cost of sales	(570)	–	–	(570)
Research and development expenditure	90	(7,845)	(3,579)	(11,334)
Segmental result	7,435	(1,496)	(1,267)	4,672
Management and administrative expenses				(1,371)
Share-based payment				(378)
Operating profit				2,923
Interest payable				(2)
Interest received				147
Profit before tax				3,068
Tax credit				221
Profit after tax				3,289

Profit and Loss
For the Year Ended 30 September 2011

	Sativex Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Consolidated £'000
Product sales	4,409	–	–	4,409
Research and development fees	–	10,822	5,216	16,038
Licensing fees:				
– signature and technical access fees	3,843	–	–	3,843
– development and approval milestones	5,337	–	–	5,337
Total revenue	13,589	10,822	5,216	29,627
Cost of sales	(1,347)	–	–	(1,347)
Research and development expenditure	266	(14,757)	(7,834)	(22,325)
Segmental result	12,508	(3,935)	(2,618)	5,955
Management and administrative expenses				(2,892)
Share-based payment				(795)
Operating profit				2,268
Interest payable				(3)
Interest received				263
Profit before tax				2,528
Tax credit				221
Profit after tax				2,749

Revenues from the Group's largest customer are included within the above segments as follows:

	Sativex Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Six months ended 31 March 2012	140	6,194	2,529	8,863
Six months ended 31 March 2011	3,137	6,349	2,312	11,797

Geographical analysis of turnover: - by destination of customer

	Six months ended 31 March 2012 £000's	Six months ended 31 March 2011 £000's	Year ended 30 September 2011 £000s
UK	247	692	1,469
Europe (excluding UK)	1,767	3,482	10,317
North America	6,534	10,087	12,625
Asia	2,530	2,315	5,216
	11,078	16,576	29,627

4. Research and development expenditure

	Six months ended 31 March 2012 £000's	Six months ended 31 March 2011 £000's	Year ended 30 September 2011 £000s
GW-funded research	3,689	2,673	6,286
Development partner-funded research	8,779	8,661	16,039
Total	<u>12,468</u>	<u>11,334</u>	<u>22,325</u>

5. Tax credit

	Six months ended 31 March 2012 £000's	Six months ended 31 March 2011 £000's	Year ended 30 September 2011 £000's
UK Corporation tax – R&D tax credit:			
Prior year	(428)	(221)	(221)
Current period	(500)	-	-
Total credit for the period	<u>(928)</u>	<u>(221)</u>	<u>(221)</u>

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

6. Earnings per share

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

	Six months ended 31 March 2012 £000's	Six months ended 31 March 2011 £000's	Year ended 30 September 2011 £000's
(Loss)/profit for the period – basic	(3,172)	3,289	2,749
(Loss)/profit for the period – fully diluted	<u>(3,169)</u>	<u>3,299</u>	<u>2,779</u>

	Number of shares	Number of shares	Number of shares
Weighted average number of shares – basic	133,071,308	131,410,184	131,945,886
Weighted average number of shares – fully diluted	<u>137,642,467</u>	<u>138,513,495</u>	<u>138,151,872</u>

7. Inventories

	31 March 2012 £000's	31 March 2011 £000's	30 September 2011 £000's
Raw materials	271	154	70
Work in progress	1,541	595	771
Finished goods	185	122	583
	<u>1,997</u>	<u>871</u>	<u>1,424</u>

Inventory is stated net of a realisable value provision of £3.0m (31 March 2011: £3.6m, 30 Sept 2011: £3.4m)

8. Trade and other receivables

	31 March 2012 £000's	31 March 2011 £000's	30 September 2011 £000's
Amounts falling due within one year			
Trade receivables	599	803	1,521
Other receivables	231	142	330
Prepayments and accrued income	476	232	430
	<u>1,306</u>	<u>1,177</u>	<u>2,281</u>

9. Trade and other payables

	31 March 2012 £000's	31 March 2011 £000's	30 September 2011 £000's
Amounts falling due within one year			
Trade payables	2,549	2,137	2,381
Other taxation and social security	543	310	441
Accruals and other payables	3,131	2,748	3,695
Defined contribution pension scheme accruals	41	45	45
	<u>6,264</u>	<u>5,240</u>	<u>6,562</u>

10. Deferred Revenue

	31 March 2012 £000's	31 March 2011 £000's	30 September 2011 £000's
Amounts falling due within one year			
Deferred signature fee income	1,344	1,490	1,294
Advance payments received	3,986	2,958	2,165
	<u>5,330</u>	<u>4,448</u>	<u>3,459</u>
Amounts falling due after one year			
Deferred signature fee income	<u>10,808</u>	<u>11,059</u>	<u>11,422</u>

Deferred signature fee income represents the balance of the non-refundable signature fees received from Almirall, Otsuka and Novartis. 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 was 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.

The Novartis up-front payment of £3.1m consisted of both a signature fee and technical access fees. £1.9m of this was earned and recognised during 2011. The remaining £1.2m has been deferred and will be recognised over the estimated 10 year term of the license, at the rate of £0.2m per year for the period from 1 October 2011 to 31 March 2015 and thereafter at the rate of £0.1m per year until 31 March 2021.

Advance payments received represent payments for research and development activities to be carried out on behalf of Otsuka. These amounts will be recognised as revenue in the next period.

11. Subsequent Events

In April 2012, GW achieved the Phase III cancer pain clinical recruitment target that triggered entitlement to receive a milestone payment of €11.9m from Almirall. This payment was received in May 2012.

12. 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.

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.