

Embargoed until 0700

21 June 2004

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

Interim Results For The Six Months Ended 31 March 2004

GW Pharmaceuticals plc, the company which is developing a range of new medicines based on cannabis and other controlled drugs, announces its interim results for the six months ended 31 March 2004.

HIGHLIGHTS

- UK regulatory approval process for Sativex® ongoing. Further information to be submitted to regulators in July 2004 which is intended to address outstanding questions
- Regulatory dossier for Sativex submitted to the Canadian regulatory authority
- Positive results from Phase III clinical trial in spasticity in Multiple Sclerosis (announced separately today)
- Positive results from Phase III clinical trial in neuropathic pain
- Positive results from Phase II clinical trial in rheumatoid arthritis pain
- Three further Phase III trials due to report by end of 2004
- Development continues on Advanced Dispensing System technology for use with methadone
- Net loss for the six months to 31 March 2004 of £6.9m (2003: £6.7m), in line with budget
- Cash and short term deposits at 31 March 2004 of £24.2m compared to £13.7m at 31 March 2003

Dr Geoffrey Guy, Executive Chairman of GW Pharmaceuticals, said: "We continue to make progress towards achieving UK regulatory approval for Sativex and remain in active dialogue with the regulators. In the next few weeks, we will be submitting further responses which are intended to address the outstanding questions. We remain confident of a positive outcome to this approval process.

Dr Guy added, "With six reported positive Phase III trials, five Phase II trials and 13 Phase I trials, we have no doubt about the strength of GW's cannabinoid research platform. I am confident that our continuing focus on the lead research programmes will ensure that GW remains well placed to deliver excellent value growth in the coming years."

A presentation for analysts is taking place today at 09.30 at Weber Shandwick Square Mile, Fox Court, 14 Gray's Inn Road, London WC1. An audio webcast of the presentation will be available on GW's website at www.gwpharm.com from 15.00 today.

Enquiries:

GW Pharmaceuticals plc

Dr Geoffrey Guy, Executive Chairman
Justin Gover, Managing Director

(21/06/04) + 44 20 7067 0700

(Thereafter) + 44 1980 557000

Weber Shandwick Square Mile

Kevin Smith / Sarah MacLeod

+ 44 20 7067 0700

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

Interim Results For The Six Months Ended 31 March 2004

During the first six months of the year, GW has made progress towards achieving regulatory approval and launch of its lead product, Sativex® in both the UK and Canada. In addition, the Group's research programme continues to yield positive clinical data to support existing target indications as well as to demonstrate the therapeutic potential of cannabis-based medicines across a range of other medical conditions. Expenditure is in line with budget and the Group's cash position remains strong.

Sativex UK Regulatory Status

Sativex is a whole plant medicinal cannabis extract containing tetrahydrocannabinol (THC) and cannabidiol (CBD) as its principal cannabinoid components. The medicine is administered by means of a spray into the mouth. Sativex will, subject to approval, be exclusively marketed by Bayer HealthCare in the UK.

Following UK regulatory submission in March 2003, GW received a list of detailed questions from the Medicines and Healthcare products Regulatory Agency (MHRA). After meetings with the MHRA, responses to all of the questions were submitted. In April 2004, GW was informed that a significant number of the questions had been resolved and that further information and clarification was required to address the remaining outstanding questions. No new questions were presented. GW was invited to seek advice from the MHRA and to submit the additional required information within the current regulatory review cycle.

GW has not altered its expectations that approval of Sativex will be granted. In recent weeks, GW's dialogue with the MHRA has continued and GW will be submitting further information intended to address the outstanding questions in July 2004.

Sativex is a first in class medicine and unique in several respects – being a modern botanical medicine, a new class of drug, cannabis-derived, and of broad therapeutic potential. Consequently, there are a wide range of issues impacting on the regulatory process. The additional information sought by the MHRA applies to sections of the dossier covering the quality, safety and efficacy of the product.

In respect of quality, GW has met with the Chemistry Pharmacy and Standards Sub-Committee of the Committee on Safety of Medicines (CSM). In respect of safety and efficacy, GW has been able to seek clarification from the MHRA in relation to their outstanding questions.

Both the additional information that has been provided to date and that now being prepared for submission comprise pharmaceutical as well as clinical information. GW's further submission will include data from the two Phase III clinical trials which have recently completed. Following submission, the information will be assessed by the MHRA and reviewed by the CSM.

Sequence of Indications in UK

GW's clinical trials programme provides support for the efficacy of Sativex in the areas of Multiple Sclerosis (MS) symptoms and neuropathic pain.

The original regulatory submission included positive data from each of four Phase III clinical trials in patients with MS and neuropathic pain. These four randomised, double-blind, placebo-controlled Phase III trials included approximately 350 patients. These findings were consistent with results from Phase II trials involving over 100 patients.

In the last week, GW has announced positive preliminary results from two further Phase III clinical trials including a total of more than 300 patients, one in MS spasticity (announced separately today) and the other in neuropathic pain.

In the area of MS, GW's trials provide evidence for the effects of Sativex in a range of different symptoms, notably spasticity, pain and sleep disturbance. A further Phase III trial is ongoing into the effects of Sativex on bladder dysfunction in MS. GW and the MHRA have discussed focusing the initial approval on a specific MS symptom and for GW to submit subsequent licence variations to broaden to other symptoms. As one of the most common symptoms of MS, GW intends to focus initially on spasticity utilising the current trials data and then to seek to broaden the licence to other symptoms in the months after first approval.

In recent discussions with the MHRA, it has been noted that the regulatory framework for approval of new medicines in neuropathic pain is under current European regulatory review. It is likely that a distinction may be drawn between central neuropathic pain (associated with conditions such as MS and spinal cord injury) and peripheral neuropathic pain (resulting from, for example, diabetes and post-herpetic neuralgia). Having obtained positive results from a number of different neuropathic pain trials and with a further study ongoing in spinal cord injury, GW is seeking confirmation as to the combination of neuropathic pain models required by the regulators to secure approvals for neuropathic pain, both central and peripheral.

Sativex Dossier Submitted in Canada

In May 2004, GW submitted a New Drug Submission for Sativex to Health Canada, the Canadian regulatory authority. This submission follows several years of dialogue between GW and Canadian officials regarding the introduction of Sativex. Subject to approval, Sativex will be exclusively marketed in Canada by Bayer HealthCare (Pharmaceutical Division).

GW anticipates that Canadians will welcome a non-smoked pharmaceutical product derived from components of the cannabis plant. In recent years, the use and availability of cannabis as a medicine has been a high profile issue in Canada.

GW is seeking approval of Sativex through the regulatory process known as a Notice of Compliance with conditions. Under this Canadian system, Sativex is being assessed for the treatment of both MS pain and neuropathic pain.

Phase III MS Trial

Also announced separately today, GW has reported positive preliminary results in a Phase III clinical trial to assess the effects of Sativex on spasticity in 189 MS patients.

In the trial, a statistically significant improvement in comparison with placebo was seen in spasticity as measured on a numerical rating scale ($p < 0.05$). This was the primary endpoint in the study.

The trial was a multi centre double-blind, randomised, placebo-controlled parallel group study of Sativex in patients with spasticity due to MS. In addition to study medication, all patients remained on their existing medication during the course of the trial.

Spasticity (spasms and stiffness) is one of the most common symptoms of MS occurring in as many as three-quarters of people with MS. Spasticity can affect many aspects of daily life, such as walking and sitting. It can range from mild to severe and change over time, often from day to day, hour to hour.

The effects shown in this trial are over and above those achieved by patients on their existing treatments. In addition to effects on spasticity, GW's previous Phase III trials have shown Sativex to have benefits in pain and sleep disturbance in people with MS.

Phase III Neuropathic Pain Trial

Last week, GW reported positive preliminary results in a Phase III clinical trial in patients with neuropathic pain. The trial was a multi centre double-blind, randomised, placebo-controlled parallel group study in 125 patients of Sativex in the treatment of peripheral neuropathic pain characterised by allodynia. In addition to study medication, all patients remained on their existing medication during the course of the trial.

Allodynia is the occurrence of pain in response to a normally non-painful stimulus (e.g. clothes touching against the skin). It is often intense and can occur in patients suffering from a range of conditions that damage the peripheral nerves (e.g. diabetes, post-herpetic neuralgia) and is a highly reliable marker of neuropathic pain.

In the Phase III trial, a statistically significant improvement in comparison to placebo was achieved in pain as measured on a numerical rating scale ($p < 0.01$), the primary endpoint of the study. In addition, positive results were obtained in the majority of secondary outcome measures including allodynia ($p < 0.05$), pain disability index ($p < 0.01$), quality of sleep ($p < 0.01$), and patients' global impression of change ($p < 0.01$).

This Phase III trial in one of the most difficult types of chronic pain adds further strong support to the body of evidence generated from GW's earlier neuropathic pain trials. The results obtained are over and above the effects of patients' existing drug treatments. GW therefore believes that Sativex may present an important therapeutic advance for patients suffering from this condition.

Phase II Rheumatoid Arthritis Trial

On 9 June 2004, GW announced positive preliminary results in the first ever controlled clinical trial of a cannabis-based medicine in the treatment of arthritis.

The multi centre double blind, randomised, parallel group study in 58 patients assessed the efficacy, safety and tolerability of Sativex compared with placebo for the treatment of pain caused by rheumatoid arthritis. Study medication was administered as an evening dose only and measures were assessed the following day.

In the Phase II trial, statistically significant improvements were seen in a range of outcome measures including morning pain at rest ($p < 0.05$), quality of sleep ($p < 0.05$), disease activity score ($p < 0.01$) and Short Form McGill Pain Questionnaire – pain at present ($p < 0.05$). Analysis of morning pain on movement, the primary endpoint, approached statistical significance in favour of Sativex.

Further research in rheumatoid arthritis will examine the optimal cannabinoid ratios in this indication prior to selecting the product candidate to enter into a pivotal Phase III trials programme.

Ongoing Phase III trials

In total, GW has completed six positive Phase III trials in the areas of MS and neuropathic pain. In addition, GW has a further three Phase III trials in progress. These multi centre double blind, randomised, parallel group trials are examining the effectiveness of Sativex in the following medical conditions:

- Cancer pain;
- Neuropathic pain in spinal cord injury; and
- Bladder dysfunction in MS.

These trials are now heading towards completion and results are expected by the end of 2004.

Safety Profile

In total, over 800 patient-years of safety data have been accumulated to date. GW's trials continue to demonstrate that Sativex is well tolerated. Adverse events are generally mild or moderate in intensity and are usually diminished through reduction of dose.

Since the beginning of GW's trials programme four years ago, patients have been provided with the option to continue on long term treatment. Approximately 75% of patients have chosen to enter into long term studies. Ongoing analysis of these data continue to provide evidence of the safety of Sativex in long term usage as well as indicators that the benefits obtained in the placebo-controlled studies are maintained undiminished over time.

New Therapeutic Areas

The exploratory rheumatoid arthritis trial provides further strong support to our belief that cannabis-based medicines may offer therapeutic potential across a range of medical conditions.

In addition to completed exploratory trials in rheumatoid arthritis and post-operative pain, ongoing Phase II clinical research is focusing on the analgesic and other potential uses of cannabidiol (CBD), a non-psychoactive cannabinoid, as well as diabetic neuropathy and Crohn's disease.

As well as exploratory clinical research, GW's in-house pharmacology team led by Professor Roger Pertwee continues to explore the primary effects of cannabinoids in conjunction with an international network of leading cannabinoid scientists.

Advanced Dispensing System

GW's Advanced Dispensing System (ADS) technology provides the ability to remotely monitor and, if required, control drug usage in real time. The technology also provides a secure and tamper-proof means of dispensing controlled drugs.

GW is actively progressing the development of ADS for secure and accountable methadone delivery in the treatment of drug addiction. Following a small pilot trial last year, a next generation methadone-specific device has been developed for trial with the National Addiction Centre. At the same time, software and electronics development and validation continues.

In the second half of 2004, the methadone device will be trialled and, if successful, this will represent a major step towards first commercialisation. Unlike the development of pharmaceutical products, ADS does not require a clinical programme to achieve regulatory

approval and commercialisation. Accordingly, next steps will focus on assessing the means to gain adoption of ADS in the drug treatment arena.

GW believes that the potential applications of this technology are considerable and will be looking to exploit further opportunities for ADS in the coming few years.

Financial Review

In the six months to 31 March 2004, GW made a net loss after tax of £6.9m compared to £6.7m in the same period last year. Prudent use of resources has ensured that costs have been kept under tight control, whilst investment in core research activities has increased.

Research and development expenditure increased to £7.1m (2003: H1 £6.5m; H2 £6.2m). This expenditure was in line with budget with the increase reflecting the ongoing investment in our second wave of Phase III trials and associated activities.

Management and administrative expenses (including amortisation of goodwill) were maintained at £1.4m (2003: H1 £1.2m; H2 £1.4m). These costs represented 16% of operating expenses in the period compared with 17% in the prior year.

Operating losses of £8.5m were offset by interest income of £0.51m (2003: H1 £0.31m; H2 £0.39m) and an R&D tax credit of £1.07m (2003: H1 £0.60m; H2 £0.95m).

Net cash outflow, before management of liquid resources and financing, was £7.9m compared to £6.6m in the comparable period last year. As at 31 March 2004 GW had cash and short term deposits totalling £24.2m.

Capital expenditure incurred in the period was £0.63m (2003: H1 £0.16m; H2 £0.13m). The increase is partly due to a new Good Manufacturing Practice clinical trials manufacturing suite installed in anticipation of the EU Clinical Trials Directive, which came into force in May of this year.

Headcount as at 31 March 2004 was 143.

In light of the extended regulatory approval timetable, GW has reviewed the speed and scope of its planned R&D growth into new areas. GW's primary focus remains on the lead research programmes and on Sativex in particular. Whilst we remain committed to the ongoing Phase II exploratory trials in new therapeutic areas, the focusing of our efforts has an impact on the rate of expansion into full Phase III programmes for the newer indications and investment into longer term early primary research. As a result of the less aggressive expansion into new areas, we are reorganising some of the research operations. As part of this review, it is likely that there will be some reduction in headcount. The effect of this review should be to reduce expenditure next year by around £3m whilst having no impact on core revenue streams. We believe that the result will be to accelerate timescales to profitability whilst achieving R&D progress, thereby providing an overall enhancement of shareholder value.

Prospects

GW remains confident of a positive outcome in the UK regulatory approval process. Over the last few years, the Group has made rapid progress towards commercialising Sativex and exploring the therapeutic potential of cannabinoids. GW has now completed six Phase III trials, five Phase II trials and 13 Phase I trials and with each new trial, we see further clinical success. Furthermore, this research addresses therapeutic areas where there is a direct need for improved therapy.

We have a solid programme which we are confident will see regulatory approvals, product launches, and commercial partnerships. In addition, we have a unique proprietary technology which provides the Group with a distinct platform for growth.

GW remains the world leader in its field with good prospects to build and enhance on this leadership position. We are confident that the fundamentals for delivering shareholder value remain in place and indeed become stronger.

– Ends –

Enquiries:

GW Pharmaceuticals plc

Dr Geoffrey Guy, Executive Chairman
Justin Gover, Managing Director

(21/06/04) + 44 20 7067 0700
(Thereafter) + 44 1980 557000

Weber Shandwick Square Mile

Kevin Smith / Sarah MacLeod

+ 44 20 7067 0700

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

GW Pharmaceuticals plc
Consolidated profit and loss account
for the six months ended 31 March 2004

	Notes	Six months ended 31 March 2004 Unaudited £000's	Six months ended 31 March 2003 Unaudited £000's	Year ended 30 September 2003 Audited £000's
Turnover		-	-	5,000
Research and development costs		(7,077)	(6,486)	(12,678)
Management and administrative expenses		(1,383)	(1,163)	(2,643)
Operating loss		(8,460)	(7,649)	(10,321)
Interest receivable		508	308	699
Interest payable		(2)	(1)	(6)
Loss on ordinary activities before taxation		(7,954)	(7,342)	(9,628)
Tax credit on loss on ordinary activities	3	1,073	603	1,557
Loss on ordinary activities after taxation being retained loss for the period		<u>(6,881)</u>	<u>(6,739)</u>	<u>(8,071)</u>
Loss per share - basic and diluted	2	(6.2p)	(6.7p)	(7.8p)

All activities relate to continuing operations.

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

GW Pharmaceuticals plc
Consolidated balance sheet
as at 31 March 2004

	Notes	31 March 2004 Unaudited £000's	31 March 2003 Unaudited £000's	30 September 2003 Audited £000's
Fixed assets				
Intangible assets – goodwill		6,101	6,458	6,279
Tangible assets		1,149	941	802
		<u>7,250</u>	<u>7,399</u>	<u>7,081</u>
Current assets				
Debtors: amounts falling due within one year		2,338	1,273	2,147
Debtors: amounts due after more than one year	3	903	603	-
Cash held on deposit as short term investment		22,000	12,019	29,045
Cash at bank and in hand		2,216	1,690	2,999
		<u>27,457</u>	<u>15,585</u>	<u>34,191</u>
Creditors: Amounts falling due within one year		<u>(4,339)</u>	<u>(3,609)</u>	<u>(3,988)</u>
Net current assets		23,118	11,976	30,203
Total assets less current liabilities		30,368	19,375	37,284
Creditors: Amounts falling due after more than one year		-	(13)	(7)
Provisions for liabilities and charges		(195)	(173)	(311)
Net assets		<u>30,173</u>	<u>19,189</u>	<u>36,966</u>
Capital and reserves				
Called-up share capital		111	100	110
Share premium account		47,252	28,066	47,165
Other reserves		19,262	19,262	19,262
Profit and loss account		(36,452)	(28,239)	(29,571)
Equity shareholders' funds		<u>30,173</u>	<u>19,189</u>	<u>36,966</u>

GW Pharmaceuticals plc
Consolidated cash flow statement
for the six months ended 31 March 2004

	Six months ended 31 March 2004 Unaudited £000's	Six months ended 31 March 2003 Unaudited £000's	Year ended 30 September 2003 Audited £000's
Net cash outflow from operating activities	(8,020)	(6,769)	(8,631)
Returns on investment and servicing of finance	567	312	538
Taxation	170	-	941
Capital expenditure	(625)	(159)	(284)
Cash outflow before management of liquid resources and financing	(7,908)	(6,616)	(7,436)
Management of liquid resources	7,045	6,252	(10,774)
Financing	80	125	19,280
(Decrease) / increase in cash during the period	(783)	(239)	1,070

Reconciliation of operating loss to net cash outflow from operating activities

	Six months ended 31 March 2004 Unaudited £000's	Six months ended 31 March 2003 Unaudited £000's	Year ended 30 September 2003 Audited £000's
Operating loss	(8,460)	(7,649)	(10,321)
Depreciation charge	278	220	446
Amortisation of goodwill	178	177	356
Loss on sale of tangible fixed assets	-	1	40
(Increase) / decrease in debtors	(250)	1	(105)
Increase in creditors	234	481	953
Net cash outflow from operating activities	(8,020)	(6,769)	(8,631)

1 Basis of preparation

These accounts are unaudited and do not constitute statutory accounts within the meaning of section 240 of the Companies Act 1985. The interim results have been prepared on the basis of the accounting policies set out in the Report and Accounts for the year ended 30 September 2003. The financial information relating to the year ended 30 September 2003 has been extracted from the full report and accounts which have been delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified.

2 Loss per share

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

	Six months ended 31 March 2004 £000's	Six months ended 31 March 2003 £000's	Year ended 30 September 2003 £000's
Loss for the financial period	<u>(6,881)</u>	<u>(6,739)</u>	<u>(8,071)</u>
	Number of shares	Number of shares	Number of shares
Weighted average number of shares	<u>110,524,770</u>	<u>100,186,427</u>	<u>102,850,219</u>

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

3 Tax credit on loss on ordinary activities

	Six months ended 31 March 2004 £000's	Six months ended 31 March 2003 £000's	Year ended 30 September 2003 £000's
UK Corporation tax – R&D tax credit:			
Current period	903	603	1,557
Prior periods	<u>170</u>	<u>-</u>	<u>-</u>
Total	<u>1,073</u>	<u>603</u>	<u>1,557</u>

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

The £903,000 due under the current period is shown on the balance sheet as a debtor due after more than one year. The current period amounts are subject to the agreement of the Inland Revenue.

4 Analysis of changes in net funds

	As at 30 September 2003 Audited £000's	Cashflow Unaudited £000's	As at 31 March 2004 Unaudited £000's
Cash held on deposit as short term investment	29,045	(7,045)	22,000
Cash at bank and in hand	2,999	(783)	2,216
Debt due within one year	(51)	51	-
Finance leases	(19)	6	(13)
Total	<u>31,974</u>	<u>(7,771)</u>	<u>24,203</u>

5 Movement in Share Capital & Reserves

Group	Called-up share capital No. of shares	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Profit and loss account £000's	Total £000's
At 1 October 2003	110,354,929	110	47,165	19,262	(29,571)	36,966
New share capital issued	321,319	1	87	-	-	88
Retained loss for the period	-	-	-	-	(6,881)	(6,881)
At 31 March 2004	<u>110,676,248</u>	<u>111</u>	<u>47,252</u>	<u>19,262</u>	<u>(36,452)</u>	<u>30,173</u>