

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

**Preliminary Results for the Year Ended 30 September 2003**

GW Pharmaceuticals plc, the company which develops a range of new medicines based on cannabis and other controlled drugs, announces its preliminary results for the year ended 30 September 2003.

**Highlights**

- Regulatory dossier for Sativex® submitted to the UK authorities in March 2003
- Sativex regulatory assessment process well advanced. Completion expected during the second quarter of 2004.
- Production, supply chain and marketing teams prepared for launch of Sativex
- Marketing arrangements signed with Bayer in UK and Canada providing GW with total potential milestone payments in excess of £30m as well as a significant share of long term product sales revenues
- Bayer extend option to licence Sativex in Europe, Australia and New Zealand into 2004
- £19m net raised from share placing in June 2003
- Five Phase III clinical trials recruiting as planned and due to report in 2004
- Net loss of £8.1m (2002: £11.2m) in line with expectations
- Cash and short term deposits of £32.0m at year end (2002: £20.2m)

Dr Geoffrey Guy, Executive Chairman, commented: "Having filed the UK regulatory submission for Sativex in March 2003, the application is now well advanced towards achieving the critical milestone of regulatory approval. The final stages in the regulatory process are underway; the timing of completion of this process is a matter of scheduling within the regulatory agency and is currently expected to occur during the second quarter of 2004.

"GW and Bayer are working very closely together to prepare for the anticipated launch of Sativex and we expect to be able to move swiftly towards market launch following a successful approval. The Bayer agreement, together with a successful institutional share placing undertaken last summer, has significantly enhanced the Group's financial position.

"We anticipate that 2004 will see the regulatory approval and launch of Sativex. Achievement of this milestone would represent a transformation for GW as a pharmaceutical company and provide validation for the future therapeutic and market opportunities in our product pipeline. We have every reason to be extremely excited about the year ahead."

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](http://www.gwpharm.com) from 15.00 today.

Enquiries:

**GW Pharmaceuticals plc**  
Dr Geoffrey Guy, Chairman  
Justin Gover, Managing Director

**(21/01/04) 020 7067 0700**  
(Thereafter) 01980 557000

**Weber Shandwick Square Mile**  
Kevin Smith

**020 7067 0700**

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**Managing Director's Review**

Following the successful Phase III clinical trial results announced at the end of 2002, GW filed for regulatory approval for Sativex in the UK and is preparing for market launch. Sativex will be exclusively marketed in the UK by Bayer following the signing of a marketing agreement during the year between the two companies. This is GW's first commercial partnership, a major landmark for the Group.

**Sativex Regulatory Status**

The UK regulatory submission to the Medicines and Healthcare products Regulatory Agency (MHRA) for Sativex took place at the end of March 2003, as predicted at the time of the Group's Initial Public Offering in 2001.

The evaluation of the Sativex dossier by the MHRA continues to proceed according to the normal regulatory process and is now well advanced. Following submission, this process involved the receipt of detailed questions in the second half of 2003. After meetings with the MHRA, responses to all of the questions were submitted. The next stage in the process, which involves the assessment of GW's responses, is now taking place. The application will then be reviewed by the Committee on Safety Medicines (CSM).

The timing of these final stages of the process is entirely a matter of scheduling within the MHRA. We currently expect the process to complete during the second quarter of 2004.

In the mean time, as preparations for launch continue, the UK Home Office has been putting in place the necessary plans for placing Sativex into an appropriate schedule under controlled drugs regulations in anticipation of MHRA approval. In November 2003, Caroline Flint MP, Home Office Minister stated: "Once marketing approval has been received, we will move without delay to seek Parliament's agreement to any necessary changes to the misuse of drugs legislation. Our aim is to ensure ready and early availability of the drug as a prescribed medicine."

The regulatory dossier provides a comprehensive analysis of data to support the quality, safety and efficacy of Sativex. In effect, the dossier supports the regulatory case for the first modern botanical medicine and, in particular, it reflects the application of GW's unique expertise and range of skills in botanical science. In addition to the more conventional safety and efficacy data requirements, therefore, GW has successfully overcome considerable research challenges in plant genetics, cultivation processes, raw material standardisation, extraction technology, analytical methodology, process validation, stability testing and establishment of appropriate methods and standards for finished product manufacture.

**Bayer**

In May 2003, GW signed an exclusive UK marketing agreement with Bayer for Sativex. This agreement provided GW with a signature fee of £5m and future cash payments of up to £20m. More recently, GW and Bayer have extended their partnership to Canada, providing for further payments to GW of up to £7.75m.

As part of the original agreement, Bayer obtained an option for a limited period of time to widen this partnership for Sativex to other countries in Europe as well as Australia and New Zealand. The companies have recently agreed to extend this option period into 2004.

We believe that the arrangements with Bayer represent a validation of GW's declared strategy of late-stage licensing. In addition to potentially substantial milestone payments, GW has retained a significant share of product sales revenues. We have long believed that maximisation of shareholder returns is best achieved through focusing on revenue sharing arrangements. This can only be achieved to any significant degree when drug development companies shoulder a reasonable proportion of the risk and cost of product development so as to retain a valuable financial interest in product sales.

Bayer and GW have established a strong working relationship. Both companies share great expectations for Sativex. It will be a unique product which represents genuine scientific innovation specifically targeted to address real, important and currently unmet medical needs.

### **Ready for Launch**

GW and Bayer have been working closely together to prepare for what we hope will be one of the most exciting new product launches in recent times. The marketing, production and supply chain teams are prepared to implement the Sativex launch plan as soon as UK regulatory approval is obtained.

GW will not only be the product licence holder for Sativex but will also be responsible for commercial production. Manufacturing scale-up and technology transfer to our various manufacturing sub-contractors was completed last year and we are now operating at full commercial scale and to all appropriate manufacturing standards. Indeed, considerable quantities of stocks of active raw materials are now being produced ahead of anticipated market launch.

### **Clinical Trials Data**

An integral part of our launch plan is the presentation and publication of data from the Phase II and III clinical trials completed to date.

As reported last year, GW's randomised placebo controlled trials have shown consistently positive results in treating the symptoms of multiple sclerosis ("MS"), in particular pain, spasticity and sleep disturbance, as well as neuropathic pain associated with other intractable diseases. Importantly, every patient on each trial remains on their existing medication so that improvements seen reflect benefits over and above those obtained on available prescription medicines.

The trials have also demonstrated that Sativex has an excellent safety profile. Adverse events are generally mild or moderate in intensity and are usually diminished through reduction of dose. In total, over 700 patient-years of safety data have been accumulated to date.

At the end of each trial, patients are provided with the option to continue on long term treatment. Over 75 per cent of patients elect to continue. This programme has provided GW with important information on the long term effects of Sativex treatment. Recent analysis of the data demonstrates that benefits obtained in the placebo-controlled studies are maintained undiminished over time, with the magnitude of the change from baseline being substantial. Importantly, these benefits are maintained without any corresponding increase in dose over time - in other words, there is no evidence of tolerance to the therapeutic effects of Sativex.

Data from GW's trials have been presented at a range of international conferences including the European Congress for Treatment and Research in Multiple Sclerosis (ECTRIMS), UK Pain Society, International Cannabinoid Research Society, American Academy of Pain

Management, International Continence Society and the Royal Society of Medicine. The first publication appeared in 2003 in *Clinical Rehabilitation* and several papers are due for publication in peer reviewed journals in 2004.

### **Ongoing Phase III Trials**

GW's Phase III trials programme consists of a total of nine trials. Positive results from the first four trials have already been announced. Five additional trials are ongoing and are due to report in 2004. These randomised placebo-controlled parallel group studies examine the effects of Sativex in MS spasticity, MS bladder dysfunction, neuropathic pain in spinal cord injury, neuropathic pain (as evidenced by allodynia) and cancer pain.

Throughout its history, GW has pursued a strategy of parallel development to minimise risks and optimise use of development time. Having achieved positive results from the first four trials, the purpose of the ongoing trials is to provide supplementary data to more closely target specific symptoms, broaden the patient pool, expand therapeutic indications, support international regulatory submissions, enhance publications and provide additional marketing support.

### **New Therapeutic Areas**

In addition to Sativex, the Group continues to research cannabis and cannabinoids in a range of new therapeutic markets. A successful regulatory approval for Sativex will provide further validation of the portfolio of follow-on cannabinoid products and indications in GW's pipeline.

Our Cannabinoid Research Institute continues to advance Phase II clinical candidates as well as engaging in primary research with world leading cannabinoid scientists. This year, research has focused on post-operative pain, rheumatoid arthritis and the potential uses of Cannabidiol (CBD), a non-psychoactive cannabinoid.

In the coming year, clinical interests are being expanded into diabetic neuropathy and Crohn's disease. We also intend to evaluate the possibility of studying the effects of cannabinoids on disease modification in MS. As reported above, we have seen evidence of sustained improvements in MS symptoms in our long term clinical studies. This information, together with recent published reports showing interesting disease modification effects of cannabinoids in animal models of MS, provides us with encouragement that this important area warrants further scientific examination.

In addition to clinical research, GW's in-house pharmacology team and external collaborators are focusing on neuroprotection and anti-cancer effects.

### **Advanced Dispensing System**

We continue to make progress with the development of our Advanced Dispensing System (ADS) to dispense methadone safely and reliably for the treatment of drug addiction, although with Sativex taking priority, the ADS programme received reduced financial and resource commitment during the year. The first patient was successfully trialled in the period and a considerable amount of work undertaken in electronics, software and communications development.

We were delighted that the potential of the ADS technology was recognised this year through receipt of the Best Technology award at the AiM 2003 annual awards dinner.

In the current year, ADS represents a high priority for the Group. A next generation dispensing device is in development and validation of software and electronics is well underway. We expect that the current year will see significant progress towards the first commercialisation of ADS.

### **Intellectual Property**

GW continues its focus on building a strong intellectual property portfolio. The Group now has rights to 24 patent families and also has an option to licence other cannabinoid patents from the Hebrew University, Jerusalem. A number of patent applications are timed to grant at around the time of the launch of Sativex. We also continue to extend our plant variety registrations and trademark portfolio.

### **R&D Director**

We are pleased to report the recent appointment of Dr Stephen Wright to our senior management team as R&D Director. Dr Wright has joined GW from Ipsen, where he was Senior Vice President of Clinical Research & Development and a member of the UK Board of Directors. In this role he led teams responsible for regulatory success in both the US and Europe. He was previously at Abbott Laboratories based in the US, firstly as Medical Director of Immunosciences, then Venture Head of Neuroscience. Prior to this, he was Associate Medical Director of Glaxo UK and Director of Immunology, Inflammation and Dermatology Research of Scotia Pharmaceuticals. Dr Wright's early medical career in the NHS culminated in him becoming Consultant Senior Lecturer at The Royal Free Hospital School of Medicine. He has authored more than 100 publications.

### **Outlook**

We fully expect 2004 to be another year of significant achievement for GW. Most importantly, subject to MHRA approval, we will see Sativex launched onto the market. In addition, we expect to complete further Phase III trials and prepare international regulatory submissions. At the same time, we will look to broaden our commercial arrangements in preparation for international product launches. We also expect to advance the next wave of cannabinoid product opportunities through clinical trials and to make significant steps towards the first commercialisation of our ADS technology.

Justin Gover  
Managing Director

## Financial Review

This year has seen GW commence the transition from a cash consuming research and development company to one which generates revenues from commercial relationships. GW finished the year with greatly improved balance sheet strength that will underpin our commercial position going forward.

### Results of Operations

The Group loss for the year ended 30 September 2003 was £8.1m (2002: £11.2m). The reduced loss reflects the £5.0m received as a signature fee from Bayer.

Research and development expenditure, which is expensed as incurred, increased to £12.7m (2002: £10.7m). Management and administrative expenses increased to £2.6m (2002: £2.3m) as a result of the increasing size of the Group's activities. Management and administrative expenses (including amortisation of goodwill) account for 17% (2002: 17%) of total expenditure with research and development expenditure accounting for the remaining 83% (2002: 83%).

The average headcount of the Group for the year was 118 (2002:102) and we ended the year with 127 employees (2002: 110). Capital expenditure was £0.3m (2002: £0.7m). This modest expenditure reflects the fact that GW's manufacturing sub-contractors incur the principal capital expenditure costs associated with launch production. The Group benefited from net interest income of £0.7m (2002: £0.8m).

### Bayer Agreement

The Bayer agreement enables GW to maintain a significant share of long-term product revenues whilst also benefiting from upfront payments. In addition to the £5m fee already received, the UK agreement provides for a further £20m of future milestone payments, a significant proportion of which falls due on the initial regulatory approval of Sativex.

Of the £20m future milestones, £10m can be drawn down by GW in advance as an interest-free working capital loan facility. To date, GW has elected not to utilise this resource. On approval of Sativex, irrespective of whether GW has elected to draw down this facility, Bayer has the option to convert £10m of the future £20m milestone payments into GW shares at an agreed premium to the share price at the time of conversion.

The extension of the Bayer arrangements to Canada, which was signed after the financial year-end, provides for an additional £7.75m of future milestones as well as a significant share of product revenues.

### Share Issue

On 27 June 2003 9,904,395 new ordinary shares were placed with institutional investors at £2.00 per share. The placing was significantly oversubscribed and raised approximately £19.0m after expenses. The placing proceeds will enable the Group to accelerate the development of additional income streams arising from its core skills in cannabis medicines, phyto-medicines and secure dispensing technology. The placing also widened GW's institutional shareholder base, providing a shareholder structure more appropriate for the next phase of the Group's growth.

**Research and Development Tax Credit**

The Group has claimed a research and development tax credit of £1.56m (2002: £0.94m) which is shown as a credit to the profit and loss account. This sum is subject to agreement with the Inland Revenue.

**Liquidity and Cash Resources**

The Group's net funds comprise cash balances together with amounts held on short term deposit. Cash and short term deposits at 30 September 2003 totalled £32.0m (2002: £20.2m). The net cash outflow during the year (before financing and management of liquid resources) was £7.4m (2002: £9.9m).

David Kirk  
Finance Director

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Enquiries:

**GW Pharmaceuticals plc**  
Dr Geoffrey Guy, Chairman  
Justin Gover, Managing Director

**(21/01/04) 020 7067 0700**  
(Thereafter) 01980 557000

**Weber Shandwick Square Mile**  
Kevin Smith

**020 7067 0700**

## GW Pharmaceuticals plc

### Preliminary Results for the Year Ended 30 September 2003

#### Consolidated Profit and Loss Account

	Notes	2003 £000's	2002 £000's
<b>Turnover</b>		5,000	-
Research and development costs		(12,678)	(10,748)
Management and administrative expenses		(2,643)	(2,251)
<b>Operating loss</b>		(10,321)	(12,999)
Interest receivable		699	831
Interest payable		(6)	(1)
<b>Loss on ordinary activities before taxation</b>		(9,628)	(12,169)
Tax credit on loss on ordinary activities	2	1,557	942
<b>Loss on ordinary activities after taxation being retained loss for the financial year</b>		<u>(8,071)</u>	<u>(11,227)</u>
<b>Loss per share - basic and diluted</b>	3	(7.8p)	(11.6p)

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**

**Preliminary Results for the Year Ended 30 September 2003**

**Consolidated Balance Sheet**

	Notes	At 30 Sept 2003 £000's	At 30 Sept 2002 £000's
<b>Fixed assets</b>			
Intangible assets – goodwill		6,279	6,635
Tangible assets		802	1,002
		7,081	7,637
<b>Current assets</b>			
Debtors		2,147	1,274
Cash held on deposit as short term investment		29,045	18,271
Cash at bank and in hand		2,999	1,929
		34,191	21,474
<b>Creditors:</b> Amounts falling due within one year		(3,988)	(3,258)
<b>Net current assets</b>		30,203	18,216
<b>Total assets less current liabilities</b>		37,284	25,853
<b>Creditors:</b> Amounts falling due after more than one year		(7)	(18)
Provisions for liabilities and charges		(311)	(38)
<b>Net assets</b>		36,966	25,797
<b>Capital and reserves</b>			
Called-up share capital		110	100
Share premium account	4	47,165	27,935
Other reserves	4	19,262	19,262
Profit and loss account	4	(29,571)	(21,500)
<b>Equity shareholders' funds</b>	5	36,966	25,797

## GW Pharmaceuticals plc

### Preliminary Results for the Year Ended 30 September 2003

#### Consolidated Cash Flow Statement

	Notes	2003 £000's	2002 £000's
<b>Net cash outflow from operating activities</b>	6	(8,631)	(10,425)
Returns on investments and servicing of finance		538	857
Taxation		941	347
Capital expenditure		(284)	(667)
<b>Cash outflow before management of liquid resources and financing</b>		(7,436)	(9,888)
Management of liquid resources		(10,774)	5,729
Financing		19,280	4,438
<b>Increase in cash during the year</b>		<u>1,070</u>	<u>279</u>

#### Notes:

##### 1 Basis of presentation

The preliminary statement covers the year ended 30 September 2003. It has been prepared using the same accounting policies as those adopted in preparing the statutory accounts for the year ended 30 September 2003.

The Board of Directors of the Company approved the statement on 20 January 2004.

The 2003 and 2002 accounts received unqualified reports from the Auditors and did not contain any statements under S237(2) or (3) of the Companies Act 1985. The 2003 accounts will be filed with the Registrar of Companies following the Annual General Meeting. The 2002 accounts have been filed. The statutory accounts will be issued to shareholders shortly, together with the notice for the Annual General Meeting to be held on 2 March 2004 at 11am at Porton Down Science Park, Salisbury, Wiltshire.

The following information does not constitute the Company's statutory accounts under section 240 of the Companies Act 1985 for the year ended 30 September 2003 but is derived from those accounts.

##### 2 Tax credit on loss on ordinary activities

The tax credit of £1,557,000 (2002: £942,000) has arisen as a result of the research and development expenditure claimed under the Finance Act 2000.

At 30 September 2003 the Group had trading losses of approximately £22.0m (2002: £18.7m) available to carry forward against future tax liabilities.

The tax credit and trading losses to be carried forward for the year are subject to the agreement of the Inland Revenue.

### 3 Loss per share

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

	Basic		Diluted	
	2003 £000's	2002 £000's	2003 £000's	2002 £000's
Loss for the financial year	<u>(8,071)</u>	<u>(11,227)</u>	<u>(8,071)</u>	<u>(11,227)</u>
			2003 Number of shares	2002 Number of shares
Weighted average number of shares:			<u>102,850,219</u>	<u>96,386,304</u>

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

### 4 Reserves

	Share premium account £000's	Other reserves £000's	Profit and loss account £000's	Total £000's
At 1 October 2002	27,935	19,262	(21,500)	25,697
Equity share issue	20,041	-	-	20,041
Expense of equity share issue	(811)	-	-	(811)
Retained loss for the year	-	-	(8,071)	(8,071)
At 30 September 2003	<u>47,165</u>	<u>19,262</u>	<u>(29,571)</u>	<u>36,856</u>

### 5 Reconciliation of movements in Group shareholders' funds

	2003 £000's	2002 £000's
Loss for the financial year	(8,071)	(11,227)
New ordinary shares issued net of expenses	<u>19,240</u>	<u>4,448</u>
Net addition / (reduction) to shareholders' funds	11,169	(6,779)
Opening shareholders' funds	<u>25,797</u>	<u>32,576</u>
Closing shareholders' funds	<u>36,966</u>	<u>25,797</u>

**6 Reconciliation of operating loss to net cash outflow from operating activities**

	2003	2002
	£000's	£000's
Operating loss	(10,321)	(12,999)
Depreciation charge	446	405
Amortisation of goodwill	356	357
Loss on disposal of fixed assets	40	36
(Increase) / decrease in debtors	(105)	271
Increase in creditors	953	1,505
Net cash outflow from operating activities	<u>(8,631)</u>	<u>(10,425)</u>