

Embargoed until 0700

16 January 2002

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

Preliminary Results for the Year Ended 30 September 2001

GW Pharmaceuticals plc, the pharmaceutical company developing a portfolio of non-smoked cannabis-based prescription medicines, announces its first set of preliminary results since flotation on the Alternative Investment Market of the London Stock Exchange in June 2001.

Highlights

- New positive data from Phase II clinical trials in Multiple Sclerosis ("MS") and Spinal Cord Injury shows significant improvements in a range of symptoms
- Phase III trial in MS commenced in May 2001 and recruitment proceeding well
- Start of Phase III trial in Cancer Pain (also announced separately today)
- First international clinical trial underway in Canada
- Significant expansion of operations heralds transformation into an integrated R&D company
- Total investment raised during year of £30.5m, including £23.5m from flotation on AIM in June 2001
- Cash balances of £25.7m at 30 September 2001
- Confirmation of positive stance on cannabis-based medicines from UK Home Secretary

Dr Geoffrey Guy, Executive Chairman, commented: "The progress of our research programme, and in particular the clinical trials activity, remains on track. The Phase II trials have clearly shown that patients are receiving benefit from our medicines and we have now moved into Phase III trials, the last and most critical stage of development. GW occupies a lead position worldwide and we are uniquely placed to become the first company in the world to achieve regulatory approval for prescription cannabis-based medicines. We remain confident of being able to present data to the UK regulatory authorities in 2003, and - subject to approval - bring the first cannabis-based prescription medicine to market in early 2004."

A presentation for analysts is taking place today at 09.30 at Weber Shandwick Square Mile, Aldermary House, 15 Queen Street, London EC4. An audio webcast of the presentation will be available on GW's website at www.gwpharm.com from 3:00pm today.

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Preliminary Results for the Year Ended 30 September 2001

Managing Director's Review

This year has been one of considerable progress for the Group. GW has transformed from a young research entity into an integrated pharmaceutical research and development Group. Notably, our research activities entered the final pivotal regulatory stage with the commencement of the first Phase III clinical trial in Multiple Sclerosis. As a consequence of our ongoing progress, we remain on track to deliver our first products to market in 2004.

GW has a broad product portfolio under development with a range of cannabinoids, drug delivery technologies and target medical conditions providing significant commercial opportunities. The products are derived from standardised whole extracts of proprietary cannabis plant varieties bred to exhibit a pre-determined content of cannabinoids. The focus of GW's research to date has been on two cannabinoids – Tetrahydrocannabinol (THC) and Cannabidiol (CBD). A number of products incorporating extracts from THC plants, CBD plants and blended ratios of THC and CBD extracts, are in late stage development and are targeted at conditions for which cannabis is commonly understood to be beneficial and for which there is a strong scientific foundation for the application of cannabinoids.

Phase III Trials

GW has implemented a programme of Phase III clinical trials designed to provide the most rapid advancement towards product approval whilst at the same time minimising risk of failure. In May 2001, we commenced the first Phase III trial in Multiple Sclerosis. Recruitment for this trial is well underway and the trial is forecast to complete towards the end of 2002. In addition, a series of further Phase III trials focusing on key symptoms of Multiple Sclerosis are due to take place in 2002.

As announced separately today the Group has commenced a Phase III trial in Cancer Pain. We have also recently commenced a smaller Phase III trial in Brachial Plexus Injury, a severe form of nerve damage pain. Further Phase III trials are due to commence over the coming months. Our strategy is to form a programme of multiple Phase III studies to provide for a sound basis for regulatory submissions in a range of target medical conditions. The range and scope of the trials programme now being put in place gives us comfort that we will be able to replicate the positive findings from our earlier trials in the larger pivotal trials programme.

Phase II Trials

Much of the focus of clinical trials activity in the last year has been GW's Phase II trials, which have involved 104 patients to date. Overall, the trials now represent over 80 patient-years of experience with GW's medicines. The majority of patients in these trials suffer from Multiple Sclerosis or Spinal Cord Injury. The trials have also included patients suffering from Rheumatoid Arthritis, neuropathic pain and other intractable neurological conditions. These trials are the most comprehensive evaluation of cannabis-based medicines ever undertaken in such types of patients.

New positive data from the Phase II trials shows significant improvements in a range of symptoms even in small numbers of patients. In addition, there are definite trends indicating the superiority of active treatment over placebo in several other key outcomes. Clinically significant improvements have been seen in a number of symptoms, including pain, muscle spasm, spasticity, sleep duration and quality, bladder-related symptoms, tremor and overall improvements in quality of life. In some cases the improvement has been sufficient to transform lives. Given the previously intractable nature of these patients' symptoms, these improvements are all the more remarkable.

104 patients have entered the Phase II studies, of which 14 are still in the acute phase. Of the remaining 90 patients, 81 completed the acute phase of the study, of which 74 sustained a sufficiently beneficial response for them to opt to continue on active treatment long term.

Dr Willy Notcutt, James Paget Hospital, Great Yarmouth, has examined patients with MS and Spinal Cord Injury using a 'within patient randomised double-blind crossover' trial design. Dr Notcutt has reported that 80 per cent of patients in the trial found that GW's cannabis-based medicine reduced pain and improved their quality of life. In the first 19 patients, statistically significant lower overall symptom scores were observed with both the THC:CBD product ($p < 0.0001$) and THC product ($p = 0.004$) compared to placebo. Preliminary data on the 16 patients with pain as a key symptom demonstrated a statistically significant reduction in pain scores using the THC:CBD product ($p = 0.01$).

Positive preliminary data from two independent Phase II trials has recently been presented by researchers at scientific symposia:

- Phase II trial to assess the effectiveness of cannabis-based medicine in treating bladder dysfunction in patients with advanced MS

This open-label study was carried out in 19 patients with advanced MS (Kurtzke ≥ 6.5) by researchers under the direction of Dr Clare Fowler, National Hospital for Neurology and Neurosurgery, London. Patients demonstrated improvements using both THC:CBD and THC products. Preliminary data on the first 11 patients shows statistically significant reductions using the THC product in the following key measures: incontinence ($p < 0.001$), nocturia ($p < 0.018$), and daytime frequency ($p < 0.003$). There were also statistically significant reductions using the THC:CBD product in incontinence ($p < 0.027$) and daytime frequency ($p < 0.033$). The THC:CBD product also yielded significant increases in bladder capacity ($p < 0.016$). The authors conclude that these preliminary results "suggest that patient-controlled dosing of sublingual cannabis-based medicinal extracts may prove to be an effective additional treatment for ameliorating refractory urinary symptoms in a select group of patients with advanced MS". Final data on all patients is now being prepared for peer review publication.

- Phase II trial on patients with post-operative pain

This open-label trial was carried out in 12 patients to assess analgesia following total abdominal hysterectomy by researchers under the direction of Professor David Rowbotham, Department of Analgesia, Intensive Care & Pain Management, University Hospitals of Leicester, Leicester General Hospital. There was a clear dose response relationship with all patients reporting pain relief. The authors reported that this reduction in pain was statistically significant ($p < 0.05$) and concluded that "sublingual cannabis-based medicine extract, at the doses studied, provided analgesia in this model of acute nociceptive pain without causing significant adverse events".

Excellent Safety Profile

Data from the Phase II trials also confirms that GW's medicines have an excellent safety profile. Adverse events have been predictable and generally well tolerated. By careful self-titration (dose adjustment), most patients are able to separate the thresholds for symptom relief and intoxication. Analysis of dosage levels over extended periods shows no evidence of tolerance, thereby avoiding the requirement for patients to progressively increase their dose.

As stated above, GW has accumulated over 80 patient-years of safety data for its medicines. On the basis of data submitted, the Medicines Control Agency ("MCA") has now approved the extended use of GW's medicines (both THC and CBD containing materials) in patients for up to 24 months.

Phase I Trials

GW has completed 6 Phase I clinical trials that have assessed 14 different dosage forms and involved 48 healthy subjects. These trials were used to establish safe dosage regimen, tolerability and clinical pharmacology. All trials have to date successfully met their objectives.

Regulatory Progress

Throughout the course of GW's development programme, the company has maintained a close dialogue with the MCA. GW and its investigators now have regulatory approvals to include patients in trials to examine the following indications: relief of pain of neurological origin and defects of neurological function in multiple sclerosis, spinal cord injury, peripheral nerve injury, central nervous system damage, neuroinvasive cancer, dystonias, cerebral vascular accident and spina bifida. In addition, GW has approval to examine relief of pain and inflammation in rheumatoid arthritis as well as relief of pain in brachial plexus injury.

Whilst the UK remains the focus for GW's research programme at the present time, discussions have been held with several European regulators in the course of the last year and the company has designed its programme to cater for regulatory bodies in Europe and elsewhere around the world. In North America, Canada represents significant near term opportunities for GW whilst timescales in the United States are longer term.

Canadian Trials

During the year, GW's first clinical trial outside the UK commenced in Canada. This followed receipt of permission to commence Phase II trials from Health Canada, the Canadian regulatory authority, known as an Investigational New Drug (IND) authorisation. In this first instance, this IND relates to a specific clinical trial in patients with chronic pain, multiple sclerosis and spinal cord injury. Health Canada is the first overseas regulatory authority to evaluate GW's data and this represents a major breakthrough in terms of the international potential for GW's product portfolio.

United States

In the US, GW has held meetings with the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), the Office for National Drug Control Policy (ONDCP), National Institute for Drug Abuse (NIDA) and senior State officials in California and Maine. Although the licensing process in the US is often protracted, GW received its first import licences from the DEA and subsequently successfully imported its first cannabis extracts into the US. Pre-clinical research using these extracts is ongoing. GW's competitive position in the US remains strong.

Advanced Dispensing Systems

GW has developed advanced dispensing systems which can be applied to all its medicines and to all its drug delivery systems. In particular, the system incorporates anti-diversionary technology so as to prevent any potential abuse of cannabis-based medicines. In addition, this technology allows for the recording and remote monitoring of patient usage.

Now at late stages of implementation, we recognise the wider potential of the technology for a range of controlled and other drugs and are examining ways to ensure optimum exploitation of these technologies on behalf of shareholders.

Premises

GW currently has offices in Wiltshire and Cambridgeshire as well as dedicated hospital units in Oxford and Guernsey. The location of the Group's botanical research and cultivation operations, analytical and formulation laboratories, and production facilities cannot be disclosed for security reasons.

During the year, the Group moved into new analytical and formulation laboratories. We have extended the long-term lease on our current glasshouse and also moved into a small botanical research glasshouse adjacent to the larger facility. We have also established in-house Good Manufacturing Practice pilot production facilities and moved the clinical department to larger premises. GW has also commissioned an additional indoor growing unit on land adjacent to the

current glasshouse. On completion of this facility, which is on target for March 2002, the company will be able to produce plant material at the rate of over 30 tonnes per year.

Personnel

We were pleased to announce the appointment of David Kirk as Finance Director in September 2001. With 20 years at Arthur Andersen and the last five years spent as a director of CeNeS and other companies in the biotechnology field, David brings with him a wealth of valuable experience.

This year has seen the appointment of directors of the key operating divisions of the Group. These divisions encompass all of GW's principal development activities and are entitled: Botanical Research and Cultivation, Extraction and Production, Pharmaceutical R&D, and Special Technologies.

The Group had 85 employees at the financial year-end. Staff numbers have risen steadily during the course of the year and reflect the considerable growth in the scale of the Group's activities during this time. The Group has reached broadly appropriate staff levels for the current scope of operations and headcount growth has accordingly now slowed.

Intellectual Property Rights

An integral part of GW's research is to establish proprietary intellectual property rights to protect techniques and technologies involved in the development programme. Examples of the areas in which we have and will continue to seek protection are plant registration rights, methods of extraction patents, drug delivery device patents, patents on compositions of matter for the delivery of cannabis, methods of use patents, design copyright on devices and trademarks.

Our aim is to develop a matrix of interlocking intellectual property rights which is difficult for competitors to penetrate and a varied patent portfolio is a key part of achieving this. During the year, we have made much progress on this front. The Group is the proprietor of nine UK patent applications, three international applications and two US applications. In addition, one US patent, to which the Group is the exclusive licensee, was granted during the year. The Group is also pursuing protection for a number of its plants via the Plant Varieties Act.

Public Affairs

Since GW's inception, our research activities have been conducted under the spotlight of the world's media. This year was no exception with extensive interest in the progress of patients participating in GW's clinical trials. In February, the House of Lords Science & Technology Select Committee met to evaluate the progress in the area of medicinal cannabis research since its original report in 1998. At this meeting and at several points during the year, the UK Government confirmed in the clearest terms its policy to allow the prescription of cannabis-based medicines following approval by the MCA.

In October 2001, the Home Secretary, the Rt Hon David Blunkett, MP, confirmed his support for prescription cannabis-based medicines, stating: "Should, as I believe it will, this programme [of trials] be proved to be successful, I will recommend to the Medicines Control Agency they should go ahead with authorising the medical use".

In November 2001, the progress of patients in GW's clinical trials was the subject of the BBC's Panorama programme. This television programme was broadcast in the UK, Japan and on global news channels.

The company maintains a close co-operation with the Home Office concerning all aspects of its research activities. Elsewhere in Europe, GW has developed a dialogue with government representatives from several European countries. These meetings were requested by each country's respective government officials with the aim of understanding GW's programme and exploring means by which GW could extend its research to their countries.

Outlook

GW occupies a lead position worldwide in cannabinoid therapeutics and we are uniquely placed to become the first company in the world to achieve regulatory approval for prescription cannabis-based medicines. We remain on target to submit our first regulatory application in 2003 with a view to the first cannabis-based medicine being launched in 2004. Our research programme continues at maximum pace, the operations of the company are sound, the competitive position is strong and the team highly motivated to deliver. We are well aware that the company's programme is being monitored closely worldwide by governments, media, medical practitioners, patients and the general public. This company's history has been an extraordinary one to date and we look forward with excitement to the next twelve months.

Justin Gover

Managing Director

Financial Review

Fundraising and Initial Public Offering

On 28 June 2001, the Company's shares were admitted to the Alternative Investment Market of the London Stock Exchange (AiM) following the placing of 13,736,264 new ordinary shares with institutions at £1.82 per share. After expenses this Initial Public Offering raised approximately £23.5m. The total amount raised during the last financial year was £30.5m net (£32.0m gross) from both the IPO and pre-IPO fundraising.

Results of Operations

The Group loss for the year ended 30 September 2001 increased to £6.9m (2000: £2.2m), reflecting planned increases in research and development and administrative expenditure as described below.

Research and development expenditure increased to £6.6m (2000: £2.0m) as the Group continues to invest in its therapeutic opportunities and advance its product pipeline. It is likely that research and development expenditure will increase further in 2002.

Management and administrative expenses increased to £1.1m (2000: £0.4m) as a result of the increasing size and sophistication of the Group's activities. Management and administrative expenses (including amortisation of goodwill) account for 14per cent (2000: 16per cent) of total expenditure with research and development expenditure accounting for the remaining 86per cent (2000: 84per cent).

The Group received grant income of £0.1m (2000: £0.06m) from a SMART award for a novel inhalation device currently under development.

The Group benefited from net interest income of £0.5m (2000: £0.07m) as a result of increased cash balances following its fundraising activities during the year.

Capital expenditure increased to £0.9m (2000: £0.1m) as the Group continued to enlarge its research and development capability, improve information technology systems, and expand its extraction and production operations.

The goodwill relates to the acquisition of G-Pharm Limited during the year.

Research and Development Tax Credit

As a result of legislation allowing small and medium sized companies to claim research and development tax credits on qualifying expenditure, the Group has claimed £0.35m (2000: £0.09m) which is shown as a credit to the profit and loss account. This 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 2001 totalled £25.7m (2000: £1.7m). The net cash outflow during the year (before financing and management of liquid resources) was £6.6m (2000: £2.3m).

We expect that operating cash outflow will increase in 2002, principally as a result of increased research and development expenditure.

David Kirk
Finance Director

- Ends -

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GW Pharmaceuticals plc

Preliminary Results for the Year Ended 30 September 2001

Consolidated Profit and Loss Account

	Notes	2001 £000's	2000 £000's
Turnover		-	-
Research and development costs		(6,642)	(2,007)
Management and administrative expenses		(1,083)	(379)
Operating loss		<u>(7,725)</u>	<u>(2,386)</u>
Continuing operations		(7,576)	(2,386)
Acquisitions		(149)	-
		<u>(7,725)</u>	<u>(2,386)</u>
Interest receivable		514	70
Interest payable		(1)	(2)
Loss on ordinary activities before taxation		<u>(7,212)</u>	<u>(2,318)</u>
Tax credit on loss on ordinary activities	2	347	92
Loss on ordinary activities after taxation being retained loss for the financial year		<u>(6,865)</u>	<u>(2,226)</u>
Loss per share - basic and diluted	3	(9.0p)	(4.2p)

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 2001

Consolidated Balance Sheet

	Notes	At 30 Sept 2001 £000's	At 30 Sept 2000 £000's
Fixed assets			
Intangible assets - goodwill		6,992	-
Tangible assets		740	108
		7,732	108
Current assets			
Debtors		976	187
Cash at bank and in hand		25,650	1,729
		26,626	1,916
Creditors: Amounts falling due within one year		(1,762)	(265)
		24,864	1,651
Net current assets		24,864	1,651
Total assets less current liabilities		32,596	1,759
Creditors: Amounts falling due after more than one year		-	(4)
Provisions for liabilities and charges		(20)	-
		32,576	1,755
Net assets		32,576	1,755
Capital and reserves			
Called-up share capital		96	2
Share premium account	4	23,491	-
Other reserves	4	19,262	5,161
Profit and loss account	4	(10,273)	(3,408)
		32,576	1,755
Equity shareholders' funds	5	32,576	1,755

GW Pharmaceuticals plc

Preliminary Results for the Year Ended 30 September 2001

Consolidated Cash Flow Statement

	Notes	2001 £000's	2000 £000's
Net cash outflow from operating activities	6	(6,317)	(2,275)
Returns on investments and servicing of finance		470	68
Taxation		93	(4)
Capital expenditure		(876)	(114)
Acquisitions and disposals		30	-
Cash outflow before management of liquid resources and financing		<u>(6,600)</u>	<u>(2,325)</u>
Management of liquid resources		(22,700)	(900)
Financing		30,521	3,464
Increase in cash during the year		<u>1,221</u>	<u>239</u>

Notes:

1 Basis of presentation

The preliminary statement covers the year ended 30 September 2001. It has been prepared using the same accounting policies as those adopted in preparing the statutory accounts for the year ended 30 September 2000.

The Board of Directors of the Company approved the statement on 15 January 2002.

The 2001 and 2000 accounts received unqualified reports from the Auditors and did not contain any statements under S237(2) or (3) of the Companies Act 1985. The 2001 accounts will be filed with the Registrar of Companies following the Annual General Meeting. The 2000 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 13 March 2002 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 2001 but is derived from those accounts.

2 Tax credit on loss on ordinary activities

The tax credit of £347,000 (2000: £92,000) has arisen as a result of the research and development expenditure claimed under the Finance Act 2000.

At 30 September 2001 the Group had trading losses of approximately £9,500,000 (2000: £2,900,000) 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	
	2001 £000's	2000 £000's	2001 £000's	2000 £000's
Loss for the financial year	6,865	2,226	6,865	2,226
			2001	2000
			Number of shares	Number of shares
Weighted average number of shares:			75,949,639	53,019,905

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

4 Reserves

Group	Share premium account £000's	Other reserves £000's	Profit and loss account £000's	Total £000's
At 1 October 2000	-	5,161	(3,408)	1,753
Premium on shares issued by subsidiary	-	14,168	-	14,168
Bonus issue by subsidiary	-	(67)	-	(67)
Equity share issue	24,986	-	-	24,986
Expense of equity share issue	(1,495)	-	-	(1,495)
Retained loss for the year	-	-	(6,865)	(6,865)
At 30 September 2001	<u>23,491</u>	<u>19,262</u>	<u>(10,273)</u>	<u>32,480</u>

5 Reconciliation of movements in Group shareholders' funds

	2001 £000's	2000 £000's
Loss for the financial year	(6,865)	(2,226)
New ordinary shares issued net of expenses	<u>37,686</u>	<u>3,468</u>
Net addition to shareholders' funds	30,821	1,242
Opening shareholders' funds	<u>1,755</u>	<u>513</u>
Closing shareholders' funds	<u>32,576</u>	<u>1,755</u>

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

	2001 £000's	2000 £000's
Operating loss	(7,725)	(2,386)
Depreciation charge	259	39
Amortisation of goodwill	140	-
(Increase) / decrease in debtors	(483)	32
Increase in creditors	<u>1,492</u>	<u>40</u>
Net cash outflow from operating activities	<u>(6,317)</u>	<u>(2,275)</u>