

Preliminary Results: Year Ended 30 September 2008



GW Pharmaceuticals plc

18 November 2008



Notice

Past performance should not be seen as an indication of future performance. Actual results and developments may differ materially from those expressed or implied by this briefing depending on a variety of factors. The contents of this briefing are intended only for persons having professional experience in matters relating to investments. Persons who do not have professional experience in matters relating to investments should not rely on the contents of this briefing.

Agenda

- Highlights Justin Gover, Managing Director
- R&D Review Dr Stephen Wright, R&D Director
- Financial Results David Kirk, Finance Director
- Outlook Justin Gover, Managing Director

Highlights

- **Operations**

- Recruitment completed in Sativex Phase III MS spasticity trial. Results due late Q1 09, to be followed by regulatory submission in Q2 09
- Sativex Phase IIb/III cancer pain trial ongoing and due to complete in H2 09
- Positive results in Sativex MS pain randomised withdrawal trial
- Sativex prescription use continues to rise – product exported to 21 countries
- Otsuka cannabinoid research collaboration yields promising new psychiatric and oncology drug candidates
- Phase II trial in planning on novel cannabinoid medicine for treatment of dyslipidaemia in Type II diabetes patients

- **Financial**

- Turnover more than doubled to £11.8m (2007: £5.7m)
- Net loss for the year reduced 22% to £8.2m (2007: £10.6m)
- Cash and short term deposits at 30 September 2008 of £14.1m

Sativex Development Status

- >3,000 patients completed clinical trials
- ~50% of otherwise intractable patients show significant benefit
- Approved in Canada, named patient prescription use in UK and elsewhere
- Three major licence agreements signed with compelling commercial terms
- Data published in peer review journals and presented at international conferences

		INDICATIONS	REGIONS	PHASE I	PHASE II	PHASE III	SUBMIT	APPROVAL
SATIVEX	SPASTICITY IN MS		EU					
			Canada					
			USA					
			REST OF WORLD					
SATIVEX	CANCER PAIN		EU					
			Canada					
			USA					
			REST OF WORLD					
SATIVEX	NEUROPATHIC PAIN IN MS		EU					
			Canada					
			USA					
			REST OF WORLD					
SATIVEX	NEUROPATHIC PAIN		EU					
			Canada					
			USA					
			REST OF WORLD					

Sativex Named Patient Use

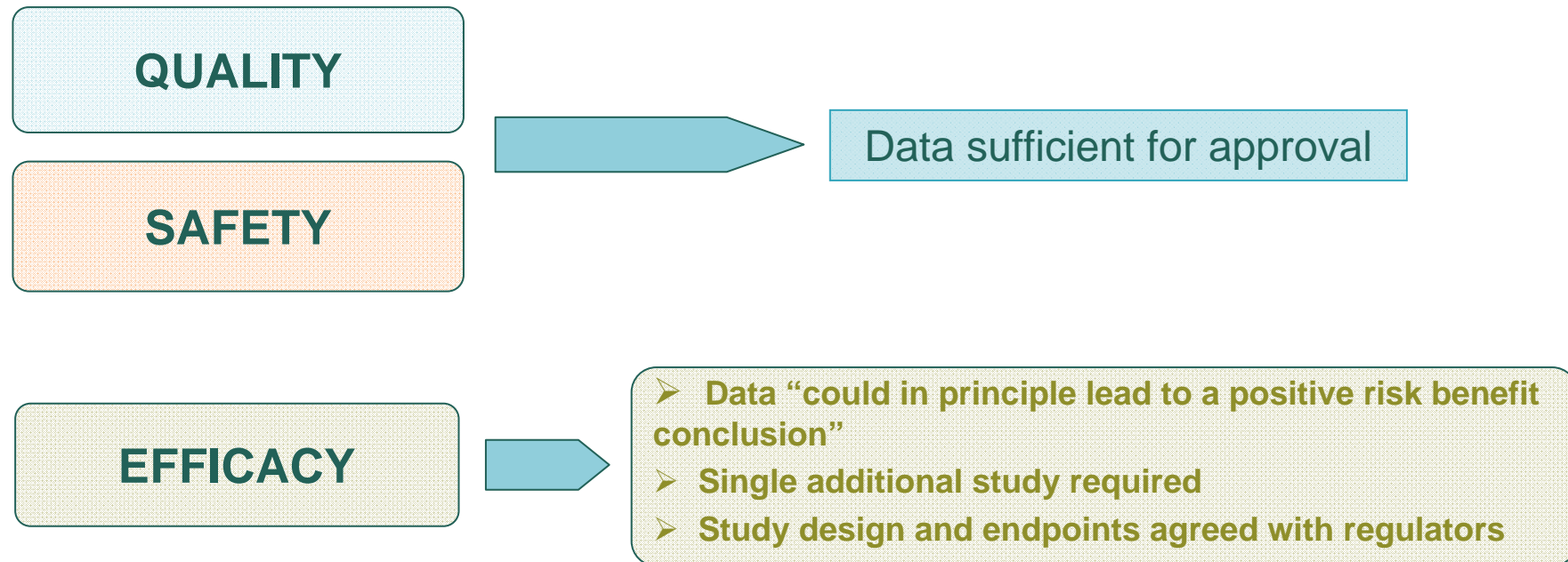
- UK
 - >2,000 patients prescribed to date
 - MS, Neuropathic Pain, Cancer Pain, Spinal Cord Injury, Rheumatoid Arthritis etc
 - >1700 physicians have prescribed Sativex
 - >90% of PCTs have reimbursed
 - Long term retention is 50%
 - Dosing and safety profile is consistent with clinical trial data
- Spain
 - Catalan government reported positive results from its Sativex access programme
 - Prescription use ongoing in Catalonia and other regions of Spain
- ROW
 - Sativex exported for prescription and clinical trial use to 21 countries

MS Spasticity



Europe: Sativex MS Spasticity Regulatory Status

- 2007 “Decentralised” submission

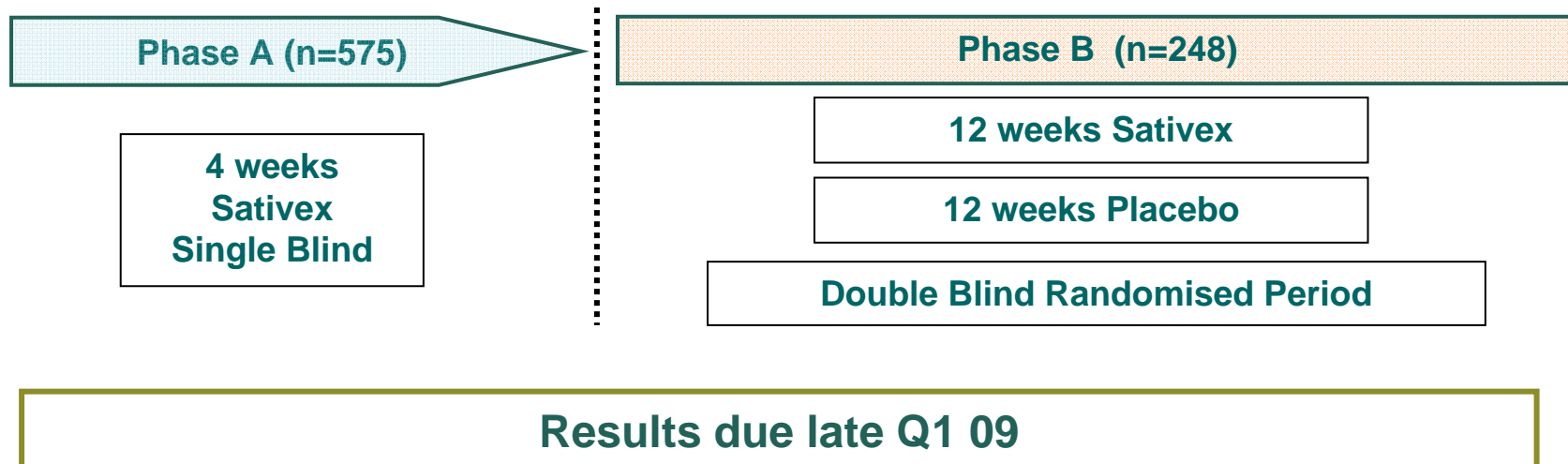


Route to approval established
Conclusions ‘validated’ by MHRA report published Dec 07

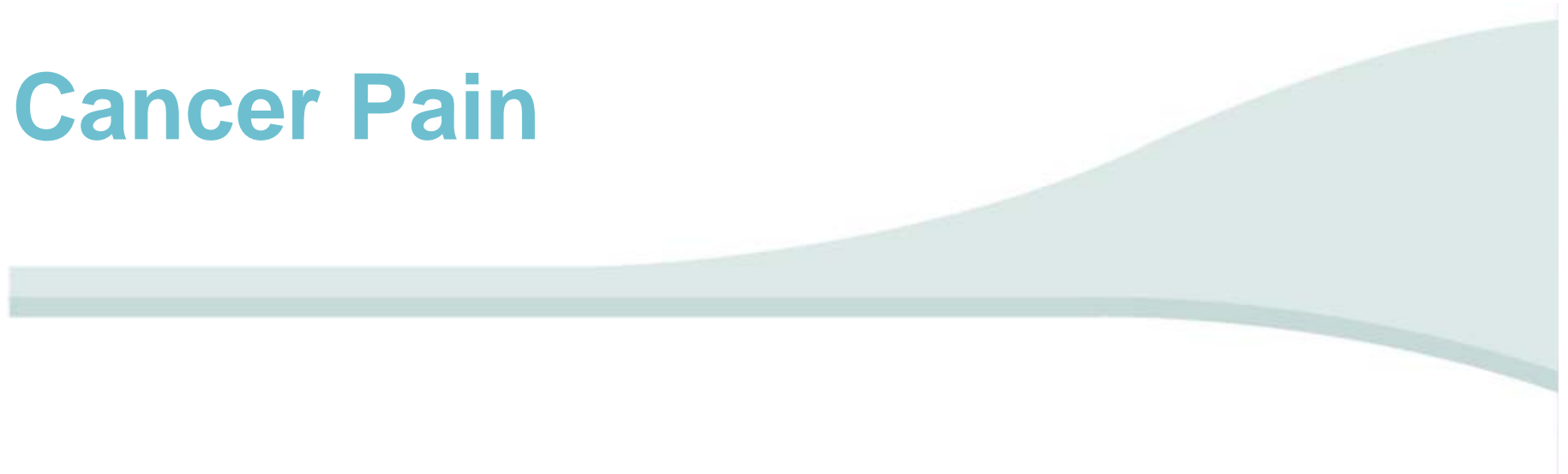
MS Spasticity Trial – Route to EU Approval

Recruitment Complete

- Outstanding efficacy issue to be resolved prior to approval
 - Regulators wish to clarify size of benefit in “responders”
 - “Post hoc” analyses of existing “responders” data show strong results ($p=0.015$)
 - Regulators have asked GW to reconfirm in a prospectively planned study
- “Enriched study” agreed with regulators
 - “Responders” identified in Phase A
 - Only responders enter the randomised study (Phase B)
 - Patient recruitment completed in just ten months



Cancer Pain

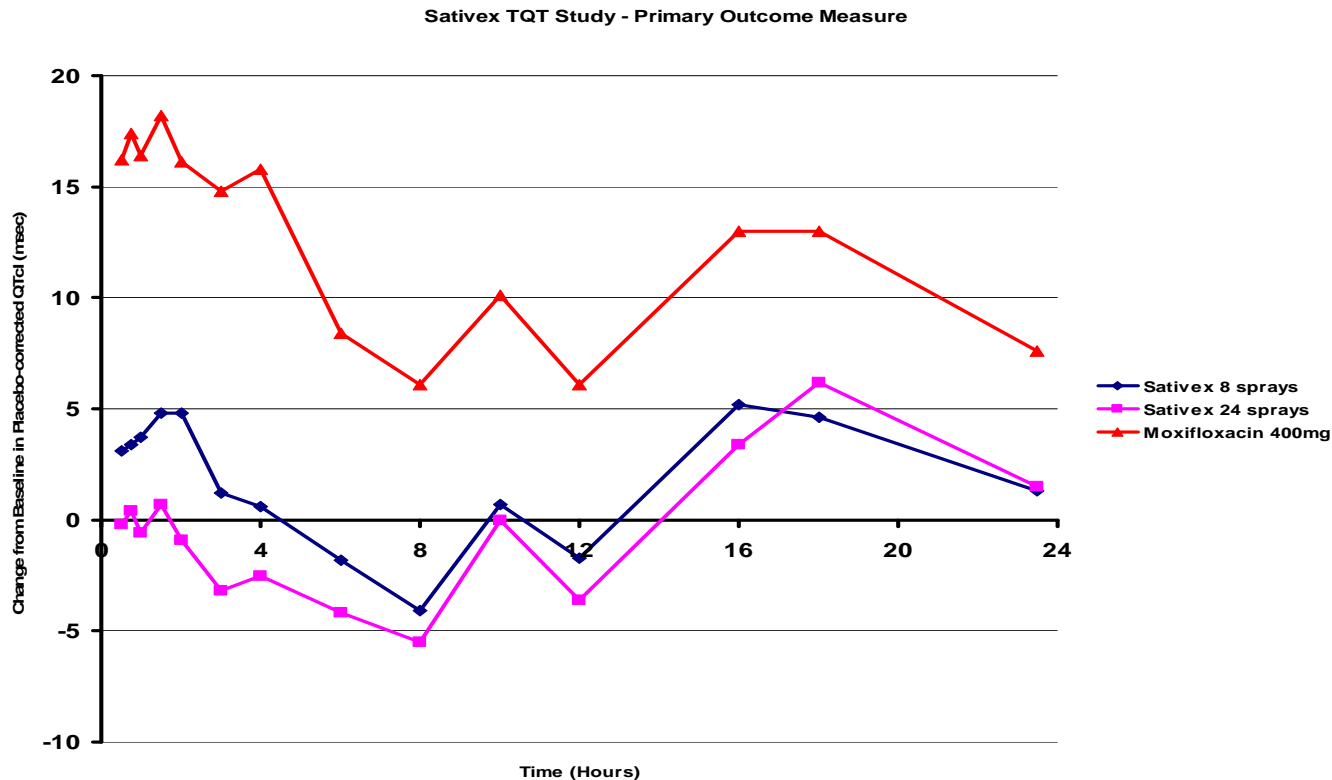


Sativex in the United States Targeting Cancer Pain

- FDA has permitted direct entry into Phase III trials
- First US pivotal efficacy clinical trial, Phase IIb/III cancer pain dose ranging study, ongoing
 - Due to complete H2 09
- Other elements of US development plan all proceeding on track
 - Extensive clinical pharmacology programme, including Thorough QT study (n=255)
- Clear path to US regulatory submission (expected 2011)
- Two further US Phase III trials planned to commence in early 2010
- All US trials funded by Otsuka
- Other indications to follow

TQT Study – Positive Primary Outcome

- TQT studies are mandated by FDA for all US regulatory applications and examine effects on cardiac conduction



Sativex does not prolong the QT interval and therefore does not carry a risk of cardiac arrhythmia (abnormal heart rhythm). This overcomes a major US regulatory hurdle.

Ongoing Phase IIb/III Cancer Pain Trial

- Primary objective
 - To evaluate the potential role and optimal dose range of Sativex as an adjunct to pre-existing pain medications
- Aim to replicate results from previous positive Phase II study (n=177)
 - Sativex significantly reduced pain vs placebo (p=0.014), primary endpoint
 - 43% of Sativex patients exhibited at least a 30% decrease in pain (p=0.024)
- 336 patients
 - Patients divided into 3 dose groups, each of which has a placebo arm
- Slower than expected recruitment has led to significant expansion of countries and centres
 - North America, Europe, South Africa
 - Other parts of world being evaluated

Due to Complete H2 2009

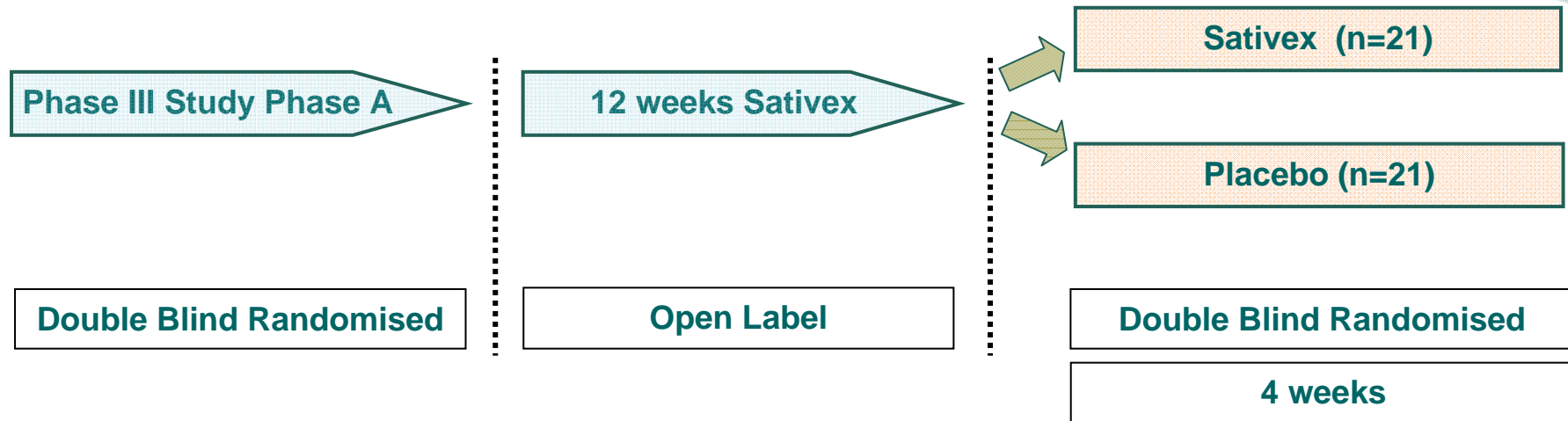
MS Neuropathic Pain



Neuropathic Pain in MS

- First Phase III Trial (n=66)
 - Positive primary endpoint: Sativex significantly improved pain relief (p=0.005)
 - Positive secondary endpoints: Sleep (p=0.003), Global impression of change (p=0.005)
- Second Phase III Trial Part A (n=339)
 - Impressive Sativex response rate: 50% gain >30% improvement in pain
 - Primary analysis narrowly missed significance due to unexpected large placebo effect
 - Statistical significance achieved when comparing fixed doses
- Second Phase III Trial Part B (n=42)
 - Randomised withdrawal design
 - Aim to show maintenance of long term efficacy
 - Positive primary and secondary endpoints

Phase III Trial Part B Randomised Withdrawal Design

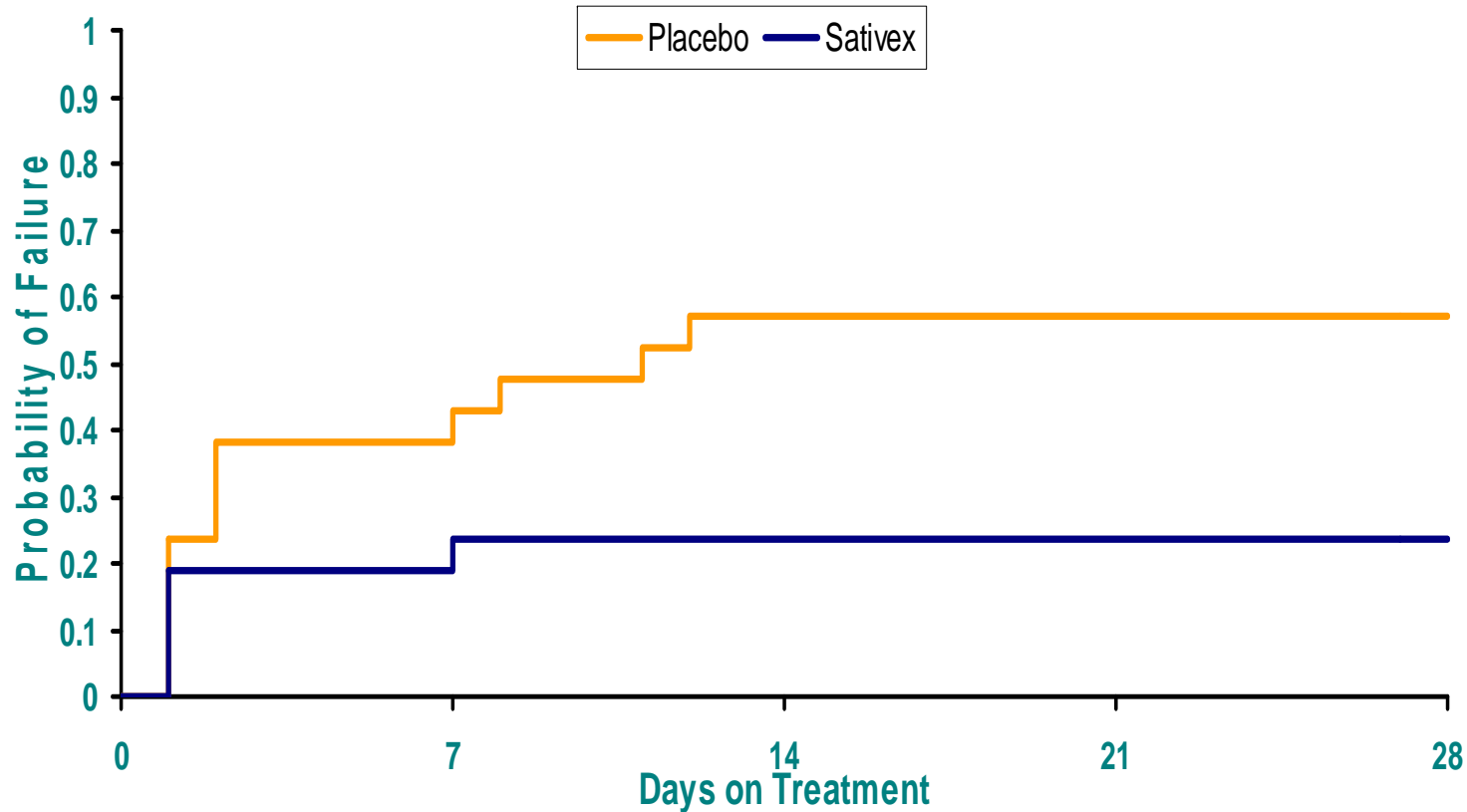


- Important similarities to the Phase III MS spasticity study due to report shortly
- Patients do not have discretion to determine their own dose
 - Dosing determined by their dose level in open label period
 - Patients not permitted to adjust their dose during double blind period
- If results in this study are replicated in the Phase III MS spasticity study, the Phase III study will meet its objectives

Randomised Withdrawal Study

Positive Primary Endpoint

Kaplan-Meier Plot: Time to Treatment Failure



Kaplan-Meier

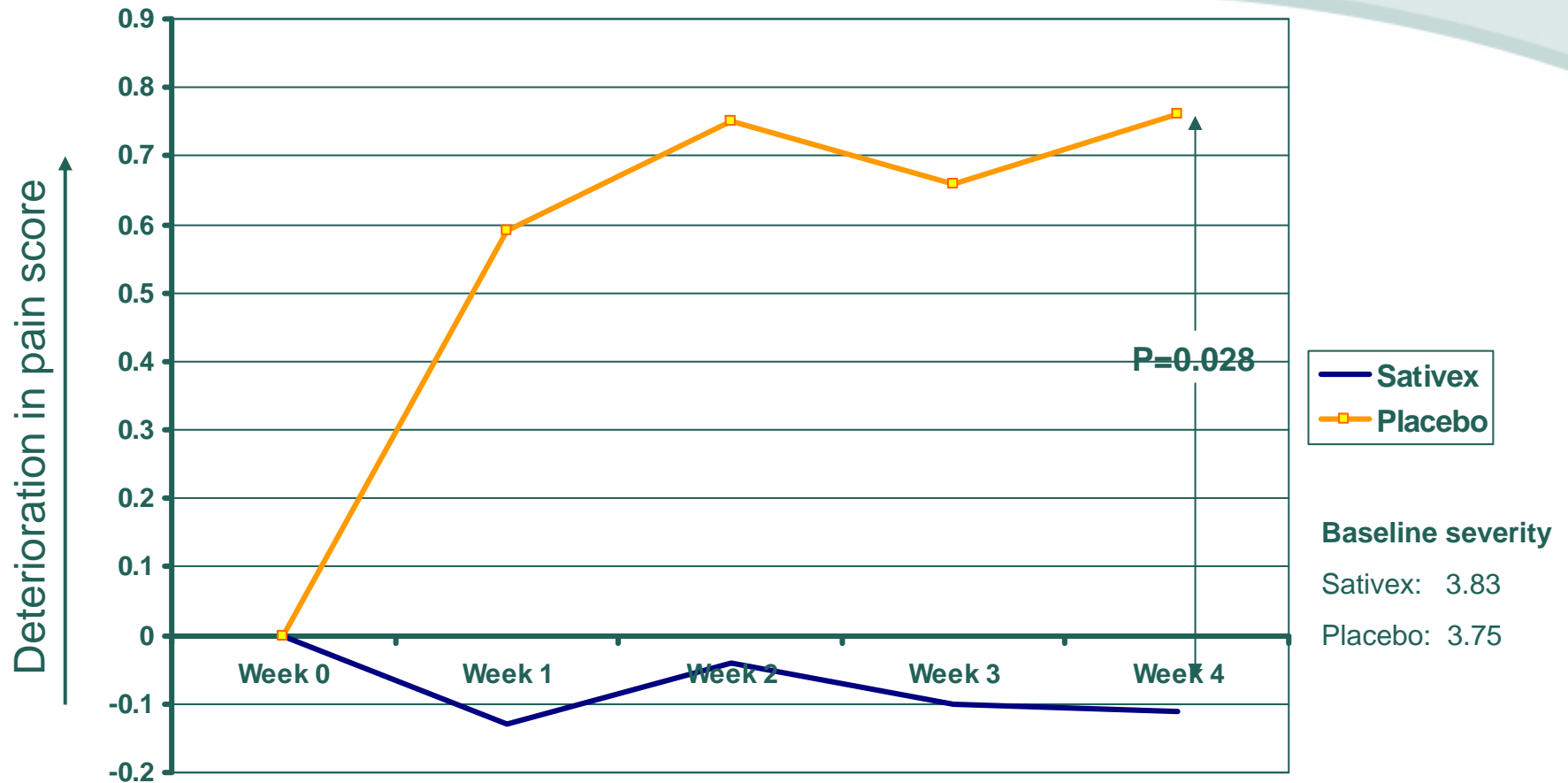
Test
Log-Rank

Chi-Square
4.392

p-value
0.036

Randomised Withdrawal Study

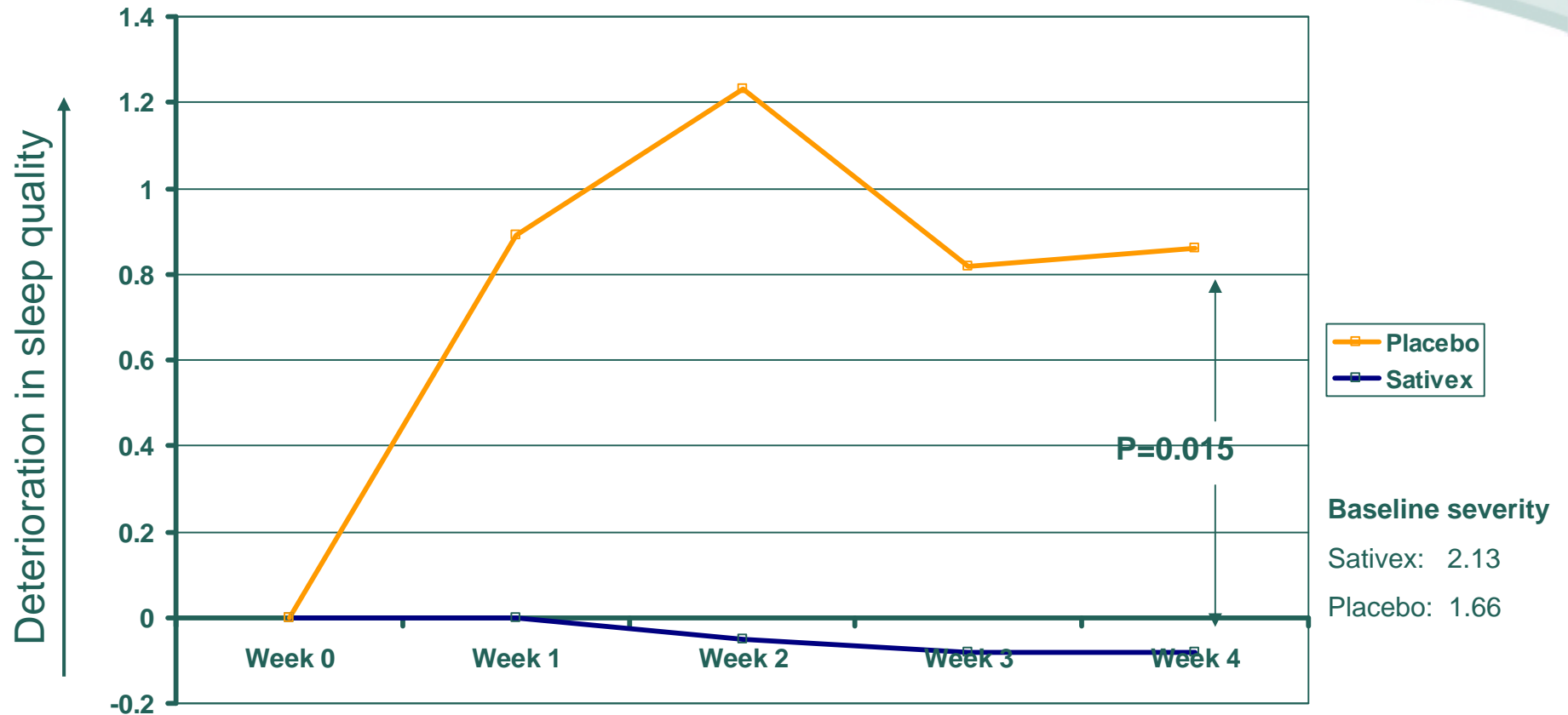
Significant Difference in Pain Scores



Mean deterioration on placebo of 24% vs mean improvement of 4% on Sativex

Randomised Withdrawal Study

Significant Difference in Sleep Quality



Mean deterioration on placebo of 56% vs mean improvement of 4% on Sativex

New Zealand

- NZ Health Ministry requested GW to set up named patient supply of Sativex
 - Sativex has now been imported and is stored at a NZ distributor
- As part of discussions, GW was invited to submit a regulatory application under Section 23 of Medicines Act 1981
 - If successful, Sativex would be approved as a prescription medicine with commitments to provide additional post-approval data
- Regulatory process ongoing
 - Questions received, responses provided
- Outcome expected in 2009

Cannabinoid Pipeline



GW-Otsuka Cannabinoid Global Research Collaboration

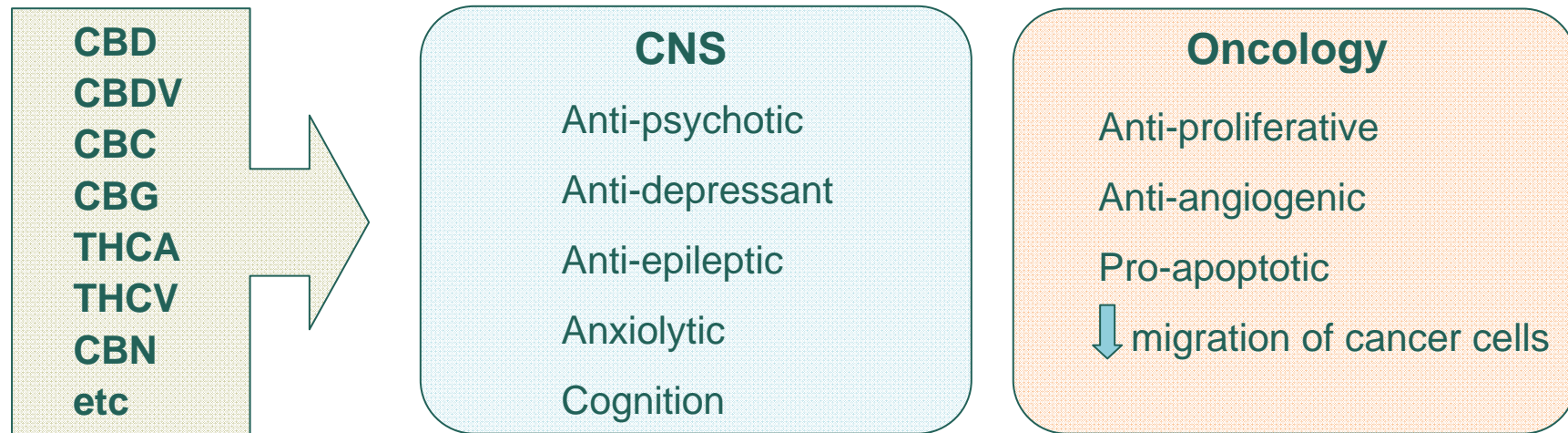
- Signed July 07
 - Otsuka are funding the evaluation of GW cannabinoids as drug candidates within the field of CNS and cancer treatment for an initial 3 year term
- Funding
 - \$9m research fund initially allocated by Otsuka for the 3 year term
 - Financial commitment exceeds that originally envisaged
 - £1.9m contribution to GW in-house costs in 2008 financial year
- Otsuka to select promising candidates for full clinical development, regulatory approval and global commercialization
- Once selected, Otsuka shall license each product on financial terms to be agreed at the time of selection, to include:
 - Upfront payments, milestones, royalties
 - Otsuka to fund global development



GW-Otsuka Research Collaboration

- Expanding the Pipeline

GW's cannabinoid drug candidates show the following pharmacological properties:



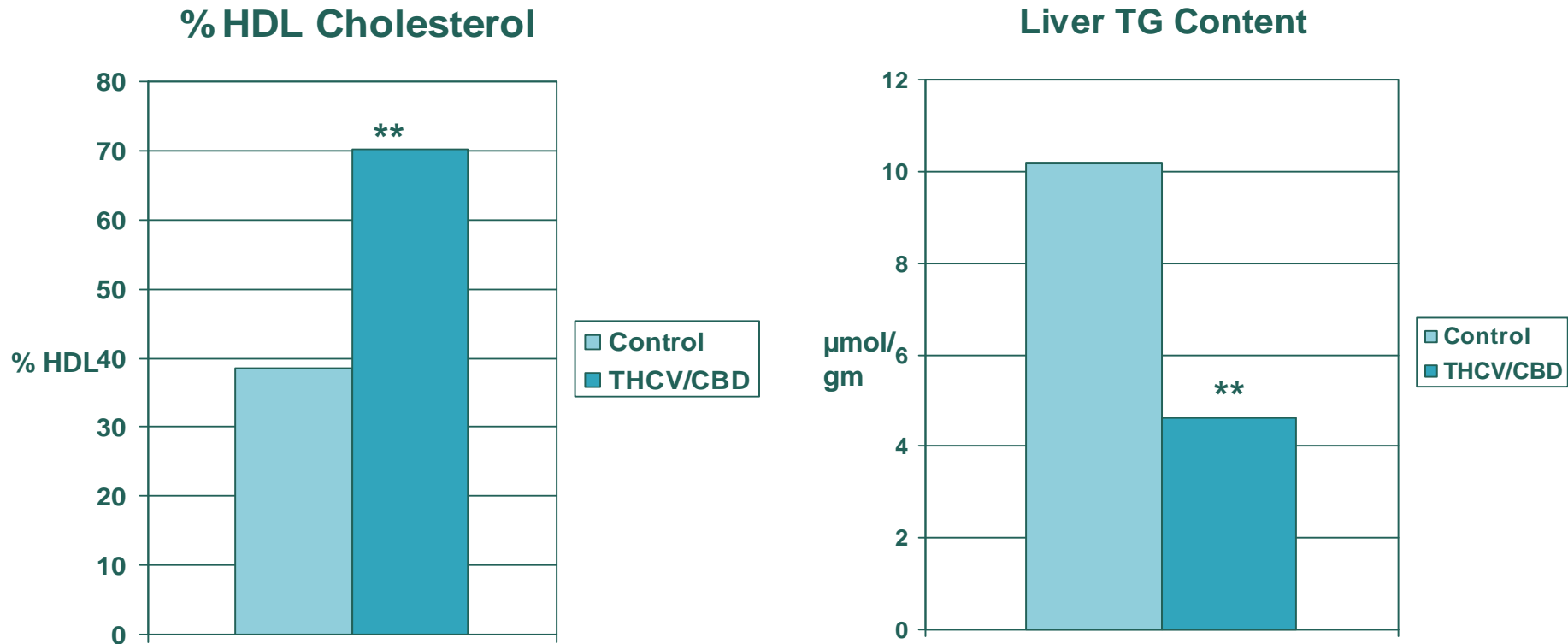
- Pharmacology programme already yielding highly promising results in psychiatric and oncology targets
- Initial focus on 6 GW cannabinoids. Research programme recently expanded to include additional cannabinoids
- Aiming to advance first candidate to Phase II clinical trials

In-House Pipeline Development: Diabetes / Metabolic syndrome

- In several models of diabetes, cannabinoid pharmacology findings include:
 - reduces fasting insulin
 - reduces leptin
 - reduces % body fat and liver triglycerides
 - increases energy expenditure
 - reduces total cholesterol
 - increases HDL (good) cholesterol
- Pharmacology of GW candidates is distinct from cannabinoid antagonist class
- Both THCv and CBD are promising drug candidates
 - Promising pre-clinical data
 - Toxicology indicates no safety concerns to date
 - Phase I successfully completed
- Data suggest THCv:CBD combination may be optimal new drug candidate
- Preparing for Phase IIa multiple dose study of THCv:CBD in the treatment of dyslipidaemia in Type II diabetic patients

Effect of THCv:CBD on % HDL (Good) Cholesterol and Liver Triglycerides

Methods: 28 day dosing in C57Bl/6 ob/ob mouse – a model of insulin resistance*



THCv:CBD shows significant improvement in Cholesterol/HDL ratio and reduction in liver triglyceride content

*Prof Mike Cawthorne, University of Buckingham

Financial Highlights



David Kirk
Finance Director



Revenue

Year ended	30 Sept 2008 £'000	30 Sept 2007 £'000
R&D fees – US development	6,299	2,202
R&D fees – Research collaboration	2,297	262
Total R&D fees	8,596	2,464
Sativex Sales	1,278	1,113
Signature Fees	1,900	1,350
Milestones	-	750
Total – Revenue	11,774	5,677

Consolidated income statement

Year ended	30 Sept 2008 £'000	30 Sept 2007 £'000 restated
Revenue	11,774	5,677
Cost of sales	(249)	(254)
Gross Profit	11,525	5,423
R&D expenditure – GW-funded	(10,431)	(12,506)
R&D expenditure – partner-funded	(8,596)	(2,464)
Administration	(2,775)	(2,882)
Share-based payment	(726)	(1,130)
Operating loss	(11,003)	(13,559)
Interest receivable	809	958
Loss before tax	(10,194)	(12,601)
Tax credit	1,974	2,015
Loss after tax	(8,220)	(10,586)
Loss per share	(6.8)p	(8.8)p

Consolidated Cash Flow Statement

Year ended	30 Sept 2008 £'000	30 Sept 2007 £'000
Operating cash outflow	(9,588)	(1,453)
Net interest received	821	960
R&D Tax credit	2,191	2,022
Capital expenditure	(440)	(500)
Equity fundraisings – share options	104	62
(Decrease)/Increase in cash	(6,912)	1,091
Cash balance	14,054	20,966

Consolidated Balance Sheet

As at	30 Sept 2008 £000's	30 Sept 2007 £000's restated
Intangible assets - goodwill	5,210	5,210
Property, plant and equipment	1,107	1,082
	6,317	6,292
Inventories	503	535
Receivables	2,572	2,815
Cash	14,054	20,966
Total assets	23,446	30,608
Other payables < 1 year	(5,363)	(4,186)
Deferred income	(19,810)	(20,759)
Total liabilities	(25,173)	(24,945)
Net assets	(1,727)	5,663

Analysis of Deferred Income

As at	30 Sept 2008 £000's	30 Sept 2007 £000's
Recognisable within 1 year:		
Otsuka advance research payments	2,511	1,560
Signature Fees	1,900	1,900
	4,411	3,460
Recognisable after 1 year:		
Signature Fees	15,399	17,299
Total deferred income	19,810	20,759

Guidance for 2009

- R&D expenditure
 - GW-funded R&D is expected to decrease by around 30%
 - Partner-funded R&D will continue to rise
- Milestones
 - A positive spasticity trial result would generate £2m milestone from Almirall
 - Subsequent UK and first mainland Europe approval would result in £13m of milestones from partners

Newsflow

- **Clinical trials**

- Results of Phase III MS Spasticity trial Q1 09
- Results of additional US clinical pharmacology studies H1 09
- Results first US cancer pain Phase II/III clinical trial H2 09
- First Otsuka candidate to enter clinical trials 2009
- Start of Phase II metabolic programme (THCV:CBD) 2009
- Peer review publication of clinical results

- **Regulatory**

- MS Spasticity submission in Europe Q2 09
- Submissions in other countries Q2 09
- Approval in Europe and elsewhere End 09
- New Zealand approval 2009

- **Research**

- Progress of CNS and oncology Otsuka collaboration
- Further metabolic syndrome research

Summary

- Clear near term regulatory pathway for Sativex in Europe in MS spasticity
 - MS Spasticity trial to report late Q1 09 with submission planned for Q2 09
- US prospects represent major value driver
 - Cancer pain programme funded by Otsuka
 - Clinical pharmacology studies proceeding well, Phase IIb/III trial to complete H2 09
 - Data available for global regulatory use
- Sativex prescription use continues to expand
 - Increasing recognition by clinicians and governments of Sativex
- Cannabinoid pipeline expansion underway
 - Otsuka funding pipeline in CNS & Oncology
 - In-house metabolic programme
- Encouraging financial results
 - Revenue growth and reduced net loss
 - Increased financial contribution from partners towards R&D