

Interim Results: Six Months Ended 31 March 2009



GW Pharmaceuticals plc

20 May 2009



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 Justin Gover, Managing Director

Highlights

Operations

- Positive results in Sativex[®] Phase III MS spasticity trial
- Sativex European regulatory submission filed and validated
 - Approval expected towards end of 2009 / early 2010
- European launch preparations underway
- Positive results in Sativex MS Spasticity randomised withdrawal study
- Sativex Phase IIb/III cancer pain trial due to report in Spring 2010
- Sativex named patient prescription use – exported to 21 countries
- Otsuka research collaboration yielding promising new drug candidates
- Metabolic research programme due to expand – Phase II in planning

Financials

- Maiden net profit: £4.0m (H1 2008: £4.2m loss)
- Turnover increased to £16.1m (H1 2008: £5.7m)
- Cash at 31 March 2009 of £11.8m
 - Additional £8m milestone received early April

Sativex[®] Oromucosal Spray

- Strong clinical trial results
 - 3,000 patients completed clinical trials
 - 1,300 patient-years of safety data
 - ~50% of intractable patients show significant benefit
- Four distinct target indications
 - MS spasticity
 - Cancer pain
 - MS neuropathic pain
 - Peripheral neuropathic pain
- Early revenues
 - Conditional approval in Canada for MS pain and cancer pain
 - Prescribed on “named patient” basis
 - 2200 patients in UK
 - Exported to 21 countries



Sativex Launch Preparations

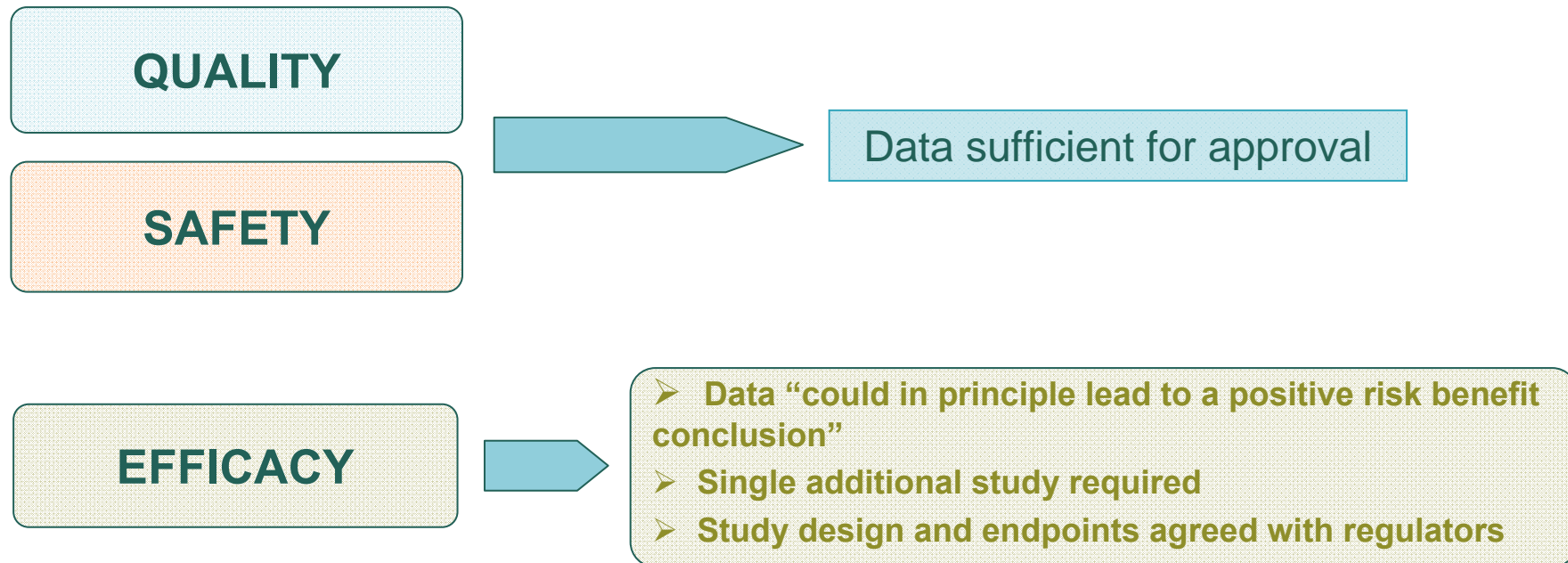
- **GW Manufacture**
 - Launch stocks already in place
 - Commercial scale production process established
 - GW taking over responsibility for GMP commercial finished product manufacture
- **UK - Bayer Schering Pharma**
 - Currently market Beta Interferon for MS
 - Dedicated MS sales team already in place
 - Relationships with 85 MS centres and opinion leaders
- **Spain - Almirall**
 - Neurology sales team already in place
 - €168m neurology sales in Spain
 - 150 MS specialist neurologists in 70 MS centres
 - Spain's largest domestic pharmaceutical company
 - Ranked 4th by market share
 - >€500m total sales in Spain

R&D Review

A decorative graphic consisting of a light blue wave-like shape that starts as a thin horizontal line on the left and expands into a larger, rounded shape on the right, positioned behind the 'R&D Review' text.

Sativex MS Spasticity 2007 Regulatory Submission Outcome

- 2007 “Decentralised” submission
 - UK, Spain, Netherlands, Denmark

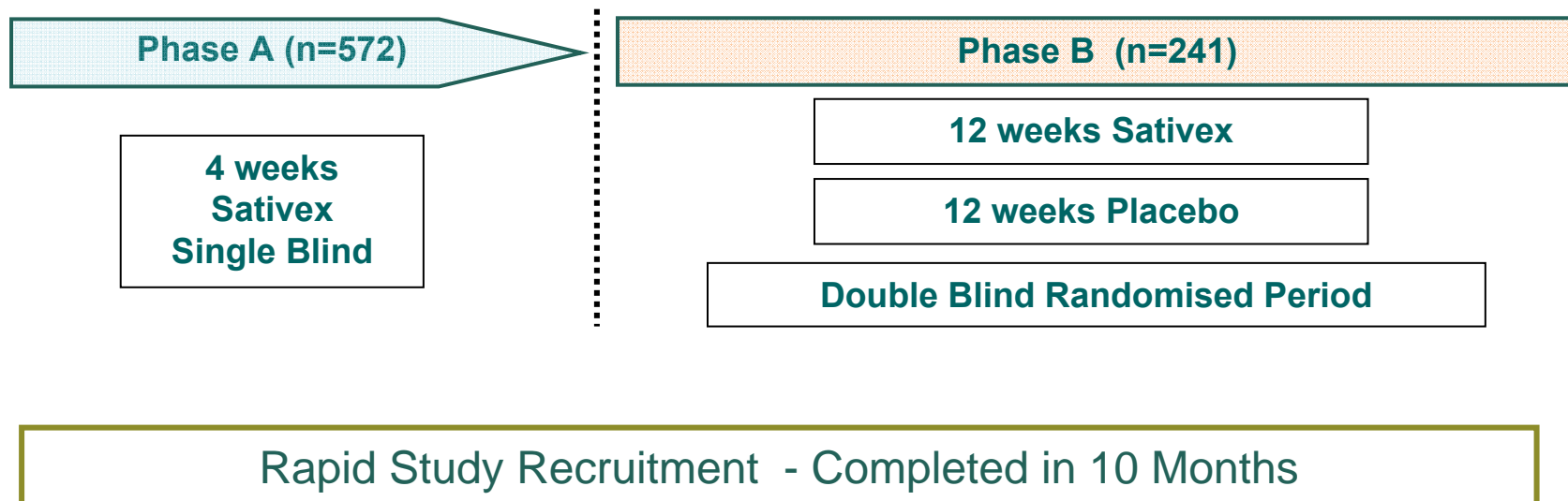


**Route to approval established - one additional Phase III study
Conclusions ‘validated’ by MHRA report published Dec 07**

MS Spasticity Trial – Route to EU Approval

Study Rationale & Design

- Outstanding efficacy issue to be resolved prior to approval
 - Regulators wish to clarify benefit in “responders” in a prospectively planned study
- “Enriched study” agreed with regulators
 - “Responders” identified in Phase A
 - More gradual dose increase during titration
 - Only responders enter the randomised study (Phase B)
 - Dosing in Phase B determined by dose taken in Phase A

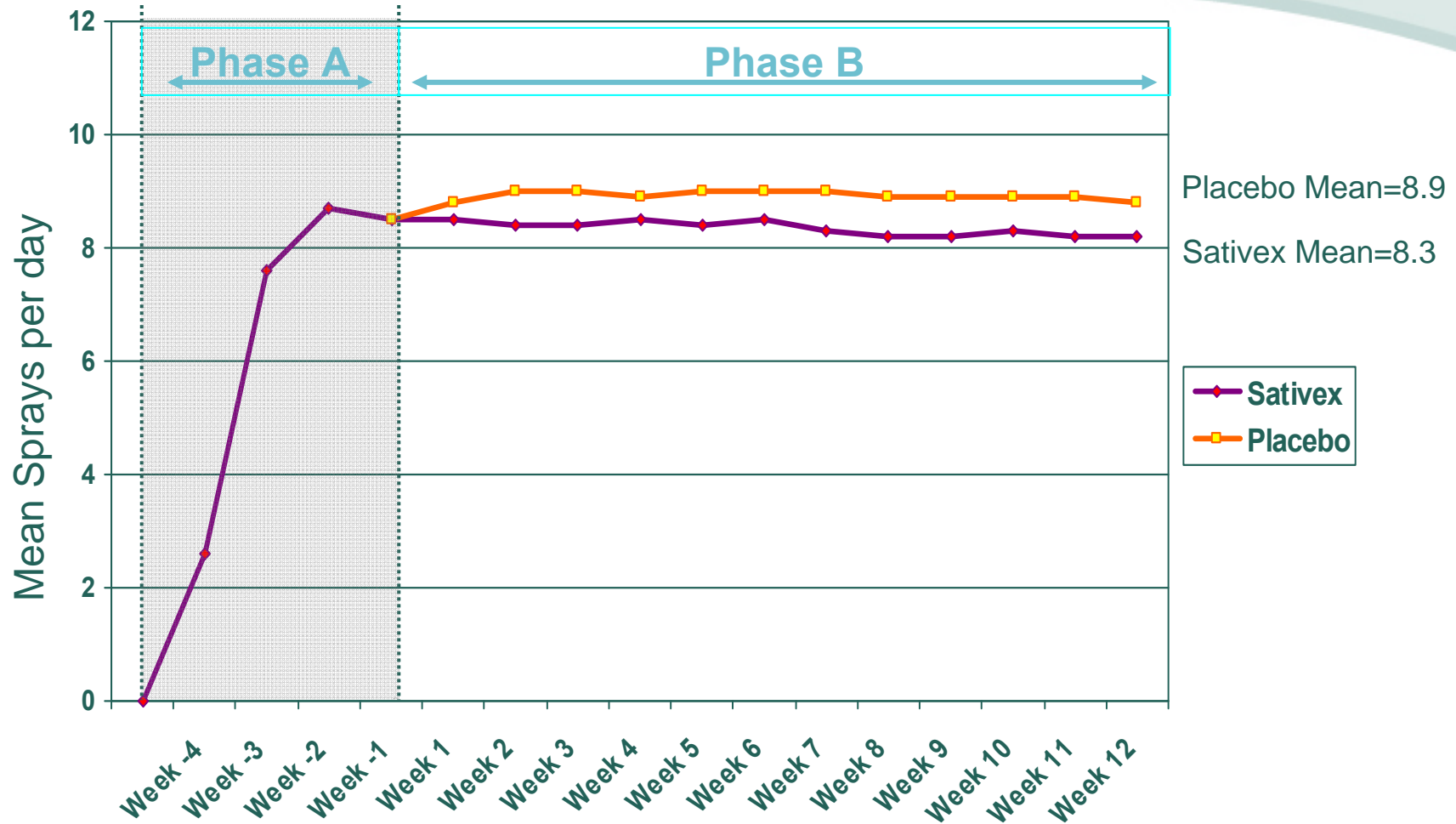


Phase III MS Spasticity Trial: Background Medication

Medication	%
Baclofen	57%
Tizanidine	19%
Benzodiazepines	17%
Others (gabapentin, dantrolene, botulinum toxin)	12%
Disease modifiers	53%

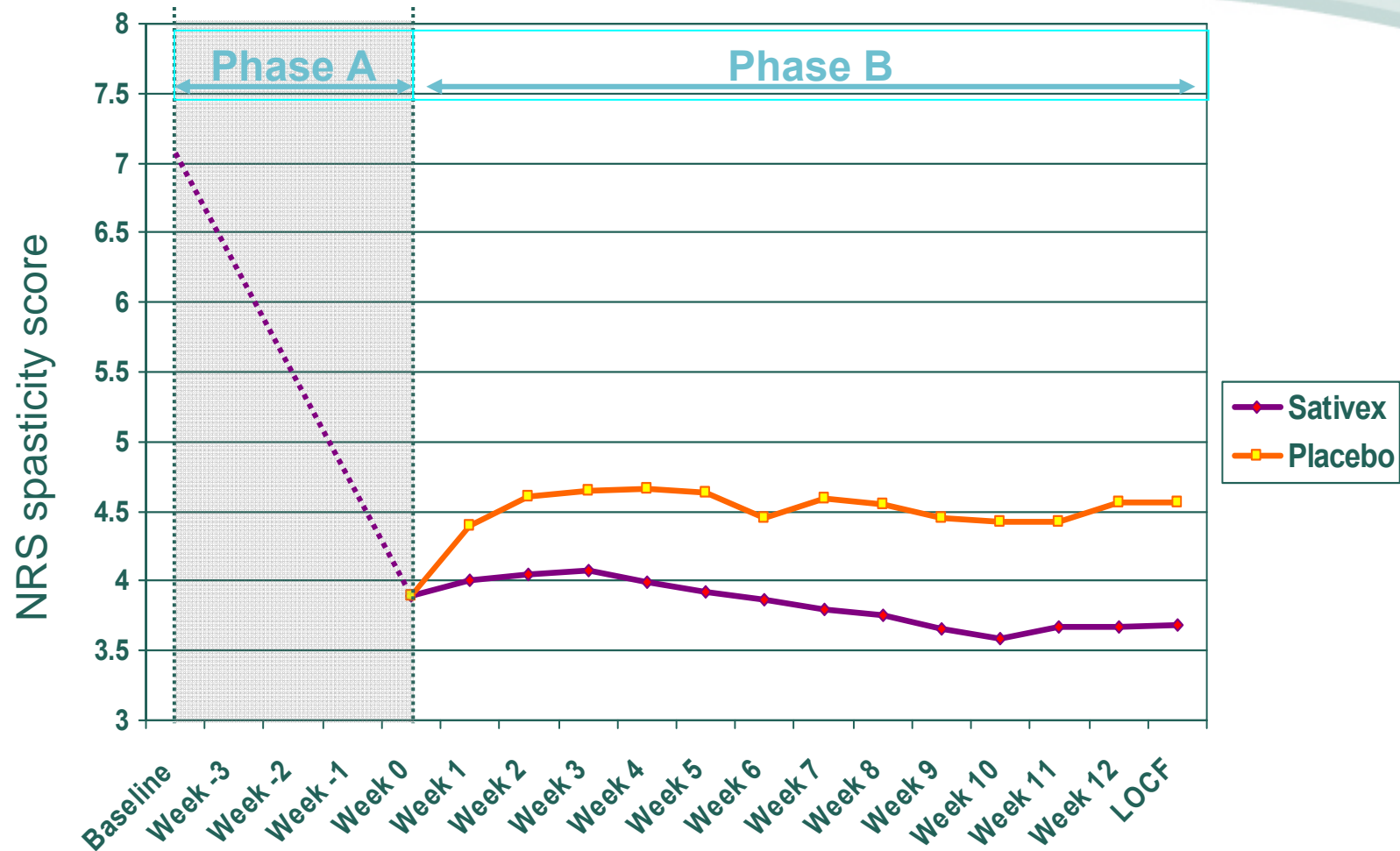
All patients have previously failed to respond to anti-spasticity therapy and continue to take their pre-existing background medication throughout the study

Phase III MS Spasticity Trial: Mean Daily Dosing



Sativex and Placebo dosing equalised for first time in a Sativex Phase III study

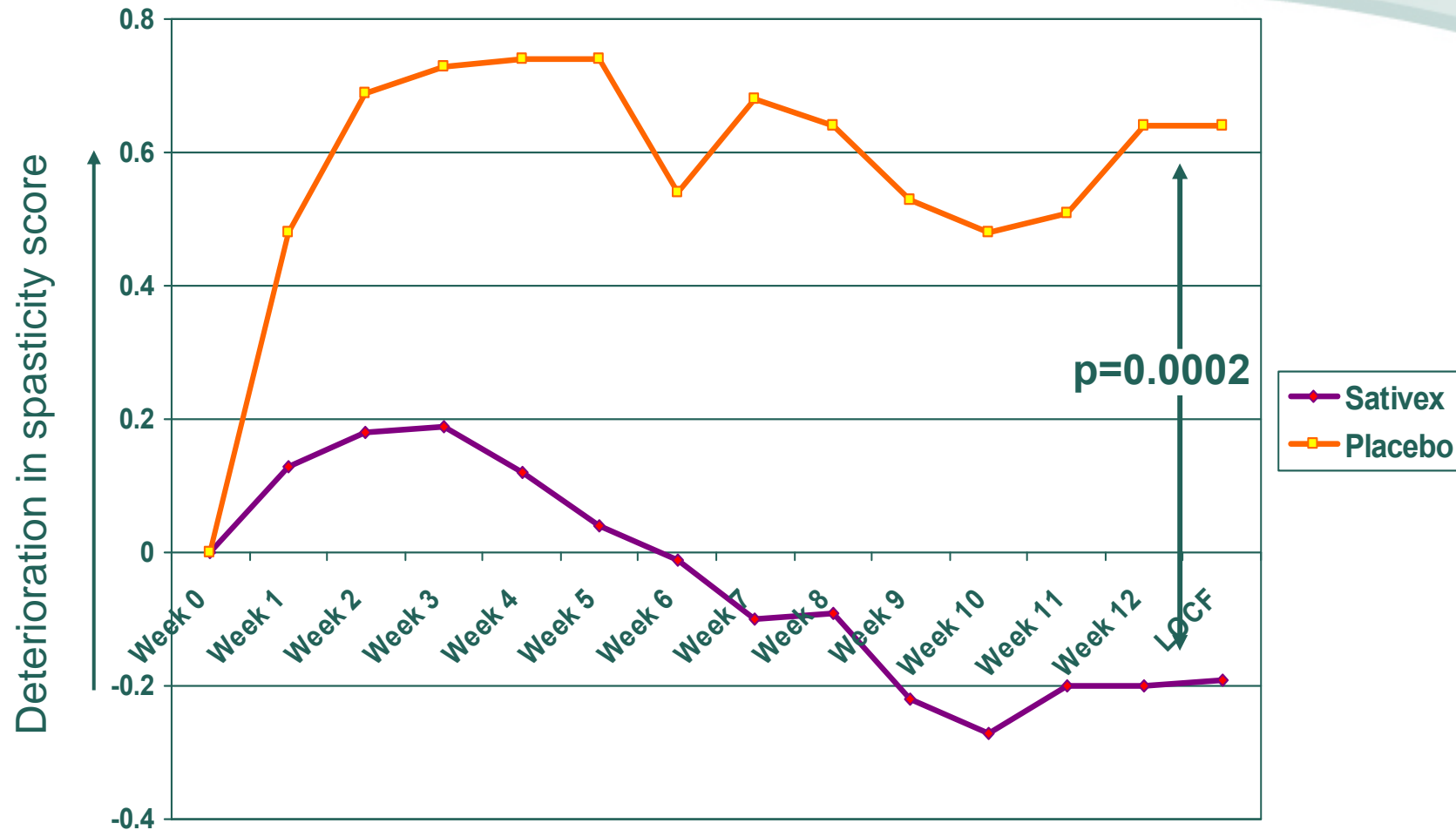
Phase III MS Spasticity Trial : NRS Spasticity scores over time



Mean 48% improvement in spasticity on Sativex over 16 weeks

Phase III MS Spasticity Trial: Primary Endpoint

Phase B Change in Spasticity scores

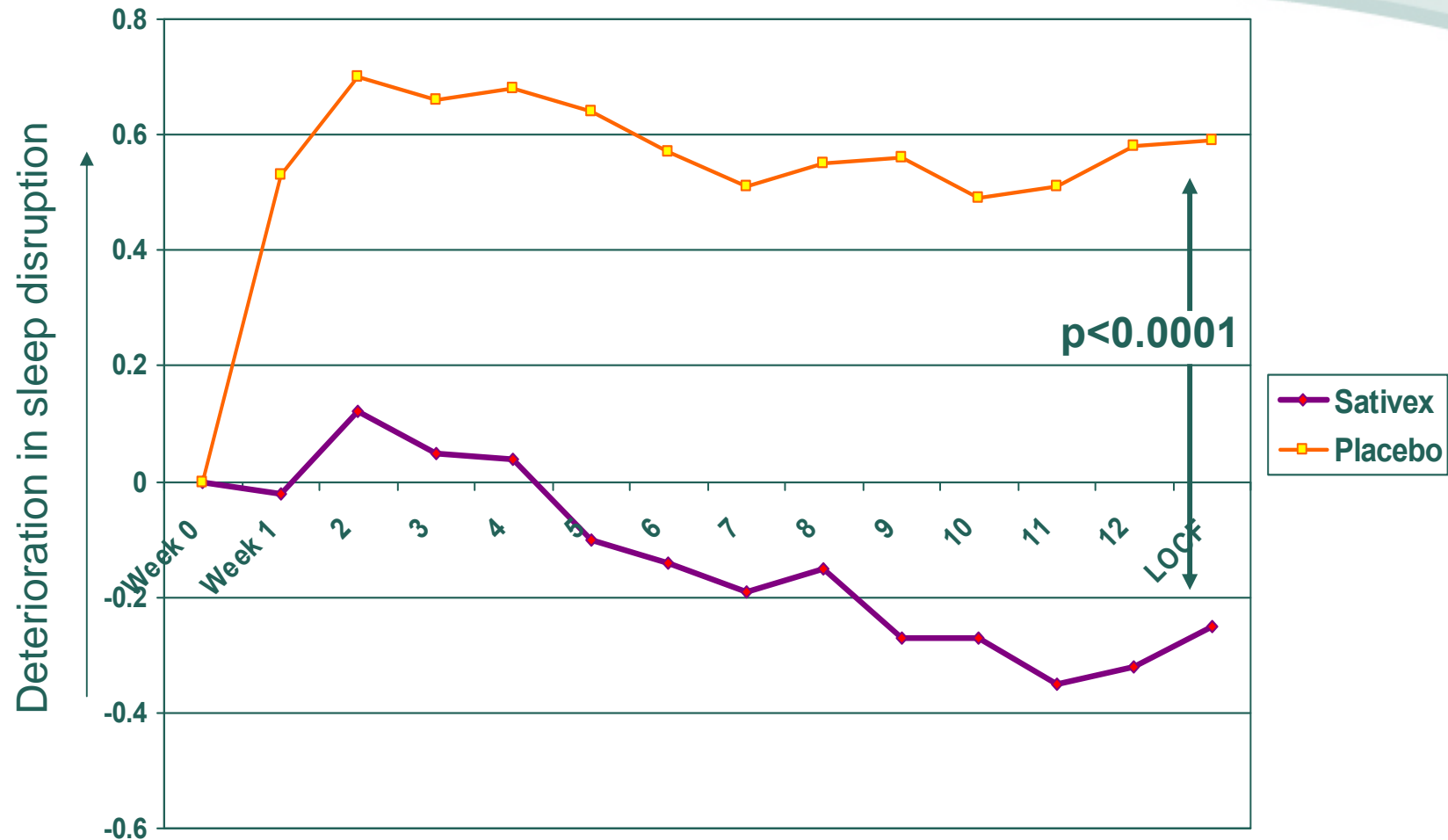


Baseline scores

Sativex: 3.87

Placebo: 3.92

Phase III MS Spasticity Trial: Secondary Endpoint Change in Sleep Disturbance scores



Baseline scores:

Sativex: 1.96

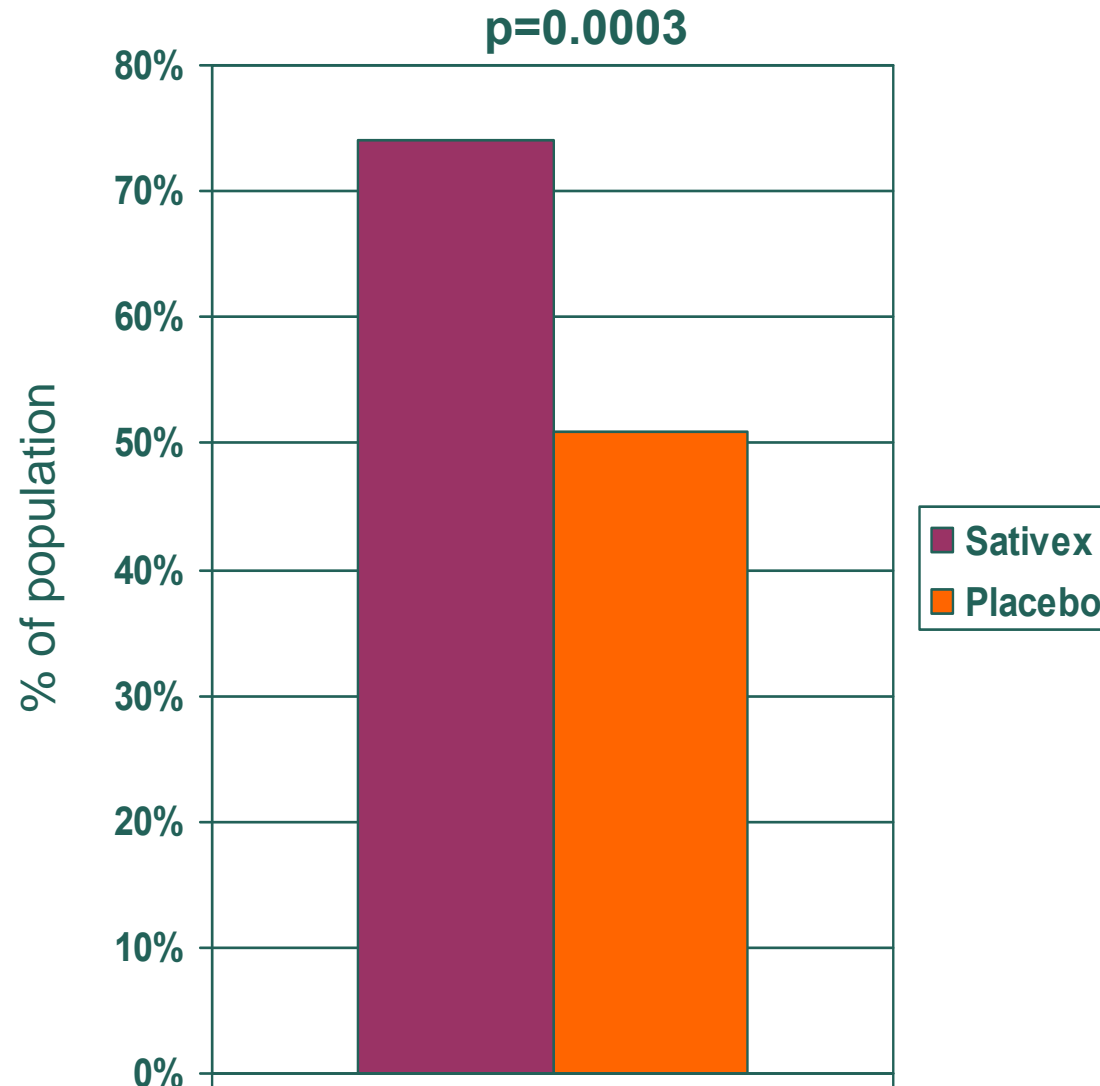
Placebo: 2.07

Phase III MS Spasticity Trial: Secondary Endpoint Change in Spasm Frequency scores



Baseline scores: Sativex: 5.61
Placebo: 5.29

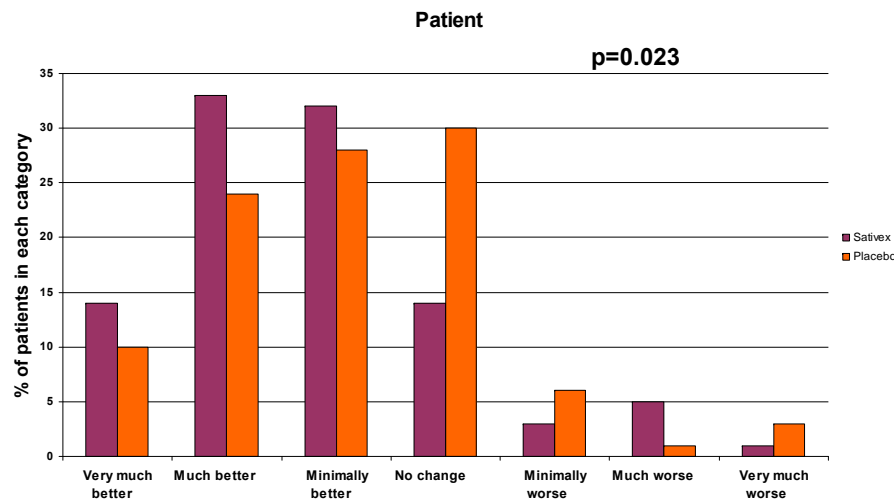
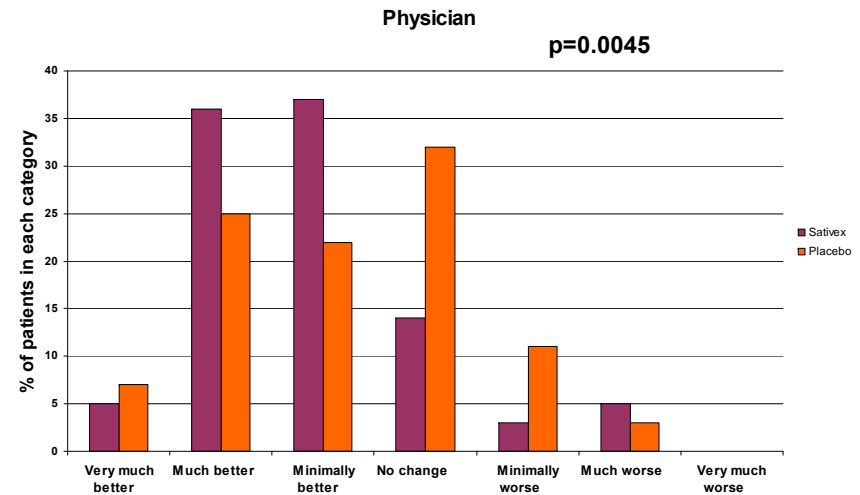
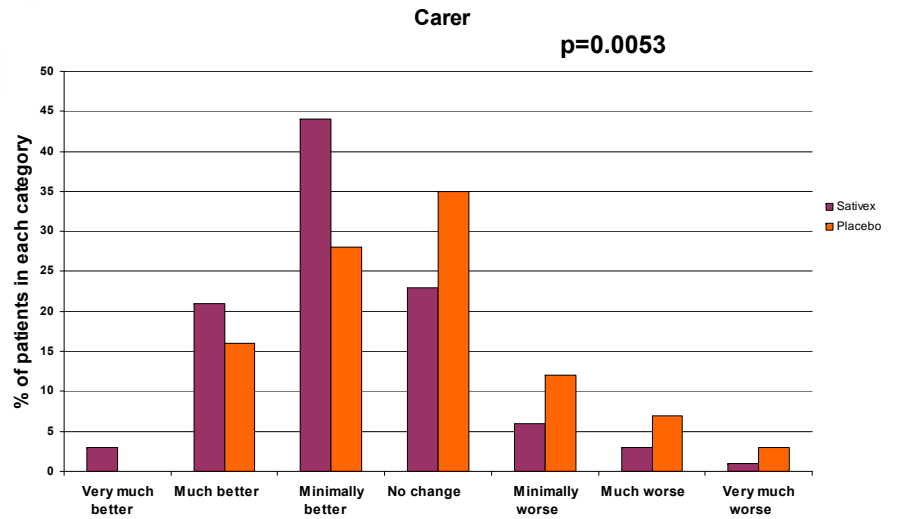
Phase III MS Spasticity Trial: Secondary Endpoint Responder Analysis: $\geq 30\%$ Response



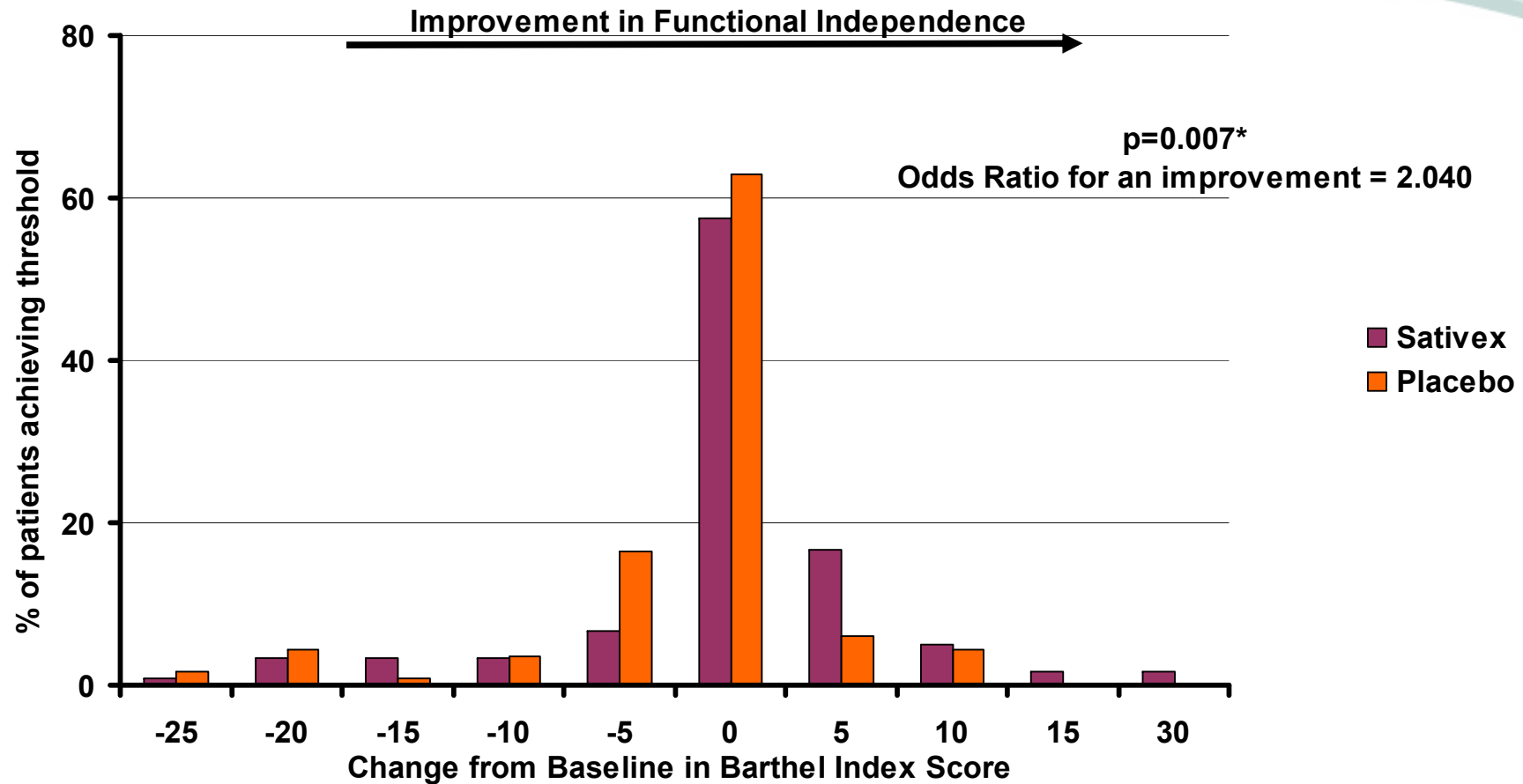
- A responder is defined as the change from the original study baseline
- All patients had been refractory to other anti-spasticity treatments
- 92/124 Sativex patients showed a response of at least 30%

Phase III MS Spasticity Trial: Secondary Endpoints

Global Impression of Functional Improvement



Phase III MS Spasticity Trial: Secondary Endpoint Barthel Index Score – Responder Analysis



The Barthel Index consists of 10 items that measure a person's daily functioning specifically the activities of daily living and mobility - including feeding, transfer, grooming, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder (Scale 0-100).

Excellent Safety Profile: Phase B Adverse Events at > 3% (All Causality)

Adverse Event	Sativex	Placebo
Urinary Infection	7%	10%
Vertigo	6%	1%
Muscle Spasm	6%	7%
Back Pain	4%	3%
Fatigue	5%	1%
Nasopharyngitis	3%	3%
Dry Mouth	3%	1%
Nausea	4%	2%
Abdominal Pain	3%	0%
Somnolence	3%	1%
Dizziness	3%	0%
MS Relapse	3%	1%
Euphoric Mood	3%	1%
Muscle Spasticity	2%	3%
Diarrhoea	2%	5%

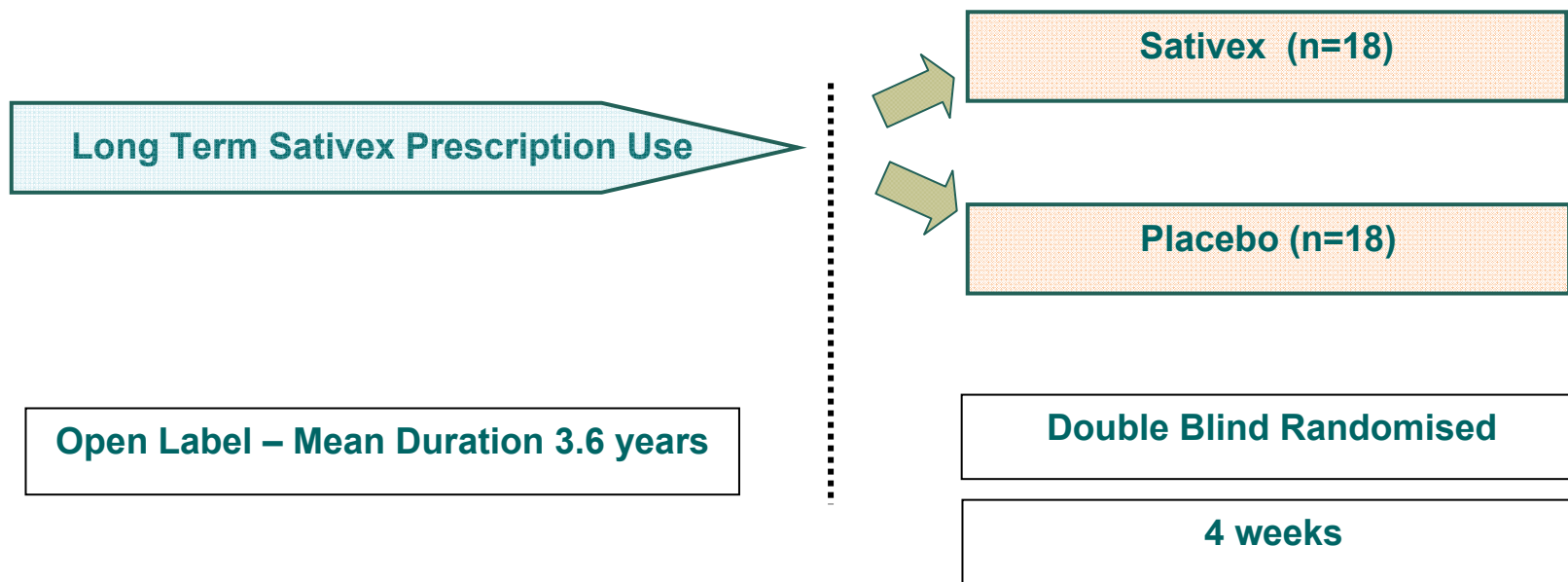
Excellent Safety Profile: Phase A Adverse Events at > 3% (All Causality)

Adverse Event	Phase A period of Study SP0604 (n=572)		Guidance from previous MS studies (n=663)
Dizziness	14%		32%
Fatigue	6%		12%
Somnolence	5%		8%
Nausea	4%		12%
Dry Mouth	4%		8%
Urinary Infection	3%		9%
Vertigo	4%		4%

Improved safety profile resulted from modified dose titration regimen employed in the study

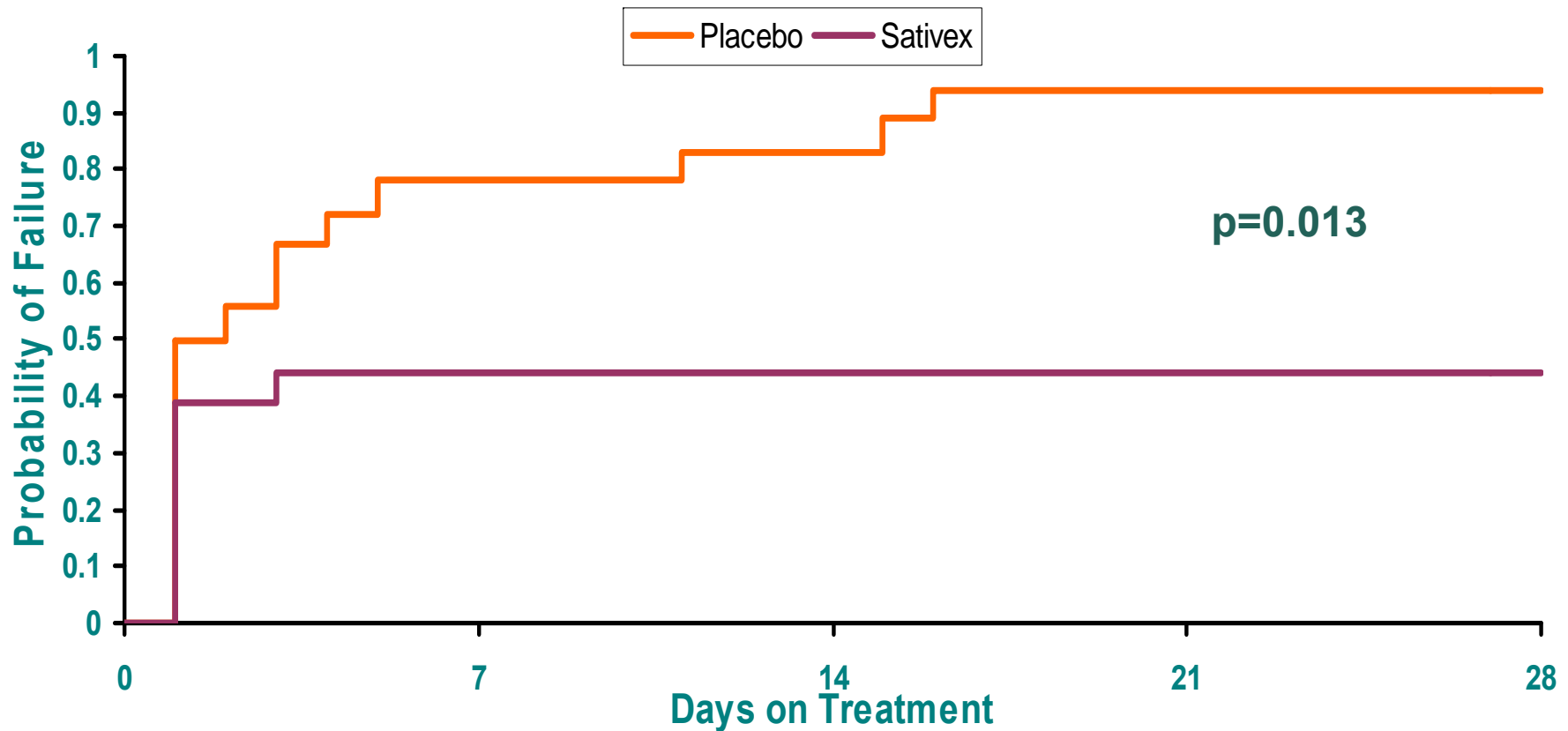
MS Spasticity “Randomised Withdrawal” Study (GWSP0702): Study Rationale & Design

- Previous regulatory application included substantial long term open label data
 - 554 patient-years of exposure
 - Data showed evidence of maintenance of efficacy and no new safety signals
- UK MHRA: “A randomised withdrawal trial following a period of open label treatment in patients considered to be responders... would satisfy the need for controlled long term efficacy data”.



GWSP0702: Positive Primary Endpoint Time to Treatment Failure

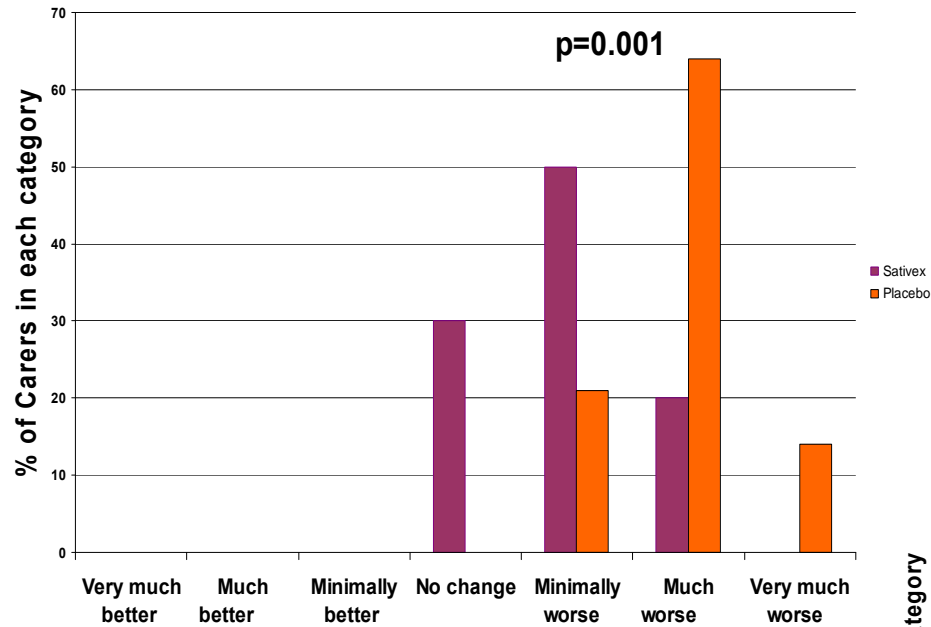
Kaplan-Meier Plot: Time to Treatment Failure



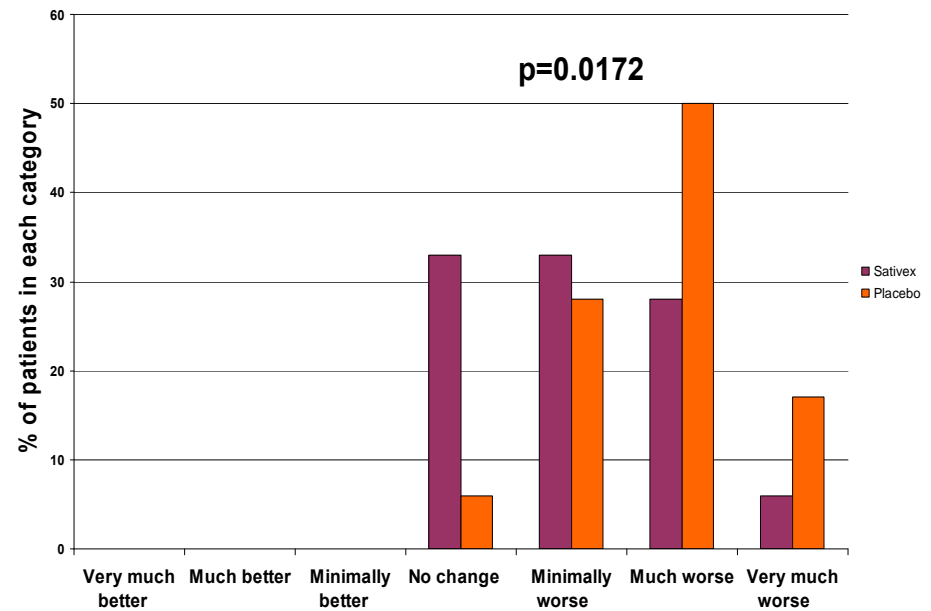
GWSP0702: Secondary Endpoints

Global Impression of Functional Improvement

Carer Impression of Change (Function)



Patient Global Impression of Change



Recent MS Spasticity Data Summary

- Phase III study results provide robust evidence of efficacy
- Randomised withdrawal study provides significant evidence of long term efficacy
- Improved Risk:Benefit
 - Low adverse event risk to non-responder
 - Sativex side effects virtually indistinguishable from placebo after 4 weeks
- Regulatory submission filed, initially in UK & Spain
 - Decentralised procedure - UK acting as Reference Member State
 - Submission already validated
 - Expansion to rest of Europe through Mutual Recognition Procedure in 2010
- GW has recently reported three positive Sativex studies using a design modified from previous studies
 - New approach is producing consistent positive results

Sativex in the United States

Initial Target: Cancer Pain

- FDA has permitted direct entry into Phase III trials
- Phase IIb/III cancer pain dose ranging study ongoing (n=336)
 - Due to complete end 09, Results Spring 2010
 - Global study (North America, Europe, S Africa, plus others)
- Previous positive Phase II study (n=177)
 - Positive primary endpoint (p=0.014)
 - 43% of Sativex patients exhibited >30% decrease in pain (p=0.024)
- Other elements of US development plan on track
 - Clinical pharmacology programme, including successful Thorough QT study (n=255)
- Clear path to US regulatory submission (expected 2011)
 - Two further US Phase III trials planned to commence mid 2010
- All global cancer pain trials and other US-targeted studies are funded by Otsuka

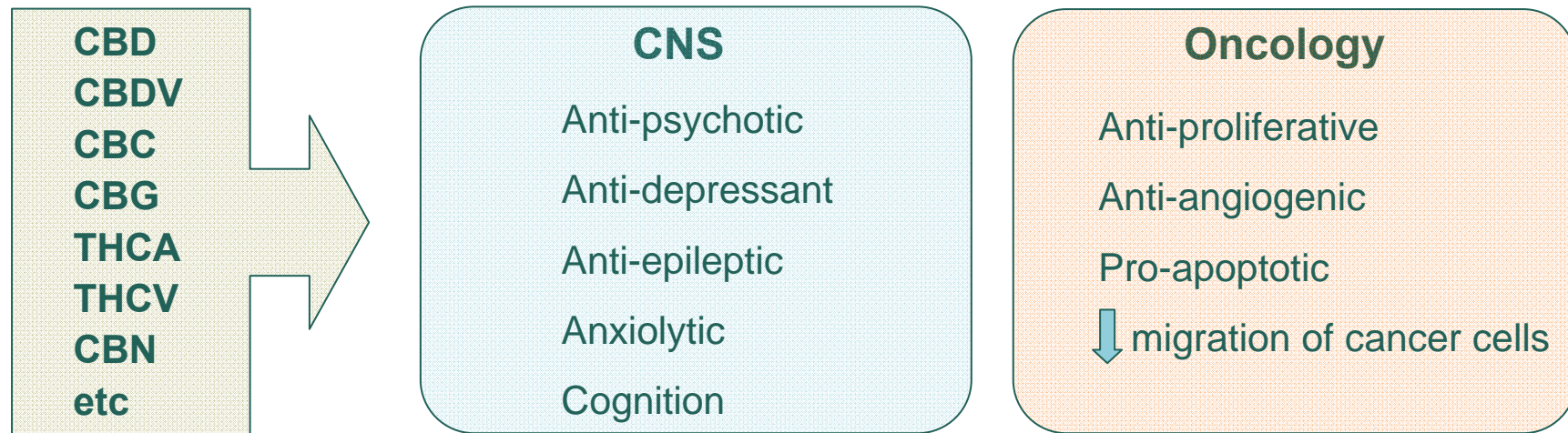
Phase IIb/III Cancer Pain Study Results Due Spring 2010

GW-Otsuka Research Collaboration

- Expanding the Pipeline

- Otsuka fund research of GW cannabinoids in the fields of CNS and oncology
- Otsuka to licence promising candidates
 - Financial terms of licence to be agreed at time of selection, to include:
 - Upfront payments, milestones, royalties
 - Otsuka to fund global development

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



Promising psychiatric, neurologic and oncologic drug candidates

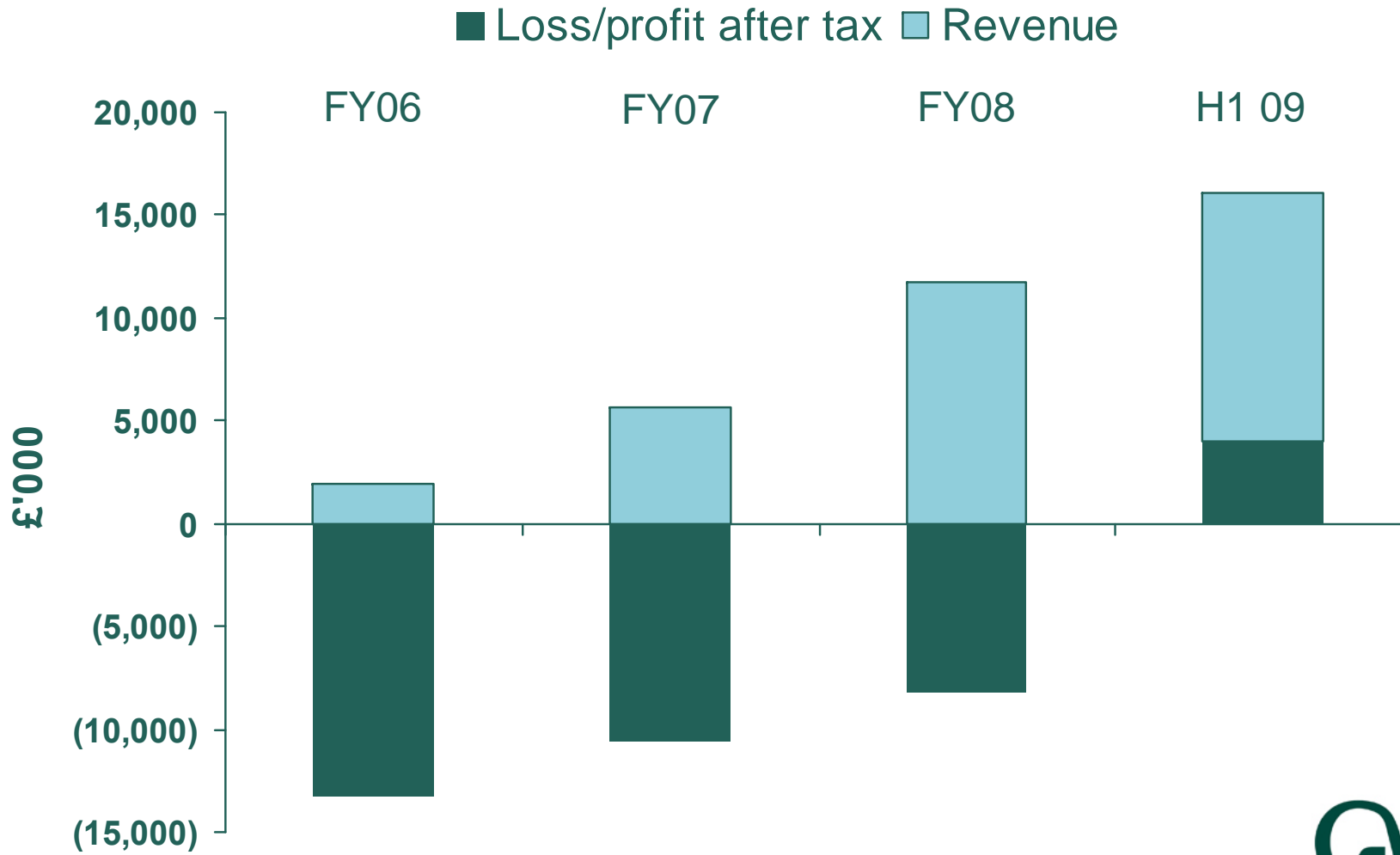
In-House Pipeline Development: Diabetes / Metabolic syndrome

- Promising cannabinoid pharmacology in several models of diabetes:
 - 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 to expand metabolic research programme
 - Plans include Phase IIa multiple dose study of THCv:CBD in the treatment of dyslipidaemia in Type II diabetic patients

Financial Highlights



Financial Profile



Revenues

Period ended	31 March 2009 £'000 <i>6 months unaudited</i>	31 March 2008 £'000 <i>6 months unaudited</i>	30 Sept 2008 £'000 <i>12 months audited</i>
Milestones	8,000	-	-
R&D Fees	6,162	4,126	8,596
Sativex Sales	974	619	1,278
Signature fees	950	950	1,900
Total – Revenue	16,086	5,695	11,774

Consolidated Income statement

Period ended	31 Mar 2009	31 Mar 2008	30 Sept 2008
£'000	<i>6 months unaudited</i>	<i>6 months unaudited</i>	<i>12 months audited</i>
Revenue	16,086	5,695	11,774
Cost of sales	(269)	(136)	(249)
Gross Profit	15,817	5,559	11,525
R&D expenditure – GW-funded	(3,741)	(5,160)	(10,431)
R&D expenditure – partner-funded	(6,162)	(4,126)	(8,596)
Administration	(1,685)	(1,550)	(2,775)
Share-based payment	(298)	(372)	(726)
Operating profit/(loss)	3,928	(5,649)	(11,003)
Interest receivable	99	464	809
Profit/(Loss) before tax	4,028	(5,185)	(10,194)
Tax credit	-	1,018	1,974
Profit/(Loss) after tax	4,028	(4,167)	(8,220)
Earnings/(Loss) per share	3.3p	(3.5)p	(6.8)p

Consolidated Cash Flow Statement

Period ended	31 March 2009 £'000 <i>6 months unaudited</i>	31 March 2008 £'000 <i>6 months unaudited</i>	30 Sept 2008 £'000 <i>12 months audited</i>
Operating cash outflow	(3,490)	(4,811)	(9,588)
Net interest received	99	443	821
R&D Tax Credit	1,792	2,191	2,191
Capital expenditure	(627)	(308)	(440)
Equity fundraisings – share options	-	7	104
Decrease in cash	(2,226)	(2,478)	(6,912)
Cash balance	11,828	18,488	14,054

£8m milestone inflow from Almirall subsequently received in early April 2009

Consolidated Balance Sheet

As at	31 March 2009 £000's <i>unaudited</i>	31 March 2008 £000's <i>unaudited</i>	30 Sept 2008 £000's <i>audited</i>
Intangible assets - goodwill	5,210	5,210	5,210
Property, Plant & Equipment	1,500	1,183	1,107
	6,710	6,393	6,317
Inventory	599	608	503
Receivables	9,010	1,935	2,572
Cash	11,828	18,488	14,054
Total assets	28,147	27,424	23,446
Trade and other payables	(7,396)	(5,212)	(5,363)
Deferred income < 1 year	(3,703)	(3,988)	(4,411)
Deferred income > 1 year	(14,449)	(16,349)	(15,399)
Total Liabilities	25,548	25,549	25,173
Net assets	2,599	1,875	(1,727)

Guidance

Previous 2009 guidance (provided Nov 08) was:

- GW-funded R&D to be 30% below that incurred in 2008
- Total R&D will continue to rise

Updated 2009 guidance:

- GW-funded R&D to be 30% lower than in 2008
- Total R&D expenditure for 2009 to be marginally higher than in 2008
- Receipt of the £8m from Almirall plus R&D fee revenue and Sativex sales should lead to GW being P&L and cash neutral for the year

2010:

- In the event of regulatory approval in the UK and Spain, currently anticipated towards end 2009/early 2010, GW expected to receive milestone payments from its partners totaling £12.5m

Newsflow

Sativex - MS Spasticity

- European MS Spasticity regulatory submission Today
- MS submissions in selected other countries H2 09
- Approvals in Europe and elsewhere End 09 / Early 10
- Launches in Europe and elsewhere Q1 2010 onwards

Sativex - Other

- Results of additional US clinical pharmacology studies H2 09
- Results of US cancer pain Phase II/III clinical trial Spring 2010
- Peer review publication of clinical results 2009 / 2010

Pipeline

- Expansion of metabolic programme (THCV:CBD) H2 09
- First Otsuka candidate to enter clinical trials 2009 / 2010
- Progress of CNS and oncology Otsuka collaboration