



Meeting patients' needs

A landmark year for GW Pharmaceuticals

Sativex[®] for MS Spasticity

Sativex is approved to treat spasticity due to Multiple Sclerosis (MS). Spasticity causes uncontrollable stiffness, muscle tension and spasms, which are often extremely painful and immobilising. Simple day to day activities that people take for granted like unscrewing the lid off a milk bottle can become very difficult. Not only does this cause huge distress, but quality of life, self-image and mood can be greatly affected.



Highlights

Operational

- Sativex receives approval in the UK, Spain, Canada and New Zealand for the treatment of spasticity due to MS
- Sativex successfully launched in the UK. Launch in Spain expected early 2011
- Sativex European Mutual Recognition Procedure filing submitted in July 2010
- Positive Sativex Phase IIb cancer pain data reported. US Phase III cancer pain programme, fully funded by Otsuka, now under way
- Phase II clinical programme of novel cannabinoid medicine in diabetes/metabolic disease commenced Q3 2010
- Otsuka research collaboration in cancer and CNS disorders extended for a further three years with additional \$12m in funding

Financial

- Net profit before tax increased to £4.6m (2009: £1.2m)
- Revenue increased 27% to £30.7m (2009: £24.1m), including Sativex sales up 64% to £2.8m (2009: £1.7m)
- Cash and short-term deposits at 30 September 2010 increased to £25.2m (2009: £20.6m)

With Sativex achieving its first major approval, 2010 was a milestone year for the Company. In this report, we seek to answer questions as to what this achievement means for GW's future.

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“I can have quite rough days and rely on Sativex to get me through.”

Linda Pack, MS patient



“The launch of any new medicine to help people with MS is good news and we know from our members that Sativex has been long awaited.”

Simon Gillespie, Chief Executive of The MS Society



Linda Pack has had relapsing, remitting MS for more than 20 years. She started taking Sativex in 2001 and has been on the medication ever since. She suffers from pain and spasticity which vary in intensity from day to day, and she can also find it very difficult to sleep at night. Effective symptom management is therefore very important to her. She loves being outdoors and spending time in her garden.

Sativex may not be suitable for all patients. Use of the product will be dependent upon individual clinical circumstances and in accordance with the defined conditions of use as described in the Summary of Product Characteristics.



Now that Sativex is approved, what is the potential for this medicine?

A: With initial approvals for Sativex in the UK, Spain, Canada and New Zealand in the treatment of MS, GW aims to maximise its potential by seeking to commercialise the medicine around the world as well as expand its use to cancer pain and other indications.

Sativex (delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)) is the first cannabinoid medicine derived from whole plant extracts from the cannabis sativa plant, and has been approved during 2010 in the UK, Spain, Canada and New Zealand to treat spasticity associated with Multiple Sclerosis (MS).

MS Spasticity Opportunity

Sativex was developed by GW in specific response to calls from the MS population for a prescription cannabis-based medicine to treat their condition. The approval of Sativex has been warmly welcomed by MS patient organisations and clinicians specialising in the treatment of the condition.

MS affects more than 1.2 million people worldwide, including an estimated 100,000 people in the UK and 500,000 people across Europe. MS affects twice as many women as men and typically develops between the ages of 20–40 years. People with MS have virtually a normal life expectancy.

Spasticity is one of the most common and most disabling symptoms of MS. It causes uncontrollable stiffness, muscle tension and spasms which are often extremely painful and immobilising. Not only does this cause people with MS huge distress, quality of life, self-image and mood can be greatly affected.

Spasticity affects most people with MS at some point. In a survey, 84% of people with MS reported symptoms of spasticity. It is widely recognised that currently available treatments for spasticity are inadequate and the clinical need for new and effective treatments for the relief of spasticity is beyond doubt. Sativex has been shown to provide effectiveness in patients for whom existing treatments have failed and hence provides an important advance in treatment options for these patients.



Bayer HealthCare



“Sativex addresses a significant unmet need offering relief to those MS patients who suffer from spasticity and associated symptoms who have been unable to obtain adequate benefit from currently available medication.”

Luciano Conde,
Chief Operating Officer, Almirall



Global Strategy

With Sativex having gained its first approvals in the UK, Spain, Canada and New Zealand, GW now aims to commercialise the medicine across the world. Sativex has already been exported to 28 countries either on named patient prescription or in clinical trials. We believe that this demonstrates a growing awareness and appreciation of Sativex amongst the medical community and gives reason to be confident about eventual regulatory approvals across much of the world.

In Europe, a regulatory submission has been filed under the Mutual Recognition Procedure (MRP) in order to seek approval in other European markets. This process is ongoing and is expected to complete around mid-2011. Following this, GW will seek to broaden the approval into additional European countries through a second round of MRP with the aim of achieving approvals across the majority of European markets in 2012.

In the United States, GW has a dedicated strategy which is outlined on page 8 of this Review.

GW is now working on plans to commercialise Sativex in Middle East, Latin America, Asia and Africa. The existing approvals in Europe enable a regulatory submission to be made in many countries within these regions and provide a high level of confidence in a positive outcome. In parallel with the regulatory evaluation, GW expects to establish distribution partnerships in these regions.

New Indications

Sativex has the potential to treat a broad range of symptoms and conditions. In addition to MS Spasticity, Sativex has demonstrated promising efficacy in clinical trials in patients with cancer pain, various types of chronic pain, as well as other symptoms such as bladder dysfunction. GW therefore aims to seek to maximise the potential of Sativex through the clinical development of additional indications.

Aside from MS spasticity, the most advanced indication in development is cancer pain. The Phase II trials programme in cancer pain has included over 500 patients and we have just embarked on a significant Phase III programme in collaboration with our partners, Otsuka. More information on this programme is found on pages 8–9.

Sativex has already been evaluated in a number of Phase II clinical trials in models of neuropathic pain (nerve damage pain) and is approved with conditions in Canada for the treatment for central neuropathic pain due to MS. Sativex has also showed positive results in a Phase II trial in treating pain due to rheumatoid arthritis. A recently published Phase II study provided clinical evidence across a range of endpoints that Sativex has beneficial effects when used for treatment of the bladder symptoms in patients with MS.

The promising Phase II data already generated for Sativex is currently being reviewed by GW in order to select an additional indication to pursue with a view to seeking future regulatory approvals.



“I have seen Sativex provide significant improvements in patients who have failed to benefit from other available medicines.”

Dr Willy Notcutt,
Consultant anaesthetist

“As the first new treatment for patients with spasticity in MS in 10 years, Sativex is a welcome option for a disease area in which there is a clear unmet need.”

Professor Patrick Vermersch,
Head of Neurology, University
Hospital of Lille, France



Dr. Willy Notcutt is a consultant anaesthetist at the James Paget University Hospitals NHS Foundation Trust in Great Yarmouth. He heads the pain clinic, which provides an integrated service for acute and chronic pain in the hospital and the community. Dr Notcutt is an established authority on cannabinoid medicines and has worked closely with GW Pharmaceuticals since the Company was founded. He was the first clinician ever to administer Sativex to a patient in a clinical trial.

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What is the strategy for Sativex in the United States?

A: The US is the world's largest pharmaceutical market and Sativex is initially being developed in the US as a treatment for cancer pain. This development is being conducted in collaboration with GW's US licensing partner, Otsuka. Following positive Phase IIb data this year, Sativex has now entered Phase III clinical development in this indication.

Cancer Pain Programme

Sativex is being developed in the US to treat pain in people with advanced cancer, who experience inadequate analgesia despite optimised chronic opioid therapy.

The cancer pain trials are designed to obtain approval in this indication from the Food & Drug Administration (FDA) in the US, but these data will also be used by GW for future regulatory applications in this indication in Europe and around the world.

In March 2010, GW announced preliminary results of a 360 patient Phase IIb cancer pain trial. The study met its key objectives of providing data to support entry into Phase III, showing statistically significant differences from placebo in pain scores, according to both the FDA-recommended continuous response analysis and the change from baseline analysis in NRS average pain score.

The results of the Phase IIb dose ranging study were consistent with a Phase IIa study in which Sativex also showed statistically significant improvements versus placebo in the continuous response analysis, as well as the mean change from baseline in NRS pain score. This study was recently published in the *Journal of Pain and Symptom Management*.

As a result of this positive Phase II data, GW and Otsuka have commenced a substantial Phase III trials programme which includes at least two Phase III trials of 370 patients per trial. The Phase III primary efficacy analysis is the continuous response analysis, the same analysis that has yielded statistically significant results in both the Phase IIa and IIb trials.

We look forward to working closely with Otsuka in progressing the Phase III development of Sativex in the United States market.





Cancer Pain Opportunity

Over one-third of patients with cancer, and more than three-quarters of those with advanced disease, have chronic pain. Currently available opioid therapies do not yield sufficient relief in a substantial proportion of these patients and there is a clear need for new treatments.

Chronic, unremitting pain in deep tissues that results from cancer adversely affects a disproportionately large portion of the population. Worldwide, more than 11 million people are diagnosed with cancer each year and it has been estimated that by 2020 that figure will rise to more than 16 million people a year. Patients with breast and prostate cancer, both of which have a propensity to spread to bone, more often experience pain than patients with uterine and cervical cancer.

Pain as an initial presenting symptom will occur in 20–40% of patients. Severe pain occurs in 20–35% of the cancer population and significantly impairs activities of daily living. The mean incidence of pain in a sample of 5,410 patients (across 22 studies) in various stages of cancer was 51%, whereas among 9,007 patients (across 38 studies) with advanced metastatic or a terminal phase of cancer, the mean incidence was 74% (Bonica, 1990).

Currently, opioids are the principal agents employed in the management of cancer pain, but the therapeutic benefit of their prolonged use is frequently offset by the development of undesirable effects such as constipation, sedation, respiratory depression and tolerance.



GW's cancer pain clinical programme is being wholly funded by Otsuka Pharmaceutical Co. Ltd, which has licensed the US commercialisation rights to this product.

The Otsuka Group comprises 145 companies and employs approximately 39,000 people in 23 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned approx \$11.7 billion in annual revenues in fiscal 2009.

Under the Sativex licence agreement, GW and Otsuka jointly oversee all US clinical development and regulatory activities. For the first cancer pain indication, GW is responsible for carrying out such activities, at Otsuka's cost. Otsuka will assume development and regulatory responsibility for the second and any subsequent indications.



“Sativex makes my work as an MS nurse so much more rewarding.”

Sue Simmons,
Research nurse



“The launch of Sativex is therefore a milestone for the NHS and the MS Trust, and we are delighted.”

Pam Macfarlane,
Chief Executive
of the MS Trust



Sue Simmons is a research nurse who looks after patients on Phase II and Phase III clinical trials for a wide range of new medicines – in the areas of both symptom relief and disease modification. She has been involved in trials with Sativex for the treatment of MS and other conditions for the last 10 years.



What does the Sativex approval mean for GW's cannabinoid pipeline?

A: The approval of Sativex is the result of 11 year's research by GW into the cannabinoid system. The approval validates our cannabinoid technology platform and enables us to progress the development of our pipeline across a range of therapeutic areas with increased confidence.

World Leader in Cannabinoid Science

GW is a recognised world leader in cannabinoid science with a close network of scientific collaborators across the world.

GW aims to consolidate this lead position by continuing to invest in, and explore the potential of, the cannabinoid system. At present, the cannabinoid system is being actively researched in the treatment of central nervous system disorders, psychiatric illness, cancer, obesity, diabetes, inflammation, cardiovascular disease, G-I disorders, movement disorders, bone disease, and more.

The cannabis plant contains more than 70 molecules known as phytocannabinoids (plant-derived cannabinoids). GW has unique access to an extensive library of phytocannabinoids and is researching a large number of these cannabinoids, each of which has different effects and applications. Examples of promising cannabinoids under active pre-clinical research by GW include THCV, CBN, CBG and CBC. In addition, GW has a broad portfolio of patent families and a prominent global position in patent filings related to phytocannabinoids.

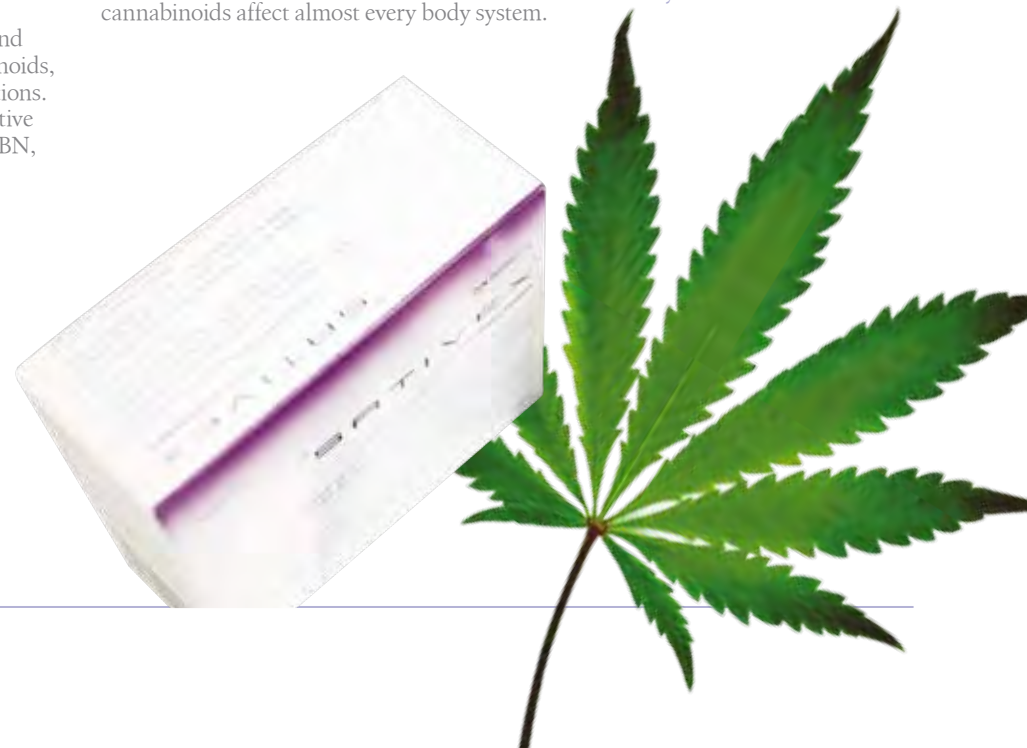
Only in the last two decades, a natural cannabinoid receptor system, the "endocannabinoid system", has been discovered in the human body. It is by interacting with, and modulating, these receptors that cannabinoids exert many of their pharmacological effects. There are at least two types of cannabinoid receptors in mammalian tissues, CB1 and CB2.

CB1 receptors are widely distributed but are particularly abundant in some areas of the brain including those concerned with movement and postural control, pain and sensory perception, memory, cognition, emotion, autonomic and endocrine functions. The role of the second type of receptor, CB2 receptor, is still under investigation but it is believed to mediate the immunological effects of cannabinoids.

The cannabinoid system interacts with many other neurotransmitter/neuromodulator systems such that cannabinoids affect almost every body system.

"The launch of Sativex is a milestone in the journey of cannabinoid medicines."

Professor John Zajicek,
Consultant in Neurology
at Derriford Hospital,
Plymouth



Target therapeutic areas

- **Diabetes/Metabolic Syndrome**
- **Inflammation**
- **Cancer Treatment**
- **Epilepsy**
- **Psychiatric Illness**

Otsuka Research Collaboration

Under a research collaboration agreement, GW and Otsuka research a range of GW cannabinoids as potential new drug candidates in the field of Central Nervous System (CNS) disorders and oncology. This agreement was originally signed in 2007 for a three year period, and in June 2010 the collaboration was extended by a further three years.

The GW-Otsuka research collaboration is led by a joint research team incorporating senior scientists from both companies. This team works in close collaboration with a number of leading cannabinoid scientists around the world.

The objective of this collaboration is to select the most promising candidates for full clinical development, regulatory approval and global commercialisation. Products selected for full development will be the subject of a license from GW. Under the terms of each product license, Otsuka Pharmaceutical will fund the global development and commercialisation of such products, and GW will receive license fees, milestone payments and a long-term commercial supply price and royalty.

In the three years since the collaboration was formed, GW-Otsuka's efforts have yielded highly promising data and new intellectual property with particular focus on epilepsy, schizophrenia and various oncology indications including glioma and prostate cancer.



“GW intends to leverage the Company's cannabinoid platform to expand, advance and partner the pipeline”

Dr Geoffrey Guy,
Chairman

Metabolic Syndrome

GW has an in-house funded programme evaluating GW cannabinoids as treatments for type 2 diabetes and metabolic syndrome. In September 2010, the first of a programme of Phase IIa exploratory clinical trials commenced.

This study programme follows a significant pre-clinical research programme on GW cannabinoids in several models of type 2 diabetes at the GW Metabolic Research Laboratory. This Laboratory is led by Professor Mike Cawthorne, Director of Metabolic Research at the Clore Laboratory, University of Buckingham, and a recognised world leading authority in the research of

new treatments for metabolic syndrome.

Results of this research have shown desirable effects of a number of GW cannabinoids on plasma insulin, leptin and adiponectin levels, hormones of particular relevance to the development and treatment of diabetes and metabolic function. In addition, these results have shown a reduction in total cholesterol with an increase in the proportion of HDL (good) cholesterol.

GW aims to perform a series of pilot Phase II studies over the next 12–18 months in this therapeutic area and believes that this research programme offers the potential for significant new pipeline opportunities.



“We are delighted with the progress of our collaboration with GW.”

Dr Taro Iwamoto, President and Director of Otsuka

“The extension of our partnership with Otsuka represents a significant endorsement of the potential of GW’s cannabinoid pipeline.”

Dr Geoffrey Guy, Chairman, GW Pharmaceuticals



Dr Yuki Yamasaki is one of a team of scientists from Otsuka who have been seconded to Europe to work on the GW-Otsuka research collaboration. Dr Yamasaki and colleagues have been working alongside cannabinoid scientists at the University of Aberdeen for the last three years. This team is now relocating to join other GW academic collaborators at the University of Reading and other universities in Italy and Spain. The GW-Otsuka research programme is led by a joint research team incorporating senior scientists from both companies.



What does the future hold for GW Pharmaceuticals?

A: With Sativex having achieved its first major approvals, a validated pipeline, healthy financial position and strong support from pharmaceutical partners, GW intends to continue to enhance its position at the forefront of cannabinoid science by maintaining investment in the development of new product candidates addressing substantial market opportunities for future out-licensing.

GW has a strong foundation from which it can progress its innovative research programmes with a view to successfully commercialising multiple new products addressing major markets with significant unmet needs. This foundation rests upon a number of business strengths outlined below.

Validated Platform

In Sativex, GW has successfully developed the world's first plant derived cannabinoid medicine. Having demonstrated that its development approach satisfies regulatory authorities with respect to quality and safety, this product has provided a regulatory platform and pathway from which GW is able to develop its pipeline of additional cannabinoid compounds. The approval of Sativex enables GW to progress the development of the Company's pipeline across a range of therapeutic areas with a high degree of confidence.

Groundbreaking science

GW is at the forefront of groundbreaking science developing innovative first-in-class medicines which meet significant unmet medical needs. Each of GW's medicines represent novel approaches and aim to provide benefits which are superior to existing treatment options.

Competitive Position

GW is proud to be a world leader in the field of cannabinoid science. Operating within the controlled substances arena with significant governmental barriers to entry, GW has sought to consolidate its competitive advantage by developing a broad platform of intellectual property rights as well as close collaborative relationships with leading cannabinoid scientists around the world. For these reasons, GW believes that it is uniquely positioned to benefit from the rich promise within the field of cannabinoid therapeutics.

Expert Team

GW has assembled a large scientific team with expertise in cannabinoid science as well as experience in the development of both plant-based prescription pharmaceutical products and medicines containing controlled substances. This range of in-house expertise allows GW to maintain in-house control over all aspects of the cannabinoid product development process as well as commercial manufacture and supply chain. In addition to GW's in-house expertise, the Company has developed an extensive international network of the most prominent scientists in the field of cannabinoid science.





Partnerships

GW has four major partnership agreements in place. In 2007, GW entered into a strategic alliance with Otsuka which comprised two separate agreements – a Sativex US licence and a global cannabinoid research collaboration. In addition, Sativex was licensed to Almirall in Europe (ex-UK) in 2005 and to Bayer Healthcare in the UK and Canada in 2003. These partnership agreements not only provide financial benefits to GW in the form of signature fees, milestones and long-term supply prices, they also serve to ensure that our partners have a significant interest in seeing GW's medicines become commercial success stories.

Financial Strength

GW has successfully implemented a business model which provides for sustained investment in its product pipeline whilst at the same time maintaining a strong cash position as well as a focus towards profitability. GW's 2010 financial results show increased turnover and profit, as well as a healthy cash balance. An important feature of this model is the relationship with Otsuka, which provides funding for both the US development of Sativex and the Company's pipeline development in CNS and oncology. The progress of Sativex into US Phase III development and the three year extension of the research collaboration allow these important financial contributions to continue for some time to come.

Industry Dynamics

There is widespread recognition within the pharmaceutical industry as to the lack of productivity on the part of the larger companies in producing new innovative medicines. GW therefore has the opportunity to play an important role as a small dynamic research oriented company with the capabilities to develop products which may enhance the pipelines of larger pharmaceutical players. As GW's pipeline advances, it believes it will have the opportunity to expand further its relationship with the industry in bringing new medicines to market.

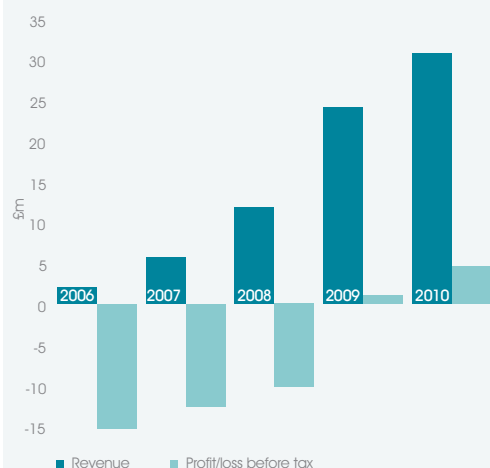
Global Opportunity

GW's research programme addresses a wide range of therapeutic areas providing global market opportunities. We aim to meet the regulatory requirements not only of the developed markets of Europe and North America, but also the fast emerging markets of Asia, Middle East and Latin America. In order to address such global opportunities, we seek to establish licence and distribution agreements with pharmaceutical companies with a strong commercial presence in each target market. GW has a strong track record in successfully managing relationships with regulatory authorities around the world and in forging successful distribution partnerships.

GW has the opportunity to play an important role as a small dynamic research oriented company with the capabilities to develop products which may enhance the pipelines of larger pharmaceutical players.

Financial review

Financial Profile



This year's financial results show strong profit growth, increased revenues, positive cash flow and a robust cash position.



Income Statement

Pre-tax profit for the year was £4.6m, compared with a pre-tax profit of £1.2m in 2009.

Revenues increased by 27% to £30.7m (2009: £24.1m), reflecting increased Sativex sales, milestone income and additional research activity carried out on behalf of Otsuka.

Milestone income comprised £10.0m received from Bayer following the UK approval of Sativex and a further £1.2m received from Bayer following approval in Canada. The prior year included an £8.0m milestone from Almirall that was paid upon achievement of positive MS Spasticity clinical trial results.

Total Sativex sales increased by 64% to £2.8m (2009: £1.7m), primarily as a result of the UK commercial launch by Bayer in the last three months of our financial year. GW's product sales to Bayer for the UK market, totalling £1.1m, included an initial launch stock order of £0.9m.

Sales in Canada remained flat year on year at £0.4m. As in prior years, this situation is due to the lack of public reimbursement for Sativex in that country. The receipt of a full approval for the MS Spasticity indication from Health Canada at the end of August provides an opportunity to seek to change this position, a process which is likely to take some time.

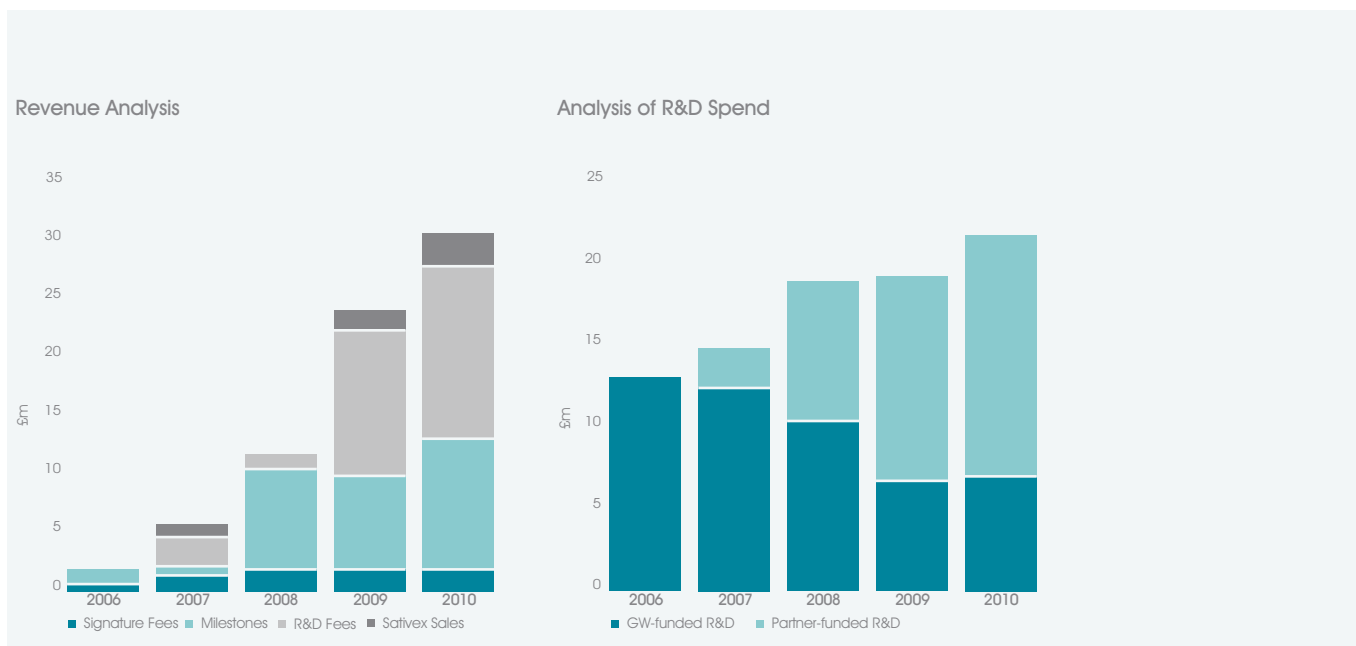
Named patient sales in Spain generated revenues of £0.4m (2009: £0.3m). Following regulatory approval in Spain, we now await pricing approval following which commercial launch can take place.

Research and development fee revenues of £14.8m represent an increase of 18% over the previous financial year. These fees consist of research and development costs incurred by GW and charged to Otsuka under the Sativex US development agreement, totalling £10.2m and the research collaboration agreement of £4.6m. Otsuka has continued to utilise the services of GW's clinical team to manage the Sativex US clinical programme. The GW clinical team will continue to play a major part in the management of the proposed Phase III trials programme that is now under way.

Total research and development expenditure, which is expensed as incurred, was £21.8m, of which £14.8m was funded by Otsuka. GW-funded research increased marginally to £7.0m but still represented just 32% (2009: 35%) of total research and development spend.

Management and administration expenditure was £3.0m (2009: £2.7m) whilst the share-based payment charge remained at £0.6m and interest receivable was £0.1m. We continue to take a very conservative approach to managing counterparty credit risk on our cash deposits.

Pre-tax profit increased from £1.2m last year to £4.6m in 2010 and revenues increased by 27% to £30.7m.



Cash Flow

Having started the year with £20.6m of cash, the Group ended the year with £25.2m, a net inflow of £4.6m. Cash flow was significantly enhanced by the receipt of £11.2m of approval milestones from Bayer and the £0.7m of funds received from the exercise of share options by members of staff.

Capital expenditure of £0.4m consisted mainly of IT and laboratory equipment.

During the year the Group also received £0.4m of research and development tax credit claimed in respect of the 2009 financial year.

Balance Sheet

The Group's net funds comprise cash balances together with amounts held on short-term deposit totalling £25.2m (2009: £20.6m).

Inventory of £0.8m consists of finished goods, consumable items and work in progress. This is stated net of a realisable value provision of £3.9m which has been calculated in accordance with the Company's inventory accounting policy.

Trade and other receivables at 30 September 2010 were £1.2m (2009: £0.8m), consisting of £0.6m of trade debtors (from sales of Sativex) and £0.6m of other receivables and prepayments.

At 30 September 2010 the Group had received £3.2m of advance payments for research activities to be carried out on behalf of Otsuka in the next six months.

Deferred signature fee revenue amounts to £13.5m (2009: £15.4m), of which £1.9m is shown as due within one year and £11.6m is shown as due after more than one year, represents the balance of non-refundable Sativex licence agreement signature fees. This will be recognised as revenue in future periods.

The Group has tax losses of £44.3m (2009: £43.7m) which are available to carry forward and relieve against future profits. The value of these losses is not reflected in the Group balance sheet.

Average headcount of the Group for the year was 120 (2009: 110).

Outlook

In 2011, we expect a £2.5m milestone from Almirall on Spanish commercial launch and a further \$4m from Otsuka on the recruitment of the first patient into the first Phase III cancer pain trial. We also expect GW funded R&D to increase by 20–30% over 2010. In the coming years, GW's financial results should feature an increasing amount of Sativex sales as demand grows and the product is launched in additional countries around the world. In addition, as a result of ongoing investment in the in-house pipeline, we continue to expect the coming years to feature increases in R&D expenditure as well as license and milestone fee revenues





Cautionary statement:

This document contains forward-looking statements that reflect GW's current expectations regarding future events, including development and regulatory clearance of GW's products. Forward-looking statements involve risks and uncertainties. Actual results and events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW's research strategies, the applicability of the discoveries made therein,

the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex and other products by consumer and medical professionals. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and the Company undertakes no obligation to update these forward-looking statements. Nothing in this document should be construed as a profit forecast.

“With a prudent financial model focused on revenue growth and partner funded R&D, we believe that GW has the assets and capability to create further valuable product opportunities.”

Dr Geoffrey Guy
Chairman





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