

13 December 2011

GW Pharmaceuticals

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
09/10	30.7	5.2	4.1	0.0	22.0	N/A
09/11	29.6	3.3	2.7	0.0	33.3	N/A
09/12e	25.1	(6.2)	(3.5)	0.0	N/A	N/A
09/13e	32.4	(1.0)	0.0	0.0	N/A	N/A

Note: *PBT and EPS exclude intangible amortisation and share-based payments.

Investment summary: A sum of three parts

GW Pharmaceuticals is an attractive lower-risk speciality pharma investment opportunity. Its evolution in the past year now allows it to be considered in three segments - Sativex Commercial, Sativex R&D and Pipeline R&D. Sativex Commercial is already profitable, reflecting GW's transition to a commercial business following EU approvals and launches of Sativex in multiple sclerosis spasticity. The two R&D segments provide significant further upside and have both demonstrated recent progress with a number of clinical trials recently initiated or about to start.

Sativex commercial: Approvals and filings

GW booked £4.4m of Sativex sales in FY11 reflecting commercial availability in four EU countries. Sales growth is expected; it will be determined by market access, reimbursement and promotional activities in existing markets and by new launches. Launches are planned in other European countries pending local approvals or the second round MRP filing (due to complete mid-2012). A Middle East regulatory filing by Novartis and possible Australia approval are expected next year.

R&D: Sativex and other cannabinoids

The third Sativex Phase III cancer pain trial (initiating H112) should not affect US filing timing in 2014 (after data from two core Phase III trials). Pilot Phase IIa trials of other cannabinoids in metabolic disease are ongoing; an ulcerative colitis study will start in H112. The Otsuka research collaboration has yielded promising breast cancer data.

Financials: Revenue fluctuations due to stocking

Timing of Sativex deliveries to partners will result in lumpy half-year revenues, but with year-on-year growth. Milestones could be triggered by new launches (also in Novartis regions). For FY12 internal R&D spend will be 40-50% higher due to in-house Phase II trials; a loss is expected (enabling R&D tax credit claim). UK patent box legislation could limit future tax payments. FY12 cash should be £18.2m.

Valuation: DCF-based valuation of £229m

Greater than expected market share/growth/price and new indications/geographies for Sativex, or clinical progress in cancer pain would represent upside to our £229m base case valuation. This does not yet include early-stage R&D or potential deals.

Price 90p
Market cap £121m

Share price graph



Share details

Code GWP
Listing AIM
Sector Pharmaceuticals & Biotechnology
Shares in issue 133.1m

Price

52 week High 130p Low 87p

Balance sheet as at 30 September 2011

Debt/equity (%) N/A
NAV per share (p) 13.3
Net cash (£m) 28.3

Business

GW Pharmaceuticals is a UK company focused on developing cannabinoids as pharmaceuticals. Lead product Sativex is marketed in a number of European countries for multiple sclerosis-associated spasticity. GW has three business segments: Sativex commercial, Sativex R&D and Pipeline R&D.

Valuation

	2011	2012e	2013e
P/E relative	316%	N/A	N/A
P/CF	55.7	N/A	N/A
EV/sales	3.1	4.0	3.3
ROE	19%	N/A	N/A

Revenues by geography

UK 5.0% Europe 34.8% N. America 42.6% Other 17.6%

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Investment summary: A sum of three parts

Company description: Cannabinoid-focused speciality pharma

GW Pharmaceuticals is a UK company entirely focused on R&D into plant-based cannabinoids as pharmaceutical products. Lead product, Sativex, has been launched as a therapy for multiple sclerosis associated spasticity in four EU countries (UK, Spain, Germany and Denmark), with additional launches expected in 2012-13. GW has matured to the stage whereby its business can be divided into three activities: (1) **Sativex commercialisation** (GW is partnered with Bayer, Almirall, Otsuka and Novartis, which have provided aggregate signature fees/milestones of £59m, with potential further milestones of £211m and an effective royalty rate of 20-30%); (2) **Sativex R&D** (it is also under Phase III evaluation in the US for the treatment of opioid-refractory cancer pain, and has supporting clinical trial data in indications such as neuropathic pain and bladder dysfunction); and (3) **Pipeline R&D** (GW has a cancer/CNS research collaboration with Otsuka and is investing in internal R&D). GW has raised £60m in equity since listing on AIM (2001), and has 152 employees, with plans to expand operations to c 170 to support Sativex commercialisation and R&D activities.

Valuation: DCF-based valuation of £229m, with potential for upside

Our base case valuation of £229m is based on a DCF model to 2020 with a 12.5% cost of capital and a 2% TGR. This valuation may be conservative: we currently assume a 65% development risk to potential cancer pain revenues. As Sativex commercial launch is at an early stage there are various uncertainties including pricing (we assume the UK price represents an international benchmark) and sales trajectories (impacted by market access, reimbursement, stocking and patient compliance). Additional upside should also arise if off-label Sativex use is significant (especially within indication but for different symptoms) or if other indications are pursued and/or other R&D projects progress. Licensing deals (for Sativex or other cannabinoid programmes) are possible in the midterm, but are not explicitly valued until the timing/deal economics are confirmed.

Sensitivities: Skewed to commercial risks

With Sativex launched in a number of European countries, GW is now a commercial-stage business and hence a lower-risk investment proposition, although there is high single-product risk associated with Sativex. Completion of the EU regulatory processes to date mitigates approval risk in major territories, but launch timings remains a sensitivity as do the commercial risks associated with pricing and usage. EU approval has also set a precedent and defined the regulatory pathway for approval of other plant-derived cannabinoid therapeutics in Europe; however, key sensitivities remain. These include Sativex market penetration and use (approved and off-label) for additional indications, and the value in the early stage R&D portfolio (currently not included in the valuation).

Financials: Recurring Sativex revenues ≠ recurring profitability (yet)

GW's cash balance at end-FY11 was £28.3m. Year-on-year growth in Sativex sales is expected, but may be lumpy in half-year periods due to partner stocking and timings of further approvals and launches. Milestones may be forthcoming (a £250k approval milestone on Italy approval in FY12), most likely on launches (no explicit guidance for FY13 although we model £2.5m). GW-funded R&D will be 40-50% higher in FY12 (we model £9.1m) due to investment in the Phase II metabolic and inflammation trials. A pre-tax loss of £6.2m is expected for FY12 (enabling claim of R&D tax credits). We forecast end-FY12 cash of £18.2m.

Outlook: Sativex sales and R&D pipeline momentum

GW Pharmaceuticals is making the transition from an R&D company to a commercial business and is an attractive opportunity for investors seeking relatively low-risk healthcare exposure. Its investment case has been de-risked by the approval and ongoing launches of its lead drug Sativex in Europe. Sativex, a metered-dose oromucosal spray, is a combination of two principal cannabinoids, THC (delta 9 tetrahydrocannabinol) and CBD (cannabidiol)¹ and has been commercially launched for multiple sclerosis (MS) associated spasticity. FY11 results show that GW's Sativex commercial business segment is profitable, even though it is at a relatively early stage its commercial launch. Future sales growth from Sativex is expected, with launches planned in additional European countries (either where local approvals and launches are pending, or in countries subject to a second round MRP filing). However, as revenues booked by GW will depend on stocking patterns at partners, revenues will be lumpy on a half-year basis; year-on-year, growth is expected, although GW does not expect to be profitable in all future periods. Significant newsflow is also expected over the coming 18 months (Exhibit 1).

GW also has plans for Sativex beyond MS and for its wider cannabinoid pipeline (Sativex R&D and Pipeline R&D are its two other business segments). Exhibit 2 (overleaf) summarises the development status of Sativex in various indications; Exhibit 3 details the Sativex licensing arrangements; and the non-Sativex R&D pipeline is shown in Exhibit 4.

Exhibit 1: Upcoming newsflow

Date	Business segment	Event	Comment
Q112	Pipeline R&D	Start of Phase IIa study in inflammation	62-pt pilot study of GWP42003 in refractory ulcerative colitis
May 2012	-	Interim results	Update on commercial progress (Sativex sales, patient uptake), pipeline progress, regulatory timelines and financials
H112	Sativex commercial	Middle East regulatory submission in MS spasticity	Partner Novartis responsible for regulatory filing. Potential approval in 2013
H112	Sativex R&D	Start of third Phase III trial in cancer pain	540-pt trial with enriched design, results expected 2015+. Two ongoing pivotal Phase III trials to read out end-2013
Q2/Q312	Sativex commercial	EU launches in MS spasticity	Almirall to launch in Italy, Sweden, Austria and Czech Republic
Mid-2012	Sativex commercial	Second round MRP approval	Application submitted November 2011. Finalisation of complete list of countries (c 10) in which application is being made is underway. Launches expected from Q113
Mid-2012	Sativex commercial	Australia approval	Launch expected in Q113 (may be associated with milestone from Novartis). Potential to launch in NZ in a similar timeframe
H212	Pipeline R&D	Update on Phase II metabolic disease programme	Three exploratory studies ongoing (dyslipidaemia in Type 2 diabetics, non-alcoholic fatty liver disease and antipsychotic-induced weight gain and dyslipidaemia)
Ongoing	Pipeline R&D	Progress towards clinic in oncology and epilepsy	Otsuka R&D collaboration funds CNS and oncology research. Promising preclinical data generated to date

Source: Edison Investment Research

Sativex commercialisation: A growing revenue source

GW's commercial Sativex business is profitable on a stand-alone basis and represents a source of growing revenues. Sativex sales were £4.4m in FY11 (end-September 2011) – up 59% from the £2.8m earned in FY10 – which coupled with £9.2m of upfront and milestone payments from partners, translated into a segmental profit of £12.5m. Sativex is at an early stage in its commercial launch and near-term revenue growth is expected, both from increased penetration and sales in the European territories where it is already launched, and from further approvals and launches in Europe over the next 24 months. In addition, GW's most recently secured partner, Novartis, will be progressing Sativex in its territories with regulatory filings planned for the Middle East and Australia.

¹ Each 100µl spray contains 2.7mg of THC and 2.5mg of CBD.

Exhibit 2: Sativex R&D summary

Indication	Trial design/notes
Spasticity in MS (approved)	Approved in the UK (launched June 2010), Spain (launched March 2011), Germany, Denmark (both July 2011), Canada (Bayer proceeding with reimbursement discussions), New Zealand (Novartis to confirm plans) and Czech Republic (launch in 2012). Further EU approvals sought under MRP: recommended for approval in six EU countries in March 2011 (three national approvals pending: Almirall anticipates launch in Sweden, Italy and Austria in 2012), with second MRP expanding this started in H211. Regulatory submissions filed in Israel and Australia, and planned in the Middle East and South Africa. Specific indication: symptomatic improvement in patients suffering from spasticity as a result of MS who do not have adequate relief with existing medication.
Cancer pain (Phase III)	Approved for this indication in Canada. Two core Phase III studies for relief of persistent pain in advanced cancer ongoing: 380-pt SPRAY III trial (results: Dec 2013) and 380-pt study (results: Dec 2013). Patients will then be enrolled in a 760-pt long-term open-label extension trial with sites in Europe, North and Latin America, and Asia (results: Aug 2014). Each of the Phase III trials will have five weeks on low- to mid-dose therapy (3-10 sprays/day) with primary endpoint of continuous-response % change from baseline. Third Phase III trial with enriched study design in 540-pts to start H112 (results: Dec 2015). Trials fully funded by Otsuka. Cancer pain is the lead indication in the US (US use patent granted April 2011); submission is possible early 2014. If data from the core studies are sufficient for filing, this will occur before read-out of the third study. EU filings, using the same data, expected at the same time. Prior 360-pt Phase IIb trial in opioid-refractory cancer pain showed significant improvement ($p < 0.05$) for low-dose (1-4 sprays/day) and mid-dose (6-10 sprays/day) groups and both groups combined: full data to be published in peer reviewed journal in 2011. Likely indication: advanced cancer patients with pain not wholly alleviated with optimised opioid therapy.
Neuropathic pain (peripheral and due to MS)	Approved for neuropathic pain in MS in Canada. 66-patient Phase III demonstrated efficacy in reducing pain ($p=0.005$) and sleep disturbance ($p=0.003$) in neuropathic pain in MS. A 339-pt Phase III did not show statistical significance in primary endpoint (30% or greater improvement in VAS), but significant results were seen at equal dosing and in a randomised withdrawal extension study. Two of three Phase III trials in peripheral neuropathic pain completed with statistically significant results.

Source: Edison Investment Research

Exhibit 3: Sativex licensing arrangements

Partner/territory	Financial terms
Bayer HealthCare UK/Canada	£32.75m total milestones payable, of which £20m has been triggered to date. Transfer price less the manufacturing cost results in a c 30% effective royalty on sales.
Almirall/Europe (ex-UK)	£12m signing fee plus milestones of £30m. £22.5m received (£8m paid on Phase III MS data, £2.5m on first EU launch [Spain]). Transfer price less manufacturing cost results in a c 25% effective royalty.
Otsuka/US	\$18m signing fee plus \$255m in milestones: \$22m received (\$4m paid on start of Phase III cancer pain trial). Transfer price less manufacturing cost results in a c 20% effective royalty. Otsuka funds all development for cancer pain, additional indications and in any future formulations. Joint oversight of all US clinical development and regulatory activities. GW responsible for clinical development in cancer pain indication, with costs reimbursed. Otsuka has responsibility for all subsequent indications.
Novartis Australia/NZ, Asia (ex-Japan, China/HK), Middle East (ex-Israel/Palestine) and Africa	\$5m upfront payment, plus additional approval and commercial milestones of up to \$28.75m and royalties (Edison assumes mid-teens) on net sales. Next milestone assumed on first launch (Australia?). Novartis holds exclusive commercialisation rights (all indications) and responsibility for regulatory filings. GW responsible for manufacture and supply (structured as COGS plus margin).

Source: Edison Investment Research

Exhibit 4: GW Pharmaceuticals non-Sativex R&D summary

Product/indication	Trial design/notes
GWP42003/GWP42004 THCv:CBD – metabolic syndrome, T2D/NAFLD/anti-psychotic-induced dyslipidaemia	Programme of three exploratory Phase II studies. Two trials ongoing: 62-pt Phase IIa (GWMD1092) exploring activity of 1:1 and 20:1 ratios of GWP42003:GWP42004, and as single agents in Type 2 diabetes and dyslipidaemia (fully recruited, results: Oct 2012), and 24-pt Phase IIa (GWMD09112) of CBD alone in non-alcoholic fatty liver disease, NAFLD (results: 2012). 60-pt Phase II (GWMD09126) trial to start Q411 in antipsychotic-induced dyslipidaemia (in schizophrenic pts). Preclinical models indicate THCv:CBD reduces fasting insulin, leptin and body fat, reduces total cholesterol and increases energy expenditure and HDL.
GWP42003/inflammation	62-pt Phase IIa pilot study of GWP42003 in refractory ulcerative colitis to start Q112 (primary endpoint: remission/MAYO score of ≤ 2 after 10-wks). Positive data in several <i>in vivo</i> models (inhibition of neutrophil chemotaxis, chemically and immunologically induced inflammation, in colon pre-neoplasms) and mouse DNBS induced colitis model. Preclinical data in dermatology and respiratory. Pilot study with cannabinoid showed improvement on Crohn's disease activity index (36.8% vs 3.5% placebo). 58-pt study of Sativex in rheumatoid arthritis showed significant analgesic effect and reduction in disease activity (Blake et al, 2006).
GWP42006/epilepsy	Covered by Otsuka R&D collaboration. Lead compound selected (GWP42006). Preclinical studies suggest similar efficacy to valproate. Extensive preclinical evaluation ongoing with numerous candidates (including GWP42003 and GWP42004) prior to taking decision to move into the clinic.
THC:CBD/glioma	Covered by Otsuka R&D collaboration. Preclinical studies show synergistic activity of low-dose Sativex with temozolomide in U87MG model, and when orally administered in orthotopic graft models. Mechanism of action: interference with mTOR-mediated suppression of apoptosis.
Cannabinoids (incl. combinations)/other CNS/anti-cancer indications	Covered by Otsuka R&D collaboration. Evaluation of various cannabinoids (including CBD, CBDV, CBC, CBG, THCA, THCv, CBN) as single agents and in combination for other CNS (anti-psychotic, anti-depressant and anxiolytic) and anti-cancer indications. Candidates identified for prostate, colon and breast cancer following <i>in vitro</i> and <i>in vivo</i> cancer studies; positive effects seen in HER2+, hormone sensitive and triple negative breast cancer. Combinations shown to be more efficacious than single compounds, and synergy seen with standard care therapies.

Source: Edison Investment Research

European roll-out gathering momentum

Sativex has been available in the UK and certain other European countries on a named-patient or similar exceptional basis since 2005. Sativex was first commercially launched in the UK by Bayer for MS spasticity² in Q210; its market sales since launch stand at £3.3m. Launch in the UK permitted filing of submissions in other European countries by Almirall under the mutual recognition procedure (MRP), which completed in March 2011. Sativex has since been approved and launched in Germany and Denmark, is approved in Czech Republic (pending launch) with pricing decisions and launches expected in Italy, Sweden and Austria in Q2/Q3 2012. Exhibit 5 provides a summary of Sativex's progress and status in the European countries where it is sold.

Exhibit 5: Commercial revenues generated by Sativex and its status

Country	FY11 sales	Approval/launch	Comments
UK	£1.4m	June 2010	Launch triggered £10m milestone (Bayer). Price: £125 per 10ml vial (c £11 per day). FY11 was first full year of sales (FY10: £1.2m, including initial launch order). Sales affected by market access environment: expect steady growth rather than rapid uptake. GW/Bayer 2012 focus is on securing NHS funding from PCTs. Confirmation that NICE will be considering Sativex as part of its MS treatment guidelines (timing of publication uncertain) should assist in getting formulary access at PCTs.
Spain	£0.6m	July 2010/March 2011	Launch triggered £2.5m milestone (Almirall). Price: €450 per 3x10ml vial. FY11 revenues represent four months of sales; economic climate has dampened launch trajectory. Eight-month gap between approval and launch due to pricing and reimbursement negotiations; concluded February with full reimbursement as hospital dispensed medicine. Sales growth to be determined by progress in formulary listings (on a hospital-by-hospital basis).
Germany	£1.2m	2011: May/July	£250k received on launch (Almirall). Price: €460 per 3x10ml vial. FY11 revenue represents three months of sales, with steep month-on-month growth rate. Largest European market opportunity for Sativex (c 50% of the Almirall opportunity). Sales growth to be supported by programme of promotional/educational initiatives in 2012.
Denmark	£0.1m	2011: June/July	FY11 revenue represents three months of sales. Price: as in Spain. Wholly-owned subsidiary established. 'Soft launch' in summer; full sales effort now underway.
NPS	£0.3m	2005	Named patient sales have fallen significantly (£1.2m in FY10) as commercial launches have taken place. As GW books 100% of the NPS price vs 30-40% of in-market commercial sales, FY11 Sativex revenues do not reflect the 120% volume growth.

Source: Edison Investment Research

GW has also embarked on a second MRP to expand Sativex approval into around 10 additional countries (the country list is being finalised). This MRP process is expected to complete around mid-2012, with national approvals being granted from H212 and first launches expected from Q113. Ex-UK Europe partner Almirall is highly positive on the prospects for Sativex in its territories; at its Q3 results, management stated that Sativex is expected to become one of Almirall's top 15 products in 2012 (implying €15m+ of in-market sales). Almirall has also been increasingly high-profile with its marketing activities to key opinion leaders, running a satellite symposium at the ECTRIMS annual meeting in October where it presented data from three Phase III trials in >1,500-pts and everyday clinical practice data confirming Sativex's efficacy and tolerability profile.

Post-MRP approval, the primary determinant of the launch timings of Sativex in other European countries is the conclusion of local pricing and reimbursement discussions (which may yield further small milestones, eg £250k is due on Italian pricing approval). So far, pricing has been relatively consistent within Europe. Favourable reimbursement status and negotiation of market access hurdles (formulary listings) are key, as they will ultimately define the market opportunity for Sativex in the countries in which it is approved. Progress is being made on both fronts in the UK and Spain, where the Sativex launch trajectory has been steady rather than rapid as in Germany where access is more straightforward.

² Sativex has been approved by the MHRA as a therapy for multiple sclerosis (MS) associated spasticity in patients who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity-related symptoms during an initial trial of therapy ([prescribing information](#)).

Outside Europe: Further near-term filings expected by Novartis

Regulatory filings in Europe have paved the way for the submission of Sativex in MS spasticity in other non-European territories. Sativex has been filed by Novartis in Australia, with a filing in the Middle East planned in 2012. Australian approval is expected in mid-2012, with a probable commercial launch in early-2013 that may be coupled to launch in New Zealand (Sativex was approved in November 2010, but not yet launched for commercial considerations related to reference pricing). Undisclosed milestones may be due from Novartis on launches.

Commercial progress in Canada continues to be slow. Due to the challenging reimbursement environment, Bayer is not yet promoting Sativex despite it being approved for relief of neuropathic pain in MS, as an adjunctive analgesic for adults with advanced cancer and moderate to severe cancer pain despite opioid therapy, and adjunctive treatment for MS spasticity in adults.³

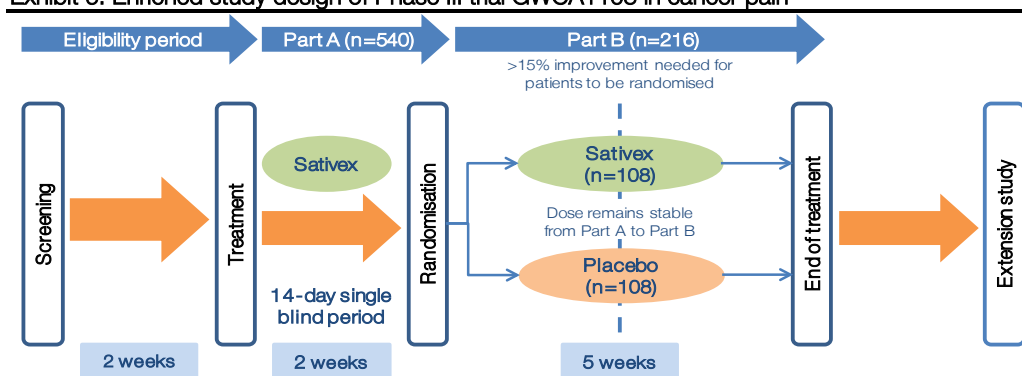
Sativex R&D: Maximising value through label extension

GW has a broader plan for Sativex outside global approval in MS spasticity, and is seeking to maximise value through development in additional indications. Cancer pain is potentially the most valuable of these, and thus it is the most developmentally advanced, with a Phase III programme funded by partner Otsuka underway. For regulatory and commercial reasons, cancer pain is the lead indication for Sativex in the US, where, at present, there are few non-opioid drug options.

Third cancer pain trial in planning

Two 380-pt dose-ranging cancer pain Phase III trials are ongoing and will be followed by an open-label extension study. The two trials will study low to mid-doses⁴ of Sativex (3-10 sprays/day) over five weeks of treatment in advanced cancer patients with pain not wholly alleviated with optimised opioid therapy. The primary endpoint is continuous response analysis (where all responders are characterised by percentage improvement) based on the absolute change in Numerical Rating Scale (NRS) from baseline.⁵ These trials, in combination with positive Phase II data already obtained from over 500 patients, should create a regulatory package of >1,250-patients. This may be further supplemented by a third trial, which has progressed into advanced planning; this trial will have an enriched study design (Exhibit 6) similar to that employed in the MS spasticity programme and is designed to provide data on how Sativex will be used in a real-life cancer pain setting. Despite not reading out until late-2015, inclusion of this extra trial is not expected to affect filing timelines.

Exhibit 6: Enriched study design of Phase III trial GWCA1103 in cancer pain



Source: GW Pharmaceuticals, Edison Investment Research

³ The former indications were approved under Health Canada's Notice of Compliance with Conditions (NOC/c) policy, while the MS spasticity indication has a full marketing authorisation (Notice of Compliance).

⁴ Given the less favourable tolerability (GI and CNS side-effects) seen in the high-dose arm of the Phase IIa trial.

⁵ The key efficacy parameter in the product labelling of several recently approved medicines for pain in the US.

The two core Phase III trials are expected to be sufficient for filing (read out is expected end 2013), and, if data is positive, the NDA will be submitted before the third reads out. This timeline suggests potential US filing in 2014 (a year later than our previous expectation) with first US sales in 2015.

As around half of the patients being enrolled in the Phase III trials will be at centres in Europe, Latin America and Asia, this data is also anticipated to be used for the European submission and also, potentially, in other regions. The partnership with Novartis (which has a strong oncology franchise), should exploit the significant cancer pain opportunity in non-US and non-European regions.

Other indications and trials

GW has stated that it intends to pursue late-stage Sativex development in a third, undisclosed, indication. Sativex has already been studied in a range of clinical trials in non-MS and cancer pain indications,⁶ and commercial opportunities are currently under evaluation in select indications, ie other MS symptoms (eg bladder dysfunction) and pain. Label extensions may boost Sativex's value given the differing market opportunities for different indications (eg the Asian cancer pain market is larger than that for MS). Future clinical trials supporting label extensions may be run by GW, clinical investigators and/or partners.

Pipeline R&D: Beyond Sativex

Sativex approval has validated GW's cannabinoid platform, defined the EU regulatory pathway for cannabinoids, strengthened GW's cash position through milestone receipts and provides recurring sales revenues. Consequently, GW is now better positioned to be able to invest in early-stage R&D. GW is making progress with its earlier-stage pipeline, both self-funded and as part of the Otsuka CNS and oncology research collaboration (evaluating GW's cannabinoid library, derived from its chemotypes⁷). While GW's R&D continues to be largely funded by Otsuka (either under the US Sativex deal or the research collaboration), internal investment is increasing, with Phase II pilot studies in metabolic disease (ongoing) and inflammation (planned).

Proprietary research

GW's in-house research is focused on diabetes/metabolic disease and on inflammation. The focus of metabolic R&D is primarily on THCv (GWP42003, a neutral CB1 antagonist thought to decrease food intake and increase energy expenditure), CBD (GWP42004, a non-psychoactive compound believed to alter circulating lipid levels and control fat distribution) monotherapy and in combination. THCv is also being evaluated in inflammatory indications.

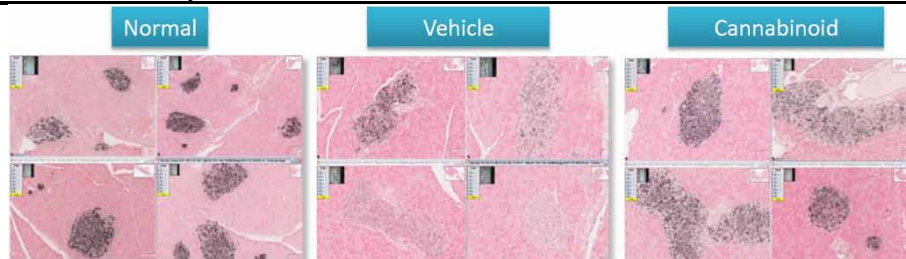
A programme of small-scale exploratory Phase IIa trials focused on lipid metabolism/distribution in patients with diabetes and metabolic diseases is ongoing; the overall aim is to assess the effects of THCv/CBD on a range of primary and secondary metabolic parameters (cholesterol and lipid levels, glucose control and insulin sensitivity). The data from the three studies in different patient populations (expected in H212) should indicate whether cannabinoid therapy is efficacious in metabolic disease and also identify the indication(s) where there is greatest potential for further clinical development. Two trials are underway (the dyslipidaemia in Type 2 diabetes trial is fully recruited, with the fatty liver disease study still recruiting) and a third (assessing weight gain and dyslipidaemia in patients with functional psychosis) is due to initiate in Q411.

⁶ Please refer to Exhibit 4 in our outlook note '[The grass is greener...](#)', published 13 October 2010.

⁷ Chemotypes are plant varieties whose chemical composition varies because of specific breeding and/or different environmental growing conditions. Each of GW's chemotypes is responsible for expressing a different cannabinoid; the cannabinoids produced by each chemotype contribute to GW's proprietary compound library.

GW's earlier preclinical studies have provided evidence for the role of cannabinoids in metabolism, with beneficial effects demonstrated in several Type 2 diabetes models on metabolic hormone (insulin, leptin and adiponectin), total cholesterol (and the balance of LDL/HDL cholesterol) and liver triglyceride levels. Most recently, GW has shown that cannabinoids have a protective effect on insulin-producing pancreatic islet cells (Exhibit 7); important in the context of an anti-diabetic drug.

Exhibit 7: *In vivo* efficacy of GW cannabinoid in the db/db mouse model of diabetes



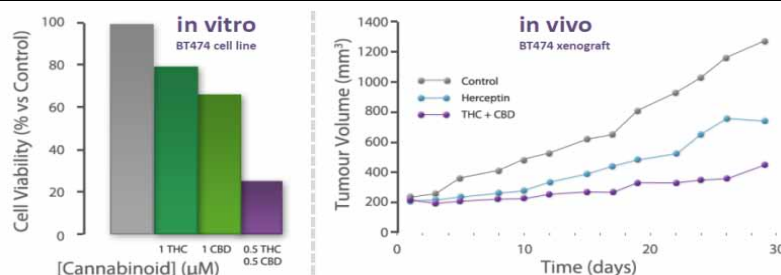
Source: Cawthorne *et al*, GW Pharmaceuticals, Edison Investment Research

The anti-inflammatory effect of cannabinoids has also been observed in several *in vivo* models, and in small-scale clinical studies in RA and Crohn's disease. GW has broadened its activity in this indication. It has entered into a research collaboration on the effect of cannabinoids in airway inflammation models, and in early 2012 will be embarking on a 62-pt Phase IIa pilot study in patients with ulcerative colitis patients that are refractive to first-line treatment (5-ASA).

Otsuka CNS and oncology collaboration

GW's global cancer and CNS research collaboration with Otsuka will run to June 2013⁸; extension last year means that the additional \$12m research funding commitment by Otsuka should enable further progress. Promising preclinical *in vitro* and *in vivo* data on cannabinoids in epilepsy (under extensive evaluation prior to moving into clinic) and various cancer models (glioma, prostate, colon and breast cancers⁹) have been generated under the collaboration. Newly released data (Exhibit 8) indicates that there is synergy between THC and CBD in Her2+ breast cancer, which have in combination demonstrated better efficacy than Herceptin in the BT474 xenograft model.

Exhibit 8: Synergism of THC and CBD in Her2+ breast cancer



Source: Sanchez *et al*, GW Pharmaceuticals, Edison Investment Research

Sensitivities

With Sativex launched in four European countries (and recommended for approval in four others), GW is now a commercial-stage business and hence a lower-risk investment proposition, even though the entirety of our valuation is currently associated with Sativex. Completion of the regulatory processes in the EU to date mitigates EU regulatory risk in major territories (the first

⁸ Candidate selection would be followed by a separate licensing deal with specific terms negotiated at that time.

⁹ Please refer to Exhibit 6 in the Edison Review note 'On a roll', published May 23 2011.

approvals have set a precedent and defined the regulatory pathway for approval of other plant-derived cannabinoid therapeutics in Europe), leaving only the commercial risks associated with pricing and usage of Sativex. The remaining regulatory risk relates to the timing of further approvals: this and the completion of country-specific pre-launch administrative requirements may affect the timing of launch, either positively or negatively. Various other assumptions have been made in our valuation model, which could vary on both the upside and downside, including the pricing of Sativex (and potentially other cannabinoid products), market penetration, use (approved and off-label) for additional indications and the future value inherent in the early stage R&D portfolio, which is currently not included in the valuation.

Valuation

Our £229m valuation is based on a DCF model to 2020 with 12.5% cost of capital, and a modest 2% terminal growth rate. The revenue model is shown in Exhibit 9.

Exhibit 9: Base case Sativex revenue model (non-risk-adjusted)

Note: *At each expected transfer price under each licensing deal; excludes GW's manufacturing cost.

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Canada patients with MS spasticity	57,750	63,525	69,878	76,865	84,552	93,007	102,308	112,538	123,792	136,171
Sativex market share	1.2%	1.0%	0.9%	1.0%	1.5%	2.0%	3.0%	4.0%	5.0%	5.0%
Cost per patient per year (£)	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998
Sativex sales (Canada; £'000)	1,991	1,809	1,885	2,304	3,802	5,576	9,200	13,494	18,554	20,409
GW revenue (Canada; £'000)*	796	724	754	922	1,521	2,230	3,680	5,398	7,422	8,164
Canada mod. to sev. cancer pain patients	29,546	30,137	30,740	31,354	31,982	32,621	33,274	33,939	34,618	35,310
Sativex market share	0.0%	0.0%	0.0%	0.0%	2.0%	4.0%	6.0%	7.0%	8.0%	9.0%
Cost per patient per year (£)	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499
Sativex sales (US; £'000)	0	0	0	0	959	1,956	2,992	3,561	4,151	4,763
GW revenue (US; £'000)*	0	0	0	0	383	782	1,197	1,424	1,660	1,905
US mod. to sev. cancer pain patients	739,093	768,657	799,403	831,379	864,635	899,220	935,189	972,596	1,011,500	1,051,960
Sativex market share	0.0%	0.0%	0.0%	0.0%	0.5%	1.0%	3.0%	4.0%	4.5%	5.0%
Cost per patient per year (£)	4,496	4,496	4,496	4,496	4,496	4,496	4,496	4,496	4,496	4,496
Sativex sales (US; £'000)	0	0	0	0	19,439	40,433	126,149	174,927	204,665	236,502
GW revenue (US; £'000)*	0	0	0	0	5,054	10,512	32,799	45,481	53,213	61,490
EU patients with MS spasticity	352,800	370,440	388,962	408,410	428,831	450,272	472,786	496,425	521,246	547,309
Sativex market share	1.0%	1.6%	2.5%	3.5%	4.6%	5.8%	6.9%	7.8%	8.7%	9.4%
Cost per patient per year (£)	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998
Sativex sales (£'000)	10,635	17,878	29,251	42,849	58,810	78,538	97,080	115,698	135,936	154,833
GW revenue (EU; £'000)*	3,612	5,882	10,317	15,517	21,266	28,564	35,333	42,076	49,404	56,283
EU mod. to sev. cancer pain patients	502,860	512,917	523,176	533,639	544,312	555,198	566,302	577,628	589,181	600,964
Sativex market share	0.0%	0.0%	0.0%	0.0%	1.0%	2.0%	3.0%	4.0%	5.0%	7.5%
Cost per patient per year (£)	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499
Sativex sales (£'000)	0	0	0	0	8,158	16,643	25,463	34,630	44,153	67,554
GW revenue (EU; £'000)*	0	0	0	0	2,855	5,825	8,912	12,120	15,454	23,644
Novartis territories mod. to sev. cancer pain patients	980,577	1,000,189	1,020,192	1,040,596	1,061,408	1,082,636	1,104,289	1,126,375	1,148,902	1,171,880
Sativex market share	0.0%	0.0%	0.0%	0.0%	1.0%	2.0%	3.0%	4.0%	5.0%	7.5%
Cost per patient per year (£)	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499	1,499
Sativex sales (£'000)	0	0	0	0	5,303	10,818	16,551	22,509	28,700	43,910
GW revenue (RoW; £'000)*	0	0	0	0	795	1,623	2,483	3,376	4,305	6,587
Novartis territories patients with MS spasticity	107,759	110,453	113,214	116,044	118,946	121,919	124,967	128,091	131,294	134,576
Sativex market share	0.0%	0.0%	1.0%	1.5%	2.0%	2.5%	3.0%	4.0%	5.0%	6.0%
Cost per patient per year (£)	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998	2,998
Sativex sales (£'000)	0	0	3,394	5,218	7,131	9,137	11,238	15,359	19,678	24,204
GW revenue (RoW; £'000)*	0	0	509	783	1,070	1,370	1,686	2,304	2,952	3,631
GW total Sativex revenue (£'000)*	4,409	6,606	11,580	17,222	32,945	50,907	86,089	112,179	134,409	161,704

Source: GW Pharmaceuticals, Edison Investment Research

This base case valuation may be conservative as there are a number of uncertainties associated with the early-stage of the Sativex launch. Considerable upside may result from clarity on:

- **Pricing assumptions:** pricing is a key sensitivity; we continue to assume that the UK price of Sativex (£125 per 10ml) provides an international benchmark, but assume a higher US price.
- **Sales trajectories:** reimbursement and market access are important determinants of Sativex's growth trajectory. Promotional/educational initiatives are also ongoing. Sativex is still at an early-stage in its launch, hence sales trajectories and market share are difficult to accurately

assess. We will update our model once Sativex is more established in its various markets.

Other factors that may affect sales growth include: (1) **Stocking**: there may be a lag between booking of GW revenues and in-market sales due to stocking-in by partners, who buy Sativex batches from GW. Confirmation of estimated purchase orders would provide some clarity on near-term revenues; and (2) **Patient compliance**: we assume 75% compliance (ie, a daily cost of £11 in MS would imply an annual cost of £4k, we model a £3k annual cost).

- **Progress in other indications**: clinical progress of Sativex in the US should increase our probability of success weighting, which would concomitantly increase our valuation. We currently ascribe a 65% development risk to potential cancer pain revenues (US and Europe).

Additional upside should also arise if off-label Sativex use is significant (especially within indication but for different symptoms) or if other indications are pursued and/or other R&D projects progress. While new licensing deals (for Sativex or other cannabinoid programmes) are possible in the near to mid term, we do not explicitly value these until the timing and deal economics are confirmed.

Financials

GW's FY11 revenues of £29.6m were lower than in FY10 (£30.7m) due to lower milestone receipts (£11.2m booked in FY10). In FY11 revenue comprised of: £5.3m of milestone income (£2.75m from Almirall on launches, £2.6m from Otsuka on Phase III cancer pain trial start), £4.4m of Sativex sales (with a 69% margin vs 72% in FY10¹⁰), and £3.8m of signature/technical access fees (£1.9m from deferred release of Almirall and Otsuka fees, £1.9m from Novartis's upfront payment).

Consistent with prior periods, R&D spend was mainly partner funded (£16m vs £6.3m of internal spend). Admin costs were marginally lower than FY10 (£2.9m vs £2.96m). Operating profit was £2.27m, with reported PBT of £2.5m and year-end cash of £28.3m.

GW's future revenues will be contingent on a number of variables:

- **Sativex sales**: year-on year sales growth is expected, but revenues booked by GW will be affected by partner stocking and further approval/launch timings. Revenues may be lumpy over the half-year periods due to timing of deliveries. Exhibit 10 shows our sales assumptions.

Exhibit 10: Edison sales projections for GW's share of Sativex revenues

Sativex sales (£ 000s)	2011	2012e	2013e
Canada - MS	796	724	754
UK - MS	1,402	1,510	2,478
Spain - MS	602	800	1,338
Germany - MS	1,208	2,840	5,015
Other EU - MS	400	731	1,487
Novartis territories - MS	-	-	509
Total Sativex sales	4,409	6,606	11,580

Source: Edison Investment Research

- **Milestone receipts**: milestones may be forthcoming from existing Sativex deals or new pipeline agreements. In FY12 we expect deferred recognition of £1.3m and a £250k Italian approval milestone. There is no guidance for FY13; but Sativex launches in Australia and the Middle East could trigger milestones from Novartis (we model receipts of c £2.5m).

GW-funded R&D for FY12 is guided to be 40-50% higher (we model £9.1m) due to investment in the Phase II metabolic and inflammation trials. GW expects to report a loss for FY12 (we forecast £6.2m pre-tax); it should be able to claim an R&D tax credit in 2012 (the FY11 tax credit receipt related to the FY10 claim). GW also has significant unutilised tax losses (c £40m available as of

¹⁰ The margin on named product sales of Sativex is higher than on commercial sales.

30 September 2011); hence, we do not expect tax to be paid until around 2015 and then at a low rate assuming implementation of the [UK patent box scheme](#). We forecast end-FY12 cash of £18.2m.

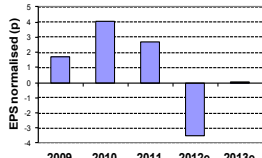
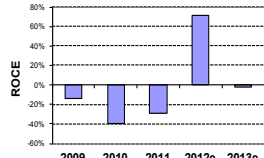
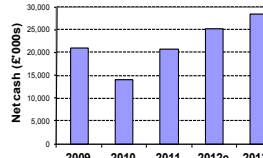
While GW is planning manufacturing capacity expansion to support commercial operations (ahead of potential Sativex US launch for cancer pain) and pipeline growth, this will require limited GW capex (ie for new equipment) as the building work will be funded by the owners of GW facilities.

Exhibit 11: GW Pharmaceutical financial model

Note: 2010 and 2011 revenue includes milestones received under the Bayer, Almirall and Novartis deals.

Year end 30 September	£'000s	2009	2010	2011	2012e	2013e
		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		24,121	30,676	29,626	25,146	32,370
Cost of sales		(433)	(752)	(1,347)	(2,180)	(3,821)
Gross profit		23,688	29,924	28,279	22,966	28,549
EBITDA		2,114	5,868	3,652	(5,402)	(146)
Operating profit (before goodwill and except.)		1,658	5,142	3,064	(6,402)	(1,146)
Intangible amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Share-based payment		(634)	(630)	(795)	(900)	(900)
Operating profit		1,024	4,512	2,268	(7,302)	(2,046)
Net Interest		128	92	260	250	150
Profit before tax (norm)		1,786	5,234	3,324	(6,152)	(996)
Profit before tax (FRS 3)		1,152	4,604	2,528	(7,052)	(1,896)
Tax		353	37	221	1,497	1,023
Profit after tax (FRS 3)		1,505	4,641	2,749	(5,555)	(873)
Average number of shares outstanding (m)		125.0	129.9	131.9	133.1	133.1
EPS - normalised (p)		1.7	4.1	2.7	(3.5)	0.0
EPS - FRS 3 (p)		1.2	3.6	2.1	(4.2)	(0.7)
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed assets		7,068	6,776	7,078	8,078	9,578
Intangible assets		5,210	5,210	5,210	5,210	5,210
Tangible assets		1,858	1,566	1,868	2,868	4,368
Investments		0	0	0	0	0
Current assets		22,323	27,216	32,024	24,239	22,672
Stocks		551	780	1,424	2,134	3,740
Debtors		1,171	1,217	2,281	3,878	4,459
Cash		20,601	25,219	28,319	18,228	14,473
Current liabilities		(9,125)	(9,714)	(10,028)	(8,516)	(9,153)
Creditors		(4,531)	(4,594)	(6,569)	(7,226)	(7,948)
Short-term borrowings		0	0	0	0	0
Deferred revenue & advance payments		(4,594)	(5,120)	(3,459)	(1,290)	(1,205)
Long-term liabilities		(13,544)	(11,605)	(10,602)	(9,312)	(8,022)
Long-term borrowings		0	0	0	0	0
Deferred revenue		(13,499)	(11,599)	(10,602)	(9,312)	(8,022)
Other long-term liabilities		(45)	(6)	0	0	0
Net assets		6,722	12,673	18,472	14,489	15,075
CASH FLOW						
Operating cash flow		(571)	3,935	2,133	(8,342)	(2,902)
Net interest		127	92	241	250	150
Tax		1,791	397	221	0	1,497
Capex		(1,061)	(434)	(891)	(2,000)	(2,500)
Expenditure on intangibles		0	0	0	0	0
Acquisitions/disposals		0	0	0	0	0
Financing		6,261	628	1,396	0	0
Dividends		0	0	0	0	0
Net cash flow		6,547	4,618	3,100	(10,092)	(3,755)
Opening net debt/(cash)		(14,054)	(20,601)	(25,219)	(28,319)	(18,228)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	0	(0)
Closing net debt/(cash)		(20,601)	(25,219)	(28,319)	(18,228)	(14,473)

Source: Edison Investment Research, GW Pharmaceuticals accounts

Growth	Profitability	Balance sheet strength	Sensitivities evaluation	
			Litigation/regulatory	●
			Pensions	○
			Currency	◐
			Stock overhang	○
			Interest rates	○
			Oil/commodity prices	○

Growth metrics	%	Profitability metrics	%	Balance sheet metrics	Company details
EPS CAGR 09-13e	N/A	ROCE 12e	71.3	Gearing 12e	N/A
EPS CAGR 11-13e	N/A	Avg ROCE 11-13e	14.5	Interest cover 12e	25.6
EBITDA CAGR 09-13e	N/A	ROE 12e	N/A	CA/CL 12e	2.8
EBITDA CAGR 11-13e	N/A	Gross margin 12e	91.3	Stock turn 12e	31
Sales CAGR 09-13e	7.6	Operating margin 12e	N/A	Debtor days 12e	56
Sales CAGR 11-13e	4.5	Gr mgn / Op mgn 12e	N/A	Creditor days 12e	105
				Address: 1 Cavendish Place, London, W1G 0QF	
				Phone	44 207 2910555
				Fax	44 207 2910550
				www.gwpharm.com	

Principal shareholders (15 August 2011)	%	Management team
M&G Investment Management	13.8	Managing director: Justin Gover
Dr Geoffrey Guy	13.2	Managing director since 1999. Previously head of corporate affairs at Ethical Holdings and before that was at BDO Management Consultants in Hong Kong.
Dr Brian Whittle	7.6	
Preston Parish	5.0	Finance director: David Kirk
Great Point Partners	4.4	Joined GW in 2001. Finance director at CeNeS 1997-2000. Was a founding director of Amura, and until June 2001 NED of Avlar Bioventures. Worked for Arthur Andersen from 1975.
Justin Gover	3.0	
T Rowe Price International	2.8	R&D director: Stephen Wright
Forthcoming announcements/catalysts	Date	Joined GW in 2004 from Ipsen, where he had been senior VP of clinical R&D. Formerly medical director of Immunosciences and venture head of neuroscience at Abbott Laboratories. Also worked at Glaxo in the UK, and earlier at Scotia Pharmaceuticals.
Phase IIa in ulcerative colitis starts	Q112	
H112 results	May	
Sativex: Middle East regulatory filing	H112	Executive chairman: Dr Geoffrey Guy
Sativex: third cancer pain Phase III start	H112	Founded GW in 1998. Founded Ethical Holdings in 1985, serving as its chairman and CEO until 1997. In 1990, co-founded an Ethical subsidiary, Phytopharm , which floated in 1996 and which he chaired until 1997. Formerly also a director of Amarin (the subsequent name of Ethical), Lotus Healthcare, Oxford Health Management and Medi-Ject.
Sativex: further EU launches (Italy, Sweden, Austria, Czech Republic)	Q2/Q312	
<i>Note: * = estimated</i>		
Companies mentioned in this report:		
Almirall, Bayer Health Care, Novartis, Otsuka		

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